

DRUG ABUSE CONTROL AMENDMENTS OF 1965

89-1  
In 8/4  
1-68

y4  
.In 8/4  
89-1

HEARINGS  
BEFORE THE  
COMMITTEE ON  
INTERSTATE AND FOREIGN COMMERCE  
HOUSE OF REPRESENTATIVES  
EIGHTY-NINTH CONGRESS

FIRST SESSION

ON

H.R. 2

A BILL TO PROTECT THE PUBLIC HEALTH AND SAFETY BY  
AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC  
ACT TO ESTABLISH SPECIAL CONTROLS FOR DEPRESSANT  
AND STIMULANT DRUGS, AND FOR OTHER PURPOSES

JANUARY 27, 28; FEBRUARY 2, 9, AND 10, 1965

Serial No. 89-1

Printed for the use of the  
Committee on Interstate and Foreign Commerce



COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

OREN HARRIS, Arkansas, *Chairman*

HARLEY O. STAGGERS, West Virginia	WILLIAM L. SPRINGER, Illinois
WALTER ROGERS, Texas	J. ARTHUR YOUNGER, California
SAMUEL N. FRIEDEL, Maryland	SAMUEL L. DEVINE, Ohio
TORBERT H. MACDONALD, Massachusetts	ANCHER NELSEN, Minnesota
JOHN JARMAN, Oklahoma	HASTINGS KEITH, Massachusetts
LEO W. O'BRIEN, New York	WILLARD S. CURTIN, Pennsylvania
JOHN E. MOSS, California	GLENN CUNNINGHAM, Nebraska
JOHN D. DINGELL, Michigan	JAMES T. BROYHILL, North Carolina
PAUL G. ROGERS, Florida	JAMES HARVEY, Michigan
HORACE R. KORNEGAY, North Carolina	ALBERT W. WATSON, South Carolina <sup>1</sup>
LIONEL VAN DEERLIN, California	TIM LEE CARTER, Kentucky
J. J. PICKLE, Texas	
FRED B. ROONEY, Pennsylvania	
JOHN M. MURPHY, New York	
DAVID E. SATTERFIELD III, Virginia	
DANIEL J. RONAN, Illinois	
J. OLIVA HUOT, New Hampshire	
JAMES A. MACKAY, Georgia	
JOHN J. GILLIGAN, Ohio	
CHARLES P. FARNSLEY, Kentucky	
JOHN BELL WILLIAMS, Mississippi	

W. E. WILLIAMSON, *Clerk*

KENNETH J. PAINTER, *Assistant Clerk*

*Professional Staff*

ANDREW STEVENSON  
KURT BORCHARDT

JAMES M. MENDER, Jr.  
WILLIAM J. DIXON

<sup>1</sup> Resigned from Congress Feb. 1, 1965.

## CONTENTS

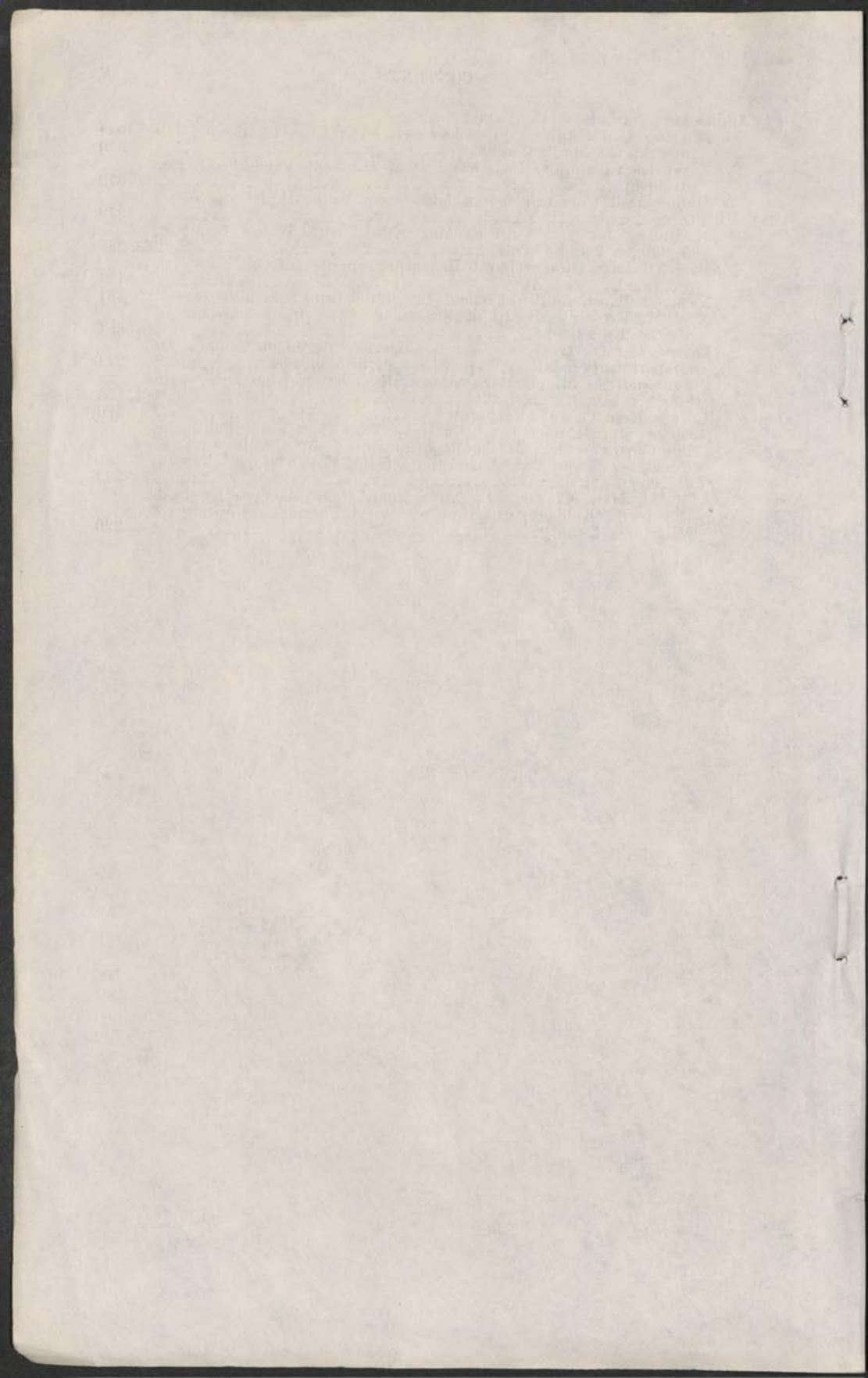
	Page
Hearings held on—	
January 27, 1965.....	1
January 28, 1965.....	145
February 2, 1965.....	223
February 9, 1965.....	257
February 10, 1965.....	317
Text of H. R. 2.....	2
Report of—	
Bureau of the Budget.....	8
Commerce Department.....	15
Federal Trade Commission.....	16
Health, Education, and Welfare Department.....	8
Interstate Commerce Commission.....	15
Justice Department.....	17
National Academy of Sciences.....	18
Treasury Department.....	14
Veterans' Administration.....	14
Statement of—	
Brill, Dr. Henry, Committee on Alcoholism, Council on Mental Health, American Medical Association.....	145
Delaney, Hon. James J., a Representative in Congress from the State of New York.....	230
Donelan, Paul R. M., Department of Legislation, American Medical Association.....	145
Dwyer, Hon. Florence P., a Representative in Congress from the State of New Jersey.....	223
Ellenbogen, Theodore, Acting Assistant General Counsel, Department of Health, Education, and Welfare.....	335
Fort, James, counsel, public affairs, American Trucking Associations.....	208
Goodrich, William W., Assistant General Counsel, Department of Health, Education, and Welfare.....	101, 335
Griffith, Dr. John, director, Oklahoma Mental Health Planning Committee.....	300
Jehle, Philip F., Washington representative and associate general counsel, National Association of Retail Druggists.....	121
Kelly, John T., legislative counsel, Pharmaceutical Manufacturers Association.....	164, 185
Kitto, Dr. William, associate director, Department of Drugs, American Medical Association.....	145
Larrick, Hon. George P., Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare.....	20, 101, 335
Mattia, Dr. V. D., executive vice president, Hoffman-LaRoche, Inc., Nutley, N.J.....	287
McMullen, Jay L., CBS News, New York, N.Y.....	271, 281
Minish, Hon. Joseph G., a Representative in Congress from the State of New Jersey.....	228
Nottingham, J. Curtis, president, American Pharmaceutical Association.....	188
Peters, Dr. Lawrence, executive vice president for scientific affairs, McNeil Laboratories, Fort Washington, Pa.....	232
Rankin, Winton B., Assistant Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare.....	20, 101, 335
Rooke, Ralph R., on behalf of National Association of Retail Druggists.....	121
Sadusk, Dr. Joseph F., Jr., Director of Medicine, Food and Drug Administration, Department of Health, Education and Welfare.....	20

## Statement of—Continued

	Page
Smith, Dr. Austin, president, Pharmaceutical Manufacturers Association	164, 185
Smoyer, Stanley, counsel, McNeil Laboratories, Fort Washington, Pa.	232
Steeves, Robert F., director, Legal Division, American Pharmaceutical Association	188
Stetler, C. Joseph, executive vice president and general counsel, Pharmaceutical Manufacturers Association	164, 185
Sullivan, Hon. Leonor K., a Representative in Congress from the State of Missouri	317
Vanik, Hon. Charles A., a Representative in Congress from the State of Ohio	226
Yapalater, Dr. Alvin R., White Plains, N.Y.	258
Zbinden, Dr. Gerhard, vice president for research, Hoffman-La Roche, Inc., Nutley, N.J.	287
Additional information submitted for the record by—	
American Federation of Labor and Congress of Industrial Organizations, letter from Andrew J. Biemiller, director, department of legislation	377
American Hospital Association, letter from Kenneth Williamson, director, Washington Service Bureau	378
American Legion, statement of Randel Shake, director, National Child Welfare Commission	375
American Medical Association, letter from Dr. F. J. L. Blasingame	159
American Osteopathic Association, statement of Dr. William Baldwin, Jr.	382
American Pharmaceutical Association, letters from William S. Apple, executive director	207, 374
American Trucking Associations:	
Accident statistics, table	213
Drugs and driving—Some precautions for highway safety	218
Summary of ICC hours of service regulations	217
Consolidated Brooklyn Retail Pharmacists Association, telegram from Benjamin Levine, president, and Moe Weiss, executive secretary	377
Federation of Homemakers, statement of Ruth Desmond, president	383
Florida State Board of Health, letter from Frank S. Castor, director	370
Florida State Pharmaceutical Association, letter from R. Q. Richards, secretary-manager	382
Food and Drug Administration:	
Addiction to Nonbarbiturate Sedative and Tranquilizing Drugs, from Clinical Pharmacology and Therapeutics, May-June 1964	33
Barbiturate Use in Narcotic Addicts, from American Medical Association Journal, August 3, 1964	63
Drug Abuse and Addiction—Reporting in a General Hospital, from American Medical Association Journal, August 10, 1964	54
Letter from Hon. George P. Larrick, Commissioner	115
Letters from John L. Harvey, Deputy Commissioner	373, 374
Misuse of Valuable Therapeutic Agents: Barbiturates, Tranquilizers, and Amphetamines, report by the Committee on Public Health, New York Academy of Medicine	57
Overdosage Effects and Danger From Tranquilizing Drugs, from Journal of American Medical Association, August 10, 1963	43
Side Effects, from Psychopharmacology Abstracts, volume 4, No. 2	42
Staff memorandum on H.R. 2 concerning methods of diversion of depressant and stimulant drugs with specimen cases and comments on questions arising during hearings	336
The Problem of Barbiturates in the United States of America, from Bulletin on Narcotics, January-March 1964	66
Health, Education, and Welfare Department, letter from Wilbur J. Cohen, Assistant Secretary	369

## Additional information—Continued

	Page
Jefferson County (Ky.) juvenile court, letter from Charles C. Dibrowski, chief probation officer.....	380
Kay-Fries Chemicals, Inc., letter from H. Kent Vanderhoef, vice president.....	372
Mallinckrodt Chemical Works, letter from Victor H. Knoop, secretary.....	379
McMullen, Jay L.: "CBS Evening News" with Walter Cronkite, September 2 and 3, 1964.....	283, 285
National Association of Retail Druggists, summary of CBS television program.....	123
National Pharmaceutical Council, Inc., letter from Newell Stewart.....	381
New Mexico State Board of Pharmacy, letter from Malcolm D. Smithson, president.....	381
Peters, Dr. Lawrence, medical bibliography pertinent to abuse of nonbarbituric sedatives, hypnotics, and tranquilizers.....	234
Pharmaceutical Manufacturers Association, letters from Dr. Austin Smith.....	181, 185
Rogers, Hon. Paul G., letter from.....	370
Sullivan, Hon. Leonor K.: Let's Have More, Not Less "Politics in the Pantry"—and All Through the House—by Closing Gaps in Consumer Protection Legislation, from Congressional Record, January 26, 1965.....	322
Zablocki, Hon. Clement J., letter from, transmitting letter from Eugene L. Kaluzny, executive secretary, Pharmacists Society of Milwaukee County.....	220



## DRUG ABUSE CONTROL AMENDMENTS OF 1965

WEDNESDAY, JANUARY 27, 1965

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The committee met, pursuant to notice, at 10 a.m., in room 1334, Longworth House Office Building, Hon. Oren Harris, chairman of the committee, presiding.

The CHAIRMAN. The committee will come to order.

Today the committee initiates hearings on H.R. 2, a bill that I introduced on the opening day of this session of Congress, proposing to establish special controls over depressant and stimulant drugs.

The problem of these drugs has received a great deal of attention from many sources over the last several years.

The President's health message recommended to the Congress the passage of legislation to tighten controls over dangerous drugs and to provide increased authority over counterfeit drugs.

It will be recalled that in November 1963 the President's Advisory Commission on Narcotics and Drug Abuse, under the chairmanship of the esteemed and able Judge Prettyman, recommended increased controls over dangerous drugs.

Legislation dealing with this subject matter was passed by the Senate late in the 88th Congress, but time did not permit this committee to schedule and conduct hearings on the subject.

I announced at that time that if I were chairman of this committee during the 89th Congress, this legislation would receive early consideration by the committee and would be scheduled as the first order of business.

It has been estimated that over 9 billion barbiturates and amphetamine tablets are manufactured annually in the United States. It is also estimated that about one-half of them are sold illegally.

These drugs are useful when prescribed for, or administered to, a patient by a physician. However, many of these drugs have been subject to widespread abuses.

The present bill is a result of discussions with the people who had given a lot of study to this problem, the Department of Health, Education, and Welfare, and the Food and Drug Administration. Out of those discussions the bill, H.R. 2, was designed and was introduced by me to provide increased authority for the Food and Drug Administration in this field.

It will be the purpose of this committee to make a thorough study of this problem and the needs.

There are several witnesses to be heard, whom we will try to get to as the conditions and circumstances will permit.

H.R. 2 and such departmental reports as have been received will be included in the record at this point.

(The bill, H.R. 2, and reports referred to follow :)

[H.R. 2, 89th Cong., 1st sess.]

A BILL To protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Abuse Control Amendments of 1965".*

#### FINDINGS AND DECLARATION

SEC. 2. The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act, would discriminate against and adversely affect interstate commerce in such drugs.

#### CONTROL OF DEPRESSANT AND STIMULANT DRUGS

SEC. 3. (a) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end thereof the following:

"(v) The term 'depressant or stimulant drug' means—

"(1) any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid which has been designated by the Secretary under section 502(d) as habit forming;

"(2) any drug which contains any quantity of (A) amphetamine or any of its optical isomers; (B) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (C) any substance which the Secretary, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

"(3) any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect; except that the Secretary shall not designate under this paragraph, or under clause (C) of subparagraph (2), (A) any substance that is now included, or is hereafter included, within the classifications stated in section 4731, and marijuana as defined in section 4761, of the Internal Revenue Code of 1954 (26 U.S.C. 4731, 4761), or (B) peyote (mescaline) but only insofar as its use is in connection with the ceremonies of a bona fide religious organization.

The provision of subsections (e), (f), and (g) of section 701 shall, subject to the provisions of section 511(f), relating to advisory committees, apply to and govern proceedings for the issuance, amendment, or repeal of regulations under subparagraph (2) (c) or (3) of this paragraph."

(b) Chapter V of such Act (21 U.S.C., chap. 9, subch. V) is amended by adding at the end thereof the following new section:

#### "DEPRESSANT AND STIMULANT DRUGS

"SEC. 511. (a) No person shall manufacture, compound, or process any depressant or stimulant drug, except that this prohibition shall not apply to the

following persons whose activities in connection with any such drug are solely as specified in this subsection:

"(1) Manufacturers, compounders, and processors who are regularly engaged, and are otherwise qualified, in preparing pharmaceutical chemicals or prescription drugs for distribution through branch outlets, through wholesale druggists, or by direct shipment. (A) to pharmacies or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for their use in research, teaching, or chemical analysis.

"(2) Wholesale druggists who maintain establishments in conformance with local laws and are regularly engaged in supplying prescription drugs (A) to pharmacies, or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for their use in research, teaching, or clinical analysis.

"(3) Pharmacies, hospitals, clinics, and public health agencies, which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs upon prescriptions of practitioners licensed to administer such drugs for patient under the care of such practitioners in the course of their professional practice.

"(4) Practitioners licensed by law to prescribe or administer depressant or stimulant drugs, while acting in the course of their professional practice.

"(5) Persons who use depressant or stimulant drugs in research, teaching, or chemical analysis and not for sale.

"(6) Officers and employees of the United States, a State government, or a political subdivision of a State, while acting in the course of their official duties.

"(7) An employee of any person described in paragraph (1) through paragraph (5), and a nurse or other medical technician under the supervision of a practitioner licensed by law to administer depressant or stimulant drugs, while such employee, nurse, or medical technician is acting in the course of his employment or occupation and not on his own account.

"(b) No person, other than—

"(1) a person described in subsection (a), while such person is acting in the ordinary and authorized course of his business, profession, occupation, or employment, or

"(2) a common or contract carrier or warehouseman, or an employee thereof, whose possession of any depressant or stimulant drug is in the usual course of his business or employment as such.

shall sell, deliver, or otherwise dispose of any depressant or stimulant drug to any other person.

"(c) No person, other than a person described in subsection (a) or subsection (b) (2), shall possess any depressant or stimulant drug otherwise than (1) for the personal use of himself or of a member of his household, or (2) for administration to an animal owned by him or a member of his household.

"(d) (1) Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any depressant or stimulant drug shall, upon the effective date of this section, prepare a complete and accurate record of all stocks of each such drug on hand and shall keep such record for three years. On and after the effective date of this section, every such person manufacturing, compounding, or processing any depressant or stimulant drug shall prepare and keep, for not less than three years, a complete and accurate record of the kind and quantity of each such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and every such person selling, delivering, or otherwise disposing of any depressant or stimulant drug shall prepare or obtain, and keep for not less than three years, a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person from whom it was received and to whom it was sold, delivered, or otherwise disposed of, and the date of such transaction. No separate records, nor set form or forms for any of the foregoing records, shall be required as long as records containing the required information are available.

"(2) (A) Every person required by paragraph (1) of this subsection to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing any depressant or stimulant drug, and every person in charge, or having custody, of such records, shall, upon request of an officer or employee designated by the Secretary permit such officer or employee at reasonable times to have access to and copy such records. For the purposes of verification of such records and of enforcement of this section, officers or employees designated by the Secretary are authorized, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to enter, at reasonable times, any factory, warehouse, establishment, or vehicle in which any depressant or stimulant drug is held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of, and to inspect, within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on violation of this section or section 301(q); and to inventory any stock of any such drug therein and obtain samples of any such drug. If a sample is thus obtained, the officer or employee making the inspection shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample obtained.

"(B) No inspection authorized by subparagraph (A) shall extend to (i) financial data, (ii) sales data other than shipment data, (iii) pricing data, (iv) personnel data, or (v) research data, which are exempted from inspection under the third sentence of section 704(a) of this Act.

"(3) The provisions of paragraphs (1) and (2) of this subsection shall not apply to a licensed practitioner described in subsection (a)(4) with respect to any depressant or stimulant drug received, prepared, processed, administered, or dispensed by him in the course of his professional practice.

"(e) (1) The Secretary may by regulation exempt any depressant or stimulant drug from the application of all or part of this section when he finds that regulation of its manufacture, compounding, processing, possession, and disposition, as provided in this section or in such part thereof, is not necessary for the protection of the public health.

"(2) The Secretary shall by regulation exempt any depressant or stimulant drug from the application of this section, if (A) he finds that such drug consists of one or more substances not having a depressant or stimulant effect on the central nervous system or a hallucinatory effect in such combination, quantity, proportion, or concentration so as to prevent the ingestion or absorption of the substance or substances therein which do have either such effect in sufficient amounts or concentrations as, within the meaning of section 201(v), to (i) be habit forming because of their stimulant effect on the central nervous system, or (ii) have a potential for abuse because of their depressant or stimulant effect on the central nervous system or their hallucinatory effect, or (B) such drug may, under the provisions of this Act, be sold over the counter without a prescription.

"(f) (1) In any proceeding for the issuance, amendment, or repeal of a regulation under subparagraph (2)(C) or (3) of section 201(v), whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in the petition of any interested person, the petitioner, or any other person who will be adversely affected by the proposal or by the Secretary's order issued in accordance with section 701(e)(1) if placed in effect, may request, within the time specified in this paragraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report with respect to one or more of the following matters: (A) whether or not the substance involved has a depressant or stimulant effect on the central nervous system or a hallucinatory effect, (B) whether the substance involved has a potential for abuse because of its depressant or stimulant effect on the central nervous system, and (C) any other scientific question (as determined by the Secretary) which is pertinent to the determination of whether such substance should be designated by the Secretary pursuant to subparagraph (2)(C) or (3) of section 201(v). The request for referral under this paragraph, or the Secretary's referral on his own initiative, may be made at any time before or within thirty days after publication of an order of the Secretary acting upon the petition or proposal.

"(2) The Secretary may by regulation condition referrals to an advisory committee pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the per diem and travel costs arising by reason of

such referrals. Such regulations may provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds pursuant to this paragraph.

"(3) Upon request that any petition, order, or proposal be referred to an advisory committee as provided in paragraph (1), or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under paragraph (5) of this subsection and shall refer to such advisory committee the matter set forth in paragraph (1) of this subsection for study thereof and for a report on such matters. As soon as practicable after such referral, but not later than sixty days thereafter, unless the advisory committee extends this period for an additional thirty days, the advisory committee shall certify to the Secretary a report on such matters, together with all underlying data and a statement of the reasons or basis for its findings. Within thirty days after such certification, the Secretary shall, after giving due consideration to such report and to all data then before him, issue the order required by section 701(e) (1).

"(4) The deliberations of such advisory committee shall be conducted in accordance with regulations promulgated by the Secretary in order to assure independent study and impartial consideration of the matters set forth in paragraph (1) of this subsection. The right to consult with the advisory committee shall be reasonably afforded to the person who has filed the petition or who has requested referral to the advisory committee, or to any other interested person, as well as to representatives of the Department of Health, Education, and Welfare. All data considered or received by the advisory committee shall be made a part of the record of its proceedings.

"(5) The advisory committee referred to in paragraph (1) shall be composed of impartial experts, qualified in the subject matter referred to the committee and of adequately diversified professional background, selected by the Secretary from a panel proposed by the National Academy of Sciences, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the advisory committee. The size of the advisory committee, which shall not be less than three, shall be determined by the Secretary. Members of the advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the advisory committee (including travel time), and shall in addition be reimbursed for their necessary travel and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding appointment and compensation of employees of the United States. The Secretary shall furnish the advisory committee with adequate clerical and other assistance.

"(6) Any report, underlying data, and reasons certified to the Secretary by such advisory committee shall be made a part of the record of any public hearing held pursuant to section 701(e) (3), if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report of such committee upon the request of the Secretary, any interested party, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing."

#### REGISTRATION OF PRODUCERS AND WHOLESALERS OF DEPRESSANT AND STIMULANT DRUGS

SEC. 4. (a) Section 510(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by redesignating paragraph (2) thereof as paragraph (3) and by inserting immediately after paragraph (1) the following new paragraph:

"(2) the term 'wholesaling, jobbing, or distributing of depressant or stimulant drugs' means the selling or distribution of any depressant or stimulant drug to any person who is not the ultimate user or consumer of such drug;"

(b) Subsection (b) of section 510 of such Act is amended (1) by inserting immediately after "drug or drugs" the following: "or in the wholesaling, jobbing,

or distributing of any depressant or stimulant drug", and (2) by adding at the end thereof the following: "If any such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of any depressant or stimulant drug, such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe."

(c) Subsection (c) of section 510 of such Act is amended (1) by inserting immediately after "drug or drugs" the following: "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug", and (2) by adding at the end thereof the following: "If such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of any depressant or stimulant drug such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe."

(d) Subsection (d) of section 510 of such Act is amended by inserting "(1)" immediately after "(d)" and by striking out the period at the end thereof and inserting in lieu thereof the following: "or the wholesaling, jobbing, or distributing of any depressant or stimulant drug. If any depressant or stimulant drug is manufactured, prepared, propagated, compounded, or processed in such additional establishment, such person shall, at the time of such registration, indicate such fact, in such manner as the Secretary may by regulation prescribe."

"(2) Every person who is registered with the Secretary pursuant to the first sentence of subsection (b) or (c) or paragraph (1) of this subsection, but to whom the second sentence of subsection (b) or (c) or of paragraph (1) of this subsection did not apply at the time of such registration, shall, if any depressant or stimulant drug is thereafter manufactured, prepared, propagated, compounded, or processed in any establishment with respect to which he is so registered, immediately file a supplement to such registration with the Secretary indicating such fact, in such manner as the Secretary may by regulation prescribe."

(e) The heading of such section 510 is amended by inserting "and Certain Wholesalers" immediately after "of Producers".

#### PROHIBITED ACTS

Sec. 5. Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end thereof the following new paragraph:

"(q) (1) The manufacture, compounding, or processing of a drug in violation of section 511(a); (2) the sale, or delivery, or other disposition of a drug in violation of section 511(b); (3) the possession of a drug in violation of section 511(c); (4) the failure to prepare or obtain, or the failure to keep, a complete and accurate record with respect to any drug as required by section 511(d); (5) the refusal to permit access to or copying of any record as required by section 511(d); or (6) the refusal to permit entry or inspection as authorized by section 511(d)."

#### GROUNDS AND JURISDICTION FOR JUDICIAL SEIZURE AND CONDEMNATION

Sec. 6. The first sentence of section 304(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 204(a)) is amended by inserting before "Provided, however," the following: "and any depressant or stimulant drug which has been manufactured, compounded, processed, sold, delivered, disposed of, or is possessed, in violation of section 511, any drug which is a counterfeit drug, and any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found".

#### PENALTIES

Sec. 7. (a) Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)) is amended by inserting after the final word "fine" and before the period the following: "Provided, however, That any person who, having attained his eighteenth birthday, violates section 301(q) (2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his eighteenth birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than \$2,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than \$15,000, or both such imprisonment and fine".

(b) Section 303(b) of such Act (21 U.S.C. 333(b)) is amended by inserting after the word "shall" the following: "(except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses)".

#### AUTHORITY OF INSPECTORS TO CARRY FIREARMS

SEC. 8. (a) Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by inserting at the end thereof the following new subsection:

"(g) Officers or employees of the Department designated by the Secretary to conduct investigations or inspections relating to depressant and stimulant drugs may, when authorized by the Secretary, carry firearms."

(b) Section 1114 of title 18 of the United States Code is amended by striking out "or any security officer of the Department of State or the Foreign Service" and by inserting in lieu thereof the following: "any security officer of the Department of State or the Foreign Service, or any officer or employee of the Department of Health, Education, and Welfare designated by the Secretary of Health, Education, and Welfare to conduct investigations or inspections under the Federal Food, Drug, and Cosmetic Act".

#### COUNTERFEITING OF DRUGS

SEC. 9. (a) The Congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine; that, while such drugs are deemed misbranded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act, the controls for the suppression of the traffic in such drugs are inadequate because of the difficulty of determining the place of interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls with respect to such drugs without regard to their interstate or intrastate origins.

(b) Paragraph (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended (1) by inserting "(1)" immediately after "(g)", (2) by redesignating clauses (1), (2), (3), and (4) thereof as clauses (A), (B), (C), and (D), respectively, (3) by striking out "clause (1), (2), or (3)" and inserting in lieu thereof "clause (A), (B), or (C)", and (4) by adding at the end thereof the following:

"(2) The term 'counterfeit drug' means a drug which, or the container or labeling of which, bears the trademark, trade name, or other identifying mark, imprint, or device of a person other than the person or persons authorized to use it on such drug, container, or labeling, or which bears any likeness thereof."

(c) Paragraph (i) of section 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(c) is amended by inserting "(1)" immediately after "(i)" and by adding at the end thereof the following new subparagraphs:

"(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

"(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug."

(d) Section 303 of such Act (21 U.S.C. 333(c)) is amended by inserting immediately before the period at the end thereof the following: "; or (5) for having violated section 301(i) (2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i) (3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug".

## APPLICATION OF STATE LAW

SEC. 10. Nothing in this Act shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

## EFFECTIVE DATE

SEC. 11. The foregoing provisions of this Act shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted; except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act, to register their names, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such effective date, and (2) section 201(v) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and the provisions of sections 8 and 10 shall take effect upon the date of enactment of this Act.

EXECUTIVE OFFICE OF THE PRESIDENT,  
BUREAU OF THE BUDGET,  
Washington, D.C., January 28, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This will acknowledge your letter of January 19, 1965, requesting the views of the Bureau of the Budget regarding H.R. 2, a bill to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

As you know, the President, in his message to the Congress on advancing the Nation's health, recommended legislation "to bring the production and distribution of barbiturates, amphetamines, and other psychotoxic drugs under more effective control." H.R. 2 is substantially in accord with the President's recommendations. The Bureau of the Budget therefore strongly favors enactment of legislation along the lines of H.R. 2.

Sincerely yours,

PHILLIP S. HUGHES,  
Assistant Director for Legislative Reference.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
January 27, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of January 19, 1965, for a report on H.R. 2, a bill to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes. The bill would be known as the Drug Abuse Control Amendments of 1965.

The bill has two major purposes; i.e., (1) to provide a much needed strengthening of the controls available under the Food, Drug, and Cosmetic Act with respect to the barbiturates, the amphetamines, and such other prescription drugs as the Secretary may (after opportunity for hearing) designate because they contain habit-forming central nervous system stimulants or because they otherwise have a potential for abuse by reason of their depressant, stimulant, or hallucinogenic effect on the central nervous system; and (2) to provide additional sanctions under the act that will help to suppress the counterfeit drug evil. For the cogent reasons stated in sections 2 and 9 of the bill, it would apply to such drugs whether or not they have moved in interstate commerce.

Legislation along the lines of this bill would carry out the recommendations in the President's health message of January 7 of this year that the Congress

enact "legislation to bring the production and distribution of barbiturates, amphetamines, and other psychotoxic drugs under more effective control" and, further, that it enact "authority to seize counterfeit drugs at their source."

The bill would require registration of manufacturers and wholesalers of the above-mentioned depressant and stimulant drugs, and the maintenance of accurate records with respect to such drugs by persons engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of them, and would make such records and the establishments and vehicles involved subject to our inspection. The bill would prohibit manufacture, possession (except for one's own use or use in one's household), or delivery of these drugs except by regularly established manufacturers and wholesalers, pharmacies, hospitals, physicians, and the like. The Secretary may exempt any such drugs, in whole or in part, from regulation if he determines this to be consistent with the protection of the public health, and he is directed to exempt over-the-counter drugs and, further, drugs which contain a stimulant, depressant, or hallucinogenic substance in such combination, or in such negligible quantity or concentration, that they will not cause the effect or have the potential for abuse at which the bill is aimed. In view of the criminal element engaged in the traffic in these drugs, authority for our inspectors to carry firearms could be conferred by the Secretary. Civil and criminal sanctions for violations, including increased penalties for sale of these drugs to minors and judicial seizure authority for drugs involved in a violation, are also provided by H.R. 2.

The bill, as above indicated, also recognizes and deals with the growing and hazardous problem of counterfeit drugs—those drugs which falsely purport, by markings and labeling, to be medicines made by well-recognized manufacturers but are, in fact, clandestinely manufactured by others with no concern for quality or safety.

In view of the imminence of hearings before your committee, at which we expect to appear in general support of this bill and to explain fully the justification for this measure, we shall not burden this report with a detailed analysis and comment, or with a recital of the legislative and other studies and reports and the long experience that demonstrates the urgent need for its enactment. We shall, however, summarize below our recommendations for clarifying and strengthening amendments to the bill.

1. *Form and manner of recordkeeping.*—The bill's recordkeeping provisions will enable us to detect, sooner than we otherwise could, illegal diversions of depressant and stimulant drugs. Except for the initial inventory which the bill requires, its recordkeeping requirements can normally be fulfilled by records traditionally kept by responsible business. However, as brought out in our testimony, the provision that no separate records or set forms for records shall be required "as long as records containing the required information are available" could, if literally construed, place an undue burden both on our inspectors and on establishments subject to inspection. It would be preferable, we think, to express the congressional intent in this respect in legislative history rather than in the form of a rigid limitation in the bill, but if the provision is retained we suggest that it be clarified by inserting the words "readily and conveniently" (or words of like import) before "available" on page 7, line 25. This would make clear that the required records are not to be kept in such disorder and disarray as to prevent an expeditious inspection.

2. *Procedure for listing drugs under the bill.*—It would be our purpose, if this legislation is enacted, to consult knowledgeable scientists in and out of Government in determining which drugs should, from time to time, come within the scope of section 201(v). While the provision for referral of these matters to advisory committees is not needed by us to accomplish such consultation, we would have no objection to an advisory committee procedure along the lines of that proposed in the bill, to give industry the opportunity to call for an advisory committee of outside scientists when it wishes to do so. If the advisory committee process is retained, however, we recommend that the bill require the record of the proceedings of the committee to include, besides the data formally presented, a record of all contacts made with the committee or its individual members with regard to the subject matter before the committee. The record should reflect the data or other submissions outside of the formal proceedings and should be available for review by any interested party as soon as the Secretary publishes his order. These new provisions are suggested to act as a check upon efforts to bring hidden or improper pressures upon committee members.

We reiterate the suggestion, made in reports on predecessor bills, that a plenary rulemaking procedure is not best suited to a proceeding in which scientific and judgmental questions are likely to be primary, and that the provisions of section 4 of the Administrative Procedure Act allow ample room for presentation of the issues. The bill's provision for an ad hoc advisory committee appointed from a panel chosen by the National Academy of Sciences should be ample reassurance to industry in this connection.

3. *Seizure authority.*—Section 6 of the bill provides for judicial seizure and condemnation of depressant or stimulant drugs manufactured, compounded, processed, sold, delivered, or disposed of in violation of the bill. We suggest that certain strengthening and clarifying amendments of a substantive and procedural nature are desirable as means for more effective enforcement.

(a) Under the bill, a libel of information would have to be filed with the appropriate Federal court and served by the U.S. marshal before violative depressant or stimulant drugs or counterfeits could be detained. Obtaining the libel and executing seizure under it usually takes several days. Arrests and seizures are often executed far from the offices of Federal judges who issue the arrest warrants and libels. Yet speed is often of the essence in these cases. An inspector who has personal knowledge of the violation or reasonable ground for the belief that the violation has occurred should be empowered to detain and remove the articles prior to the time a libel of information is filed. This would assure the arrest of the articles until the usual judicial process can be issued.

(b) We suggest that the bill, or at least the legislative history, make clear that a violation by failure to keep or afford access to proper records renders the drugs involved subject to seizure and condemnation, a matter that in the absence of such clarification may lead to litigation on this issue. We believe that such violations, unless inadvertent, would usually be indicative of illicit manufacture or dealing. Seizure does not necessarily mean destruction upon entry of a decree of condemnation. The court could then, under section 304(d) of the act, restore the drugs to their owner notwithstanding a decree of condemnation if the violation is made good by preparing proper records of the drugs and affording access thereto, which should be feasible for any reputable firm.

(c) Provision should, we believe, also be made for the seizure and condemnation of machinery and other equipment used in the unregistered or otherwise violative manufacture of stimulant or depressant drugs. Otherwise, the detection of illegal manufacture of the drugs and their seizure could become essentially a mere annoyance to criminals who will spirit the equipment to a new base for manufacturing operations.

(d) We believe that the seizure and condemnation authority of section 6 should also extend, as is now true of narcotics, to any conveyance in which contraband stimulant or depressant drugs or counterfeit drugs are unlawfully transported, carried, or held. Innocent third parties holding valid liens upon such conveyances, and other innocent owners of such conveyances, should, of course, be protected.

In this connection, we suggest that the bill make clear that 40 U.S.C. 304i, which authorizes the U.S. district courts to turn over seized and condemned articles to the seizing agency, for use in official business, is to be applicable to articles validly seized and condemned under this bill. Presently, we rent automobiles for use in undercover work. This provision would allow the FDA, within such limits as may apply under other applicable provisions of law, to use in future investigations automobiles which have been seized by us and condemned by a court because of their previous involvement in an offense covered by the bill.

These added enforcement provisions are basically comparable with provisions in existing Federal laws to regulate illicit production and distribution of alcoholic beverages and hard narcotics.

4. *Authority to arrest and refer for prosecution.*—We believe that the bill should empower our inspectors to serve and execute arrest warrants and other process with respect to violations involving depressant or stimulant or counterfeit drugs, and should further authorize them to make arrest without a warrant if the offense is committed in their presence or if, in the case of a felony, they have probable cause to believe that the person arrested has committed or is committing such an offense. Comparable powers are vested in narcotic agents and certain other law enforcement officers in the enforcement of laws entrusted to them.

In this connection, a clarifying amendment to section 305 of the act seems likewise desirable. That section provides that, before referring a case for prosecution to the U.S. attorney, we shall notify the person charged and give him an opportunity to submit to us his views on the matter. This practice is generally appropriate and followed in practice, but in certain types of cases, such as will arise under this bill, prior notice to the person charged could seriously prejudice the contemplated prosecution and the source of the illicit drug supply might vanish before we could reach it. Hence, although as held by the Supreme Court, compliance with section 305 is not a jurisdictional prerequisite to prosecution by the U.S. attorney, it seems desirable to make clear in section 305 that it should not be followed where the Secretary finds that to do so would jeopardize a criminal proceeding or proceedings.

It should be emphasized, however, that such an amendment to section 305 would in no way obviate the need for the arrest powers recommended above for these cases. In a few selected cases, in which prior notification to the person charged would have seriously jeopardized the proceeding, it has, to be sure, been possible to file a criminal information without such prior notice. When such informations have been filed (by the U.S. attorney), however—identifying the defendant by name and specifying the nature of the violation—they have usually become a public record. The premature availability of this information may seriously impair our ability to trace distribution of illegal drugs back to the source of supply. Although the defendant may wish to cooperate by assisting us in apprehending his source of supply, the publicity attending his arrest could alert and in the past has alerted the supplier, thus making contact with him difficult and hazardous. This arrest procedure is also cumbersome in that it requires an initial illegal sale upon which the criminal information can be based, and at least a second contact coordinated to a time at which the U.S. marshal is available to serve the arrest warrant. Ordinarily, contacts with peddlers are made entirely on the peddlers' terms and are often subject to last minute changes, delays, or postponements to avoid detection by law enforcement officials.

5. *Counterfeit drugs—firearms for inspectors.*—The various provisions of this bill relating to counterfeit drugs will aid us in our attempt to eradicate the traffic in these drugs. The provision permitting the seizure of equipment used to make counterfeit drugs will aid the Government in destroying this noxious trade at its foundation. These strong provisions are needed. Counterfeit drugs are not manufactured under proper safeguards and controls; they are often subpotent and contaminated. These drugs are both fraudulent and dangerous.

Hardened criminals are becoming increasingly involved in the counterfeit drug traffic as they are in the traffic in illegal depressant and stimulant drugs. For this reason we recommend that section 8 of the bill—which would enable us to authorize FDA inspectors to carry firearms while conducting investigations or inspections relative to depressant or stimulant drugs—be extended to counterfeit drugs.

We recommend enactment of the bill with the above-suggested modifications. We are enclosing, for the committee's convenience, draft language to carry out these modifications as well as certain additional technical suggestions made by staff.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

WILBUR J. COHEN,  
Assistant Secretary.

DRAFT OF AMENDMENTS TO H.R. 2 TO CARRY OUT RECOMMENDATIONS IN REPORT OF DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, PLUS TECHNICAL SUGGESTIONS BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE STAFF

I. AMENDMENTS TO CARRY OUT RECOMMENDATIONS IN THE DEPARTMENT'S REPORT

1. *Amendment as to form and manner of recordkeeping.*—On page 7, line 25, insert "readily and conveniently" before "available".

2. *Procedure for listing depressant and stimulant drugs.*—(a) Strike out lines 24 and 25 on page 3 and lines 1, 2, and 3 on page 4 (except the closing quotation marks), and insert in lieu thereof the following: "Regulations for the designation of drugs pursuant to subparagraph (2) (C) or (3) of this paragraph shall be issued, amended, or repealed upon public notice of proposed rule making and in accordance with the procedure set forth in section 4 of the Administrative Pro-

cedure Act but subject to the provisions of section 511(f) (relating to advisory committees)."

(b) On page 10, line 19, strike out "701(e)(1)" and insert "201(v)"; on page 12, line 14, strike out "shall", and in lines 15 and 16 strike out "issue the order required by section 701(e)(1)" and insert "shall by order confirm or modify any order theretofore issued by him upon the petition or other proposal before him or, if no such prior order was issued before the referral to the advisory committee, shall by order act upon such petition or proposal".

(c) On page 13, line 1, insert "or other matter, in whatever form and from any source," after "data", and in line 2, after "advisory committee", insert ", and all written or oral contacts by any person with the committee or any member thereof with respect to the subjectmatter before the committee (including the matters submitted or discussed in such contacts)"; and in line 3, add the following sentence: "Such record shall, upon publication of the Secretary's order issued after consideration of the committee's report, be open to inspection by any interested party."

(d) Add closing quotation marks on page 13, line 24, and strike out the paragraph beginning on page 13, line 25, and ending on page 14, line 11.

3. *Judicial seizure and condemnation authority.*—Amend section 6 (except for the section heading) to read as follows:

"SEC. 6. (a) Subsection (a) of section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended by inserting '(1)' after '(a)' and redesignating clauses (1) and (2) of the proviso thereto as '(A)' and '(B)', respectively; and by adding at the end of such subsection the following new paragraphs:

"(2) Except as otherwise provided in paragraphs (3) and (4) of this subsection, (A) Any depressant or stimulant drug with respect to which a prohibited act within the meaning of section 301 (p) or (q) by any person has occurred, (B) Any drug that is a counterfeit drug, (C) any container of such depressant or stimulant drug or of a counterfeit drug, (D) any conveyance in or upon which such depressant or stimulant drug or a counterfeit drug has been or is being transported, carried, or held, (E) any equipment used in manufacturing, compounding, or processing a depressant or stimulant drug with respect to which drug a prohibited act within the meaning of section 301(p) or (q), by the manufacturer, compounder, or processor thereof, has occurred, and (F) any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which such drug, container, or conveyance is found.

"(3) No conveyance used by any person as a common carrier in the transaction of business as a common carrier shall be forfeited under paragraph (2) unless the owner or (except in the case of a railway car or engine) the person in charge of such conveyance was at the time involved a consenting party, or privy, to the illegal act described in clause (D) of paragraph (2).

"(4) No conveyance shall be condemned under paragraph (2) by reason of any act or omission established by its owner to have been committed or omitted by any other person while such conveyance was unlawfully in the possession of such other person who acquired such possession in violation of the criminal laws of the United States or of any State or Territory.

"(5) As used in this section, the term 'conveyance' includes every description of vehicle, vessel, aircraft, or other contrivance used, or capable of being used, as a means of transportation on land, in water, or through the air."

"(b) (1) The first sentence of subsection (b) of such section 304 is amended by inserting ', conveyance, equipment, or other thing proceeded against' after 'article'.

"(2) Subsection (d) of such section 304 is amended by inserting '(1)' after '(a)' and redesignating clauses (1) and (2) of the second sentence of such subsection as '(A)' and '(B)', respectively; and by adding at the end of such subsection the following new paragraphs:

"(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any conveyance, equipment, or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

"(3) (A) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any conveyance or equipment or thing (other than a drug) is decreed, the court shall allow the claim of any

claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such conveyance, equipment, or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such conveyance, equipment, or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to depressant or stimulant drugs or counterfeit drugs.

"(B) In any proceeding under this section involving paragraph (2) of subsection (a), the Department of Health, Education, and Welfare shall, for the purposes of the application of section 304 of the Act of August 27, 1935, 49 Stat. 880 (40 U.S.C. 304i), relating to the disposition of property forfeited by court decree, be deemed to be the agency which seized such property if the seizure was effected by or at the request of such department or an officer or employee thereof, whether or not such seizure preceded the institution of the proceeding under this section."

4. *Amendments as to authority of enforcement personnel.*—Change the heading of section 8 and the provisions of section 8(a) of the bill (p. 18, lines 17-24) to read:

"POWERS AND PROTECTION OF ENFORCEMENT PERSONNEL

"SEC. 8. Section 702 of the Federal Food, Drug, and Cosmetic Act (21 USC 372) is amended by adding at the end thereof the following new subsection:

"(e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this Act relating to depressant or stimulant drugs or to counterfeit drugs may, when so authorized by the Secretary—

"(1) carry firearms;

"(2) execute and serve search warrants and arrest warrants;

"(3) execute seizure by process issued pursuant to libel under section 304;

"(4) make arrests without warrant for offenses under this Act with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

"(5) make, prior to the institution of libel proceedings under section 304(a)(2), seizures of drugs, containers, or conveyances, or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 304(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 304(a)(2) shall be instituted promptly and the property seized be placed under the jurisdiction of the court."

II. TECHNICAL AMENDMENTS SUGGESTED BY STAFF

1. Insert "and counterfeit drugs" in the title of the bill after "depressant and stimulant drugs".

2. On page 4, at the end of line 14, insert "in conformance with local laws." This is to parallel the same phrase on page 5, line 2.

3. On page 8, line 15, insert the following after "is": "(or in which such officers or employees have reason to believe that it is)".

4. On page 10, line 2, strike out "so".

5. On page 17, line 10, strike out "204" and insert "334". (This change should be disregarded if the section is rewritten as suggested above under point I.3.)

6. On page 18, line 21, strike out "(g)" and insert "(e)". (This change should be disregarded if the revision suggested above under point I.4 is made.)

7. On page 14, strike out the closing quotation marks in line 11 and insert the following between lines 11 and 12:

"(g) As used in this section and in sections 301 and 304, the term 'manufacture, compound, or process' shall be deemed to refer to 'manufacture, preparation, propagation, compounding, or processing' as defined in section 510(a), and the term 'manufacturers, compounders, and processors' shall be deemed to refer to persons engaged in such defined activities."

THE GENERAL COUNSEL OF THE TREASURY,  
Washington, D.C., January 28, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request for the views of this Department on H.R. 2, to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

The proposed legislation would amend the Federal Food, Drug, and Cosmetic Act by making certain changes and additions providing for Federal regulation of the manufacture, processing, distribution, and possession of "depressant or stimulant drugs" moving in or otherwise affecting interstate commerce. Administration of the provisions of the bill would be vested in the Secretary of Health, Education, and Welfare.

It seems clear that the abusive use of barbiturates, amphetamines, and other habit-forming depressant or stimulant drugs which effect the central nervous system has become extensive and is a contributing factor in juvenile delinquency, crime, and in many deaths and accidents. Moreover, the existing laws do not provide adequate controls to prevent the illicit distribution of these drugs. Therefore, the Treasury Department favors enactment of legislation which would accomplish this purpose.

The Department has been advised by the Bureau of the Budget that there is no objection from the standpoint of the administration's program to the submission of this report to your committee.

Sincerely yours,

FRED B. SMITH,  
Deputy General Counsel.

VETERANS' ADMINISTRATION,  
OFFICE OF THE ADMINISTRATOR OF VETERAN AFFAIRS,  
Washington, D.C., February 9, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This refers to your request for a report by the Veterans' Administration on H.R. 2, 89th Congress, a bill to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

The purpose of this bill, as disclosed by its title, is to place certain restrictions on the manufacture, compounding, processing, counterfeiting, distribution, delivery, use, and possession of depressant or stimulant drugs in order to prevent their misuse and thereby protect the public health and safety. "Depressant and stimulant" drugs are defined, in general terms, as any drug containing barbituric acid and amphetamine, their salts and/or optical isomers, or other habit-forming central nervous system stimulants, and includes any other drug that has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect.

The provision of the bill most applicable to the Veterans' Administration would require our pharmacists to inventory and record all depressant or stimulant drugs on hand, as of the effective date of the bill, and thereafter maintain adequate disposition records on all such drugs. These records would then be made available, at reasonable times, for inspection by an officer or employee of the Department of Health, Education, and Welfare.

We now maintain all prescriptions and pharmacy orders for a period of 2 years; therefore, the provision of the bill requiring records of depressant or stimulant drugs sold, delivered, or otherwise disposed of, accompanied by the name and address of the person from whom it was received and to whom it was sold, delivered, or otherwise disposed of, would have very little effect on our procedures, other than the taking of the initial inventory.

Although we now maintain a complete system of records with respect to these depressant or stimulant drugs, and take every action necessary to insure against their misuse, we support any action necessary to protect the public health.

While there would be some additional recordkeeping required if this bill were to be enacted, it would not present an insurmountable problem. We cannot estimate the amount of increased cost, but it should not be excessive.

In view of the public health advantages in legislation of this type, we recommend favorable consideration of this bill by your committee.

We are advised by the Bureau of the Budget that there is no objection from the standpoint of the administration's program to the presentation of this report to your committee.

Sincerely,

A. H. MONK,

*Acting Deputy Administrator.*

(For and in the absence of W. J. Driver, Administrator).

---

INTERSTATE COMMERCE COMMISSION,  
Washington, D.C., January 28, 1965.

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR CHAIRMAN HARRIS: In response to your request of January 19, 1965, I am authorized to submit the following comments with respect to H.R. 2 on behalf of the Commission's Committee on Legislation.

Under section 204(a) of the Interstate Commerce Act the Commission is charged with the responsibility of establishing reasonable requirements for the safety of operation and equipment of common carriers by motor vehicle. In the discharge of this duty the Commission has investigated many serious accidents involving motor carriers and also has inspected numerous motor carriers while en route. These investigations and inspections reveal that on numerous occasions amphetamine drugs have been found in the possession of truckdrivers.

I know you are aware how difficult it is to establish conclusive proof that drugs have been used by commercial drivers involved in accidents. Rarely is it possible for the Commission to be at the scene of an accident or to initiate an investigation until some time after an accident has occurred. We necessarily depend heavily upon the investigation made at the scene by State and local officers, many of whom may not be aware of the significance of the problem. Despite these limitations, our experience convinces us that the use of such drugs by drivers of motor carriers is extensive and is frequently the cause of accidents which result in serious injury or death.

The Commission is convinced that the use of stimulant and depressant drugs by drivers of motor carriers is increasing, and that misuse of these drugs creates a grave threat to highway safety. We believe that there is an urgent need for more effective control over the manufacture and distribution of such drugs.

Although we are unable to offer any helpful comment on specific provisions of the bill, we strongly favor the objectives of H.R. 2.

Respectfully submitted.

CHARLES A. WEBB,

*Chairman, Committee on Legislation.*

JOHN W. BUSH.

EVERETT HUTCHINSON.

---

GENERAL COUNSEL OF THE DEPARTMENT OF COMMERCE,  
Washington, D.C., February 18, 1965.

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This letter is in further reply to your request for the views of this Department with respect to H.R. 2, a bill to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

H.R. 2 is a public health measure which would provide for the regulation of depressant and stimulant drugs such as barbiturates and amphetamine. With certain specified exceptions, persons are prohibited from manufacturing, compounding, processing, or possessing these drugs, or selling them to unauthorized persons. Records of stock on hand must be kept for 3 years by manufacturers, processors, and sellers. The Secretary of Health, Education, and Welfare may, by regulation, exempt any of these drugs from the prohibition if such regulation

is not necessary for the protection of the public health. The operation of State law in this field is protected.

The bill also provides for the establishment of an advisory committee of impartial experts to advise the Secretary of Health, Education, and Welfare, at the latter's request, on matters relating to whether or not a drug, which may be the subject of controversy, "has a depressant or stimulant effect on the central nervous system or a hallucinatory effect"; and it gives drug manufacturers who may object to the listing of a drug as having the above undesirable effects an opportunity to request the referral of the matter to the advisory committee for study. Its findings are then to be submitted to the Secretary of Health, Education, and Welfare for determination of the drug's status. The bill also makes the counterfeiting of drugs a Federal offense.

The Department of Commerce fully recognizes the evils and dangers attendant upon the unregulated and indiscriminate use of and trafficking in habit-forming drugs, particularly those arising from their sale to minors. We have supported legislation to protect the consumer and provide high business standards for proper labeling and packaging of food, drugs and other consumer commodities.

The bill also seeks to reduce the burden to business in various ways. The inspection provisions in the bill are clearly limited. Inspectors are not permitted to examine financial, pricing, personnel, nor research data. They also are prohibited from inspecting sales data other than shipments. Separate records or set forms for data would not be required as long as records containing the required information were available.

We recommend that it be made plain in the legislative history that the authority to control any depressant or stimulant drug which has the "potential for abuse" means that such potential must be clear and not remote and speculative.

We have been advised by the Bureau of the Budget that there would be no objection to submission of our report from the standpoint of the administration's program.

Sincerely,

ROBERT E. GILES.

FEDERAL TRADE COMMISSION,  
Washington, D.C., February 23, 1965.

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request of January 19, 1965, for comment on H.R. 2, 89th Congress, 1st session, a bill to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

The purposes of the bill is to control the illicit traffic in depressant, stimulant, or hallucinatory drugs by strictly regulating their manufacture, possession, and sale. These drugs, barbiturates, amphetamine, and similar substances—are to be regulated in a manner comparable to the control of narcotic drugs under the Harrison Narcotic Act (26 U.S.C. 4731), and of marihuana under the Marihuana Act (26 U.S.C. 4761).

The bill also contains provisions relating to the counterfeiting of drugs, with the term "counterfeit drug" being defined as "a drug which, or the container or labeling of which, bears the trademark, trade name, or other identifying mark, imprint, or device of a person other than the person or persons authorized to use it on such drug, container, or labeling, or which bears any likeness thereof."

As we understand the practice of "counterfeiting" drugs proscribed by section 9 of the bill, it could in some instances be regarded as an unfair or deceptive act or practice in commerce within the purview of section 5 of the Federal Trade Commission Act as well as "misbranding" within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act. If the Commission determined that a proceeding would be in the public interest, it would thus be empowered to act under section 5(b) of the act. However, the Commission is of the view that if a prohibition of counterfeiting like that contained in section 9 of the bill is found warranted, it could more effectively be administered by the Food and Drug Administration (as is provided for in the bill) than by the Federal Trade Commission.

Also, it is our belief that the regulation of the illicit traffic in depressant and stimulant drugs does not have any relationship to the operations or activities of the Federal Trade Commission.

By direction of the Commission :

PAUL RAND DIXON, *Chairman.*

N.B.—Pursuant to regulations, this report was submitted to the Bureau of the Budget on February 18, 1965, and on February 19, 1965, the Bureau of the Budget advised that there is no objection to the submission of this report from the standpoint of the administration's program.

JOSEPH W. SHEA, *Secretary.*

DEPARTMENT OF JUSTICE,  
OFFICE OF THE DEPUTY ATTORNEY GENERAL,  
*Washington, D.C., February 23, 1965.*

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H.R. 2) to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes.

The bill would amend the Federal Food, Drug and Cosmetic Act to establish greater control over the manufacture and distribution of depressant and stimulant drugs, including barbiturates, amphetamines, and other similar drugs, and provide stricter controls over the traffic in counterfeit drugs. In order to achieve these objectives the bill would require all persons who manufacture, process, and distribute such drugs, with the exception of physicians acting in the course of their professional practice, to maintain suitable records reflecting the distribution of the drugs from their manufacture to their disposition to an ultimate consumer. Such records would be required to be open for inspection by authorized representatives of the Secretary of Health, Education, and Welfare. Also, the bill would authorize the broad inspection of factories, warehouses, establishments, and vehicles in which the drugs are processed and held. Further, all processors, producers, and wholesalers of the drugs would be required to register with the Secretary. The bill would provide criminal penalties for failure to comply with any of its requirements and would authorize seizure and condemnation of drugs not meeting such requirements.

The bill would, in general, implement that the portion of the President's health message of January 7 of this year in which he recommended legislation "to bring the production and distribution of barbiturates, amphetamines, and other psycho-toxic drugs under more effective control" (H. Doc. No. 44, 89th Cong.). We favor this objective and believe that the bill will achieve the desired purpose. However, we feel that the measure should be amended in two respects.

Section 511(d)(1) would require every person selling, delivering or otherwise disposing of any depressant or stimulant drug to maintain complete and accurate records of the kind and quantity of each drug received, sold or delivered, the name and address of the person from whom it was received and to whom sold or delivered, and the date of the transaction. Under this language, carriers would be required to maintain such records. There is no provision, however, requiring shippers of drugs to advise a carrier whether the shipment consists of such drugs; accordingly, requiring carriers to comply with the absolute terms of 511(d)(1) is unreasonable. However, section 511(d)(2)(A) (pertaining to the inspection of records by representatives of the Secretary) raises some doubt concerning the keeping of records by carriers. That subsection states that "Every person required by paragraph (1) of this subsection to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing any depressant or stimulant drug" [emphasis added] shall permit their inspection. This language implies that carriers are not absolutely required to maintain the records prescribed by section 511(d)(1). If carriers are intended to be excluded from the mandatory keeping of records, it should be expressly stated.

Section 9 of the bill would provide for stronger measures to combat traffic in counterfeit drugs. While we favor stricter controls over such drugs where public health is endangered, we object to the definition of "counterfeit drug" contained in section 9(b)(2) of the bill. We are advised that the Department

of Health, Education, and Welfare has submitted a proposed substitute definition of "counterfeit drug" reading as follows:

"The term 'counterfeit drug' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor, other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer or distributor."

We approve of this revised definition and believe that it would strengthen the legislation.

Two typographical errors are noted in the bill. In section 6, on line 10, page 17, the citation "(21 U.S.C. 204(a))" should read "(21 U.S.C. 334(a))." Also, in section 9, on line 18, page 20, the citation "(21 U.S.C. 331(c))" should be "(21 U.S.C. 331(i))."

The Bureau of the Budget has advised that there is no objection to the submission of this report from the standpoint of the administration's program.

Sincerely,

RAMSEY CLARK,  
Deputy Attorney General.

NATIONAL ACADEMY OF SCIENCES,  
Washington, D.C., February 10, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: This letter is concerned with a bill, H.R. 2, to establish special controls for depressant and stimulant drugs, which we understand is before the Committee on Interstate and Foreign Commerce.

My immediate purpose in writing to you is to raise the question of the wisdom of one particular provision of the bill, directly involving the services of the National Academy of Sciences. This is contained in the proposed section 511(f)(5) of the Food, Drug, and Cosmetic Act. Under the bill, certain advisory committees would be appointed by the Secretary of Health, Education, and Welfare from panels of names submitted to him by the Academy. The arrangement is presumably modeled after a procedure laid down in the pesticides amendments to the Food, Drug, and Cosmetic Act.

Our experience with the pesticides amendments, under which we have named a number of panels to the Commissioner of the Food and Drug Administration, has led us to feel that the procedure there specified is not entirely sound or satisfactory.

First, the proper scientific and technical balance of such a committee is a most important factor in its effectiveness. The Academy is reluctant to name a panel without having responsibility for the final selections and appointments. Further, the Academy is reluctant to ask individuals to serve without then being able to insure that the information, facilities, and resources provided to them are fully commensurate with the need for the utmost care and wisdom in their deliberations and conclusions. I make this point as a matter of sound principle and practice, entirely without implication as to the way the pesticide arrangement has operated in the past; indeed, I can assure you that no one serving on any committee appointed under those amendments has ever complained to the Academy with regard to these matters.

Second and more important, it is our conviction, born of our experience, that questions of the kind with which the specially appointed committees will be called upon to deal are not best treated on an ad hoc basis. If there is to be consistency together with a growing body of sound philosophy in the advice given to the Secretary of Health, Education, and Welfare in these very difficult matters, it should be sought from a standing committee that has had an opportunity to become familiar with the law and with the policies, practices, and problems of the Department. It is true that the specific cases encountered are likely to be so different as to be beyond the competence of any single committee; but a standing committee can always consult with appropriate experts when the situation calls for highly specialized knowledge.

We have on several occasions in the past recommended that a system of advisory committees, named from among the most competent scientists of the

country, be formed by the Food and Drug Administration within its own structure to assist the Commissioner in the discharge of his responsibilities. We understand that committees advisory to the Administration's Bureau of Medicine and several of its subdivisions have recently been appointed. These might go far toward meeting the present need.

In a discussion of this matter during the past weekend the Council of the National Academy of Sciences agreed that for the Academy to serve its most appropriate and useful purpose as a non-Federal body, it should not be directly involved in the administrative and regulatory actions of the Food and Drug Administration. It seems clear that advisory groups appointed as part of a governmental appeal procedure may have to be closely controlled by special regulations and limitations, and that these may not be compatible with the practices of the Academy in the discharge of its fundamental and historic function of advising the Government without direct involvement in the Government's internal administration.

At the same time the Academy, if called upon, would be glad to assist the Food and Drug Administration in the establishment of its own advisory resources, both for dealing with general questions and for specific regulatory problems. The Academy already has a Drug Research Board, established in part to consider basic principles and practices in the advancement and control of the uses of drugs.

I hope that you will give consideration to our position in this matter. We are prepared, of course, to discuss it with the committee or its staff in any way that will be helpful.

In respect of the major purpose of H.R. 2, I want to assure you that the Committee on Drug Addiction and Narcotics of our Division of Medical Sciences, which has for 35 years played a prominent role in the promotion of research on the abuse of drugs, is convinced that designated categories of stimulant and depressant drugs should be brought under more effective control. That committee is in full sympathy with the primary purposes of the bill. Its Chairman, Dr. Dale Cameron, has testified at the current hearings.

Sincerely yours,

FREDERICK SEITZ, *President.*

Mr. SPRINGER. Mr. Chairman?

The CHAIRMAN. Mr. Springer.

Mr. SPRINGER. I have a short statement, which is as follows:

The increasing threat to public health and safety from the illicit traffic in and misuse of stimulant and depressant drugs is now well recognized. Government and industry alike are determined to diminish and, hopefully, remove this hazard by strengthening the machinery for control. H.R. 2 is intended to accomplish this end.

There have been other bills in the previous Congress on this subject. One such bill passed the Senate and this committee carefully considered the desirability of acting quickly on a similar measure toward the end of the 88th Congress. Because there was room for controversy and misunderstandings concerning the best methods for control, and the drugs needing control, it was decided, and I think wisely, to defer action until the 89th Congress, when thorough consideration could be given to these very important issues.

Since that time there has been much work done by the staff of this committee, the Government agencies concerned, and the industries to which the new law would apply are trying to work out a bill strong enough to catch the transgressor and fair enough to put a limit on the administrative burden necessarily inflicted upon legitimate and scrupulous manufacturers and distributors of these products.

To say that H.R. 2 meets all these requirements would be to prejudge the case before hearing the witnesses, who undoubtedly will disagree on some provisions. It can be said, however, that in this bill we have an excellent starting point to work out sound and proper legislation for

the control of present abuses in the use, distribution, and widespread counterfeiting stimulants and depressants.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank you for your splendid statement.

The first witness will be the Honorable George P. Larrick, Commissioner of the Food and Drug Administration, Department of Health, Education, and Welfare.

Commissioner Larrick, we will be glad to hear from you. I believe you have some of your staff members with you. I think it would be appropriate to identify them for the record.

**STATEMENT OF HON. GEORGE P. LARRICK, COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WINTON B. RANKIN, ASSISTANT COMMISSIONER; AND DR. JOSEPH F. SADUSK, JR., DIRECTOR OF MEDICINE**

Mr. LARRICK. Mr. Chairman, in 1962 a bill bearing your name was handled by this committee and became law, and imposed a tremendous responsibility on the Food and Drug Administration, particularly in the medical field.

I would like to introduce to the committee today the gentleman who handles that responsibility: Dr. Joseph F. Sadusk, Jr., on my right, is the new Director of Medicine for FDA. He has been with us since last April. He served on the faculties of Yale, Stanford, New York College of Medicine, and George Washington University. He is a distinguished physician. He came to us from George Washington University Medical School as chairman of the department of preventive medicine and community health, and director of the clinics.

I think the country and the FDA is most fortunate in having a man of this caliber to keep us on a straight path so far as the medicine involved in enforcing the law that you handle is concerned.

Mr. Winton B. Rankin, Assistant Commissioner, on my left, has been before you many times with me.

The CHAIRMAN. Glad to have you back with us, Mr. Rankin.

Mr. RANKIN. Thank you.

The CHAIRMAN. I hope as a result of our 1962 act we didn't give you too hard a job, and that you have not found it so difficult to carry out that your problems have been insurmountable.

Mr. LARRICK. We have had problems, Mr. Chairman, but I think we will handle it.

The CHAIRMAN. Very good.

You may proceed.

Mr. LARRICK. It is a pleasure to appear before you today to discuss the pressing need for improved controls over the distribution of depressant, stimulant, and hallucinatory drugs and of counterfeit drugs. Existing law is inadequate. President Johnson, in his January 7 message on "Advancing the Nation's Health," recommended legislation to bring production and distribution of these drugs under more effective control. H.R. 2, now before your committee, goes a long way toward meeting this problem.

We appeared before this committee with the former Secretary of our Department, Senator Ribicoff, in June 1962 when the committee

was holding hearings on H.R. 11581, a bill you introduced to give effect to the President's recommendations for strengthening the Federal drug laws. Part C of title I of that bill provided special controls for barbiturate and stimulant drugs. Secretary Ribicoff urged adoption of these controls to combat the serious public health problems stemming from the abuse of these drugs.

Mr. Chairman, these serious problems have not abated during the 2½ years since that testimony was delivered. In that period, July 1962 through December 1964, there have been 311 convictions under the present inadequate Federal law for illegal sales of prescription drugs. Of these, 299 involved drugs covered by the provisions of H.R. 2. Tranquilizers were involved in 67 of these cases.

Most of the drugs we will be discussing here today are valuable therapeutic agents. Barbiturates are central-nervous-system depressants used in a variety of conditions where a hypnotic or sedative effect is desired. Amphetamines and similar central-nervous-system stimulants are used in the treatment of depression and the control of appetite. Tranquilizers aid in the treatment of distressed and disturbed patients. Unfortunately, however, these and similar acting drugs are subject to widespread misuse and abuse for nonmedical purposes. Their nonmedical use on a do-it-yourself basis has contributed to the rising toll of deaths on our highways, juvenile delinquency, violent and bizarre crimes, suicides and other antisocial behavior.

As early as 1951, the Subcommittee on Narcotics of the House Committee on Ways and Means under the chairmanship of Congressman Hale Boggs explored the problems created by illegal sales and abuse of barbiturates and considered the action needed to correct the situation. It considered the possibility of subjecting barbiturate drugs to controls similar to those applying to narcotics such as opium and heroin. Evidence was presented before the committee to establish that barbiturates had habit-forming properties, resulted in serious withdrawal symptoms when the drugs were discontinued, and posed the hazard of accidental overdose and death. Indeed, barbiturates were shown to be a major cause of accidental death from poisoning—where the patient's brain was "put to sleep" by overdose. Dr. Paul B. Dunbar, then Commissioner of Food and Drugs, believed that narcotic type controls were needed since barbiturates were being used in the same illicit manner as narcotics, were being distributed through bars, motels, houses of ill repute and similar outlets. The investigative and enforcement techniques needed to apprehend the vendors of such drugs were the same as those used by the Bureau of Narcotics against narcotic violators. Our department and other agencies concluded, however, that less stringent controls should be tried.

During the 84th Congress, the House Subcommittee on Narcotics again held hearings to consider the need for additional Federal legislation in this area. By that time, the illegal distribution of amphetamines had become a widespread problem, so the hearings covered them as well as barbiturates. The subcommittee recommended to the Ways and Means Committee in 1956 that the manufacture and distribution of both amphetamines and barbiturates should be sub-

ject to more stringent Federal controls, including penalties for their unauthorized possession.<sup>1</sup>

The subcommittee concluded that these drugs should be regulated under the commerce clause of the Constitution rather than the taxing power.

The subcommittee found, among other things, that illicit traffic in these drugs, unlike the traffic in narcotics, attacked small as well as large communities. It found that a problem of growing proportions had been created by chronic users of barbiturates and amphetamines who were a menace to the public when driving on our streets and highways. In our experience, these findings are more significant today than they were in 1956. Since that time, the problem has grown by leaps and bounds.

The illegal traffic in amphetamines spawned in the truck stops, service stations, and roadside taverns has spread throughout the Nation. Organized rings bootleg barbiturate and amphetamine drugs. Nearly 1 million amphetamine tablets were seized in November 1962 from a man who offered to sell FDA and Tennessee investigators one-half million tablets at a time. Some of these rings cover many States, and deal in millions of tablets and capsules. Amphetamines, for example, can be purchased at wholesale at less than \$1 per thousand, and sold at wholesale in the illegal traffic at \$30 to \$50 per thousand, and at retail at 10 to 25 cents each, and more. The very substantial profits involved have contributed to the magnitude of dealing with this problem.

The early development of illegal traffic in amphetamines occurred primarily along truck routes. Truckdrivers learned that use of these drugs permitted them to drive for longer periods without rest or to make more trips per week. So, some drivers started using them. Unfortunately, they did not realize that, while the drugs stimulate the nervous system, they do not eliminate physical fatigue. They mask fatigue, and ultimately the driver suffers seriously impaired reflexes, dangerous hallucinations, or periods of semiconsciousness while driving. This faced us with a new inspectional problem involving the diversion of amphetamines from the legitimate channels of wholesale and retail drug dispensing to sale in restaurants, bars, and truck stops. We had the new task of finding where the diversions were occurring and seeking to bring to justice both the diverters and the illegal merchants.

I wish to strongly emphasize, Mr. Chairman, that the trucking associations and others interested in highway safety have gone to great lengths to acquaint drivers with the hazards resulting from the use of amphetamines. And, obviously, most of the truck drivers of this country do not resort to their use.

But the tragic results of abuse of barbiturates and amphetamines by teenagers were graphically described in testimony presented in 1962 before the Subcommittee to Investigate Juvenile Delinquency, Senate Judiciary Committee.<sup>2</sup>

In an effort to assess the use and potential misuse of the drugs, which at present constitute the main problem, we conducted a survey of all

<sup>1</sup> Report to the House Committee on Ways and Means from the Subcommittee on Narcotics, p. 24, May 10, 1956.

<sup>2</sup> Hearings before the Subcommittee To Investigate Juvenile Delinquency, Senate Committee on the Judiciary, 87th Cong., 2d sess., pts. 12, 13; 1962.

known manufacturers, brokers, and distributors of basic amphetamine and similar stimulant chemicals and of barbiturates. We wanted to obtain accurate and current information about the amounts produced, the amounts exported and imported and the identity of all firms engaged in such enterprise. Unfortunately, our survey of production figures was incomplete because records kept by several basic manufacturers were grossly inadequate and also because two of the Nation's largest pharmaceutical firms declined, as was then their legal right, to provide the information requested. Nevertheless, we did learn that at least enough basic material was produced in 1962 to make over 9 billion doses of barbiturates and amphetamines combined. Probably half of these ended up on the bootleg market.

While we have been discussing barbiturates and amphetamines almost exclusively, it is important to point out that this bill is aimed also at other types of drugs capable of causing similar or related ill effects and there are a number of such drugs already known to be misused to some extent. For example, you may recall rather extensive publicity a few years ago about serious abuses that have developed around some of our larger educational and research institutions from experimentation with drugs which produce hallucinations and other mental aberrations when administered in minute doses. One of these is a chemical commonly referred to as LSD-25, its chemical name is *d*-lysergic acid diethylamide tartrate. In addition to producing the immediate hallucinations and aberrations which the experimenters sought, this drug has been found capable of inducing lasting changes in the mental and emotional stability of some users; and, there are instances in which college students who took doses of the drug for thrills or for nonscientific experimentation became disturbed to the point that they had to leave college or even enter mental institutions. The drug also produces strong suicidal tendencies in some victims.

Mr. Chairman, we have completed a criminal action against two men who were arrested on April 3, 1963, when they attempted to sell an undercover FDA inspector \$15,000 worth of LSD-25 at his home. On other occasions, they had offered over \$165,000 worth of the drug to FDA undercover inspectors.

The defendants, Bernard Roseman and Bernard Copely, were charged with nine counts of smuggling, misbranding the drug, dispensing a prescription drug without a prescription, and conspiracy. The Honorable George B. Harris sentenced Copely and Roseman to 5 years each on two smuggling charges, and 1 year each on seven charges of violation of the Federal Food, Drug, and Cosmetic Act. In sentencing the defendants, Judge Harris remarked that the Food and Drug authorities should recommend legislation appropriate to deal with these types of drugs to interested congressional committees.<sup>3</sup>

Mr. Chairman, this is what we are doing today.

Tranquilizers are being increasingly implicated by medical evidence as agents of drug abuse. In an article appearing in the August 10, 1963, issue of the Journal of the American Medical Association, members of the Public Health Service's National Clearinghouse for Poison Control Centers reported on 968 cases of tranquilizer ingestions occur-

<sup>3</sup> *United States v. Roseman*, DND Calif. (Crim. No. 39,333), June 3, 1964.

ring from July 1959 through December 1960. In conclusion, the authors stated:

Intentional ingestion was known to be the etiological basis in 35 percent of the cases reviewed. It becomes evident that the popularity of tranquilizers as suicidal agents must now rival that of the barbiturates.<sup>4</sup> It is reasonable to assume that most of these were drugs dispensed on prescription.

In a study conducted at the Boston City Hospital, Boston, Mass., from October 1961 to May 1962, a total of 82 drug abusers and addicts was reported. Of the 82, 44 were addicted to narcotics, 24 were abusers of barbiturates and amphetamines, 10 abused tranquilizers, and 2 each abused bromides and inhalers.<sup>5</sup>

Authorities in the field, including Dr. Hamburger, have taken the position that many of the tranquilizers are very close to the barbiturates in their effects, although not in chemical structure. Tranquilizers, like barbiturates, can cause tolerance and psychic and physical dependence.<sup>6</sup> The addicting properties of meprobamate have been rather extensively reported in the literature, and this literature clearly shows that this drug and certain others of the so-called tranquilizers are subject to abuse. Mr. Chairman, I now offer copies of the cited articles for the record.

The CHAIRMAN. We would be glad to have that. Is this an article by Dr. Carl F. Essig?

Mr. LARRICK. It is each of the articles which I have specifically referred to in my testimony, and which are listed as footnotes in the copy of the testimony you have before you. "The Problem of Barbiturates in the United States" by Joel Fort, M.D., from the Bulletin on Narcotics of January to March 1964; "Barbiturate Use in Narcotics Addicts" from the Journal of the American Medical Association, August 3, 1964; "Misuse of Valuable Therapeutic Agents, Barbiturates, Tranquilizers, and Amphetamines," a report by the committee on public health of the New York Academy of Medicine; "Drug Abuse and Addiction Reporting in a General Hospital," John A. Schremly, M.D., and Philip Solomon, M.D., Boston. And, finally, "Overdosage Effects and Dangers From Tranquilizing Drugs," Charles H. McKown, et al., in the Journal of the American Medical Association for August 10, 1963.

The CHAIRMAN. Have you had occasion to read the article by Carl F. Essig, of Lexington, Ky., of the National Institutes of Mental Health, the addition and research center of the U.S. Department of Health, Education, and Welfare?

Mr. LARRICK. Dr. Sadusk has it with him. He and his staff have reviewed it with care.

The CHAIRMAN. Well, I have read a part of it—since it deals with the subject from another source I wonder if there would be any objection to it being included in the record, too?

Mr. LARRICK. No, I think that is an excellent suggestion, sir, so we offer it also.

<sup>4</sup> McKown, Verhulst, and Crotty. "Overdosage Effects and Danger From Tranquilizing Drugs," 185 J.A.M.A. 425, 430 (1963).

<sup>5</sup> Schremly and Solomon. "Drug Abuse and Addiction," 189 J.A.M.A. 512 (1964).

<sup>6</sup> "Misuse of Valuable Therapeutic Agents: Barbiturates, Tranquilizers, and Amphetamines," a report by the committee on public health, the New York Academy of Medicine, May 11, 1964. Hamburger, "Barbiturate Use in Narcotics Addicts," 189 J.A.M.A. 366 (1964).

Fort, "The Problem of Barbiturates in the United States," 16 Bulletin on Narcotics, 17, 31 (1964).

The CHAIRMAN. Let them be included in the record following the statement.

I think probably your entire statement should be included in the record, as you desire here this morning, along with the footnotes, because I think they are important for reference.

Mr. LARRICK. Thank you, Mr. Chairman.

President Kennedy, in his consumers' protection message of March 15, 1962, recommended legislation which would establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines. In September 1962, the President called the White House Conference on Narcotic and Drug Abuse. In discussing the problems associated with narcotics and other drugs, the President said:

One problem meriting special attention deals with the growing abuse of non-narcotic drugs, including barbiturates and amphetamines. Society's gains will be illusory if we reduce the incidence of one kind of drug dependence, only to have new kinds of drugs substituted. The use of these drugs is increasing problems of abnormal and social behavior, highway accidents, juvenile delinquency, and broken homes.

The abuses associated with the nonmedical use of barbiturates, stimulant drugs, and tranquilizers were also considered in some detail in the final report of November 1963, of the President's Advisory Commission on Narcotic and Drug Abuse. As you know, Mr. Chairman, President Johnson has directed the several agencies of the executive branch which have an interest in this matter to take steps to bring the full power of the Federal Government to bear on the problem. On July 15, 1964, President Johnson stated:

Narcotic and other drug abuse is inflicting upon parts of the country enormous damage in human suffering, crime, and economic loss through thievery. The Federal Government, being responsible for the regulation of foreign and interstate commerce, bears a major responsibility in respect to the illegal traffic in drugs and the consequences of that traffic. That responsibility is shared by several departments of the Government and by a number of divisions, bureaus, etc., within them. I now direct those units to examine into their present procedures, to bring those procedures into maximum activity, and wherever necessary put into effect additional programs of action aimed at major corrections in the conditions caused by drug abuse. I desire the full power of the Federal Government to be brought to bear upon three objectives: (1) The destruction of the illegal traffic in drugs, (2) the prevention of drug abuse, and (3) the cure and rehabilitation of victims of this traffic. Attention is called to the program described in the report of the President's Advisory Commission on Narcotic and Drug Abuse.

The FDA program against illegal distribution of these drugs is conducted primarily by inspectional staffs located in 18 district offices. However, investigation of illegal sales of prescription drugs represents only a small part of our inspection activities. We must also inspect over 100,000 food, drug, and cosmetic establishments and collect samples of their products. In fiscal year 1964, we used 56 inspector man-years out of a total force of 687 man-years to investigate illegal drug sales, primarily sales of amphetamines and barbiturates.

On the average, then, we used just a little over one man per State to deal with this problem.

Mr. Chairman, the findings in sections 2 of H.R. 2, and their implementation in the operative parts of the bill, are particularly timely. As you are aware, to regulate dangerous drugs under the Food, Drug, and Cosmetic Act, we must prove that they are in interstate commerce.

For some time, to be sure, courts have accepted testimony as proof of interstate commerce when the tablets in question bore characteristic markings and striations identified only with tablets known to be manufactured outside of the State and when this evidence was supported by the testimony of an official of the Board of Pharmacy that the powder from which the tablets were pressed was not manufactured in the State.

On the other hand, on May 1, 1964, Hubert O. Boyd, trading at Pat's Truck Stop, was convicted at Richmond, Va., in a Federal court, on three counts of illegal dispensing of amphetamines on this type of evidence. On October 16, 1964, the Court of Appeals for the Fourth Circuit reversed the conviction on these counts holding that the evidence failed to establish that the drugs had been shipped in interstate commerce. The Fifth Circuit on December 7, 1964, reached a different result in a similar case. This bill, if enacted, would resolve the conflict. In order to make regulation and protection of interstate commerce in barbiturates and amphetamines effective, regulation of intrastate commerce is necessary because, among other things, such drugs, when held for illicit sale, usually do not bear labeling showing their place of origin. Moreover, to subject interstate commerce to the needed controls without applying them to intrastate commerce would have the effect of discriminating against and depressing interstate commerce.

Mr. Chairman, I wish to address myself briefly to a few provisions of section 3. The definition of the term "depressant or stimulant drug" does not include tranquilizers by name; but, if this bill is enacted, we intend to see that those that have a potential for abuse are covered by regulation. The evidence we have cited indicates that already certain tranquilizers are being abused. When the bill becomes effective there will no doubt be a tendency to substitute such tranquilizers in the illicit traffic. We therefore, believe that they will require controls such as those afforded by this bill.

The prohibition of possession of depressant or stimulant drugs by unauthorized persons except for one's individual or for other legal use would give FDA an additional tool to deal with illegal traffic. The unauthorized possession of drugs with such potentiality for harm as those intended to be covered by H.R. 2, should, in our view be a prohibited act as the bill provides.

Most legitimate manufacturers and distributors keep records of inventories and of receipts and deliveries without compulsion of law. Except for initial inventory which the bill would require, the record-keeping provisions of H.R. 2 can be met by records traditionally kept by responsible manufacturers, wholesalers, retailers, and hospitals. A firm that fails to keep records on depressant and stimulant drugs is, in our opinion, a proper candidate for suspicion. In our view the provisions of the bill which makes failure to keep required records unlawful and subject to the criminal and civil sanctions of the Food and Drug Act are essential. I would suggest two clarifying amendments.

First, we believe that the bill, or at least its legislative history, should make clear that failure to comply with the recordkeeping requirements of the bill is ground for seizure of the drugs involved. While I would so interpret the language of the bill as now drafted, I

am told that this is not free from doubt under the language of section 6 in its present form. We can see no good reason why the failure to keep these essential records or to afford access to them to our inspectors should be any less a ground for seizure than direct proof of illicit traffic in these drugs. Seizure need not result in ultimately depriving a legitimate manufacturer or dealer of these drugs, because, as we understand section 304(d) of the Food and Drug Act, the court would be authorized to allow the violator to bring himself into compliance by constructing and making available proper records of the drugs involved, which should not be too difficult for a really legitimate manufacturer or dealer.

Second, Mr. Chairman, the bill's recordkeeping provisions specify that no separate records or set forms shall be required as long as records containing the required information are available. We have no quarrel with the spirit of this provision, for we have said in the past that the type of records normally in use, such as invoices, shipping records, or the like, would ordinarily serve, so long as they readily afford the information desired. In its present form, however, this provision would sometimes place an undue burden on both FDA and the establishment being inspected. For example, a firm which manufactures tens or even hundreds of different articles might have all of the required information on depressant or stimulant drugs contained in invoices which may be filed with invoice for all products the firm distributes. We ran into such a situation recently where we inspected the records of a small firm in New York, having an annual gross volume of only \$250,000 in depressant and stimulant drugs. This was less than 10 percent of the firm's total gross volume. The records on depressant and stimulant drugs were not segregated from the records of other products. It took our inspectors 250 man-hours to check these records. I would, therefore, suggest that, preferably, this provision be deleted from the bill and the matter be left to be worked out sensibly in practice in the light of appropriate language in the committee report, or at least that the provision be appropriately clarified, perhaps by inserting the words "readily and conveniently" before the word "available" on page 7, line 25.

Ordinarily, manufacturers would prefer that our inspectors would not remain in their establishment 250 man-hours.

Licensed practitioners authorized by their State law to use and prescribe these drugs are exempt by the bill from accounting by records for drugs dispensed in their professional practices. It has been suggested that if physicians are exempt, so should be pharmacists, or vice versa. But there is a great quantitative difference in the amounts of these drugs directly handled by these two professions. There are approximately 52,000 retail drugstores and 125,000 registered pharmacists in the United States. The great majority of these professional people not only abide by the law but constitute an important source of information which aids our investigation. I am personally proud to be an honorary member of the American Pharmaceutical Association and the National Association of Retail Druggists. Less than 1 percent of this country's pharmacists have been convicted of illegally dispensing depressant or stimulant drugs since 1953. But even though this is a low percentage, it totals over 1,100 criminal convictions. Less than three dozen physicians have been so

convicted. The application of the recordkeeping requirements is therefore necessary and should be retained. If the committee wishes to consider an amendment making the recordkeeping provisions of the bill applicable to physicians also, the Department has no objection.

The bill provides for the registration of wholesalers handling depressant or stimulant drugs, and it requires manufacturers who are already required to register generally under present laws, to indicate that they are engaged in making such drugs. These provisions will aid in preventing diversions from legitimate channels of distribution.

It would be our purpose, if this legislation is enacted to consult knowledgeable scientists in and out of Government in determining which drugs should come under the scope of the proposed section 201(v). While provision for referral of these matters to advisory committees is not needed by the Government to accomplish such consultation, we would have no objection to an advisory committee procedure, such as that proposed in the bill, to give industry the opportunity to call for an advisory committee of outside scientists when it wishes to do so. If the advisory committee process is retained, however, we recommend that the bill require the record of the proceedings of the committee to include, beside the data formally presented, a record of all contacts made with the committee or its individual members with regard to the subject matter before the committee. The record should reflect the data or other submission outside of the formal proceedings and should be available for review by any interested party as soon as the Secretary publishes his order. These new provisions are suggested to act as a check upon efforts to bring hidden or improper pressures upon committee members. Your committee may also wish to consider whether formal rulemaking proceedings for the listing of a drug, as would be required under the bill, are really needed for this purpose. Our experience indicates that such a proceeding can drag on for years. You may wish to consider, instead, utilizing the rulemaking procedure in section 4 of the Administrative Procedure Act. This section has been used extensively under the Food, Drug, and Cosmetic Act; for example in the promulgation of regulations for investigational use of new drugs.

Mr. Chairman, the seizure provisions under section 6 of H.R. 2, in our judgment, do not give the Government all the authority it needs for proper enforcement. Under the bill, a libel of information would have to be filed before violative depressant or stimulant drugs or counterfeits could be detained. Obtaining the libel and executing seizure under it usually takes several days. Arrests and seizures are often executed far from the officers of Federal judges who issue the arrest warrants and libels. Time is often critical, especially when contraband articles are carried in a vehicle. An inspector who has personal knowledge of the violation or reasonable grounds to believe that the articles are subject to seizure and condemnation should be empowered to detain and remove the article prior to the time a libel of information is filed. This would assure the arrest of the articles until the usual process can be issued.

FDA inspectors should also be able to seize, and the courts should be authorized to condemn, any conveyance in which violative stimulant or depressant drugs or counterfeit drugs have been unlawfully

transported, carried, or held. This provision would not apply to conveyances stolen from their legal owners or common carriers, the owners of which are not a party to such illegal transportation, carriage, or holding. Innocent third parties holding valid liens upon such conveyances should also be protected. In this connection, we suggest that the bill make clear, that the provisions of 40 U.S.C. 304(i) authorizing the district court to turn over to the seizing agency for use in official business, any property condemned by the court, shall apply to seizures under this bill. Presently, we rent automobiles for use in undercover work. This provision would allow FDA to use automobiles which have been seized and condemned because of their previous illegal involvement in connection with future investigations. These added enforcement provisions are basically comparable with provisions in existing Federal laws to regulate illicit production and distribution of alcoholic beverages and narcotics.

Mr. Chairman, I have been asked to advise you that the Justice Department has not had an opportunity to give this matter of seizures of vehicles full consideration, and if the committee decides to provide for forfeiture of automobiles, it may wish to seek the advice of that Department.

Provision should also be made for the seizure and condemnation of machinery and equipment used in the unregistered or other unlawful manufacture of stimulant or depressant drugs. Otherwise, the detection of illegal manufacture of the drugs and their seizure could become essentially a mere annoyance to criminals who would spirit equipment to a new base to continue their manufacturing operations.

Finally, I believe that the bill should give our inspectors, when authorized by us, the power to serve and execute warrants and other process, and the power to make arrests without warrants for offenses with respect to these drugs when the offense is committed in the officer's presence or, in the case of a felony, when the officer has reasonable cause to believe that the person so arrested has committed or is committing the offense. I am advised that the narcotic agents and the law enforcement officers of certain other agencies now have such powers.

Just as in the matter of seizures, so in the case of the matter of arrests, the absence of these powers is likely to result in the escape of the criminal. Under the present practice even in those few selected cases, such as the *Carl Royal* case, in which prior notice to the person charged is not given under a provision of the act that I shall discuss presently, there is serious risk that the attendant advance publicity will result in putting the illicit drug supply beyond our reach. Under that practice, in such case, a criminal information is filed by the U.S. attorney at the request of the FDA. The criminal information must identify the defendant by name and specify the nature of the violation. In our experience, when informations are filed by the U.S. attorney, they immediately become a public record and are open to the scrutiny of the press. The availability of this information to the press may seriously impair FDA's ability to trace distribution of illegal drugs back to the source of supply. If the defendant wishes to cooperate by assisting FDA in apprehending his source of supply, the publicity attending his arrest could alert and has alerted his supplier, thus making contact with him difficult and hazardous. The arrest procedure now

used in such cases is also cumbersome in that it requires an initial illegal sale upon which a criminal information filed by the U.S. attorney can be based, and at least a second contact coordinated to a time at which the U.S. marshal is available to serve the arrest warrant. Ordinarily, contacts with peddlers are made entirely on the peddlers' terms and are often subject to last minute changes, delays, or postponements to avoid detection by law enforcement officers.

In the context of my suggestion on arrests, another clarifying amendment to the present law seems desirable. Section 305 of the Food, Drug, and Cosmetic Act provides that a person against whom a criminal proceeding is contemplated by us shall, before we refer the matter to the U.S. attorney, be given notice by us and afforded an opportunity to present his views on the matter. In general, this practice is appropriate and is followed by us, but in certain types of cases, such as those that are likely to arise under this bill, prior notice to the person charged could, for reasons that I have already explained, result in aborting the particular proceeding and others before they start. While the Supreme Court has held that compliance with section 305 on our part is not a jurisdictional prerequisite to the prosecution by the U.S. attorney, it would nevertheless seem desirable to make clear in section 305 that it should not be followed where the Secretary finds that to do so would jeopardize the contemplated proceeding or other proceedings.

Mr. Chairman, section 8, which permits the Secretary to authorize our inspectors to carry firearms when investigating depressant and stimulant drugs, fills a void which has given us great concern—concern for the safety of our inspectors. Many dangerous drug investigations follow the pattern of a criminal investigation. Such an investigation was recently terminated against Carl Everett Royal of Galax, Va., by a plea at Richmond, Va., on November 30, 1964. The Virginia State Police, the Harrisonburg city police, the Rockingham County sheriff's office advised our inspectors that the sale and distribution of "pep pills" and "goof balls" were widespread. Two of our inspectors went "undercover" under the guise of drug peddlers. They made a buy of a pusher who identified his source as Carl Royal. Carl Royal subsequently sold our inspectors a quantity of 5,000 amphetamine tablets and later 50,000 amphetamines, and still later 100,000. At this point, he was apprehended. Through Carl Royal, we ascertained the source of these drugs. Ultimately, we traced distribution from this primary source to peddlers in Ohio, West Virginia, Maryland, and North Carolina. State and local police officers participated extensively in this chain of investigations.

Racketeers are taking over this lucrative business. The criminals with whom our inspectors deal are armed and would not hesitate to kill. Our agents have been informed repeatedly by drug bootleggers that they would be killed if they turned out to be Government men. One of our inspectors was held at gunpoint in Los Angeles for over 5 hours by an amphetamine peddler who was using his own wares and who repeatedly threatened to kill him. It is, indeed, a miracle and our good fortune that no inspector has been killed. For several years, we have had a small program to train agents in self-protection and proper methods of conducting the investigations, and have participated in excellent schools conducted by the Bureau of Narcotics, certain Defense

Department units, and the outstanding Los Angeles County Sheriff's Academy. An expanded, though still modest program, is still underway to train a small group of selected inspectors to make use of special law enforcement technique. We feel that if our inspectors are permitted to carry firearms, they will be better able to protect themselves. The provision of section 8 which makes it a Federal offense to assault or kill officers who conduct inspections under the Food, Drug, and Cosmetic Act will be a further measure of protection. However, Mr. Chairman, we do believe that section 8 of this bill should be amended to authorize FDA inspectors to carry firearms also while conducting investigations or inspections related to counterfeit drugs.

The authority to designate officers who may carry firearms is given to the Secretary, who may if he wishes, delegate this authority to the Commissioner. As Commissioner, I would only permit men whom I know to be well trained and who would not abuse this authority to carry firearms. I wish to emphasize, Mr. Chairman, that FDA inspectors could not carry firearms while conducting normal investigations.

This bill provides for increased penalties for an illegal sale of depressant or stimulant drugs by an adult to a juvenile. The Senate Judiciary Committee hearings already mentioned pointed out the detrimental social consequences of juvenile delinquency stemming from drug abuse. We anticipate that the increased penalty provisions would help deter illegal sales to juveniles.

Mr. Chairman, I wish to speak now about a very vicious type of crime which is dealt with in section 9 of H.R. 2. A counterfeit drug, like counterfeit money, is a fraud on the public. More important, however, is the imminent danger which it presents to the health of the user. Enormous profits can be made by counterfeiting legitimate drugs with minimal risks of penalties under the present law. For this reason, the activity has become widespread and sometimes is nationwide in scope.

The counterfeit drug is not manufactured under the controls or with the care that is necessarily taken for the legitimate drug it imitates, and there is no guarantee that the counterfeit drug contains the amounts, quality, and kinds of ingredients the legitimate drug contains. A consumer who is sold a counterfeit drug may have his health and even his life dependent on a product which has little or no resemblance to the drug prescribed by his physician, except for labeling or appearance. In turn, his physician may be misled in his intended therapeutic regimen by the different response of the patient to the drug from that anticipated.

Production and distribution of counterfeit drugs are bootleg operations. Special equipment for their production such as tableting dyes, tableting punches, and capsule marking machines are secreted and put to us surreptitiously.

After being produced under conditions designedly hidden from inspection by the Food and Drug Administration and all other State and local officials, counterfeit drugs are distributed by equally devious means. These have included shipment in unmarked cartons and containers. No matter the route, however, the ultimate consumer receives a counterfeit drug in place of a trustworthy medicine. He is defrauded, and his health is jeopardized.

For example, eight men and two firms, one a pharmaceutical company and the other a packaging company, were charged by the Justice Department with counterfeiting and distributing a variety of drugs, including two well-known tranquilizers. The charges specified counterfeiting of Miltown and Equanil tranquilizers; Diuril and Hydrodiuril, diuretics; Esidrix and Serpasil, blood pressure reducers; Tedral, an antiasthma drug; and Meticorten, a multipurpose drug used in severe cases of rheumatoid arthritis and many other inflammatory conditions. The tablets, though stamped and shaped to look genuine, were manufactured and labeled fraudulently and packaged in unlabeled bottles and bags. The shipments, labeled variously as "Beads and Machine Tools," "Ceramics," and "Water Softener" were distributed by car and air freight in five States. Some of the individuals involved were prosecuted and convicted under State law. The Department of Justice, for policy reasons, declined to prosecute under Federal law.

At an apothecary in Decatur, Ga., a total of 3,430 counterfeit Dexadrine, Dexamyl, and Diuril tablets were seized by the Federal court at the request of our inspectors. The imitation Dexedrine, a central nervous system stimulant, and imitation Dexamyl, a mixture of an antidepressant and sedative drugs, for appetite depression, were contained in dispensing bottles bearing labeling indicating the tablets to be legitimate products of a well-known reputable manufacturer, Smith, Kline, & French Laboratories, of Philadelphia. The counterfeit tablets of Diuril, a potent diuretic and antihypertensive agent, were contained in a bottle bearing what appeared to be the legitimate label of another well-known reputable firm, Merck & Co. In November of 1961, the apothecary was found guilty and fined \$3,000.

A Federal grand jury in New York indicted two men for introducing into interstate commerce about 60,000 counterfeit tranquilizer tablets. The tablets looked like and were represented as being two well-known tranquilizer drugs, Miltown and Equanil. The tablets were subpotent, and their labeling did not bear necessary directions for use, and were otherwise deficient. The drugs were shipped by public bus in unidentified packages from New York to New Orleans where they were picked up by our inspectors. One defendant plead guilty and was fined \$200. The other was convicted after trial and was given a 3-year suspended sentence and placed on probation for a year.

Ethical pharmaceutical houses have been a great help to us in the conduct of counterfeit investigations.

In June 1964, our inspectors, aided by a legitimate drug firm, were able to arrange a contact with two persons known to deal in suspect drugs. The meeting place was the Newark, N.J., airport. One of our inspectors agreed to purchase a substantial quantity of counterfeit Dexedrine and Dexamyl Spansules, Smith, Kline & French Laboratories products, for the ostensible purpose of a later sale in Omaha, Nebr. The "buy" was made and analysis proved the drugs to be counterfeit. Our inspectors made two additional buys and shortly thereafter learned of a secret room concealed behind a movable stairway in the private residence of one of the individuals involved. A legal search of the premises by our inspectors resulted in seizure of

nearly 1 million counterfeit pills, drug paraphernalia, and arrest of the counterfeiters. Trial in this case is still pending.

Because of the clandestine methods by which counterfeit drugs are manufactured and distributed and the burden they impose on interstate commerce in legitimate drugs, their regulation as contemplated by this bill, whether they are in interstate commerce or not, is absolutely essential to the effective protection of the public health.

I should like to add in conclusion, Mr. Chairman, that with its report on this bill, the Department has submitted for the committee's convenience draft language to carry out the recommendations I have here outlined, plus technical and perfecting amendments suggested by staff.

Mr. Chairman, this hearing being held today is, in a sense, historic. It is the product of 2 decades of FDA investigation, congressional hearings spanning 13 years, and 40 bills introduced into Congress in the past 14 years. The bill will go far in putting an end to the tragic traffic in the human misery which has been described today. We believe it will give us the tools, when supported by adequate appropriations, to adequately deal with the problems which face us. However, if our experience demonstrates that the powers granted us need strengthening, we will come back to this committee with proposals for additional legislation.

Thank you, Mr. Chairman.

If the committee has any questions, I will be happy to try to answer them.

(The documents referred to follow:)

[From *Clinical Pharmacology and Therapeutics*, May-June 1964, 5:334-343]

**ADDICTION TO NONBARBITURATE SEDATIVE AND TRANQUILIZING DRUGS\***

(Carl F. Essig, M.D., Lexington, Ky., National Institute of Mental Health, Addiction Research Center, U.S. Department of Health, Education, and Welfare, Public Health Service)

Increasing numbers of nonbarbiturate sedative drugs are being introduced into medical practice. Despite their nonbarbiturate chemical structure and regardless of designations other than "sedative-hypnotic," at least six of the newer depressant drugs can cause states of intoxication and physical dependence that are clinically similar to those induced by barbiturates. These drugs are meprobamate (Miltown, Equanil), glutethimide (Doriden), ethinamate (Valmid), ethchlorvynol (Placidyl), methyprylon (Noludar), and chlordiazepoxide (Librium). The behavioral effects of these drugs and their combination with ethanol may become an increasingly important public hazard. The abstinence syndromes that can result from the abrupt withdrawal of excess dosages of these drugs include convulsions and psychotic behavior. Death has been attributed to withdrawal of meprobamate and methyprylon. Office or ambulatory withdrawal of any of these drugs after use in large dosage is not recommended. Gradual dosage reduction or barbiturate substitution prior to its gradual withdrawal during hospitalization is suggested. Substitution of diphenylhydantoin (Dilantin) or any of the phenothiazines as the sole means of support during sedative-hypnotic drug withdrawal is a questionable practice.

\*Presented (in part) at a symposium of the pharmaceutical sciences section committee of the American Association for the Advancement of Science, Cleveland, Ohio, December 1963. Received for publication Feb. 25, 1964.

Reports of controlled experiments in man that confirmed the addictive properties of the barbiturates appeared in 1950.<sup>21, 22</sup> Barbiturate intoxication is marked by intellectual impairment, drowsiness, poor judgment, emotional lability, slurred speech, nystagmus, tremor, and a staggering gait.<sup>21, 22</sup> Abrupt withdrawal of barbiturates after extended and excessive use can result in a serious withdrawal syndrome, which includes apprehension, weakness, anorexia, nausea, vomiting, disturbances in cardiovascular function, tremulousness, insomnia, grand mal convulsions, and a delirium associated with disorientation, delusions, and hallucinations.<sup>21, 22</sup> The striking resemblance between barbiturate and ethanol intoxication, as well as the similarity of barbiturate withdrawal to delirium tremens, have been noted.<sup>22</sup>

Since 1950, an increasing number of nonbarbiturate sedative drugs has been introduced into medical practice. Some have been categorized as "tranquilizers," "relaxants," "psychotropic agents," or the term "nonbarbiturate" has been emphasized, but both the intoxication and physical dependence induced by these drugs are barbituratelike.

Intoxication refers to the drowsiness, impaired mentation, and motor incoordination caused by excessive amounts of these agents. Physical dependence is defined as an altered biologic state caused by consumption of a drug so that its use must be continued in order to prevent the development of specific symptoms and signs (withdrawal syndrome). Addiction is a condition in which an individual abuses a drug to the extent that the user, society, or both are harmed. Other characteristics of addiction include a tendency to increase the dose, psychic dependence, and physical dependence.

This report will emphasize the medical aspects of the intoxications and serious abstinence syndromes that can result from use of newer nonbarbiturate sedative-hypnotic drugs. Deaths have occurred during withdrawal of a barbiturate, as well as each of two drugs to be discussed in this report.<sup>4, 22, 23</sup> A survey of these drugs is presented to aid in the prevention and to assist in the diagnosis and treatment of physical dependence to and the abstinence syndrome due to these agents.

#### MEPROBAMATE (MILTOWN, EQUANIL, Meprospan, MeproTabs)

Meprobamate has been described as a tranquilizer or relaxant and was said to be nonaddicting.<sup>3</sup> Data derived from both animal and man indicate that it has intoxicating and addicting properties not unlike those of the barbiturates.

Both deep sleep and a wide-based staggering gait were observed in dogs that had received large doses of meprobamate.<sup>17</sup> The development of tolerance to the anticonvulsant actions of this drug has been demonstrated in mice.<sup>54</sup> During periods of 124 to 188 days, four dogs tolerated doses of meprobamate that were increased from 1.6 to 8.0 or 8.8 grams daily. Physical dependence to meprobamate was also demonstrated in the dogs because major convulsions developed following withdrawal of the drug.<sup>17</sup>

In man, when the dose exceeds 1.2 to 1.6 grams daily, meprobamate, like the barbiturates, induces drowsiness or sleep.<sup>26, 28, 29, 46, 57</sup> Coma has been observed following excessive doses of meprobamate,<sup>30</sup> and deaths have resulted from ingestion of 240 and 350 milligrams per kilogram.<sup>49</sup> Like the barbiturates, meprobamate induces slurred speech, staggering, and falling.<sup>17, 25, 28, 29</sup> Self-injury and an automobile accident have been attributed to meprobamate-induced incoordination.<sup>30</sup> Impairment of motor coordination and reaction time has been demonstrated in human subjects who had received 1,600 milligrams of meprobamate prior to testing on a multiple stimulus-response apparatus.<sup>30</sup> The combined effects of ethanol (blood levels of 50 milligrams percent) and meprobamate (1,600 milligrams per day) have been studied in 22 subjects. Significant impairment of motor performance and judgment was noted and it was concluded that patients should be warned of the potential danger of alcoholic beverages when taking meprobamate.<sup>61</sup>

Tolerance probably accounts, in part, for the tendency of some to increase the dose of this drug. Two patients who were "overdoing" self-medication developed dysarthria and incoordination.<sup>28</sup> One report notes that 13 of 600 patients had increased the dose of meprobamate beyond that prescribed, so that the physician had to discontinue the drug.<sup>39</sup> Of 47 patients, 35 developed staggering or falling during the first 3 days they received either 3.2 or 6.4 grams of meprobamate daily but these signs diminished over the next 4 to 7 days, suggesting that some tolerance to the drug had developed.<sup>26</sup>

See footnotes on p. 40.

There is ample evidence that meprobamate can induce physical dependence in man. Like the barbiturates, there is also a safe minimal daily dose that can be abruptly withdrawn without causing clinically significant abstinence signs. This "safe" minimal dose probably lies between 1,600 and 2,400 milligrams daily. Thus, 60 patients received 400 milligrams of meprobamate 3 times daily for 8 weeks and failed to develop clinically significant withdrawal signs during placebo substitution.<sup>7</sup> No definite evidence of abstinence was observed after withdrawal of meprobamate from 2 patients who had been taking 1,600 milligrams daily.<sup>38</sup> On the other hand, 6 of 25 schizophrenic patients who received 2,400 milligrams of meprobamate daily for 9 months had convulsions following its abrupt withdrawal.<sup>3</sup> Mild, moderate, and severe abstinence reactions were observed in a well-controlled study of 47 psychiatric patients who received 3.2 or 6.4 grams of meprobamate prior to abrupt placebo replacement.<sup>39</sup> Thirty subjects were classified in the mild category characterized by insomnia, vomiting, tremors, muscle twitches, anxiety, headache, and ataxia. Twelve other subjects had moderate abstinence reactions in which severe insomnia, anorexia, hallucinations, delusions, depressed affect, and catatonia were noted in addition to the characteristics listed in the mild category. Severe abstinence responses were observed in four patients, three of whom had from one to three convulsions in addition to the withdrawal symptoms already noted. Psychotic behavior (eight patients) and convulsions appeared within 36 to 48 hours of abstinence. In eight patients with hallucinosis, anxiety, and tremulousness after withdrawal, the clinical picture was described as resembling delirium tremens.<sup>39</sup> One patient who received 4 grams of meprobamate for 3 months had nervousness, headache, and one grand malconvulsion 34 hours after abrupt withdrawal.<sup>38</sup> Abstinence convulsions have been observed following withdrawal of 5.6 and 6.4 grams daily of meprobamate.<sup>39 47</sup> Doses of this order are not unusual in addiction-prone individuals who tend to increase their daily consumption of drugs that cause physical dependence.<sup>19 39 47 53</sup>

Like the barbiturates, meprobamate induces 20 to 30 per second fast waves in the waking human electroencephalogram.<sup>9 20 32 46 57</sup> Meprobamate withdrawal can result in paroxysmal discharges in the electroencephalogram.<sup>9 38 39</sup> EEG spiking was noted in six of seven patients during meprobamate withdrawal after the drug had been used for more than a month in doses of 65 milligrams per kilogram or more. In the same study the EEG abnormalities persisted for 1 to 2 weeks.<sup>6</sup>

Death has been attributed to meprobamate withdrawal. A 38-year-old white man gradually increased his consumption of meprobamate from 1.6 to 10 grams daily before suddenly decreasing it to 1.6 grams during the 12 hours preceding withdrawal reaction. He complained of nervousness, sweating, and tremulousness. He became insomolent, restless, hyperthermic (104° F.), then had repeated grand mal seizures which subsided. Despite treatment in the hospital with magnesium sulfate, pentobarbital fluids, cooling measures, and vasopressor agents, the patient's temperature rose to 107.8° F. Blood pressure fell, oliguria developed, and the patient died 68 hours after admission. Death was attributed to meprobamate withdrawal; a hemoglobinuric nephrosis, found at autopsy, was considered to be a contributory cause.<sup>39</sup>

#### GLUTETHIMIDE (DORIDEN)

Although this drug is categorized as a nonbarbiturate sedative, it can induce intoxication and physical dependence in both animal and man.

Ten dogs that received this drug developed a staggering gait and somnolence. Progressive intoxication of the dogs with glutethimide to daily dose levels of 300 to 424 milligrams per kilogram per day resulted in the death of five. One of the surviving dogs had four major convulsions following abrupt withdrawal of 300 milligrams per kilogram daily of this drug. The high mortality rate in dogs during progressive glutethimide intoxication has not been observed in similar studies of either meprobamate or sodium barbital.<sup>19</sup>

Glutethimide intoxication occurring in persons using 2.5 to 5 grams daily is characterized by drowsiness, thick speech, staggering, an "acute brain syndrome" with disorientation, impaired memory, and inability to do the simplest arithmetic problems.<sup>40 41 51</sup>

Coma has been reported in adults after the ingestion of 5, 10, 12, and 15 grams of glutethimide.<sup>5 13 42</sup> Death has been caused by 12 grams. The lethal dose is estimated to be 10 to 20 grams.<sup>42</sup>

See footnotes on p. 40.

Case reports of patients who increased their daily dose of glutethimide during periods of weeks to months suggest that tolerance develops to this drug. One patient who was instructed to take 1 gram of glutethimide at bedtime increased the dose to 6 to 8 grams daily during a 2-year period.<sup>34</sup> Another, who was given a prescription for 1.75 grams daily, complained that this dose of glutethimide no longer "calmed his nerves." At the patient's insistence the dosage was increased and within 2 months he was taking at least 20 grams a week.<sup>31</sup> Another report cites five cases in which glutethimide consumption ranged from 4 to 12 grams daily.<sup>41</sup>

The glutethimide abstinence syndrome is very much like that due to the withdrawal of barbiturates or meprobamate. Withdrawal symptoms include nausea, vomiting, agitation, tremulousness, tachycardia, fever, sweating, incontinence, tonic muscle spasms, abdominal cramping, difficulty in swallowing, headache, disorientation, hallucinations, and convulsions.<sup>34 40 41 44 51</sup>

The first reported glutethimide abstinence convulsions occurred in a non-epileptic individual who had been taking 3 to 5.5 grams of the drug daily. The abstinence seizures began 16 hours after the last dose of glutethimide, and there were 3 more major convulsions during the next 5 hours. Convulsions ceased after the administration of sodium phenobarbital. The patient recovered during gradual withdrawal of the latter.<sup>44</sup> Glutethimide abstinence seizures have been observed as late as the sixth day after withdrawal.<sup>51</sup> The occurrence of major convulsions after glutethimide withdrawal has been noted in five reports.<sup>34 40 41 44 51</sup> It is suggested in one of the reports that tolerance, habituation, and addiction may develop if the daily dose exceeds 2.5 grams.<sup>51</sup> In some persons, glutethimide withdrawal has been followed by delirium characterized by tremulousness, disorientation, confusion, and hallucinatory behavior.<sup>34 40</sup>

Glutethimide further resembles the barbiturates and meprobamate in that it can induce fast frequencies (20 to 30 per second) in the waking electroencephalogram.<sup>34 37</sup>

#### ETHINAMATE (VALMID)

This drug is a short-acting sedative not recommended by the manufacturer for continuous daytime sedation. Moreover, it is not categorized as a tranquilizer or nonbarbiturate.<sup>45</sup>

Although death did not result from 28 grams of ethinamate in one case, it did occur after 15 grams in another.<sup>11 12</sup>

A pharmacist is reported to have begun the use of ethinamate after being told it was a short-acting, nonaddicting sedative. He said it helped his restlessness and gave him a "kick" not experienced during prior use of barbiturates. The subject increased the daily dose of ethinamate from 2 or 3 grams to 15 grams and became progressively confused, agitated, and disoriented. He was hospitalized, and on the second day of withdrawal had a grand mal convulsion. Thereafter, hallucinations, agitation, syncopal episodes, tremors, and hyperactive reflexes developed.<sup>14</sup> He became addicted a second time, and while using 13 grams of ethinamate daily was noted to have an unsteady gait with frequent falls. In a hospital, 12 hours after withdrawal, he became agitated, hyperactive, disoriented, and delusional; he also had hallucinations. On the second day after withdrawal four grand mal convulsions were observed. Treatment with promazine led to a drop in blood pressure and the drug was discontinued. By the 11th day after withdrawal, he seemed to be more calm, and subsequently became progressively more rational and coherent. He was discharged on the 36th day of hospitalization with no evidence of organic sequelae.<sup>14</sup> The same report also described a patient with epilepsy who had been taking 4 to 5 grams of ethinamate in addition to diphenylhydantoin. Despite continuation of the latter, sudden withdrawal of ethinamate resulted in sleeplessness, disorientation, visual hallucinations, and several convulsions.<sup>14</sup>

#### ETHCHLORVYNOL (PLACIDYL)

Ethchlorvynol is described by the manufacturer as a nonbarbiturate hypnotic-sedative that can be used to relieve insomnia, anxiety, and muscular tension. However, it is not advertised as a nonbarbiturate, and its habituation potential is mentioned. An exaggerated response to it can develop when combined with ethanol or other sedative drugs.<sup>48</sup>

Profound unconsciousness was reported in two alcoholic males who had ingested 500 and 750 milligrams of ethchlorvynol, respectively. It was postulated that alcoholic liver damage accounted for the marked depressant effect of

See footnotes on p. 40.

ethchlorvynol in the men because the authors had observed that duration of sleep following this drug was prolonged sixfold in rats that had 75 percent of their livers excised previously.<sup>9</sup> Algeri and colleagues<sup>1</sup> quote a personal communication stating that five adults had become comatose and remained so for 5 to 7 days following ingestion of 10 to 25 grams of ethchlorvynol. All recovered, but another, who had taken 49.5 grams of ethchlorvynol, died 2 days later. Two persons died who had consumed unknown amounts of ethchlorvynol. The blood levels of the drug were 10 times those (13.8 and 14.8 milligrams per hundred cubic centimeters) of an experimental subject who had taken 1 gram of the drug.<sup>1</sup>

Like the barbiturates, meprobamate and glutethimide, ethchlorvynol has been reported to induce fast frequencies in the human electroencephalogram.<sup>20</sup>

Physical dependence to ethchlorvynol developed in a woman who began its use for "anxiety." The dose had been increased to 1,500 milligrams per day, and this amount had been used for months. Generalized weakness, staggering, nocturnal muscular aching, trancelike episodes, diplopia, dysarthria, memory loss, and psychomotor retardation developed. Approximately 4 days after withdrawal of the ethchlorvynol, the patient began to misidentify people and had auditory as well as visual hallucinations. On the fifth day of abstinence three grand mal convulsions developed. During the next 3 days the patient became agitated, delirious, and had tactile as well as visual hallucinations. Improvement began on the 10th day after withdrawal, and the patient was described as being "completely cleared" when discharged from the hospital on the 28th day.<sup>23</sup>

Repeated bouts of ethchlorvynol intoxication have been described in two patients who required hospitalization several times. Their clinical state was described in terms such as confusion, disorientation, lethargy, apathy, unsteady gait, slurred speech, staggering, ataxia, and weakness.<sup>5</sup>

Another patient began using ethchlorvynol as a hypnotic, increasing the nighttime dose from 500 to 1,000 milligrams before taking it during the day. The amount used was gradually increased during a period of 1½ to 2 years to a total daily level of 4 to 5 grams. At an unspecified time after discontinuing the drug, the patient developed a fainting spell, a convulsive attack, insomnia, auditory and visual hallucinations, as well as violent behavior. The patient recovered but it may be of more than passing interest that her husband was subsequently hospitalized for chronic ethchlorvynol intoxication.<sup>5</sup>

A man with a 15-year history of alcohol and barbiturate abuse was given ethchlorvynol by his physician. The patient increased the dose to a daily level of 2 to 3 grams during a 6 to 7 month period before discontinuation. At an unspecified time thereafter he had five grand mal convulsions, but apparently there was no psychotic behavior. The patient recovered. The convulsions were attributed to ethchlorvynol abstinence.<sup>9</sup>

The foregoing case reports indicate that 1,500 milligrams daily of ethchlorvynol is sufficient to cause a degree of physical dependence which can result in major abstinence signs after withdrawal of the drug.

#### METHYPRYLON (NOLUDAR)

Methyprylon is recommended by the manufacturer for both insomnia and daytime tension. It is not called a tranquilizer or advertised as a nonbarbiturate sedative. The manufacturer does not mention the drug's addiction potential.<sup>48</sup>

Recovery from a total overdose of 3.4 grams of methyprylon has been reported, and 23 more cases of methyprylon poisoning are summarized in which there were no deaths despite doses of up to 20 grams.<sup>49</sup> However, a case is reported elsewhere in which death occurred 5 days after ingestion of 6 grams of methyprylon.<sup>50</sup> The clinical picture of methyprylon intoxication resembles that seen after barbiturate overdosage.<sup>49,50</sup> Some believe the drug has a wider margin of safety than the barbiturates.<sup>49</sup>

An alcoholic subject took methyprylon in a suicidal attempt prior to using the drug in increasing amounts chronically. Although the daily dose of methyprylon is not mentioned, the patient's intoxication was described in terms of confusion, ataxia, and slurred speech.<sup>24</sup>

A man who began taking methyprylon as a hypnotic (400 mg.) increased the dosage not only for that purpose but also began its daytime use until he was ingesting 2.4 grams daily. After 2 or 3 days of abstinence, he became confused, restless, and excited. Sweating and polyuria were also noted. The subject developed auditory and visual hallucinations, but convulsions were not observed

prior to recovery several days later.<sup>33</sup> A patient who had used methyprylon for 3 months would not tell how much she had been taking, although it was known she could obtain 100 of the 200 milligram tablets at a time. During the first 5 days after withdrawal, there were multiple generalized convulsions sometimes at 20 to 30 minute intervals. It is noteworthy that there was no previous history of convulsive seizures. Hallucinations were also observed, and the patient appeared "schizophrenic" prior to recovery.<sup>33</sup>

A nurse who had taken barbiturates for 5 years began using methyprylon instead in order to terminate the use of the barbiturates. Daily intake of methyprylon had varied from 7.5 to 12 grams daily during the previous 18 months. During the first day of withdrawal, marked jerking movements of all extremities were observed, and the patient reported insomnia. Auditory hallucinations were reported on the second day. The woman stated that previous self-imposed attempts at methyprylon withdrawal had caused convulsions. In addition to hallucinations, marked nervousness, generalized hyperreflexia, and increased jerking movements developed. On the fifth day the subject was found unconscious and breathing noisily just prior to death. The woman had refused hospitalization. For withdrawal she had used a mixture containing prochlorperazine (Compazine), promazine (Sparine), methadone, and thiamine chloride. The frequency with which the drug mixture was used is not stated. Death was attributed to myocardial degeneration resulting in congestive cardiac failure.<sup>4</sup>

#### CHLORDIAZEPOXIDE (LIBRIUM)

Chlordiazepoxide is recommended for irrational fears, anxiety, and tension. It is not categorized as a tranquilizer or nonbarbiturate, but is described as one of the safest psychopharmacologic compounds available. The recommended adult dose ranges from 15 to 300 milligrams daily, but up to 300 milligrams can be given during a 6-hour interval. The manufacturer also indicates that chlordiazepoxide can induce drowsiness, ataxia, and withdrawal symptoms like those seen with barbiturates and meprobamate. There is an added warning against concomitant use of this drug with other psychotropic agents or ethanol.<sup>46</sup>

A 30-year-old woman took 625 milligrams of chlordiazepoxide at one time without becoming comatose.<sup>33</sup> Another instance of overdosage (an undetermined number of capsules) resulted in a semicomatose state compatible with arousal for eating.<sup>52</sup> In a series of 12 patients who took overdoses of chlordiazepoxide (ranging from 200 to 2,250 milligrams) there were no deaths. Three of the patients ingested over 1,000 milligrams without becoming comatose; in contrast, 3 individuals who took 300, 330, and 500 to 600 milligrams, respectively became comatose.<sup>50</sup>

There is no doubt that chlordiazepoxide can induce drowsiness, ataxia, and dysarthria. The two former were the most frequent side effects reported in a series of 212 patients.<sup>55</sup> Both dissociative and acute rage reactions have been attributed to the effects of this drug.<sup>55, 58</sup> Reaction time, decision reaction time, tapping speed, and a flicker fusion test were all significantly impaired by 40 milligram doses of chlordiazepoxide.<sup>50</sup> In a group of 68 drivers who were taking 5 to 100 milligrams daily of chlordiazepoxide, there were 6 major and 10 minor automobile accidents during a 90-day period. This represented a tenfold increased incidence of accidents as projected by the department of public safety statistics for that State.<sup>43</sup> Eight patients observed that chlordiazepoxide rendered them more sensitive to ethanol.<sup>58</sup> There were skeletal fractures in two patients who fell while taking chlordiazepoxide.<sup>50</sup>

One of the effects of this drug on the electroencephalogram is that of low-voltage fast frequencies, which were described as similar to those seen with meprobamate.<sup>50</sup>

A controlled study of chlordiazepoxide in 36 hospitalized psychiatric patients showed that there can be physical dependence to this drug. Eleven of the subjects were abruptly withdrawn from the drug by substituting a placebo without their knowledge. Ten of this group had received the drug for 5 months or longer. The final dosage level was 300 milligrams in five and 600 milligrams in six of the patients. Ten of the eleven subjects developed symptoms or signs of withdrawal. Insomnia, anorexia, agitation, nausea, twitching, sweating, and convulsions were observed in one or more of this group. Two patients who had been receiving 600 milligrams of the drug daily had major convulsions on the 7th and 8th

See footnotes on p. 40.

days of abstinence. One had a seizure during drug therapy in a prior study, but the other had no known convulsion previously. Another subject had two major convulsions 12 days after abrupt withdrawal of chlordiazepoxide (300 milligrams daily). Most of the abstinence manifestations appeared between the 4th and 8th days after withdrawal but by the 10th day had decreased in severity or disappeared. Five of the eleven patients in the withdrawal study developed mild electroencephalographic abnormalities such as slow frequencies (6 to 10 per second) in three, mixed fast (20 to 25 per second) and slow (7 per second) in one, and fast (20 to 25 per second) frequencies in another. The onset of convulsions in two patients seemed to coincide with the nearly complete disappearance of drug from the plasma. The authors conclude that the chlordiazepoxide abstinence syndrome is slower to develop and less acute than the meprobamate or barbiturate withdrawal syndrome.<sup>27</sup>

#### DISCUSSION

It is evident that a wide variety of drugs induce sedation, sleep, and motor incoordination. The striking resemblance of the major signs of intoxication and withdrawal symptoms produced by the drugs discussed in this report, ethanol and the barbiturates, indicates the possibility that their mechanisms of action are similar. Because so many drugs with sedative-hypnotic effects have been shown to induce intoxication and physical dependence when used to excess, clinicians might well be skeptical about new depressant drugs introduced as not having habit-forming or addiction potential. Skepticism is also warranted when such drugs are categorized as other than sedative hypnotic, or their mechanism of action is suggested to be entirely different from that of older depressant drugs.

It is likely that more drugs with sedative effects will be added to an already growing list, and it is necessary that these drugs be made prescription items so that physicians can help regulate their use. Such regulation requires an awareness of whether the drug has addiction potential; if so, special caution is indicated in prescribing. Usually physicians are advised not to prescribe sedative-hypnotic drugs to known drug addicts or individuals with character disorders (sociopaths). However, individuals in these two groups are often difficult to identify by history taking or physical examination. Two more common groups of addiction-prone individuals are usually described as alcoholic and psychoneurotic. Predicting which patients in the latter categories are more likely to abuse sedative-hypnotic drugs is difficult, and the usual safeguards are to limit the amount of drug prescribed and prevent refilling of the prescription.

The intoxications that can result from excessive amounts of drugs or from their combination with ethanol may become a very important public health problem. As indicated in this report, the clouded mental state and impaired motor coordination associated with these intoxications are conducive to vehicular accidents, injury by falling, loss of or interference with useful employment, accidental setting of fires, violent or assaultive behavior, and fatal overdosage in the user.

Withdrawal treatment for physical dependence to each sedative-hypnotic drug has not been determined by means of controlled experiments in man; however, it is probable that the principles of barbiturate-withdrawal treatment are applicable.<sup>28 29 31 32</sup> Thus, if the drug (and its previous daily dose) can be determined, it should be withdrawn at the rate of one therapeutic dose per day. If, during withdrawal, the patient becomes apprehensive, tremulous, or insomnolent, dosage reduction should be discontinued for 1 or 2 days, or until the signs disappear.

If drug and daily dosage cannot be determined, it is likely that a barbiturate can be safely substituted and slowly withdrawn, as in the management of glutethimide and alcohol withdrawal.<sup>30, 44</sup> Pentobarbital should be administered in 0.2-gram doses every 2 hours until a state of mild intoxication develops, the patient stabilized at that daily dose level for several days, and then the pentobarbital withdrawn at a rate of 0.1 gram daily.<sup>33</sup> Such treatment must be carried out in the hospital because of the seriousness of the illness and the need to prevent acquisition of contraband drugs by the patient.

See footnotes on p. 40.

The use of other sedative drugs during withdrawal is not necessary and might complicate or confuse the treatment. Diphenylhydantoin (Dilantin) is not effective against barbiturate-withdrawal convulsions in man<sup>15</sup> or dog<sup>16</sup>; hence, its use during withdrawal from sedative drugs is contraindicated. It is also doubtful whether Rauwolfia alkaloids or phenothiazine derivatives should be administered in place of sedative-hypnotic drugs during the first week after withdrawal because of their convulsant properties and because they might aggravate the hypotensive aspects of the abstinence syndrome, as noted in the case of ethinamate withdrawal.<sup>14</sup>

It is possible that acute overdosage of one or more of these drugs can be superimposed on a state of chronic intoxication to the same or other sedative-hypnotic agents. In such cases, the patient may be successfully treated for the acute intoxication (coma) only to enter a withdrawal syndrome. If a severe degree of physical dependence had been established, a serious abstinence illness or even death might ensue. Patients recovering from acute sedative-hypnotic drug poisoning should also be observed for the possibility of chronic intoxication so that a gradual reduction regimen can be instituted if indicated.<sup>23</sup>

## REFERENCES

1. Algeri, E. J., Katsas, G. G., and Luongo, M. A.: Determination of ethchlorvynol in biologic mediums and report of two fatal cases, *Am. J. Clin. Path.* 38: 125-130, 1962.
2. Barsa, J. A., and Kline, N. S.: Use of meprobamate in the treatment of psychotic patients, *Am. J. Psychiat.* 112: 1023-1026, 1956.
3. Berger, F. M.: Meprobamate: Its pharmacologic properties and clinical uses, *Internat. Rec. Med.* 169: 184-196, 1956.
4. Berger, H.: Addiction to methyprylon, *J.A.M.A.* 177: 63-65, 1961.
5. Blakey, H. H., Barringer, T., and Billig, O.: Acute Doriden intoxication, *South. M. J.* 49: 172-174, 1956.
6. Bokonjic, N., and Trojaborg, W.: The effect of meprobamate on the electroencephalogram, during treatment, intoxication, and after abrupt withdrawal, *Electroencephalography & Clin. Neurophysiol.* 12: 177-183, 1960.
7. Boyd, L. J., Cammer, L., Mulinos, M. G., Huppert, V. F., and Hammer, H.: Meprobamate addiction, *J.A.M.A.* 168: 1839-1843, 1958.
8. Cahn, C. H.: Intoxication by ethchlorvynol (Placidyl). Report of four cases, *Canad. M. A. J.* 81: 733-734, 1959.
9. Carr, D. J., and Crampton, R. F.: Ethchlorvynol, *Brit. M. J.*, 5325: 262, 1963.
10. Charet, R., Brill, B., and Ellso, C.: Coma after Miltown overdose, *Ann. Int. Med.* 45: 1211-1212, 1956.
11. Davis, R. P., Blythe, W. B., Newton, M., and Welt, L. G.: Treatment of intoxication with ethinyl cyclohexyl carbamate (Valmid) by extracorporeal hemodialysis; Case report, *Yale J. Biol. & Med.* 32: 192-196, 1959.
12. Editorial note: Current concepts in therapy sedative hypnotic drugs. V. Nonbarbiturates, *New England J. Med.* 256: 314-316, 1957.
13. Eidelman, J. R.: Doriden intoxication, *Missouri Med.* 53: 194, 1956.
14. Ellinwood, E. H., Ewing, J. A., and Hoaken, P.C.S.: Habituation to ethinamate, *New England J. Med.* 266: 185-186, 1962.
15. Essig, C. F.: Addictive and possible toxic properties of glutethimide, *Am. J. Psychiat.* 119: 993, 1963.
16. Essig, C. F., and Carter, W. W.: Failure of diphenylhydantoin in preventing barbiturate withdrawal convulsions in the dog, *Neurology* 12: 481-484, 1962.
17. Essig, C. F.: Withdrawal convulsions in dogs following chronic meprobamate intoxication, *A.M.A. Arch. Neurol. & Psychiat.* 80: 414-417, 1958.
18. Essig, C. F., and Ainslie, J. D.: Addiction to meprobamate (correspondence), *J.A.M.A.* 164: 1382, 1957.
19. Ewing, J. A., and Fullilove, R. E.: Addiction to meprobamate, *New England J. Med.* 257: 76-77, 1957.
20. Fraim, M. K.: Physical, mental, and emotional effects of Librium in hospitalized psychotic patients, *Dis. Nerv. System* 21: (suppl.) 435-457, 1960.
21. Fraser, H. F., Isbell, H., Eisenman, A. J., Wikler, A., and Pescor, F. T.: Chronic barbiturate intoxication, *Arch. Int. Med.* 94: 34-41, 1954.

22. Fraser, H. F., Shaver, M. R., Maxwell, E. S., and Isbell, H.: Death due to withdrawal of barbiturates, *Ann. Int. Med.* 38: 1319-1325, 1953.
23. Fraser, H. F., and Grider, J. A.: Treatment of drug addiction, *Am. J. Med.* 14: 571-577, 1953.
24. Glatt, M. M.: Drug treatment of insomnia (correspondence), *Brit. M. J.* 1: 50-51, 1959.
25. Haizlip, T. M., and Ewing, J. A.: Meprobamate habituation. A controlled clinical study, *New England J. Med.* 258: 1181-1186, 1958.
26. Henry, C. E., and Obrist, W. D.: The effect of meprobamate on the electroencephalogram, *J. Nerv. & Ment. Dis.* 126: 268-271, 1958.
27. Hollister, L. E., Motzenbecker, F. P., and Degan, R. O.: Withdrawal reactions from chlordiazepoxide (Librium), *Psychopharmacologia* 2: 63-68, 1961.
28. Hudson, H. S., and Walker, H. L.: Withdrawal symptoms following ethchlorvynol (Placidyl) dependence, *Am. J. Psychiat.* 118: 361, 1961.
29. Ideström, C., and Cadenius, B.: Chlordiazepoxide, dipiperon and amobarbital, *Psychopharmacologia* 4: 235-246, 1963.
30. Isbell, H., Fraser, H. F., Wikler, A., Belleville, R. E., and Eisenman, A. J.: An experimental study of the etiology of "rum fits" and delirium tremens, *Quart. J. Stud. Alcohol* 16: 1-35, 1955.
31. Isbell, H., Altschul, S., Kornetsky, C. H., Eisenman, A. J., Flanary, H. G., and Fraser, H. F.: Chronic barbiturate intoxication. An experimental study, *A.M.A. Arch. Neurol. & Psychiat.* 64: 1-28, 1950.
32. Isbell, H.: Addiction to barbiturates and the barbiturate abstinence syndrome, *Ann. Int. Med.* 33: 108-121, 1950.
33. Jensen, G. R.: Addiction to Nolutar. A report of two cases, *New Zealand M. J.* 59: 431-432, 1960.
34. Johnson, F. A., and Van Buren, H. C.: Abstinence syndrome following glutethimide intoxication, *J.A.M.A.* 180: 1024-1027, 1962.
35. Kinross-Wright, V., Cohen, I. M., and Knight, J.: The management of neurotic and psychotic states with Ro 5-0690 (Librium), *Dis. Nerv. System* 21: (suppl.) 23-26, 1960.
36. Kornetsky, C.: Effects of meprobamate, phenobarbital and dextro amphetamine on reaction time and learning in man, *J. Pharmacol. & Exper. Therap.* 123: 216-219, 1958.
37. Ladwig, H. A.: An electroencephalographic study of Doriden, *A.M.A. Arch. Neurol. & Psychiat.* 74: 351-355, 1955.
38. Lemere, F.: Drug habituation (correspondence), *J.A.M.A.* 160: 1431, 1956.
39. Lemere, F.: Habit forming properties of meprobamate, *A.M.A. Arch. Neurol. & Psychiat.* 76: 205-206, 1956.
40. Lloyd, E. A., and Clark, L. D.: Convulsions and delirium incident to glutethimide (Doriden) withdrawal, *Dis. Nerv. System* 20: 1-3, 1959.
41. Luby, E. D., and Domino, E. F.: Additional evidence of the addiction liability of glutethimide in man, *J.A.M.A.* 181: 46-48, 1962.
42. McBay, A. J., and Katsas, G. G.: Glutethimide poisoning, *New England J. Med.* 257: 97-100, 1957.
43. Murray, N.: Covert effects of chlordiazepoxide therapy, *J. Neuropsychiat.* 3: 168-170, 1962.
44. Ossenfort, W. F.: Drug addictions, *Dallas M. J.* 43: 229-232, 1957.
45. Pellegrino, E. D., and Henderson, R. R.: Clinical toxicity of methyprylon (Nolutar). Case report and review of twenty-three cases, *J. M. Soc. New Jersey* 54: 515-518, 1957.
46. Pfeiffer, C. C., Riopelle, A. J., Smith, R. P., Jenney, E. H., and Williams, H. L.: Comparative study of the effect of meprobamate on the conditioned response on strychnine and pentylenetetrazol thresholds, on the normal electroencephalogram, and on polysynaptic reflexes, *Ann. New York Acad. Sc.* 67: 734-745, 1957.
47. Phillips, R. M., Judy, F. R., and Judy, H. E.: Meprobamate addiction, *Northwest. Med.* 56: 453-454, 1957.
48. Physicians' Desk Reference to Pharmaceutical Specialties and Biologicals, ed. 17, Oradell, N.J., 1963, Medical Economics, Inc.
49. Powell, L. W., Mann, G. T., and Kaye, S.: Acute meprobamate poisoning, *New England J. Med.* 259: 716-718, 1958.

50. Reidt, W. V.: Fatal poisoning with methyprylon (Noludar), a non-barbiturate sedative, *New England J. Med.* 255: 231-232, 1956.
51. Sadwin, A., and Glen, R. S.: Addiction to glutethimide (Doriden), *Am. J. Psychiat.* 115: 469-470, 1958.
52. Sussex, J. N.: The use of Librium in office treatment of mixed neurotic states, *Dis. Nerv. System* 21: (suppl.) 53-56, 1960.
53. Swanson, L. A., and Okada, T.: Death after withdrawal of meprobamate, *J.A.M.A.* 184: 780-781, 1963.
54. Swinyard, E. A., Chin, L., and Fingl, E.: Withdrawal hyperexcitability following chronic administration of meprobamate to mice, *Science* 125: 739-741, 1957.
55. Tobin, J. M., and Lewis, N. D. C.: New psychotherapeutic agent, chlordiazepoxide, *J.A.M.A.* 174: 1242-1249, 1960.
56. Toman, J. E. P., and Christensen, E. K.: Ethchlorvynol (Placidyl) compared with secobarbital and pentobarbital for EEG sedation, *Fed. Proc.* 15: 492, 1956.
57. Tucker, K., and Wilensky, H.: A clinical evaluation of meprobamate therapy in a chronic schizophrenic population, *Am. J. Psychiat.* 113: 698-703, 1957.
58. Walzer, R. S., Kurland, M. L., and Braun, M.: Clinical trial of methamindiazepoxide, *Am. J. Psychiat.* 117: 456-457, 1960.
59. Winfield, D. L.: The use of chlordiazepoxide in clinical electroencephalography, *J. Neuro-psychiat.* 2: 191-194, 1960.
60. Zbinden, G., Bagdon, R. E., Keith, E. F., Phillips, R. D., and Randall, L. O.: Experimental and clinical toxicology of chlordiazepoxide (Librium), *Toxic. & Appl. Pharmacol.* 3: 619-637, 1961.
61. Zirkle, G. A., Ott, B. M., and King, P. D.: Meprobamate and small amounts of alcohol, *J.A.M.A.* 173: 1823-1825, 1960.

[Psychopharmacology Abstracts, vol. 4, No. 2, U.S. Department of Health, Education, and Welfare, Public Health Service]

#### SIDE EFFECTS

(Abstracts 141-144)

141. Essig, Carl F.: Addiction to nonbarbiturate sedative and tranquilizing drugs. *Clinical Pharmacology and Therapeutics*, 1964, 5, 334-343:

"Increasing numbers of nonbarbiturate sedative drugs are being introduced into medical practice. Despite their nonbarbiturate chemical structure and regardless of designations other than 'sedative hypnotic,' at least six of the newer depressant drugs can cause states of intoxication and physical dependence that are clinically similar to those induced by barbiturates. These drugs are meprobamate (Miltown, Equanil), glutethimide (Doriden), ethinamate (Valmid), ethchlorvynol (Placidyl), methyprylon (Nodudar), and chlordiazepoxide (Librium). The behavioral effects of these drugs and their combination with ethanol may become an increasingly important public hazard. The abstinence syndromes that can result from the abrupt withdrawal of excess dosages of these drugs include convulsions and psychotic behavior. Death has been attributed to withdrawal of meprobamate and methyprylon. Office or ambulatory withdrawal of any of these drugs after use in large dosage is not recommended. Gradual dosage reduction or barbiturate substitution prior to its gradual withdrawal during hospitalization is suggested. Substitution of diphenhydantoin (Dilantin) or any of the phenothiazines as the sole means of support during sedative-hypnotic drug withdrawal is a questionable practice." (Author abstract.) (National Institute of Mental Health Addiction Research Center, Lexington, Ky.)

142. Barlow, A. M.: Antidepressant drugs. *British Medical Journal*, 1964, 5384, 694 (letter):

"A letter by the pathologist who performed an autopsy on a 55-year-old woman with a 7-year history of mental disease points out that the combination of phenelzine and imipramine, which was found at therapeutic levels upon analysis,

was only a possible cause of death. He demands a greater degree of proof, if conclusions are to be drawn from such findings. The patient in question had not only taken prescribed drugs, but also imipramine, meprobamate, and chlorpromazine from supplies remaining after previous drug treatment." (Department of Pathology, Royal Infirmary, Huddersfield, Yorkshire, England.)

143. Bacon, H. M.: Eosinophilia associated with chlorpromazine therapy. *American Journal of Psychiatry*, 1964, 120, 915-916:

"The first case of eosinophilia with chlorpromazine therapy is reported. A 34-year-old woman with history of paranoid delusions and hallucinations was treated with 50 mgm of chlorpromazine t.i.d. and h.s. There were no eosinophils present on admission. Three weeks later marked eosinophilia without physical symptoms was noted and chlorpromazine was discontinued. The patient's recovery was slow with Stelazine (5 mgm t.i.d.), but when ECT was later instituted with good results the patient was discharged." (Dalhousie University, Halifax, N. S., Canada.)

144. Bevan, Edward: Antidepressant drugs and liver damage. *British Medical Journal*, 1964, 5382, 562 (letter):

"A letter comments on the remarks by Sir William Wilcox in 1932, when he stressed that barbiturates in general and 'Nembutal' in particular were dangerous drugs because of the risk of their causing liver damage." (No address.)

---

[From the *Journal of the American Medical Association*, vol. 185, No. 6, Aug. 10, 1963]

#### OVERDOSAGE EFFECTS AND DANGER FROM TRANQUILIZING DRUGS

(Charles H. McKown, M.D., Henry L. Verhulst, M.S., and John J. Crotty, M.D., Washington, D.C.)\*

Over a 17-month period 968 cases of tranquilizer ingestion reported to the National Clearinghouse for Poison Control Centers were reviewed for tranquilizer toxicity and side effects. Anticipated pharmacological actions were correlated with symptomatology, etiology, and age of patients involved. Of 378 patients who ingested phenothiazine derivatives, 113 revealed CNS depression, 90 ingested the tranquilizer intentionally, and 254 were less than 13 years of age. The corresponding figures for 151 cases of Rauwolfia alkaloid ingestion were 25, 4, and 142, respectively; for 280 cases of substituted diol ingestion, 135, 166, and 63, respectively, and for 115 cases involving drugs of miscellaneous structure, 36, 49, and 57, respectively. The clinician's attention is called to the frequency of CNS depression after tranquilizer ingestion and the high incidence of suicide attempts with the less potent tranquilizers.

Tranquilizers have been manufactured and used extensively over the past decade. As with all new products, information revealing toxicity and side effects is desirable in order that we may be enlightened and gain insight into the complications and hazards accompanying their use in clinical medicine. To supplement such information, 968 cases of tranquilizer ingestion reported to the National Clearinghouse for Poison Control Centers from July 1959, through December 1960, were reviewed. Each report was evaluated regarding type of drug ingested, age of the patient, necessity of hospitalization, and manifestations of the acute phase of toxicity.

Although other classifications of tranquilizers exist, a frequently used classification of structural similarity was employed in this review. On this basis, the total number of cases may be divided into six groups (table 1). Those tranquilizing agents which do not bear a structural similarity to other psychophama-

\*Member of technical staff (Dr. McKown), Director (Mr. Verhulst), and Associate Director (Dr. Crotty), National Clearinghouse Poison Control Branch, Division of Accident Prevention, Department of Health, Education, and Welfare, U.S. Public Health Service.

cologic agents were placed under "miscellaneous structure." The group named "combined drugs" refers to single preparations comprised of two or more structurally dissimilar tranquilizers. Reported ingestions of two or more individual tranquilizers are classified under "multiple ingestion." Not included in this review were ingestions of tranquilizers with other products which might alter or mask the manifestations of the tranquilizer.

TABLE 1.—*Psychopharmacological agents ingested in 968 cases*

Agent	Number	Percent
Phenothiazine derivatives.....	378	39.0
Rauwolfia alkaloids.....	151	15.6
Substituted diols.....	280	28.9
Miscellaneous structure.....	115	11.9
Combined drugs.....	21	2.2
Multiple ingestion.....	23	2.4
Total.....	968	100.0

To better correlate the etiological factors of the ingestion with the severity and characteristics of the resultant intoxication, three age groups have been established: (1) children, birth to 12 years; (2) young adults, 13 through 35 years; and (3) adults, 36 years and older.

The children could not be expected to be aware of the nature of tranquilizers; therefore ingestion, in all likelihood, would be unintentional or subsequent to mistaken identity. This group, which is not yet exposed to the problems and emotional adjustments of adolescence and adulthood, should possess a low suicide potential.

The young adult age group includes the periods of adolescence and major living adjustments which may precipitate neuropsychiatric problems, many of which are characterized by anxiety. The adult age group includes the period of decreased physical and mental activity, frequently characterized by anxiety and depression. Most people receiving tranquilizer therapy for organic disease are in the adult age group.

Although hospitalization certainly must be considered in evaluation of the severity of the intoxication, no differentiation can be made between those patients hospitalized solely because of the drug effects and those hospitalized primarily for neuropsychiatric reasons. Since the case reports are frequently made during the phase of acute toxicity, this review does not include information concerning an extended clinical course and convalescence. For the same reason, chronic toxicity and fatality reports are not included.

To attain uniformity in the interpretation of symptomatology, central nervous system (CNS) depression has been described in decreasing levels of severity as coma, stupor, or drowsiness. Although a check space for coma as a symptom was provided on the report forms, clinical conditions described as unconscious, unable to be aroused, or deep sleep were also included in this category. Similarly, those described as semiconscious, semicoma, or incoherently sleepy are categorized as stupor. Drowsiness denotes patients whose clinical condition has been described as sleepy, lethargic, minimal CNS depression but coherent, or drowsy.

Extrapyramidal-tract motor activity, as designated in the review, refers to patients who revealed muscle spasm, rigidity, torticollis, oculogyric crisis, or muscle fasciculations. Ataxia, hypotonia, weakness, and other nonspecific symptoms were not incorporated in the data, since it was not possible to determine if these alluded to CNS depression, injury or deformity of an extremity, or an extrapyramidal manifestation. Hyperpyrexia, abdominal pain, tachycardia, and respiratory symptoms were more logically explained by associated pathology, except where so stated, rather than as toxic manifestation of tranquilizer ingestion.

TABLE 2.—Ingestion of phenothiazines—Dimethylamines

Data reported	Chlorpromazine, number					Promazine, number					Other, number		
	Total	Children	Young adults	Adults	Un-known	Children	Young adults	Adults	Un-known	Children	Young adults	Adults	Un-known
<b>Etiology:</b>													
Accidental ingestion.....	97	58	2		3	31	2			3			
Mistaken identity.....	1	1								1			
Accidental overdose.....	58	28	15		2		6	4	1		1		1
Suicidal intent.....	17	7	3		1	5			1				
Unknown.....													
<b>Hospitalization:</b>													
Yes.....	63	18	17	11	1	8	5	2	1	3			
No.....	63	34	9			13	2	1	1	1			
Unknown.....	54	15	8	4	5	15	2	1		1	1		1
<b>Symptoms:</b>													
None.....	61	29	9	3	1	15	1			1			
1 or more:													
Drowsy.....	25	11	6	1		6	1						
Stupor.....	41	15	11	6	1	4	2	1		1			
Coma.....	14	5	3	3		2			1				
Convulsions.....	3	1				1							
Hypotension.....	2		2										
Vertigo.....	2					1							
Nausea.....	3					1	2						
Vomiting.....	1					1							
Cyanosis.....													
Extrapyramidal.....	2	2											
Other.....	3												
Unknown.....	30	6	4	2	4	8	2	2		1	1		
<b>Total</b> .....	180	207	34	15	6	36	9	4	3	4	1		1

\* Includes 1 receiving prescribed dosage.

† Includes dyspnea, abdominal pain, tachycardia, etc.

TABLE 3.—Ingestion of phenothiazines—Piperazines

Data Reported	Trifluoperazine, Number				Prochlorperazine, Number				Perphenazine, Number				Other, Number				
	Total	Children	Young adults	Adults	Unknown	Children	Young adults	Adults	Unknown	Children	Young adults	Adults	Unknown	Children	Young adults	Adults	Unknown
<b>Etiology:</b>																	
Accidental ingestion.....	122	33				53	1			25				10			
Misaken identity.....	2					2											
Accidental overdose.....	8					4		1		2							
Suicidal intent.....	32		11				13	6			1				1		
Unknown.....	20	3			2	7	1			4			1	1			1
<b>Hospitalization:</b>																	
Yes.....	43	2	5			14	11	4		4				2			
No.....	79	19	2			34	4	1		11				2			
Unknown.....	69	15	4		2	21	3	3		16	1		1	2			
<b>Symptoms:</b>																	
None.....	96	28	6			34	3	1		20							
One or more:																	
Strowsy.....	19	4	3			6	1			4	1						
Stupor.....	10					4	2	2									
Coma.....	4		1			1		2							2		
Convulsions.....	1						1										
Hypotension.....	1							1									
Vertigo.....	1							1									
Nausea.....	4						1										
Vomiting.....	4						2	1		1							
Swallowing.....	12					6	2							2			
Cyanosis.....	1																
Extrapyramidal.....	15						9	4		2				1			
Other.....							2	1		3				1			
Unknown.....	31	4	1		2	14	2	1		3			1	4			1
<b>Totals.....</b>	191	36	11		2	269	18	8		31	1		1	11	2		1

<sup>1</sup> Includes dyspnea, abdominal pain, tachycardia, ataxia, etc.

<sup>2</sup> Includes 1 receiving prescribed dosage.

<sup>3</sup> Includes 3 receiving prescribed dosage.

## PHENOTHIAZINE DERIVATIVES

Phenothiazine derivatives constitute the largest single group of tranquilizers ingested, approximately 39 percent of the total. To evaluate the effects of the phenothiazines on the CNS and the autonomic nervous system more accurately, a structural grouping has been used. This grouping divides the phenothiazines into three categories: (1) those with a propyl-dimethylamino subgroup, (2) those with a propyl piperazine subgroup, and (3) those with a methyl piperidyl subgroup. Those phenothiazines whose action and usage are primarily antihistaminic were not incorporated into the study.

The total number of cases reviewed in the propyldimethylamino subgroup was 180. In most of these cases the drugs were chlorpromazine (122) and promazine (51). Cases known to be in the children's age group accounted for 55 percent of the chlorpromazine ingestions and 71 percent of the promazine ingestions. Whereas approximately one-fourth of the children who ingested tranquilizers of the propyl-dimethylamino subgroup were hospitalized, over one-half of the young adults or adults were known to require hospitalization. In approximately 44 percent of the cases symptoms of CNS depression were revealed, with 14 instances of coma. There were three reports of convulsions and two reports of extrapyramidal manifestations. Interestingly, in one case reported in this group the patient was receiving the prescribed dosage.

In the second subdivision, phenothiazine derivatives containing a propyl piperazine subgroup, there were 191 cases, with trifluoperazine accounting for 49, prochlorperazine for 95, and perphenazine for 33. As would be expected with substitution of a piperazine subgroup in place of a terminal dimethylamino moiety, there is evidence of increased extrapyramidal stimulation.<sup>1</sup> Extrapyramidal manifestations were reported in 15 cases in this subgroup, and 13 of these were prochlorperazine ingestions. Seven patients sought medical care for symptoms occurring while receiving a prescribed dosage of prochlorperazine. In the dimethylamino and piperazine subgroups, of the reports involving children, about 90 percent were consequent to accidental ingestion. In the young adult and adult age groups, a similar percentage of suicide attempts was reported. It is known that the dimethylamino phenothiazine derivatives possess greater sedative properties than the piperazine phenothiazine derivatives.<sup>2</sup> This phenomenon was supported by the findings in this review. Of the 180 reports of ingestion of drugs with the dimethylamino subgroup, symptoms of depression (drowsiness, stupor, or coma) were manifested in 44 percent. Conversely, only 17 percent of the 191 patients ingesting drugs with the piperazine subgroup were felt to be in a state of clinical depression. Although tranquilizers with the piperazine subgroup are known to possess greater antiemetic activity, there were 16 reports of patients experiencing nausea or vomiting;<sup>1</sup> only 3 such cases were reported after ingestion of tranquilizers with the dimethylamino subgroup. Two cases of hypotension were noted following ingestion of a dimethylamino-subgroup tranquilizer and one case after ingestion of a piperazine-subgroup tranquilizer. Only four cases of coma and one case of convulsion were reported subsequent to piperazine-subgroup ingestion.

See footnotes on p. 53.

TABLE 4.—*Ingestion of Rauwolfia alkaloids*

Data reported	Total	Reserpine, number				Rauwolfia Serpentina, number				Other, number			
		Children	Young adults	Adults	Un- known	Children	Young adults	Adults	Un- known	Children	Young adults	Adults	Un- known
<b>Etiology:</b>													
Accidental ingestion.....	129	96			2	27				4			
Mistaken identity.....	3												
Accidental overdose.....	1		1										
Suicidal intent.....	4		1				1						
Unknown.....	13	10		1		1							
<b>Hospitalization:</b>													
Yes.....	29	21	1	1	1	1				2	2		
No.....	59	43				13				1			
Unknown.....	63	46	1		1	14				1			
<b>Symptoms:</b>													
None.....	68	41								4	1		
1 or more:													
Drowsy.....	14	14											
Stupor.....	10	9									1		
Coma.....	1			1									
Convulsions.....													
Hypotension.....	2	1	1										
Vertigo.....	1	1											
Nausea.....	1												
Vomiting.....	4		1		1	1							
Cyanosis.....					1								
Extrapyramidal.....													
Flushing.....	20	20											
Unknown.....	24	18			2	4							
<b>Total.....</b>	<b>151</b>	<b>110</b>	<b>2</b>	<b>1</b>	<b>3</b>	<b>28</b>	<b>1</b>			<b>4</b>	<b>2</b>		

: Includes 1 receiving prescribed dosage.

The third type of structurally similar phenothiazine derivative contains a methyl piperidyl moiety. In view of the small number of cases (seven) reported, little comparison can be drawn to the other two subgroups.

TABLE 5.—Ingestion of substituted diols

Data reported	Total	Meprobamate, number				Phenaglycodol, number			
		Children	Young adults	Adults	Unknown	Children	Young adults	Adults	Unknown
<b>Etiology:</b>									
Accidental ingestion	65	53	9	1	1	1			
Mistaken identity	2		1	1					
Accidental overdose	17		8	7			1	1	
Suicidal intent	166	2	99	59	6				
Unknown	30	7	7	10	5		1		
<b>Hospitalization:</b>									
Yes	124	4	66	49	3		1	1	
No	76	33	33	10					
Unknown	80	25	25	19	9	1	1		
<b>Symptoms:</b>									
None	72	39	22	9	1	1			
<b>One or more:</b>									
Drowsy	31	3	19	7	2				
Stupor	64	4	33	23	3		1		
Coma	40	4	16	18	2				
Convulsions	3		1	2					
Hypotension	2		1	1					
Vertigo	2		1	1					
Nausea	3	1	2						
Vomiting	7		3	4					
Cyanosis	4		2	2					
Extrapyramidal	1			1					
Others <sup>1</sup>	1		1						
Unknown	47	9	22	10	4		1	1	
<b>Total</b>	<b>280</b>	<b>62</b>	<b>124</b>	<b>78</b>	<b>12</b>	<b>1</b>	<b>2</b>	<b>1</b>	

<sup>1</sup> Includes dyspnea, abdominal pain, tachycardia, ataxia, etc.

## RAUWOLFIA ALKALOIDS

Although preparations of the Rauwolfia alkaloids have been used for medical purposes for many years, only in the past decade have we come to understand and make extensive therapeutic use of these drugs.<sup>3</sup> The Rauwolfia alkaloids reviewed in the study contain tertiary indole bases and are naturally occurring or semisynthetic. These drugs are known to produce mild depression of the CNS, a decrease in the sympathetic activity, and an increase in the parasympathetic activity.<sup>4</sup> With the development and widespread use of other tranquilizing agents, the utilization of Rauwolfia alkaloids for the treatment of neuropsychiatric disturbances has decreased.<sup>5</sup> Today they are used primarily for their effects upon the autonomic nervous system and more specifically in the treatment of hypertensive vascular disease and thyrotoxicosis.<sup>5,6</sup>

Of the 151 cases of Rauwolfia alkaloid ingestion reported, 116 were ingestions of reserpine and 29 of the whole root of *Rauwolfia serpentina*. A remarkably low incidence of ingestion of the Rauwolfias is observed in the young adult and adult age groups, i.e., only 4 percent of the total number of cases reported. Although mental depression is a common (and frequently serious) behavioral side effect of the Rauwolfia drugs, only four suicide attempts were reported for this group.<sup>5</sup> Symptoms occurred in approximately 39 percent of cases, but only two cases of hypotension were noted. About one-third of those manifesting symptoms, and 13 percent of the total number of Rauwolfia intoxications, were seen to have flushing of the skin. Although some form of CNS depression was reported in approximately 44 percent of the symptomatic cases, there was only one report of coma. Of the children reported, who comprise 95 percent of the cases in this group of tranquilizers, 24 of 142 required hospitalization. The Rauwolfia alkaloids are reported to lower the convulsive threshold in man, and extrapyramidal symptoms are known to occur;<sup>5</sup> however, neither convulsions nor extrapyramidal manifestations were observed in this review.

See footnotes on p. 53.

TABLE 6.—Ingestion of tranquilizers with miscellaneous structure

Data reported	Total				Chlordiazepoxide, number				Hydroxyzine, number				Ethchlorvynol, number				Other, number			
	Chil- dren	Young adults	Adults	Un- known	Chil- dren	Young adults	Adults	Un- known	Chil- dren	Young adults	Adults	Un- known	Chil- dren	Young adults	Adults	Un- known	Chil- dren	Young adults	Adults	Un- known
<b>Etiology:</b>																				
Accidental ingestion.....	6	3	1	1	33			1	2								11			
Misaken identity.....			1	1				1												
Accidental overdose.....					1		1													
Suicidal intent.....		20	10		1	5				4	6							3		
Unknown.....		2			2					1							2			
<b>Hospitalization:</b>																				
Yes.....	1	6	6	6	4	1	1	1	1	1	5	3	3	1			3	1		
No.....	2	11	3	3	10	2	1	1	1	1	1	1	1				8	1		
Unknown.....	3	8	3	3	13	2	2				2	2	2				2	1		
<b>Symptoms:</b>																				
None.....	5	6	6	6	25	1	1	1	1								6			
1 or more:																				
Drowsy.....		5	2	2	2															
Stupor.....		0	3	3				1	1											
Coma.....		0																		
Convulsions.....		1																		
Hyponatremia.....																				
Vertigo.....																				
Nystagmus.....		1			1															
Vomiting.....		2																		
Cyanosis.....		1																		
Extrapyramidial.....		1																		
Other <sup>1</sup> .....		1																		
Unknown.....	1	0	1	1	8	4								2	1					
<b>Total.....</b>	6	25	12	12	36	5	2	2	2	5	6	6	6	13	3		115			

<sup>1</sup> Includes dyspnea, abdominal pain, tachycardia, ataxia, etc.

## SUBSTITUTED DIOLS

Although other structurally similar drugs are now in clinical use, only the reports of meprobamate and phenaglycodol ingestions are included in this review. Of the 280 reported cases of substituted-diol ingestions, 276 were ingestion of meprobamate. Meprobamate causes depression of the CNS.<sup>7</sup> There is evidence that another pharmacological effect is skeletal muscle relaxation, although its effectiveness when compared with other relaxants is controversial.<sup>8,9</sup> There is current concern regarding a true benefit derived from meprobamate when used in treatment of neuroses and psychoses characterized by anxiety.<sup>10</sup>

Of the reported ingestions of meprobamate only 22 percent were in children. This is in sharp contrast to the phenothiazines, of which 68 percent of the ingestions were by children, and to the Rauwolfias, which showed 94 percent of the ingestions in the children's age group. The 166 suicide attempts with meprobamate far exceed those with any other drug reported in the study and represent the etiology in 60 percent of the cases received. Associated with this high incidence of suicide attempt was the known hospitalization of 122 patients. Although the CNS depression resulting from meprobamate ingestion is considered to be less extensive than that of several other tranquilizers,<sup>11</sup> 49 percent of those ingesting meprobamate manifested symptoms of the depression, and there were 40 cases of coma. Three patients were known to convulse, and there were two instances of hypotension. Interestingly, one patient revealed a fever of unknown origin.

## MISCELLANEOUS STRUCTURE

Tranquilizers are sometimes classified according to the degree of CNS depression which they effect. We have used a classification based upon structural similarity, for better correlation of intoxication manifestations common to chemically similar drugs. As would be expected, there are several tranquilizing drugs that do not fall into the foregoing structural groupings. These drugs are considered separately under the designation "miscellaneous structure." Of the 115 cases reported, 43 involved chlordiazepoxide hydrochloride ingestion, 43 hydroxyzine hydrochloride ingestion, and 13 ethchlorvynol ingestion.

The CNS depression produced by chlordiazepoxide hydrochloride is comparable to that by meprobamate but less potent than by the phenothiazine derivatives.<sup>12,13</sup> Anticonvulsant effects and skeletal-muscle-relaxing properties are also attributed to this drug.<sup>12,14</sup> Chlordiazepoxide hydrochloride has been used in the treatment of chronic alcoholism because of its ability to allay withdrawal symptomatology and delirium tremens.<sup>15</sup> As with meprobamate, the incidence of children's ingestion of chlordiazepoxide hydrochloride represents a smaller portion of the total than occurred with the other tranquilizers—only 14 percent. In 70 percent of the cases reported, the patients received medical attention for suicide attempt. Approximately 40 percent revealed some type of CNS depression, including two cases of coma. Of the 43 patients ingesting chlordiazepoxide hydrochloride, 13 were known to have been hospitalized. There were no reports of convulsions.

Hydroxyzine hydrochloride produces CNS depression, but, like meprobamate and chlordiazepoxide hydrochloride, it is a less potent depressant than the phenothiazines.<sup>15,16</sup> The skeletal-muscle relaxant properties and antiarrhythmic properties attributed to this drug are not well documented clinically.<sup>17</sup> In contrast to chlordiazepoxide hydrochloride and meprobamate, the incidence of hydroxyzine hydrochloride ingestion in the children's age group is relatively high, representing 84 percent of the total ingestions. There were only six suicidal attempts in this group. Only 7 percent of the patients revealed manifestations of CNS depression, and there were no instances of coma or convulsions. Six of the patients ingesting hydroxyzine hydrochloride were known to require hospitalization.

Ethchlorvynol is considered to be a stronger CNS depressant than chlordiazepoxide hydrochloride and hydroxyzine hydrochloride.<sup>18</sup> Although only 13 case of ethchlorvynol ingestions were reported, it was interesting to find that 8 of the patients revealed some evidence of CNS depression, and in 2 cases coma was reported. The fact that 9 of 13 cases reviewed were known to require hospitalization tends to confirm the sedative properties of this drug.

See footnotes on p. 53.

## COMBINED DRUGS AND MULTIPLE INGESTION

Of the 21 cases of combined drug ingestion, 12 patients revealed manifestations of CNS depression, and 12 were known to have been hospitalized. Since the pharmacological effects of these combined medications are not well defined, it is difficult to correlate results with those discussed above. Of the 23 cases classified under multiple ingestion, 13 patients revealed manifestations of CNS depression, and 13 were known to have been hospitalized. Without dosage information for the individual drugs ingested, no conclusions as to synergism and potentiation can be drawn. As would be anticipated, suicide attempts were made in 16 (70 percent) of the cases of multiple ingestions.

## COMMENT

If the question of poisoning arises, immediate information may be obtained by telephone from the nearest poison control or poison information center. The poison control centers provide facilities, medication, and personnel for emergency treatment. A standard report form supplying identifying and clinical data is utilized for all inquiries and treated cases. These reports are reviewed and evaluated in an effort to understand better the etiology, diagnosis, and treatment of poisoning.

Tranquilizers represented 2.4 percent of all poisonings reported to the National Clearinghouse for Poison Control Centers in 1959 and 1960. Intentional ingestion was known to be the etiological basis in 35 percent of the cases reviewed. It becomes evident that the popularity of tranquilizers as suicidal agents must now rival that of the barbiturates. As with other medications and many potentially toxic household materials, the large number of accidental ingestions of tranquilizers in children must reflect negligence or lack of awareness by more knowledgeable members of the household.

In general, fewer children manifested symptoms or required hospitalization than persons in the other age groups. More people were known to manifest symptoms and require hospitalization after suicide attempts, and, as expected the preponderance of those attempting suicide were in the young adult and adult age groups. With the increased usage of tranquilizers and frequent occurrence of moderate to severe CNS depression consequent to overdosage, it becomes apparent that intoxication with a psychopharmacological agent must be considered in the differential diagnosis of an unconscious patient. A knowledge of toxicity and complicating side effects is imperative in the satisfactory treatment of tranquilizer poisoning.

Without attempting to review the indications for specific drug therapy in neuropsychiatric disturbances, it is generally recognized that the phenothiazines are used more frequently for more severe disturbances than the other drugs studied. The information gathered, however, indicates that a proportionally greater number of suicide attempts occurred with drugs that are frequently prescribed for minor, nonhospitalized emotional disturbances. This should serve to call the physician's attention to the danger in the casual administration of such medication subsequent to an indefinite diagnosis, and should emphasize the need for careful observation and frequent reevaluation of patients known to have access to tranquilizers.

Department of Health, Education, and Welfare, U.S. Public Health Service, Washington 25, D.C. (Dr. McKown).

## GENERIC AND TRADE NAMES OF DRUGS

Promazine hydrochloride—Sparine Hydrochloride.  
 Trifluoperazine hydrochloride—Stelazine Hydrochloride.  
 Prochlorperazine—Compazine.  
 Reserpine—Rauloydin, Raurine, Rau-Sed, Reserpoid, Sandril, Serfin, Serpasil, Serpate, Vio-Serpine.  
 Rauwolfia serpentina—Raudixin, Ruaserpa, Rauval.  
 Meprobamate—Equanil, Equanil L-A, Meprospan, Mepro tabs, Miltown.  
 Chlordiazepoxide hydrochloride—Librium.  
 Hydroxyzine hydrochloride—Atarax, Vistaril Parenteral.  
 Ethchlorvynol—Placidyl.

## REFERENCES

1. Ayd, F. J., Jr.: Phenothiazine Tranquillizers, Eight Years of Development, *Med Clin N Amer* 45: 1027-1040, 1961.
2. Friend, D. C.: Phenothiazines, *Clin Pharmacol Ther* 1: 5-10, 1960.
3. Bein, H. J.: Pharmacology of Rauwolfia, *Pharmacol Rev* 8: 435-483, 1956.
4. Freedman, D. Y., and Benton, A. J.: Persisting Effects of Reserpine in Man, *New Eng J Med* 264: 529-533, 1961.
5. Hollister, L. E.: Complications from Psychotherapeutic Drugs II, *New Eng J Med* 264: 345-347, 1961.
6. Canary, J. J., and Schaaf, M.: Reserpine in Thyrotoxicosis, *New Eng J Med* 257: 435-442, 1957.
7. Batterman, R. C., et al: Clinical Re-Evaluation of Daytime Sedatives, *Postgrad Med* 26: 502-509, 1959.
8. Nyquist, R. H.; Cormarr, A. E.; and Bors, E.: Comparative Study of Antispasmodic Drugs in Patients with Spinal Cord Injuries, *Arch Phys Med* 39: 683-691, 1958.
9. Harshe, W. N.: Clinical Study of Meprobamate Used as Muscle Relaxant Compound, *Okla Med Ass* 53: 135-137, 1960.
10. Loranger, A. W., and Prout, C. T.: Evaluation of Antidepressants, Letter to Editor, *New Eng J Med* 267: 839 (Oct 18) 1962.
11. Domino, E. G.: Human Pharmacology of Tranquillizing Drugs, *Clin Pharmacol Ther* 3: 599-644 (Sept) 1962.
12. Randall, L. O., et al: Psychosedative Properties of Metaminodiazepoxide, *J Pharmacol Exp Ther* 129: 163-171, 1960.
13. Pennington, V. M.: Comparative Study of Chlordiazepoxide and Meprobamate, *Med Times* 90: 841-846 (Aug) 1962.
14. Zbinden, G., et al: Experimental and Clinical Toxicology of Chlordiazepoxide, *Toxic Appl Pharmacol* 3: 619-637, 1961.
15. Lawrence, F. E., et al: Chlordiazepoxide in Treatment of Alcoholism, *J Neuropsychiat* 2: 93-96, 1960.
16. White, R. P., and Boyalty, L. D.: Neuropharmacology Comparison of Atropine, Scopolamine, Benactyzine, Diphenhydramine, and Hydroxyzine, *Arch Int Pharmacodyn* 127: 260-273 (Sept) 1960.
17. Weil, M. H., and Sadrann, R. B.: Cardiovascular Effects of Hydroxyzine, *Amer J Cardiol* 6: 1085-1088 (Dec) 1960.
18. Pan, S. Y., et al: Pharmacological Studies on Hypnotic and Anticonvulsant Actions of Ethyl beta-chlorovinyl, *J Pharmacol Exp Ther* 114: 326-333 (July) 1955.

[From the American Medical Association Journal, 189:512-514, Aug. 10, 1964]

DRUG ABUSE AND ADDICTION—REPORTING IN A GENERAL HOSPITAL

(John A. Schremly, M.D., and Philip Solomon, M.D., Boston)<sup>1</sup>

Although drug abuse and addiction has been a social problem since the latter 19th century, there are no reliable incidence or prevalence statistics currently available. Hambourger<sup>2</sup> reported on the prevalence of the abuse of barbiturates. In the decade studied (1928-37) only 85 of 1,250,000 general hospital admissions were diagnosed as barbiturate addicts. Of the 85, only 42 took barbiturates daily. It was puzzling to learn that over the 10 years barbiturate addiction accounted for only 0.11 percent of more than 300,000 admissions to one of the largest hospitals surveyed, the Boston City Hospital. This was all the more remarkable since acute barbiturate poisoning represented almost 20 percent of the total number of all cases of poisoning (approximately 2,000, excluding alcohol and carbon monoxide) admitted to this hospital.

The present authors decided to investigate the current degree of drug abuse and addiction in the Boston City Hospital. A preliminary survey of the records of the past 2-year period (1959-61) revealed that only 10 cases of drug abuse or addiction had been reported by the house officers. A systematized running study was then undertaken of the number of patients with drug abuse or addiction admitted to the Boston City Hospital. All the important drugs known to have abuse potential were included.<sup>3</sup> It was anticipated that a much greater number of cases would be found than the previous hospital records indicated. Although the taking of drugs when not indicated medically constitutes abuse, only those patients who abused drugs daily for 1 month or longer were considered reportable for purposes of this study. Alcohol was excluded from this study.

PROCEDURE

All new cases of drug abuse or addiction admitted to the emergency floor of the Boston City Hospital over an 8-month period (October 1961-May 1962) were counted. House officers were requested to diagnose and report to the authors each new case. An appropriate checksheet (available upon request) was provided for convenience in reporting. All submitted cases were relatively easy to validate since the data requested was minimal and the criteria readily available. One of the authors saw the majority of patients and upon documentation the sum of \$1 was paid to the reporting house officer. All patients age 15 and over admitted to the emergency floor were thus screened on a 24-hour round-the-clock basis during the 8-month period.

A technique of random sampling was also employed in the hopes of uncovering otherwise missed or "hidden" abusers. The middle 4 months (December 1961-March 1962) were more closely screened by the authors beyond the ordinary routine afforded by the usual house officer coverage on the emergency floor. At weekly intervals, every 20th patient of any sort was interviewed, varying the day at random, with the purpose of eliciting the diagnosis of drug abuse or addiction. The average number seen during a 24-hour period was 15. Elopements, those who departed before they could be seen, varied from one to two in any given sampling. Children under 15 years of age, maternity patients (who enter via a special route bypassing the emergency floor), and persons dead on arrival were omitted from the count in establishing every 20th patient for interviewing. The next in succession (21st) was counted when any reason disqualified a patient in the regular order of rotation. The average number missed per 24-hour sampling was 1.

Approximately 100,000 patients were admitted to the emergency floor over the 8 months studied; primarily they were in the lower socioeconomic group, ranged in age from infancy to senescence, were mainly Roman Catholic, and were equally divided between Caucasian (largely Irish and Italian) and Negro. Approximately 400 were admitted daily.

<sup>1</sup> Dr. Schremly is chief of the Men's Addiction Service of the U.S. Public Health Service Hospital, Lexington, Ky. Dr. Solomon is an associate clinical professor of psychiatry at Harvard Medical School and physician-in-chief, Psychiatry Service, at the Boston City Hospital.

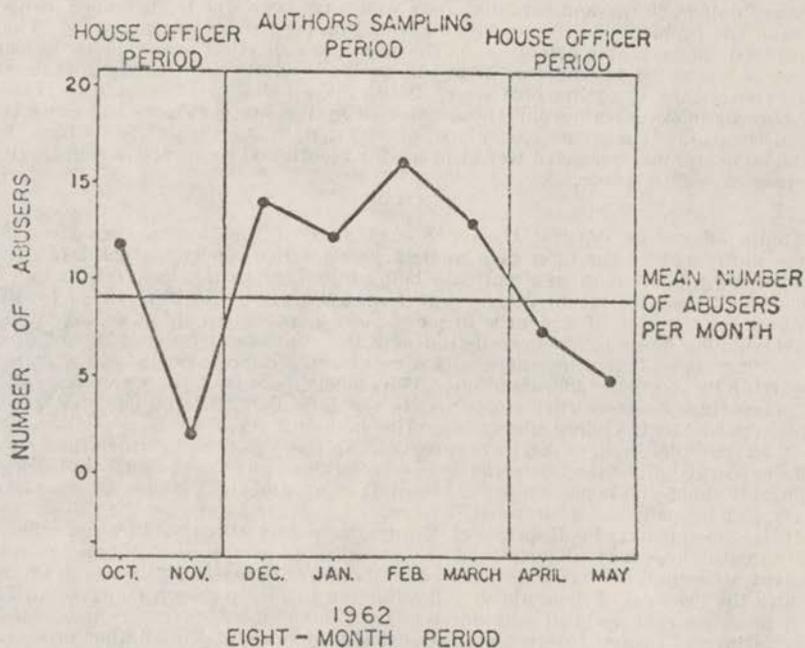
<sup>2</sup> Hambourger, W. E.: "Promiscuous Use of Barbiturates: II. Analysis of Hospital Data," *J.A.M.A.*, 114:2015, 1940.

<sup>3</sup> Expert Committee on Addiction-Producing Drugs—11th Report, WHO Technical Reporting Service, 211:1-16, 1961.

## RESULTS

A total of 82 drug abusers and addicts was reported during the 8-month study (Figure). Forty-four were addicted as follows: diacetylmorphine (heroin), 32 (four of these also abused barbiturates), terpin hydrate with codeine, 5; paregoric 3; morphine sulfate, 2; dihydrohydroxycodone (Percodan), 1; codeine, 1. Thirty-eight were abusers as follows: barbiturates, 17; one of these also abused meperidine hydrochloride (Demerol Hydrochloride); meprobamate, 5; dextroamphetamine sulfate, 4; both barbiturates and dextroamphetamine sulfate, 3; glutethimide (Doriden), 2; bromides, 2; an inhaler (Valo) containing 150 mg. of 2-amino heptane carbonate, 150 mg. of d-l desoxyephedrine carbonate, 50 mg. of phenylpropanolamine carbonate, menthol and aromatics, 2; and chlordiazepoxide hydrochloride (Librium), ethchlorvynol (Placidyl), and propoxyphene hydrochloride (Darvon), 1 each. Among the heroin addicts, two also abused marijuana, one, lysergide (LSD-25), and one, propoxyphene hydrochloride. By comparison, the authors in their routine hospital work diagnosed only 2 cases in the total of 28 reported during the 2 separate periods when the house officers did all the routine checking.

A check of both the Boston City Hospital and the Commonwealth of Massachusetts Food and Drug Division records indicated that only six new cases were officially reported to either of these agencies during the 8-month period. The authors had offered psychiatric consultation, but had made no attempt to alter current procedures of reporting for medical or legal reasons.



Comparison of number of abusers uncovered during control and sampling period.

## COMMENT

There was great discrepancy between the number of drug abusers and addicts actually discovered in the 8 months of routine checking on the new admissions to the hospital and the number reported to the official agencies of the State during that same period. The 6 patients reported constituted only 7 percent of the total 82 patients who should have been reported. The 6 in 8 months compare statistically with the 10 in 2 years 1959-61, mentioned previously. Obviously, the officially reported figures fall, by an order of magnitude, to portray the facts.

Careful search also disclosed hidden cases of drug abuse and addiction among patients who did not readily divulge their history of drug activity. In a 4-month period the authors detected 13 cases in addition to the 41 that were diagnosed by the house officers during the same period. Yet these 13 represented random sampling of only every 20th patient. If the same ratio held and all patients admitted had been seen by us, presumably some 260 hidden cases might have been discovered. The implication is that there may be far more drug abusers and addicts in the general population than has ever been suspected (apparently 3 per 1,000).

It would be interesting and important to inquire why house officers do not report cases of drug abuse and addiction in the officially designated manner. We purposely avoided showing an interest in this question in order not to influence the behavior of the house officers. It is our strong impression from talking to house officers subsequently that few of them know that they are supposed to make such official reports. Some do know but feel that apparently no one checks up on them on these matters and conclude that presumably the whole thing is of little concern. In the busy life of a house officer what can be neglected often is neglected.

It would be interesting to know whether these same attitudes and practices exist also among practicing physicians in the community. They may be even more motivated to avoid filling out the proper forms by virtue of a desire to "protect" their private patients from the stigma of public reporting. The increased results of the house officers during the period when the authors were present doing the random sampling may well have been due to increased awareness of the problem of drug abuse and addiction because of our presence. That increased interest and attention to the problem can elicit many more hidden cases is suggested by the fact that the authors, admittedly more experienced interviewers, by sampling only every 20th new admission were able to detect 32 percent more cases beyond those detected by the house officers (13 cases beyond the 41). It must be recognized, however, that the 4 months in which the random sampling took place were the winter months when admissions generally were greater in number.

#### SUMMARY

House officers on duty at the emergency floor of the Boston City Hospital were motivated by the offer of a monetary reward to report instances of drug abuse and addiction in new patients being admitted to the hospital. After a period of 2 months, random sampling of all new admissions was made by the authors for a period of 4 months to see if more experienced interviewing would detect hidden cases of drug addiction and abuse missed by the house officers. Following these 4 months, there was a return to 2 more months of motivated reporting by the house officers alone. The official records of the Commonwealth of Massachusetts were then examined to see how many of the detected cases were reported by the house officers in routine fashion.

Of 82 cases detected, only 6 were reported. In the 4 months in which the house officers worked alone they detected 28 cases. In the 4 months the authors worked alongside them, the house officers detected 41 cases and the authors, by sampling every 20th new admission, detected 13 more.

It is concluded: (1) Because of failure to report diagnosed cases, official statistical figures may underestimate by an order of magnitude the true amount of drug abuse and addiction in the community; (2) Increased interest and attention to the problem of drug abuse and addiction in new patients being admitted to a large general hospital may elicit many hidden cases otherwise undetected. The failure of proper interest and attention may account for another order of magnitude in the underestimation of drug abuse and addiction in the community.

(1824 Beacon Street, Brookline, Mass., 02146 (Dr. Solomon).)

#### GENERIC AND TRADE NAMES OF DRUGS

Meprobamate—Equanil, Equanil L-A, Wyseals, Meprospan, Meprotabs, Mil-town.

Glutethimide—Doriden.

Chlorodiazepoxide hydrochloride—Llibruim.

Ethchlorvynol—Placidyl.

Propoxyphene hydrochloride—Darvon.

## MISUSE OF VALUABLE THERAPEUTIC AGENTS: BARBITURATES, TRANQUILIZERS, AND AMPHETAMINES

(A report by the Committee on Public Health, New York Academy of Medicine)

The reported widespread misuse of valuable therapeutic agents—narcotics offer a striking example—represents a public health problem of major proportions.

Mounting evidence indicates that there are three families of drugs of proven usefulness which are being misused as much if not more than narcotics. These drugs are the barbiturates, tranquilizers, and amphetamines.

Barbiturates are most commonly used to induce sleep. But a large amount is prescribed also for anxiety, nervousness, tension, and other poorly defined conditions. Other normal medical uses for these drugs are as anticonvulsants (in cases of epilepsy), anesthesia and preanesthesia, and for research investigation, particularly in neurophysiology. While there are perhaps 50 barbiturates being marketed for clinical use, the ones most frequently prescribed in the United States are barbital, available as Veronal; phenobarbital, as Luminal; pentobarbital, as Nembutal; and secobarbital, as Seconal.

Official Government reports on production and sale of barbiturates in this country show that since 1954 at least 700,000 pounds of these substances have been produced each year. In 1960, the figure was 852,000 pounds which, it has been estimated, would provide enough raw material to make approximately 6 billion 1-grain barbiturate capsules or tablets, or about 33 for every man, woman, and child in the United States.

In addition, there have been over 1 billion tablets of another sedative drug, glutethimide—available as Doriden—distributed in the United States in the past 7 years. This drug has been described as barbituratelike in chemical structure and pharmacological effect, though the manufacturer promotes it as a nonbarbiturate.

The problems arising from the misuse of barbiturates have engaged the committee's attention for many years. In 1956, the committee published the third of its reports on this family of drugs and outlined a series of recommendations for controlling their use.

However, it appears that barbiturates continue to be widely misused. A study prepared by the Health Department of the City of New York reveals that in the period between 1957 and 1963, inclusive, there were 8,469 cases of barbiturate poisoning in this city. Of this total, 1,165 cases were fatal and listed as suicides or due to undetermined causes. The rest, nonfatal, included 4,179 attempted suicides; 744 accidental poisonings; and 2,351 poisonings due to undetermined circumstances.

Furthermore, it has been demonstrated by a group of investigators at the Addiction Research Center in Lexington, Ky., that barbiturates taken regularly in large quantities produce all three characteristic symptoms of addiction: tolerance, physical dependence, and psychic dependence.

Tranquilizers and ataraxics are being offered as safer, equally effective, and dependable replacements for barbiturates in the treatment of tension, stress, and for relieving anxiety. The three principal groups of compounds in this family of drugs are phenothiazine derivatives, including chlorpromazine, which is available as Thorazine; rauwolfia derivatives, adaptations of Indian snake-root; and a miscellany of compounds including the bestselling meprobamate, available as Miltown and Equanil and chlordiazepoxide, available as Librium. According to one expert, several of these are misrepresented as tranquilizers since they are pharmacologically closer to sedatives and have been reported by several objective observers to have the same addicting properties as barbiturates.

And in a recent hearing on specialized drugs and drug problems before a subcommittee of the U.S. Senate, it was noted that in 1961, Americans ingested a mountain of tranquilizers weighing 1,400,000 pounds.

More recently, tranquilizers were described as rivaling barbiturates as suicide pills. From a study of 968 tranquilizer poisonings reported over a 17-month period in 1959-60 to the U.S. Public Health Service's National Clearinghouse for Poison Control Centers, it was noted that most of the suicides attempted with tranquilizers had involved the mildest of these drugs. In addition, it was found that numerous cases of stupor, convulsions, and coma resulted from overdose of tranquilizing drugs. But in some cases, deleterious effects were reported from the use of prescribed dosage.

The use of tranquilizers and barbiturates with suicidal intent points up the fact that suicide, as the fifth leading cause of death in the United States, has become a major public health problem. The seriousness of the situation has impelled a number of medical and nonmedical agencies throughout the country to institute suicide prevention programs.

In New York City, the department of hospitals has organized a 24-hour suicide prevention telephone service in five of the municipal hospitals. Persons in need of help are advised to call INGersoll 2-3322 at any hour of the day or night. A psychiatrist will be available to respond to callers seeking aid.

Another agency in New York City which has been established for the purpose of dealing with suicidal crises is a Save-a-Life League. The league has offices in midtown Manhattan but is prepared to render aid to anyone in need who calls Murray Hill 7-2142.

Amphetamines act primarily as stimulants to the central nervous system. They are effective in relieving fatigue, lightening emotional depression and, because they tend to suppress the appetite, in the control of obesity. When prescribed by responsible physicians, these drugs are found to be helpful in treating neurotic and depressed patients. When misused, they borrow energy which the body cannot afford to spend.

The most commonly used amphetamines are benzedrine and dexedrine. And because this drug promotes alertness—especially in combination with alcohol—it is most attractive to thrill-seeking youths. According to a report presented to a U.S. Senate Subcommittee on Juvenile Delinquency, the use of amphetamines by juveniles and young adults is mushrooming all over the country. It was stated that they are used increasingly by children and are linked with delinquency.

Moreover, the so-called pep pills are all the fashion among college youths and teenagers. It is reported that amphetamines are a large element in wild orgiastic binges in college communities throughout the Nation. Meanwhile, a number of investigators have pointed out that amphetamines alone and in combination with barbiturates have addictive properties.

The consequences of misuse of any of these three drugs are many, including death; temporary or permanent damage to the brain or nervous system; poisoning; and addiction. Children or youths who have been made stuporous by the ingestion of sedatives or tranquilizers or euphoric by use of amphetamines are most vulnerable or prone to sexual offenses, either as victim or perpetrator.

In recent years, a considerable number of serious accidents on the highways and in the air were traced to the use of amphetamines or tranquilizers by persons operating the vehicles. Tranquilizers were blamed in 1959 when a pilot taking them crashed a plane, killing all 26 aboard. More recently, when police searched 2 trailer trucks which had been involved in a multiple-vehicle accident on the New Jersey Turnpike, they discovered a total of 14 benzedrine tablets. The two truckers had been trying to fight off fatigue with the drugs. They also had been traveling more than 60 miles an hour in a 35-mile zone in heavy fog. The accident killed them and four others.

Dangerous episodes listed as accidents may take place when a person takes a single overdose of one of these drugs, or repeated doses at short intervals of barbiturates. Death or near death can result and survival often depends on heroic measures. And when there is no clear evidence of an attempt at suicide, these instances are listed as poisonings under undetermined circumstances.

Not all persons who die from misuse of barbiturates intend to kill themselves. Some have no thought of suicide but die from an accidental overdose of the drug. Then there is a second group of persons who threaten to kill themselves but do not really intend to die. Death comes when they miscalculate in the dosage or in their arrangements to be saved. But, of course, there are persons who misuse the barbiturates especially for suicide and do succeed in their purpose.

The extent of the problem is pointed up in a study prepared for the United Nations Bulletin on Narcotics in which it is hypothesized "that the total number of people in the United States using barbiturates, other sedatives, stimulants, and tranquilizers would approach 5 million, not to mention several hundred thousand marijuana and narcotics users \* \* \*. There are also problems involving glue sniffing (by young children) \* \* \* drinking cough syrups containing codeine and alcohol, and abuse of a whole range of other substances affecting the mind, including lysergic acid (LSD) and mescaline (peyote)."

Nevertheless, there is an astonishing lack of solid data about the abuse of barbiturates in the United States. The Advisory Commission on Narcotics and Drug Abuse, appointed in 1963 by President Kennedy, reported that the

records of various agencies connected with drug abuse frequently are inaccurate, incomplete, and unreliable. The Commission report went on to say that there are large numbers of drug abusers who never come to the attention of the community; that there is an increasing abuse of nonnarcotic drugs concomitant with a decrease in the abuse of narcotics; that there is an entirely new and increasing abuse of drugs periodically on a spree basis; and that the possible abuse of barbiturates and amphetamines may be increasing because they are cheaper, easier to handle, and more easily obtainable.

The findings of the President's Advisory Commission have been documented by a wholesale number of articles in the lay magazines on the widespread use of "goof balls," marihuana, glue-sniffing, and even narcotics among juveniles on sprees.

The first effort, on a Federal level, to control the use of barbiturates and amphetamines in this country was the so-called Durham-Humphrey amendment in 1951 which specifically restricted these drugs to prescription and refill only upon the authorization of a physician. The Congress also said that the barbiturates posed a special problem not common to all drugs because they are desired by addicts for nonmedical use and the legislators predicted that this would call for further controls in the future.

Several years later, committees of both Houses of Congress heard testimony on the barbiturate problem in this country. A bill introduced at that time to amend the Federal Food, Drug and Cosmetic Act would have prohibited the manufacture, sale or possession of barbiturates except by persons specifically authorized by the bill and would have required that records be kept of all transactions involving these drugs. This bill and other subsequent congressional efforts to increase controls on barbiturates failed to pass. According to an observer: "The public health problem commented upon by Congress has not improved and in fact has worsened since 1956 with large amounts of barbiturates escaping from legitimate channels of commerce at every level of the chain of distribution."

At the present time, Federal law in the United States applies solely to barbiturates shipped in interstate commerce; requires no inventory control; but does require that copies of purchase orders for these drugs be made available for inspection for appropriate Government agencies.

In 1962, Congress rejected provisions to increase the controls of barbiturates as proposed in H.R. 11581 and in S. 1552. In 1963, S. 553 was introduced for the same purpose but failed to pass. It has been revised and introduced again in the current session of Congress as S. 2628.

The entire problem is described succinctly in the findings and declarations of sec. 2 of the proposed bill:

"The Congress hereby finds and declares that there is a widespread illicit traffic in barbiturates, in psychotoxic drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, may cause a wide variety of acute and chronic changes in psychological functioning, social behavior, or personality, such as difficulties in judgment and coordination, disorderly thinking, disturbances in mood, bizarre and abnormal perceptual experiences, and more severe behavior disturbances such as attempted suicide and antisocial activities; that this illicit traffic results in extensive sale and distribution of such drugs to juveniles and youths, as well as adults, not under the supervision of a licensed practitioner; that the use of such drugs by juveniles, when not under the supervision of a licensed practitioner, may lead them to perform acts of delinquency and crime and to experiment with narcotic drugs, which experimentation may result in narcotic addiction; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highway and otherwise has become a threat to the public health and safety, making additional regulations of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that the regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act, would discriminate against and depress interstate commerce in such drugs."

A model State law concerning hypnotic or somnifacient drugs, patterned after the Federal law, was suggested by the Council of State Governments in 1955. This model law is similar to the recommendations proposed by the Committee on Public Health in its 1956 report except in the following particulars: Although it requires that refilling of a prescription must be specifically authorized, it does not specify a minimum interval between renewals, the total number of renewals, and the expiration date of the prescription. On the other hand, it includes a section on penalties. One of the provisions in the model law is similar to that recommendation made by the Committee on Public Health which provided that the physician must maintain records of barbiturates distributed by him.

Until 1963, the law in the New York State controlling barbiturates provided that duly authorized prescriptions for these drugs had a life of 6 months. Prescriptions could be refilled a number of times within this period.

Prompted by the desire to bring the New York law into conformity with the Federal regulations, the New York State Legislature in 1963 enacted sec. 6814 of the State Education Law. The principal provisions of this new law remove the 6 months' life of the prescription and require only that such a prescription shall be written by a duly authorized person and that the druggist must record on the prescription the date of the refilling.

The New York State Penal Law, sections 1747-b and 1747-c, provides that any person who sells, exchanges, or gives away barbiturates or amphetamines in violation of the State education law, shall be liable to imprisonment for not more than a year, or a fine of not more than \$500, or both, upon conviction for a first offense; but if the violation is a second offense, the person shall be liable to imprisonment for not more than 2 years, or a fine of not more than \$1,000 or both.

For the past 10 years, the New York City sanitary code and the health code which replaced it have contained a regulation providing that prescriptions for barbiturates had a life of 3 months. At the present time, however, efforts are being made to change this regulation in order to bring it into conformity with the less restrictive State and Federal laws.

In 1946, the committee on public health was asked by the New York City commissioner of health to give its opinion on the desirability of extending restrictive measures regarding the sale and distribution of barbiturates. The commissioner submitted to the committee a draft of proposed regulations which were drawn up in cooperation with the New York office of the Federal Bureau of Narcotics.

The committee studied the proposed changes in the regulations and expressed the view that in the interest of public health, the suggested extension of control should not operate to interfere with the freedom of physicians in their practice; rather it should guard against misuse by the dispenser and the user.

The committee recommended the following specific regulations:

1. Prescriptions should be refillable when so indicated by the issuing physician; but such prescriptions should indicate a minimum interval between renewals and the total number of renewals. No prescription containing a barbiturate should be refilled after 6 months from the date of issuance.

The committee pointed out that in certain conditions, the treatment makes renewals necessary. And while it was aware that in some cases, an unnecessary financial hardship is imposed on the patient who must return to the physician for a new prescription, the committee felt that it is important for the physician to see the patient occasionally in order to evaluate the treatment.

2. Pharmacists should not reveal the content or furnish copies of prescriptions to patients.

3. Prescriptions should carry suitable information about the identity of the patient and the prescriber.

4. In an emergency, a physician should be allowed to transmit to a pharmacist by telephone a prescription for not more than 6 average doses of barbiturate drugs provided a written prescription is supplied to the dispensing pharmacist within 72 hours. Should the pharmacist fail to receive such a written prescription, he should notify the health department of the omission.

5. Proper records of dispensed barbiturates should be kept by physicians, dentists, and veterinarians.

6. Manufacturers, wholesalers, and jobbers should maintain suitable records of sales and distribution, and inventories of stocks.

7. Pharmacists should keep records of bills of purchase of barbiturates and copies of prescriptions on which drugs were dispensed, including notation of amounts dispensed upon refilling.

8. Barbiturates should not be supplied to any person except on prescription or in the course of legal sale within the drug trade.

All of the committee's recommendations, in either their original or slightly varied form, were incorporated in the sanitary code by the end of 1947.

In the 10 years between 1946 and 1956, the committee continued to study the misuse of barbiturates. And at the end of this period, it published a report which made the following recommendations:

1. The model law controlling the manufacture and distribution of barbiturates should be adopted by all States. Large cities with home rule should have laws patterned after this act.

2. A realistic effort toward enforcement of the model law when enacted is an essential step. An adequate staff of inspectors to examine records should be organized. Efforts at enforcement should be concentrated on the large cities where the rates of incidence of barbiturate poisoning are highest.

3. An educational campaign should be conducted by health departments and medical and pharmaceutical societies to remind their members of their responsibilities of acquainting patients with the dangers of misuse of barbiturates. At the same time, there should be a campaign, using all media, to inform the public of the risks attached to misuse of barbiturates.

4. Above all, it is highly desirable that adequate funds should be provided to support research on the causes of unrest, anxiety, and tension that are so prevalent among the population and are the basis for such great use and misuse of barbiturates.

Research should take into account the popularly held belief that psychoactive drugs are a cure-all for every emotional and psychological stress, whether slight or great, and a means to attain "happiness." Thus, some persons are known to take an amphetamine in the morning, a tranquilizer to get through the day, and a barbiturate at night. As a result, these persons develop an overwhelming dependence on such drugs.

But until research develops the desired information, there should be initiated immediately an educational campaign designed to teach the public that both the goal of "happiness" and the use of psychoactive drugs to achieve that goal are illusionary.

At this point, it is clear that misuse of barbiturates, tranquilizers, and amphetamines presents different problems according to the segments of the population and the variety of consequences attendant on such misuse: juveniles may injure their health, engage in antisocial or immoral acts, or may incur poisoning or addiction; both juveniles and adults may have auto accidents as a result of taking sedatives, tranquilizers or stimulants; adults may incur poisoning or near death from overdose of these drugs, particularly barbiturates; accidental death may result from overdose of barbiturates; and, finally, barbiturates and related drugs may be used to commit suicide.

The remedies which the committee proposes must be seen against the background of the hazards listed above:

1. Federal law should be designed to control the movement of barbiturates, amphetamines and other psychotropic drugs in order to combat the illicit traffic in these drugs and to prevent their continued misuse.

2. The Federal law on the prescription of barbiturates should be more restrictive. The committee feels it should be more in accord with the first recommendation in the 1946 report.

3. There should be stricter enforcement of the existing law on dispensing barbiturates and amphetamines so that they do not get into the hands of juveniles.

4. Motor vehicles should not be operated by drowsy drivers. Barbiturates, tranquilizers, amphetamines, and antihistamines may produce mental confusion, drowsiness, or postpone drowsiness. Persons who have taken them in a dosage that would produce these effects should not drive while under their influence.

5. Suicide is a major cause of death. But there are agencies which stand ready to give aid in thwarting suicide and rescuing the victim. The existence of these agencies should be given the widest publicity through all media of communication. In New York City, the telephone number of the emergency suicide prevention agencies of the department of hospitals should be made known to all the residents. The telephone number of the Save-A-Life League,

and other agencies geared to provide aid to a would-be suicide, should also be disseminated widely. Finally, there should be a provision for mandatory psychiatric examination of a person immediately after regaining consciousness following an unsuccessful attempted suicide by an overdose of these drugs.

6. There should be an educational campaign to change the present public workshop of "happiness" and "tranquillity." This attitude on the part of many people produces an almost slavish dependence on psychotropic drugs.

(Approved by the Committee on Public Health, the New York Academy of Medicine, May 11, 1964.)

## BIBLIOGRAPHY

- Amphetamine-barbiturate combinations. Annotations, *Brit. Med. J.*, No. 5317: 1456-7, (Dec. 1), 1962.
- Antidepressants help in suicide prevention. Third of series on the medical aspects of suicide, *Medical Tribune*, Sept. 10, 1962.
- Authorities suggest measures to prevent suicide. Fourth of series on the medical aspects of suicide, *Medical Tribune*, Sept. 17, 1962.
- Barbiturate poisoning, *Medical Tribune*, Apr. 26, 1963.
- Clearer danger signs needed for prevention of suicide. Second of series on medical aspects of suicide, *Medical Tribune*, Sept. 3, 1962.
- Committee on Public Health Relations, The New York Academy of Medicine. Report of Subcommittee on Barbiturates, Dec. 6, 1943, Mimeographed.
- Committee on Public Health Relations, The New York Academy of Medicine. Control of Barbiturates, Nov. 19, 1945, Mimeographed.
- Committee on Public Health, The New York Academy of Medicine. Report on Barbiturates, *Bull. N.Y. Acad. Med.* 32: 456-81, June 1956.
- Dodd, T. J., U.S. Senator (D., Conn.), Statement: Proposed legislation relating to illegal traffic in dangerous drugs, Mar. 12, 1964.
- Drugs and behavior. Annotations, *The Lancet* 1: 805 (Apr. 11), 1964.
- Dublin, L. I. *Suicide: A Sociological and Statistical Study*. New York, Ronald Press, 1963. 240 pp.
- Fort, J. The Problem of Barbiturates in the United States of America. *United Nations Bulletin on Narcotics*, 1963, pp. 1-26 (incl. three tables).
- Goldman, R. P. Instant Happiness, *Ladies Home Journal*, Oct. 1963, pp. 67-71.
- Interagency Coordination in Drug Research and Regulation. Hearing before the Subcommittee on Reorganization and International Organizations of the Committee on Government Operations, United States Senate, Eighty-eighth Congress, First Session; Agency Coordination Study (Pursuant to S. Res. 27, 88th Cong., As Amended), Review of Cooperation on Drug Policies Among the Food and Drug Administration, National Institutes of Health, Veterans' Administration, and other agencies. Mar. 21, 1963, Part 4, pp. 1269-2171.
- Litman, R. E., and others. Investigations of equivocal suicides, *J.A.M.A.* 184: 924-9, 1963.
- Meprobamate toxicity. *Medical Letter on Drugs and Therapeutics*, Dec. 9, 1960, p. 100.
- McKown, C. H., Verhulst, H. L., and Crotty, J. J. Overdosage effects and danger from tranquilizing drugs, *J.A.M.A.* 185: 425-30, 1963.
- New York City Department of Health. *Barbiturate Poisonings in New York City, 1939-1963 (Incomplete)*.
- Phone plan seeks to curb suicides, *The New York Times*, Aug. 26, 1963.
- President's Advisory Commission on Narcotic and Drug Abuse, Final Report, Nov. 1963, pp. 1-123.
- Suicide, a top death cause, becoming problem for GPs. First of series on medical aspects of suicide, *Medical Tribune*, Aug. 27, 1962.
- Tranquillizer use as poison noted, *The New York Times*, Aug. 10, 1963.
- Tuckman, J., Youngman, W. F., and Bleiberg, B. M. Attempted suicide by adults, *Public Health Reports* 77: 605-14, 1962.
- Tuckman, J., and Youngman, W. F. Suicide risk among persons attempting suicide, *Public Health Reports* 78: 585-7, 1963.
- Tuckman, J., and Youngman, W. F. Identifying suicide risk groups among attempted suicides, *Public Health Reports* 78: 763-6, 1963.
- U.S. Department of Health, Education, and Welfare, Public Health Service. Some facts about suicide, causes and prevention. Publications and Reports Section, National Institute of Mental Health, Bethesda, Md., Public Health Service Publication No. 852, Health Information Series No. 101, 1961. 11 pp.

[From the American Medical Association Journal 189: 366-377, Aug. 3, 1964]

## BARBITURATE USE IN NARCOTIC ADDICTS

(Ernest Hamburger, M.D., Lexington, Ky.)\*

Accumulating data concerning physical dependence on barbiturates by narcotic addicts and reviewing case records to elicit patterns of barbiturate use are the two major phases of this study.

It is suspected by many authorities that barbiturates are increasingly being used as drugs of psychic and physical dependence. A review of the literature shows that little is known about the actual extent of barbiturate use in the general population. Although statistics concerning the use of barbiturates are limited, some information is available. It is known that the equivalent of 26 doses of barbiturates for every man, woman, and child were produced in the United States in 1955.<sup>1</sup> Barbiturate production is believed to have increased significantly since then.

A number of serious and complex cases involving the problem of barbiturate use in narcotic addicts prompted the author to investigate this problem at the U.S. Public Health Service Hospital in Lexington, Ky. The study was divided into two phases. The first was to accumulate as much experience as possible concerning the clinical problem of psychic and physical dependence on barbiturates in the narcotic addict population of the hospital. The second phase was a review of 1,000 consecutive case records of first-admission narcotic addict patients in order to elicit occurrence and possible patterns of barbiturate use.

*Clinical impressions.*—Physical dependence on barbiturates may not be evident because a tolerance has been acquired. However, if the user takes an amount of the drug beyond his tolerance, acute intoxication to barbiturates occurs. Acute intoxication leads to difficulty in concentration, mood shifts without apparent cause in the environment, irritability, self-neglect, and infantile behavior. Lateral-gaze nystagmus, dysarthria, ataxia on standing and walking, as well as a positive Romberg's test can be demonstrated. Longer periods of sleep also occur. When the patient's tolerance for barbiturates is built up sufficiently, he may not show any of these features, although he may be taking up to 2,000 milligrams of barbiturates in 24 hours.

TABLE 1.—Barbiturate use in narcotic addicts<sup>1</sup>

	<i>Narcotic addicts</i>
No history of barbiturate use or physical dependency on barbiturates.....	676
History of barbiturate use but no evidence of physical dependence.....	98
Evidence of physical dependency on barbiturates detected.....	228
Total.....	1,000

<sup>1</sup>This table indicates number of barbiturate users in 1,000 narcotic addicts. Many giving a history of barbiturate use but no sign of dependence were prisoners who were withdrawn from drugs prior to admission to the hospital.

Abstinence signs and symptoms in most, but not all, patients occur in the following sequence: the patient manifests a diffuse restlessness and anxiety; irritability and insomnia are seen at this point; if untreated, body temperature climbs slowly, rising as high as 105° F. (40.6° C.) in the very late stages; the pulse rate increases accordingly; when the patient stands from the supine or sitting position, the pulse rate increases by 16 to 36 pulsations per minute; postural hypotension can also be demonstrated; increasing muscle tone and brisker reflexes are found; and blepharoclonus can be elicited. (Blepharoclonus can be demonstrated by tapping the glabella [area immediately between and above the eyes]. Normally, a few blinks are seen and then accommodation occurs. A positive response is a rapid fluttering of the eyelids, which increases instead of decreases.) These responses are probably due to increased neuromuscular irritability. Delirium and grand mal convulsions may occur at this point. If relief is not given by substitution therapy with barbiturates, coma and death may follow.<sup>2,3</sup> Diphenylhydantoin (Dilantin) sodium has been shown to offer no

\*Dr. Hamburger is a surgeon for the U.S. Public Health Service at the U.S. Public Health Service Hospital.

See footnotes on p. 65.

appreciable help in convulsions of this etiology. There is some evidence to lead to the conclusion that diphenylhydantoin sodium is contraindicated in convulsions due to the barbiturate abstinence syndrome.<sup>4</sup>

TABLE 2.—Type of narcotic drug used by barbiturate users<sup>1</sup>

Narcotic drug	Number not using barbiturates	Number using barbiturates	Total
Heroin.....	504	228	732
Cocaine—Camphorated opium tincture (Paragoric).....	63	33	96
Meperidine (Demerol) hydrochloride.....	29	12	41
Morphine sulfate.....	30	23	53
Dihydromorphinone (Dilaudid) hydrochloride.....	25	17	42
Methadone hydrochloride.....	10	8	18
Mixture of hydrochlorides of opium alkaloids (Pantopon).....	4	3	7
Total.....	665	324	989

<sup>1</sup> Eleven patients used such a great variety of drugs, it was impossible to determine the nature of their narcotic drug choice.

Difficulties may arise when the physician must deal with the problem of narcotic addiction and barbiturate dependency. Examples of this are numerous. Is excessive sleeping caused by opiate or barbiturate intoxication? Is insomnia due to opiate or barbiturate abstinence? Are irritability and mood shifts caused by one or the other abstinence syndrome or unrelated? These and other questions can be resolved only by using demonstrable signs of intoxication and abstinence to these drugs.

Glutethimide (Doriden), ethchlorvynol (Placidyl), carbromal (Carbrital), and meprobamate (Miltown, Equanil) are included with those drugs which, though chemically not barbiturates, clinically are almost identical in action. It has been shown that these drugs, like barbiturates, can cause tolerance, psychic dependence, and physical dependence.<sup>5-8</sup> Thirty patients shown to be dependent on very large amounts of barbiturates or similar drugs were interviewed at length. Fifteen had been using pentobarbital (Nembutal), seven, glutethimide, five, secobarbital (Seconal) sodium, and three, a combination of secobarbital and amobarbital (Tuinal) sodium. Psychiatric evaluation of these 30 patients revealed that they all had personality disorders. Some were classified as inadequate personalities with definite dependency needs unmet in their pre-drug-use period. Others were primarily passive-dependent personalities, who behaved in a childlike, pleading fashion, and manifested helplessness in practically all phases of life. Physicians often find it difficult to refuse medication to this type of patient in face of their persistent pleadings. These personality disorders are notoriously resistant to successful psychiatric treatment.

Interview questioning of a larger number of patients found to be physically dependent on barbiturates was undertaken in order to elicit their motives for this drug abuse. Many felt that the ease of obtaining barbiturates and their low cost (as compared to heroin), encouraged supplementation of this drug to opiates. Indeed, total substitution of barbiturates for narcotics in times of short supply was claimed by some. It was noted that several patients who, on initial admission interview, stated that they were addicted to a narcotic only, were shown during withdrawal and physiological tests to be primarily addicted to barbiturates. When told of their condition, some admitted to taking large amounts of barbiturates. They implied that they were ashamed of the barbiturate use, although not of the narcotic addiction. Others still insisted that they had not taken any barbiturates. They could only account for the abstinence syndrome to barbiturates by suggesting that the sellers of heroin were diluting it with barbiturates, the purpose being to give the customer some type of subjective sensation when the substance was injected.

Barbiturate gratification is somewhat different than opiate gratification, according to those who had been physically dependent on both. Oblivion, release from the present situation, and not euphoria (a "kick" or "high"), was often the factor that started the patient on the road to barbiturate use.

See footnotes on p. 65.

TABLE 3.—*Barbiturate addiction in relation to race*<sup>1</sup>

	White	Negro	Total
No barbiturate history.....	335	341	676
History of barbiturate intake with no physical dependency....	60	36	96
Physical dependency on barbiturates.....	177	51	228
Total.....	572	428	1,000

<sup>1</sup> A definite statistical difference detected. (Significant beyond 0.001 level.)

*Statistical review.*—The first statistical study done was to determine what percent of narcotic addict patients claimed to take barbiturates and what percent were physically dependent. Table 1 shows that 32.4 percent claimed or showed signs of barbiturate use. Only 22.8 percent were actually noted to be physically dependent. As shown in table 2, there are no significant differences in the barbiturate users' choice of narcotic drugs. A definite difference was detected when barbiturate use was compared between races. Many more whites than Negroes were barbiturate users. In table 3 it is seen that 73 percent were white, while 27 percent were Negroes. This was found to be statistically significant beyond the 0.001 level.

The use of barbiturates by narcotic addicts occurs quite frequently. It has been shown that 22.8 percent of narcotic addicts admitted to the U.S. Public Health Service Hospital in Lexington, Ky., were physically dependent on barbiturates, while another 9.6 percent claimed to be dependent on these drugs at one time. No apparent relationship between the type of narcotic used and barbiturate use was discovered. However, a definite relationship was found between race and barbiturate use in the narcotic addict; the white narcotic addict is much more likely to use barbiturates.

Physical dependency on barbiturates may not cause obvious signs of intoxication because of the development of tolerance. The barbiturate intoxication and abstinence syndromes were discussed as necessary adjuncts to the evaluation of the barbiturate user. Gradual substitution reduction treatment using barbiturates relieves and prevents the barbiturate abstinence syndrome. Some of the nonbarbiturate sedatives cause tolerance, psychic dependence, and physical dependence quite similar to that caused by barbiturates. Patients with personality disorders, particularly those with inadequate and passive-dependent personalities, seem to constitute the bulk of barbiturate users. Oblivion from the present situation, rather than euphoria, seems to be the motivation to use barbiturates.

(Department of Psychiatry, University of Colorado Medical Center, Denver.)

#### *Generic and trade names of drugs*

Glutethimide—Doriden.

Ethchlorvynol—Placidyl.

Meprobamate—Equanil, Equanil L-A, Wyseals, Meprospan, Mepro tabs, Miltown.

#### REFERENCES

1. Public Health Service, U.S. Department of Health, Education, and Welfare: Barbiturates as Addicting Drugs, Washington, D.C.: Publication No. 545, U.S. Government Printing Office.
2. Fraser, H. F., et al.: Chronic Barbiturate Intoxication, *Arch. Intern. Med.* (Chicago) 194: 34-41 (July) 1954.
3. Isbell, H.: Treatment of Barbiturate Addiction, *Postgrad. Med.* 9:3 (March) 1951.
4. Essig, C. F.: Failure of Diphenylhydantoin in Preventing Barbiturate Withdrawal Convulsions in Dog, *Neurology* (Minneapolis) 12: 481-484 (July) 1962.
5. Essig, C. F.: Addictive and Possible Toxic Properties of Glutethimide, *Amer. J. Psychiat.* 119:10 (April) 1963.
6. Essig, C. F., and Ainslie, J. D.: Addiction to Meprobamate (Equanil and Miltown), *JAMA* 164: 1382 (July 20), 1957.
7. Essig, C. F.: Withdrawal Convulsions in Dogs Following Chronic Meprobamate Intoxication, *Arch. Neurol.* (Chicago) 80: 414-417 (Oct.) 1958.
8. Lemere, F.: Habit Forming Properties of Meprobamate, *Arch. Neurol.* (Chicago) 76:205-206, 1956.

[From Bulletin on Narcotics, 16: 17-35, January-March 1964]

### THE PROBLEM OF BARBITURATES IN THE UNITED STATES OF AMERICA

(By Joel Fort, M.D., lecturer, School of Criminology, University of California; director, Center for Treatment and Education on Alcoholism, Oakland, Calif.)

#### I. INTRODUCTION

As long as man has existed, drugs such as alcohol, marijuana and opium have been used for relief of anxiety, tension, or fatigue; for treatment of illness; and for religious reasons. The abuse of these drugs and of more modern compounds which also affect the brain has been a major social and health problem in many widely separate countries and epochs. In this historical context, therefore, it is not difficult to understand the contemporary widespread use and abuse of the derivatives of barbituric acid (malonylurea) accidentally discovered by Von Baeyer in 1863 (112). The hypnotic significance of substituting various radicals in position five was discovered in 1903 (barbital or veronal) and given impetus in 1912 with the introduction of phenobarbital (luminal). Since that time it is variously estimated that up to 2,500 barbiturates and thiobarbiturates have been synthesized with perhaps 50 being marketed for clinical use, the most used ones in the United States being nembital (pentobarbital), seconal (secobarbital), amytal (amobarbital), and tinal (amobarbital and secobarbital). All of these synthetic derivatives have similar chemical structures and similar pharmacological properties, with the main clinical variations being the onset and duration of their action. Levi (77) has summarized the trade names, chemical names, structural formulas, and molecular composition of the barbiturates and their clinical use. Other dates of specific historical significance in the evolution of sedatives and hypnotics include the 1840's, when the action of bromide was recognized, 1869 when chloral hydrate was introduced, 1882 when paraldehyde was introduced, and 1954 when the phenothiazine tranquilizers came into general use. As Glatt (45) has pointed out, each of these drugs or drug families including the barbiturates has aroused similar controversies and debates about their merits and dangers. Since the time of the First World War there appears both to have been a rapid increase in the use of the various barbiturates and a gradual institution of government attempts at control. In the following sections of this monograph an attempt will be made to collectively review and synthesize what is "known" about the extent of barbiturate use and abuse in the United States. As will be seen, there exist major lacunae in knowledge about this problem.

#### II. PHARMACOLOGY: PHYSIOLOGY AND THERAPEUTIC USES

Among the physiological effects of the barbiturates are respiratory depression proportional to the dose administered; a decrease in tonus of the gastrointestinal musculature and a decrease in gastric secretion; and a complex of effects on the autonomic nervous system (47). There appears to be no impairment of liver, renal, or cardiovascular functioning. The long-acting barbiturates and metabolized by the kidney and the short-acting ones by the liver. The central nervous system effects of the barbiturates are sometimes briefly summarized by saying they have a depressant action on all segmental levels and all levels of functional organization. Either increased fast activity or slow activity can occur in the electroencephalogram, seemingly based on individual differences and not correlated with intensity of intoxication or behavioral effects. With more than normal clinical doses a form of intoxication occurs which includes ataxia, nystagmus, and slurring of speech. Wikler (122) has summarized the neurophysiological action as a selectivity for the medial ascending reticular activating system, with specific depressant actions on the hypothalamus, spinal cord, and sympathetic ganglia. He goes on to say that it is likely that these drugs exert quite specific patterns of effects both on behaviour and on neuro-organization, but better correlation of these will depend on more detailed and more comprehensive descriptions of the behavioral effects as well as investigation of the effects of graded doses on the temporal and spatial diffusion of neuroimpulses. A number of investigators have now reported that both large doses and small "therapeutic" doses impair reaction time, visual perception, and attention even up to 14 hours after injection (53). The barbiturates have little effect on the pain threshold unless an amount sufficient to impair consciousness is administered (55). Reported effects of the barbiturates on cognitive functions, learning, perception, hypnosis, etc. are unclear as to their significance or implications (29).

## III. USE, PRODUCTION, SALE, AND PRESCRIBING OF BARBITURATES AND RELATED DRUGS

The most common therapeutic use of the barbiturates is for the production of sleep, which is brought on within 20 to 60 minutes and resembles natural sleep. Thus it would appear that the most common complaint for which barbiturates are prescribed would be insomnia. However, large amounts are also prescribed for anxiety, nervousness, tension, and other poorly defined or physically unexplainable complaints. The therapeutic dose prescribed for sedation is generally smaller than for hypnotic effects. Other normal medical uses of these drugs are as anticonvulsants (phenobarbital for epilepsy), anesthesia (thiopental) and preanesthesia, diagnostic agents to differentiate organic from functional psychiatric disorders or functional disorders from malingering, narcoanalysis, sleep therapy for psychosis (rarely used in the United States), and for research investigation, particularly in neurophysiology. Some authorities feel that the barbiturates offer unique advantages in that they can produce any degree of depression from sedation to anesthesia, thus lending themselves to a wide variety of uses. However the ease with which they can be prescribed also results in their being employed when other sedatives or other forms of treatment might be preferable.

The reports of the U.S. Tariff Commission (111) on production and sale of barbituric acid (table 1) show that since 1954 at least 700,000 pounds of these substances have been produced each year. More than half of the amount produced each year is sold in undiluted or bulk form, and the rest presumably in various specific commercial preparations. Figures on amounts produced refer to known manufacturers, and probably additional quantities are produced by unknown, unregistered, or illicit manufacturers. The framework of present State and Federal legislation makes it impossible to ascertain the full details of manufacture and distribution. It seems safe to assume, however, that the amount of barbituric acid derivatives produced would be roughly equivalent to the amount used. The 1960 figure of 852,000 pounds, although not representing total production, would still be enough raw material to make approximately 6 billion 1-grain barbiturate capsules or tablets, or about 33 for every man, woman, and child in the United States. Over 1 billion tablets of another sedative drug, barbiturate-like in chemical structure and pharmacological effect, Doriden, have been distributed in the United States in the past 7 years, according to its manufacturers.

TABLE 1.—Barbituric acid and derivatives

	Production	Sales		
		Quantity	Value	Unit value per pound
	<i>Pounds</i>	<i>Pounds</i>		
1961.....	700,000	407,000	\$1,903,000	\$4.68
1960.....	852,000	456,000	2,429,000	5.33
1959.....	819,000	583,000	2,853,000	4.89
1958.....	790,000	513,000	2,433,000	4.74
1957.....	755,000	467,000	2,369,000	5.18
1956.....	756,000	467,000	2,483,000	5.32
1955.....	864,000	486,000	2,807,000	5.78
1954.....	798,000	524,000	3,204,000	6.11
1953.....	634,000	427,000	2,757,000	6.45
1952.....	537,000	418,000	3,034,000	7.26
1951.....	789,000	481,000	2,934,000	6.09
1950.....	688,500	499,100	2,739,500	5.49
1949.....	679,800	388,900	2,337,200	6.01
1948.....	679,800	455,800	2,116,400	4.64
1947.....	900,100	768,600	3,843,500	5.00
1946.....	806,500	650,900	3,093,500	4.75
1945.....	582,100	556,500	3,025,000	5.44
1944.....	559,200	558,400	3,119,800	5.59
1943.....	583,000	664,000	3,400,000	5.12
1942.....	607,000	487,000	2,430,000	4.99
1941.....	531,000	512,000	2,263,000	4.42
1936.....	231,167	174,188		

NOTE.—Sales include only that portion of the original product which is sold in undiluted or un-compounded form including that sold in bulk, and that sold in packages.

Production data are for medicinal chemicals in bulk. They do not include finished preparations (tablets, capsules) manufactured from bulk medicinal chemicals.

Systematic, nationwide records are not available on the number of prescriptions written for barbiturates or other sedatives alone, or the amount of drugs ordered on each prescription. However, a nationwide sampling by the retail drug industry indicates that 14 to 18 percent of all prescriptions fall into the category of sedatives and tranquilizers ranking first or second in popularity, and also constituting 18 percent of all refill prescriptions (24). Barbiturates rank between first and third at different times, in frequency of prescription within the sedative and tranquilizer category (11 to 12 percent). (One writer states that 3 to 4 billion doses of barbiturates are legally prescribed each year.) This compares with the 7 percent for barbiturate prescriptions alone reported in England (45). An estimate in 1957 was that 36 million prescriptions were written for 1.2 billion tranquilizers, and it now constitutes a \$250-million-per-year retail business. Reports of local, State, and Federal law enforcement officers and the U.S. Food and Drug Administration indicate that hundreds of thousands of barbiturate tablets or capsules are being sold illegally each year in the United States by professional criminals as well as by some manufacturers, pharmacists, and physicians (1, 17, 97, 110).

There are more than 7,000 drug and chemical wholesalers in the United States and more than 56,000 retail drugstores with total sales in 1960 of \$7,530 million. Table 2 (103) shows a breakdown of 1954-58 shipments of tranquilizers, barbiturates, etc. Table 3 shows a breakdown of the various barbituric acid derivatives, tranquilizers, etc., produced in 1960.

TABLE 2.—U.S. Department of Commerce census of manufactures

	Value of shipments including interplant transfers	
	1958	1954
Tranquilizers, sedatives, and hypnotics.....	1 \$236, 802, 000	(?)
Barbiturates in preparation without other active agents:		
Parenteral.....	7, 501, 000	\$2, 343, 000
Oral solids (and liquids).....	14, 767, 000	17, 333, 000
Other forms.....	4, 214, 000	4, 009, 000
Barbiturates in preparations containing other active agents:		
Oral solids and liquids.....	10, 956, 000	10, 650, 000
Other forms.....	2, 639, 000	3, 543, 000
All other hypnotics and sedatives (except barbiturates and narcotics).....	6, 699, 000	4, 770, 000
Tranquilizers, excluding Rauwolfia preparations:		
Oral forms.....	126, 615, 000	-----
All other forms.....	10, 954, 000	-----
Tranquilizers, sedatives, hypnotics not specified by kind.....	209, 000	-----
Cough syrups, elixirs, expectorants (including narcotic preparations):		
Containing anti-histaminics.....	21, 322, 000	22, 226, 000
Not containing antihistaminics.....	28, 536, 000	-----
Internal analgesics, narcotic (excluding cough and cold items, G.-I.) preparations:		
Parental.....	10, 109, 000	8, 194, 000
Oral.....	15, 595, 000	19, 788, 000
Other.....	2, 517, 000	57, 000

<sup>1</sup> Not including undetermined amount reported as "not specified by kind."

<sup>2</sup> Not available.

TABLE 3.—Production and sales of barbiturates and tranquilizers (1960)

Medical chemicals	Production (pounds)	Sales		
		Quantity (thousand pounds)	Value (thousand dollars)	Unit value per pound
Barbituric acid derivatives, total.....	852,000	456	12,429	\$5.33
5-allyl-5-(1-methylbutyl)-barbituric acid (secobarbital) and salt.....		16	111	6.94
5-ethyl-5-(1-methyl-n-butyl)-barbituric acid (pentobarbital).....		7	41	5.86
5-ethyl-5-(1-methyl-n-butyl)-barbituric acid, sodium salt.....	80,000	34	208	6.12
5-ethyl-5-phenylbarbituric acid (phenobarbital, luminal).....	270,000	237	703	2.97
5-ethyl-5-phenylbarbituric acid sodium salt.....	17,000	11	42	3.82
All other.....	485,000	151	1,342	8.77
Tranquilizers (cyclic).....	175,000	18	555	30.83
Tranquilizers: 2-methyl-2-n-propyl-1,3-propanediol dicarbamate (acyclic).....	989,000	970	3,480	3.59

The most recent listing for physicians of approved drugs available for prescription (87) include 49 listed as hypnotics, and 136 as sedatives plus more than 100 different barbiturate preparations. A number of drugs are listed in more than one of these three categories, but the total number of preparations available is even greater if one includes the various forms of each drug, such as tablets, capsules, sirup, spansules, gradumets (two different long-release dose forms designed to dissolve at different time intervals to provide a sustained blood level usually for a 12-hour period), suppositories, elixirs, etc. Many different manufacturers produce these drugs, and they are also often produced in combination with various other substances such as analgesics or antispasmodics. There are also available to the public more than 130 other preparations called sleeping aids with such names as At-Eaze, Dormeez, Doze-Off, Lullaby, Quietabs, Relax, Serene, Somninx, Super-Sleep and Tranquil (usually containing some combination of an antihistaminic, aspirin, and belladonna or scopolamine). All of these are available without prescription since they do not contain barbiturates or other habit-forming drugs. An example of the range or recommended uses for the barbiturate drugs is the following quotation about nembutal gradumets (pentobarbital sodium 100 milligrams in a long-release dose form): "Especially useful for continuous daytime sedation, obviates the need for multiple small doses or other short-acting barbiturates for daytime sedation, obviates the use of longer acting barbiturates which may produce cumulative effects; specific indications include anxiety, restlessness, irritability, and adjunctive use in dermatosis, allergies, hyperthyroidism, psychoneuroses, cardiovascular disorders, toxemia of pregnancy, menopausal syndrome, premenstrual tension, nausea and vomiting, motion sickness, gastrointestinal disturbances." The only sedative or tranquilizer being produced in greater official or legal quantities than barbiturates is meprobamate, which although advertised as a tranquilizer has been shown to be pharmacologically more related to sedatives, including being addicting. One of the most heavily prescribed compounds is Dexamy, or like combinations of amphetamines and barbiturates, seemingly considered a cure-all by many physicians.

## IV. ABUSE AND ADDICTION

Figures and information cited above would tend to indicate that amounts of barbiturates far in excess of therapeutic needs are being produced and distributed. In doing the research for this monograph, it can be said that I learned much more about what is not known concerning the abuse of barbiturates than about what is known. As is brought out in a recent book on narcotics (25), there is an astonishing lack of accurate and complete data, a predominance of opinion rather than fact, emotion rather than reason, lack of planning, omissions, duplications, and misuse of statistics. If this can be rightly said about the use and abuse of narcotics in America, it is all the more true about the problem of barbiturates. A special ad hoc panel on drug abuse appointed in 1963 by President Kennedy stated in its report that the present records of various agencies connected with drug abuse are frequently inaccurate, incomplete and unreliable, generally limited to individuals apprehended by enforcement agencies, and uncoordinated with other agencies, thus demonstrating a marked need for a standard core of information common to all record systems (1). They go on to state that there are large numbers of drug abusers who never come to the attention of the community; that there is increasing abuse of nonnarcotic drugs concomitant with a decrease in the abuse of narcotics; that there is an entirely new and increasing abuse of drugs periodically on a spree basis; and that the possible abuse of barbiturates (and amphetamines) among juveniles may be increasing because they are cheaper, easier to handle, and more readily obtainable. One physician's estimate is that there are at least 1 million people taking sleeping pills in this country, with 10 to 25 percent of the habitual users being unsuspecting addicts. Another has said that there are 50,000 true addicts and many more habitues. I would hypothesize that the total number of people using barbiturates, other sedatives, stimulants, and tranquilizers would approach 5 million, not to mention our several hundred thousand marihuana and narcotic users and 75 million users of alcohol, including 6 million alcoholics. There are also problems involving sniffing of glue or gasoline fumes, drinking cough sirups containing codeine and alcohol, and abuse of a whole range of other substances affecting the mind, including lysergic acid and mescaline (peyote).

The World Health Organization has given the following definition of drug addiction:

"Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synethetic). Its characteristics include:

"(1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;

"(2) A tendency to increase the dose;

"(3) A psychic (psychological) and generally a physical dependence on the effects of the drug;

"(4) Detrimental effect on the individual and on society."<sup>1</sup>

<sup>1</sup> World Health Organization, Technical Report Series, No. 116, 1957.

TABLE 4.—Habit-forming drugs specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act

PARENT SUBSTANCE, BARBITURATE ACID

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts
5-Allyl-5-cyclopentenylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Cyclopentol and Cyclophen. Sandoptal.
5-Allyl-5-isobutylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Alurate and Nunal.
5-Allyl-5-isopropylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Narcoummal.
5-Allyl-5-isopropyl-1-methylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Eunarcou.
5-(2-Bromoallyl)-5-isopropyl-1-methylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Sigmoidol, Rectidion, and R239.
5-(2-Bromoallyl)-5-(1-methylbutyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Pernoston and Pernocton.
5-sec-Butyl-5-(2-bromoallyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Dial, Allobarbital, Allobarbitone, Curral, and Diadol.
5,5-Diallylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Deba, Dormonal, Hypnogene, Malonal, Medinal, Sedeval, Veronal, Uronal, and Vesperal.
5,5-Diethylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Cyclonal sodium, Dorico soluble, Evipal sodium, Evipan sodium, Hexanastab, Hexobarbitone sodium, and Methenexyl sodium.
1,5-Dimethyl-5-(1-cyclohexenyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Proponal.
5,5-Dipropylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Etovall, Neonal Butobarbital, and Soneryl.
5-Ethyl-5-butylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Butisol sodium.
5-Ethyl-5-sec-butylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Cyclobarbitone, Namuron, Palinum, Phanodorm, Phano-dorm, and Tetrahydrophenobarbital.
5-Ethyl-5-(1-cyclohexenyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Fentalen.
5-Ethyl-5-cyclopentenylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Hebaral and Ortal sodium.
5-Ethyl-5-hexylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Amytal.
5-Ethyl-5-isobutylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Ipral.
5-Ethyl-5-isopropylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	844, Embutal, Nembutal, Napethal, Pentyl, Intraval sodium, Nesdonal sodium, Pentothal sodium, and Thiotal sodium.
5-Ethyl-5-(1-methylbutyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Delvinal sodium.
5-Ethyl-5-(1-methylbutyl)-2-thio-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Barbenyl, Barbiphenyl, Dorminal, Euneryl, Gardenal, Luminal, Nunol, Neurobarb, Phenonyl, and Sonomal.
5-Ethyl-5-phenylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Mebaral, Phemitone, and Promthal.
5-Ethyl-5-(1-piperidyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Noctal and Nostal.
5-Isopropyl-5-(2-bromoallyl)-barbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Rutonal.
5-Methyl-5-phenylbarbituric acid.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	
All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the foregoing chemical derivatives of barbituric acid.	Allylbarbituric acid and Allylisobutylbarbituric acid.....	
Sodium-5-allyl-5-(1-methylbutyl)-barbiturate.....	Allylbarbituric acid and Allylisobutylbarbituric acid.....	Secobarbital sodium and Evronal sodium.
All salts of the foregoing chemical derivatives formed by replacing the sodium with lithium, potassium, magnesium, calcium, strontium, or ammonium radical.	Allylbarbituric acid and Allylisobutylbarbituric acid.....	

Wikler has suggested that the term "drug addiction" be restricted to the compulsive use of such agents as are harmful to the user or society, or both, and which for various reasons are condemned by the culture in which the individual lives. Isbell prefers restricting the term "addiction" to physical dependence, as distinct from habituation, which he defines as a state in which a person compulsively uses the drug as one of his major means of adaptation to stress. In common usage in the United States the term is used synonymously with illegal use or abuse of drugs which affect the brain. Without exception, all the individuals who have studied this problem agree that there is extensive abuse of the barbiturates, that it constitutes a serious social and health problem, and that it is increasing.

Senator Thomas Dodd, chairman of the U.S. Senate Subcommittee on Juvenile Delinquency, stated this year that 5 billion dangerous drug (barbiturates and amphetamines) pills find their way into the illegal market each year, that these are produced almost entirely by American firms, and that the use of these drugs by juveniles and young adults is mushrooming all over the country. He went on to add that these drugs cause people to commit various serious crimes; that they are increasingly used by children who formerly were not delinquent; that in some places the drugs have become substitutes for heroin; and that in Los Angeles since 1954 arrests involving dangerous drugs have increased 468 percent. Some say that the group using barbiturates most frequently consists of 30- to 50-year-old urban women.

In a similar vein the California attorney general has claimed that there is a new and growing problem with the dangerous drugs, and a whole new class of addicts is being created. He cites the California figures which show that the number of arrests for dangerous drug offenses (no distinction being made between amphetamines and barbiturates) climbed 31 percent from a figure of 3,807 in 1960 to 5,016 in 1961. Similar situations are said to exist in San Diego and San Francisco with half the juvenile drug arrests involving misuse of the dangerous drugs. However, the San Diego figures include those individuals turned over for prosecution by the U.S. Bureau of Customs for illegally bringing dangerous drugs across the Mexican border into California. Newspapers in San Francisco, Washington, D.C., and Texas have reported serious and growing problems with the promiscuous sale and use of barbiturates. The executive director of the New York City Youth Board has reported that 25 percent of the children studied by his agency are involved in the use of drugs ranging from narcotics to barbiturates. The director of the Student Health Service at the University of California has publicly expressed concern about the peddling of barbiturates and tranquilizers to students. The policy director of Newark, N.J., has described an alarming increase in use of, and addiction to, barbiturates by teenagers since 1959 along with a doubling of the death rate from barbiturate poisoning. Until August 1962 there was no law in New Jersey making sale or possession of barbiturates illegal. They now have penalties of up to 1 year in prison. Newark has also conducted an extensive educational campaign with schools and businesses, and has enlarged its narcotics bureau.

Multiple or combined use of various drugs must also be occurring to an unknown extent, particularly joint use of barbiturates and alcohol. This would be of special significance in terms of the nearly 40,000 highway deaths and much greater number of injuries occurring yearly in America, with one-third to one-half associated with drinking. California has made it unlawful for a person to drive while under the influence of any dangerous drug (including barbiturates) "to a degree which renders him incapable of safely driving". Fines and jail sentences are stipulated with the penalty increasing if bodily harm results. Nearly 20,000 deaths by suicide and 1,700 accidental deaths from poison occur yearly, with 3,000 per year or more being attributed to barbiturates. New and tighter laws on the use and sale of barbiturates are now being called for in California, Texas, Indiana, Hawaii, and other States. A growing body of similar anecdotal and statistical material now exists to sketch the framework of the problem with the precise details not yet available.

Despite conclusive evidence to the contrary, many physicians in the United States appear to think and act as though barbiturates are completely harmless drugs that can be prescribed in unlimited quantities. While doctors deny the dangers, police offices continue to collect data showing a relationship between these drugs and delinquency. The addicting properties also seem

unknown or are denied by many physicians with both ignorance and callousness seeming to be involved. As the President's panel pointed out, the medical community has yet to define the range of legitimate medical use of these drugs. Individual doctors and Medical Association representatives repeatedly minimize or deny the existence of any barbiturate problem, with such statements as "I have prescribed barbiturates for thousands of patients in 30 years of practice, and have never seen a single case of addiction." The pharmaceutical manufacturers and the American Medical Association have both opposed increased governmental control of the barbiturates (105), and in 1962 they were successful in having Congress eliminate a key section dealing with barbiturates from the new drug control legislation passed following the worldwide thalidomide debacle. Illustrative of at least three major medical errors in the clinical use of barbiturates was another event heard around the world, the tragic death of the motion-picture actress Marilyn Monroe. Despite long evidence of emotional instability and severe depression, Miss Monroe's physicians, including a psychoanalyst, according to newspaper reports, had been prescribing barbiturates for many months; prescribing them in large quantities far in excess of ordinary use, and also prescribing concurrently other sedatives and tranquilizers; and permitting her to refill large prescriptions within a short period of time—e.g., 50 pentobarbital capsules obtained just prior to her suicide only a few days after a previous 50 had been prescribed. The U.S. Public Health Service has stated that, although useful depressants of the central nervous system when taken in small amounts under medical supervision, the barbiturates can be dangerous, intoxicating drugs, habit forming and addictive when taken in large and uncontrolled amounts (109). That some, probably large, segment of the barbiturate problem is iatrogenic seems indisputable with drugs being loosely and hurriedly prescribed for patients whom the doctor is too busy to talk with or examine thoroughly. A letter sent to me last year by a Los Angeles woman illustrated this point. She had written as follows to a doctor who opposed more stringent controls of the barbiturates: "The experience of living with a barbiturate addict is a hell in which you wander helplessly, receiving little or no help from the medical profession. Why don't you doctors think when you prescribe pills? Probably a pill is the easiest way out for you—but how about the families who bear the later burden?"

Acute intoxication or poisoning from barbiturates accounts for about 25 percent of all patients admitted to general hospitals with some form of poisoning. In addition to the number of deaths mentioned above, there are indications that acute barbiturate intoxication is increasing at an alarming rate. In 1958 alone, 1,111 cases of barbiturate poisoning were reported to the New York City Poison Control Center. As with the other facets of this problem, comprehensive nationwide statistics are not available. Mild, moderate, and severe forms of acute barbiturate intoxication have been described. These are differentiated primarily by the degree of unconsciousness with the severe form involving a comatose patient who cannot be aroused by stimulation, slow and shallow respiration, markedly depressed reflexes, rapid pulse, and a fallen blood pressure. The details of diagnosis and treatment of this condition have been described in many clinical reports (60). The literature indicates that a wide variety of treatments are utilized, and that no single treatment has gained universal acceptance. The main difference of opinion centers around whether or not to utilize central nervous system stimulants or analeptics in addition to supportive measures. Dobos et al. (21), in a study of 141 patients, found that those treated with amphetamine, caffeine, or picrotoxin did no better than those treated supportively with regard to the duration of coma, number of complications, or mortality rate. Other writers have advocated use of Metrazol, bemegrade, ACTH, electrostimulation, hemodialysis, and more recently Tham (trihydroxymethylaminomethane), a buffer and diuretic. Whatever regimen is used, there seems to be an overall mortality rate of about 4 percent.

With a now classical series of papers published in the early 1950's (35, 37, 63, 64, 65) Isbell and his coworkers at the Addiction Research Center in Lexington, Ky., conclusively demonstrated that barbiturates taken regularly in large quantities produce all three of the characteristic symptoms of addiction: tolerance, physical dependence, and psychic dependence or habituation. Ingestion of

TABLE 3  
U.S. Food and Drug Administration Information Chart for Law Enforcement Agencies

<p>Preliminary identification of certain RESTRICTED DRUGS</p> <p>For use by law enforcement agencies</p> <p>These drugs are not narcotics, but watch out for them.</p> <p><b>BARBITURATES</b> have additive and hypoxic effects. They affect people much like alcohol but leave no odor on the breath. Overconsumption may cause death, since they depress the respiratory center. They are used in the production of anesthesia with: Intoxication, coma, death, accidents, assaults, wild parties, delinquency.</p> <div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Secobarbital sodium "Seconal"</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Amobarbital sodium "Amytal"</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Pentobarbital sodium "Nembutal"</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Secobarbital plus amobarbital "Tuinal"</div> </div> <p>Barbiturate drugs. Actual size. A few specimens of barbiturates, also known as "red birds", "goof balls", "yellow jackets", "blue heaven", etc.</p> <p>Other brands</p>	<p><b>BARBITURATES</b></p> <p>Barbiturates are valuable drugs for legitimate medical purposes but can be very harmful if misused. A person under the influence of barbiturates acts like one who is drunk. The effects of barbiturates are similar to those of alcohol. The degree of intoxication observed depends mostly on how used to the drug he is. Habitual users keep taking more and more, and in time they get up to amounts that would kill anybody who has not grown accustomed to the drug gradually.</p> <p>The person who "gets drunk" on barbiturates follows about the same course as one who gets drunk on alcohol. He has a flushed face, his eyes are red, he is small and slower to react. After taking more he becomes sluggish, gloomy, maybe quarrelsome. His tongue gets thick, he staggers about for a while, and then gradually slips into a deep sleep, or, especially if he has had a lot of the drug, he may slip into a coma. The person who has had a lot of barbiturates is very hard to wake in prompt. Barbiturates are more dangerous than alcohol at this stage because they are not vomited, and all that is taken will be absorbed unless the stomach is pumped.</p> <p>Even when there is no sign of life a doctor should be called at once because some sick. Those who become dependent upon the drug must have it to keep from getting worse. If they do not get it, they will die. The doctor who has the drug must possibly get any of the drug the doctor does not allow.</p> <p>Whenever a person acts like he has had a little or a bit to drink but there is no odor of alcohol, it is possible he has been using barbiturates. Sometimes barbiturates and alcohol are taken together. This produces what looks like an ordinary drunk but is much more dangerous. The person who has been taking barbiturates for a "kick" and not as medicine, the U.S. Food and Drug Administration is interested in where he got them and whether a doctor prescribed them. It is illegal to distribute these drugs without a prescription, or to refill a prescription for them without the signature of the doctor. In the United States illegal possession is an offense. Illegal possession is a crime under Federal law. A person who has been confined from a person who does not normally handle such drugs in his business or profession. Each illegal delivery, with or without payment, is a separate offense with a maximum penalty of \$1,000 and 1 year imprisonment (later prior conviction the maximum penalty is higher).</p> <p><b>What to do</b></p> <p>Whenever you suspect that barbiturates or amphetamines are being illegally distributed, you may inform our office at the address shown on the front of this sheet. All information will be kept confidential, and you will not be involved in any way. You will be advised by telephone of the progress of the investigation. Inspectors and are generally based on undercover "boys" by the location of the drugs under their direction. While it is not always possible to get into evidence the drugs a user bought before our investigation begins, we are always interested in getting samples of any found in his possession, with a copy of the labeling on their container, if there is one.</p> <p style="text-align: right;">U.S. Department of Health, Education and Welfare Food and Drug Administration</p>
<p>Federal law prohibits sale without a doctor's prescription, or refilling of a prescription without consent of the doctor. If illegal sale is suspected, please notify:</p> <p style="text-align: center;">U.S. Department of Health, Education and Welfare Food and Drug Administration, Room 506, Federal Office Building, San Francisco 2, California.</p> <p>See next page for table of information on the effects of various drugs.</p>	<p>1 The symbols used in the representation of the capsules are the following: "Round" — red; "Numbered" — yellow; "Angular" — blue; "Triangular" — red and blue.</p>

less than 0.4 gram daily for 6 weeks or more will be followed by minor withdrawal symptoms if the drug is abruptly discontinued; up to 0.6 gram daily for a comparable period of time will produce moderate symptoms including anxiety, tremor and weakness, if abruptly withdrawn; and 0.8 gram or more daily for 6 weeks or longer will produce severe addiction and withdrawal, with an average of 75 percent of such patients having convulsions and 60 percent a toxic psychosis or delirium. The symptoms of chronic intoxication are similar to those of chronic alcoholism, including similar changes in the functioning of the central nervous system. It has been found that adequate doses of either alcohol or barbiturates will suppress the withdrawal symptoms arising from addiction to the other. Barbiturate addicts generally prefer the short-acting compounds, pentobarbital or secobarbital.

Withdrawal or abstinence symptoms develop within 8 to 16 hours after the drug is discontinued, progressing in the untreated case to convulsions on the second day, and delirium on the third day. Abrupt withdrawal of barbiturates from addicted persons is absolutely contraindicated. The treatment of choice is to stabilize the person for several days on an amount of one of the rapid-acting barbiturates sufficient to maintain a continuous state of mild barbiturate intoxication (usually a dose of 0.2 to 0.3 gram every 6 hours). Gradual withdrawal of 0.1 gram daily is then begun until the patient is completely withdrawn. Present evidence would be against placing reliance on anticonvulsant drugs or tranquilizers during the withdrawal period. Following successful completion of the withdrawal treatment, there should begin the much more difficult long-term treatment to prevent a relapse to the use of the drug.

#### V. CAUSES

A complex combination of pharmacological, sociological, and psychological forces undoubtedly interacts in a particular individual to produce abuse of or addiction to the barbiturates or other drugs affecting the central nervous system.

Among the sociological factors would be accessibility and availability of the drug either through illegal channels or by too ready and excessive prescription on the part of physicians; attitudinal tolerance toward the use of the drug by one's family, peer group, or society; advertising pressures; disturbed family or social relationships; general national and international tensions; availability of other possible outlets for anxiety or tension; and chance exposure to the drug with experience of "euphoria." A group much broader than those who ordinarily use narcotics appears to be involved in barbiturate abuse in terms of socioeconomic class, prior delinquency, or psychological makeup.

Numerous psychiatric explanations have been proposed for drug addiction (2, 125). These are invariably speculative, descriptive, and nonspecific. Most are untestable or based only on a single class of variables. Furthermore few barbiturate "addicts" have been intensively studied as such, so that theoretical formulations come primarily from study of narcotic addicts. Addicts have been described as immature, suspicious, intolerant of stress or frustration, passive, and overdependent. Most drug addicts are diagnosed as having some form of character disorder (inadequate personality, etc.) or to a lesser extent, neurosis.

As far back as 1919 (99) it was suggested that neurotic individuals use chemical agents to seek relief from anxiety ("negative euphoria"); psychopaths for elation ("positive euphoria"); psychotics to relieve depression; and normals to relieve pain. Where physical dependence occurs it would be an undesired side effect which would make euphoria more difficult to attain.

Psychoanalytic formulations speak of the addict as a person whose psychosexual development has been arrested at, or has regressed to, the oral level with resulting frustration, hostility, self-destructiveness, and depression. The drug then serves to relieve these symptoms, in part by inducing euphoria. A predisposition to use drugs is considered to exist prior to the actual experience.

Wikler (125) has proposed a "pharmacodynamic formulation" which says that different classes of drugs alter patterns of behavior in different ways, through different effects on motivations of a primary or secondary nature. The drug use is an attempt at self-therapy and the choice of a particular drug depends upon whether it facilitates or hinders specific patterns of behavior acceptable to the user. He suggests also that the self-perpetuating nature of barbiturate use is related directly to its pharmacologic properties, as is the case with opiates. Also as tolerance develops, a new motivation, the relief of withdrawal symptoms, becomes a major source of gratification, replacing other drives, e.g., in narcotic addicts: pain, sexuality, and expression of aggression. Ulti-

mately complications of a legal, economic, family, vocational or health nature ensue and "treatment" becomes necessary and may be imposed upon the person. Relapse is affected by the pleasure in the instantaneous relief of abstinence provided by the drug, by the occurrence of conditioned symptoms long after "cure"; and by rejection on the part of society.

Another possible conceptualization is the Pavlovian concept that in relatively low dose ranges barbiturates augment "internal inhibition" with large doses possibly exerting an opposite effect. Masserman and Siever (79) concluded that amobarbital disorganizes recently formed, intricate, and complexly motivated adaptive patterns into earlier and more direct perception responses, thereby temporarily mitigating experimentally induced neurotic behavior. Bailey & Miller (4) found that amobarbital produces a greater decrement in the avoidance motivated by fear than in the approach motivated by hunger. Hill et al. (55) found in man that pentobarbital did not reduce anxiety associated with anticipation of pain.

Addiction may exist in individuals with all types of personality organization (and addicts may recover without any apparent change in personality). Chein's work (15) on the premorbid personality of addicts showed specific psychiatric disturbances predisposing to addiction. Gerard (42) held that all juvenile (narcotic) addicts were very disturbed individuals who would probably have required help in meeting their problems whether or not they took drugs.

From all this we can go on to agree with Wikler (122) that behavioral effects are not isolated, elementary changes in consciousness, perception, emotion, ideation, or learning which are simply increased or decreased by depressants or stimulants, but are complex patterns of change proceeding in time, involving all of these aspects of behavior to varying degrees, and dependent not only on the drug, but also on biographical and environmental factors.

Thus to understand the causes of barbiturate abuse requires a multifactorial, multidimensional approach with much fuller use of experimental methodology including controls, objective measurements, statistical techniques, and operational definitions.

#### VI. TREATMENT, PREVENTION, AND RESEARCH

The treatment of overdosage and of physical addiction has been described above. The difficult problem is to treat the chronic underlying illness which we might call barbiturism (if we can redefine that term to parallel alcoholism). For best results the heavy user or addict to barbiturates should be hospitalized both for management of withdrawal and for institution of long-term treatment. Thorough psychiatric evaluation and physical rehabilitation should come first, followed whenever possible by vocational training, social-work services, and psychiatric treatment, including group and individual psychotherapy. Adequate facilities for such hospital treatment are rarely available, and even less available are outpatient facilities where the services and treatments begun in the hospital could be continued. The failure of physicians to recognize this illness also presents a barrier.

It is unlikely that treatment, even if extensively available and maximally effective, will ever solve what is apparently a large and growing problem. Preventive measures based upon extensive education of physicians and the public about the proper uses of barbiturates and upon widespread research beginning with the compilation of accurate statistics are the only things likely to be successful. A punitive approach of increasing penalties for excessive or illegal use of barbiturates will not stem the tide of social and psychological forces leading to addiction. Preventive approaches that might be used in addition to education include decreasing the availability of barbiturates; removing existing sources of "infection" (addicts via treatment and peddlers via prison) from the community; reducing the number of potentially susceptible individuals by mental health programs, by correction of deleterious social and economic conditions, and by allowing alternative, constructive outlets for anxiety and frustrations.

Innumerable research projects are necessary before we "solve" the problem of barbiturates. This should include comparative studies of regular, irregular, and nonusers of barbiturates to be correlated with personality and with cultural background; study and comparison of various treatment methods and programs; longitudinal studies of the natural history of "barbiturism," with and without treatment, epidemiological investigations; further study on the mechanisms of action of barbiturates and the physical basis of addiction; systematic evaluation

of current legislation and law-enforcement methods; and development of accurate and detailed national statistics so that programs can be based on a solid foundation of fact rather than opinion, and reason rather than emotion.

#### VII. PRESENT AND PROPOSED LEGISLATION AND ENFORCEMENT

A 1952 report of the Expert Committee on Addiction-Producing Drugs of the World Health Organization recommended increased national controls over barbiturates, including dispensing only on prescription, specifying the number of times a prescription may be refilled, and keeping a careful record of all prescriptions. At subsequent sessions, the Committee stated that barbiturate consumption continued to increase and constituted a danger to public health, and expressed the view that while, at the time, control measures at the national level were sufficient, they needed close attention and in some instances definite strengthening. The Expert Committee also expressed the opinion that barbiturates are habit forming and, in some cases, can produce true addiction (characterized by physical dependence).

Meanwhile, the United Nations Commission on Narcotic Drugs, a functional organ of the United Nations Economic and Social Council, had placed the question of barbiturates on its agenda in 1956, and in 1957 passed a resolution recommending governments to take the appropriate legislative and administrative measures of control to prevent their abuse. In its 1960 session the Commission, like the WHO Expert Committee, expressed the view that barbiturates should not be sold without medical prescription except where a very weak preparation was involved. Subsequently two attempts, one at the Plenipotentiary Conference for the Adoption of a Single Convention on Narcotic Drugs, held in New York in 1961, and the other at the 1962 session of the Commission on Narcotic Drugs, both narrowly failed to command enough support for a move toward the international control of barbiturates. However, the 1962 session of the Commission on Narcotic Drugs confirmed that the abuse of barbiturates still represented a social danger and a danger to public health, and recommended governments to take the appropriate measures to place the production, distribution, and use of these drugs under strict control.

The so-called Durham-Humphrey amendment enacted in 1951 was the first Federal legislation in the United States to specifically restrict barbiturates (and amphetamines) to prescription and refill only upon the authorization of a physician. The Congress also said that the barbiturates posed a special problem not common to all drugs, because they are desired by addicts for non-medical use and predicted this would call for further legislative controls in the future.

A Presidential interdepartmental committee surveyed the problem in 1954, pointed out similarities between the individual and social problems raised by narcotic abuse and those raised by barbiturate abuse, going on to recommend study of the extent and effects of the improper use of the barbiturates in order to determine what Federal, State, and local regulatory controls would be necessary. Committees of both the House of Representatives and Senate of the 84th Congress received testimony on the barbiturate problem in this country. The House committee concluded that the barbiturates, unlike narcotics, should be regulated under the commerce power of Congress rather than the taxing power, and that more stringent Federal control over the manufacture and distribution of these drugs was necessary (106). They also made a series of detailed recommendations which tragically have yet to be adopted. A bill introduced at that time to amend the Federal Food, Drug, and Cosmetic Act would have prohibited the manufacture, sale, or possession of barbiturates except by persons specifically authorized by the bill, and would have required that records be kept of all transactions involving barbiturates. This bill and other subsequent congressional bills to increase controls on barbiturates, failed to pass. As Stephens (98) has said: "The public health problem commented upon by Congress has not improved, and, in fact, has worsened since 1956, with large amounts of barbiturates escaping from legitimate channels of commerce at every level of the chain of distribution."

Current Federal law in the United States applies solely to barbiturates shipped in interstate commerce; requires no inventory control; and does not require that copies of purchase orders for these drugs be made available for inspection by appropriate Government agencies. Those barbiturates shipped in interstate commerce must meet certain standards of strength and quality and must bear the statement, "Caution: Federal law prohibits dispensing without prescription."

The recently adjourned 1962 session of Congress specifically rejected provisions to increase controls on barbiturates (H.R. 11581 and S. 1552). If passed, this would have limited the manufacture, compounding, processing, or possession of barbiturates (and amphetamines) to certain specifically enumerated classes including registered manufacturers, pharmacists, physicians, researchers, etc.; would have prohibited the manufacture or sale of such drugs by those not authorized by law; would have required detailed records to have been prepared and kept for 3 years of all such drugs manufactured or sold and to whom; and would have authorized inspection and inventory by designated officials. This proposed legislation, and previous attempts to improve the controls on barbiturates was opposed in whole or in part by the Pharmaceutical Manufacturers Association, the National Association of Retail Druggists, and by the American Medical Association. These special interest groups in their testimony claimed that the FDA wanted excessive authority and such legislation was unnecessary, discriminatory, and based on insufficient inquiry (despite extensive hearings going back to 1955). The congressional testimony indicates that from July 1, 1949, to April 1962 over 1,100 cases were prosecuted (144 in the fiscal year 1961 alone) involving illegal sales of prescription drugs (a "substantial" portion of which were barbiturates) by retail druggists and 1,900 defendants were convicted. During that same period only 17 cases against physicians were prosecuted with a total of 20 convictions. A separate bill, which was introduced in Congress in 1962 without being acted upon, would have regulated importation of barbiturates, provided for seizure of drugs brought in illegally, and set minimum and maximum sentences for importing, buying, selling, receiving, or concealing such drugs.

Among the complicated and dangerous factors brought out by the lengthy congressional hearings on the drug industry and by the experience of the experts of the Food and Drug Administration is the practice of the drug manufacturers of selecting only "cooperative" physicians for clinical testing of drugs, often writing their papers for them, seeing that they are published when favorable, and suppressing negative results or reports of adverse effects. In addition, the American Medical Society, which derives one-half of its total income from advertising revenue in its journals, 7 years ago drastically reduced its standards of accuracy and truthfulness for advertising. Among the advertising statements at present being published are the following examples, some of which were cited in the above-mentioned congressional investigation of the drug industry: "When you prescribe a single morning dose \* \* \* she will stick to her diet more willingly. She will feel better all day long"; "Provides a night of undisturbed rest virtually identical to physiologic sleep"; "In obstetrics, gynecology, well tolerated for use during complete pregnancy cycle"; "Unsurpassed safety, prompt action, and a cheerful wakening without hangover"; "So gentle, yet so persuasive, sure as the sunrise", etc. The advertisements commonly used attempt to convey images of youth, beauty, radiant health, serenity, happiness, security, pleasure, and sometimes sexuality. They frequently attempt to stress that the drug is completely safe, nonaddicting, and without side effects. They are often full of nonsequiturs, incomplete information, distortions, and misrepresentations. The busy practicing physician would ordinarily use a sedative drug on the basis of what he has seen in the advertisements about its safety and efficacy.

Internal bureaucratic conflicts have also hampered passage of new legislation in this field, including such things as arguments over whether the Food and Drug Administration or the Federal Bureau on Narcotics should handle the enforcement, and if it were the Food and Drug Administration, should they have police power. Effective operation of the Food and Drug Administration, even within the present quite limited Federal legislation, is hampered by insufficient personnel and budget. The FDA carries on its program against illegal distribution of barbiturates mainly through 600 inspectors located in 18 district offices across the United States. Only one part of the day-to-day activities of these inspectors involves surveillance of prescription drugs to prohibit illegal sale without prescription. Investigations of illegal sales are undertaken when information is received indicating violations of the Durham-Humphrey amendment either by pharmacists or totally illicit outlets. Fewer than 10 physicians are available in the FDA to review reports on inspection findings (or on advertising practices).

The new general legislation passed by Congress in 1962 following the thalidomide controversy, in order to "insure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority," provides for factory inspection and requires that

manufacturers of drugs (including barbiturates) register with the Government. Thus, bootleg production of barbiturates will now be illegal, but the FDA will be unable to do anything when they discover violations upon inspection unless interstate commerce is involved. Present penalties of a \$1,000 fine plus 1 year in jail may be adequate if they can be invoked against violators. When the FDA finds a user of dangerous drugs, they must work backward to try to catch the supplier furnishing drugs illegally but, since interstate shipment must be proved and since no records are available for inspection, they must rely on circumstantial evidence, which is difficult and time consuming to prepare.

Other Federal laws and another Federal agency, the U.S. customs service, are also involved with the illegal traffic in barbiturates, particularly at the Mexico-California border. Considerable testimony by law enforcement officials in California states that huge quantities of barbiturates manufactured by American companies are shipped to Mexican border towns where they are sold without prescription to American consumers. A single firm shipped 1 million tablets into one Mexican town within 23 days, and another firm shipped 600,000 tablets into the same town in a 3-day period. These drugs are sold by the manufacturer for 76 cents per thousand units, and are peddled illegally for 10 cents a unit, or more than 1,000 percent profit. In the fiscal year 1960, the U.S. customs service seized only 3,635 units of dangerous drugs purchased in Mexico and smuggled into the United States. No specific penalties exist against such smuggling and, when detected, it is handled in the same manner as would be smuggling of clothing, etc.

One further abuse which appears to require Federal regulation is the mail-order business of providing small or large quantities of barbiturates and other drugs to anyone writing in claiming to be a physician or pharmacist. Such orders are filled by out-of-State drug manufacturers without investigation of the legitimacy of the person ordering the drugs. Again, since present Federal laws do not require that records be kept or that the Government receive duplicates of purchase orders, no effective control exists for this form of illegal trafficking.

It has been pointed out by the FDA that in order to make regulation and protection of interstate commerce in barbiturates effective, regulation of intrastate commerce is necessary because such drugs, when held for illicit sale, often do not bear labeling showing their places of origin and because, in the form in which they are held or consumed, a determination of their place of origin is sometimes difficult or impossible. They also state that to subject interstate commerce to the needed controls without applying them to intrastate commerce would have the effect of discriminating against and depressing interstate commerce.

Paralleling the Federal concern and development of legislation, there has been concern in various States about the abuse of barbiturates. Back in 1955 the Council on State Governments proposed a model State barbiturate act for those States which might require new legislation or might wish to broaden or strengthen their existing legislation. This act would require careful and specific record-keeping, including inventories and prescriptions; ban refills of prescriptions unless specifically authorized; require physicians to confirm telephone orders for a drug in writing within 72 hours; prohibit possession of the drug unless prescribed by a physician; bar the use of fraud, deceit, misrepresentation, or subterfuge in obtaining the drug; require that records be open to inspection, and provide for a fine up to \$1,000 or imprisonment for not more than 1 year or both for a first offense and a combination of \$10,000 or 3 years or both, for a subsequent offense.

Most State food and drug laws are very inadequate, particularly in their enforcement provisions. The present California law is probably the most adequate in this respect (86). This law states that any person who possesses a hypnotic drug without a prescription is guilty of a misdemeanor; any person furnishing a dangerous drug to an adult except upon prescription is guilty of a misdemeanor; any person furnishing a hypnotic drug to an adult without having a license to do so is guilty of a misdemeanor (when furnished to a minor it is considered a felony). Prescriptions for dangerous drugs may be refilled at any time upon the oral authorization of the physician or by the written authority on the original prescription. Those licensed to furnish hypnotic drugs and all physicians, dentists, chiropractors and veterinarians are required to fill out a hypnotic-drugs purchase order form in triplicate for each order from a supplier. The original and duplicate orders must be forwarded to the supplier. Any person who alters or forges the quantity of dangerous drugs in any prescription or who uses a

forged prescription is punishable by a fine of \$100 to \$500 for a first offense and imprisonment from 6 months up to 6 years for subsequent offenses. No inventory control, recordkeeping or inspection is required. Those who ship barbiturates into California must be registered with the State board of pharmacy. In 1960 the legal sale in California alone of sedative and hypnotic drugs totaled \$4 million. Not even rough estimates of the illegal sales are available.

It has been announced that during this fiscal year the Food and Drug Administration will survey State and local food and drug laws and facilities to determine what improvements are needed.

#### VIII. CONCLUSIONS AND RECOMMENDATIONS

(1) Adequate objective data are not at present available to draw final conclusions about the dimensions of the barbiturate problem (barbiturism) in the United States or to propose complete "solutions".

It seems vital before more years pass that new or already existing State and Federal agencies be assigned the specific responsibility of compiling and maintaining accurate statistics about the production, sale, users, prescribing, abuse, arrests, convictions, sentences, hospitalizations, suicides, driving offenses, and other data involving barbiturates. Similar data should also be collected on the other sedatives, hypnotics, tranquilizers, and on narcotics, alcohol, and stimulants, including interrelationships with barbiturates.

To facilitate the compilation of accurate data, such things as physicians' prescriptions and distributors' shipments should be recorded in duplicate with one copy going to the above-mentioned agency. This might be accomplished easily by the use of partially pre-punched IBM cards which could be tabulated by computers as they come in.

(2) The figures on production and prescribing of barbiturates, the statements of physicians minimizing or denying any problem, and the law enforcement reports all indicate serious deficiencies of knowledge and practice on the part of the American medical profession in regard to the barbiturates.

Either organized medicine must "clean its own house" by establishing responsible standards for prescription of the barbiturates or legal controls should be instituted to insure that prescriptions for barbiturates be limited to an amount that would not be sufficient in quantity or length of time prescribed to produce habituation or addiction and would be less than lethal if consumed all at once. These prescriptions should have the amount written both in figures and words, should not be refillable without a new prescription (or at the least should state in writing the minimum time between refills and the maximum number of refills) and should not be given for simple insomnia or daytime sedation or as treatment for emotional problems.

In part, this is an educational problem and should be combined with additional educational efforts directed at physicians, particularly psychiatrists, and beginning in medical school, about the nature and extent of habituation and addiction and about the prevention, diagnosis, and treatment of barbiturate addiction.

A genuine doctor-patient relationship should exist with thorough history taking and physical examination before prescribing barbiturates.

(3) Manufacturers, distributors, and dealers in barbiturates should be strictly regulated and controlled through uniform Federal legislation to prohibit misleading, incomplete, or false advertising claims; to require registration and licensing; to require that complete inventories and records be maintained of all transactions involving barbiturates and that these records be open to official (and regular) inspection at any time; to permit shipping or handling only by Federal purchase orders (in duplicate with a copy to the Federal agency) and only by and to those having legitimate need; and to make illegal intrastate, interstate, and international shipments a Federal offense.

Prescriptions of these drugs should carry a prominent label warning both about its being habit forming and dangerous to take before driving (or performing other highly skilled acts).

(4) International action has already been taken (see p. 27 above) in the form of recommendations for countries to watch out in this field; such action should be taken again in order to bring about legislative changes in countries which do not require prescription for barbiturates so that such countries would establish penalties for illegal possession and do their best to prohibit shipment or transport into another country if and when that country has declared the entry of such drugs on its territory as illegal. Along with this the U.S. Customs Bureau needs to be made aware of that danger and given additional powers to deal with

the importation of large amounts of barbiturates into this country in the same way as it is empowered to stop other dangerous imports.

(5) Professional societies and licensing boards for physicians and pharmacists in each State should maintain active educational programs for their members and licensees, and should institute formal regulations and penalties for abuses in prescribing or selling barbiturates.

These groups and such organizations as the American Medical Association should also take a positive-active role in supporting badly needed State and Federal legislative controls as outlined in the above recommendations.

(6) Extensive educational and preventive programs for the general public should be instituted beginning at the high school level (10th and 12th grade) and stressing objective, detailed, technical presentations by knowledgeable teachers, health educators or experts in the field. The content should include the proper uses of barbiturates and other dangerous drugs; the physiological and psychological effects; and the possible dangers of habituation, addiction, or driving under the influence of these drugs.

There should also be a public health educational effort to counteract the apparently widespread beliefs and attitudes fostered by our mass media and advertising industry, that sedatives and tranquilizers are harmless, easy, non-addictive answers for worry, tension, business and family problems, etc.

(7) Illicit possession or sale of barbiturates should be made a criminal offense, but care should be exercised to establish penalties that are reasonable deterrents rather than paradoxically) creating a greater criminal problem and increased illegal traffic through excessive penalties.

Driving vehicles under the influence of barbiturates should be prohibited and penalized in the same manner as driving under the influence of alcohol.

Local, State and National law enforcement agencies should give increased attention to the barbiturate problem and to improving their cooperation and coordination, which are often sadly deficient.

(8) In line with the 1962 recommendations of its Citizens Advisory Committee, the Food and Drug Administration should be reorganized with scientist-administrators in top policy positions and increased attention to education of physicians and the general public. I believe that the FDA should also be given an increase in budget, personnel and enforcement powers to carry out my recommendations made above as well as their present responsibilities.

(9) Specific, specialized treatment and rehabilitation programs should be established for barbiturate abusers. This should include general hospital treatment for withdrawal when necessary and outpatient rehabilitation (similar to that now in existence for alcoholism) including psychotherapy, social work services and, where a law violation has occurred, intensive probation or parole supervision.

In the meantime, existing rehabilitation programs for alcoholics or narcotics addicts should be modified or expanded to include barbiturate (and stimulant) abusers.

Civil commitment procedures should be established for barbiturate addicts to permit lengthy voluntary or involuntary hospitalization when necessary without criminal stigma.

Barbiturates Anonymous (B.A.) chapters or groups should be organized in our major cities along lines parallel to Alcoholics Anonymous or Narcotics Anonymous in order to provide an additional avenue of treatment.

Simple, practical chemical testing methods for barbiturates in urine or blood should be developed and then widely used for detection of possible illicit use in connection with driving, criminal offenses, diagnosis of unconsciousness, and as part of rehabilitation or control programs (analogous to the use of Nalline with narcotic addicts).

Since an increasing proportion of the American public depends upon medical insurance to help pay hospital costs, we need to include coverage for barbiturate addiction in such plans.

(10) Accelerated research programs are necessary to ascertain the psychological and sociological reasons for drug use and the choice of a particular drug; the factors leading to abuse and addiction; and a host of other unsolved problems (see sec. VI). Only a small fraction of Federal research funds have been given for research on addiction with almost none for barbiturates per se.

(11) Safer and less toxic, but equally effective and dependable drugs should be sought as replacements for the barbiturates. A sedative or hypnotic without concomitant euphoriant properties or one with an unpleasant taste or odor—for

example, paraldehyde—might reduce habitual use. Tranquilizers fulfill these criteria only to a limited extent, and several of the ones in common usage such as Librium (chlordiazepoxide), and Miltown or Equanil (meprobamate) actually appeared to be misrepresented as tranquilizers since they are pharmacologically closer to sedatives and have been reported by several objective observers to have the same addicting properties as the barbiturates (26, 56a).

The inclusion of corrective (73) or safeguard drugs in barbiturate preparations should be tried more widely to ascertain whether it will prevent fatal overdoses from being taken.

(12) While all of the above are attempted or accomplished, we must also seek to correct the general social and psychological problems underlying abuse of barbiturates—the disturbed family relationships; feelings of cynicism, rootlessness, or rebellion; immaturity and aimless thrill seeking. We must simultaneously reduce the number of potential addicts, reduce the availability of drugs, and decrease attitudinal tolerance toward the drugs.

We are dealing here with a problem that affects many more people than narcotics addiction, yet has received far less attention. However, it will do us little good if the barbiturates, because of the growing reports of their dangers, fall into ill repute as did the bromides, only to be replaced with another equally harmful and possibly less beneficial drug. We seem to be concerned about the barbiturates because their over use is associated in our minds with irresponsibility and escapism, with lowering of productivity, impaired judgment and coordination, and antisocial behavior. On the other hand to a limited extent it is possible that both the individual and society are the better if some people have shifted, as reported, from narcotics to barbiturates.

As I have stated in the past, the problem of abuse of any drug cannot be understood apart from the total context of drug use and the society in which it occurs (33). "Barbiturism" is a chronic disease with many causes and no one treatment. We would gain little by proposing oversimplified panaceas. Nevertheless we should immediately embark upon an all-out attack on the barbiturate problem, along each of the dimensions discussed above.

As President John F. Kennedy stated at a White House Conference on Narcotic and Drug Abuse, "it should be our earnest intention to insure that drugs should not be employed to debase mankind, but to serve it."

#### REFERENCES

1. Ad hoc Panel on Drug Abuse, Progress Report, The White House, 1962.
2. Arieti, Silvano: American Handbook of Psychiatry, vol. I, Basic Books, Inc., New York, 1959.
3. Ausubel, David P.: Drug addiction: physiological, psychological and sociological aspects, Random House, New York, 1958.
4. Bailey, C. J. & Miller, N. E.: The effect of sodium amytal on an approach-avoidance conflict in cats. *J. Comp. Physiol. Psychol.*, 45: 205-208, 1952.
5. Bain, J. A.: Enzymatic aspects of barbiturate action. *Fed. Proc.* 11: 653-567, 1952.
6. Bales, L. N.: Goofballs, read birds, yellow jackets, red devils and other barbiturates and their effects. *Peace Officers' Association of the State of California Proceedings*, 29: 59-62, 1949.
7. Beecher, H. K.: The powerful placebo. *J.A.M.A.*, 159: 1602-1606, 1955.
8. Beecher, H. K., McDonough, F. K. & Forbes, A.: Similarity of effects of barbiturate anesthesia and spinal transection. *J. Neurophysiol.* 2: 81-88, 1939.
9. Belleville, R. E. & Fraser, H. F.: Tolerance to some effects of barbiturates. *J. Pharmacol. & Exper. Ther.*, 120: (4) 469-474, 1957.
10. Bergman, P. S., Stroo, H. H. & Feinstein, R.: Mental and electroencephalographic changes following intravenous barbiturates in organic disease of the brain. *Amer. J. Psychiatry*, 110: 770-773, 1954.
11. Brazier, M. A. & Finesinger, J. E.: Action of barbiturates on the cerebral cortex. *Arch. Neurol. Psychiatry*, 53: 51-58, 1945.
12. *Britannica Book of the Year. Narcotics*, 472-473, 1958.
13. Brody, T. M. & Bain, J. A.: Barbiturates and oxidative phosphorylation. *J. Pharmacol.*, 110: 148-156, 1954.
14. Brody, T. M. & Bain, J. A.: Effect of barbiturates on oxidative phosphorylation. *Proc. Soc. Exp. Biol.*, 77: 50-53, 1951.
15. Chain, I. & Rosenfeld, E.: Juvenile narcotic use. *Law and Contemporary Problems*, 22: 52-68, 1957.

16. Cohen, B. D., Senf, R. & Huston, P. E.: Effect of amobarbital (amytal) and effect on conceptual thinking in schizophrenia, depression and neurosis, *Arch. Neurol. Psychiatry*, 71: 170-180, 1954.
17. Dangerous Drugs, Public Hearing, Assembly Interim Committee on Criminal Procedure, California Legislature, 1961.
18. Davis, H.: The prescribing of barbiturates, *Brit. J. Addiction*, 53: 102, 1957.
19. Dews, P. B.: Comparison of effects of phenobarbital and chlorpromazine on discriminatory performance in pigeons. *J. Pharmacol.*, 116: 16, 1956.
20. Dews, P. B.: Studies on behaviour. I. Differential sensitivity to pentobarbital of pecking performance in pigeons depending on the schedule of reward. *J. Pharmacol.* 113: 393-401, 1955.
21. Dobos, J. K., Phillips, J. & Covo, G. A.: Acute barbiturate intoxication, *J.A.M.A.*, 176: 268-272, April 1961.
22. Domino, E. F.: A pharmacological analysis of the functional relationship between the brain stem arousal and diffuse thalamic projection systems. *J. Pharmacol.*, 115: 449-463, 1955.
23. Domino, E. F., Fox, K. E. & Brody, T. M.: Pharmacological actions of a convulsant barbiturate (sodium-5-ethyl-t-(1,3-dimethylbutyl) barbiturate)—I. Stimulant and depressant effects. *J. Pharmacol.*, 114: 473-483, 1955.
24. Drug Trade News, 10 E. 15th St., N.Y., N.Y., 1961-1962.
25. Eldridge, William B.: Narcotics and the law. American Bar Foundation, 1962.
26. Essig, C. F. & Ainslie, J. D.: Addiction to meprobamate (Equanil, Miltown). *J.A.M.A.* 146: 1382, 1957.
27. Essig, C. F. & Carter, W. W.: Failure of diphenylhydantoin in preventing barbiturate withdrawal convulsions in the dog. *Neurology*, 12: 7, July 1962.
28. Essig, C. F. & Flannery, H. G.: Convulsive aspects of barbital sodium withdrawal in the cat. *Experimental Neurology*, 3: 2, February 1961.
29. Eysenck, H. J.: Handbook of Abnormal Psychology. Basic Books, Inc., New York, 1961.
30. Felsing, J. M. von, et al.: Personality and reaction to drugs. *J.A.M.A.* 157: 1113, 1955.
31. Fischelis, Robert P.: A review of the present status of barbiturate regulation; before the conference on regulation and use and distribution of barbiturates, Washington, D.C., October 12, 1945. *J. Pharmaceutical Assoc.*, 35: 193-204, July 1946.
32. Fort, J.: Narcotics: The international picture. *Calif. Youth Authority Quarterly*, 14: summer 1961.
33. Fort, J.: The use and abuse of alcohol and narcotics around the world. Proceedings, III World Congress of Psychiatry, McGill Univ. Press, 1962.
34. Fraser, H. F.: Tolerance to and physical dependence on opiates, barbiturates, and alcohol. *Annual Review of Medicine*, 8, 1957.
35. Fraser, H. G. et al.: Chronic barbiturate intoxication: further studies. *Archives of Internal Medicine*, 94: 34-41, July 1954.
36. Fraser, H. J. & Isbell, H.: Abstinence syndrome in dogs after chronic barbiturate medication. *J. Pharmacol. and Exper. Therap.*, 112: 261-267, November 1954.
37. Fraser, H. F., Isbell, H., Eiseman, A. J., Wikler, A. & Pescor, F. T.: Chronic barbiturate intoxication. Further studies. *Arch. Neurol and Psychiatry*, 94: 34-41, July 1954.
38. Fraser, H. G., Shaver, M. R., Maxwell, E. S. & Isbell, H.: Death due to withdrawal of barbiturates. *Ann. Int. Med.*, 38: 1319-1325, June 1953.
39. Fraser, H. G., Wikler, A., Belleville, Essig & Hill, H. E.: Minimum dose of barbiturates required to produce physical dependence. *Federation Proceed.*, 15: 1, March 1956.
40. Frenkel-Brunswik, E.: Meaning of psychoanalytic concepts and confirmation of psychoanalytic theories. *Scientific Monthly*, 79: 292-300, 1954.
41. Gellhorn, E.: Physiological processes related to consciousness and perception. *Brain*, 77: 401-415, 1954.
42. Gerard, D. & Kornetsky, C.: Adolescent opiate addiction: a study of control and addict subjects, *Psychiatric Quart.*, 29: 457, 1955.
43. Gerard, R. W.: The biological roots of psychiatry. *Amer. J. Psychiatry*, 112: 81-90, 1955.
44. Gibbs, F. A. & Maltby, G. L.: Effect on the electrical activity of the cortex

- of certain depressant and stimulant drugs—barbiturates, morphine, caffeine, benzedrine and adrenalin. *J. Pharmacol.*, 78: 1-10, 1943.
45. Glatt, M. M.: The abuse of barbiturates in the U.K., *Bull. on Narcotics*, XIV: 2, Apr.-June 1962.
  46. Goldstein, S. W.: Barbiturates—are they narcotics? *Jour. Amer. Pharmaceutical Assoc.*, 36: 97-100, April 1947.
  47. Goodman, L. S. & Gilman, A.: The pharmacological basis of therapeutics. The MacMillan Co., N.Y., 1956.
  48. Goodnow, R. E., Beecher, H. K., Brazier, M. A. B., Mosteller, F. & Taguri, R.: Physiological performance following a hypnotic dose of a barbiturate. *J. Pharmacol.*, 102: 55-61, 1951.
  49. Hambourger, W. E.: Promiscuous use of the barbiturates, *J.A.M.A.*, 2015, 1940.
  50. Hambourger, W. E.: A study of the promiscuous use of the barbiturates, *J.A.M.A.*, 1340, 1939.
  51. Heath, R. G.: The problem of the clinical evaluation of sedative and hypnotic drugs, *Symposium on Sedatives and Hypnotics*. 57-80, Williams and Wilkins, Baltimore, 1954.
  52. Hebb, D. O.: The organization of behaviour. A neurophysiological theory. Wiley, N.Y., 1949.
  53. Hill, H. E. & Belleville, R. E.: Effects of chronic barbiturate intoxication on motivation and muscular coordination. *Arch. Neurol. Psychiatry*, 70: 180-188, 1953.
  54. Hill, H. E., Belleville, R. E. & Wikler, A.: Motivational determinants in the modification of behaviour by morphine and pentobarbital. *Arch. Neurol. and Psychiatry*, 77: 28-35, 1957.
  55. Hill, H. E., Belleville, R. E. & Wiker, A.: Studies on anxiety associated with anticipation of pain. II. Comparative effects of pentobarbital and morphine. *Arch. Neurol. Psychiatry*, 73: 602-608, 1955.
  56. Hoch, Paul H. & Zubin, J., edit.: Problems of addiction and habituation. Grune and Stratton, Inc., N.Y., 1958.
  - 56a. Hollister, L. E. et al.: Withdrawal reactions from chlordiazepoxide (Librium). *Psychopharmacologia*, 2: 63-68, 1961.
  57. Huston, P. E. & Singer, M. M.: Effect of sodium amytal and amphetamine sulfate on mental set in schizophrenia. *Arch. Neurol. Psychiatry*, 53: 365-369, 1945.
  58. Inventory (North Carolina Alcoholic Rehabilitation Programme). Barbiturates as addicting drugs, 9: 10-12, Sept.-Oct. 1959.
  59. Isbell, H.: Abuse of barbiturates. *J.A.M.A.*, 162: 660, 1956.
  60. Isbell, H.: Acute and chronic barbiturate intoxication. *Veterans Adm. Tech. Bulletin*, August 15, 1951.
  61. Isbell, H.: Addiction to barbiturates. *Annals of Internal Medicine*, 33: 108-121, July 1950.
  62. Isbell, H.: Addiction to hypnotic and sedative drugs. *Assn. of Food and Drug Officials of the U.S.*, XXIII, 1, January 1959.
  63. Isbell, H.: Manifestations and treatment of addiction to narcotic drugs and barbiturates. *Medical Clinics of North America*, 34: 425-438, March 1950.
  64. Isbell, H. & Fraser, H. F.: Addiction to analgesics and barbiturates. *J. of Pharmacol. and Exper. Therap.*, 99: 355-397, Aug. 1950.
  65. Isbell, H., Altschul, S., Kornetsky, C. H., Eisenman, A. J., Flanary, H. G. & Fraser, H. F.: Chronic barbiturate intoxication: an experimental study. *Arch. Neurol. and Psychiatry*, 64: 1-28, July 1950.
  66. Isbell, H., Fraser, H. F., Wikler, A., Belleville, R. E. & Eisenman, A. J.: An experimental study of the etiology of "rum fits" and delirium tremens. *Quart. J. Stud. on Alcohol*, 16: 1-33, March 1955.
  67. Kahn, R. L., Fink, M. & Weinstein, E. A.: Relation of amobarbital test to clinical improvement in electroshock. *Arch. Neurol. Psychiat.*, 76: 23-29, 1956.
  68. Kalinowsky, L. B.: Convulsions in non-epileptic patients on withdrawal of barbiturates, alcohol, and other drugs. *Arch. Neurol. and Psychiatry*, 48: 946-956, December 1942.
  69. Kass, E., Retterstøl, N. & Sirnes, T.: Barbiturate intoxication and addiction as a public health problem in Oslo. *Bull. on Narcotics*, XI: 3, 15-29, 1959.
  70. Kety, S. S.: Consideration of pharmacological agents on the over-all circulation and metabolism of the brain. *Neuro-pharmacology*, Josiah Macy Jr. Foundation, New York, 13-89, 1954.

71. King, E. E., Naquet, R. & Magoun, H. W.: Action of pentobarbital on somatic afferent conduction in the cat with special reference to the thalamic relay. *J. Pharmacol.*, 113: 31, 1955.
72. Kline, N. S.: Psychopharmacology. *Progress in Neurol. and Psychiat.*, 19: 441-464, 1958.
73. Koppányi, Theo. & Fazekas, J. F.: The use of correctives in the prevention of barbiturate intoxication. *Amer. J. of the Med. Sciences*, 226: 597-606, Dec. 1953.
74. Kornetsky, C. H.: Psychological effects of chronic barbiturate intoxication. *A.M.A. Arch. of Neur. and Psychiatry*, 65: 557-567, May 1951.
75. Kornetsky, C. H.: Relationship between Rorschach determinants and psychosis in barbiturate withdrawal syndrome. *A.M.A. Arch. of Neur. and Psychiatry*, 72: 452-454, Oct. 1954.
76. Levi, Leo, Ph.D.: The barbituric acids, their chemical structure, synthesis and nomenclature. *Bull. on Narcotics*, IX: 1, 30-41, 1957.
77. Levi, L. & Hubley, C. E.: Detection and identification of clinically important barbiturates. *Analytical Chem.*, 28: 1591, 1956.
78. Lindemann, E. & Felsing, J. M.: Drug effects and personality theory. *Psychopharmacologia*, 2: fasc. 1, 1962.
79. Masserman, J. H. & Siever, P. W.: Dominance, neurosis and aggression. *Psychosom. Med.*, 6: 7-16, 1944.
80. Maynert, E. W. & Van Dyke, H. B.: The metabolism of barbiturates. *Jour. Pharm. and Exper. Therap.*, 96: 217, 1949.
81. McNally, W. D.: The use and abuse of barbiturates. *Michigan Med. Soc. Jour.*, 41: 635-642, August 1942.
82. Narcotics, a symposium. *Law and Contemporary Problems*, 22: 1-154, winter 1957.
83. New and nonofficial remedies, J. B. Lippincott Co., Philadelphia, 1962.
84. Nyswander, M.: The drug addict as a patient, Grune and Stratton. New York, 1956.
85. Parker, K. D. & Kirk, P. L.: Separation and identification of barbiturates by gas chromatograph. *Analytical Chem.*, 33: Sept. 1961.
86. Pharmacy laws of California and administrative rules of board of pharmacy, 1962.
87. Physician's Desk Reference, 16th ed. Med. Econ. New Jersey, 1961.
88. Pohlisch, K.: Ober psychische reactionsformen bei arzneimittelvergiftungen. *Monatsschr. f. Psychiat. u Neurol.*, 69: 351-367, 1928.
89. Problem of barbiturates in the United States of America. *Bull. on Narcotics*, IX: 15-19, Apr.-June 1957.
90. Pruitt, R. S.: Medicolegal aspects of the sale and use of barbiturates. *Missouri Med. Assoc. Jour.*, 44: 419-423, June 1947.
91. Behavioral research in preclinical psychopharmacology. *Psychopharmacology Ser. Center Bull.*, U.S. Dept. Health, Education, Welfare, 1962.
92. *Psychopharmacology Ser. Center Bull.*, U.S. Dept. H.E.W. 2: 1, March 1962.
93. Quarton, G. C. & Talland, G. A.: The effects of methamphetamine and pentobarbital on two measures of attention. *Psychopharmacologia*, 3: fasc. 1, 1961.
94. Rosner, H., Levine, S., Hess, H. & Kaye, H.: A comparative study of the effect on anxiety of chlorpromazine, reserpine, phenobarbital and a placebo. *J. Nerv. Ment. Dis.*, 122: 505-512, 1955.
95. Sargant, W., Slater, P., Halstead, H. & Glen, M.: Effects of alcohol and sodium amytal on intelligence test score. *Lancet*, 1: 617-618, 1945.
96. Shideman, F. E., Ph.D.: Clinical pharmacology of hypnotics and sedatives. *Clin. Pharmacol. and Therap.*, 313: 1961.
97. Special Study Commission on Narcotics, Interim and final report. State of California, June 1961.
98. Stephens, M. R.: The food and drug administration's responsibilities and obligations in drug distribution. Address. Annual Convention of the American College of Apothecaries. Feb. 1960.
99. Straus, E.: Zur pathogenese des chronischen Morphinismus. *Monatsschr. f. Psychiat. u. Neurol.*, 46: 1-20, 1919.
100. Taylor, N.: Flight from reality, Duell, Sloan and Pearce, New York, 1949.
101. Tompkins, D. C.: Drug addiction: A bibliography. Bureau of Public Administration, Univ. of California, Berkeley, 1960.
102. Trichter, J.: The barbiturate problem of the city of New York, Food and Drug Cosmetic Law Jour., 7: 222-224, March 1952.

103. U.S. Commerce, Dept. of: Report on tranquilizers and stimulants, Office of Technical Service, Govt. Research, 1961.
104. U.S. Congress: House of Rep. report pursuant to H.R. 357. The relationship between highway accidents and use of drugs by drivers. Spec. Subcom. on Traffic Safety. H. Rep., 2971, 84: 2, Wash., D.C., 3 Jan. 1957.
105. U.S. Congress: House of Rep. Drug Industry act of 1962. Hearings, Comm. in Interstate and Foreign Comm. 87th Cong., 1962.
106. U.S. Congress: House of Rep. Traffic in, and control of narcotics, barbiturates, and amphetamines. Hearings, Subcommittee of the Committee on Ways and Means, 84th Cong., 1955-56.
107. U.S. Congress: Drug industry antitrust act. Hearings, Subcommittee on Antitrust and Monopoly of the U.S. Senate Committee on the Judiciary 87th Congress, 1962. See particularly part 6: Advertising Provisions.
108. U.S. Congress: Administered prices in the drug industry. Hearings, Subcommittee on Antitrust and Monopoly of the U.S. Senate Committee on the Judiciary, 86th Congress, 1960. See particularly part 16: Tranquillizers.
109. U.S. Public Health Service: Barbiturates as addicting drugs. National Institute of Mental Health. Publication 545, Wash., D.C., 1957.
110. U.S. Congress: Senate: Treatment and rehabilitation of juvenile drug addicts. Subcommittee to Investigate Juvenile Delinquency, Committee on the Judiciary. Hearings, pursuant to S.R. 173 and S.R. 303, Dec. 1956, 984: 2, Wash., D.C., 1957.
111. U.S. Tariff Commission: Report: synthetic organic chemicals, U.S. production and sales. U.S. Gov. Print. Office., Wash., D.C., 1936-1961.
112. Von Baeyer, A.: Untersuchungen uber die harnsauregruppe, *Annalen der Chemie*, 127: 1, 199 (1863); 130: 129 (1864).
113. Von Felsinger, J. M., Lasagna, L. & Beecher, H. K.: The persistence of mental impairment following a hypnotic dose of a barbiturate. *J. Pharmacol.*, 109: 284-291, 1953.
114. Weinstein, E. A., Kahn, R. L., Sugarman, L. A. & Malitz, S.: Serial administration of the "Amytal test" for brain disease. Its diagnostic and prognostic value. *Arch. Neurol. Psychiat.*, 71: 217-226, 1954.
115. Wikler, A.: Drug Addiction. *Tice's Practice of Med.*, vol. VIII, 1957, p. 17-49.
116. Wikler, A.: Fundamentals of scientific research in psychiatry. *Neuropsychiatry*, 2: 87-98, 1952.
117. Wikler, A.: Neurophysiological aspects of the opiate and barbiturate abstinence syndromes. *Proceedings of the Assn. for Research in Nervous and Mental Disease*. Williams and Wilkins Co., Baltimore, 1953.
118. Wikler, A.: On the nature of addiction and habituation. *British J. of Addiction*, 57: 2, July 1961.
119. Wikler, A.: Opiate addiction. Psychological and neurophysiological aspects in relation to clinical problems. Thomas, Springfield, 1952.
120. Wikler, A.: A psychodynamic study of a patient during experimental self-regulated readdiction to morphine. *Psychiatric Quart.*, 26: 270-293, 1952.
121. Wikler, A.: Relationships between clinical effects of barbiturates and their neurophysiological mechanisms of action. *Fed. Proc.*, 11: 647-652, 1952.
122. Wikler, A.: The relation of psychiatry to pharmacology. Williams and Wilkins, Baltimore, Md., 1957.
123. Wikler, A.: The uses of drugs in psychiatric research. *Amer. J. Psychiat.*, 112: 961-969, 1956.
124. Wikler, A., Fraser, H. F., Isbell, H. & Pescor, F. T.: Electroencephalograms during cycles of addiction to barbiturates in man. *Electroenceph. Clin. Neurophysiol.*, 7: 1-13, 1955.
125. Wikler, A. & Raser, R. W.: Psychiatric aspects of drug addiction, in symposium on drug addiction, ed. by Eddy, N. B. *Amer. J. of Med.*, 14: 566-570, May 1953.
126. Winick, C.: The use of drugs by jazz musicians. *Soc. Problems*, 7: 240-253, winter 1959-60.
127. Wold, S. & Ripley, H. S.: Studies on the action of intravenously administered sodium amytal. *Amer. J. Med. Sci.*, 215: 56-62, 1948.
128. Wortis, J.: Soviet psychiatry, Williams and Wilkins, Baltimore, 1950.
129. Yost, O. B.: The bane of drug addiction. Macmillan, N.Y., 1954.
130. Young, J. Z.: Doubt and certainty in science. Oxford, Clarendon Press, London, 1951.
131. Zimmering, P., Toolon, J., Safrin, R. & Wortis, S. B.: Drug addiction in relation to problems of adolescence. *Amer. J. Psychiat.*, 109: 272-278. 1952.

The CHAIRMAN. Thank you, Mr. Larrick, for your very forceful and interesting presentation.

We shall be glad to receive the information which you so readily agreed to submit, and the language to carry out the recommendations which you have made, for the consideration of the committee.

Mr. LARRICK. That, sir, is now attached to the Secretary's letter which was delivered to you just a few minutes ago.

The CHAIRMAN. Very well. Then it is already included in the record.

Mr. Rogers, any questions?

Mr. ROGERS of Texas. Just one or two, Mr. Chairman.

On page 7, at the top, you refer to, the term is "covered by regulation," Mr. Larrick. Now, that is in regard to the definition of the term "depressant and stimulant drug." How far do you feel that the Congress ought to go in permitting your department to make the determination as to what should be covered by regulation and what should not be covered by regulation?

Mr. LARRICK. Mr. Rogers, that ultimately is a decision for the committee to make, of course. But my view is that with proper safeguards, the details of the administration of the statute should best be delegated to the enforcement agency rather than to have us coming back up before this committee at very frequent intervals, asking you to add drugs to the list.

I might say that the Narcotic Act for a long time had provisions that required any new narcotic to be added to the list only on congressional enactment. That became difficult; difficult for the enforcement agency, difficult for the busy committees of Congress; and so a procedure was worked out which delegated that responsibility to the administrative branch of the Government, with safeguards to prevent abuse, and to give persons aggrieved an access to the courts.

Mr. ROGERS of Texas. But you are asking the Congress, then, to grant to you rulemaking powers with regard to these different articles that actually makes it possible for you to adopt a rule that has the effect and the power of substantive law; are you not?

Mr. LARRICK. It would have the force and effect of law, and would be very similar to the power to make food standards, the power to pass on new drugs, and many other powers that this committee and the Congress has seen fit to delegate to the Secretary, and he, in turn, to the Food and Drug Administration.

Mr. ROGERS of Texas. Well, Mr. Larrick, of course, the thing that disturbs me is there have been some very terrible mistakes made in delegation of power. Now, we have a Constitution, and this is supposed to be the lawmaking power—the lawmaking part of this organization. Yet there is a continuous and a consistent demand by departments downtown for Congress to delegate its powers to those departments downtown.

Now, those departments downtown are not primarily responsible to the electorate. And I think the time has come when we are going to have to call a stop to this thing, and I think we ought to spell it out very clearly. Otherwise, we might as well amend the Constitution and say that the lawmaking power of this body is the right to delegate to others the right to make laws.

Mr. LARRICK. Mr. Rogers, my answer to that would be that I think it is our responsibility to point out to you the nature and extent of the problem involved, to present also what view we may have as to the advantages to the public by the expeditious additions to the list, and then you, with your broader experience and knowledge, make the decision of just how you choose to handle it.

Mr. ROGERS of Texas. Well, of course, I think that is right, but I don't think that is being done in many instances when the departments downtown merely change from one day to the next the ingredients necessary to send a man to the penitentiary, which is what is being done. I think it is a very dangerous situation. And I think that although we haven't had perhaps too much difficulty with it so far, that we are moving into the area where we will.

Now, with regard to the seizure, in your first suggested amendment, your desire to have the right on the part of the inspectors to seize this material—I can appreciate your problem very, very clearly, having served as a district attorney—I know what you are up against on some of these things.

Now, the point is this, though. How far can you go in granting this sort of power? Would it satisfy you and your organization, insofar as being able to effect these seizures, to say that you could seize this on the condition that you moved immediately to a Federal judge to acquire whatever proper authority is vested in the judicial branch of this Government; to authorize that to be done, so the possibility of people's rights being encroached upon would not be occurring?

Mr. LARRICK. Mr. Rogers, I think that definitely should be done. That is what we propose.

Mr. ROGERS of Texas. You are not asking, then, just a blanket authority to seize and hold this for subsequent trial?

Mr. LARRICK. No. Essentially we are asking we detain it until we can get to the court, the district attorney, and get the papers. And I think that should be done very expeditiously.

Mr. ROGERS of Texas. Now, with regard to the records, it seems to me—and, of course, you know a great deal more about this problem than I probably ever will—but it seems to me if you go to the source, the original source of manufacturing of this sort of thing, and work from there, that you would have a much easier job than waiting until they get into the retail field.

Mr. LARRICK. That is quite right. The plan would be to go to the manufacturer and from him to go to the wholesaler, and from him to go to the retailer, and at each level to look for diversion—because there is diversion or a possibility of diversion at all levels. We haven't found any diversion from wholesalers.

Mr. ROGERS of Texas. Your recordkeeping—as I understand it now, the records are being kept along with everything else.

We will say in the drug wholesale house, if they sold a bill of goods for \$10,000, and a thousand of that was products we are talking about here, that they may be worked into that invoice in a hundred different places, and you have to ferret them out.

Now, as I understand it, you advocate that a separate set of books and records be kept with regard to those drugs covered by this bill.

Mr. LARRICK. I would make that language, Mr. Rogers, quite general, and give the firms the latitude of recordkeeping, so that if it were a reasonable record that they are now keeping, which would make it possible for us to find the part that we want, we would not require them to have a special form or even a separate record.

For instance, one firm may use computers. They may have it all in one big batch. But they can punch a key and bring out all the amphetamines and another for barbiturates—that would be quite satisfactory.

What I would want would be a set of records which would be reasonably available within a reasonable length of time to give us the information and achieve the purposes of the bill.

Mr. ROGERS of Texas. Of course, that is very well. The only trouble is, Who is going to determine what "reasonable" is? What is reasonable to one man is unreasonable to another.

Mr. LARRICK. Basically—just like the Harris bill that was passed—the great bulk of the firms that we deal with, will do everything they can to abide by the law once it is passed. The great bulk of the honest manufacturers would abide by the law without any difficulty.

It is in the fringe elements that we begin to find falsification of records and obstructionist tactics. At that level, language is needed to prevent one from combining records of his entire year's production, thus requiring our inspectors to stay in there days to get the information that we want. In the meantime, the people down the line to whom it has been diverted can destroy their records, and we lose the trail.

Mr. ROGERS of Texas. Now, you say here, "It has been suggested that if physicians are exempt, so should pharmacists be, or vice versa."

Now, who suggested that?

Mr. LARRICK. Now, wait a minute. You ask who suggested that—Mr. ROGERS of Texas. What I am getting at is, What is your recommendation?

Mr. LARRICK. We recommend that they be exempt.

Mr. ROGERS of Texas. The pharmacists?

Mr. LARRICK. No, sir, the physicians.

Mr. ROGERS of Texas. Why?

Mr. LARRICK. Because we only had 36 violations in a period since 1953, whereas we had 1,100 at the retail drug level.

Mr. ROGERS of Texas. That 36 could turn loose as many rats on the country as the 1,100, though, could it not?

Mr. LARRICK. That is why we say that if the committee in its wisdom desires to include the physicians, we have no objection.

Mr. ROGERS of Texas. I know; but I refer to your recommendations that they physicians be exempt.

Mr. LARRICK. My testimony today isn't exclusively my testimony. I am speaking for the Department. After extensive discussion and much deliberation, the view of the Department was that as a practical matter, the physician should be exempt.

Mr. ROGERS of Texas. The Department thinks that as a practical matter the physician should be exempt?

Mr. LARRICK. Right—from the recordkeeping.

Mr. ROGERS of Texas. Why is that practical?

Mr. LARRICK. Because they didn't think the incidence—the number of violations—was great enough to justify the task of recordkeeping that would be involved.

Mr. ROGERS of Texas. Well, did you consult with the A.M.A. or anyone else about this?

Mr. LARRICK. We didn't need to consult with them. We knew they would oppose that—

Mr. ROGERS of Texas. I mean they want to be exempt, don't they?

Mr. LARRICK. Dr. Sadusk reminds me that today's practice of medicine less and less involves the dispensing of drugs. A great many doctors that you go to today don't give you any drugs, they give you a prescription.

Mr. ROGERS of Texas. Well, they would not need to keep any record.

Mr. LARRICK. That is quite right. If they didn't handle any drugs, they wouldn't need to.

Mr. ROGERS of Texas. If you are talking about doctors—I believe you said 3 dozen—that would be 36 doctors—as against 100 pharmacists. Now, as I understand you, you said “convictions,” not “individuals.” One pharmacist could commit a hundred different violations, and be convicted on it.

Mr. LARRICK. I want to make it very clear here today that this is not an attack or indictment of pharmacy. They are very sensitive about this.

I think you will hear from the pharmacists, without question.

Mr. ROGERS of Texas. There are other questions I would like to ask, but I am going to quit, Mr. Chairman.

The CHAIRMAN. What would be the result, in your opinion, if the pharmacies were exempt?

Mr. LARRICK. I think it would very, very seriously handicap the efficient enforcement of the law.

Let me say, today if our men go out to look at prescription files, we do not have the authority to do it—as we all in this room very well know. There wouldn't be one pharmacist, in my opinion, in a hundred, certainly not more than one or two, that would not let us look at them. The ones that are likely not to let us look at them are the people that are in trouble.

But, basically, the pharmacists whose prescription files we don't need to look at do not object to our looking.

The CHAIRMAN. What you are asking for here is what has been sought over a long period of time—

Mr. LARRICK. And we have never gotten it.

The CHAIRMAN. What you have described here is the authority to go in and look at prescriptions in the pharmacy.

Mr. LARRICK. We have narrowed this. If the pharmacist kept his prescriptions for drugs subject to this bill in one file and prescriptions for other drugs separately, we would just be able to look at the former.

The CHAIRMAN. In other words, to make it clear—if a pharmacy kept separate records, you could, under this authority, look only at prescriptions that have to do with these types of drugs.

Mr. LARRICK. To doublecheck on that, let me consult with my attorney, whom I did not introduce—Mr. William Goodrich, who you know.

He says that is correct.

The CHAIRMAN. Well, if he says it is correct, knowing him as I do, it is correct.

Mr. LARRICK. That is right, sir.

The CHAIRMAN. I think, for the record, before we get any further—could you define a barbiturate?

Mr. LARRICK. A barbiturate is a synthetic drug which may be produced by a chemical process from barbituric acid.

The CHAIRMAN. Could you then describe an amphetamine?

Mr. LARRICK. Well, an amphetamine is a synthetic drug with a very complex chemical structure which is generally thought of, in medical parlance, as a powerful stimulant.

The CHAIRMAN. A harmful stimulant?

Mr. LARRICK. Powerful.

I want to emphasize these drugs are very important to legitimate medical practice, and with their use for those practices we have no objection.

The CHAIRMAN. Then do you propose specifically to get at these particular two types of drugs?

Mr. LARRICK. Yes, sir—and others that have similar properties.

The CHAIRMAN. Others with similar properties, by regulation, after a hearing?

Mr. LARRICK. After a proposal and a hearing if requested, and a regulation.

The CHAIRMAN. Are there other drugs that are similar and have the same effect?

Mr. LARRICK. There are others that have either the same effect or very similar effects.

The CHAIRMAN. Well, why are they not included specifically?

Mr. LARRICK. We thought it best to allow a procedure which would permit persons who are in the business of making these drugs, and who would not agree with us in complete detail, to have an opportunity to present the complex scientific evidence that would be weighed and a record be made so that if they disagreed with our decision they could go to the courts.

You would be sitting here weeks and weeks if you have to go into a hearing on whether or not each tranquilizer and each stimulant drug and each drug that causes hallucinations is or is not the kind of a drug that is spoken of in this statute.

The CHAIRMAN. That is what I am talking about.

Are you familiar with the drug methylprylon?

Mr. LARRICK. I would have to look it up, Mr. Chairman.

The CHAIRMAN. You mentioned in your statement Meproamate, I believe.

Mr. LARRICK. That is right.

The CHAIRMAN. Then you must be familiar with that drug.

Mr. LARRICK. We are very familiar with it. I am not sure that the manufacturers would agree with our conclusion. I haven't asked them. Meproamate.

The CHAIRMAN. Does it have the same effect?

Mr. LARRICK. In the case of some people.

The CHAIRMAN. The same as a barbiturate?

Dr. SADUSK. I think it is fair to say that Meprobamate in a number of people will have the same type of deleterious effect if used in a fashion not for therapeutic purposes, and particularly when continued in high dosage so that a type of dependence is produced. And, indeed, the medical literature shows, as demonstrated in the medical paper which Mr. Larrick referred to, from the Boston City Hospital—of those people coming in as addicts there were a substantial number, I believe approximately 25 percent, that had used tranquilizers and among which the principal one used now is Meprobamate.

The CHAIRMAN. The point is, we have to consider, among other things, the competitive situation—we believe we have the finest system of competitive free enterprise of any nation or any society of people. What is going to be the result to the competitors of the barbiturates if the competitors produce similar results and they are not included? And you take, as you mentioned a moment ago, a year or 2 years or an indefinite period of time before you make a determination?

Mr. LARRICK. I don't think there is any question of a doubt that many more people abuse barbiturates today than abuse Meprobamate.

I don't think it is possible to have legislation in this field that won't create some temporary competitive problems and disadvantages. It is true, Mr. Chairman, in almost all regulations.

The CHAIRMAN. Yes; I know that is true, but I don't think it behoves you or me to bring it about arbitrarily.

Mr. LARRICK. No, sir. I would hope to minimize that by the very best administration we are capable of bringing to it.

The CHAIRMAN. Well, under the bill that passed the other body last year, I was advised that even aspirin could be brought under it.

Mr. LARRICK. That is incorrect, sir.

The CHAIRMAN. That could not have been done?

Mr. LARRICK. That could not have been done.

The CHAIRMAN. Could it be done under this?

Mr. LARRICK. It could not be done.

The CHAIRMAN. My only interest in these questions, to follow up on Mr. Rogers first question awhile ago is to make sure that we not arbitrarily give an advantage to one pharmaceutical manufacturer over another. I am going to present you four or five names that I wish you would look into and advise the committee whether or not they have similar characteristics as those derivatives of barbituric acid.

Mr. LARRICK. Very well, sir. You will give us an opportunity to submit that at a later date, I take it.

The CHAIRMAN. Yes, I would like to do that, because I mentioned one of them and you didn't know what it was. I don't, either.

Mr. MOSS. Mr. Chairman, would you yield at that point?

The CHAIRMAN. Yes.

Mr. MOSS. I wonder if in the compilation of the information requested by the chairman you could indicate whether the manufacturers of the named preparations also engage in the manufacture of preparations with a barbiturate base?

Mr. LARRICK. We would be very glad to.

I think perhaps I should say this: When you are speaking of drugs like Meprobamate, those are drugs that are restricted—the name is probably a trademark name, and the drug is restricted to people who own a patent or have licensed that patent.

Now, on drugs like the barbiturates, for the most part anybody can make them. They are not protected in that fashion. But I would be very glad to indicate that fact. There are some barbiturates that are restricted to a firm that holds a patent on them and maybe a trademark. But the great bulk of the barbiturates are open to anybody to make and sell.

The CHAIRMAN. Mr. Springer?

Mr. LARRICK. We now have the information on the drug that neither you nor I know about.

The CHAIRMAN. Well, Doctor, maybe you could pronounce it correctly.

Dr. SADUSK. Mr. HARRIS, the generic name is methylprylone. Its trade name is Noludar. It falls in the same group of drugs as does Doriden, or gultethimide, and also thalidomide.

Now the problem basically in the designation of these drugs is that here are so very many. There are probably well over 50 barbiturates. Then as you come into the tranquilizers, it is just a question of those which have been on the market for a longer period of time and are more advertised, so that they are used in a popular fashion.

Now, if one tries to bring into the law each specific tranquilizer, it is just a question of the popular ones which are on the market and readily for sale—if you take those off, then the next 6 months a new type of tranquilizer is produced and comes on the market and is subject to abuse.

The CHAIRMAN. You say it is—it has the same characteristics of those others?

Mr. SADUSK. One characteristic is that of producing a hypnotic effect for slooping. It is just one of the class of drugs. But it does not necessarily fall into the same adverse reaction characteristics.

The CHAIRMAN. I thought we took care of the thalidomide problem a couple of years ago.

Dr. SADUSK. Yes; that drug never appeared on the market, but it just so happens that drug you asked about falls in the same group of Piperazine derivatives.

The CHAIRMAN. Well, you understand what I am trying to get at, don't you, Doctor—not to give one manufacturer an advantage over somebody else if it can be avoided. That has never been our purpose.

Mr. SPRINGER. Mr. Commissioner, you recall that in the bill which we passed a couple of years ago, one of the very big points of argument about the bill was the amount of time which you were allowed in which to make a determination so that they could either accept a decision or go on to court. Isn't that right?

Mr. LARRICK. Correct.

Mr. SPRINGER. And we raised that from 90 days to 6 months?

Mr. LARRICK. Yes. But also, Mr. Springer, you did not really hold this to any limit. You gave us whatever time was necessary

to basically resolve the question of whether the drug was safe and effective for its intended use.

Mr. SPRINGER. Did we limit you?

Mr. LARRICK. You gave us some very strong advice.

Mr. SPRINGER. But we did not limit you?

Mr. LARRICK. No; you did not specifically limit us.

Mr. SPRINGER. Are you sure about that?

Mr. GOODRICH. You limited the times, but did not make them automatically effective. Under our regulations today, though, anyone who is dissatisfied at the end of the period, can file over protest and go on to court; this is what you indicated we should do.

Mr. SPRINGER. That is what I want to know. You could at that point file a protest and go on to court.

Now, how many days was that?

Mr. GOODRICH. Six months.

Mr. SPRINGER. Now, may I ask you this: I don't know that this is applicable. We are probably getting into a highly competitive field.

Would this same provision be reasonable in this bill, or would that other bill be applicable to the provisions of this bill?

Mr. LARRICK. Well, I think basically the considerations would be reversed. I think in the case of new drugs, the manufacturer who is seeking the new drug application wants us to proceed with the utmost dispatch in his desires to get it on the market as fast as possible.

In the case of this bill, I would think the manufacturer normally—there might be exceptions to this—who disagreed with our conclusion about the habit-forming character of the drug, would want us to go in the other direction. They would want us not to issue the regulation at all, and the longer we took the better.

As far as I am concerned—

Mr. SPRINGER. You think that would be the position, say, of those who are manufacturing drugs?

Mr. LARRICK. I think there would be many, many that would agree with us. But I think there would be circumstances where the judgmental decisions that would have to be made about the desirability of putting this drug on the list in light of all the facts would be a matter of real controversy.

Mr. SPRINGER. Well, at least this is a thought we could take into consideration.

Mr. LARRICK. And I think the same principle of giving them access to scientists outside Food and Drug, as you have done, and giving them access to the courts, to keep us from being arbitrary and capricious, and so on, would be in the public interest.

Mr. SPRINGER. All right.

Now, Mr. Commissioner, I want to see if I can tie this together, what you are doing. And I want to do this in about 2 or 3 minutes, if I can.

First, you are trying to prohibit the possession of depressant or stimulant drugs by unauthorized persons.

Mr. LARRICK. Right.

Mr. SPRINGER. That is No. 1; right?

Mr. LARRICK. Right.

Mr. SPRINGER. The second thing you are trying to force under this law a requirement that the manufacturer and distributor keep records of inventories, receipts, and deliveries.

Mr. LARRICK. Yes.

Mr. SPRINGER. That is No. 2.

Mr. LARRICK. Right.

Mr. SPRINGER. Now—and that the failure to keep this would be grounds for seizure of the drug.

Mr. LARRICK. Right.

Mr. SPRINGER. Now, would there be a penalty prescribed in addition?

Mr. LARRICK. Yes. A criminal penalty.

Mr. SPRINGER. Now, third, you would provide for the registration of wholesalers handling depressant or stimulant drugs. That is No. 3; correct?

Mr. LARRICK. Correct.

Mr. SPRINGER. Fourth, providing for probably an advisory committee. Is that correct?

Mr. LARRICK. Providing for an advisory committee.

Mr. SPRINGER. All right.

Five, that the FDA, your inspectors, should be able to seize and the courts will be authorized to condemn any conveyance in which the violative stimulant, depressant drugs, have been unlawfully transported, carried or held; is that right?

Mr. LARRICK. Subject to the condition that if the conveyance—someone has a lien on it, and they had no part in this illegal transaction, they would be protected. If the vehicle had been stolen, as they very often are, the original owner would be protected. Subject to those qualifications our inspector could detain it until there was time to go to the Federal judge and get it legally seized.

Mr. SPRINGER. Now, as a part of that same thing, you would have a right to use the automobiles which have been seized and condemned; is that correct?

Mr. LARRICK. Yes. We would—after a very brief time I would guess we would turn these automobiles over to the GSA, and they would assign them out to Government bureaus.

Mr. SPRINGER. Now, sixth, it would provide for seizure and condemnation of machinery and equipment used in the unregistered or unlawful manufacture of stimulant and depressant drugs.

Mr. LARRICK. Correct.

Mr. SPRINGER. Seventh, that your inspectors, when authorized, could make arrests, to serve and execute warrants, and make arrests without warrants for offenses with respect to these drugs when the offense is committed in their presence.

Mr. LARRICK. Correct.

Mr. SPRINGER. No. 8, would permit your Secretary to authorize your inspectors to carry firearms.

Mr. LARRICK. May I interrupt, Mr. Springer? On No. 7, in addition to being authorized to make arrests when the crime was committed in his presence, if the offense was a felony, he could make the arrest on the basis of probable cause to believe that the offense had been committed.

Mr. SPRINGER. That is the regular law?

Mr. LARRICK. It is just the same as the other agents that have similar duties now have.

Mr. SPRINGER. Eight, you would authorize your inspectors to carry firearms, and that could be designated by the Secretary—that authority could be designated to you; correct?

Mr. LARRICK. Right.

Mr. SPRINGER. No. 9, the bill provides for increased penalties for illegal sale of depressant or stimulant drugs by any adult to a juvenile.

Mr. LARRICK. Right.

Mr. SPRINGER. No. 10, that would have to do with counterfeit drugs, is that correct?

Mr. LARRICK. Correct.

Mr. SPRINGER. In other words, manufacture of drugs which are really not those drugs at all.

Mr. LARRICK. Right.

Mr. SPRINGER. Now, may I ask you if there is anything else that is a major part of this bill that I have left out?

Mr. LARRICK. It is very difficult to think that fast. I have before me a complete analysis of H.R. 2 which I would like to submit for the record, or sit down and go over the bill.

Mr. SPRINGER. Can you tell me how many pages that involves?

Mr. LARRICK. Three and a half.

Mr. SPRINGER. Mr. Chairman, I will ask unanimous consent it be put in the record at this point.

Mr. LARRICK. And then of course the amendments we have suggested have already been incorporated in the record by the chairman.

The CHAIRMAN. You have sufficient copies to provide for each member of the committee?

Mr. LARRICK. No, sir. But we will get them.

Mr. SPRINGER. Mr. Chairman, may I ask they mail to each member of the committee a copy of that summary?

Mr. LARRICK. Yes, sir. I think you have covered it.

The CHAIRMAN. I think it would be better procedure for you to supply the committee with sufficient copies, and we will get it to each member.

Mr. LARRICK. Right, sir.

The CHAIRMAN. And I think it would be appropriate for this résumé that you speak of to go in the record immediately following your letter that I referred to a moment ago, which you have just referred to.

Mr. LARRICK. Very good, sir.

Mr. SPRINGER. You cannot think at this point, Mr. Commissioner, of anything that I have left out?

Mr. LARRICK. No, sir; I cannot.

Mr. SPRINGER. Thank you.

Mr. LARRICK. I think it is a very good analysis.

Mr. SPRINGER. Thank you.

The CHAIRMAN. Mr. Macdonald?

Mr. MACDONALD. Mr. Larrick, it is nice to see you again.

Mr. LARRICK. Thank you, sir; it is good to see you again.

Mr. MACDONALD. When you gave your description of barbiturates, you said that they were synthetic drugs produced from barbituric acid.

I am wondering, since I was a premedical student myself, exactly what the makeup of that acid might be.

Mr. LARRICK. Barbituric acid is a chemical which you know, as a premedical student, has an acid radical on the end of it. You can take this structural formula of barbituric acid and substitute one element for another and make changes in that structure and come up with a whole series, a great different number of different derivatives of barbituric acid which have similar but somewhat different characteristics.

For instance, you can take this compound, hook on it some chemicals, and make it a short-acting barbituric acid that the dentist could give you when you are going to have a tooth extracted.

You can make some other substitutions—

Mr. MACDONALD. Is that novocaine?

Mr. LARRICK. This is not novocaine, but it would have somewhat similar effects.

You can have it made in a form that could be injected and act as a complete anesthesia while you are being operated on.

You have a whole series, long acting, short acting, deep acting, and with various characteristics, all of which is a depressant to your ability to feel pain.

Mr. MACDONALD. Producing anesthesia?

Mr. LARRICK. Yes; you can get complete anesthesia.

Mr. MACDONALD. The reason that I ask is that it seems to me that the definition is so broad that it would affect practically every drug on the market.

Mr. LARRICK. No; the definition is very precise and very exact, and it could be found in any textbook of pharmacology.

Mr. MACDONALD. Well, with all due respect, your answer was not that precise.

Mr. LARRICK. All right. If you wish, I will supplement the record with a very precise, more carefully considered definition.

Mr. MACDONALD. All right. And because of the time, I will ask just one more question.

As Mr. Watson knows, because we have had this discussion within the committee, I am no great advocate of States rights, but what restraint would this act put on the activities of a local pharmacy? Would the pharmacist have to keep a great number of records and report back to you every time he sold any of the drugs encompassed by the act?

Mr. LARRICK. The chairman referred to some of the occasions when we have discussed pharmacists' records before.

The law now, the Durham-Humphrey law, requires the pharmacist to keep records of every prescription that they fill. There is no question he has to keep the record. If it is an oral prescription, he has to write it down. The only problem for us was he doesn't have to show it to us.

Now, in this bill, this would not cover the whole, longstanding controversy. It would only cover part of it.

He would have to show us the records that he now has to keep with respect to the drugs that would be covered by this bill.

Now, he could elect to show us his whole prescription file. In my personal judgment, that would be what most of the pharmacists who

haven't anything to worry about would do. Some might prefer to keep these records separate and thus keep us out of the other parts of the prescription file.

Mr. MACDONALD. Well, they would send them to you here physically in Washington?

Mr. LARRICK. I beg your pardon?

Mr. MACDONALD. They would physically send them?

Mr. LARRICK. No, they would not have to send them. If we want to look at them, we have to go to the pharmacy.

Now, he would also have to keep the invoices. Our objective here is to see from the invoices the quantity of these dangerous drugs that he receives. Then by looking at his prescriptions, we could compare the quantity received with the quantity sold. And we do a great deal of that now. And where we find a discrepancy of 5,000, 10,000, 15,000, our suspicions are greatly aroused.

Mr. MACDONALD. How many pharmacists are there in the country?

Mr. LARRICK. 125,000 pharmacists, and 52,000 drugstores. And I pointed out in my testimony, this testimony is in no way intended to be a reflection on ethical pharmacy in this country. I have the greatest respect for this profession. But like every profession in the world, even the ministry, there are people in it who do not comply with the ethics of the majority, and those are the people that we are seeking to deal with here.

I want to emphasize that pharmacy generally is entirely above reproach, and they have been quite helpful to us in discharging our obligations.

Mr. WATSON. Mr. Chairman, will my States rights friend from Massachusetts yield to me for a question?

Mr. MACDONALD. I would be happy to yield to my Republican friend.

Mr. WATSON. Mr. Larrick, earlier did I not understand you to say that recently even in the absence of the authority for you to examine these records, that most of the druggists cooperate fully—only two or three do not?

Mr. LARRICK. Fully.

Mr. WATSON. Well, that being true, why do you need this authority to examine the records, when presently those two or three who refuse to show you the records, you could, upon a proper showing, obtain a court order to examine that record, could you not?

Mr. LARRICK. The number of pharmacists is so great that the small percentage resulted in 1,100 cases in the Federal court.

Mr. WATSON. Yes, sir. But upon a proper showing, even if they refused to let you examine the records, under current law, you could obtain a court order to examine that record, could you not?

Mr. GOODRICH. I don't think so, Congressman—not unless they were charged with some offense, or you had a grand jury subpoena, or something of that kind.

Mr. WATSON. Wouldn't that be a proper showing, and a proper presentation for you to make, rather than indiscriminately to examine the records—to go ahead and show to the court there is the probability that a crime either has been committed or is being committed?

Mr. GOODRICH. Our concern is to try to pinpoint the points of diversion where the public is being hurt. And the inspection authority is for that purpose. The bill is to require a keeping of records from the

manufacturing level to disposition level, so that points of diversion can be located and the public protected.

The prosecution of the offenses might involve a grand jury subpoena. But inspections are to find out where violations have occurred, and hopefully to prevent them.

Mr. WATSON. Am I to understand—and this is the last question—that presently those druggists who refuse to let you examine their records, that you are totally without legal recourse, and you let them continue unabated?

Mr. LARRICK. No; I could not honestly say that.

By tortuous, involved procedures, by sending undercover people into the drugstore, by attempting buys, by watching the drugstore, and see who goes in, and by very expensive and involved procedures, we generally can make a case. This is an attempt to separate the sheep from the goats and do it in a painless fashion. We have the right to go into the manufacturer's establishment and look at his records completely. And it is not a reflection on him. It is an inspection process rather than criminal proceeding.

Mr. WATSON. Thank you.

Mr. LARRICK. Could I make one comment for Mr. Rogers?

We put in the section 10 "nothing in this Act shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery or other disposal of any drug in any State in contravention of the laws of that State."

We have tried to go along with States rights.

Mr. ROGERS of Texas. Thank you.

Mr. MACDONALD. Well, sir, in that case, don't pharmacies—and I ask this not by way of argument but just for information—don't pharmacies already have to comply with local statutes within the communities in which they do business, and also those of the State health bureau?

Mr. LARRICK. I would say that most detailmen from pharmaceutical houses go in and look at these prescription files without restriction. I would say that the narcotic inspectors have the power to go in and look at them. The State drug inspectors have a right to go in and look at them. The Alcohol Tax Unit people have a right to go in and look at them. It helps them with their enforcement activities.

And we would like to have the same help.

Mr. MACDONALD. I am not arguing that point. I am just asking you a question.

Mr. LARRICK. Yes; that is right.

Mr. MACDONALD. I take it from your answer, from your response to my question—I don't know if it is an answer or not—that local pharmacies are already obligated by law to be responsive to the wishes of the local community and of the State in which they operate.

Mr. LARRICK. It varies somewhat from State to State, but in general that is correct.

Mr. MACDONALD. Then why does the Federal Government need to act in this area? Are you saying that the local communities and the States are not doing their job properly?

Mr. LARRICK. No. I am saying that the local communities and the States and the Federal Government need to work together when a problem involves both interstate commerce and local commerce. And there is no point to your passing these wonderful laws that you have given

us over the years to deal with interstate commerce if the chain is broken at any point and the protection is denied to the ultimate consumer.

Mr. MACDONALD. For a concrete example—and this will be my last question, or statement—if a State tells you that a certain pharmaceutical house or a certain pharmacy seems to be breaking the law, do you mean to say that you don't already work together at this point?

Mr. LARRICK. No. We work together tremendously. In my testimony I told of cases where we worked with many States.

But let's just take one of the better implemented States that has pretty good laws in this direction. The funds available to them permit the employment of one pharmacy inspector.

Mr. MACDONALD. What State is that?

Mr. LARRICK. Indiana. We work very, very closely with the State. We have the closest cooperation. When the State inspector reports problems to us that are a federal obligation we look into them. But if this bill is made law—I haven't testified to this here—we could not discharge this increased obligation unless we have a tremendously increased group of people. We cannot discharge this obligation with the facilities we have.

The CHAIRMAN. I was going to get to that sooner or later.

Mr. LARRICK. But we would welcome anything the States can and will do; we are glad to help them.

Mr. MACDONALD. Well, I do not like to get ahead of my chairman, which I very rarely do.

The CHAIRMAN. Go right ahead.

Mr. MACDONALD. But I was wondering what increase in force would your department need to implement this law if it were passed?

Mr. LARRICK. If this law—if this bill becomes law, we will have an increased responsibility to regulate an estimated 1,000 firms who manufacture stimulant and depressant drugs, about 1,300 drug wholesalers, drug manufacturers, branch outlets, 52,000 retail stores, 6,900 hospitals, 1,700 public health agencies.

Now, those are the people that in general are law-abiding ethical folks.

Other outlets which also are ethical law-abiding people, but places where these drugs are kept, and from which diversion could occur, involve 230,000 physicians, 84,000 dentists, 15,000 veterinarians.

Now, in addition to that, we have the whole underground traffic—the bars, the truck stops, the houses of ill fame, and so forth.

Mr. MACDONALD. I read your testimony, sir. But I am asking how many people you would need.

Mr. LARRICK. To master that job, we would need to set up what amounts to a separate criminal investigatory group in the Food and Drug Administration which, in my judgment, would require in the neighborhood of \$10 million.

Mr. MACDONALD. And how many people would that require?

Mr. LARRICK. Approximately 500 people. I don't want to be held too closely to this until I see the form in which the bill passes, if it does.

Mr. MACDONALD. Thank you, Mr. Chairman.

The CHAIRMAN. The House is going in session. There is no legislative program. In order that we may get along with the hearings, the

committee will adjourn until 2 o'clock, at which time we would ask you to come back, Commissioner Larrick.

The committee will recess until 2 o'clock.

(Whereupon, at 12:05 p.m., the committee recessed, to reconvene at 2 p.m., the same day.)

AFTERNOON SESSION

The CHAIRMAN. I want to apologize for being delayed, but I was called into another session which lasted a little longer than I intended, and I just could not get away. I am sorry we detained you, Commissioner—and members of the committee.

I believe Mr. Younger is next. Do you have any questions?

Mr. YOUNGER. Yes; thank you, Mr. Chairman.

STATEMENT OF HON. GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WINTON B. RANKIN, ASSISTANT COMMISSIONER, AND WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL—Resumed

Mr. YOUNGER. Thank you, Commissioner, for a very fine and lucid explanation of the bill.

There are some inconsistencies, though, as I see them.

For instance, on page 6 you say, "The definition of the term 'depressant' or 'stimulant' drug does not include tranquilizers by name but if this bill is enacted we intend to see that those that have a potential for abuse are covered by regulation."

Now, in the report of the President's Advisory Commission on Narcotics and Drug Abuse, they definitely list elements of drug abuse and they enumerate them by name.

My point is, if they can do that by name, then why shouldn't those names be in the bill?

Mr. LARRICK. They could be put in the bill, Mr. Younger. First let me say that the statement in my testimony about some tranquilizers being included in what we would try to list was an attempt on our part to be quite fair and let the persons involved know that we do have that purpose. If the committee chooses to deal drug by drug, with very intricate scientific, medical and other matters that would be involved in an individual listing or with language more complex than my associate, Dr. Sadusk, used this morning in addressing himself to one of them, that certainly would be quite acceptable. But I think it would be placing a burden on this committee that would not be consistent with their broad responsibilities in other directions.

Mr. YOUNGER. Well, you gave as one of the reasons why you did not want to enumerate them because the manufacturers could not agree with your definition of the drug.

Now, we cannot write legislation that every manufacturer is going to agree to. We might as well start out with that premise.

Mr. LARRICK. Right.

Mr. YOUNGER. So that it seems to me that in preparing this bill, we ought to include all the drugs that we know of where there is

abuse—tranquilizers and all, as you mention a number of them in here classified as such.

Mr. LARRICK. We would be glad to give our views of the ones that we think there is enough evidence now to include. But this President's Advisory Committee was making a broad, general report. One of the drugs that they included was alcohol. Now, I would not be inclined to recommend that that be included.

Mr. YOUNGER. They have enumerated a lot of things that would not come under the purpose of this bill.

Mr. LARRICK. Right.

Mr. YOUNGER. Or this legislation. I am talking about only those under barbiturates, and then they give five other drugs in that classification, under barbiturates, which evidently are drugs that are subject to abuse.

Mr. LARRICK. Well, now, are those derivatives of barbiturates?

Mr. YOUNGER. No.

Mr. LARRICK. They are tranquilizers.

Mr. YOUNGER. Yes, they are tranquilizers.

Mr. LARRICK. They could be included by the committee or you could give persons who might not share that view an opportunity here to express themselves at length about this very complex scientific field, or if you care to you could delegate that to us. But we will leave that to you.

Mr. YOUNGER. I am more inclined to agree with Mr. Rogers, that where we can enumerate something in the act, we ought to enumerate it in the act, and not leave it to regulation by the Bureau of Food and Drug.

Mr. LARRICK. If you have the time to go into it—

Mr. YOUNGER. If possible, Mr. Chairman, I would like to have Mr. Larrick furnish us that information on these other drugs, tranquilizers, so that we can consider it when we write the bill, if he will do that.

The CHAIRMAN. Just what information do you have in mind? I am not clear.

Mr. YOUNGER. The enumeration of the tranquilizers by name, so it can be included in the bill, along with barbiturates and the derivatives of barbiturates.

The CHAIRMAN. I must confess that I do not know how far-reaching the term "tranquilizers" is.

Mr. YOUNGER. These are specific.

The CHAIRMAN. I presume there would be several hundred of them, would there not?

Mr. LARRICK. A great many.

Mr. CARTER. Mr. Chairman.

The CHAIRMAN. Dr. Carter. I am glad to have a doctor on this committee.

Mr. LARRICK. I am glad you identified him as a doctor.

Mr. CARTER. There are numerous tranquilizers, and certainly many of them are not habit forming. Neither do they have so many undesirable effects. We have discussed meprobamate, that it might be habit forming. Well, it might be. It has not been definitely proven that it is that way. We know that it is quite a useful drug. And the main objection I see to that is that it has been counterfeited in some

cases. Actually now it is given only on prescription, and is not bought over the counter—at least not in my State. It has to be prescribed first by a physician. And in doses such as most physicians give, it should not be harmful.

There are many tranquilizers, of course, some of the phenothiezenes, which have caused trouble. All manufacturers have to include that in their brochures on the subject.

I feel like the main intent of the bill rather should be toward the amphetamines and the barbiturates. To me those are the drugs which are more dangerous and should be regulated, as the chairman suggests.

The CHAIRMAN. Thank you very much, Dr. Carter.

Commissioner, I asked you this morning if you would furnish us such information as you have regarding some of these and you said you would be glad to if I furnished you the list. I have listed them in this memorandum which I will let you have.

Mr. LARRICK. Thank you.

The CHAIRMAN. You can give us such information as you may have that you feel would be advisable to give to the committee.

Mr. LARRICK. Thank you.

Mr. YOUNGER. Those are practically the same five that are mentioned in the President's Commission.

One other question, Mr. Larrick.

On page 13 you mention the arrest and conviction, and one defendant plead guilty and was fined \$200 and another one had a trial and got a 3-year suspended sentence. That seems like a pretty light fine or penalty, if that is all they would get.

Mr. LARRICK. I agree.

Mr. YOUNGER. That isn't very much of a deterrent.

Mr. LARRICK. I agree, Mr. Younger.

Mr. YOUNGER. When you are dealing in a product that potentially has thousands of dollars of profit.

Mr. LARRICK. Another case in California; one of the defendants got 17 years. There may have been some mitigating circumstances. I do not know all of the things that led the court to this conclusion. But we felt when we prosecuted the case we brought all the facts we had to the attention of the court, and our responsibility was terminated. Then his responsibility is to fix the penalty. I think that penalty was very light.

Mr. YOUNGER. You have no cases that have gone to the Supreme Court and the Supreme Court has turned them loose?

Mr. LARRICK. No, we have no case where the Supreme Court fixed the penalty. We have had cases in this general area that have gone to the Supreme Court dealing with the statutes that you gentlemen have passed through here, validating them. But outside of that, penalties have never gone beyond the lower court.

Mr. YOUNGER. Well, then, in this particular bill the penalties are more severe?

Mr. LARRICK. The penalties are more severe in the case of a sale by an adult to a minor. But the bill fixes a maximum penalty of a first offense of a thousand dollars and 1 year in jail, or if it is charged as a felony, a deliberate violation, a maximum penalty of 3 years in jail for each count and a fine of \$10,000.

Our general philosophy has been over the years that the courts are perhaps better prepared to fix penalties than are the prosecutors.

Mr. YOUNGER. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Van Deerlin.

Mr. VAN DEERLIN. Thank you, Mr. Chairman.

I wonder, Mr. Commissioner, if the problem raised by the chairman and Mr. Younger, and earlier by Mr. Rogers, does not perhaps find its root in section 3, paragraph 3 of the proposed legislation.

Any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have and by regulation designates as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect.

You specifically removed aspirin this morning, as an example, from the coverage of this legislation. Yet I recall in my very early years, before I moved on to more rugged stimulants, like sloe gin fizz, that aspirin combined with Coca-Cola could produce potentially antisocial behavior, and I wonder if a substitution of "evidence of abuse" rather than "potential for abuse" in this direction might cleanse the legislation so that some of the objections which are anticipated to it might be met.

Mr. LARRICK. Well, obviously that is a question to which the committee should give attention, and no doubt will.

Basically, since 1938 the legislation which this committee has taken the leadership in handling, under the protection of the public health and welfare, in the matter of foods, drugs and cosmetics, the basic philosophy that has gone through all that legislation has been to substitute prevention for punishment. The philosophy has been to set up the statute in such a way that it will prevent violations instead of punishing them after they are committed.

The philosophy of H.R. 2 is that philosophy which the committee has considered many times, and which was reflected in the message that President Kennedy sent to the Congress in his consumer protective message of March 15, 1962, where he recommended legislation which would—

establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines.

Then he called the White House conference that Mr. Younger referred to. In discussing the problems associated with these narcotics and other drugs, the President said, "One problem meriting special attention deals with the growing abuse of nonnarcotic drugs, including barbiturates and amphetamines. Society's gains will be illusory if we reduce the incidence of one kind of drug dependence only to have new kinds of drugs substituted."

Now, that is our reason for putting this on the basis of prevention rather than punishment after the fact.

Mr. VAN DEERLIN. Well, yes. I was not thinking of punishment. But I was thinking in terms of writing legislation.

It will be true, will it not, that there are literally thousands of drugs which if improperly used have the potential for producing antisocial behavior. Might it not be—

Mr. LARRICK. There are not that many that would be within the definitions of this statute, in my opinion, that would be capable of producing antisocial behavior. They would be numerous, but limited.

Mr. VAN DEERLIN. Do you agree that that word "potential" may be one of the pitfalls?

Mr. LARRICK. I do not think it is a pitfall, but I think it is highly argumentative.

Mr. VAN DEERLIN. Now, something of more concern to my district, Mr. Larrick. I represent an area which borders for many miles on Mexico. In the hard narcotics, the problem is one of importation of drugs from Mexico to the United States. The area that we are discussing in this legislation, the reverse is true. We have quite a threat posed by deliveries of drugs that are consigned to Mexico out of bonded warehouses in Los Angeles and in San Diego. There is absolutely no control over these trucked commodities after they leave the bonded warehouse. This is because they are shipped on consignment for foreign delivery, they are picked up at the bonded warehouse, perhaps 125 miles from the border, by a truck which may be owned and operated out of Baja California.

Narcotics agents in southern California tell me that they have repeated instances of the failure of these truck drivers to get to the border before they begin disposing of their delivery.

Mr. LARRICK. That is narcotics or barbiturates?

Mr. VAN DEERLIN. This is barbiturates, amphetamines, all the drugs that are prescription drugs on this side of the border, that may be sold without prescription on the other side.

Now, there is nothing in this legislation that would do anything about that.

I wondered if you had any proposals?

We obviously cannot assign agents to every truckload that goes out from the bonded warehouses. Must we move the warehouses near the border, or will it be possible to designate certain carriers that will be licensed for this?

Mr. LARRICK. We would be very glad to have any suggestions that you or any other members of the committee could offer to solve that problem.

We have had undercover agents and agents not under cover investigating that particular situation for a long time. We have been in touch with the narcotic agents to whom you refer. We have been in touch with the attorney general of your State, and with the enforcement officials in the State.

We have yet to be able to prove that there is a diversion of the barbiturates and amphetamines between the bonded warehouse and the border. We have been able to show that there are substantial amounts that go across the border, perfectly legally, because of the failure of restriction to our exports, and then leak back into this country.

We have been in touch with the Mexican authorities, the police, and the others who have the power to help us, and they are giving us a great deal of help.

I will say that these Mexican officials ask us the somewhat embarrassing question, "Why are you not concerned about the barbiturates and amphetamines that are shipped to Mexico? Why do you concern yourself exclusively with those that come back into this country?"

I don't know the complete answer to your question, except if this bill, by requiring a recordkeeping of the amounts and where they go and when, at every level of distribution, would give us a tool in tracing

these shipments and keeping abreast of it far better than we have now.

Today we learn about it after the fact.

If this bill were enacted, we would get those facts at any time that we went to the firms to get them, and could follow through and know there was this truckload going to be at the bonded warehouse, and we could be sure it went to Mexico.

My personal view is that maybe later we need to give broader consideration about some restrictions on what we permit for export.

Mr. VAN DEERLIN. Because there is no question, I believe, that teenagers and young people in southern California show a higher incidence of the use of these barbiturates and amphetamines than in other parts of the country.

Mr. LARRICK. I don't know whether it is a higher incidence or whether your law-enforcement officials are just doing a better job keeping track of it. There probably is a higher incidence, because we find that where you have the groups of Mexicans and minority groups, that the incidence of abuse of hard narcotics in these tends to be higher.

Mr. VAN DEERLIN. We have got some excellent statistics on non-minority neighborhoods where they have been available just across the street from the schoolhouse.

Mr. LARRICK. No question about it. Your comments are very well taken.

Mr. VAN DEERLIN. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Nelsen.

Mr. NELSEN. First I wish to thank Mr. Larrick for his usual, fine presentation.

I would like to pursue the point that was made by our chairman of that, relative to the competitive situation that may be developed by the identification of one product and the failure to mention other products of equal dangerous potential.

I notice in your statement, on page 2, you refer to—the second paragraph:

During the 84th Congress, the House Subcommittee on Narcotics again held hearings to consider the need for additional Federal legislation in this area. By that time the illegal distribution of the amphetamines had become a widespread problem, so the hearings covered them as well as barbiturates.

This indicated a need to expand the application of laws where new drugs appeared on the market.

And then on page 3, the last paragraph, reading from your statement:

While we have been discussing barbiturates and amphetamines almost exclusively, it is important to point out that this bill is aimed also at other types of drugs capable of causing similar or related ill effects, and there are a couple of such drugs already known to be misused to some extent.

This quote certainly admits equally dangerous drugs.

Then we turn to page 4, and there we find in the statement, quoting from the next to the last paragraph:

It becomes evident that the popularity of tranquilizers as suicidal agents must now rival that of barbiturates.

Then it further goes on in the last paragraph and points out the number of abuses in these other related products.

So it seems to me that then also taking the President's report here, and the graph, which I have here, which shows the related items that are of equal application—would seem to me that there is a just reason to be concerned by those who may be a legitimate and pharmaceutical firm of competitive problems where one is identified and another is not.

I think you have already covered that and the chairman has covered it. It would be my suggestion that you should give some thought to broadening the identification or using a more general term that would encompass all of them. I hope that FDA will recognize this potential problem.

Mr. LARRICK. Right. That's a very good comment.

You realize, all of you—some people thought perhaps my testimony was to the effect that we would take these drugs off the market. We are not going to take these drugs off the market from the standpoint of their legitimate use by doctors.

Mr. NELSEN. I understand.

Of course my feeling would be this. If I were a competitor and the law specifically mentions barbiturates and amphetamines and the firm I represented sold an equally dangerous drug certainly I would immediately take advantage of the fact that that language points to one or two items while the others that might be just as dangerous are not included, and I would be foolish if I did not use that as an argument when I was selling my product.

So I think your objective, I am sure, would be like ours—that you would want your testimony and you want this bill to be fair in every respect, as much as we can.

Of course, there are always the opportunities for distortion, I presume, no matter how we write the language.

Mr. LARRICK. Thank you, Mr. Nelsen. I thoroughly agree with you.

Mr. NELSEN. Thank you very much.

The CHAIRMAN. Mr. Satterfield.

Mr. SATTERFIELD. Thank you Mr. Chairman—Mr. Larrick, I notice on the first page of your statement you refer to 311 convictions under the present inadequate Federal law. Were these convictions obtained by your particular department?

Mr. LARRICK. Yes, sir.

Mr. SATTERFIELD. And were they for selling without prescription?

Mr. LARRICK. Selling drugs restricted to prescription sale without a prescription.

Mr. SATTERFIELD. Am I correct, that what is being sought in this bill is to enlarge the jurisdiction of your department beyond sales by prescription to include control at the point of manufacture as well as in transportation?

Mr. LARRICK. To carry it through the whole channel of distribution from manufacturer clear up to final sale to the consumer, but exempting over-the-counter drugs from this bill altogether.

Mr. SATTERFIELD. And would it exempt those hard narcotics that are handled now by the Bureau of Narcotics?

Mr. LARRICK. It would not change their status. It would leave the control of narcotics in an agency which in my opinion is and has been doing an excellent job and would not change their responsibility or authority at all.

Mr. SATTERFIELD. In other words, you would be doing with these drugs that do not classify as hard narcotics, the same thing that the Narcotics Bureau is doing with the hard narcotics.

Mr. LARRICK. Not quite the same thing, because the narcotic law imposes much more detailed restrictions on the distribution of the drugs that they handle. Every doctor who prescribes a narcotic drug has to be licensed. The whole procedure is controlled with great meticulousness in every area. They have to get licenses to manufacture. They only have very few who can manufacture the basic narcotic, and a limited number that can compound it into others. And every step of it is policed with infinite care.

Now, control under H.R. 2 would be a less arduous control. No one has to send their records to us except the wholesalers have to register. The manufacturers have to register now.

But in general they have to keep the records. They do not have to be licensed. And they would not have to send records to us. But they would have to make them available to us when we call for them.

But in many particulars, this is a less arduous type of control, compared to the narcotic control.

Mr. SATTERFIELD. That's all, Mr. Chairman.

The CHAIRMAN. I'm sorry. What did you say about over-the-counter drugs?

Mr. LARRICK. Over-the-counter drugs are exempted.

The CHAIRMAN. Exempted?

Mr. LARRICK. In this bill, if we reached the conclusion that a drug intended to be dealt with here, had the potential for harm and misuse, we would put it under prescription under the authority we now have and therefore we would not need to cover over-the-counter drugs.

The CHAIRMAN. Is Miltown an over-the-counter drug?

Mr. LARRICK. No, sir; it is not.

The CHAIRMAN. Mr. Cunningham.

Mr. CUNNINGHAM. No, thank you, Mr. Chairman, I have no questions.

The CHAIRMAN. Mr. Ronan.

Mr. RONAN. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Harvey.

Mr. HARVEY. I just have one question, Mr. Chairman.

Mr. Larrick, what authority does your organization have at the present time regarding the over-the-counter drugs? You can designate which ones are prescription drugs and which ones are not prescription drugs?

Mr. LARRICK. We had no power in dealing with the drug that is an old drug—that is a drug that was on the market before 1938, until the Durham-Humphrey Act passed this committee and the Congress. The latter act specifies the conditions under which a drug must be dispensed on prescription. We express an opinion as to whether or not it is an over-the-counter or a prescription drug. For the most part our opinions have been observed.

But any new drug—and that covers the great gamut of drugs today—in the new drug applications, we have the right to tell the applicant that in our judgment it is not a safe drug for sale unless it is put on prescription. For all practical purposes, our decision in that matter is binding. Manufacturers have the right to challenge it and can

have a hearing, they can build a record, and they can go to the court. But as a practical matter, on a day-in-and-day-out basis, the authority that we have exercised has been controlling.

Mr. HARVEY. Let me ask this second question.

Does your organization have any comparable grant of authority at the present time as would be spelled out here on page 3 of this bill within the definition of depressant and stimulant drugs, where the language is very broad—for example, in section (c), page 3, line 6, you speak of—

any substance which the Secretary after investigation has found to be and by regulation designated as "habit forming" because of its stimulant effects—

and going on—

any drug which contains any quantity of substance which the Secretary after investigation has found to have and by regulation designates as having potential for abuse.

Do you have any comparable grant of authority at the present time where the Secretary can designate the particular drugs?

Mr. LARRICK. Yes, sir. We have that type of authority delegated by the Congress in many areas. We have it with regard to foods and drugs. In the first place, you cannot put a new drug on the market at all unless you can satisfy the Food and Drug Administration that the drug is both safe and effective. But again, this committee wrote in safeguards so that the man that is aggrieved can build his record and carry the case to court and see if our decisions were proper.

But all through, on the question of what substances can be added to food, what is a habit-forming drug now that must bear the warning "Warning, may be habit forming" and in many other sections of the act, even dealing with whether or not a tolerance can be fixed for a pesticide.

I assume because these problems are so technical and so involved that Congress has seen fit to delegate very broad grants of authority to the Department, and then to attempt to surround them with safeguards that would limit our bureaucratic activity if we indulged in it.

Mr. HARVEY. Thank you. I have no further questions, Mr. Chairman.

The CHAIRMAN. I'm sorry, Mr. Broyhill, I apologize for passing you up.

Mr. BROYHILL. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Gilligan.

Mr. GILLIGAN. Mr. Chairman, I have just one question for Mr. Larrick.

You made reference on page 15 of the drafts of the bill—I would agree that what we are being given are additions to existing language which I do not have before me.

If such establishment is engaged in the manufacture, preparation, propagation, compounding, processing of any depressant or stimulant drug, such person shall at time of registration indicate such fact.

Do all persons presently engaged in the manufacture, preparation, propagation, et cetera, of drugs—are they now required to register?

Mr. LARRICK. Yes, sir. That was part of the Harris bill of 1962.

Mr. GILLIGAN. Does this registration amount to licensing?

Mr. LARRICK. No, sir; it does not. It is largely a catalog of firms that are engaged in this business. It means that a firm cannot start up in this business without notifying us. It gives us an opportunity to know where to go to make inspection. It provides a means by which the vendors of drugs that can only be sold to people legitimately in the drug business can look and get a pretty good indication that this fellow is registered and therefore he is in the drug business.

Mr. GILLIGAN. Well, then, for instance, repeated violations on the part of a manufacturer, let's say, who is pumping out vast quantities of these drugs and marketing them in ways that are unsatisfactory to the Food and Drug Administration, the registration or licensing—there being no licensing, the license cannot therefore be lifted.

Mr. LARRICK. No, sir. We would have to go to court and seek to enjoin. The burden would be on us to seek to enjoin.

Mr. GILLIGAN. I see. It occurred to me because there are provisions later about the seizure of vehicles, the seizure of equipment, and so forth, that those strictures are somewhat more onerous on the purveyors, transporters, pushers of these things than are those on the manufacturer.

Mr. LARRICK. You may have a very good point there, Mr. Gilligan. We think—

Mr. GILLIGAN. I am not suggesting that you seize plants now.

Mr. LARRICK. If you gentlemen decide to adopt this bill or a similar bill—we would be better able to take care of situations such as we found in New Jersey recently. A counterfeiter was operating in a hidden room behind movable stairs leading to a recreation room. There was a small drug plant in that room with mixing and tableting equipment—all the equipment needed to make these pills. While we could not seize the recreation room, under this bill, we could seize everything in there that they used to make the drug. And I believe such authority would be a tremendous help. If the counterfeiters can keep the basic equipment, then they just move it and start manufacturing again.

The CHAIRMAN. Will the gentleman yield at that point?

Mr. GILLIGAN. Surely, Mr. Chairman.

The CHAIRMAN. Under present law can't you get to that situation?

Mr. LARRICK. We cannot seize equipment. In the first place, it is not interstate. We do not have the power to seize equipment. We cannot even seize the pills that we find in that man's hidden basement because they never did move in interstate commerce. But under this bill, we could.

The CHAIRMAN. Well, recently I saw, and you refer to it in your statement, that you located a cache of amphetamines or barbiturates, or whatever they were—over a million of them, I think. How did you get them?

Mr. LARRICK. Well, we got—

The CHAIRMAN. The thing I want to clear up is this. I think there should be a greater clarification of what you cannot do under present law and what you can do if we give you this extension.

Now, I am not at all satisfied that you have done all you can do under present law in every circumstance.

Mr. LARRICK. Well, that's probably right, because we are probably not ingenious enough.

The CHAIRMAN. I think we ought to be very clear about it. I think if we are going to make a record we might as well make the record so that not only the public, who is interested, but the industry who is involved—and that vast majority, as you referred to them this morning, of people who do not engage in the so-called violations. Consequently, as you know it has been my feeling for the last several years, that your agency could be a little more firm and have gotten to a little more of these violations if you had pursued it.

Now, I am inclined to think that maybe the problem is the lack of personnel and money to employ the personnel, as much as it is the lack of authority that you contend.

Now, that is a lot in one paragraph.

But I want to be clear in my own mind that the Department of HEW and your great agency are going and have done all you can with the law that you have.

Mr. LARRICK. First let me say that I think very definitely we will need more money and more facilities as these technical problems grow. I do not think any group would be wise to claim that they are perfect in the administration of the law or anything else.

But I can assure you we try very hard to use the full power of the statutes and the rules that you give us, and the full facilities that our friends on the Appropriation Committee—

The CHAIRMAN. There is no limitation under present law upon the money that you are authorized to get, is there?

Mr. LARRICK. Yes. We are prohibited by law to ask for more than the budget authorizes.

The CHAIRMAN. Well of course that is a budget matter. I am talking about what the law is.

Mr. LARRICK. Congress can do what they want to do; yes, sir.

The CHAIRMAN. I know that. But you would be in the same situation if we gave you authorization to go shoot everybody that dispensed these drugs. You would still have to have a budget that would come up from downtown.

Mr. LARRICK. Right.

The CHAIRMAN. Now under present law if your budget would include funds for the personnel and you had 500 additional people to put out to catch these so-called thugs and criminals and would-be violators, you could accomplish a whole lot more under present law than you are accomplishing, could you not?

Mr. LARRICK. We could accomplish more, though we would still fall very far short of doing the job for the public that we could do with this bill.

The CHAIRMAN. Well—

Mr. LARRICK. This bill or something like it is very necessary to protect the public health in this situation.

The CHAIRMAN. Well, now, would I be correct to say that what you need is this additional authorization so you can get at the root of the evil?

Mr. LARRICK. I think that would be a very fair statement—so that we could get at intrastate commerce as well as interstate commerce, so that our inspectors can arrest these people when they commit the crime and not have to go back and try to get a warrant and find later that the culprits have skipped out, so that illegal pills that we find in

the trunk of a car can be detained while we go back to the court and get an order to seize them—I think this bill would improve our efficiency very, very greatly. But we would definitely have to have the facilities to enforce it.

The CHAIRMAN. Well, I must confess that I get a little bit confused about this intrastate problem that you have mentioned innumerable times. The Constitution does not give the power of Congress to pass laws that would affect purely and solely intrastate operations.

Mr. LARRICK. Well, I'm certainly not going to argue as a layman with a very distinguished lawyer about constitutional law. But there have been a number of laws passed, one of them in the Food, Drug, and Cosmetic Act, that deals with margarine that you will recall. It is based on the philosophy that if the practice complained of in intrastate commerce, either the railroads, as you know a great deal about, or in commodities is such a burden on the interstate article, it then can be controlled under the Federal Constitution. Now, that is what my lawyers have advised me as a fact.

Mr. YOUNGER. Will the gentleman yield?

The CHAIRMAN. I have taken your time, and I am sorry, Mr. Gilligan.

Mr. YOUNGER. Will the gentleman yield for one question?

Mr. GILLIGAN. Certainly.

Mr. YOUNGER. I do not understand, when you say that you go into a place and find a quantity of these drugs, and you cannot do anything because those pills have not moved in interstate commerce. Is that what you say?

Mr. LARRICK. Yes. If the article—

Mr. YOUNGER. Just a minute. Then we are agreed on that. But where does the material come from that made the pills?

Mr. LARRICK. If we can prove the material came in interstate commerce—and that goes to the heart of one of Mr. Harris' questions—as we can occasionally, then we have jurisdiction and assert it.

Mr. YOUNGER. Or where the machinery comes from.

Mr. LARRICK. Even if we know—the statute covers foods and drugs and cosmetics and hazardous household substances. It gives us no authority up to now at all over the machinery, to confiscate it.

Mr. YOUNGER. If the machinery is in interstate commerce, according to the rules that we have had in some of these bills, then the product is in interstate commerce. It is the same as the little drugstore; if they sell something manufactured outside the State they are in interstate commerce.

Mr. LARRICK. If you put this type of machinery under the statute, we can seize it. But as of now, the statute does not deal with machinery.

Mr. YOUNGER. Then that ought to be in the bill, too.

Mr. LARRICK. It is in the bill with respect to equipment used to counterfeit drugs.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Any further questions, Mr. Gilligan?

Mr. GILLIGAN. Just one more, Mr. Chairman.

On the business of counterfeit drugs, they are so defined as drugs which carry the trademark, trade name, or other identifying mark, imprint, device, and so forth.

Suppose I were to, with the help of a chemistry major, go into the manufacture in my basement of something which I would simply call superduper goofballs. It would have amphetamine or some other hallucinatory drug in them. Could you presently come under existing law, do anything to prevent me from continuing the manufacture and dispensing of these?

Mr. LARRICK. Would you sell them outside the State or buy your raw materials outside the State?

Mr. GILLIGAN. Let's assume I do not. I purchase the drugs at a local drug house—although I suppose many of them can be traced overseas or something eventually.

Mr. LARRICK. If your raw materials came from outside the State or if your finished materials move outside the State and you conducted the type of operation you have described, you would not have registered under the statute—that is a criminal act. We probably would find that your manufacturing controls were not adequate and that is a criminal offense under the statute. We probably, analyzing your materials, would find that they were not up to the potency or were contaminated with bacteria or were dangerous, and that would be a violation of the statute. Under circumstances that you recite I think that using the ingenuity that the chairman is always asking us to use we would find some way to prosecute you.

Mr. GILLIGAN. I wouldn't attempt it, then.

Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Carter?

Mr. CARTER. No questions.

The CHAIRMAN. Mr. Larrick, although you have presented a very good statement, and I share the comments of other members in complimenting you for it, and although you have presented for the record, I believe, a three-and-a-half-page brief and analysis of the bill, some question was raised this morning about the exemptions.

Now, what does the bill provide, exempt everybody and then turn around and have a protest which if they do certain things they are brought under it? Is that the procedure? Maybe Mr. Goodrich would want to talk to this.

Mr. LARRICK. I do not follow the question.

The CHAIRMAN. Well, take section 511 on page 4. The section starts out "no person shall manufacture, compound or process a depressant or stimulant drug" and so forth, except this prohibition shall not apply to the following persons. And then the bill says who the prohibition shall not apply to. That goes clear on through page 6. Is that just a drafting technique?

Mr. LARRICK. Yes, sir. This is a technique as I understand it designed to let the record show conclusively who is entitled to deal in these drugs without being bothered by the Government.

Mr. GOODRICH. The overall purpose is to define the legitimate channels of commerce and to restrict these drugs within those channels and make possession outside the channels an offense.

The CHAIRMAN. I thought we already had that under present law.

Mr. LARRICK. No, sir.

The CHAIRMAN. You mean anybody can go into the manufacture of drugs now if they want to?

Mr. GOODRICH. No; under the law we passed in 1962 he has to register and a few other things. But there is no licensing provision, there is no restriction on the type of person.

The CHAIRMAN. Well, he has to register and then he has to comply with all the requirements as to the product he is manufacturing.

Mr. GOODRICH. He has to have good manufacturing practices and the other factors that we had in there. But there is no specification as to who may legitimately possess these drugs.

Mr. LARRICK. This deals with possession primarily.

The CHAIRMAN. What I am trying to get at is this: Are we adopting a new procedure with reference to anyone who might want to go into the manufacture or processing of the drug?

Mr. GOODRICH. We are specifying here the legitimate persons who can have them at each level.

Now, under existing law there are some regulations under 502(f) (1), failure to bear adequate directions for use of drugs, which in a general way cover this same thing, but not in terms of the specificity that we have here.

Mr. LARRICK. And we are putting in law something that in the other case is in the regulation.

Mr. GOODRICH. Right.

The CHAIRMAN. In other words, you are saying a man who is regularly engaged, who has registered, or who is in the legitimate channels of distribution is exempted.

Mr. GOODRICH. Right.

Mr. LARRICK. So long as he continues to do business only in legitimate channels and with legitimate doctors.

The CHAIRMAN. And the same approach to the wholesaler, the wholesale druggist, and the pharmacist, hospitals, and so forth.

Mr. GOODRICH. Right.

The CHAIRMAN. I believe you said that you have not had any consultation with the Department of Justice.

Mr. LARRICK. On that one point of confiscation of automobiles. That was the point I believe that the Budget Bureau thought they would be concerned with.

The CHAIRMAN. Well, I was somewhat intrigued with the suggestion you had this morning to give you the authority when you found an automobile that we being used, to take it and start using it for your own.

Mr. LARRICK. That is an imitation of what is in the statutes dealing with narcotics and bootleg liquor. They have that power now.

The CHAIRMAN. They have the authority now?

Mr. LARRICK. I think the language—

The CHAIRMAN. If they seize an automobile that is engaged in narcotics traffic then under the law they can refuse and usually do to return it back to the person. But I thought that they had to sell it or dispose of it by sale at public auction.

Mr. LARRICK. Years ago the Secretaries of this Department used to get their cars through this procedure, from the Narcotic Bureau. The General Services Administration would exercise general supervision over all cars, no matter how procured. And they would say what happened to these cars. They could say they would be assigned to a

Government agency, or they could say they would be sold. If they felt it was an economy to the Government to use them, they would turn them over to them.

The CHAIRMAN. That is revealing.

Commissioner, thank you very much for your patience and your presence here today, together with your associates. We appreciate the thorough discussion you have given us on this subject. If there are any other questions that arise during the course of the hearings, we will suggest to you later meetings.

Mr. LARRICK. I thank you very much for the usual very pleasant hearing which always is a great challenge to one's knowledge of the subject, because you sure go into it in depth.

The CHAIRMAN. Well, thank you very much. We hope to make a good record.

(The following letter was received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
FOOD AND DRUG ADMINISTRATION,  
Washington, D.C., February 8, 1965.

Hon. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives,  
Washington, D.C.

DEAR MR. CHAIRMAN: AS YOU requested at the hearing on H.R. 2 on January 27, 1965, we are supplying for the record: (1) information on the drugs Glutethimide, methyprylon, ethchlorvynol, ethinamate, meprobamate, and clordiazepoxide and (2) a precise definition of barbiturate and amphetamine.

I. Question: Are these six drugs similar to barbiturates and amphetamines in therapeutic use? Chemical structure? Physiological effects?

(a) Therapeutic use and physiological effects?

All six subject drugs are central nervous system depressants and in this respect resemble the barbiturates in that they lower the level of central nervous system excitability. Because of some of the undesirable side effects of the barbiturates, such as physical and psychic dependence, "hangovers," paradoxical excitement, and suicidal attempts, some of the nonbarbiturate hypnotics and sedatives were developed. Glutethimide, methyprylon, ethchlorvynol, and ethinamate fall into this group of nonbarbiturate depressants. These four sedative-hypnotics are somewhat less potent central depressants than the barbiturates. Patients who are unable to take barbiturates or react poorly to them may be able to take the newer non-barbituric-acid derivatives. It will be noted that chronic use of all these drugs produces incoordination, impaired judgment, and drowsiness.

The barbiturates act as sedative-hypnotic-anesthetic agents. Glutethimide, methyprylon, ethchlorvynol, and ethinamate resemble the barbiturates as sedative-hypnotics. Taken at bedtime, they relieve insomnia, and administered during the day in small doses, they reduce restlessness and emotional tension. In larger doses, they may produce deeper degrees of depression.

Meprobamate and clordiazepoxide are used as "tranquilizers" implying they lower the level of central nervous system excitability without interfering with the patient's sensorium. They are further classified as "minor" tranquilizers, in that they are useful mainly for the symptomatic treatment of the common psychoneuroses and as adjuncts in somatic disorders complicated by anxiety and tension. (They are not effective for control of severely disturbed psychotic patients, as are "major" or more potent tranquilizers, i.e., the phenothiazines.)

The six subject drugs are not similar to amphetamines, which are central nervous system stimulants, raising the level of central nervous system excitability. Amphetamines are classified as sympathomimetic amines in that they mimic the actions of the sympathetic nervous system, but their central effect is more prominent than their peripheral autonomic effect. Ampheta-

mines, therefore, have a totally opposite effect than the six drugs cited above, in that they cause increased wakefulness, attentiveness, and alertness. They also act to suppress the appetite, and are used as an adjunct in the management of obesity. Because of the increased sense of euphoria produced by the amphetamines, they have been widely used in the treatment of depression and alcoholism. They may also be used in the management of narcolepsy, postencephalitic parkinsonism, and as analeptics to overcome the depression caused by overdosage of some of the sedatives. Drug abuse and psychic dependence on the amphetamines may occur in individuals with unstable personalities. These drugs are contraindicated in states of hypertension, cardiovascular disease, hyperthyroidism, hyperexcitability, and agitated prepsychotic states.

(b) Chemical structure.

None of the six subject drugs resembles amphetamine chemically.

The barbiturates feature a nitrogen-containing heterocyclic ring. A different nitrogen-containing heterocyclic ring is found in chlordiazepoxide, glutethimide, and methyprylon. Meprobamate and ethinamate contain the carbamate moiety giving some chemical resemblance to the nitrogen-containing ring of the barbiturates. Any chemical resemblance that exists, however, is not sufficient to regard any of these six as belonging to the barbiturate class of drugs.

II. Question: Are these drugs addictive? Do they cause physical dependence? Are they habituating?

All six of the subject drugs cited apparently may produce habituation and addiction, as defined by the World Health Organization. (See attached WHO definitions.) Sudden withdrawal of any of these drugs after chronic use at high dosage level produces withdrawal symptoms similar to those occurring after barbiturate withdrawal, e.g.:

- (1) Excitement.
- (2) Gastrointestinal symptoms.
- (3) Delirium.
- (4) Hallucinations.
- (5) Delusions.
- (6) Convulsions.
- (7) Cardiovascular collapse.

For information on the physiologic effects and addiction potentials of the six drugs cited, there is attached an information sheet for each drug.

Also attached is a copy of an article by Dr. Carl F. Essig of the National Institute of Mental Health which was published in "Clinical Pharmacology and Therapeutics," May-June 1964, describing the addictive properties of these six drugs.

III. Question: Do the manufacturers who make these drugs also make barbiturates and amphetamines?

In regard to the question "Do the manufacturers who make these drugs also make barbiturates and amphetamines?", a search of the available publications listing drug distributors indicates that the Eli Lilly Co. (ethinamate), Ciba Pharmaceutical Co. (glutethimide), Abbott Laboratories (ethchlorvynol), and Wyeth Laboratories (meprobamate) distribute one or more barbiturates and one or more products classified as sympathomimetic agents, though not necessarily amphetamine. Roche Laboratories (methyprylon and chlordiazepoxide) is listed as a supplier of at least one barbiturate; Wallace Laboratories (meprobamate) markets a product containing dextro-amphetamine in combination with meprobamate, and Riverton Laboratories, another manufacturer of meprobamate, is not listed in these sources as a supplier of barbiturates or amphetamines.

We have not determined whether these firms manufacture the barbiturates and sympathomimetic agents which they supply.

IV. Question: What is the precise definition for the record of: Amphetamines? Barbiturates?

(a) Amphetamine is a substituted beta-phenylethylamine having sympathomimetic effects. Its central nervous system stimulating effect is prominent, permitting its use as an analeptic and also leading to its abuse. This stimulating action is present in its chemical isomers (particularly the dextro form) and in chemically similar sympathomimetic amines such as methamphetamine.

(b) A barbiturate is a substituted derivative of barbituric acid (malonylurea) having central nervous system depressant properties with clinical usefulness as a sedative, hypnotic, or anesthetic.

We hope this information will answer the committee's questions.

Sincerely yours,

GEO. P. LARRICK,  
*Commissioner of Food and Drugs.*

The World Health Organization defines addiction:

"Drug addiction is a state of periodic or chronic intoxication detrimental to the individual and society, produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include:

"(1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;

"(2) A tendency to increase the dose; and

"(3) A psychic (psychological) and sometimes a physical dependence on the effects of the drug" (WHO Technical Report Series 21, 1950).

Definition by the WHO Expert Committee on Drugs Liable To Produce Addiction: "Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include:

"(1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;

"(2) A tendency to increase the dose;

"(3) A psychic and generally a physical dependence on the effects of the drug; and

"(4) An effect detrimental to the individual and to society."

"Drug habituation is a condition resulting from the repeated administration of a drug. Its characteristics include:

"(1) A desire (but not a compulsion) to continue taking the drug for the sense of improved well-being that it engenders;

"(2) Little or no tendency to increase the dose;

"(3) Some degree of psychic dependence on the effect of the drug, but absence of physical dependence and hence of an abstinence syndrome; and

"(4) A detrimental effect, if any, primarily to the individual" (JAMA, 163: 1622, 1957).

(In addiction, there is physical dependence; in habituation there is psychic but no physical dependence. *Am. Pract. & Digest Treat.*, 8: 1100, July 1957, H. G. Sahl.)

The addiction syndrome includes: physical dependence, psychologic dependence, and the development of tolerance. (F. L. Fancett, *Proc. Staff Meetings, Mayo Clinic*, 33: 45, 1957.)

WHO Technical Report Series No. 273, "WHO Expert Committee on Addiction-Producing Drug," 13th report, 1964. Page 9, Terminology in Regard to Drug Abuse:

"Drug dependence" is defined as a state arising from repeated administration of a drug on a period or continuous basis \* \* \*. The Expert Committee recommends substitution of the term 'drug dependence' for the terms 'drug addiction' and 'drug habituation.'"

Page 13, under "Types of Drug Dependence":

"Drug dependence of morphine type \* \* \*. The abstinence syndrome is the most characteristic and distinguishing feature of drug dependence of morphine type.

"Drug dependence of barbiturate type \* \* \*. The abstinence syndrome, etc.

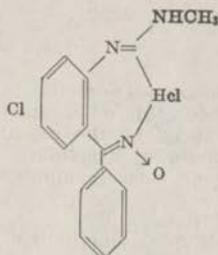
"Drug dependence of cocaine type \* \* \*. (no physical dependence, so no abstinence syndrome).

"Drug dependence of amphetamine type \* \* \*. (no physical dependence or abstinence syndrome).

"Drug dependence of cannabis type \* \* \*. (marihuana) no physical dependence."

## CHLORDIAZEPOXIDE

(Librium, manufactured by Roche; also in combinations such as Librax)

*Chemical structure**Action and uses*

Relief of anxiety and tension; injected, for relief of agitation and hyperactivity. E.g.: tension headache, preoperative and postoperative apprehension, premenstrual tension, chronic alcoholism, behavior disorders in children, and "whenever anxiety and tension are concomitants of gastrointestinal, cardiovascular, gynecologic, or dermatologic disorders," hysterical and panic states, psychoses, drug withdrawal symptoms.

*Side effects*

Drowsiness, ataxia, syncope, paradoxical reactions (excitement, stimulation, elevation of affect and acute rage), rashes, nausea, change in libido, agranulocytosis and hepatic dysfunction. "Withdrawal symptoms following discontinuation of therapy have not been reported when recommended dosages have been employed; however, abrupt cessation after prolonged overdosage (300 to 600 milligrams daily for more than 5 months) has produced withdrawal symptoms similar to those seen with barbiturates or meprobamate (including convulsions). Caution must therefore be exercised in administering the drug to individuals known to be addiction-prone, or whose history suggests they may increase the dosage on their own initiative."

*Precautions*

In the elderly limit dosage to preclude ataxia or oversedation. "As is true of all CNS-acting drugs, until the correct maintenance dosage is established, patients should be advised against possibly hazardous procedures requiring complete mental alertness or physical coordination. In general, concomitant administration with other psychotropic agents is not recommended \* \* \*." Possible combined effects with alcohol. "The usual precautions in treating patients with impaired renal or hepatic function should be observed."

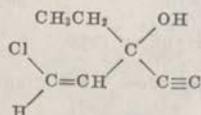
*Dose*

Oral: 5-10 milligrams t.i.d. or q.i.d. up to 20-25 milligrams t.i.d. or q.i.d. Children.

Parenteral: 50-100 milligrams I.M. or I.V. initially—followup doses. Need to individualize.

## ETHCHLOVEYNOL

(Placidyl, manufactured by Abbott)

*Chemical structure**Action and uses*

"A nonbarbiturate hypnotic-sedative \* \* \* used as a hypnotic to treat insomnia due to mild nervous tension, anxiety, or excitement, and as a daytime sedative in the management of mild anxiety and tension states. It is often used preoperatively and also as a sedative during labor. It is particularly useful when barbiturates are contraindicated or not desired."

*Precautions*

"Habituation may develop. In cases of prolonged administration, physical dependence may be evidenced by withdrawal symptoms upon sudden discontinuance of this drug. Thus, the drug should be gradually tapered off rather than abruptly withdrawn. An exaggerated response may occur when the drug is administered along with alcohol or other sedative-hypnotic agents."

*Overdosage*

(Only treatment of acute overdosage discussed.) "Pentylentetrazol has been shown to be the analeptic of choice \* \* \*."

*Side effects*

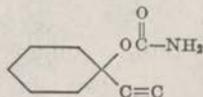
"Hangover" discussed, nausea, syncope, mild excitation.

*Dosage*

500 milligrams h.s. for hypnosis. For daytime sedation: 100 milligrams b.i.d. to 200 milligrams t.i.d. for adults. As a premedicant: 200 to 500 milligrams the evening before surgery. As a sedative in labor: 500 or 1,000 milligrams at the onset of labor followed by 1,000 milligrams in the hospital after routine preparation for delivery.

## ETHINAMATE

(Valmid, manufactured by Lilly)

*Chemical structure**Action and uses*

"For simple insomnia caused by mental unrest, excitement, fear, worry apprehension, or extreme fatigue." Sedative. Not a barbiturate and not habit forming, according to the manufacturer.

*Side effects and precautions*

Occasional physical dependence by emotionally disturbed persons. "In such instances, when the medication was abruptly discontinued, withdrawal symptoms were observed, including convulsions." Therefore, if patient has been taking overdoses, withdraw slowly and gradually. Mention of abuse.

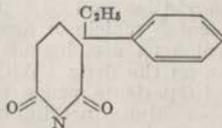
Not suitable for continuous daytime sedation.

*Dosage*

One or two tablets 15 to 20 minutes before retiring—some patients require more (tablets are 0.5 gm.).

## GLUTETHIMIDE

(Doriden, manufactured by Ciba)

*Chemical structure**Action and uses*

"An orally effective nonbarbiturate sedative for nighttime, daytime, and preoperative sedation \* \* \* duration of action is short—4 to 8 hours. Thus, it rarely causes 'hangover.' In recommended dosage, glutethimide does not cause respiratory depression (a particular advantage in preanesthetic sedation) \* \* \*."

*Precautions*

"Careful supervision of dosage is advised, especially for patients with a known propensity for taking excessive quantities of drugs. Excessive and prolonged use of glutethimide in susceptible persons (e.g., alcoholics, former addicts,

and other severe psychoneurotics) has sometimes resulted in dependence and withdrawal reactions \* \* \*."

#### Overdosage

(Long discussion.) "Effects of glutethimide are exaggerated by alcohol and other sedatives." Acute, chronic overdosage \* \* \*. "Available information indicates that abrupt discontinuance of glutethimide after prolonged overdosage will, in most cases, cause withdrawal symptoms. These symptoms range from anxiety to grand mal seizures, and include abdominal cramping, chills, numbness of extremities, and difficulty in swallowing." Treatment of chronic glutethimide intoxication discussed \* \* \* stepwise reduction \* \* \*. "Phenothiazines, anticonvulsants, and short-acting barbiturates have been administered during the period of withdrawal, but clear advantages of this therapy have not been shown."

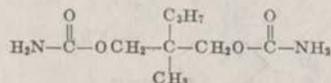
#### Dosage

Insomnia, 0.5 gm. h.s. Daytime sedation, 0.125 to 0.35 gm. t.i.d. after meals. Total daily dosage above 1 gm. is not recommended for continuing therapy.

#### MEPROBAMATE

(Equanil, manufactured by Wyeth; Miltown, manufactured by Wallace; Meprospan, manufactured by Wallace; Mepro tabs, manufactured by Wallace; also exists in many combinations with other drugs, such as d-amphetamine, hydrochlorothiazide, decadron, etc.)

#### Chemical structure



#### Action and uses

**Equanil:** Anxiety control and skeletal muscle relaxation. Tranquilizing action different from the barbiturates. No side effects such as depression, undue sedation, bizarre extrapyramidal reactions. Also used as an anticonvulsant, as in petit mal epilepsy. Not of proven value in grand mal and may sometimes precipitate grand mal attacks in persons susceptible to both grand and petit mal. "Although not a hypnotic, Equanil fosters normal sleep through both its antianxiety and muscle-relaxant properties."

**Miltown:** Effective in anxiety and tension states, muscle relaxant in orthopedic and rheumatic conditions and in certain neurological conditions such as cerebral palsy. Sometimes used as an anticonvulsant agent in petit mal epilepsy. Although not a hypnotic, fosters normal sleep, etc. Supportive therapy of the alcoholic.

#### Important precautions

**Equanil:** Excessive and prolonged use in susceptible persons has been reported to result in dependence on or habituation to the drug. Reduce dosage slowly if it has continued for weeks or months. Patients on meprobamate may have lowered tolerance to alcohol. "Should drowsiness, ataxia, or visual disturbance occur, the dose should be reduced. If the symptoms continue, the patient should not operate a motor vehicle or any dangerous machinery."

**Miltown:** Excessive and prolonged use, in susceptible persons has been reported to result in dependence on the drug. Withdraw slowly. Motor vehicle warning. Alcohol warning. In patients prone to both petit and grand mal epilepsy, meprobamate may sometimes precipitate grand mal attacks. Give cautiously to suicidal patients.

#### Indications

**Equanil:** As above, plus management of chronic alcoholics and nocturnal enuresis in childhood.

#### Side effects

**Equanil:** Drowsiness, ataxia, allergies, anemia, etc. "Lemere has raised the question of possible habit formation \* \* \*." Especially alcoholics. Suicidal attempts.

**Miltown:** Above, plus fast EEG activity.

*Contraindications*

Equanil: History of previous hypersensitivity reaction.

Miltown: Same as Equanil.

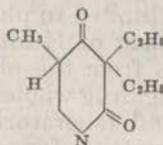
*Dose*

Equanil: 400 mg. t.i.d. or q.i.d. up to 2,400 mg. daily. Children \* \* \*.

Miltown: 400 mg. tablets t.i.d. or q.i.d., not above 2,400 mg. Children \* \* \*.

## METHYPRYLON

(Noludar, manufactured by Roche)

*Chemical structure**Action and uses*

Insomnia—"brings restful sleep to all types of insomniacs, even those who are overanxious or tense \* \* \* low in toxicity, well-tolerated by all age groups, including elderly patients, and cumulation or addiction is unlikely."

*Dosage*

One capsule (300 mg.) h.s. Do not exceed recommended dosage.

The CHAIRMAN. Is Mr. Rooke here, Mr. Ralph Rooke?

Mr. Rooke, we understand you are here in behalf of the National Association of Retail Druggists and that you have with you the Honorable Philip F. Jehle, Washington representative, associate general counsel of the organization. We are glad to have you. If you have a statement we will be glad to have you present it to us.

**STATEMENT OF RALPH R. ROOKE, IN BEHALF OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; ACCOMPANIED BY PHILIP F. JEHLER, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL OF THE NARD**

Mr. ROOKE. Mr. Chairman, my name is Ralph R. Rooke and for 44 years I have practiced pharmacy in Richmond, Va., where I now own and operate three community drugstores.

I am a past president of the Virginia Pharmaceutical Association and the National Association of Retail Druggists.

My appearance here this morning is as chairman of the Committee on National Legislation of the National Association of Retail Druggists, which has its headquarters at 1 East Wacker Drive, Chicago, Ill.

Accompanying me is Philip F. Jehle, Washington representative and associate general counsel of the NARD.

As you know, the NARD is a professional association having a nationwide membership of more than 38,000 independent drugstore owners. The NARD speaks for these family pharmacists on all national legislative matters affecting their professional and business interests.

Let me express at the outset the appreciation of the Nation's independent druggists for your committee's decision to explore fully and objectively the need for special Federal controls for depressant

and stimulant drugs. The information to be developed through these public hearings can and, I am sure, will be of invaluable assistance in clarifying the competitive and professional issues involved in this extremely important subject.

As we read the bill, H.R. 2 is intended to assist the Food and Drug Administration in wiping out, once and for all, illegal trafficking in amphetamines, barbiturates, and such other drugs as are capable of producing serious depressant and stimulant effects. Toward this goal, the bill establishes the following stringent Federal controls on the manufacture, sale, and distribution of stimulant and depressant drugs:

(1) Production would be limited to pharmaceutical manufacturers registered with the Department of Health, Education, and Welfare.

(2) Distribution channels from the pharmaceutical manufacturer through the patient, including drug wholesalers (registered) and retail druggists and all clinics and laboratories, but exempting medical practitioners, would be accountable for all such drugs manufactured, shipped, received, sold, dispensed, or distributed.

(3) All individuals and corporations handling such drugs would be required to keep detailed inventory records for inspection by FDA agents. The prescription files of the pharmacist would be subject to such FDA inspection.

(4) FDA agents would be authorized to carry firearms while performing their inspections and investigations.

(5) The HEW Secretary would appoint a professionally qualified advisory committee to assist him in resolving scientific questions pertaining to stimulant and depressant drugs.

With the praiseworthy objectives of H.R. 2, the NARD and its members are in complete agreement. Right-thinking Americans everywhere are interested in efforts to suppress illegal trafficking in stimulant and depressant drugs. But, while endorsing the proposed legislation in principle and purpose, the NARD must register its vigorous objection to the bill's authorizing FDA agents to inspect, among other business and professional records, the pharmacist's prescription files. H.R. 2, no matter how meritorious it may be in general, should not be allowed to be used as a stalking horse by FDA for grabbing more enforcement power than is actually needed and will perhaps be wisely used.

As the members of this committee know, FDA officials have tried for many years to get statutory authority to search the pharmacist's professional records, including his prescription files. However, with commendable consistency, the Congress has withheld such powers from the Food and Drug Administration as being unjustified. Unfortunately, the message implicit in these congressional decisions—the latest being in 1962 when the Harris-Kefauver drug amendments became law—seems to have been lost upon those intent on assuming new and broader authority for themselves.

This committee should in our opinion reject FDA's latest plea for prescription file inspection authority just as it has all previous requests. FDA should not be granted authority which would (1) unjustly discriminate against the profession of pharmacy (the medical profession, which dispenses large quantities of drugs, including stimulant and depression drugs, is exempted completely from the bill),

(2) broadly duplicate State drug enforcement activity, and (3) be unnecessary since almost all druggists voluntarily cooperate with FDA agents and search warrants are available to deal with the others, whenever probable cause exists.

On the subject of H.R. 2's discrimination against the profession of pharmacy, much more than the pharmacist's pride is involved. Members of this committee are aware that in many sections of the country, retail pharmacists and dispensing physicians; that is, doctors who sell drugs to their patients, are in vigorous competition. Therefore, to apply H.R. 2's onerous and expensive requirements to pharmacists while exempting physicians, grants a tremendous competitive advantage to the latter. I cannot conceive of this committee's taking such unjust and unwarranted action.

Mention must also be made that the exemptive language of H.R. 2 relieves physicians, insofar as stimulants and depressants are concerned, of their obligation under existing law to maintain records of drugs dispensed to their patients. (See CCH Food, Drug, and Cosmetic Law Reporter at par. 70,193.111.)

As a result of the public hearings being held on H.R. 2, I think it probable that this committee will decide that the proposed legislation would strengthen the national campaign against illicit trafficking in stimulants and depressants. Such favorable action would be supported by the Nation's independent druggists provided the committee makes it abundantly clear that it has no intention of authorizing FDA agents to inspect prescription files. To insure this result, the committee may amend the bill to include pharmacists as well as physicians in the bill's exemptive language.

Thank you, Mr. Chairman, for this opportunity to present the views of the Nation's independent druggists on this extremely important legislation affecting the profession of pharmacy.

Mr. Chairman, aside from my prepared statement, I have here a summary prepared by the pink sheet of last fall's CBS television program dealing with abuse of amphetamines and barbiturates in which it is stated very clearly where these illicit drugs are obtained, and how easily they are obtained, and in which, in my opinion, the FDA has the authority already to control, and I would like to include that in the record.

The CHAIRMAN. Very well. You may include it with your statement.

(The document referred to follows.)

SUMMARY PREPARED BY THE PINK SHEET OF LAST FALL'S CBS TELEVISION PROGRAM DEALING WITH ABUSE OF AMPHETAMINES AND BARBITURATES

EXPERIENCE OF FICTITIOUS M'MULLEN SERVICES IN GETTING BARBITURATES AND AMPHETAMINES: FROM CBS TELEVISION SEPTEMBER 2

First, we found that in many States wholesalers of barbiturates, amphetamines, or other Rx drugs are required to obtain a license and to keep records of purchases and sales. Those who repackage and sell in interstate commerce are generally required to register with the FDA—and according to the FDA, manufacturers should check on the legitimacy of a new wholesale buyer.

But to what extent can a would-be wholesaler without registration or license number purchase quantities of barbiturate and amphetamine drugs from legitimate producers or manufacturers?

To find out we created McMullen Services. In New York City on May 4, 1964, McMullen Services rented an office in this building at 35 West 45th Street. In

room 605 we began operations. We ordered 250 letterheads and envelopes. The letterhead included our telephone number, which was not listed in the telephone directory, and the words "Export-Import."

At the First National City Bank of New York we opened a regular checking account. Next we bought a copy of the Drug Topics Red Book. This book lists drug manufacturers that sell barbiturate and amphetamine drugs.

Then we sent out letters to 24 companies in 11 States requesting their catalogs. We received price catalogs with no questions asked from 17 of the 24 drug companies contacted. We eliminated five of these because they have sales representatives in the New York area who could easily check on us. That left us with 12 companies—and we placed orders with all of them.

In Philadelphia, Richlyn Laboratories said no sale unless you send us your FDA registration number. But Harvey Laboratories asked us no questions, promptly shipped us a carton in response to our order for 40,000 phenobarbital tablets. Jan Laboratories—also in Philadelphia—filled our order for 2 pounds of amphetamine sulfate powder and 4 ounces of phenobarbital powder.

In Worcester, Mass., Cowley Pharmaceuticals asked us no questions and shipped us a carton invoiced for 100,000 phenobarbital tablets and 5,000 amphetamine capsules.

In Chicago, Savoy Drug refused to ship without receipt of our license number, as did Bates Laboratories, which demanded our FDA registration number. But Maizel Laboratories did not check with us, and filled our order for 5,000 vials of phenobarbital.

In Portland, Oreg., Haack Laboratories responded to our order for 25,000 phenobarbital tablets.

In Baltimore, Md., the Barre Drug Co. asked for our State license number, but Carroll Chemical did not question us, and filled the order of McMullen Services for 50,000 phenobarbital tablets.

In Miami, Fla., we placed an order with Zirin Laboratories. Zirin accepted the order without question. But the actual shipment, 5 pounds of amphetamine powder—equal to 441,000 5-milligram tablets—came from Hexagon Laboratories in New York City. Hexagon, a producer of amphetamine powder, did not question McMullen Services.

In the mood of confidence, McMullen Services then wrote to 27 more companies. This time we asked for direct price quotations on generally larger amounts of barbiturates and amphetamines. Only 13 of the 27 companies complied with our requests. We placed orders with seven of them.

From Canton, Ohio, Bowman-Braun Pharmaceuticals shipped a carton labeled 75,000 phenobarbitals.

From Buffalo, N.Y., Direct Laboratories also sent us a shipment invoiced as 75,000 phenobarbital, but Barry Martin Pharmaceuticals in Miami and four other companies refused to ship—unless McMullen Services presented an authorization.

Kirkman Laboratories in Seattle, Wash., went further. It asked the New York State Board of Pharmacy whether a license had been issued to us. The board sent two rather grim-faced inspectors to pay a surprise visit to McMullen Services. The books of McMullen Services are now closed. We have not opened the cartons we received. We have asked the FDA to do that.

We believe that we received the equivalent of 1,075,000 pills. Our total cost—\$600.28 or about 6 cents per hundred pills. Their retail price in drug stores—about \$6 a hundred. Experts estimate that the value of 1,075,000 pills sold in the black market is between \$250,000 and \$500,000.

To purchase these pills we had contacted 51 companies—placed orders with 9 of them. We do not know many of the companies we contacted attempted to investigate us. We do know that by the time the State inspectors arrived, 47 percent of our orders had been delivered by companies in eight States. . . .

Mr. ROOKE. That concludes my statement, sir.

The CHAIRMAN. Is that the name of the atricle we are talking about? It looks like a white sheet to me.

Mr. ROOKE. That is a reproduced copy, Mr. Chairman.

The CHAIRMAN. Thank you very much for your statement.

Mr. Macdonald?

Mr. MACDONALD. No, thank you, Mr. Chairman.

The CHAIRMAN. Mr. Springer?

Mr. SPRINGER. You are the second person, Mr. Rooke, that I have congratulated in the 14 years that I have been a member of this committee, for the brevity and completeness of their statement. The last one who came here was Bobby Kennedy, the Attorney General, so I do believe that there is a great deal to be said for being brief and to the point, having a good statement outlining what you have in mind. This is it, and it is done in less than four pages, which is a record on an important subject such as this.

Mr. ROOKE. Thank you, sir.

Mr. SPRINGER. I would like to turn, if I may, for just a moment, to page 2 of your statement, the second paragraph.

The first objection, as I understand it, is that it discriminates against you. You say in the second point, "broadly duplicates State drug enforcement activity."

Now, would you tell me, for instance, in Virginia, what your State board of registration—in Illinois it is called the State board of registration and education, which has charges of narcotics and such.

Mr. ROOKE. Yes.

Mr. SPRINGER. Now, what kind of job or surveillance or inspection do they do in Virginia; for instance?

Mr. ROOKE. Sir, they have complete authority to inspect our prescriptions. If we sell any of these prescriptions other than on a physician's prescription, we are subject to revocation of our license to practice pharmacy.

Mr. SPRINGER. Do they have the right to come in and inspect your prescription?

Mr. ROOKE. Yes.

Mr. SPRINGER. They do?

Mr. ROOKE. In all 50 States, I am confident.

Mr. SPRINGER. In other words, the State board of registration and education can come in and inspect any of your prescription boxes; is that correct?

Mr. ROOKE. Yes.

Mr. SPRINGER. Would that cover stimulants and depressants, too?

Mr. ROOKE. Yes, sir.

Mr. SPRINGER. In other words, that covers barbiturates and everything that is contemplated being covered by this bill?

Mr. ROOKE. Any so-called legend drug, barbiturates, amphetamines, anything that requires a prescription that cannot be filled over the counter, the State law covers it.

Mr. SPRINGER. In other words you can at the present time only sell this by prescription in Virginia?

Mr. ROOKE. That is right.

Mr. SPRINGER. All this is covered by this bill; is that true?

Mr. ROOKE. That is right.

Mr. SPRINGER. So we would then be inspected by your State board?

Mr. ROOKE. Yes.

Mr. SPRINGER. Now, how often, for instance, do they inspect in the State of Virginia, roughly; once a month, once in 2 months?

Mr. ROOKE. In Virginia someone stated this morning that some States only have one inspector, but in Virginia we have three. We are inspected every 60 days. I have enough inspectors. We recently

added a third one so that all stores in the State of Virginia could be inspected regularly every 60 days.

Mr. SPRINGER. Now, would you just give this committee a little bit of an idea of what kind of records you keep in your stores in Virginia. You have a particular store in which you have an interest. I believe that is true.

Mr. ROOKE. Yes.

Mr. SPRINGER. What kind of records do you keep?

Mr. ROOKE. The only record we keep is the prescription. Of course, they have access to our invoices. They have access to the wholesaler's invoices if they so desire. But usually our prescription files are the only things that they inspect.

I don't know that it is in the State law, but I am confident that any wholesaler selling me from my store, and I have 2 pretty good prescription stores, if I bought 10,000 amphetamine tablets, I am sure there would be some suspicion. And the board of pharmacy would probably be notified that I had purchased this many.

That is the usual procedure and which I know has happened.

Mr. SPRINGER. Now, that is as to State drug enforcement.

Mr. ROOKE. Yes.

Mr. SPRINGER. Now, in the third place you say:

be unnecessary since almost all druggists voluntarily cooperate with FDA agents and search warrants are available to deal with the others whenever probable cause exists.

Mr. ROOKE. Yes.

Mr. SPRINGER. What do you mean by that?

Mr. ROOKE. I would say that usually these inspections, these additional inspections, come from cases wherein some member of some family has been getting hold of some of these drugs and taking overdoses and maybe the husband or the wife has called the board of pharmacy and said "I think that my husband," or "my wife," or "my daughter," "is getting drugs from this particular store. Will you look into it?" And they look into it very carefully.

Mr. SPRINGER. Would these search warrants be available to the Food and Drug Administration, or only to your State board or are search warrants available to FDA agents as well as your State board of education and registration?

Mr. ROOKE. Yes, sir.

Mr. SPRINGER. In other words, FDA on probable cause can get a search warrant?

Mr. ROOKE. They certainly can; yes, sir; they can in Virginia.

Mr. SPRINGER. Is your counsel there a lawyer?

Mr. JEHLE. Yes, sir; I am.

Mr. SPRINGER. Are you in agreement with this?

Mr. JEHLE. Yes, sir; I am. I am not saying it is a relatively easy matter but it is possible. I am sure that in the past FDA has received such search warrants.

Mr. SPRINGER. To whom do they apply, to the local court or to the Federal court?

Mr. JEHLE. Federal court, sir.

Mr. SPRINGER. They apply to the Federal court?

Mr. ROOKE. Yes.

Mr. SPRINGER. That is on probable cause, is that right?

Mr. ROOKE. Yes.

Mr. SPRINGER. And they have to show that to the Federal judge or a commissioner of the Federal judge?

Mr. ROOKE. Yes.

Mr. SPRINGER. In order to get the warrant, is that correct?

Mr. ROOKE. Yes.

Mr. SPRINGER. That is all, Mr. Chairman.

Mr. ROOKE. Mr. Chairman, if I might add one other comment. One of our main objections to this prescription file inspection that Mr. Larrick didn't bring out this morning would be just the physical impossibility of anyone other than a pharmacist, a well-qualified, a practicing pharmacist, to be able to identify these prescriptions once they inspected them. There are so many combinations of them, thousands of them, that would come under this act, and we as pharmacists feel, among other things, that these people coming in, I don't think enough pharmacists will be available, if they had 1 for each State and we took 50 out of the pharmacists available, it would create a shortage, that you could get that many.

I am quite confident no one other than a pharmacist who is completely familiar with formula or prescription bottles; would be capable of making these inspections, and it would certainly create a tremendous burden for pharmacists to have to undergo all that inspection, particularly perhaps by someone who might not know what he was looking for.

Mr. SPRINGER. Let me ask you, did you hear the testimony this morning? Did you hear the testimony this morning?

Mr. ROOKE. Yes.

Mr. SPRINGER. Was there any indication there by Mr. Larrick as to approximately how many inspectors he would have to have to do this job nationwide?

Mr. ROOKE. I did not hear Mr. Larrick state how many he thought he would need, no, sir.

Mr. SPRINGER. Do you think it would take, for instance, any more than three in the State of Virginia?

Mr. ROOKE. What?

Mr. SPRINGER. Would it take any more than three in the State of Virginia?

Mr. ROOKE. I would say that it would take at least three and maybe four or five could do a better job.

Mr. SPRINGER. The same number that you have for State inspection, is that correct?

Mr. ROOKE. Yes.

Mr. SPRINGER. You inspect, then, you say, every 2 or 3 months?

Mr. ROOKE. Yes. I would say certainly it would take three and perhaps more.

Mr. SPRINGER. That is all, Mr. Chairman.

The Chairman. You don't contend that this requires a periodic inspection by the HEW, the Food and Drug Administration?

Mr. ROOKE. I think it would just depend on how much inspection they wanted. I don't know just how much; there is not implied here how much inspection is wanted or required.

The Chairman. They want authority to go in wherever they have grounds to believe that a violation may be taking place.

I don't see that there is any requirement or even any implication that this is a regular monthly or annual inspection procedure by the Federal Government here.

Mr. JEHLE. I would like to add just one thing, Mr. Chairman, if I may. It is true that the number of inspections annually is not set forth anywhere in the bill. It is left to administrative discretion, but I am sure that once FDA gets this authority, which it has been working so strenuously for, for many, many years—I suppose ever since the first act was passed in 1906—that FDA will try to justify to Congress this new authority. They will try to show that they are using it aggressively and effectively.

We could expect FDA investigators to be running around inspecting stores at any time of the day or night and causing a great deal of harassment.

I have been around government myself long enough to know that there would be some agents trying to justify their existence, and the more druggists they inspected, the more their salaries would go up, and the more they inspected, the more help they would need.

We are all familiar with Parkinson's law. Within a relatively short period of time FDA would have more inspectors than in any other division, branch, or agency of the Department of Health, Education, and Welfare.

The CHAIRMAN. This has been a fear of the retail drug industry over the years, but it is also recognized that through this industry there is a very large outlet for drugs which certain people are going to try to demand and obtain.

Mr. JEHLE. Yes, sir; there are roughly about 130 cases a year, about 10 or 12 a month, something like that, and these are relatively insignificant cases.

The CHAIRMAN. I think it was something like 1,100 mentioned this morning.

Mr. JEHLE. Over a 10-year period.

The CHAIRMAN. Over a 10-year period in all?

Mr. ROOKE. I have practiced pharmacy in Virginia for 44 years, and I don't know, I don't recall of but one pharmacist serving any time in any penitentiary or jail for violation of these laws. And so I don't know how far reaching it is in other States, but certainly down in Virginia we have not had it, and I think that is a pretty good example.

And in my travels over the Nation and in my contacts with the pharmacists, that 1,300 in 10 years, I would say that many of those violations, several of them, were probably of the heart and not of the mind, because I do know of instances where the pharmacists have been shocked with the tale of woe that they could not reach their physician and they needed a few tablets to tide them over until they could get him, and have been arrested on that account.

The CHAIRMAN. We will go into that a little later. Mr. Pickle, do you have any questions?

Mr. ROOKE. Mr. Chairman, our organization conducts an educational program through our Journal, in attempting to tell our pharmacists how not to make these mistakes. I frankly don't think that this is a problem.

I don't think the amount of these preparations that go through the drugstores amount to a drop in the bucket. I think it would just create additional trouble for the pharmacist and not accomplish anything.

Mr. PICKLE. Thank you, Mr. Chairman.

Mr. Rooke, are your State inspectors all licensed pharmacists?

Mr. ROOKE. They have to be; yes, sir, that is a requirement.

Mr. PICKLE. Is this true of all the States?

Mr. ROOKE. I am not positive but I know of a great many that that is a requirement. Do you happen to know?

Mr. JEHLE. No, Mr. Pickle, I don't have that information, but if you wish, I would get it for the record.

Mr. PICKLE. If the FDA inspectors were licensed pharmacists, would this meet your objection?

Mr. ROOKE. I would much prefer not to have any more inspections but I would be much more susceptible to that if that were—

Mr. PICKLE. Your State inspectors do not harass you now?

Mr. ROOKE. No, sir.

Mr. PICKLE. But you state the FDA inspectors would harass you because they would be Federal inspectors.

Mr. ROOKE. I think it would be more inspections, and I say I think unless they were pharmacists, I just don't think that most of the times that they would know what they were looking for.

For instance, Mr. Larrick is head of his Department, and there were some inconsistencies in his statement this morning.

For instance, he said that meproamate was one that they only looked for under tradenames. Well, that is absolutely not right because it is made by the millions under the chemical name of meproamate, and so I just think you have to be a pharmacist to know these things.

Mr. PICKLE. I certainly understand it would be helpful if the inspector were a pharmacist.

Mr. ROOKE. Yes.

Mr. PICKLE. I don't know that it would be mandatory that such would be a requirement, but of course I can see that it would help. But it doesn't quite follow to me simply because they would be Federal inspectors that automatically they would harass you as opposed to your State people.

Mr. ROOKE. No, sir, I am sure that would not be true.

Mr. PICKLE. Would you say that it would be fair that a State inspector, because he is appointed by the State law, that the Governor and the governing body, would have a tendency to be a little more lax in their inspection than there would be someone from outside?

Mr. ROOKE. No, sir. In our State I am afraid they would be a little more strict.

Mr. PICKLE. More strict?

Mr. ROOKE. If there were any inconsistencies I assure you that—

Mr. JEHLE. Mr. Pickle, if I may just clarify one point, I wouldn't want the record to suggest that our objection to H.R. 2 is based only upon fear of harassing tactics by FDA agents. That isn't true.

Our objections are three in number, and they were set forth on page 3 of the NARD statement. First, the professional discrimination involved; second, the fact that Federal inspection would be unneces-

sarily duplicatory of State enforcement efforts and, third, it is unnecessary. It shouldn't be mandatory. The voluntary program we think is working very well.

Most all druggists—and Mr. Larrick admitted this this morning—there are only a very few druggists who refuse to let an FDA agent inspect the pertinent records.

We don't think the entire profession should be penalized for the recalcitrance of just a few, especially when FDA can go to court and get a search warrant for them.

The CHAIRMAN. Will the gentleman yield at that point? How are you going to get at those few recalcitrants? You know there is no reason for law against murder except to handle the occasional person who commits murder.

Mr. JEHL. I have great confidence in the legal section of FDA. I know that they are extremely resourceful over there and very vigorous in their work, and they get search warrants wherever it is necessary, sir. They do a real good job.

Mr. ROOKE. I wouldn't intend to imply that they would be any more strict than our State inspections under any circumstances, but in a busy drugstore, for instance, one of mine fills about 200 prescriptions a day with 2 pharmacists. Taking the time with the files to inspect those files is quite an inconvenience.

Mr. PICKLE. When you say that there is really not a need for this, are you saying that this is not then a major problem facing our country?

Mr. ROOKE. No, sir. I think it is a problem, but I don't think the drugstore is the source of it.

Mr. PICKLE. This may be too broad a question, then, but what is the answer in this field?

Mr. JEHL. Mr. Pickle, I am going to help in answering that question. In fact, this is the second time I have been disappointed in the FDA testimony.

There are admittedly about 9 billion amphetamine and barbiturate capsules produced every year, but that is about all we know other than the fact that FDA says that 50 percent of those pep pills are illegally diverted.

Well, so far as pharmacies being the source of that diversion or even a significant part of it, that just isn't so. Most of the cases brought against druggists involve a very small number of capsules. I can't see these as being important cases at all.

Mr. ROOKE introduced into the record this pink-sheet summary of the CBS program which showed where the real sources of this illegal diversion are. We have got 4.5 billion capsules we are concerned with.

All the druggists in the country couldn't account for even a tiny fraction of that. The druggists aren't the source, and nothing is going to be done about making a more effective drug-abuse law by covering the pharmacists.

Mr. PICKLE. Sir, if your people are 98-percent pure—

Mr. JEHL. I think like Ivory, about 99.99.

Mr. PICKLE. Let's say you approach Ivory then. Then why would you object to a limitation on that small percent to help improve this overall picture?

Mr. JEHL. As Mr. Rooke pointed out, Mr. Pickle, we are being professionally discriminated against, and as the chairman expressed it so well this morning in questioning Mr. Larrick, this bill should not place any group or any person or any company at a competitive disadvantage.

Yet that is what this bill will do. It will put the Nation's independent retail druggists at a very serious competitive disadvantage as compared with dispensing physicians, that is, those who sell drugs to their patients.

Mr. PICKLE. This leads into the last question. You do object to the fact that physicians are exempt?

Mr. JEHL. No, sir. I want to make it quite clear I am not asking that they be brought into this soup with us.

Mr. PICKLE. I will read your statement here:

To insure this result, the committee may amend the bill to include pharmacists as well as physicians in the bill's exemptive language.

Let's work this in reverse. If we put in both physicians and pharmacists, would that suit you? Would that be satisfactory?

Mr. JEHL. We would still object. That would remove the objection so far as discrimination is concerned; yes, sir. The other two objections would still apply, duplicatory of State efforts in this area, and unnecessary.

Mr. PICKLE. Now if the doctors would be agreeable to this language, would you then accept it?

Mr. ROOKE. I would prefer not to have the burdensome procedure of Federal inspections for all these preparations that come under this bill.

Mr. JEHL. I think, Mr. Pickle, it would be well for the committee to pursue some of the reasons for this professional discrimination. I don't think that FDA gave a completely candid answer to the questions in that area. There are other reasons why, although Mr. Larrick was refreshingly candid in saying that doctors would protest, and protest vigorously. In fact, they are afraid that this bill would go down the drain I think, if the doctors were included.

Mr. PICKLE. That is all, Mr. Chairman.

Mr. MACDONALD. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

Mr. Rooke, do you consider the drugstore in connection with the clinics which the doctors own as a retail drugstore, or do you consider that the doctors are dispensing drugs?

Mr. ROOKE. The doctors do dispense a great many drugs through their clinics and their offices; yes, sir.

Mr. YOUNGER. I know. I mean where they have a large clinic with a lot of doctors and they have a pharmacist in connection with the clinic.

Mr. ROOKE. No.

Mr. YOUNGER. All he does is just fill prescriptions; do you consider that a part of your retail drug organization, or is that a part of the dispensary for the physicians in the sale of drugs?

Mr. ROOKE. Well, I think this bill would include that drugstore just the same as it would mine. There would be no difference there. I don't see that there would be any.

He has to be registered pharmacist. It has to be a registered pharmacy and subject to the same inspections as any other drugstore.

Mr. YOUNGER. Now on the other hand, you are aiming at the physician who sells drugs right out of his own office.

Mr. ROOKE. Yes, sir.

Mr. YOUNGER. He has the drugs there and sells them to the patients.

Mr. ROOKE. Yes, sir.

Mr. YOUNGER. How extensive is that in the medical profession?

Mr. ROOKE. It is less extensive I think in Virginia than in some other States. However, we do have quite a bit of it in Virginia. We have quite a bit of it, more than we would like.

Mr. YOUNGER. In other words, if we put the pharmacists under this bill, certainly the doctors that dispense their own drugs and sell them ought to come under it.

Mr. ROOKE. Yes.

Mr. YOUNGER. Is that right?

Mr. ROOKE. Yes, I would certainly think so.

Mr. YOUNGER. And your feeling is that clinics already are under it?

Mr. ROOKE. Yes.

Mr. YOUNGER. If the pharmacists are under it, the pharmacy and clinic is under it—

Mr. ROOKE. He has a pharmacy, a medical building, or a clinic, it has to conform with the same regulations as my store or anyone else's pharmacy would, so that is included anyway.

Mr. YOUNGER. How much trouble would it be to have your prescriptions that deal in barbiturates and so forth separate from your other prescriptions?

Mr. ROOKE. It would be quite a lot. We have two separate files anyway for narcotics and nonnarcotic prescriptions.

If we had to have a third one, there are so many combinations of these barbiturates and amphetamines that it would entail quite a problem, three sets of numberings and all that sort of thing. It would entail quite a problem.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. MACDONALD. Before I recognize Mr. Satterfield, I would just like to ask one question of my own. Were you here this morning and did you listen to the answers given by the Commissioner?

Mr. ROOKE. I was here for most of his testimony.

Mr. MACDONALD. I had quite a hard time following his description of a barbiturate. Do you agree with his definition or do you have a different one?

Mr. ROOKE. It is rather difficult, and I thought Commissioner Larrick's was probably about as clear as I can come to explaining what it was.

Mr. MACDONALD. In general would you say that possibly under the definition which was given by the Commissioner, barbiturate would touch almost every drug that is prescribed in a pharmacy—cough medicines, aspirin, et cetera?

Mr. ROOKE. No, sir.

Mr. MACDONALD. I am asking this; I do not state it to be the case.

Mr. ROOKE. I wouldn't quite agree with that.

Mr. MACDONALD. Mr. Satterfield?

Mr. SATTERFIELD. I have no questions, Mr. Chairman.

Mr. MACDONALD. Mr. Devine?

Mr. DEVINE. Is there any control at all on the pharmacist level of amphetamines?

Mr. ROOKE. I don't believe I quite got the question, sir.

Mr. DEVINE. I say is there any control now at the level of the pharmacist as far as the distribution of the amphetamines is concerned?

Mr. ROOKE. Any control?

Mr. DEVINE. Yes.

Mr. ROOKE. Oh, yes, sir. Prescriptions are required.

Mr. DEVINE. They are required?

Mr. ROOKE. They are not allowed to be refilled without the doctor's permission. They can only be filled once, and the doctor can specify on this prescription whether he wants it refilled once, twice, or three times.

Mr. DEVINE. That is the type that they claim are rather freely distributed at truck stops and things of that nature?

Mr. ROOKE. What is that?

Mr. DEVINE. Isn't that the type that they allege is rather freely distributed at truck stops and places of that nature?

Mr. ROOKE. That is where we have had a number of truck stops in the State of Virginia that have been raided and inspected, and quite large numbers of these preparations have been confiscated. That is really one of the sources of supply.

Mr. DEVINE. Those are bootleg operations generally, aren't they?

Mr. ROOKE. That is right, sir.

Mr. DEVINE. And does the same thing apply to barbiturates?

Mr. ROOKE. Barbiturates I don't believe are causing as much trouble as the amphetamines at this time, certainly not in Virginia. I have not heard of any trouble with barbiturates in Virginia at all. Now where they are getting them in other States and where it is a problem I would say that is probably the same situation. The same situation exists there.

Mr. DEVINE. That is all, Mr. Chairman.

Mr. MACDONALD. Mr. Ronan?

Mr. RONAN. No questions.

Mr. MACDONALD. Mr. Nelsen?

Mr. NELSEN. In your statement you made reference to the fact that the State inspectors could ask for a report on your prescriptions that you have made. Now if the Federal authorities worked through the State authorities, they could get the information, could they not?

Mr. ROOKE. Yes, sir; they certainly can.

Mr. NELSEN. And is it possible that the Federal inspectors would only be active in areas where there was evidence of the sale of these drugs? I just wonder, I am trying to think how results could be obtained by working with State authorities.

Dealing with the State, obviously this information is available to your State inspectors. Now do you find it a harassment coming from the State, and why would it be more of a harassment with the Federal man than it is with the State man?

Mr. ROOKE. I don't think it probably would be much more or any more. We don't consider it a harassment from the State inspectors. We feel that that is what our State says they should do, and it is all

right for them to do it, and I am sure the Federal inspectors could get the information they want from the State inspectors without calling on us. It would be available for them.

Mr. NELSEN. I just merely wanted to assure you that none of us here want to make it difficult for any one of our business enterprises. I think we all agree that if there is an area that we can improve our Federal regulations, I am sure you would agree that we should do it.

We want to do it the best possible way, and I am sure that Food and Drug would also. I want to thank you for your fine statement and your associate, Mr. Jehle; I also thank you.

Mr. ROOKE. Thank you, sir. We certainly want to cooperate in any way we can.

Mr. MACDONALD. Dr. Carter?

Mr. CARTER. No questions.

Mr. JEHLE. Mr. Macdonald, I wonder whether it would be possible for us to insert in the record at this time a list of questions concerning amphetamine and barbiturate production and distribution that we think should be answered by the Food and Drug Administration before this committee completes its consideration of this bill.

I don't see how it is possible for this Committee to intelligently legislate in this area without knowing just who is producing these amphetamines and barbiturates, and how many are being produced by each company, and there should be a breakdown of distribution according to classes of customers. At least I would like to submit it for the record.

I think also you should know what percentage of each amphetamine manufacturer's production is distributed to physicians in the form of professional samples, and the same should be obtained in the case of barbiturate samples. I would like to submit that for whatever possible use.

Mr. MACDONALD. I am sure that any pertinent questions that go to the heart of this matter—and I am sure that your questions do—would be made part of the record. As Congressman Nelsen said, he would be happy to—

Mr. NELSEN. Yes, Mr. Chairman. I am sure if the witness is searching for an answer for his questions, perhaps they should be submitted to the Food and Drug Administration, and a request made for information as an answer to the questions, which could also be made a part of the record, and I would be most happy to see that all the information would be compiled and brought here.

Mr. JEHLE. Thank you, Mr. Nelsen.

Mr. MACDONALD. May I ask you a question I tried to ask this morning but I didn't take the time: How many physicians are engaged in dispensing drugs?

Mr. JEHLE. Altogether too many, Mr. Macdonald. The Senate Antitrust Subcommittee is quite concerned about the somewhat related problem of M.D.-owned pharmacies, and also has a great deal of information dealing with dispensing physicians. But I would like to have Mr. Rooke answer that question from his own experience as a practicing pharmacist in Virginia.

Mr. ROOKE. Well, Mr. Chairman, I can cite one specific example that a physician in my area, whose secretary comes into my place occasionally, and she came in one evening and said, "The doctor had

36 patients," they were not very far from me, and I said, "What happened to the prescriptions? I didn't get any." She said, "He didn't write any."

I said, "Didn't they get any medication?" She said, "Yes." That is just one specific example, and that is becoming quite a practice in a lot of areas. Of course, the doctor includes the price of the prescription, I mean of the medication along with the price of the call. Does that answer your question, sir?

Mr. MACDONALD. In a way. And my second question is how does it affect this bill if a number of doctors, as a concrete example, owned a pharmacy, which I think is not unknown in Virginia. Certainly it is not unknown in Massachusetts.

Would they as proprietors of a pharmacy, whether it was carried in their name or just in the name of say six doctors who joined together, would this bill affect them or not in your opinion?

Mr. ROOKE. No, sir; I don't think this would affect it at all, because there again it would have to be in the State of Virginia—and I am sure that applies to other States too.

Mr. MACDONALD. Would they be exempt under this bill, or would they be subject to the terms of the bill if it did pass, sir?

Mr. ROOKE. The pharmacy would be covered in this bill, whichever way, whether you have inspection or prescription files or whether you don't.

Mr. MACDONALD. My direct question is this, sir; perhaps I didn't phrase it exactly: If there were six doctors—

Mr. ROOKE. Yes.

Mr. MACDONALD (continuing). Practicing out of a medical center and each one of the six doctors is an expert in a different field, one in arthritis, one in throat and nose, et cetera, and as a part of their medical center, they have an establishment which is not a pharmacy, in that from it they would not sell milkshakes and the like but from it they do dispense medicine, would this type of establishment be included under the terms of the bill as you read it?

Mr. ROOKE. No, sir.

Mr. MACDONALD. Pardon me.

Mr. ROOKE. No, sir; that would not be subject to any inspection at all. I think I am right on that, Mr. Jehle.

Mr. CARTER. Will the speaker yield?

Mr. MACDONALD. I yield.

Mr. CARTER. I beg to disagree. I think that any pharmacy like that which has a licensed pharmacist to dispense certainly would come under that law.

Mr. MACDONALD. Doctor, if you will yield back to me, I would like to ask you, because you have much more knowledge in this field than I do, but if such a sale would go through what is known as a pharmacy—

Mr. CARTER. They call those things apothecaries as the usual thing.

Mr. MACDONALD. Excuse me?

Mr. CARTER. Apothecaries or pharmacies. They have a licensed pharmacist of course over them, certainly the ones that I know of.

Actually I know of no group, no medical group, that has a pharmacist just to supply the medicine for that group. Dispensing has been going on—there are some doctors who still dispense, but there are not too many of them, very few, and I don't think that there would be a

great many types of inspections that anybody wished to give them. There shouldn't be at any rate. I yield back.

Mr. MACDONALD. Thank you, Mr. Chairman.

Mr. ROOKE. I am not sure, sir, that your question has been completely answered.

Mr. MACDONALD. Well, we have had one opinion.

Mr. ROOKE. I believe, Doctor, that you stated that if a pharmacist were in charge of this operation, this dispensing of drugs, that he would be subject to inspection.

Mr. CARTER. Yes, sir, that would have to be licensed as any other pharmacist would.

Mr. ROOKE. Yes, sir, I understood your question that if he had a storeroom to dispense these, the physicians themselves dispensed it, then it would not be subject to this.

Mr. MACDONALD. Yes, sir, and I know that perhaps you are restricted to Virginia law, so I am not asking you about the 50 States, but the question I was really asking was this: Say there were four, five, or six doctors who established a joint operation. They did not necessarily employ a registered pharmacist, but they did have a central office through which they put out certain types of drugs which called for a prescription. Would this type of transaction be covered by this bill as you read it?

Mr. JEHLE. The individual practitioners would be clearly exempted by the language of this bill.

Mr. ROOKE. I don't care how many drug rooms they had, unless it were licensed as a pharmacy, and a pharmacist in charge, it would not be covered.

Mr. JEHLE. They would be acting as pharmacists, Mr. Macdonald, but because of their character as physicians, they would be exempted under this bill.

Mr. MACDONALD. And one last question, Mr. Chairman. Is this usual? Can a doctor dispense prescription drugs?

Mr. ROOKE. He has every right to do that if he sees fit to. There are no restrictions on that.

Mr. MACDONALD. You mean it is just his moral obligation? Why does he go through a pharmacy if he can do it by himself? Why the middleman?

Mr. JEHLE. I think because he sees an ethical conflict, Mr. Macdonald, between his obligations to his patients to prescribe the best medicine possible and his desire to make the greatest profit out of his drug dispensing.

He has a very serious ethical issue there. It is a conflict, and one that the AMA has recognized in the past.

Mr. MACDONALD. AMA has an ethical obligation to keep the pharmacist in business?

Mr. JEHLE. No, no, sir. You asked about the physician. You asked why all physicians don't dispense.

Mr. MACDONALD. Yes.

Mr. JEHLE. And I said there is a very serious ethical issue involved, and this is an ethical issue which the AMA and the NARD and others in the professions of pharmacy and medicine are now struggling with.

The physician who dispenses or who sells medicine has a very serious ethical or moral issue. On the one side, he has his obligation as a physi-

cian to prescribe the best possible medicine. On the other hand, as a dispensing physician, he is a businessman, a pharmacist as it were, and he has an obligation there, a duty to maximize the profits of his dispensing, and some of them do it. Up until 1954 AMA condemned that very practice.

Mr. MACDONALD. Since we won't go into a discussion of the capitalistic system, I just wish to thank you.

Mr. JEHLER. Thank you, Mr. Macdonald.

The CHAIRMAN. Mr. Larrick said this morning that under the provisions of the bill proposed here, a pharmacist could keep separate records, and all of the prescriptions that he has dealing with this kind of product could be kept in one place, one record, and all of his other prescriptions kept in the second record, and he was asking for authority to inspect only those where barbiturates, amphetamines, and things of that kind were involved.

Mr. JEHLER. That is all the authority that this bill would give him, too, Mr. Chairman.

I would like to make it clear it pains us to disagree with a fine and honorable public servant like George Larrick. We think he is an able and outstanding Commissioner of the Food and Drug Administration.

The CHAIRMAN. I am sure he appreciates that.

Mr. JEHLER. But in this issue we think he is wrong.

The CHAIRMAN. I am sure he will appreciate the compliment, but what I wanted to ask is what problems would that entail on the pharmacist?

Mr. ROOKE. It would entail, Mr. Chairman, quite a bit of a problem. I mentioned earlier that we keep two files anyway, one for narcotics and one for nonnarcotics.

The CHAIRMAN. That is what I was going to ask about, if you didn't discuss it.

Mr. ROOKE. Yes, sir. Well, if we kept a third one, of course, that would entail more problems.

I don't know that we as a practicing pharmacist, that all of us would know exactly, as the borderline hasn't been drawn, as to what an amphetamine and a barbiturate are, what comes under this provision.

The CHAIRMAN. Of course this bill describes specifically what comes under it with reference to barbiturates and amphetamines. Then it makes a provision that certain others can be brought under after a hearing by the agency.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. And when the agency makes the determination and a drug is brought under, then you know specifically what is and what isn't.

Mr. ROOKE. If he ever gives you that information, you are going to have a heavy document, because the manufacturers are combining these amphetamines with so many estrogens, hormones and various other combinations, the same as they are with barbiturates, we won't need very much, but one file, but we will have to scrutinize that formula on that bottle very carefully to know whether it comes under that, where it goes, whether it comes under the amphetamine-barbiturate classification, general classification, or narcotic, sometimes both.

Sometimes you have a narcotic, a barbiturate, and an amphetamine all combined, and we don't know where that is going.

The CHAIRMAN. In other words, these prescriptions will come with a mixed content.

Mr. ROOKE. Manufacturers are manufacturing them that way now. I think the doctor over there will agree with that.

Mr. CARTER. Yes, sir; that is true.

Mr. ROOKE. So that would be as I see it almost physically impossible for him to give you that information, and they are coming out with new ones all the time.

The CHAIRMAN. You don't object to keeping a record insofar as the narcotic business is concerned, do you?

Mr. ROOKE. Keeping a record?

The CHAIRMAN. Yes.

Mr. ROOKE. Well, Mr. Chairman, they have all the record they want. We have to order those on special forms. We have to obtain them from the Bureau of Narcotics.

Maybe this thing put under that type of purchase would be a good idea, but we have to buy these forms at a penny apiece, to purchase all the narcotics that we have, so all he has to do is go to the Bureau of Narcotics and find out how many have been purchased and where they came from.

The law doesn't require that we keep them separate, but we keep them separate, so it will make it convenient for our State inspectors to see how many narcotics we are dispensing. Up until recent years the narcotic problem has been the only one who had.

The CHAIRMAN. The drug industry is doing such a tremendous job with its continued progress in the field, it is bringing in other things now that, from the information we get here, have effects almost as severe as narcotics.

Mr. ROOKE. Yes.

The CHAIRMAN. Now if that is the case it seems to me that the industry, the legitimate industry that you represent, including not only the pharmacists but the doctors and all, should be in here trying to tell us how we can meet this problem.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. Now it seems to me that we ought to get some help out of you as to how we can meet that part of it.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. If we are going to protect the public.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. How are we going to treat with it? Do you contend that there is no way that we can get at the activity if certain pharmacists decide they wanted to get into the illegal drug business?

Mr. ROOKE. Yes, sir, Mr. Chairman. They have that authority now. All it means is obtaining a warrant, and, also, through the State boards and inspectors they have it.

The CHAIRMAN. Well, that is another question. You have inspections through the State board inspectors. You don't object to that; do you?

Mr. ROOKE. No, sir; we don't object to the State board inspectors. We welcome it. If we are doing something wrong, we would like to know it. But we don't believe we are doing anything wrong on this

amphetamine business. We don't think this is the source of it to begin with it.

The CHAIRMAN. That is true, and it was made very clear.

Mr. ROOKE. And we believe that there is a principle involved here, that if we are going to be singled out, why not the dentists and the osteopaths and the physicians and all. Inspect all of them.

The CHAIRMAN. All right, if they are handling them and are distributing them, then perhaps they ought to be included.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. There are some loopholes through which this distribution is being made. The contention, though, "Don't bother our industry even though we have 1,100-and-some-odd who have been convicted of engaging in this business over the last 10 years."

Mr. ROOKE. Yes, sir.

The CHAIRMAN. By a very hard approach by the FDA they have been convicted. They say they are having a difficult time in keeping up with the illegal traffic, as we have heard described here. You heard it said they can do more than they do under the present law, but they insist they can't.

Mr. ROOKE. I am in accord with that.

The CHAIRMAN. If they do have that hard a time, then the only thing that we can suppose is that many persons are getting by.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. And it seems that everybody insists, newspapers and periodicals, the manufacturing industry, even you who are in the dispensing business seem to admit, that there is a lot of this illegal traffic going on.

Mr. ROOKE. Yes.

The CHAIRMAN. I have the feeling that we all ought to get together and put the best brains that we have to meet the problem.

Mr. ROOKE. I am in complete accord with that, sir.

The CHAIRMAN. It is not a question of trying to gig somebody because he might be a physician or because he might be a trucker. It is a question of stopping those who would engage in this kind of business.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. That seems to be prevalent all over the country, from the reports that we are getting.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. And if the drug industry is going to be permitted to develop more and more and more of these drugs, which if it can do, in order to do something for the health of the people, that they ought to, then it seems to me that there should be a way of handling this.

Mr. ROOKE. I think so.

The CHAIRMAN. And that is what we are trying to get at.

Mr. ROOKE. Yes, sir.

The CHAIRMAN. You say it is perfectly all right for a State inspector to come around and inspect you. You don't object to that at all. But you don't like for a Federal inspector to come around.

Mr. ROOKE. Chairman, we are just trying to get away from too much inspection.

I think you agree, sir, that we have too much of that anyway, and if it will accomplish something, all right, but we as the NARD, we can't see that it is going to accomplish anything.

Mr. JEHLE. We don't believe that the pharmacy is the source of any significant amount of illicit diversion.

The CHAIRMAN. You know that there is a lot of this illicit diversion.

Mr. ROOKE. We know, according to FDA's figures, about 50 percent of the 9 billion amphetamine and barbiturate capsules produced are diverted. But FDA quit in its statistical presentation at that point.

The CHAIRMAN. Why don't you supply that information?

Mr. JEHLE. I have tried, sir, to get this information and have been unable to do so. But I know that FDA has the information or most of it.

It would be very helpful to this committee if FDA could tell this committee who is producing amphetamines and barbiturates, and how much each is producing, and could give a further breakdown of the annual sales of amphetamine and barbiturate capsules to four important classes of customers: physicians, wholesalers, hospitals, and drugstores. That information should be given.

I don't see how this committee can make an intelligent determination as to the sources of illegal diversion without having that information. Let's find out how much goes to those four classes of customers.

I also think there should be some information submitted by FDA regarding the sampling of amphetamines and barbiturates, professional sampling.

The CHAIRMAN. What do you mean by professional samples?

Mr. JEHLE. A professional sample, sir, is sort of a trial or starter dose of the particular medicine.

The CHAIRMAN. That is what they take around and give to the druggists and physicians?

Mr. JEHLE. Yes, sir. I remember an FDA representative saying last year in testimony before a congressional committee that up to 40 and 50 percent of a drug is sampled at certain times. That is a pretty substantial amount. I don't think after the drug has been on the market for any length of time the sampling is as high as that.

The CHAIRMAN. We are going to have some pharmaceutical people here to find out.

Mr. JEHLE. I have submitted a list of questions that I think will be very helpful if answered by FDA. It would certainly assist this committee in its very important responsibilities with respect to this legislation.

The CHAIRMAN. We want to develop all the information we can. Mr. Macdonald has a question.

Mr. MACDONALD. It is a simple question asked from innocence perhaps. You say 50 percent is diverted. I take it by being diverted, you mean from the normal channels?

Mr. JEHLE. Yes, sir.

Mr. MACDONALD. Where does the other 50 percent go?

Mr. JEHLE. That goes through legitimate channels, that is, sold on prescription.

Mr. MADDONALD. That is not diverted. Where does the other 50 percent go?

Mr. JEHLE. Oh, to truck stops and bawdy houses, you know, some of the places described.

Mr. MACDONALD. I heard the statement this morning, but who does this?

Mr. JEHLE. Who does that?

Mr. MACDONALD. Yes.

Mr. JEHLE. You mean how does it get from the manufacturer to the bawdy house, for example?

Well, CBS found out that one of their employees, named McMullen, wrote to a number of producers of amphetamines and barbiturates, and without identifying his company as being in the pharmaceutical field—just McMullen and Associates—was able to obtain 100,000 amphetamines in one case, and 50,000 barbiturate capsules in another.

I have the figures here. In summary. McMullen says:

We have received the equivalent of 1,075,000 pills. Our total cost \$600.28, or about 6 cents per hundred pills. These 1,075,000 pills, if sold in the black market, would bring between \$250,000 and \$500,000.

This company got them over a period of 2 or 3 weeks. I want to make it clear they didn't get them from any of the better known, the truly outstanding ethical drug houses. I am not saying that.

The CHAIRMAN. You are talking about the wholesale house or the manufacturer?

Mr. JEHLE. No, sir. McMullen Services, McMullen is a CBS creation.

Mr. ROOKE. They just set up a bogus company, ordered them, and got them.

Mr. JEHLE. They sent out letters to 24 companies in 11 States requesting catalogs.

Mr. MACDONALD. Allow me to interrupt you. From whom did they get it, the producer, the wholesaler, the retailer?

Mr. ROOKE. No. Mr. Macdonald, a druggist buys in relatively small quantities. If druggists ever ordered 40,000 phenobarbital capsules, there would be a Federal investigation.

The CHAIRMAN. That wasn't the question I asked.

Mr. JEHLE. He said from whom. From manufacturers. Richlyn Labs, Cowley Pharmaceuticals, Savoy Drug of Chicago, Portland, Oreg., Haack Laboratories over in Baltimore, the Barry Drug Co., Miami, Fla., Zirin Laboratories.

Mr. ROOKE. He has it documented here.

Mr. JEHLE. Canton, Ohio, Bowman-Braun Pharmaceuticals.

The CHAIRMAN. Are they manufacturers?

Mr. JEHLE. Yes, sir; they are manufacturers.

Mr. MACDONALD. Manufacturers or wholesalers?

Mr. JEHLE. Manufacturers so far as I know.

Mr. MACDONALD. You mean there is no Federal control over the manufacturers of these things?

Mr. JEHLE. Some companies, the less responsible companies, were selling to whoever puts in an order for them.

Mr. MACDONALD. Doesn't the HEW have any control over the manufacture of them?

Mr. JEHLE. Yes, sir; they have some control, but apparently these companies should be registered.

Mr. MACDONALD. Why can't FDA shut this off?

Mr. JEHLE. I don't know. I think that would have been a very good question for the FDA people. I am sure that this type of practice—

Mr. MACDONALD. I am asking you.

Mr. JEHLE. Yes, I think FDA has taken action since this case, to prevent repetition of this type of practice, this type of situation from developing, but the point is that there were 1,075,000 capsules purchased in just a few weeks' time. You asked where four and a half billion capsules came from.

Mr. ROOKE. I would say there wouldn't be a wholesaler in the city of Richmond that had 40,000 amphetamine tablets, if I were to try to get them.

The CHAIRMAN. They may not, sir, but the way things are going, you never know when it might show up in Richmond.

Mr. JEHLE. Yes, sir.

The CHAIRMAN. You heard the statement this morning about the trucker in Richmond who had so many. It could be had in Richmond as well as in Little Rock, Ark., or any other place.

Mr. JEHLE. Mr. Van Deerlin put his finger on another source of this illicit diversion. He talked about the drug coming back from Mexico. That is a very serious situation, and I think FDA should be pushing to close up that loophole.

The CHAIRMAN. That is true, but we are talking about this one right now.

Mr. PICKLE. I just wanted to ask you in connection with this company that bought all these drugs, are you saying that the manufacturers supplied those amounts to them thinking that they were dealing in the under-the-counter markets?

Mr. JEHLE. No, no, sir.

Mr. PICKLE. Illicit trade?

Mr. JEHLE. I would like to make that clear. I just don't know. I think that most of these companies are reputable, but they were a little bit careless in their sales practices.

Mr. PICKLE. Wouldn't an accurate statement be that because it is a general laxness in the regulatory distribution of these drugs, that this is the very reason that a company can set themselves up, ostensibly as a drug concern, and buy these products almost indiscriminately. It is easy to buy; isn't it?

Mr. JEHLE. Yes, sir.

Mr. PICKLE. Then you are saying surely that we do need some kind of control on these other outlets?

Mr. JEHLE. Yes, sir.

Mr. PICKLE. You are talking about hospitals, clinics, drugstores, across the border, and others. So you would like to see that kind of control established, but still you say "Leave me out."

Mr. JEHLE. Yes, we say that for a reason, sir. We say that because the pharmacy is not a significant source of the diversion of these amphetamine and barbiturate tablets.

Mr. MACDONALD. Will you yield, Mr. Pickle?

Mr. PICKLE. I yield back to the chairman.

Mr. MACDONALD. I know Mr. Pickle is more of an expert about across the border than I am, but I think that will be a small part of it.

Wouldn't it be reasonable to assume that somebody in FDA, if they had a record of a half million pills of whichever sort you are talking about, and I can never pronounce the words correctly, I call them barbiturates—I don't know what you would call it—I have heard it called by four different names during the course of these hearings—

and the other end, the sort of pickups, wouldn't it seem reasonable that somebody in FDA, if they saw a shipment of a half million pills going some place, would think that this isn't exactly logical?

Mr. JEHL. Yes.

Mr. ROOKE. There would be very definite reason; yes, sir. If I bought 2,000 of them, there would be a reason. Well, I wouldn't say 2,000, but maybe 5,000 or any other drugstore that I know of, there would be some reason to think there was maybe some diversion there.

Mr. MACDONALD. Isn't there some way already in the law as to how this can be stopped?

Mr. ROOKE. Well, there is a law, the State law. If these prescriptions go out from any drugstore other than on a bona fide, qualified physician's prescription, the pharmacist has violated the law, and he is subject to revocation of his license to practice his profession.

Mr. MACDONALD. I am not talking about that. I am talking about the fact that a half million, which I think is the figure used—

Mr. ROOKE. A half billion, sir.

Mr. MACDONALD. Well, a half billion. I am used to dealing with the budget over here, and I may get confused. However, say a half billion pills get ordered by a fly-by-night, which I suppose would not be listed in Dun & Bradstreet, if the list which you have read is correct. Wouldn't it cause some concern within the regulatory agency that is charged with the duty of protecting the public, if a half billion or even a half million are ordered, and there are no accompanying State regulatory pharmacy regulations that seem to regulate such a transaction?

As the law now stands—wouldn't that put the FDA on notice that something peculiar was going on?

Mr. ROOKE. It seems to me, sir, it very definitely would be of some serious concern as to where they are going and why, and what is going to be done with them.

Mr. MACDONALD. Hasn't this in fact happened?

Mr. ROOKE. According to this survey here by CBS, it happened. I don't know whether in reality this was done just to test that to see how freely they could be obtained. I don't know otherwise how often it has happened. I have heard no evidence of their going through any legitimate channels to that extent.

The CHAIRMAN. Mr. Carter.

Mr. CARTER. Mr. Macdonald, it isn't just a half billion. It is 4½ billion tablets that go out, or did in 1962, to these bootleg places, and so on, 4½ billion, half of the entire product. Of course, this is in the statement of Mr. Larrick this morning to that effect.

Actually the big amount of these amphetamines is not the ones that are getting misplaced or not the ones that go through the regular channels through the drugstores, through the hospitals, clinics, and so on, but it is this 4½ billion capsules which have been diverted from the factory which go from the factory to truck stops, and so on, to different persons.

I feel among the first things we must do is to regulate the manufacture and the sale at the source, it seems to me. I don't believe there is any law to that effect to take care of that.

Mr. ROOKE. I would certainly like to thank Dr. Carter for clarifying that. That, in our opinion, is really the trouble right there.

The CHAIRMAN. Mr. Jehle, do you know whether or not the information that is obtained by an inspector, as an example, in Virginia, can be given to a Federal Food and Drug inspector?

Mr. ROOKE. Mr. Chairman, I am not completely familiar with that. I know that the State authorities, the board, works very closely with the Narcotic Division.

I would certainly assume that they would with amphetamines and the barbiturates. As a matter of fact, they investigate numerous cases together in cooperation in Virginia. I don't know just what the law is, but I would certainly assume that that is already a law, and they have complete cooperation there.

Mr. JEHLE. I would believe that is the case, Mr. Chairman.

The CHAIRMAN. So you feel, then, that there is ample opportunity for cooperation between Federal and State authorities now, insofar as the pharmacist is concerned, for FDA to obtain all the information they need to enforce the law?

Mr. JEHLE. Yes, sir; and further information along this line will be forthcoming from FDA's current study of State drug laws.

That started some 18 months or 2 years ago, something like that, and I am sure within a reasonably short period of time FDA will be coming out with a report on the subject. They are studying, among other things, the adequacy of the State drug laws.

The CHAIRMAN. Any further questions?

Mr. MACDONALD. No, thank you, Mr. Chairman.

The CHAIRMAN. I thank you very much, Mr. Rooke and Mr. Jehle, for your presence and the information that you have presented to the committee.

Mr. JEHLE. Thank you, sir.

Mr. ROOKE. Mr. Chairman.

The CHAIRMAN. Yes, Mr. Rooke.

Mr. ROOKE. One more statement. It has been a real pleasure for me to see my own Congressman here this afternoon. We think a lot of him in our State.

The CHAIRMAN. We are glad to have him with us, and we are very glad to have him on this committee. I am sure he will join us in the cordial welcome accorded you today.

The committee will adjourn until 10 o'clock in the morning, at which time the first witness will be the representatives of the American Medical Association.

(Whereupon, at 4:30 p.m., the committee recessed, to reconvene at 10 a.m., Thursday, January 28, 1965.)

## DRUG ABUSE CONTROL AMENDMENTS OF 1965

THURSDAY, JANUARY 28, 1965

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The committee met at 10 a.m., pursuant to recess, in room 1334, Longworth Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

I would like to call to the attention of the members of the committee that pursuant to a request of the committee yesterday of Commissioner Larrick, there is a narrative analysis of H.R. 2 at each place for the benefit of the members.

This morning the first witness, as we continue hearings on H.R. 2, to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act, will be Dr. Henry Brill, West Brentwood, N.Y.

Dr. Brill, I believe you have with you Dr. William Kitto, associate director of the American Medical Association, and also Mr. Paul Donelan, from the department of legislation.

Gentlemen, we shall be glad to have your testimony.

STATEMENT OF DR. HENRY BRILL, COMMITTEE ON ALCOHOLISM AND ADDICTION, COUNCIL ON MENTAL HEALTH, AMERICAN MEDICAL ASSOCIATION; ACCOMPANIED BY DR. WILLIAM KITTO, ASSOCIATE DIRECTOR, AMERICAN MEDICAL ASSOCIATION DEPARTMENT OF DRUGS; AND PAUL R. M. DONELAN, AMERICAN MEDICAL ASSOCIATION DEPARTMENT OF LEGISLATION

The CHAIRMAN. Dr. Brill, I believe you are the spokesman for the group.

Dr. BRILL. Yes, sir.

The CHAIRMAN. If I have not properly identified each of you, it would be a good thing for you to do so, so we will have it in the record.

Dr. BRILL. Mr. Chairman, and members of the committee, I am Henry Brill, a physician residing in West Brentwood, N.Y., where I am the director of the Pilgrim State Hospital. My specialty is psychiatry and neurology, and I am clinical professor of psychiatry at New York School of Psychiatry and a member of the committee on alcoholism and addiction, a standing committee of the Council on Mental Health of the American Medical Association. With me are Dr. William Kitto, associate director of the AMA Department of Drugs, and Mr. Paul R. M. Donelan of the AMA Department of Legislation.

The American Medical Association supports H.R. 2. The AMA Council on Mental Health has found that a significant problem exists in the abuse of barbiturates and amphetamines. This opinion has recently been shared by the association's council on drugs. Although it is difficult to obtain reliable data on which to estimate the volume of illicit traffic in these agents, it has become increasingly apparent that the concern regarding the abuse of barbiturates and amphetamines may be well founded. This bill, which would amend the Federal Food and Drug Act to establish controls in the manufacture and distribution of central nervous system depressant and stimulant drugs, seeks to curtail the illicit traffic in these drugs.

I should like to point out, at the outset, that the term "depressant and stimulant drugs" includes a wide array of drugs which are recognized as medically proven and useful. They are an important part of the physician's armamentarium in the treatment of his patients, and are therapeutically beneficial when taken as prescribed by him. The drugs within each category are intended to achieve different therapeutic results. The barbiturates, and other drugs within the depressant category, are intended for use as sedatives, while the amphetamines and other similar drugs would be indicated for use as stimulants.

Both depressant and stimulant medications are widely used by the practicing physician. Some of the medical uses of the barbiturates and other depressant drugs are to relieve insomnia, to relieve apprehension, tension, and nervousness, or to produce partial or complete unconsciousness, as an anesthesia. They are also used as aids to complete relaxation in psychiatric examination and therapy. Another valuable use is in the control of convulsive disorders. The stimulant drugs might be used in supportive treatment of certain depressive states, in the treatment of certain behavior disorders of childhood, or as temporary curbs of appetite in weight-control programs.

Unfortunately, the depressant and stimulant drugs are sometimes used without direction of a physician, either for their thrill effect, to overcome fatigue, to produce a sense of well-being, as an escape from reality, or to induce a feeling of elation or lack of responsibility.

Abuse of these drugs may lead to, among other effects, the impairment of mental functioning resulting in poor judgment and sense of timing, loss of emotional control, mental confusion, various types of abnormal behavior, irritability or depression, failure of muscular coordination, and diminishment or loss of reflexes. In addition, abuse of stimulants can result in a symptomatology of excessively rapid beating of the heart, hypertension, nervousness, emotional tension, increased tendon reflexes, and hallucinations. Abuse may lead to or aggravate anti-social behavior, and may result in conduct causing serious harm. In considering legislation concerning these drugs, however, the beneficial therapeutic effects of the drugs, as well as the results of their abuse, should be kept in mind.

The American Medical Association has a deep measure of interest in legislation which affects the well-being of our citizens. It shares the concern of this committee with respect to the wrongful, nonmedical use of depressant and stimulant drugs. The physician, perhaps more than anyone else, recognizes the potential harm resulting from abuse of these drugs. On the other hand, the physician knows that any drug has a potential for abuse.

While the AMA generally supports the enactment of H.R. 2, we believe that certain changes can be made which may improve the effectiveness of this measure.

The term "depressant and stimulant drugs" includes not only amphetamines and barbiturates, but also, as defined in H.R. 2, any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a "potential for abuse" because of its depressant or stimulant effect on the central nervous system or because of its hallucinatory effect. We suggest that the legislation might properly be restricted at this time to barbiturates and amphetamines, inasmuch as these are the only two classes of drugs for which any significant misuse is shown.

It is argued by some that a control of one drug whose use is abused would result in a shift of use to another depressant or stimulant drug and a similar abuse. The Secretary is accordingly authorized, among other things, to extend the authority of this law, by regulation, to the drug which has acquired new and widespread abuse. Since the Secretary can exempt from this act drugs whose regulation is not necessary for the protection of the public health, it would seem logical that this same requirement be incorporated as a guiding standard for the Secretary in designating additional drugs to be included. Accordingly, we suggest that section 3(a) be amended so that in subparagraph (3) the definition of "depressant or stimulant drugs" would mean—

any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse leading to adverse effect on the public health because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect; except \* \* \*.

If this suggestion is considered favorably by the committee, we further recommend that the determination of whether the public health is adversely affected should be made by the Advisory Committee.

The AMA regards those provisions of the bill relating to an Advisory Committee as salutary. Through their implementation, the Secretary may receive the advice and consultation of an impartial group of experts. Additional beneficial use of this committee could be obtained if the Secretary would be required to consult with them before the proposal of a new regulation. This appears to be the intent of the recommendation of the President's Advisory Commission, where, in its "Report on Narcotic and Drug Abuse," it stated (p. 44):

In determining the specific drugs which fall within the scope of his regulatory power over dangerous drugs, the Secretary of Health, Education, and Welfare should be advised by a standing committee composed of experts from both within and without the Federal Government and should act in accordance with fair rulemaking procedures.

Finally, we recommend that the number of experts composing the Advisory Committee be increased to at least seven. This change would broaden the base of opinion of the committee and would make the committee more representative of the scientific community. Also, if the Advisory Committee were to be made a standing committee for a fixed period of time, it would not be necessary to constitute such a committee upon each occasion when its consultation is required.

In conclusion, let me again state the AMA's concern with the increasing report of nonmedical use of the drugs under consideration, particularly among the youth of our Nation. However, legislation alone may not be the answer. Much misuse is founded on a lack of understanding of the serious consequences which may result from use of these drugs. It seems, therefore, that a program of education could forewarn our youth of these serious, often disastrous, effects.

Mr. Chairman, we wish to thank you for this opportunity of presenting the views of the American Medical Association. We will now be pleased to attempt to answer any questions which the committee may have.

The CHAIRMAN. Doctor, thank you very much for your concise and very fine statement on this subject. It gets right to the point and that is what we want.

Mr. O'Brien, any questions?

Mr. O'BRIEN. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you Mr. Chairman.

Dr. Brill, I notice that you recommend that the bill be very limited in the drugs that it covers for regulation, if I understand your paper.

Dr. BRILL. Yes, sir. The initial recommendation was that it be limited to the barbiturates and the amphetamines. But the entire bill is supported and this would include drugs with hallucinogenic effect also.

Mr. YOUNGER. We have had a lot of testimony on cases where the tranquilizers are abused just as much as have been the other drugs. There are certain designated pills in the tranquilizer field that can be designated. Why should they not be included in the bill if we are going to do anything, rather than leave them out?

Dr. BRILL. The opinion of the association was that if there was a great deal of discussion as to whether other drugs should be included, the association would have been happy to support a bill which included amphetamines and barbiturates alone. But the association is quite willing to see the broader field of drugs included.

Mr. YOUNGER. Thank you. I have one other question: In the practice of medicine, how many or what percentage of the doctors dispense and sell drugs themselves out of their own office?

Dr. BRILL. True dispensing physicians, in the full sense of the term, are a small and decreasing minority. But the exact definition of a dispensing physician becomes a difficult matter; many physicians occasionally dispense a dose or a few doses of medication.

Mr. YOUNGER. Then you do not believe that it is practiced to a great extent. Yet if we keep the pharmacies in the bill, should we not include the doctors who do dispense and sell drugs out of their own office, and they should be required to keep a record?

Dr. BRILL. I think it would be very difficult to make an exact definition. If one included all dispensing, this would impose a great and an unnecessary burden on the medical profession, especially since, according to Commissioner Larrick's testimony, in the last 10 years less than three physicians a year have been involved in any difficulty because of the dispensing of these drugs.

Mr. YOUNGER. Thank you.

Dr. BRILL. May I interpose one statement I didn't complete?

I neglected to discuss the term "tranquilizer" specifically enough. This is a broad term. It includes many very important substances that do not have a potential for abuse. It also includes some substances which do have a potential for abuse. For this reason, the term "tranquilizer" is not a very useful one to define the substances that would fall within this bill. But I think that the other terms, "depressant" and "stimulating" and "hallucinogenic" drugs, which are already in the bill, cover it quite adequately.

Mr. YOUNGER. In the President's Commission's report, they enumerate five specifically by name, and the Commissioner yesterday mentioned some by name. On those that are known by name why shouldn't they be included where the Commission and the Commissioner, himself, admit that there is abuse?

Dr. BRILL. The difficulty arises in the fact that if one were to begin listing, it would be a very long list. If one included only a short list, it would be quite likely that some not named would be just as potentially abusable as those that are named. So naming them specifically would burden the law, would quite likely create unfair impressions, and in the opinion of the association is not necessary.

Mr. YOUNGER. This is rather an unusual position for the AMA to take because, if I understand their position, they have not in the past been willing to leave everything to the regulation of pure Food and Drug, but want specific laws passed.

Dr. BRILL. I recognize what you mean. The AMA feels that a scientific body, acting as consultants, would be quite adequate to cover this situation.

Mr. YOUNGER. Thank you. That is all.

The CHAIRMAN. Mr. Kornegay.

Mr. KORNEGAY. I have just one question, Mr. Chairman.

Dr. Brill, I gather from your answers to my colleague's questions and your statement here that you are suggesting greater participation and reliance upon the advisory committee in designating the drugs to be covered under regulation; is that correct?

Dr. BRILL. Yes, sir. Early participation.

Mr. KORNEGAY. In other words, get the advisory group in at the inception?

Dr. BRILL. Yes, sir.

Mr. KORNEGAY. Thank you.

The CHAIRMAN. Mr. Springer, have you any questions?

Mr. SPRINGER. I have no questions. It was a very good statement.

The CHAIRMAN. Mr. Friedel, have you any questions?

Mr. FRIEDEL. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Nelsen.

Mr. NELSEN. Dr. Brill, on the first page of your testimony you mention that there has been significant problems existing in the abuse of barbiturates and amphetamines. You single those two out, but is it not true that there have also been abuses in other areas, perhaps equally disturbing?

Dr. BRILL. It is true that abuses of other drugs have been reported, and they are equally disturbing in the sense that there is a potential for abuse. But in terms of duration of experience and extent of experience, barbiturates and amphetamines have the firmest foundation

for concern, if I can put it that way. We have been dealing with them longer and on a larger scale than the other substances.

Mr. NELSEN. You mentioned a moment ago, Doctor, that is all of them were to be named, the list would be very long, and it would create quite a problem.

You mention that two are mentioned in the bill and the rest are not. It would seem to me that we ought to take into account what was brought into the testimony yesterday, the potential competitive situation that might exist. We want to be careful that our language is drawn to correct the problem, and at the same time not to create one unfairly in any area. I am sure you understand.

Mr. BRILL. I do, and I think that the wording in our statement takes this into consideration because amphetamines, and especially the barbiturates, are classes of drugs and do not involve a particular competitive situation.

Mr. NELSEN. In the President's report, other drugs are mentioned. I am sure you have seen that report where they name other drugs. I am not a pharmacist so I will not attempt to name them.

Dr. BRILL. Yes.

Mr. NELSEN. But you do agree that these other products that are named also do have a potential danger if they are abused, do you not?

Dr. BRILL. Yes, sir. May I add that there is a reason for not naming drugs more specifically than is necessary because of the effect on patients. I personally have had patients come to me, patients who were receiving various medications that were necessary for their well-being. They were very much concerned because such drugs had been specifically named in the press or in various other public media.

So because of the effect on patients, I think undue specificity, should be avoided.

Mr. NELSEN. In some cases have you prescribed the use of barbiturates or amphetamines yourself as a physician?

Mr. BRILL. Yes, sir.

Mr. NELSEN. Would those same patients be alarmed because certain drugs are named in the bill? Wouldn't your argument sort of defeat the fact that you do name two and you don't name the rest? Wouldn't your argument fit in that case, also?

Dr. BRILL. The argument up to a point, I would have to agree, would apply. But one would want to restrict this as much as possible. In addition, these substances are ordinarily dispensed under names other than the general terms "amphetamines" and "barbiturates," so that they are not really pointed out quite as specifically as that.

Mr. NELSON. Thank you.

The CHAIRMAN. Mr. Van Deerlin.

Mr. VAN DEERLIN. You mentioned that the dispensing of drugs by physicians is declining. Do you mean in their offices? Or might it be assumed that there is a decline in the ownership of dispensing drug outlets owned by physicians?

Dr. BRILL. Our statement applies only to physicians dispensing for money in their office. It applies to a practice which once was widespread and now is very minor. It does not apply to ownership of pharmacies.

Mr. VAN DEERLIN. It would be assumed by you, I guess, that in any drug dispensing through retail outlets in which physicians are the exclusive owners, the provisions of this bill on the reporting would apply, would they not?

Dr. BRILL. Yes, sir.

Mr. VAN DEERLIN. Just like any other drugstore?

Dr. BRILL. Just like any other drugstore.

Mr. VAN DEERLIN. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Curtin.

Mr. CURTIN. No question, Mr. Chairman.

The CHAIRMAN. Mr. Satterfield.

Mr. SATTERFIELD. No questions.

The CHAIRMAN. Mr. Cunningham?

Mr. CUNNINGHAM. Doctor, is alcohol considered a drug?

Dr. BRILL. In some context, yes; usually, no.

Mr. CUNNINGHAM. Have you had experiences of so-called anti-social behavior as a result of alcohol which would be much greater than the abuse by these drugs we are speaking of?

Dr. BRILL. Speaking personally, I would say yes. This was not included in the consideration by the association, but I would certainly have to agree with that.

Mr. CUNNINGHAM. If it is considered a drug, I was wondering about the possibility of alcohol being dispensed by a physician, as an experiment.

Dr. BRILL. I think this experiment was once tried and resulted in very unhappy complications.

Mr. CUNNINGHAM. Thank you.

The CHAIRMAN. I might suggest, Doctor, in that case I am sure many more doctors would get back into the business of distribution.

Mr. Mackay.

Mr. MACKAY. Doctor, I would like you to amplify your reasons on page 4, for this suggested addition of the words "leading to adverse effect on the public health." What did you consider to be the inadequacy of the language as stated in the printed bill?

Dr. BRILL. For example, ether can be abused, yet there is no indication at this time that ether would have an adverse effect on the public health. So the association felt that there should be some indication, some scientific evidence that this has implications for difficulties on a wider scale.

Mr. MACKAY. Thank you.

Dr. BRILL. Incidentally, the statement is made that any drug can be abused. In a very broad context, one could maintain this thesis.

The CHAIRMAN. Doctor, anything can be abused. Too much sugar, too much bread—

Dr. BRILL. Or food.

The CHAIRMAN. Anything that the human body consumes or which an animal consumes can lead to abuse, can it not?

Dr. BRILL. Yes, sir.

The CHAIRMAN. Mr. Carter?

Mr. CARTER. Dr. Brill, do you think there is widespread abuse of tranquilizers?

Dr. BRILL. Widespread? No.

Mr. CARTER. Do you find many deleterious effects from the use of tranquilizers?

Dr. BRILL. I would prefer the word occasional.

Mr. CARTER. Which tranquilizers, in your opinion, cause these deleterious effects?

Dr. BRILL. I am sure you understand that a full list would be very extensive, and I am afraid, beyond my immediate capacity. To name some and not others would be unfair.

Mr. CARTER. I mean which might cause the difficulty that we have with the amphetamines or the barbiturates?

Dr. BRILL. Perhaps I can reach this point by saying that the phenothiazines, the major tranquilizers, reserpine, and that class of drugs, are not subject to abuse. A very large number of the other drugs that fall into this class are subject to abuse.

Mr. CARTER. You really don't find too much abuse, though, of the use of tranquilizers, is that true?

Dr. BRILL. That is true, so far.

Mr. CARTER. They don't have the bad effects of amphetamines or barbiturates, as a usual thing?

Dr. BRILL. I think that the potential is there. We are speaking about the contrast between a potential and an actual abuse. In actuality, I would certainly agree that this is not an extensive problem.

Mr. CARTER. Thank you, sir.

Mr. SATTERFIELD. Would the gentleman yield?

Mr. CARTER. Yes.

The CHAIRMAN. Mr. Satterfield.

Mr. SATTERFIELD. I would like to get back for a minute to a question Mr. Mackay asked you. It seems to me that what you are saying here by the insertion of the words "leading to adverse effect upon the public health," is that regulation should be confined to those drugs that would have a permanent or lasting effect and thus affect public or individual health.

Isn't it true that any drug, stimulant, or depressant that affects the central nervous system might have a temporary effect that would lead to misjudgment, carelessness?

Dr. BRILL. We are talking specifically about chronic use rather than the effect of a single dose. I think this is the distinction you are making, if I understand you correctly.

Mr. SATTERFIELD. I was thinking this was the distinction you made in your report.

Dr. BRILL. Yes, I think that is right.

Mr. SATTERFIELD. I take it from your report, that you feel the discretion that is left with the department to ascertain which additional drugs fall within the purview of this proposed bill should be confined only to those with lasting effect, and not to those producing temporary effect in determining how it may affect public safety.

Dr. BRILL. I think the issue of "a lasting effect"—and this may be a question of semantics—is that all of these substances have a temporary effect which is reproduced time and time again. It is this repetition of the temporary effect, the compulsive drive toward a repetitious use, that constitutes abuse.

But the problem to which the association was addressing itself with this term was the determination of whether a given substance had the

necessary qualities to be attractive enough to be a potential threat to public health. That is, that it would attract people to a sufficient degree so that it was a threat in this field.

Mr. SATTERFIELD. Then you would include depressants or stimulants that would not necessarily have a lasting effect but, due to frequency of use, would constitute an equivalent of that effect.

Dr. BRILL. Yes, sir.

Mr. SATTERFIELD. Would this not then include all drugs that would affect the central nervous system by way of depressing it or stimulating it?

Dr. BRILL. In experience, some drugs have tended to be very attractive and to constitute a potential threat within this field, other drugs have not. The basis for the use of the consultant group is to sift the scientific and medical information, and to make a determination of which drugs have this quality and which drugs do not.

Mr. SATTERFIELD. It would seem to me, to go back to the example you used, ether, while I can't conceive of anyone imbibing in ether frequently, wouldn't the result be exactly the same while one is under its influence?

Dr. BRILL. Yes, sir, the immediate effect of ether sniffing—and incidentally, one of the earliest uses of ether was in ether-sniffing parties when people became inebriated—but this is not a threat even though the immediate effect of ether sniffing is to produce an intoxication.

Mr. SATTERFIELD. Insofar as danger to public safety, health, and welfare it would nevertheless be detrimental, would it not, if improperly used?

Dr. BRILL. I think that the purpose of this bill, as I understand it, is to control the chronic, repeated, compulsive use of drugs, rather than the single, individual dose. If I may point out, insulin, which is used in the treatment of diabetes, may also produce very serious effects of the same type, with loss of consciousness.

Mr. SATTERFIELD. Thank you.

The CHAIRMAN. Are there any further questions?

Mr. Gilligan?

Mr. GILLIGAN. Thank you, Mr. Chairman.

The ether sniffing brought something to my mind that I meant to ask a little earlier. We had in our district something of a scandal a couple of years ago of a group of high school students who were engaged in glue sniffing. What is the chemical agent which causes the hallucinatory effect in glue? Is it covered in this bill or, in your opinion, should it be?

Dr. BRILL. It is not covered in the bill. It is not a drug; it is an industrial solvent. I wish I could recall the name, but I can't at this moment. There are a considerable number of industrial solvents that can produce effects.

Of course, children sometimes even go so far as to sniff gasoline to produce an intoxication.

Mr. GILLIGAN. In your opinion, therefore, there should be no attempt to cover such solvents in a bill of this type?

Dr. BRILL. I don't think there is any objection to an attempt, but it would seem extremely difficult to do this. If I were to list all the substances in our surroundings which can be used to produce intoxication, it would be a very long list. For example, nutmeg can produce a very

striking intoxication. It has been used in certain correctional facilities where the prisoners discovered it and abused it.

Mr. GILLIGAN. I have never understood before why they put it in eggnog.

Dr. BRILL. The dosage has to be large.

Mr. GILLIGAN. Thank you, Mr. Chairman.

The CHAIRMAN. Doctor, what we are trying to do is to reach those drugs which when manufactured and distributed present problems involving their abuse because of their effect on the central nervous system of the individual. This is not an attempt to try to reach an impractical situation that would be impossible to administer.

Dr. BRILL. Yes, sir.

The CHAIRMAN. For example, when I was a youngster, we used to go out in the woods and get a cross vine and light it up and smoke it. I think to attempt to reach a situation like that would present a rather ridiculous situation.

Maybe I shouldn't mention it, but I have been told that there is another branch of the legislative branch not too far from here that keeps a little box just inside the door with snuff inside of it, where they go by and sniff it every time they need it.

I suppose that would provide a little stimulant, would it not?

Dr. BRILL. Yes. It is a central nervous system effect.

The CHAIRMAN. So we could get off into a realm here that would present impossible situations. What we are trying to do now is to reach this class of stimulants which involve abuse, having an adverse effect on the health of the people and the welfare of the Nation.

Dr. BRILL. This is our understanding of the intent.

The CHAIRMAN. Are you familiar with the drug meprobamate?

Dr. BRILL. I am, sir.

The CHAIRMAN. Would you say it should come in this class?

Dr. BRILL. I think it would be a very definite candidate for inclusion; yes, sir.

The CHAIRMAN. Is it recognized medically as having a similar effect to the barbiturates?

Dr. BRILL. It would fall into the same class.

The CHAIRMAN. It would fall in the same class?

Dr. BRILL. As far as having a sedative effect. It is a tranquilizer, but it has a sedative effect.

The CHAIRMAN. Why should it not be included by name as those of the barbiturate-sodium compounds?

Dr. BRILL. This is a specific drug rather than the name of a class of drugs, like the barbiturates, and to name this one specific drug would create an unfair market situation in comparison to many, many others that have similar attributes. Either they all should be named or it would be fairer not to name any one specifically.

The CHAIRMAN. I thought a barbiturate was a specific drug.

Dr. BRILL. It is one of a class. There are many, many types of barbiturates, and they are marketed under many different names. Luminal, for example, is a very useful drug for the treatment of epilepsy. I could name many, many other barbiturates.

The CHAIRMAN. Is there a class that the meprobamate belongs to?

Dr. BRILL. Meprobamate is a specific individual drug that has not given rise to a class of chemical relatives; therefore it is a specific individual substance.

The CHAIRMAN. Are you familiar with the drug glutethimide?

Dr. BRILL. Yes, I am, sir.

The CHAIRMAN. Pardon my pronunciation of these words. I do not have a daily familiarity with them.

Would you say it would be in the same category?

Dr. BRILL. It has characteristics very similar to that of meproamate, and what we just said about meproamate would apply with equal force to it.

The CHAIRMAN. What about methyprylon?

Dr. BRILL. I think I would repeat the same words about that.

The CHAIRMAN. I would not undertake to pronounce the next one, but I will spell it for you. C-h-l-o-r-d-i-a-z-e-p-o-x-i-d-e.

Dr. BRILL. Yes, sir, I know that one.

The CHAIRMAN. What would you say about it?

Dr. BRILL. Exactly the same as I have just said about meproamate.

The CHAIRMAN. And you think it would be inadvisable to include these by specific names?

Dr. BRILL. The list would have to be extended very much and would create, in the opinion of the association, a rather unwieldy situation.

The CHAIRMAN. Let's see, then, with your suggested amendment you would add to the language in H.R. 2, in the third category, the words "leading to adverse effect on the public health."

Dr. BRILL. Yes, sir.

The CHAIRMAN. The question has been running through my mind just how that amendment would change things. I can't imagine the Secretary holding hearings and coming to a conclusion that a certain drug should be included unless he found that it would be adverse to the public health. What does the language add?

Dr. BRILL. I think the purpose of this is to give the Secretary a clearer definition with which to work and to avoid the uncertain definition which the term "abuse" alone, or "potential for abuse" alone, might give. It is to attempt to firm up the definition.

The CHAIRMAN. It might spell it out a little more specifically, but the way I see it now I don't see how it adds too much to it. But I don't see how the agency could object to it. That is the way I see it at this moment.

Dr. BRILL. From my experience in working with advisory committees of this type, I would feel that a firmer definition would be easier to work with. But I would have to agree that commonsense would undoubtedly prevail in either case.

But a firmer definition would, in the opinion of the association, be useful.

The CHAIRMAN. Then you would suggest that it be made clear that the Secretary would use or consult, rather, or seek the advice of, the advisory committee.

Dr. BRILL. Yes, sir.

The CHAIRMAN. How long a period of time would elapse from the initial proposal that a particular drug be brought under this provision before a decision could be obtained from the advisory committee and the usual procedures followed by the agency to bring in a drug that would be covered under this program? Wouldn't that require an extraordinary length of time?

Dr. KITTO. Would you repeat the question, sir? I am not sure I understand it fully.

The CHAIRMAN. I understand this provision, the third category referred to, in the bill, to which our discussion now is directed, would include any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse leading to adverse effect on the public health because of its depressant and stimulant effect on the central nervous system or its hallucinatory effect, and so forth.

That would mean that a drug would be considered by the agency, it would be referred to the advisory committee, the advisory committee would have to consider—which I think is a good procedure—and they would advise with the Secretary as to what should be done.

Following that, I suppose there would be the usual hearing which would have to be provided before a final decision is made. Wouldn't that require a lot of time?

Dr. BRILL. I would like to divide our answer into two parts. That is, the possibility of delay inherent in the regulatory structure as it is outlined in the bill, and the possibility of additional delay due to having the advisory committee consulted ahead of time.

If an expert committee had already been consulted, it is quite likely that this would reduce the overall amount of delay because a determination which had been made in advance might reduce the total number of hearings.

The CHAIRMAN. I would hope that we would not leave loopholes here for another Krebiozin thing to develop, involving the medical profession and those who suffer a dreaded disease, with great pain and mental anguish.

Dr. BRILL. Sir, with respect to the total delay which might be caused by using the administrative mechanism referred to here. I am not in a position to speak authoritatively. Perhaps we could offer a communication on that subject.

But with respect to the additional delay that might be produced by having an advisory committee come in, I note that Commissioner Lar-rick said that it was his intent to consult scientists in and out of Government to determine which drugs should come under the scope of the proposed section.

So that this, in effect, merely formalizes his intention somewhat, Again, speaking from experience, an expert committee, where the issues are clear cut, can make a determination quite rapidly. Where the issues are not clear cut and where there is considerable doubt, it takes a longer time and more information has to be sifted.

But for all practical purposes, I think that the expert committee could render opinions quite rapidly in those fields where the issues are clear cut and where the question is an important question that needs to be settled rapidly.

The CHAIRMAN. Doctor, what I am trying to get at is this: We will have some witnesses who will follow you who will tell this committee how the bill is going to affect the competitive situation, and request of this committee that we do something that would assure equitable treatment, and so forth.

This is such a highly technical field and it has such far-reaching consequences I am not sure that I am qualified to judge. As a matter of fact, I know I am not qualified to judge what should be done.

We want to protect the competitive situation, but at the same time we do not want to leave a loophole here. That is what I am seeking right now. I am seeking guidance.

Dr. BRILL. I would think from everyone's point of view it would be desirable to have an expert opinion before listing a substance. I would think from the point of view of the industry this would not be objectionable.

The CHAIRMAN. Mr. Rogers, have you any questions?

Mr. ROGERS of Florida. Doctor, are most of these drugs of which we are now speaking prescription drugs?

Dr. BRILL. Yes, sir.

Mr. ROGERS of Florida. Or they should be prescription drugs?

Dr. BRILL. They all are prescription drugs.

Mr. ROGERS of Florida. None of these are sold over the counter without a prescription, then?

Dr. BRILL. No, sir.

Mr. ROGERS of Florida. Are any of the tranquilizers sold over the counter without prescription?

Dr. BRILL. Not to my knowledge. Drugs of the type discussed in this bill should not be sold over the counter. They should be sold by prescription. It has been pointed out to me, of course, that there is in the mechanism of the Food and Drug Administration a way of changing the status of a drug from an over-the-counter status to a prescription status if it becomes obvious that this is necessary.

Mr. ROGERS of Florida. So you feel there is no loophole there that could be used?

Dr. BRILL. I think not.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Devine, have you any questions?

Mr. DEVINE. Yes, Mr. Chairman.

Dr. Brill, are you also in private practice in addition to being in a public function?

Dr. BRILL. To a very limited extent, yes, sir.

Mr. DEVINE. You are a psychiatrist and a neurologist?

Dr. BRILL. Yes, sir.

Mr. DEVINE. In your statement I notice at several places you say that you use these various drugs as hypnotic aids in psychiatric examination and therapy, but you go on to say they can create anti-social behavior and may result in conduct causing serious harm.

Are you directing this harm to the individual himself or harm to other members of society, or both?

Dr. BRILL. Both. A very simple example is when a man is in his automobile and he is intoxicated. His judgment is affected and he is a danger to himself and to others.

Mr. DEVINE. You are talking about intoxication. But a barbiturate could do the same thing, I suppose, an excess.

Dr. BRILL. Yes, sir.

Mr. DEVINE. Do you know roughly about how many people in this Nation we are talking about who are addicted to these sedatives and depressants? Perhaps that is an unfair question to ask you.

Dr. BRILL. The fact is that the data to answer your question, to my knowledge, does not exist.

Mr. DEVINE. It does not exist?

Dr. BRILL. It does not exist. One can make various estimates, and there are all kinds of estimates made. But a reasonably firm answer I couldn't give you.

Mr. DEVINE. The reason for the question is this. Here we are, an arm of the Federal Government, perhaps moving into an area where we again are trying to save ourselves from ourselves. I am reminded in one of the subcommittees of this committee where I think that our traffic fatalities for one year now are 40,000.

Dr. BRILL. Yes, sir.

Mr. DEVINE. I don't know whether we are going to save ourselves from automobile drivers or what. I am just wondering if you have any numerical figures which indicate a great need for this type of legislation to save ourselves from ourselves.

Dr. BRILL. I am afraid I can't give you a numerical figure. I can tell you that it is not at all unusual, in my own personal experience, to see heroin addiction complicated by addition to barbiturates. So it certainly is not rare that barbiturates are abused, and abused in a very serious context.

Mr. DEVINE. I am sure you don't have any opinion that in the event that we enact this legislation that it will stop the bootlegging of barbiturates or amphetamines, or anything else, do you?

Dr. BRILL. I think the hope is that it would very materially reduce it.

Mr. DEVINE. That is your opinion and that of your association?

Dr. BRILL. Yes, sir.

Mr. DEVINE. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Pickle, have you any questions?

Mr. PICKLE. Mr. Chairman, I am sorry I arrived late. My questions may have been asked, but they will not take but a minute.

How many physicians in your estimate dispense medicines of this kind, as contrasted to prescriptions? What percentage of physicians in the country dispense them?

Dr. BRILL. Virtually all physicians occasionally give a dose of medication, especially under emergency conditions. But when one speaks of systematic dispensing for a fee from the physician's office—in the old-fashioned sense of a dispensing physician—I think that this is a relatively rare practice and is decreasing.

But when one attempts to define the term "dispensing physician," one runs into a continual problem; the definition is extraordinarily difficult.

Mr. PICKLE. I understand it is. But could you give me an estimate? Do you have 5 or 10 percent of the physicians that dispense? What figure would you use?

Dr. BRILL. I am afraid that the figure that you are asking for is not available. But I would again say that the vagueness of the definition would make this figure relatively difficult to interpret in any case.

Mr. PICKLE. Could you get for the committee an estimate, percentage-wise, a rough estimate, of those physicians who do dispense? You know generally, according to the law that is laid out to us, where you would draw the line, perhaps better than we.

Dr. BRILL. We shall try.

(The following letter was later received in connection with the above colloquy:)

AMERICAN MEDICAL ASSOCIATION,  
Chicago, Ill., February 4, 1965.

HON. OREN HARRIS,  
*Chairman, Interstate and Foreign Commerce Committee, U.S. House of Representatives, Washington, D.C.*

DEAR CONGRESSMAN HARRIS: On January 28, 1965, at the hearings held on H.R. 2 by the House Interstate and Foreign Commerce Committee, Congressman Pickle asked the American Medical Association witness, Dr. Henry Brill, for information as to the number of physicians presently in practice in this country who would dispense the drugs under consideration. Dr. Brill indicated that he did not think such information was available but would try to obtain the data.

It is not clear from the context whether the reference was to the physician who only dispenses drugs on occasion, or to the physician who dispenses a variety of drugs, having in mind perhaps the physician in rural areas whose patients would not have access to a pharmacy. Both might be termed a "dispensing physician," and a question of definition would have a great bearing on the number of physicians falling within any classification.

There still exist situations where the physician dispenses drugs in areas where no pharmacy is close by—principally in rural areas—in order to provide the medications needed by his patient. However, these would represent, as Dr. Brill stated, a small and "decreasing minority." They would, in fact, represent a very small percentage of practicing physicians. On the other hand, if the physician who may dispense medications occasionally or on an emergency basis were included, this number would of course be greater. We regret that actual figures are not available.

The colloquy between the witness and Congressman Pickle related to the provision of the bill exempting physicians from the recordkeeping requirements of the bill. Aside from the burdensome and onerous characteristics of such legislation which would be imposed on physicians, there is also the important factor of physician-patient relationship which should be considered. This confidential relation between the physician and patient should not be violated. Since other testimony at the hearings showed that physician involvement in improper dispensing was minuscule and that the total amount of these drugs dispensed from such physician source would be extremely small in relation to the number dispensed through other channels, there appear to be no factors present which would warrant a breach of this confidential relationship.

In this connection, I should also like to correct a figure in our testimony relating to the number of physicians in our country. The present number would approximate 285,000 rather than 200,000, as inadvertently stated by our witness in his testimony. (The figure 200,000 would more closely approximate AMA membership.) Commissioner Larrick had earlier stated that, in a 10-year period, less than three dozen physicians have been convicted of unlawful dispensing of these drugs. Under these facts, we submit it would be unwarranted to remove the provision exempting physicians from the act, and we urge that the bill not be changed insofar as this exemption is concerned.

I should like also to comment on our recommendation that an advisory committee should be consulted by the Secretary before proposing a regulation to include additional drugs under the act. At the hearing you expressed concern over the delay which might ensue from this procedure. It was not contemplated that this preliminary consultation should involve a formal hearing procedure. The more formal procedures are spelled out in the bill and relate the actions which may be taken subsequent to the Secretary's proposal. The preliminary reference for committee advice could be summary and informal. Conceivably, the longer, formal procedures could be obviated by an earlier recommendation of the committee, and thus the overall time which could elapse would be materially reduced.

I would appreciate your making this letter a part of our testimony.

Sincerely,

F. J. L. BLASINGAME, M.D.

Mr. PICKLE. My other question was, and it may have been asked earlier: Under section 511, physicians are exempt from the inspection provision. For my own information, if you have not answered this, why do you object to a representative of the FDA coming in to look at your records the same as the bill requires of the pharmacists?

Dr. BRILL. I think that the keeping of special records on the part of physicians would be unwarranted because of the very small amount of dispensing that is done, and the undue burden that it would place on the medical profession.

Mr. PICKLE. Then your primary reason would be because of the burden it places on him and not because it is any violation of a professional ethic?

Dr. BRILL. Well, I think that one could raise the question of professional ethics, but practical experience is equally important. Experience shows that in the last 10 years, only three physicians a year have been in difficulties because of dispensing this type of medication, out of the 275,000 in the country.

So according to experience this is a very minor question.

Mr. PICKLE. Then the overriding reason is that it is an undue burden and not necessary?

Dr. BRILL. I would say so, yes, sir.

Mr. PICKLE. This is the same testimony, basically, that the pharmacists gave yesterday. The bill requires that they be covered. You say that very few of your doctors are involved. I can't understand why, then, there would be such great objection to having these records to be made available from them, including the pharmacists.

Dr. BRILL. When I said that only three physicians a year are involved, I meant that only three physicians a year had gotten into difficulties. So in order to find a very small number, a very large amount of routine record keeping and inspection would be called for.

I think this would be an unwieldy and unjustifiable effort on the part of the medical profession.

Mr. PICKLE. That is all, Mr. Chairman.

The CHAIRMAN. Do you wish to comment on whether or not the pharmacists should be included?

Dr. BRILL. I think not, sir.

The CHAIRMAN. Mr. Broyhill, have you any questions?

Mr. BROYHILL. No questions.

The CHAIRMAN. Mr. Kornegay?

Mr. KORNEGAY. Thank you, Mr. Chairman.

Doctor, let me ask you this: Does this bill in the three definitions cover medications that are commonly referred to as pep pills?

Dr. BRILL. Yes, sir.

Mr. KORNEGAY. In other words, they would be included in the bill?

Dr. BRILL. Yes, they would.

Mr. KORNEGAY. Does it also include such drugs as benzedrine, and I think there is one under the trade name of "No-do," and things of that sort?

Dr. BRILL. It does include benzedrine. However, "No-do" is a caffeine substance which is not included. It is not a pep pill, as I understand it.

Mr. KORNEGAY. To my recollection, that particular pill is sold without prescription so it would not be covered.

Dr. BRILL. Yes. This is not a pep pill.

Mr. KORNEGAY. What effect do pills, such as "No-do," have on a person? Is it a stimulant?

Dr. BRILL. The effect of "No-do" depends, I believe, on the caffeine content, and that is the same effect as drinking a large amount of coffee, perhaps five, six, or seven cups of coffee.

Mr. KORNEGAY. A concentrated drink of coffee?

Dr. BRILL. Yes, sir.

Mr. KORNEGAY. Thank you.

The CHAIRMAN. I don't know what else we will bring into this.

Mr. Watson?

Mr. WATSON. Thank you, Mr. Chairman.

Pursuing the line of questioning of Mr. Pickle, do not the physicians receive quite a heavy volume of professional samples of all of these amphetamines and barbiturates, all physicians?

Dr. BRILL. Physicians do receive samples. It has been pointed out to me, and I think this is correct, that if the bill were enacted, this would very likely stop.

Mr. WATSON. I am not suggesting that the physicians be included in the bill, but as a fact is it not true that they receive a large volume of professional samples? My question would be: What do you do with them?

Dr. BRILL. I personally dispose of them carefully, throw them away, so that they don't fall into the wrong hands. Occasionally, if there is an indication, I give them to a patient for trial.

Mr. WATSON. And you think that would be the practice followed by the reputable physicians?

Dr. BRILL. I think so, either to use them where they are indicated or, if one has no use for them, to dispose of them so that they do not fall into the wrong hands. Begin a psychiatrist, I would be particularly sensitive about not having my patients come in contact with these things, from the wastebasket.

Mr. WATSON. I have one further question. Rather than to allow the indiscriminate examination of all of these prescriptions by the FDA, do you think it might be possible perhaps to bottom this on a volume or a frequency basis? In other words, require the druggist to single out those prescriptions that have been refilled numerous times, or perhaps filled in large quantities.

Do you think that might be a helpful step?

Dr. BRILL. I think perhaps it would be better if I did not try to comment on that. It is a rather complex issue. It falls partly into another field. I might be misleading.

Mr. WATSON. Thank you, sir.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Curtin?

Mr. CURTIN. Dr. Brill, are these drugs that we are here talking about habit forming?

Dr. BRILL. Yes, sir. The ones that are important are habit forming.

Mr. CURTIN. Both the stimulant and depressant drugs?

Dr. DRILL. In the sense that there is psychic habit that is formed, not necessarily a physical habit. Perhaps you refer to the idea that once the habit is formed the person becomes ill when the drug is

stopped, physically ill. These drugs do not necessarily cause an outbreak of physical symptoms when they are withdrawn.

But the emotional habit is the important one.

Mr. CURTIN. Does the body acquire an immunity from the use of these drugs so that to get the same effect from a continued use you have to increase the amounts?

Dr. BRILL. In many cases there is a tolerance. In other cases there is not. This is a rather complex question in pharmacology. But in many cases, tolerance builds up in the way you describe it, in the case of many drugs.

Mr. CURTIN. So in general there is such an immunity?

Dr. BRILL. This is not an important aspect of the problem. In many cases it builds up, as you say, an immunity, but I wouldn't want to make a general statement that this is a quality that is important in making this decision.

Mr. CURTIN. Thank you.

The CHAIRMAN. Mr. Friedel.

Mr. FRIEDEL. Dr. Brill, on page 5, in the last paragraph, your state, "However, legislation alone may not be the answer." Would you care to elaborate on that?

Dr. BRILL. Yes, sir. We have had some experience with legislation, and we know that public opinion and public attitudes are very important. It was the opinion of the association that every effort should be made to influence the public through education as well as through legislation, through a diffusion of accurate knowledge as to the dangers inherent in the abuse of these medications.

Mr. FRIEDEL. How could you do that if you don't keep records to show where misuse of drugs occurs?

Dr. BRILL. The information that we referred to is diffused through the educational structure of the country, through the schools, the high schools, the colleges, through instrumentalities of State and local governments, and through education departments.

It has to do with a description of the dangers of drug abuse in the educational system and in the public media.

Mr. FRIEDEL. Thank you.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Is it only after the passage of this bill that these drugs would be prescription drugs, or are they presently prescription drugs?

Dr. BRILL. They are presently prescription drugs, sir.

Mr. ROGERS of Florida. The only way a person can now get these drugs is to go to a physician or to a pharmacist to get a prescription?

Dr. BRILL. Unless they are bootlegged.

Mr. ROGERS of Florida. Unless they are bootlegged?

Dr. BRILL. I think that is correct.

Mr. ROGERS of Florida. In keeping the record, then, we are simply trying to see if the manufacturer sells all of his drugs manufactured to the pharmacist or to physicians or whatever it may be, just to trace them so that he can know if there is any slippage.

This is mainly what the bill would do, then.

Dr. BRILL. One of the main things is to pick up the possibility of diversion of drugs. This diversion can occur in many, many different ways in the long line, the long channel, from manufacturer to consumer.

Mr. ROGERS of Florida. Does the pharmacist have the right to prescribe these drugs?

Dr. BRILL. No, sir.

Mr. ROGERS of Florida. Only a physician?

Dr. BRILL. Yes, sir.

Mr. ROGERS of Florida. And you feel that since the pharmacist would have to keep a record of how he dispenses them, then he, in effect, in keeping the record for the physician. Would that be true?

Dr. BRILL. He would be keeping the record of what the physician has prescribed, except, of course, in those minor instances where the physician hands out a drug for emergency use, or in the case of the small number of dispensing physicians. The answer is yes.

Mr. ROGERS of Florida. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN Mr. Gilligan?

Mr. GILLIGAN. I have just one last question. Doctor, in the report of the President's Advisory Commission on Narcotic and Drug Abuse, on page 44, the specific recommendation is made that legislation should not be limited to the barbiturates and the amphetamines, but should extend to all nonnarcotic drugs capable of producing serious psychotoxic and antisocial effects when abused.

A little later it states any new legislation should be broad enough to include all hypnotic, stimulant, and depressant drugs affecting the central nervous system in such a way as to be classified as psychotoxic.

That is a term that is neither in the bill before us or in your statement. Would you think that an improvement on the language, to include the term psychotoxic, for instance, in place of some of the language you have suggested about leading to adverse effect on the public health?

Dr. BRILL. The bill meets the needs and conforms to the intent of the material which you read quite fully, but the word psychotoxic is an undesirable word for many reasons. The association would agree that it would be better not to use it in the bill.

Mr. GILLIGAN. We have been talking in terms of classifications. One class is drugs containing barbiturate acid, one is amphetamine, or its derivatives, and the third seems to be the category which is giving us trouble.

Psychotoxic seems to suggest here that it is a term which covers a classification of drugs. My question is: Would it be a useful and embracing term to use here and get us away from the necessity of listing drugs, or is it one that, in your opinion, would simply further confuse the situation?

Dr. KERR. I think the use of the term "psychotoxic" would further confuse the situation, because a drug may well be psychotoxic in abuse but not psychotoxic in its normal use. Therefore, since this would be an ambiguous term, I think it better not to be considered for use in the context of this legislation.

The terminology as presently used is, in my opinion, far better than the use of the term "psychotoxic."

Mr. GILLIGAN. Thank you.

The CHAIRMAN. What did you say was better to be used?

Dr. KITTO. I said the term "psychotoxic" is a term which, if used, would be ambiguous, and I feel that it is properly omitted from the language of the bill.

The CHAIRMAN. I thought I heard you say some other term.

Dr. KITTO. I said the terms that are currently used in the bill are, in my opinion, far better than the use of this term.

The CHAIRMAN. Dr. Brill, thank you very much, you and Dr. Kitto, and Mr. Donelan. We are very glad to have had you present this morning. Thank you for your patience with members of the committee and for your contribution that you have made to us on this very important and highly significant legislation.

Dr. BRILL. We thank you, sir.

The CHAIRMAN. The next witness will be Dr. Austin Smith, of the Pharmaceutical Manufacturers Association.

I believe you have Mr. Stetler and Mr. Kelly with you, Dr. Smith.

It would be appropriate, I think, to let you identify yourself and those who are with you.

**STATEMENT OF AUSTIN SMITH, M.D., PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY C. JOSEPH STETLER, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL OF PMA; AND JOHN T. KELLY, PMA LEGISLATIVE COUNSEL**

Dr. SMITH. Thank you, Mr. Chairman. On my left is Mr. Stetler and on my right, Mr. Kelly. Mr. Stetler is executive vice president and general counsel for the Pharmaceutical Manufacturers Association, and Mr. Kelly is legislative counsel. I am the president of the association. Obviously, they are lawyers and I am medically trained. I feel a little lonely between two lawyers, but that is the way it is today.

The statement which we prepared for your consideration, Mr. Chairman, and members of the committee, is before you. I would like to conserve your time, with your permission, and just speak to certain sections. Then, we will try to answer whatever questions may occur to you and your colleagues.

The CHAIRMAN. Doctor, your entire statement will be included in the record. You may proceed as you desire.

Dr. SMITH. Thank you, sir.

The first page refers to the witnesses and to the makeup of the Pharmaceutical Manufacturers Association. As we appear today, we would like to express appreciation on behalf of the association for the opportunity to comment on the bill that is before you for consideration.

On page 2, there are a couple of paragraphs to which I would like to direct your attention, and then, perhaps, three or four pages that I might read in detail subsequently.

The imposition of the additional controls on the manufacture, distribution, and sale of depressant and stimulant drugs is not a new subject. Many such proposals have been made in the past, and in fact, the Pharmaceutical Manufacturers Association and one of its predecessor organization, the American Drug Manufacturers Association, have been advocating increased controls for some time. I think our

interest goes back to the late 1940's. Statements and appearances before various committees have been made since that time.

The second paragraph on page 2 gives some account of this, though not in detail.

At the bottom of page 2: The PMA believes that the bill you are considering today, H.R. 2, provides workable and, we believe, needed legislation. This is true both with respect to its provisions imposing additional controls on certain depressant and stimulant drugs and the provisions which would aid the FDA in dealing with the increasingly serious problem of counterfeit drugs.

The PMA endorses H.R. 2 with only one principal suggested modification. This concerns the provisions dealing with definitions. We believe that the provisions in the bill covering the drugs that are or may be subject to added controls are too broadly drawn and might be used to bring under the act many drugs which should not be so treated. Later in our statement we propose a change in language which we believe will remedy this problem. The new language is designed to sharpen the provision and direct them to the problem which the legislation is intended to meet.

It is important to emphasize initially that both amphetamines and barbiturates are highly beneficial in medical practice and have many important medical applications. The preceding witness, Dr. Brill, discussed this in considerable detail. I will not take your time to comment on the usefulness of these compounds, except that on page 4 there is one paragraph which may answer a question raised earlier, the extent of use of these compounds.

It is estimated that physicians treat between 5 and 10 million patients each year with a central nervous system stimulant drugs. Barbiturates are even more widely used therapeutic agents, it being estimated that approximately 20 million patients receive some treatment with them each year.

The CHAIRMAN. Would you clarify that a little more before you leave that? You say physicians treat between 5 and 10 million and then you say some 20 million patients receive some treatment.

Dr. SMITH. One has to do with the stimulants and the other has to do with the barbiturates.

The CHAIRMAN. Maybe I do not read it correctly. You say physicians treat between 5 and 10 million patients each year—

Dr. SMITH (interrupting). With central nervous system stimulant drugs. That is the amphetamines. Then, I say that the barbiturates are used even more widely, being employed in roughly 20 million patients.

The CHAIRMAN. By physicians?

Dr. SMITH. Yes.

There are data showing that a significant quantity of amphetamines and barbiturates have been diverted from legitimate drug channels. When these drugs are used for nonmedical purposes and without medical supervision in quantities exceeding the usual medical dose, abnormal and antisocial behavior, presenting serious health problems may result. It is because of these demonstrated facts that the PMA favors additional controls over the manufacture, distribution, and sale of these drugs. In view, however, of the special nature of the proposed legislation, the PMA believes that it should be carefully limited

to proved needs. Unneeded authority should not be granted nor should unwarranted burdens be imposed.

In our view, in its presently proposed form, the definition in section 3(a) of the bill of "depressant or stimulant drug" is too broad. The definition is not drawn in terms of drugs which are actually abused, but is close enough to cover drugs which are only theoretically subject to abuse. We also believe that this definition section would be improved by including in it, as exemptions from the definition of stimulant and depressant drugs, the two types of drugs which are now covered by the separate exemptive provisions found in section 3(e) (2), at pages 9 and 10 of the bill. These are the provisions for exemption pursuant to FDA regulation of, first, combination drugs in which depressants or stimulants are combined with other drugs, and, second, nonprescription (over-the-counter) drugs.

Let me discuss first the definitions now contained in section 3(a) of the bill. We have no difficulty in supporting this subparagraph (1) relating to barbiturates or with clauses (A) and (B) of subparagraph (2) covering amphetamines. Clause (C) of subparagraph (2), however, should be deleted as being unnecessary and as duplicating the authority which would be conferred under paragraph (3) which is a section specifically designed to authorize the Secretary to designate drugs other than barbiturates and amphetamines as being within the term "depressant or stimulant drug."

In addition to being superfluous, clause (2) (C) is also objectionable in that it designates drugs as "habit forming" because of their stimulating effect on the central nervous system. As applied to stimulant drugs the term is unwarranted and misleading. "Habit forming" as used presently in the Federal Food, Drug, and Cosmetic Act (sec. 502(d)) is applied to drugs which may produce physical dependence, with the consequent appearance of withdrawal symptoms when the drug is discontinued. Prevailing medical authority recognizes that the stimulant drugs under question are not "habit forming" in this sense.

Proposed subparagraph (v) (3) provides for the future incorporation of additional drugs under the controls provided by the bill. It is thus important that the criteria governing these future selections accurately reflect the conditions which justify added controls on any distribution. As presently contained in the bill, clause (3) would allow the Secretary of the Department of Health, Education, and Welfare, by regulation, to place under the controls established by the act any drug "having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect."

The PMA believes that Government regulation of the drug industry should be limited to areas where there is a demonstrated need for such intervention and controls. Therefore, we feel that a drug should not be placed under the controls of this legislation until there has been substantial actual abuse constituting a public health and safety problem.

Our position is in agreement with the position taken by the Senate Committee on Labor and Public Welfare in its report of August 14,

1964, regarding S. 2628, 88th Congress. The report stated that only drugs for which there exists—

evidence either of actual abuse or significant diversion from legitimate drug channels should be subject to the proposed controls \* \* \*.

Theoretical "potential for abuse," in the absence of any evidence that the drug has been or is being abused, is an inadequate basis for the proposed regulation. This is particularly so when the statute carries heavy criminal penalties.

The reasons for our position include:

(1) Many drugs either alone or in combination with other drugs, may have a potential for abuse. In fact they may never be abused at all or not to a degree constituting a hazard to the public health and safety. For example, although a medicine may contain a potentially abusable ingredient, so little of this ingredient may be present that the abuser would have to take an unrealistically massive dose in an effort to get a desired effect. A medicine may also contain other ingredients, which, when taken in massive doses, would cause toxic or other undesirable side effects thus discouraging abuse. As a practical matter, therefore, it is unlikely that many products having some substance theoretically capable of abuse would in fact be abused.

(2) Bringing under these controls by regulation a large number of merely potentially abusable drugs or drug products would dilute the importance of the regulations and handicap their enforcement.

(3) Drugs or drug products unnecessarily placed under these regulations would become needlessly stigmatized. For public health reasons, such stigmatization should be avoided wherever possible since it could result in reluctance by physicians to prescribe certain medically valuable drugs and in patient reluctance to take these drugs.

(4) Inclusion of drugs or drug products that are subject to little or no abuse would make administration of the act unnecessarily burdensome.

(5) Finally, there is a practical consideration which should not be overlooked. If provision is made for overregulation now by including drugs potentially or theoretically subject to abuse, it would be extremely difficult in the future to return to a sound and proper standard of actual abuse.

For the above reasons we respectfully urge that the committee modify the definition now contained in H.R. 2 to deal with the problem of drugs that are in fact being abused. To accomplish this purpose we recommend substitution of the following language for the first portion of paragraph (v) (3) of the bill:

Any drug which contains any quantity of a substance which the Secretary, after investigation, has found to be, and by regulation designates as being, substantially involved in drug abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect ("drug abuse" being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment and when they are obtained through illicit channels); \* \* \*.

In addition, we recommend that the following language be added to paragraph (v) (3) so that over-the-counter drugs and combination products be exempted from the definition of stimulant and depressant drugs, without any formal action by the Secretary being required:

*Provided*, That the term "depressant or stimulant drug" shall not include drugs containing, in addition to a depressant or stimulant drug, a sufficient quan-

tity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of the depressant or stimulant drug to cause a depressant or stimulating effect on the central nervous system, or a hallucinatory effect, as the principal effect of the drug; and shall not include any drug permitted under this act to be sold over the counter without a prescription, \* \* \*.

There is attached as an appendix to this statement the complete paragraph (v) as modified to reflect the PMA recommendations.

The present law provides a means of determining that over-the-counter preparations are safe for general use. There is no necessity to provide that such preparations be required to obtain a specific exemption from the regulations proposed in this bill. Rather, such preparations should be excluded, as the PMA proposes, from the definition of "depressant and simulant drugs".

Similar considerations apply to those combination drugs which, in addition to a depressant or stimulant substance, contain other drugs or substances which preclude the ingestion of a sufficient quantity of a depressant or stimulant drug to cause abusive physiological effects. The lack of necessity for regulating such combination drugs was recognized by the President's Advisory Commission on Narcotic and Drug Abuse, which stated on page 44 of its report:

The bill should exempt any drug within this definition that combines a small amount with other substances where the resultant drug is not itself liable to abuse.

Such combinations may be incapable of abuse not only due to the small quantity of the depressant or stimulant drug that they contain, but also because of the direct or side effects resulting from the other substances in the combination. This is a point to which we referred earlier. These substances may have toxic or other debilitating effects when ingested in abusive quantities, thus preventing the use of the combination to obtain the type of stimulant or depressant effect the abuser is seeking. With these self-limiting controls against the abuse of many combination products, it would appear unnecessary that they be required to be specifically exempted by the Secretary. As in the case of OTC products, it would seem preferable to exempt them from the definition of stimulant and depressant drugs.

One of the major threats to the public health has been the tremendous number of counterfeit drugs that have appeared on the market in recent years. This development has been a matter of serious concern to the drug industry, which has spent a considerable amount of time and money in attempting to eliminate the problem. We approve and wholeheartedly support the counterfeiting provisions which have been included in H.R. 2.

We earnestly hope your committee will act favorably on the recommendations we have offered, and favorably report the bill.

Again, let me express appreciation on behalf of the pharmaceutical industry for the opportunity to express our views on this legislation.

(The full statement and attached appendix referred to follows:)

STATEMENT OF AUSTIN SMITH, M.D., PRESIDENT, PHARMACEUTICAL  
MANUFACTURERS ASSOCIATION

Mr. Chairman, members of the committee, my name is Austin Smith. I am president of the Pharmaceutical Manufacturers Association on whose behalf I am appearing today. I am a physician and prior to my association with the PMA, approximately 5 years ago, I served for a number of years as secretary of the council on drugs and as editor and managing publisher of the Journal of

the American Medical Association and the other scientific publications of the American Medical Association. I am accompanied by Mr. C. Joseph Stetler, executive vice president and general counsel of the PMA, and Mr. John T. Kelly, PMA legislative counsel.

I should like to state at the outset that the Pharmaceutical Manufacturers Association appreciates the opportunity to appear before this committee to present its views on the important legislation now under consideration.

The Pharmaceutical Manufacturers Association is an association composed of some 140 member manufacturers which produce over 90 percent of the prescription drugs sold in this country. The association represents that segment of the drug industry which is concerned with products sold only on prescription or promoted primarily to the health professions.

The imposition of additional controls on the manufacture, distribution, and sale of depressant and stimulant drugs is, of course, not a new subject to the Congress. Many such proposals have been presented in past years. The PMA has long been interested in, and has consistently supported, Federal legislation in this area.

In August 1962 a member of the board of directors of the PMA appeared before this committee in support of the purpose and approach of title I, part C of H.R. 11581, 87th Congress, dealing with amphetamine and barbiturate controls. In March of 1963, the PMA sent a letter to the Honorable E. Barrett Prettyman, Chairman, President's Advisory Commission on Narcotic and Drug Abuse, in which it gave its views and recommended additional regulatory legislation to control the abuse of depressant and stimulant drugs. In 1964, the PMA submitted statements to the Honorable Lister Hill, chairman of the Subcommittee on Health, of the Senate Committee on Labor and Public Welfare, and to this committee supporting the aims of S. 2628, 88th Congress, which had been introduced by Senator Thomas J. Dodd, March 12, 1964. This bill also provided for Federal legislation imposing additional control on the manufacture, distribution, and sale of depressant and stimulant drugs.

The PMA believes that the bill you are considering today, H.R. 2, provides in general, workable and, we believe, needed legislation. This is true both with respect to its provisions imposing additional controls on certain depressant and stimulant drugs and the provisions which would aid the FDA in dealing with the increasingly serious problem of counterfeit drugs.

The PMA endorses H.R. 2 with only one principal suggested modification. This concerns the provisions dealing with definitions. We believe that the provisions in the bill covering the drugs that are or may be subject to added controls are too broadly drawn and might be used to bring under the act many drugs which should not be so treated. Later in our statement we propose a change in language which we believe will remedy this problem. The new language is designed to sharpen the provisions and direct them to the problem which the legislation is intended to meet.

It is important to emphasize initially that both amphetamines and barbiturates are highly beneficial in medical practice and have many important medical applications. Even now, they may lawfully be dispensed only on prescription of a licensed practitioner. When taken as directed medically they are effective and safe. H.R. 2 seeks to preserve the right of the medical profession to use these proven drugs as needed; the bill strikes at the nonmedical, illicit, and abusive use of the drugs, which has uniformly been condemned by PMA.

Amphetamine is a central nervous system stimulant. Such stimulants are valuable in combating a variety of mild depressive states, such as those attending the menopause, chronic organic diseases, and postoperative recovery, and are drugs of choice in the treatment of narcolepsy (a condition in which the patient sleeps excessively), and postencephalitic Parkinsonism. These drugs are also extensively prescribed singly or in combination with barbiturates as an aid in the treatment of overweight—they reduce appetite and also treat the underlying emotional condition that is often responsible for overeating.

Barbiturates, including such well-known drugs as amobarbital, pentobarbital, phenobarbital, and secobarbital, are widely prescribed hypnotics and sedatives. They are central nervous system depressant drugs.

These compounds are indicated for use in insomnia, nervous tension, hysteria, for general anesthesia, in labor, in certain psychiatric treatment and other indications. When used in the doses usually prescribed, they carry no real hazard of tolerance or physical dependence.

It is estimated that physicians treat between 5 and 10 million patients each year with central nervous system stimulant drugs. The barbiturates are even more widely used therapeutic agents, it being estimated that approximately 20 million patients receive some treatment with them each year.

There are data showing that a significant quantity of amphetamines and barbiturates have been diverted from legitimate drug channels. When these drugs are used for nonmedical purposes and without medical supervision in quantities exceeding the usual medical dose, abnormal and antisocial behavior, presenting serious health problems, may result. It is because of these demonstrated facts that the PMA favors additional controls over the manufacture, distribution, and sale of these drugs. In view, however, of the special nature of the proposed legislation, the PMA believes that it should be carefully limited to proven needs. Unneeded authority should not be granted nor should unwarranted burdens be imposed.

In our view, in its presently proposed form the definition in section 3(a) of the bill of "depressant or stimulant drug" is too broad. The definition is not drawn in terms of drugs which are actually abused, but is loose enough to cover drugs which are only theoretically subject to abuse. We also believe that this definition section would be improved by including in it, as exemptions from the definition of stimulant and depressant drugs, the two types of drugs which are now covered by the separate exemptive provisions found in section 3(e)(2), at pages 9 and 10 of the bill. These are the provisions for exemption pursuant to FDA regulation of, first, combination drugs in which depressants or stimulants are combined with other drugs, and, second, non-prescription (over-the-counter) drugs.

Let me discuss first the definitions now contained in section 3(a) of the bill. We have no difficulty with subparagraph (1) relating to barbiturates or with clauses (A) and (B) of subparagraph (2) covering amphetamines. Clause (C) of subparagraph (2), however, should be deleted as being unnecessary and as duplicating the authority which would be conferred under paragraph (3) which is a section specifically designed to authorize the Secretary to designate drugs other than barbiturates and amphetamines as being within the term "depressant or stimulant drug." In addition to being superfluous, clause (2)(C) is also objectionable in that it designates drugs as "habit forming" because of their stimulating effect on the central nervous system. As applied to stimulant drugs the term is unwarranted and misleading. "Habit forming" as used present in the Federal Food, Drug, and Cosmetic Act (sec. 502(d)) is applied to drugs which may produce physical dependence, with the consequent appearance of withdrawal symptoms when the drug is discontinued. Prevailing medical authority recognizes that the stimulant drugs under question are not habit forming in this sense.

Proposed subparagraph (v)(3) provides for the future incorporation of additional drugs under the controls provided by the bill. It is thus important that the criteria governing these future selections accurately reflect the conditions which justify added controls on any distribution. As presently contained in the bill, clause (3) would allow the Secretary of the Department of Health, Education, and Welfare, by regulation, to place under the controls established by the act any drug "having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect \* \* \*."

The PMA believes that Government regulation of the drug industry should be limited to areas where there is a demonstrated need for such intervention and controls. Therefore, we feel that a drug should not be placed under the controls of this legislation until there has been substantial actual abuse constituting a public health and safety problem.

Our position is in agreement with the position taken by the Senate Committee on Labor and Public Welfare in its report of August 14, 1964, regarding S. 2628, 88th Congress. The report stated that only drugs for which there exists "evidence either of actual abuse or significant diversion from legitimate drug channels should be subject to the proposed controls \* \* \*." Theoretical "potential for abuse," in the absence of any evidence that the drug has been or is being abused, is an inadequate basis for the proposed regulation. This is particularly so when the statute carries heavy criminal penalties.

The reasons for our position include:

(1) Many drugs either alone or in combination with other drugs, may have a potential for abuse. In fact they may never be abused at all or not to a degree constituting a hazard to the public health and safety. For example, although

a medicine may contain a potentially abusable ingredient, so little of this ingredient may be present that the abuser would have to take an unrealistically massive dose in an effort to get a desired effect. A medicine may also contain other ingredients, which, when taken in massive doses, would cause toxic or other undesirable side effects, thus discouraging abuse. As a practical matter, therefore, it is unlikely that many products having some substance theoretically capable of abuse would in fact be abused.

(2) Bringing under these controls by regulation a large number of merely potentially abusable drugs or drug products would dilute the importance of the regulations and handicap their enforcement.

(3) Drugs or drug products unnecessarily placed under these regulations would become needlessly stigmatized. For public health reasons, such stigmatization should be avoided wherever possible since it would result in reluctance by physicians to prescribe certain medically valuable drugs and in patients' reluctance to take these drugs.

(4) Inclusion of drugs or drug products that are subject to little or no abuse would make administration of the act unnecessarily burdensome.

(5) Finally, there is a practical consideration which should not be overlooked. If provision is made for overregulation now by including drugs potentially or theoretically subject to abuse, it would be extremely difficult in the future to return to a sound and proper standard of actual abuse.

For the above reasons we respectfully urge that the committee modify the definition now contained in H.R. 2 to deal with the problem of drugs that are in fact being abused. To accomplish this purpose we recommend substitution of the following language for the first portion of paragraph (v) (3) of the bill:

"Any drug which contains any quantity of a substance which the Secretary, after investigation, has found to be, and by regulation designates as being, substantially involved in drug abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect ('drug abuse' being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment and when they are obtained through illicit channels); \* \* \*."

In addition, we recommend that the following language be added to paragraph (v) (3) so that over-the-counter drugs and combination products be exempted from the definition of stimulant and depressant drugs, without any formal action by the Secretary being required:

"Provided, That the term 'depressant or stimulant drug' shall not include drugs containing, in addition to a depressant or stimulant drug, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of the depressant or stimulant drug to cause a depressant or stimulating effect on the central nervous system, or a hallucinatory effect, as the principal effect of the drug; and shall not include any drug permitted under this act to be sold over the counter without a prescription, \* \* \*."

There is attached as an appendix to this statement the complete paragraph (v) as modified to reflect the PMA recommendations.

The present law provides a means of determining that over-the-counter preparations are safe for general use. There is no necessity to provide that such preparations be required to obtain a specific exemption from the regulations proposed in this bill. Rather, such preparations should be excluded, as the PMA proposes, from the definition of "depressant and stimulant drugs."

Similar considerations apply to those combination drugs which, in addition to a depressant or stimulant substance, contain other drugs or substances which preclude the ingestion of a sufficient quantity of a depressant or stimulant drug to cause abusive physiological effects. The lack of necessity for regulating such combination drugs was recognized by the President's Advisory Commission on Narcotic and Drug Abuse, which stated on page 44 of its report: "The bill should exempt any drug within this definition that combines a small amount with other substances where the resultant drug is not itself liable to abuse."

Such combinations may be incapable of abuse not only due to the small quantity of the depressant or stimulant drug that they contain, but also because of the direct or side effects resulting from the other substances in the combination. These substances may have toxic or other debilitating effects when ingested in abusive quantities, thus preventing the use of the combination to obtain the type of stimulant or depressant effect the abuser is seeking. With these self-limiting controls against the abuse of many combination products, it would appear unnecessary that they be required to be specifically exempted by the

Secretary. As in the case of OTC products, it would seem preferable to exempt them from the definition of stimulant and depressant drugs.

One of the major threats to the public health has been the tremendous number of counterfeit drugs that have appeared on the market in recent years. This development has been a matter of serious concern to the drug industry, which has spent a considerable amount of time and money in attempting to eliminate the problem. We approve and wholeheartedly support the counterfeiting provisions which have been included in H.R. 2.

We earnestly hope your committee will act favorably on the recommendations we have offered, and favorably report the bill.

Again let me express appreciation on behalf of the pharmaceutical industry for the opportunity to express our views on this legislation.

#### APPENDIX TO STATEMENT OF DR. AUSTIN SMITH

Section 201(v) of the Food, Drug, and Cosmetic Act incorporating changes proposed by Pharmaceutical Manufacturers Association:

"(v) The term 'depressant or stimulant drug' means—

"(1) any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid which has been designated by the Secretary under section 502(d) as habit forming;

"(2) any drug which contains any quantity of (A) amphetamine or any of its optical isomers; or (B) any salt of amphetamine or any salt of an optical isomer of amphetamine; or

"(3) any drug which contains any quantity of a substance which the Secretary, after investigation, has found to be, and by regulation designates as being, substantially involved in drug abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect ('drug abuse' being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment and when they are obtained through illicit channels): *Provided*, That the term 'depressant or stimulant drug' shall not include drugs containing, in addition to a depressant or stimulant drug, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of the depressant or stimulant drug to cause a depressant or stimulating effect on the central nervous system, or a hallucinatory effect, as the principal effect of the drug; and shall not include any drug permitted under this Act to be sold over the counter without a prescription: *And provided further*, That the Secretary shall not designate under this paragraph, (A) any substance that is now included, or is hereafter included, within the classifications stated in section 4731, and marihuana as defined in section 4761, of the Internal Revenue Code of 1954 (26 U.S.C. 4731, 4761, or (B) peyote (mescaline) but only insofar as its use is in connection with the ceremonies of a bona fide religious organization."

The above provision would be substituted for lines 10 through 23, page 3, of H.R. 2, 89th Congress. Incorporation of the above provision would make unnecessary and call for the deletion of section 511(e)(2), found at lines 21 through 24, page 9, and lines 1 through 11, page 10, of H.R.2.

Dr. SMITH. If there are any questions, we would be pleased to answer them. With your permission, may Mr. Stetler and Mr. Kelly respond to the questions? I don't pretend to have all the answers. They are much more informed in some areas. We will try to supplement each other's comments.

The CHAIRMAN. Very well. We will be glad to have one of you comment on whatever questions might be propounded.

First, let me go back. I assume that amphetamines would be the type of drug that would be prescribed by the physician as a central nervous system stimulant?

Dr. SMITH. That and for other reasons, sir.

The CHAIRMAN. That and for other reasons?

Dr. SMITH. Yes.

The CHAIRMAN. Could I assume, then, that for certain reasons amphetamines and barbiturates could either be used?

Dr. SMITH. They couldn't be used interchangeably, but they can be used for the specific conditions for which they are indicated. Sometimes they may be used concurrently. The body is a peculiar thing, and drugs and dosages often are adjusted according to the needs of that body. Barbiturates, in general, are depressants and the amphetamines, in general, are stimulants, but it is conceivable that you could give a depressant and a stimulant at the same time, or at least to the same patient at different times.

The CHAIRMAN. You have answered my question. Generally speaking, barbiturates are depressants.

Dr. SMITH. That is right.

The CHAIRMAN. And generally speaking amphetamines are stimulants.

Dr. SMITH. That is right.

The CHAIRMAN. We are talking about the nervous system now.

Dr. SMITH. Yes.

The CHAIRMAN. I intended to ask Dr. Brill this question a moment ago. Yesterday, we had a definition of amphetamines and we also had a definition of barbiturates. Are you in a position to give us the definition of a "goof ball"?

Dr. SMITH. Goof ball is a slang term that is used like many other terms. It applies to a stimulant kind of drug, just as the term, say "yellow jacket" or "red ball" applies to some of the barbiturates. Where these terms came from, I don't know. In general, I suppose in part from the color and in part from the effect that they have on some people when they are taken.

The CHAIRMAN. Then, what would be the definition of a pep pill?

Dr. SMITH. A pep pill would be a stimulant, in general.

The CHAIRMAN. And a goof ball might be a stimulant or it might be a depressant?

Dr. SMITH. It could be, depending on the effect in the body.

The CHAIRMAN. On page 8, I have some questions concerning your proposed amendment.

In the first place, you suggest that (C) in subparagraph (2) be stricken. Am I correct?

Mr. STETLER. That is correct.

The CHAIRMAN. You do that on the basis that the intent of this language is fully covered in clause (3).

Mr. STETLER. That is the primary reason, yes. We think it is a duplication. It is also somewhat misleading in that it identifies specifically the stimulant drugs as habit forming, which is not consonant with the definition of that term in the Food and Drug Act.

The CHAIRMAN. You would recommend other language which is included in your statement. You say for the first portion of paragraph (v) (3), and I suppose you have that included in the appendix to your statement, is that right?

Mr. STETLER. Yes. What that statement in the appendix does is to take that paragraph of the bill as you have it and incorporates our amendment and merely shows the whole section of the bill as we would propose it. Permit me to read it to you.

Any drug which contains any quantity of a substance which the Secretary, after investigation, has found to be, and by regulation designates as being,

substantially involved in drug abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect ('drug abuse' being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment and when they are obtained through illicit channels).

This particular recommendation deals with our suggestion that we not deal just with potential for abuse, but that the authority of the Food and Drug Administration to include other drugs under these controls be limited to those where abuse has been demonstrated and so found by the FDA.

The CHAIRMAN. Then you revise the entire paragraph.

Mr. STETLER. This revises part of paragraph 3. We do pick up part of it further down in the latter part of the paragraph, on half of line 15 down to line 23. We pick up the bill's language again in our amended paragraph in the appendix.

The CHAIRMAN. Do you mean beginning with (a) ?

Mr. STETLER. Beginning with the middle of line 15, reading, "That the Secretary shall not designate under this paragraph." We pick up part of that language again. I might indicate that preceding this proposed new language has been added to another paragraph which we show on page 8. This is intended to write into the definition section the two provisions now in the bill, to be accomplished by regulation, which would exempt over-the-counter drugs and combination drugs. This is more of a technical amendment, in our opinion.

The CHAIRMAN. Is that what you intend to do here, to exempt what is called over-the-counter drugs?

Mr. STETLER. Yes, to put that in the definition section.

The CHAIRMAN. I know what you are doing, but I am asking what is your intention.

Mr. STETLER. That is the intent.

The CHAIRMAN. Is that the sole purpose and intent of your suggested language?

Mr. STETLER. There are two intents in this amendment. One is to exempt, by statute, the over-the-counter drugs, and the other is to exempt by statute the so-called combination products. These are the products that have other ingredients besides an amphetamine or a barbiturate.

The CHAIRMAN. Do you think that the language in the bill includes over-the-counter drugs?

Mr. STETLER. Yes, sir.

The CHAIRMAN. Do you think that the language in the bill includes combination drugs?

Mr. STETLER. It does include combination drugs. But it is defined differently than we have proposed. I think there is no question with respect to the over-the-counter drug. Our purpose, intent, and aim is the same. On the combination products there is a difference between the language used in the bill and the language we have suggested. But, in both instances, the bill does now contemplate exemption by regulation by FDA of over-the-counter drugs and combination products as they are defined in the bill.

The CHAIRMAN. Is Mr. Goodrich in the room?

We want to get all the information we can as we go along. Since you have had a lot to do with putting this together, Mr. Goodrich, was it intended to include any of the over-the-counter drugs?

Mr. GOODRICH. No, sir. Mr. Larrick pointed out yesterday that it was not. The difference is that he is proposing in this definition to bring up that exemption as a matter of statutory right, whereas, we would cover it in a regulation, the difference being that if we charge someone with violation under his proposal, we would have to prove to the jury that it was not an over-the-counter drug or that it was not one of these combinations. It would involve a case-by-case proof of something that all of us agree on. There is a drafting technique. Ours is superior, we think.

The CHAIRMAN. The purpose of this diversion right at this moment, which I hope, Doctor, you will not mind, is to get what is intended. It was not intended to include over-the-counter drugs.

Mr. GOODRICH. Not at all.

The CHAIRMAN. Is it intended to include combination drugs?

Mr. GOODRICH. Not intended to include combination drugs which have another drug which does away with the potentiality for abuse and stimulation or sedation, where you have a combination drug. We have had that as a part of the Durham-Humphrey bill for years. We do have some exemptions there, excepting those from prescription dispensing. This is what he proposes to cover here.

The CHAIRMAN. What we are trying to do is get what is intended and what is needed. Even though you think you have superior language to accomplish this purpose, we will have some staff consideration of this, too, to see if we cannot come up with superior language to the superior language.

Mr. GOODRICH. I am sure you will.

Mr. ROGERS of Florida. May I ask a question?

The CHAIRMAN. Yes.

Mr. ROGERS of Florida. Did you say that the intent was not to cover the over-the-counter drug, but that this would be covered in the administrative procedure?

Mr. GOODRICH. There is a specific provision, but it is a question of placement. They are pulling their provision up to the basic definition so that as a matter of enforcement, whenever you wanted to bring a criminal case, you would have to negate this exemption the way they have it written out. I am sure when we discuss this with your counsel we can show you as a matter of criminal pleading and enforcement that this is not a proper way to do it.

Mr. ROGERS of Florida. Thank you.

Mr. CURTIN. Would the Chair yield for a question?

The CHAIRMAN. Yes.

Mr. CURTIN. Then aren't you, Mr. Goodrich, seeking to change the burden of proof? Aren't you suggesting that we say to a suspected offender, "You are guilty and now prove yourself innocent," rather than our present procedure of presuming a suspected offender to be innocent?

Mr. GOODRICH. Not at all. The problem here is a medical, scientific question, of whether a drug actually is one of these combinations that because of the two drugs in it does not have the potentiality for abuse. The whole pattern of this is to eliminate that sort of a question from a case-by-case endorsement, and to make this law actually work. This is a recordkeeping, proper manufacture, and other provision of the law. It doesn't deal with this type problem. There is no use injecting it

by putting it as a proviso in this exemption. I only saw this language 10 minutes ago, so I speak from that limited language.

The CHAIRMAN. We will give you an opportunity to comment on it later.

Mr. STETLER. I won't go into a debate on the preferable language, but I think we might point out one thing in our thinking in suggesting this, and that is that if it is the intent of the committee, as we think it is, in the bill, to exempt over-the-counter preparations and these combination drugs from the controls imposed by the legislation, we think it is very appropriate to say so in the legislation. The language as now included in the bill says that the Secretary shall, by regulation, do this. Sometimes there is a matter of time, in terms of how long it takes by regulation to do some of the things that are described in the act. If this is the intent of the committee, to do this, and we assume it is, then we say why not do it in the statute? Why wait for whatever length of time is taken for the Secretary to accomplish it by regulation. That is our point.

The CHAIRMAN. Mr. Macdonald.

Mr. MACDONALD. Throughout the testimony, and everything I have read relating to the subject matter of the proposed act, we keep hearing the words "potential for abuse." In this connection I was amazed yesterday to read in the paper that somebody had been charged here in the District of Columbia with murder by use of aspirin. I suppose that, if the allegation holds up, wouldn't it be fair to say that even aspirin has a potential for abuse?

Dr. SMITH. Practically anything has a potential for abuse, depending on health or the state of the body. We think, therefore, that the word "potential" is such a vague word that it should not be included in an act of this kind; that, instead, scientific reasoning should be brought to bear and whoever is to issue the order, the Secretary in this instance, would make use of this scientific reasoning.

You are quite right, sir, that practically anything has a potential of harm. There is an old definition of a poison. A poison is "just too much." Well, it depends on the situation and on the person.

Mr. MACDONALD. We are talking about superior language. Can you suggest something that would improve upon the word "potential"?

Dr. SMITH. Yes. We are proposing specifically that reference to the use of the word "potential" be deleted, and that, instead, there be included language which, in effect, says there shall be proof that this does cause harm.

Mr. MACDONALD. Proof in a specific case or proof in terms of general chemical characteristics?

Dr. SMITH. It would be proof directed to the class of products or the product that would be involved. You might say chemistry. Proof in terms of harm to the body.

Mr. MACDONALD. By that you mean any body? Or the average body? In law school they keep talking about the average man, with prudent use, et cetera. What would be potentially harmful or have a potential for abuse for one person, I suppose, wouldn't for another. Would the criterion be based on a person-by-person analysis? Or how else do you propose to establish whether or not something would have potential for abuse?

Dr. SMITH. Congressman, we are differentiating between potential, which, in effect, could be interpreted to mean theoretical, and practical proof, which we are trying to encompass with the use of the word "substantial." We feel that if something is theoretically capable of causing harm, then it would be possible for all sorts of useful products to be put in this class of restriction that doesn't seem justified. On the other hand, if the Secretary or the administering agency turns to a scientific body for advice and guidance, it seems reasonable and probably without exception, that that body would determine whether or not the advantages outweighed the disadvantages, and what constituted substantial proof of harm to society. We feel that with the wording we have proposed here, if the Secretary is requested to demand substantial proof, then he will have to turn to scientific bodies for this advice and would not be able to depend upon theoretical reasoning. This is what, we feel, the use of the word "potential" might lead to.

Mr. MACDONALD. My last question: Yesterday, during the testimony given by one particular spokesman from the pharmaceutical industry, that gentleman produced proof, which he read into the record, alleging that some 4 or 4½ billion different types of capsules or containers, of the kind this hearing is considering and which are shipped out by pharmaceutical companies such as you represent, are in fact potentially harmful. I asked him the question, Isn't there presently some agency that could check on this practice and prevent it? Actually, my next question is not directed to you personally, but Isn't there some code of ethics within the Pharmaceutical Manufacturers Association itself which would prevent this sort of practice without there being a need for legislation? In other words, don't you have any self-policing?

Dr. SMITH. We attempt to, within the limits of the law.

Mr. MACDONALD. What are the limits of the law? I ask that from ignorance.

Dr. SMITH. This is an area where guidance has to be provided without enforcement. We don't have the power to bring about certain enforcing measures that would control the activities of our members. One thing to be remembered, I think, is that the Pharmaceutical Manufacturers Association represents about 140 members which make about 90 percent of the prescription drugs that are sold today. But there are many other manufacturers who don't belong to the PMA. Some of them deal in counterfeit drugs, which is a subject to which we have referred elsewhere in the testimony. So, we don't have control over the manufacturers of the type that I think you would hope might exist.

As far as other legislative matters or regulation is concerned, with the amendments, the new amendments, to the Federal Food, Drug, and Cosmetic Act, there is additional control exerted as far as good manufacturing practice and records are concerned. I would hope that the members of the PHA recognize the significance of these manufacturing practices.

But realizing that there are many other things to be considered, including the activities of groups whose interest is not necessarily in sick people, we feel that there is justification for an additional step of control, such as is proposed in this bill.

Mr. MACDONALD. Thank you, Mr. Chairman.

The CHAIRMAN. What do you think about the proposed language of Dr. Brill and those with him, recommended by the American Medical Association?

Mr. STETLER. Again, we have just been exposed to that, as you have, this morning. I think the language is not too different, although they have not suggested in their amendment that the words "potential for abuse" be eliminated. They still have that. So, I think, really, the defect that we anticipated in the language of the bill might be carried over in their language.

The CHAIRMAN. They limit the effect of the word "potential."

Mr. STETLER. Yes, they do have limiting language and the effect of that might be the same. However, "leading to adverse effect on the public health" is not a real specific term. That, too, is subject to some considerable interpretation which I believe would be less specific than our language, which would necessitate a finding of substantial abuse, and on that basis to then control the drug. I think ours is a little more specific. I think as I heard them discuss their language, we basically have the same thing in mind in what we are trying to accomplish.

The CHAIRMAN. Mr. Curtin?

Mr. CURTIN. No question.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

I wanted to get into the problem that was just taken up with you about your present practices as manufacturers. To whom do you sell these drugs once you have made them, the prescription drugs? Do you sell them to people who are licensed, and must they produce this license before they are allowed to purchase from you? What is the present practice?

Dr. SMITH. The prescription drugs, which is the industry that I represent, are sold primarily to wholesalers, to retail pharmacists, to hospitals, to some other groups, and occasionally, to private practitioners, those individuals who, perhaps, do not have readily available the services of pharmacies locally. These are the people who would buy such drugs. They are sold to those who are entitled to do business, or who have a license to practice.

Mr. ROGERS of Florida. What showing must they make to you before you complete a sale?

Dr. SMITH. Well, I can't tell you, sir, what the individual practices of the firms are, but in theory, at least, either they know their customers or they find out about their customers. Management demands that their personnel find out about these customers.

Mr. MACDONALD. Yesterday, it was testified to that over 50 percent of the prescription drugs that were manufactured went out as samples. I found that hard to—well, not believe, because the gentleman was obviously telling the truth—but as a practice it seemed to me to be very peculiar. Obviously, if firms are sending samples, they are not sending them to proven customers.

Mr. CARTER. Would the speaker yield?

The CHAIRMAN. Mr. Rogers has the floor.

Mr. MACDONALD. Could I have an answer first?

Mr. CARTER. I hardly believe that they said 50 percent of their product would be sent out as samples.

Mr. MACDONALD. The gentleman who said it is in the room now.

Mr. CARTER. Mr. Larrick stated that 9 billion capsules were manufactured by the pharmacy houses and of these 9 billion capsules only one-half billion were sold through the regular channels, to wholesalers, druggists, clinics, hospitals and so on, and 4.5 billion capsules went into the black market, in other words.

The CHAIRMAN. I think that is another question. Mr. Macdonald referred to a statement made yesterday on samples.

Let's get one answer at a time to a question.

Do you care to comment on the samples, Doctor?

Dr. SMITH. Mr. Kelly asks to comment. I will see what he has to say. Maybe I will supplement it if I may.

Mr. KELLY. We were speaking a moment ago in response to Congressman Macdonald's question about controls.

The CHAIRMAN. Now, we are going off into another question. Let's complete one at a time and then we will have this record as it should be.

Mr. Rogers yielded to Mr. Macdonald and he asked about the samples provided by manufacturers. Do you wish to comment on that?

Dr. SMITH. I will answer this, Mr. Chairman. I don't know how many pills are produced or how many are distributed as samples, but I find it difficult to believe that 50 percent of the amphetamines and barbiturates made by the members of the PMA are given out as samples. Samples play a big part in the promotion of the pharmaceutical industry, that is to say, of the pharmaceutical industry which is represented here today. This involves not only sampling new products but the reminding of physicians about the older products that the individual firms make. I can't give you a figure. I just don't know. But, nevertheless, as far as the manufacturer is concerned, he would have control or should have control over what goes out as samples as much as what goes out through sales.

Mr. MACDONALD. Thank you.

Mr. ROGERS of Florida. I am still not very clear on just what actions you take to make sure you are selling through the proper media. It seems to me that any man could print up a stationery pad and call himself a doctor, have a certain address, write in and say, "I want to buy" so many drugs or pills from the manufacturer. What would prevent him from getting them?

Mr. KELLY. Mr. Rogers, I would like to call your attention to the FDA Regulation 106(B)(1). It talks in terms of the people to whom a manufacturer may lawfully sell drugs. It says that if they try to sell them to anyone else, there is a violation of this particular regulation. The people to whom we may lawfully sell are specifically spelled out in this regulation.

Mr. ROGERS of Florida. Then you do require certain proof.

Mr. KELLY. Yes.

Mr. ROGERS of Florida. What is that?

Mr. KELLY. The proof that the person is regularly engaged. It is spelled right out in the Federal regulations if you want me to read it.

Mr. ROGERS of Florida. Must he be a pharmacist, licensed to dispense drugs?

Mr. KELLY. It says:

In the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage or wholesale distribution of prescription drugs or in the possession of a retail, hospital, or clinic pharmacy or a public health agency, regularly and lawfully engaged in the dispensing of prescription drugs, or in the possession of a practitioner licensed by law to administer or prescribe such drugs.

I think it is quite clear that the manufacturer may only sell to these people and to no one else.

Mr. ROGERS of Florida. I realize that, but what showing does the manufacturer require of the purchaser? I realize they say you are not to sell, but obviously, you are selling to someone who is putting these in the counterfeit market. How do they get in there, if you are supposed to be selling only to people licensed to prescribe or properly handle these drugs?

What showing does your organization or your member organizations require before you actually complete a sale?

Dr. SMITH. The practice would vary with the individual firm. There is no one set practice for it. As I mentioned a few moments ago, at least in theory the manufacturer should either know the person to whom he is selling or he should demand proof that the individual is lawfully engaged in practice. How this is done by the individual firms, I can't say.

Mr. ROGERS of Florida. This seems to me to be a very large problem and perhaps we should have some strengthening of the law on this. Maybe we should require that. Somewhere right at this point is the area where we get into the counterfeit drugs. Would you agree?

Dr. SMITH. Yes. There are two things, however, one that happened recently, and one that you are now considering, that would do this. The one that happened recently involve the amendments to the Federal Drug and Cosmetic Act, the so-called Kefauver-Harris amendment of 1962, and the other would be this bill that you have under consideration, which would require all people not only to register but to keep adequate records and to make these available.

The CHAIRMAN. Have you seen the report by CBS on this subject?

Dr. SMITH. Yes.

The CHAIRMAN. Do you have any comment?

Dr. SMITH. The only thing I can say, Mr. Chairman, is that no individual who was involved, at least, is a member of PMA.

The CHAIRMAN. Have you had anyone from your industry analyze it, investigate it, or go into it to determine the correctness or incorrectness of it?

Dr. SMITH. Of the report? No, sir.

The CHAIRMAN. If an industry is as large as yours, with reputation and integrity, do you think it would be an appropriate thing to do, since so much is involved?

Dr. SMITH. There are several things to be considered. One is that PMA consists of its own members, and it is quite a job to take on a review of individuals whose records and whose activities are not subject

to discussion by an organization such as PMA. Secondly, I am not sure that an association, no matter how big or how all-powerful, if it is a voluntary one, would be able to demand the kind of information that some organizations involved in a matter of this kind would likely withhold. It would seem to me that something like this is more adequately investigated by a Government agency. Today, we are testifying to a procedure that would help bring about better control and an easier approach for a Government agency to make such a study.

The CHAIRMAN. Thank you.

(The following letter was received for inclusion in the record:)

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,  
Washington, D.C., February 11, 1965.

HON. OREN HARRIS,  
Chairman, Interstate and Foreign Commerce Committee,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: On January 28, 1965, in the course of my testimony before your committee on H.R. 2, 89th Congress, you asked several questions relating to the disclosure last September by CBS News that it had, through establishment of a fictitious drug wholesaling firm, acquired from manufacturers quantities of illicit drugs (transcript, p. 231). Upon examination of the record of the hearing, I have concluded that my answers may not have fully indicated the extent of PMA's interest in this matter.

On September 3, 1964, the day following the first of three CBS-TV news broadcasts concerning the network's drug purchases, the CBS 8 a.m. radio network news and 10 a.m. TV news contained the following statement which had been obtained from a member of the PMA staff via telephone recording the previous evening:

"There is no question that the abuse of certain drugs in this country represents a social problem, one that has been recognized by the reputable manufacturers of drugs and so far as the members of the Pharmaceutical Manufacturers Association are concerned, for at least 2 years we have pushed vigorously for enactment of Federal legislation to cope with this problem."

Later that day I visited the CBS-TV studio in Washington and submitted to an interview generally covering the proper and abusive uses of amphetamines and barbiturates. The following portion of my statements was broadcast by CBS on both radio and television that evening:

"The Pharmaceutical Manufacturers Association has been advocating for several years increasing controls at the Federal level as well as at the State level over this kind of drugs. Among the controls we have been advocating are those which would call for legislation of those who make drugs, including this kind of pill, and for proper recordkeeping for those who do handle such drugs.

"In addition, we believe that there ought to be proper punishment not for the users of the drugs who often do this mistakenly or make use of these mistakenly, but punishment for those who deliberately sell these things knowing that they are violating the law."

Finally, on September 4, PMA issued a news release which was widely reflected in newspaper accounts throughout the country. A copy is enclosed. This same material was published by PMA in its bulletin, a periodical which is distributed among top executives of all of our member firms.

I believe this more fully reflects our interests and activities in connection with the CBS programs. I would greatly appreciate inclusion of this letter and enclosure in the record of the hearings on H.R. 2.

Sincerely,

AUSTIN SMITH, M.D.

[News release, Sept. 4, 1964]

The Pharmaceutical Manufacturers Association said today any failure of drug producers to check whether all their customers are legitimate receivers of prescription drugs is deplorable.

Dr. Austin Smith, president of the association representing 140 firms who produce more than 95 percent of the Nation's prescription drugs, made the comment in the wake of an exposé by CBS News which indicated that nine companies shipped "pep pill" and "goof ball" ingredients to an illicit destination. None of the nine is a member of PMA, Smith said.

"Our members have consistently recognized the social problem inherent in the abuse of amphetamines and barbiturates. These drugs can be hurtful when used unwisely without medical supervision, and helpful when wisely used," he pointed out.

"In 1962 members of this association joined in recommending appropriate Federal legislation to tighten controls over distribution of these drugs. The same year Congress enacted at our request a law which requires Federal registration of all drug producers and repackagers. It is deplorable that any seller would fail to take advantage of this requirement or otherwise satisfy himself about a firm which orders his products.

"Just in the past 2 weeks," Smith continued, "PMA has written the chairman of the House committee urging public hearings on the Senate-passed bill providing for additional specific controls over distribution of certain stimulant and depressant drugs."

Smith said that legitimate uses of amphetamine and barbiturate drugs accounted for nearly 6 percent of all prescriptions written by U.S. physicians last year.

In a filmed interview with CBS earlier this week Smith described the network's broadcast as "a dramatic illustration of the need for further control" over illicit distribution of these drugs.

Mr. ROGERS of Florida. As I understand it from your testimony, you don't feel that you should necessarily name the drugs that should be covered; you are willing to have the Secretary determine that?

Dr. SMITH. That is right.

Mr. ROGERS of Florida. Also, I noticed in your suggested amendment, in the parenthesis in subparagraph 3, on the last page of your statement, you say—

Drug abuse being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment, and when they are obtained through illicit channels.

This seems to me to place a double requirement. Shouldn't it read "or" or "and/or"?

Mr. STETLER. Possibly, but we do not think this does describe the vice this bill is directed toward. There is a general recognition that basically these are good and fine, medically indicated drugs. The vice that you are directing the legislation toward is the improper, illicit abuse of these drugs. When we talk in terms of drug abuse, we are not talking about how one person or an individual might misuse it, but how it is misused, as this says, drug abuse being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment and when they are obtained through illicit channels.

We don't anticipate that these drugs that are being abused are getting into the hands of individuals through the normal practice of a physician in prescribing drugs to his patient. It is an illicit traffic and it is a use other than a medically indicated use. We think that is the purpose of the bill.

Mr. ROGERS of Florida. I think they testified that there were some 11 pharmacists that would not be an illicit channel at all. That would be a regular channel.

Mr. STETLER. I think in this instance, if a drug was being put out for a nonmedical use through a physician or pharmacist or anyone else who might be properly licensed to practice his trade or profession, that would be an illicit movement of that drug.

Mr. ROGERS of Florida. It might rather be a use other than through therapeutic media.

Mr. STETLER. That would be for sure the illicit channel.

Mr. ROGERS of Florida. In other words, you wouldn't object to it being "and/or"; would you?

Mr. STETLER. No.

Mr. ROGERS of Florida. I wonder if the industry does have any suggestions along the lines the chairman has suggested of some self-policing or perhaps some particular recommendations to tighten up the sale from your members to the purchasers, other than, of course, just reporting as you go. For instance, some proof to be required that when they come to you, rather than having to wait maybe a year or two before the FDA gets around to saying, "This man has been buying from you but he is not authorized to purchase."

Mr. STETLER. May I comment briefly? As Dr. Smith mentioned, our association represents 140-plus manufacturers. There are about 1,000-plus manufacturers in this country. The CBS program did indicate a situation which is a bad situation; in other words a situation where certain manufacturers have put into the hands of theoretical wholesalers a dangerous drug. It was pointed out that none of these were PMA members. The way in which reputable manufacturers comply with the provision of the regulation that Mr. Kelly read vary, but I think we are not immodest when we say that reputable members in our membership do seek out the authorization and the credentials of the people that come to them who seek to purchase these drugs. I can't speak for all of them, but concerning many that we have spoken to, they have very specific ways in which they check on the validity of the customer. In doing this, of course, they do away with the opportunity or the possibility of putting their products in these illicit channels. Whoever quoted statistics, I think, may be guessing, as much as having actual data, on just how much movement of prescription drug there is through illicit channels. Certainly, they are not able to identify what the illicit channels are. I don't know at what stage of manufacturing, distribution, or selling these products get into the hands of the wrong people. Frankly, I don't think that happens through the activities of reputable manufacturers. I am sure everybody along the line feels the same way. But the fact is that the abuse does exist. Something more is necessary to correct it. This bill, we hope, will help to do that. We are not afraid of the regulation which it provides, in addition to the ones we now comply with.

Mr. ROGERS of Florida. I realize that, and I know your people are

reputable and are trying to do a good job. It is just the fact that they deal with you and you may not realize it.

Why would it not be a good idea to have a set method of determining whether a person is authorized to receive goods from your manufacturers? Couldn't this be done or else injected into the law, to have a set procedure that would be required before you even sell to them?

Mr. STETLER. Something along that line is the registration of the wholesaler. I am sure that the primary outlet for drugs from manufacturers is wholesalers.

Mr. ROGERS of Florida. The large amounts.

Mr. STETLER. Yes. And a registration of wholesalers is not objected to.

Mr. ROGERS of Florida. And they could show this registration with the purchase order.

Mr. STETLER. If they can indicate their registration number—

Mr. ROGERS of Florida. It could be checked quickly with Food and Drug.

Mr. STETLER. That would be a check.

Mr. ROGERS of Florida. Thank you.

The CHAIRMAN. That is precisely what we do in this bill. We require registration.

Mr. ROGERS of Florida. I didn't know we required the actual showing to the manufacturer. I realize we show where his sales went, but I don't think we require, in effect, the purchaser in the first instance to show his license to receive these goods. So it may be that Food and Drug may inspect their records, which are all fine because they have gone to such and such a purchaser. But it may be 3 years before they have time to check them. In the first instance, if this man was not properly registered with Food and Drug, they would never have sold to him. This is the point I was speaking to.

The CHAIRMAN. It is a good point. But there are procedures in this bill to reach that situation. We don't want to go overboard and burden the agency with something that would be impractical.

Mr. ROGERS of Florida. I agree with the chairman, that we want to stop where we can, that is, where it is possible.

The CHAIRMAN. It is well after 12 o'clock. I think it would be advisable to recess until 2 o'clock, at which time we will resume the questioning of Dr. Smith.

The committee will be in recess until 2 o'clock.

(Whereupon, at 12:28 p.m., the committee recessed, to reconvene at 2 p.m. the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will be in order.

STATEMENT OF AUSTIN SMITH, M.D., PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY C. JOSEPH STETLER, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL OF PMA; AND JOHN T. KELLY, PMA LEGISLATIVE COUNSEL—Resumed

The CHAIRMAN. Mr. Younger, do you have any questions of Dr. Smith, or Mr. Stetler, or Mr. Kelly?

Mr. YOUNGER. I have no questions, Mr. Chairman.

The CHAIRMAN. Mr. Cunningham?

Mr. CUNNINGHAM. No questions.

The CHAIRMAN. Mr. Harvey?

Mr. HARVEY. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Satterfield, do you have any questions?

Mr. SATTERFIELD. No questions, Mr. Chairman.

The CHAIRMAN. Dr. Smith, could you give any indication of approximately what percentage of the total production of drugs would be considered prescription drugs?

Dr. SMITH. Yes; I can, if I can search in my memory. We have that information.

The prescription drug business is about \$3¼ billion, and the over-the-counter business is about one-half of that. I can give you the information, Mr. Congressman. I would like to submit it to you.

The CHAIRMAN. You may supply it for the record.

But, as I recall it, the prescription drug is about twice the proprietary?

Dr. SMITH. Yes.

The CHAIRMAN. Since the members of your association produce about 90 percent of the prescription drugs, would you endeavor to get for the committee such information as you can as to the extent samples are made available to, I assume primarily, the doctors, pharmacists, and hospitals, and so forth?

Dr. SMITH. I think we can develop a representative presentation for you.

The CHAIRMAN. If you could provide us with some information about the sample distribution, we would be glad to have it.

(The following letter was subsequently received for the record:)

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,  
Washington, D.C., February 12, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: During the appearance of representatives of the Pharmaceutical Manufacturers Association before the committee on January 28, 1965, relative to H.R. 2, 89th Congress, you requested us to furnish the following information (pp. 238-239 of the hearings):

1. In 1963, according to the latest Department of Commerce figures, prescription drug business, at retail, amounted to \$2,046 million. The over-the-counter

drug business for the same year amounted to \$803 million. The prescription drug volume was thus about 72 percent of total drug sales for 1963.

2. There are, to our knowledge, no definitive figures available as to the extent samples of prescription drugs such as amphetamines and barbiturates are made available by manufacturers to physicians and dentists. Therefore, in order to obtain the information which you requested as to the distribution of such samples, we have inquired of a representative cross section of the members of our association. This inquiry indicates that for the year 1964, the sampling of prescription drugs of this type by PMA member firms amounted to approximately 3 percent of production. Usually such samples consist of an amount of the drug sufficient for an initial dosage for one or two patients. Some samples are, of course, also made available to pharmacists and hospitals. Further, because of the length of time most tranquilizers and other depressants have been on the market, I believe, without having made a special inquiry, that the sampling of these drugs would closely parallel that of amphetamines and barbiturates.

It should be pointed out that the distribution of samples is a valuable means of bringing information about drugs to the physician. Regardless of how detailed and informative package inserts or other labeling material are, there is no substitute for the experience of the physician in seeing and handling the drug and using it with the patient he knows and treats. Most doctors are interested in observing, in the treatment of their own patients, the therapeutic effects of particular drugs.

This is true not only for drugs which are being introduced or are relatively new on the market, but also for drugs which may have been available for some time. Many drug manufacturers distribute samples of these older drugs, not only because younger physicians are not necessarily familiar with them, but also because there will be many situations in a physician's practice where he will desire to observe the effect of an established drug in a particular condition or patient in order to determine its usefulness in a course of therapy.

Consequently, many of our members distribute samples of their products to physicians to introduce new products, to introduce their products to new physicians, to remind physicians of established products, and to facilitate the physician's determination of the usefulness of a drug in practice.

We also wish to take the occasion of this letter to reaffirm our support of H.R. 2 and to urge its speedy enactment into law with the amendments outlined by PMA during our appearance before the committee. We also, as indicated below, recommend two other technical amendments and will also comment briefly on positions taken by the Food and Drug Administration on two points relating to this legislation.

As stated on January 28, the PMA believes that H.R. 2 provides in general workable and needed legislation. We reemphasize, however, that provisions in the bill covering the drugs that are or may be subject to added control are too broadly drawn and might be used to bring under the act many drugs which should not be so treated. The testimony before the committee confirms the desirability of drawing the definition in terms of drugs that are in fact being abused rather than in terms of theoretical potential for abuse. We believe the hearings confirm the wisdom of not naming additional specific drugs in the legislation. Certainly, evidence necessary to make a scientific judgment with respect to other specific drugs which might be included under the bill has not been presented to the committee. The approach contained in H.R. 2 of leaving, to the FDA, for future determination the other drugs that should be subject to the new proposed controls is sound but the determination should be under a realistic standard of actual abuse.

The two technical amendments we suggest both relate to paragraph (1) of proposed section 511(a). First, we recommend that the phrase "and are otherwise qualified" on line 14 on page 4 be eliminated. As recognized by FDA, the phrase is not intended to have substantive effect or to grant any additional authority under the act. Rather, it is simply descriptive of those engaged in the manufacture, compounding, and processing of pharmaceuticals. Since it is only descriptive, and does not add to the substantive provisions of the bill, we believe that it would best be eliminated from the paragraph.

Second, we recommend that subdivisions (A) and (B) be redesignated as (B) and (C), and that the following be added after the word "shipment," on line 17 on page 4:

"(A) to manufacturers, compounders, or processors for further manufacturing, compounding, or processing, or".

As presently written, paragraph (1) of proposed section 511(a) is ambiguous in that it does not specifically authorize interplant shipments of bulk depressant and stimulant drugs, either between plants of the same manufacturer, or from a bulk manufacturer to the processor of a finished pharmaceutical item. The proposed language would make it clear that such bulk shipments are permissible, and that manufacturers of bulk items legitimately may ship them to other persons who are processors within the meaning of this paragraph and section 510(a)(1).

We have carefully considered the position taken by representatives of the Food and Drug Administration relative to the PMA recommendation that the exemption for OTC and combination drugs, now encompassed within proposed section 511(e)(2), be incorporated in proposed section 201(v)(3). We believe that the FDA has overstated the effect of the PMA recommendation on the technical pleading requirements of criminal actions. If Congress intends that these two classes of drugs be exempt from the restrictions of proposed section 511, it would seem that this purpose would indeed be better served by excluding them from the definition of depressant and stimulant drugs rather than requiring administrative action at some indeterminate future time by the Secretary. By virtue of the standards set forth in section 503(b) of the act, OTC products are not subject to abuse and should be expressly exempted by the statute itself.

Finally, we disagree with the construction Commissioner Larrick places on the present prohibitions of the act and the authority granted in section 6 to seize depressant and stimulant drugs. It is our understanding of H.R. 2 that this bill clearly does not contain any authority to seize or condemn drugs for failure of any person to maintain records with respect to such drugs as required in proposed section 511(d). This is readily evident when section 6 of H.R. 2 is compared with the seizure authority contained in section 5 of S. 2628, 88th Congress, 2d session, referred to this committee on August 17, 1964, following Senate passage. Nor do we believe that the authority sought by the Commissioner is either necessary or desirable. H.R. 2 contains plenary authority to seize drugs moving outside the legitimate channels of trade, and contains ample authority to deal with any failure to maintain the records required by section 511(d). We feel that section 6 of H.R. 2 was intended to restrict the seizure authority by excluding recordkeeping violations. Hence, it is our recommendation that section 6 not be altered.

On behalf of the Pharmaceutical Manufacturers Association, I wish to thank you again for permitting us to express our views on this important legislation. We were privileged to appear before your committee and participate in the hearings on H.R. 2 and trust that this letter will be made a part of the official record.

Sincerely yours,

AUSTIN SMITH, M.D.

The CHAIRMAN. Did I understand you to say this morning that if this bill, along the lines proposed and as recommended, were to be adopted, it will greatly reduce the samples going to people whom they are usually distributed to?

Dr. SMITH. No; we didn't say that. We didn't even comment on that, Mr. Chairman.

The CHAIRMAN. I suppose that was a prior witness.

Dr. SMITH. Someone from the American Medical Association made that statement.

The CHAIRMAN. Would you agree with that statement?

Dr. SMITH. I don't think so. I think there will be tighter control over the distribution of drugs, but I don't think it would reduce it. After all, new drugs are coming along all the time and it is customary practice to sample physicians and other practitioners, pharmacists, and hospitals. I am sure we will see the normal flow and ebb of drug sampling.

The CHAIRMAN. That being true, it is even more important that we get such information as we can from the industry about the extent of the sample business.

Mr. Kornegay, have you any questions?

Mr. KORNEGAY. No, Mr. Chairman; thank you.

The CHAIRMAN. Mr. Nelsen?

Mr. NELSEN. No questions; thank you.

The CHAIRMAN. Mr. Ronan, have you any questions?

Mr. RONAN. No, Mr. Chairman.

The CHAIRMAN. Dr. Smith, in behalf of the committee, I want to thank you, Mr. Stetler, and Mr. Kelly, for your presentation here today, and to compliment you on your testimony, and the contribution you have made to the committee.

Dr. SMITH. Thank you, Mr. Chairman.

We will supply the information you requested. If it meets with your pleasure, if there is additional information we think might have been presented today, we would like to have the privilege of providing it in a letter for you, for you and the members to share.

The CHAIRMAN. We will be glad to receive it.

Dr. SMITH. Thank you.

The CHAIRMAN. Thank you very much.

The next witness we have scheduled is Mr. J. Curtis Nottingham, president, American Pharmaceutical Association.

Mr. Nottingham, you may identify yourself for the record, if you will. I believe you have with you Mr. Robert F. Steeves, director of the legal division.

**STATEMENT OF J. CURTIS NOTTINGHAM, PRESIDENT, AMERICAN PHARMACEUTICAL ASSOCIATION; ACCOMPANIED BY ROBERT F. STEEVES, DIRECTOR OF THE LEGAL DIVISION OF THE AMERICAN PHARMACEUTICAL ASSOCIATION**

Mr. NOTTINGHAM. Mr. Chairman, I am J. Curtis Nottingham, president of the American Pharmaceutical Association, the national professional society of pharmacists. I am also a community pharmacist and practice my profession in Williamsburg, Va., where I have two pharmacies.

We are most pleased to accept the committee's invitation to present the official views of our 113-year-old national society on H.R. 2.

Accompanying me is Robert F. Steeves, director of the legal division of the American Pharmaceutical Association.

Active membership in Apha is limited to pharmacists. The only requirement for active membership in Apha is that the applicant be a pharmacist in good standing in the profession. At the present time, we have nearly 30,000 active members. We also have honorary, life, associate, and student membership categories which brings our total membership up to around 43,000.

Additionally, we have several affiliated groups. Two national affiliates are the American College of Apothecaries—a specialty group for pharmacists practicing in apothecary-type pharmacies—and the American Society of Hospital Pharmacists—a specialty group for pharmacists practicing in hospitals.

We have several State professional societies which are also affiliates. All affiliated groups require membership in the American Pharmaceutical Association as a prerequisite to membership in their association.

Our house of delegates, the policymaking body of our association, has representatives from these affiliated groups, as well as from all other specialty, State, and related groups in pharmacy. We believe that this gives our policies and statements a unique quality in that we represent all phases of the profession of pharmacy.

We wish to note the interest that you have shown in the problems facing our profession, Mr. Chairman, and express the sincere appreciation of the pharmacists of the United States for your conscientious help in drug legislation, and a number of other areas as well. The addition of the provision relating to counterfeiting drugs in H.R. 2 is certainly in the public interest and has our full support.

The American Pharmaceutical Association has been participating in hearings on legislation and general inquiries associated with barbiturates and amphetamines before both bodies of Congress for more than a decade.

In the early fifties, APHA developed and circulated a model barbiturate bill for the States to adopt, and we have had a keen interest in the problems associated first with barbiturates, then with barbiturates and amphetamines, and now with the general classifications of stimulant and depressant drugs.

As time passes, the problem grows and changes both in kind and in proportion. We recognize that the objective of H.R. 2 is to gain effective control of, and eliminate to the extent possible, the illicit trafficking in stimulant and depressant drugs for nonmedical purposes. We endorse this effort and pledge our wholehearted cooperation.

Pharmacists have a twofold interest in eradicating the illicit distribution of all drugs through unorthodox channels.

First is the public interest. We know that people endanger their lives and their health whenever they use drugs without professional consultation, particularly when they use drugs for illicit purposes. This is why our association has waged such a vigorous effort to halt the mail-order distribution of drugs. We hope that, in the near future, your committee will also give some attention to the mail-order problem.

Second is pharmacy's own interest. Obviously, as illicit distribution is eliminated, the opportunities for pharmacists to serve the public may be increased.

We have but one reservation concerning H.R. 2 and that is whether pharmacists should be included within its scope at all. There are, of course, details in H.R. 2 which would directly affect pharmacists practicing their profession, but these details are secondary to the decision of whether to include or exclude pharmacists.

For example, we note that H.R. 2 exempts physicians from the recordkeeping and other aspects of the proposal, and rightly so. We would hope that the Congress has similar faith in the integrity of the practitioners of pharmacy who, like physicians, must meet rigid educational and professional requirements for licensure and who are under the control of State professional practice boards.

In times past, we have been faced with the statistic that 78 percent of the convictions for illegal sales of barbiturates and amphetamines over the last 10 years under the Federal Food, Drug, and Cosmetic Act involve pharmacists. Stated in that manner, the statistic is alarm-

ing to you and to us. We believe, however, that examination of the statistic shows that the problem with pharmacists is not as bleak.

FDA has reported that there were nearly 1,300 such violations and even assuming that all 1,300 were pharmacist convictions, this means that we have had only 130 per year.

Now, there are approximately 90,000 pharmacists practicing as community pharmacists in the United States which reduces to fifteen-hundredths of 1 percent of the practitioners per year. The record would undoubtedly show that some of these figures reported represent repeated violators. In fact, the record shows that the 1,300 violations cover infractions by "retail drug firms, pharmacists or their employees" which means the number of pharmacist violators would be considerably less than 1,300.

As Senator Yarborough stated in questioning our representative who testified before the Senate Subcommittee on Health last summer:

As you say, the pharmacists are regulated, and if there are violations there, the Food and Drug Administration can find them. It seems to me that with 4.5 billion pills being distributed illegally every year, that you would want laws to reach out and find those people who keep no records, who are not licensed by any authority. As it is now, you find it only under State law, the violators in your own profession.

We have no information on the amounts or circumstances of the pharmacist violators which FDA has reported but, from common knowledge, we know that many of the violations involve dispensing a prescription renewal without proper authorization. Such a violation may involve a dozen or a hundred tablets, but it certainly has no relationship to the tens and hundreds of thousands of tablets and capsules involved in bootlegging.

Senator Yarborough also commented on this point in stating:

Since we do not have the facts, of course, this is guesswork. But my guess would be the same as yours, that the vast amount of these (tablets) illegally distributed were not through retail druggists.

Since all pharmacies and pharmacists are clearly identified through licensure, enforcement officials know where the drugs are located in traditional channels. In the illicit traffic, enforcement officials have no way of ascertaining which gas station, newsstand, or person is, or may be, peddling drugs illicitly.

We are as interested as the Congress and the Food and Drug Administration are in exposing pharmacists who violate the laws. The profession of pharmacy has nothing to hide. Every profession has a certain number of unethical practitioners, and we know that we have some in pharmacy, too. Our objective is to keep the percentage as small as is humanly possible so that the integrity of the vast majority of conscientious practitioners is not indicted by the foibles of the few.

When the FDA suspects that a pharmacist has violated the law—with stimulants or depressants or any other class—it can search the pharmacist's records, premises, and other details by following normal search procedures provided by law. We do not see that this presents any great problem since the search warrant procedure has worked in our form of government since early times. We would encourage the FDA to proceed in any case where it suspected a pharmacist of violating the law.

Let me reduce the problem of illicit distribution of barbiturates and amphetamines to its basics, as we see them. The FDA has extreme difficulty in locating illicit distributors because FDA cannot obtain information on who obtained these drugs. Once FDA knows the identity of the purchaser and the purchaser's location, it can then place the individual under surveillance. FDA already knows, as do State pharmacy boards who regularly inspect pharmacies, that every pharmacy in the United States possesses stimulant and depressant drugs.

From wholesaler and manufacturer records of shipments, FDA would learn the identity and location of the recipient of all drugs. Such records would also show unusual shipments of these drugs to pharmacists and physicians. Need there be any other record maintained? We think not.

Where a pharmacist is suspected of violating the law, the wholesaler or manufacturer record would show the quantity, kind, and date of shipment of the drugs and the current records of the pharmacists—required by existing law—provide a complete record of drugs dispensed lawfully.

One point we must not overlook is that FDA's responsibilities for inspection have been increased many times as a result of the Drug Amendments of 1962. FDA has stated that it can only expect to inspect the manufacturers about once every 2 years. We have no information on the number of manufacturing concerns registered with the FDA under the new law, but we do believe that it is improbable that FDA would, in the next several years, have an inspection staff large enough to take care of the wholesalers and jobbers added by H.R. 2 and still do a meaningful inspection of the 60,000 or so hospital and community pharmacies.

In light of our comments, we ask that you consider adding the word "dispense"—meaning pharmacist in the context—to proposed section 511(a)(4) so as to read:

(4) Practitioners licensed by law to prescribe, administer, or dispense depressant or stimulant drugs, while acting in the course of their professional practice.

This would then expressly provide that a pharmacist would be included as a person authorized to possess stimulant and depressant drugs, and he is not otherwise mentioned in proposed section 511.

As to the exemption of pharmacists, we would ask the committee to consider an insertion in the proposed section 511(d)(3) so as to read:

(3) The provisions of paragraphs (1) and (2) of this subsection shall not apply to a licensed practitioner described in subsection (a)(4) or to any establishment described in subsection (a)(3) which is licensed by State law to dispense or sell prescription-legend drugs with respect to any depressant or stimulant drug received, prepared, processed, administered, or dispensed by him in the course of his professional practice.

Mr. Chairman, in concluding, I want to assure you that the pharmacists of the United States are anxious to see the illicit traffic in drugs eliminated. The American Pharmaceutical Association has a trained staff of pharmacists, scientists, and lawyers who have been working in this area.

We would welcome the opportunity to be of assistance to the committee in any way we can.

The CHAIRMAN. Thank you very much, Mr. Nottingham, for your very good statement setting forth the views of your organization.

Mr. KORNEGAY, have you any questions?

Mr. KORNEGAY. No, Mr. Chairman; I have no questions.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. No questions.

The CHAIRMAN. Mr. Nelsen?

Mr. NELSEN. No questions.

The CHAIRMAN. Mr. Ronan?

Mr. RONAN. I have no questions, Mr. Chairman.

The CHAIRMAN. Mr. Cunningham.

Mr. CUNNINGHAM. Yes, Mr. Chairman.

Mr. Nottingham, is your association the only one that is nationwide composed of pharmacists?

Mr. NOTTINGHAM. Sir, the American Pharmaceutical Association is composed of individual pharmacists nationwide. There are many other organizations of pharmacists in a more limited area. For instance, I believe the National Association of Retail Druggists appeared here yesterday. This is an organization of drugstore owners. Most of them, of course, are probably pharmacists.

Mr. CUNNINGHAM. But your organization is of pharmacists?

Mr. NOTTINGHAM. Yes, sir.

Mr. CUNNINGHAM. What percentage of the pharmacists would you say, of the total, are members of your organization?

Mr. NOTTINGHAM. Are you asking me, sir, what percentage of pharmacists in the United States belong to the American Pharmaceutical Association?

Mr. CUNNINGHAM. Yes.

Mr. NOTTINGHAM. We have about 30,000 active pharmacists in our membership. Additionally, we have about 10,000 students. I believe the last record would indicate something in excess of 90,000, maybe 100,000, or so, pharmacists actively engaged in practice in the United States.

Mr. CUNNINGHAM. Of which you have about 30,000?

Mr. NOTTINGHAM. Thirty; yes, sir.

Mr. CUNNINGHAM. Do you have a code of ethics for membership in your association which deals with this particular problem we have before us?

Mr. NOTTINGHAM. Yes, sir; we certainly do.

Mr. CUNNINGHAM. If you find somebody who has gone against the code, have you taken any action? Do you have any cases of violation of your code where you have taken action?

Mr. NOTTINGHAM. Yes, sir; we do.

Mr. CUNNINGHAM. And you simply relieved them of their membership?

Mr. NOTTINGHAM. This is the only action we can take, sir.

Mr. CUNNINGHAM. On the last page, you say the American Pharmaceutical Association has a trained staff of pharmacists, scientists, and lawyers who have been working in this area.

Could you give us a little more detail as to what you mean by working in this area?

Mr. NOTTINGHAM. Yes, sir; I think so.

We have about 65 people, all of whom are in the executive capacity and administrative level, and who are pharmacists. We edit and publish two journals. We edit and publish one of the official drug compendia. We are constantly distributing information to all State organizations of pharmacists.

We have the Drug Standards Laboratory in our building where scientific and research work is carried out. I am not quite sure how to be specific, but if you do have a specific question, I will try to get the answer.

Mr. CUNNINGHAM. I was just referring to that statement that you do have a staff who are working in this area. I was wondering what kind of work they were doing in this area of illicit traffic in these two particular types of drugs.

Mr. STEEVES. Mr. Cunningham, one point mentioned earlier in the statement of Mr. Nottingham was that the model barbiturate bill, which has been implemented in many of the States, was a model bill developed by our staff and promulgated by the States.

Secondly, we have participated in surveys of how these laws were being enforced, and participated in hearings since 1950 before the Congress in studying how the profession is functioning under the laws.

This is the area of work that we have been in in terms of studying the regulatory problems and trying to help do something with it. Our staff has not been out policing, for example, or shopping, or in that area of enforcement.

Mr. CUNNINGHAM. That was the information I wanted. I compliment you on it. I wanted to have you expand on it a little bit for my own information.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Harvey?

Mr. HARVEY. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Watson?

Mr. WATSON. Mr. Chairman, I have one question.

I apologize for being late, sir.

I have not read your statement, but I glanced through the Senate hearings on the Dodd bill last year. As I recall, your principal objection was to the matter of this inspection of the prescriptions, and such as that.

Is that still your principal objection to the bill?

Mr. NOTTINGHAM. Yes, sir. I will elaborate, if I may.

We feel, sir, that the pharmacists should be accorded the same treatment in this regard as physicians. To become pharmacists, we must now go to school—that is, undertake at least 5 years of accredited college work; we have to undergo an internship; we have to pass a searching examination before our State boards.

Since we are registered and regulated, our whereabouts is well known. We feel that it would be an additional burden that would be unwarranted if we were subjected to routine inspection by Federal officers. They have search authority now, if there is any reason to suspect violations. But, to just have another group of inspectors, since we are now so closely regulated, we would hope the wisdom of the committee would be that at this time this would not be warranted.

Mr. WATSON. I am sure that all business people will share your concern about that.

Do you have any system of reporting to the FDA any excessive or abnormally large prescriptions for these barbiturates of amphetamines, or unusual frequency of prescriptions? Do you have, of your own volition, any system of reporting to the FDA about it?

Mr. NOTTINGHAM. We would do this, sir. Frankly, in my personal experience of practicing pharmacy, I have not run into this. But I have personally reported to FDA certain violations or what appeared to be violations.

There is a very fine relationship between the State boards of pharmacy, generally speaking, and their enforcement task, and this goes, in Virginia at least, with our State police force, also. Working hand in hand, these things are reported and they are repeatedly reported.

You asked me about a personal incident. I have not known of an occasion in my personal prescription practice where something was so out of line that it should be reported to the FDA. But I have known of others that were, and I have personally reported at least one.

Mr. WATSON. Thank you very much.

Mr. STEEVES. Mr. Watson, on the question that you raise, we reviewed the record of FDA's enforcement and compliance over 1964, for example, and involving the type of drug that would be covered in this bill.

Only 45 pharmacists were involved with criminal convictions. This is a far cry from the 130 a year. But in 1952, the Durham-Humphrey bill went into effect creating the prescription category of drugs.

You always find the larger number of violations right after a law is implemented. I believe that would be the history here, too, until everyone becomes accustomed to it.

The year before, 1963, though not broken down, indicates there were 135 convictions for illegal sales of prescription drugs. That figure would include pharmacists, physicians, and everyone else.

So, the problem has been reduced quite a bit, according to the statistics that appeared beyond the 1962 figure with which we have all been working.

The second point is that we do feel the exemption in the bill covers more than just the physicians. It covers a practitioner licensed by law to prescribe. This is a dentist, and an osteopath, and other people. We do not feel there should be any more regulation over them, either. It is not that their exemption should be excluded, but where you have this close State regulation, and it seems to me to be a rather small problem compared to the total, the professional practitioner should be exempted, like physicians, veterinarians, dentists, and others who are lawfully handling these drugs.

Mr. WATSON. This reduction in the number of violations, and I believe you said 45 in 1964, has that been as a result of your self-policing, or the lack of adequate personnel on the part of the FDA, or a combination of both?

Mr. STEEVES. It is probably a result of the educational process of the seriousness of the problem and putting better controls over the distribution of amphetamines and barbiturates. Certainly, the total

number of barbiturates in that period has expanded in the distribution channels, and, yet, you find that the convictions under there are reduced by, say, approximately one-third. It may have been a gradual process since 1952.

For example, in 1952, there might have been 500 violations. I don't know. I haven't seen the figures. And maybe in 1962 there may have been 50. It may have been a more gradual decline than the average would indicate.

Mr. WATSON. Thank you, sir.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Curtin, have you any questions?

Mr. CURTIN. No questions, Mr. Chairman.

The CHAIRMAN. Does anyone else have any questions?

Are you satisfied with your proposal that pharmacists would be exempted from the provisions of this act by including the words "or dispense" in subparagraph (4) of the bill you referred to?

Mr. NOTTINGHAM. Yes, sir.

Mr. STEEVES. Along with the other language, Mr. Chairman, that is suggested in the next paragraph.

The CHAIRMAN. I know.

Yesterday, we had Mr. Jehle and Mr. Rooke who testified in behalf of the National Retail Druggists Association. I assume that the two trade organizations, one of which you represent and one which they represent, are of the same and one opinion about this particular subject.

Mr. NOTTINGHAM. Mr. Chairman, I haven't seen his testimony and I did not hear it, so I cannot comment on it.

The CHAIRMAN. Since Mr. Jehle is in the room at the present time, in order to get as full and complete information as we can, I will ask him a question.

Mr. Jehle, would you be satisfied that this language change of "or dispense" would accomplish what you testified to yesterday?

Mr. JEHLE. Their testimony seems to accord with that presented yesterday by the National Association of Retail Druggists. We are in perfect agreement on this one point. We want the pharmacists exempted, and the language we suggested yesterday and their recommendations today both reach that objective.

The CHAIRMAN. You think that their language would accomplish it?

Mr. JEHLE. Yes, sir.

The CHAIRMAN. How many of the States have adopted your proposed model law?

Mr. STEEVES. At the last survey, I think there were somewhere around 30 States, Mr. Chairman, but I would also point out that there have been a few States, such as Michigan, as an example, which have repealed special legislation in the area of amphetamines because it added nothing beyond their pharmacy statutes.

When a pharmacist dispenses a barbiturate or amphetamine illegally or without authorization of a prescriber, you don't need a special statute. It is a violation, first of the Federal Food, Drug, and Cosmetics Act, and it is a violation of the State Pharmacy Act, and a violation of the State Food and Drug Act. This is certainly an armamentarium of authority without adding another act at the State level on

amphetamines and barbiturates in many instances as the State pharmacy laws are drafted today.

But the way H.R. 2 approaches the amphetamine and barbiturate problem is in the illicit traffic where you don't have these statutes, by making illegal possession, for example, a cause for conviction. Where the inspectors find a peddler with a cache of drugs in his possession, they have no authority to proceed unless they prove interstate commerce and, as I understand, they must also make a purchase to show he sold the drug in a misbranded condition. H.R. 2 removes that. So, it is a great improvement on the enforcement tools that are available for the illicit traffic, but I think it adds very little over the regulated channels of pharmacy over the current law.

The CHAIRMAN. With the exception that if the traffic is through the pharmacist, it doesn't apply.

Mr. STEEVES. That is correct. But, under the provisions of the act, if the pharmacist was acting outside the course of his professional practice, then he would have to have records and other provisions required by your proposal. In other words, as long as he is acting in the course of his professional practice, all his pharmacy laws apply to him. The minute he dispenses this without a prescription, he is no longer practicing his profession, but he is bootlegging, in popular terms, and, therefore, the exemption would no longer apply to him, no more than under the present Federal law when a physician bootlegs amphetamines. He is charged with dispensing amphetamines outside the doctor-patient relationship.

Dispensing drugs in the doctor-patient relationship is exempted under the law. But when the physician does it outside the doctor-patient relationship, he is like any other individual and does not qualify for the exemption.

The CHAIRMAN. In other words, do I understand your contention is that a pharmacist who engages in the distribution of these particular drugs without a prescription would not then be exempted from the provisions of the law?

Mr. NOTTINGHAM. That is right.

Mr. STEEVES. As you state in 511(d)(3), "dispensed by him in the course of his professional practice." The illegal distribution would not be in the course of his professional practice, in the case of a physician, a pharmacist, or any other professional person. This would be a general proposition in the law.

The CHAIRMAN. In referring to 511(d)(3) it reads:

The provisions of paragraphs (1) and (2) of this subsection shall not apply to a licensed practitioner described in subsection (a)(4)—

With your amendment, of course—

with respect to any depressant or stimulant drug received, prepared, processed, administered, or dispensed by him in the course of his professional practice.

You want to include "or to any establishment described in subsection (a)(3)." That is, pharmacists, clinics, hospitals, and public health agencies licensed by State law to dispense or sell prescription-legend drugs.

In other words, if a particular establishment is licensed by State law, and then they engage in illicit traffic, if the enforcement of that State is not sufficient or if it breaks down, there is nothing that can be

done about it on an interstate basis, is there? That, it would seem to me, might be going a little further than you would be entitled to ask.

Mr. STEEVES. The only establishments, Mr. Chairman, licensed by State law to dispense or sell prescription drugs would be pharmacies, hospitals with a pharmacy, and perhaps some clinics. So the qualification "licensed by State law" brings it into conformance with our proposed amendment in paragraph (4) of that section for pharmacists.

Otherwise, you would have the case where the pharmacist would be exempt and yet under (a) (3) the pharmacy or hospital pharmacy, if that is something separate, would then have to maintain records. So there would be no exemption under (a) (4) at all because the pharmacist in that pharmacy would have to maintain the pharmacy's records.

The CHAIRMAN. Don't you have to maintain records because of your State enforcement? Are you trying to say to us that you don't want to maintain records?

Mr. STEEVES. No, but the recordkeeping under this bill would be the only ones that would be exempted, not the regular records required by the Food and Drug Act as they are now maintained by the pharmacist. We would still continue to maintain those.

The CHAIRMAN. We would want to be perfectly sure that that is the case.

I know in our Securities Exchange Commission bill last year, we provided that the extension would not be applicable to certain insurance companies provided their State laws required certain things.

It may be that we better be sure about this, if you say that some of the States are taking a different approach to it.

Mr. STEEVES. The Food, Drug, and Cosmetic Act, in order to dispense the prescription drug now under section 503(b), requires the pharmacist to retain in his file as a voucher for the prescription drug, the prescription order the physician has written. This is the record.

The CHAIRMAN. That is under the Durham-Humphrey Act.

Mr. STEEVES. That is correct.

The CHAIRMAN. Then you come along and you are saying you would have to keep records. I don't want the implication to get into this that the Durham-Humphrey Act would be amended where you would not be required to maintain the records.

Mr. STEEVES. The intent of that amendment, Mr. Chairman, and I think the language is so drafted, would still require all records which the Federal law currently requires and the pharmacist would continue to maintain those records.

But it would exempt him, the pharmacist and the pharmacy, in this case, from any separate or special recordkeeping on this type of a drug, just as you have exempted physicians or other practitioners licensed to prescribe. This would just mean that there would be no additional record required in the pharmacy, and not that he would maintain no records.

The State law may require records in addition to those required by the Federal law. But the Federal law is the minimal. In other words, no State can permit a pharmacist to keep a record less than the Federal law requires. They can make it more stringent and they can require additional records. This has been the case in amphetamine and barbiturate State acts, wherever they may have required some additional recordkeeping provision on the State level.

As I mentioned to you, for example, Michigan repealed their law when they remodeled their Pharmacy Act 3 years ago.

The CHAIRMAN. There are no uniform laws, then, among the States?

Mr. STEEVES. What started out as uniformity in the pharmacy law has become something less than uniform. As a matter of fact, it has come to a point where a committee in our association has recommended that we now promulgate a model pharmacy law, uniform pharmacy law, which is updated with contemporary requirements as to some of these changes which have been made. The last uniform pharmacy act was drafted perhaps 20 or 25 years ago.

The CHAIRMAN. And only about 30 States adopted it?

Mr. STEEVES. All 50 States have a pharmacy law, but the 30 States I was speaking of were for the model barbiturate law, which was promulgated about 1950, or thereabouts.

The CHAIRMAN. To what extent does the average pharmacy engage in the dispensing of these types of drugs?

Mr. NOTTINGHAM. Mr. Chairman, I don't believe I can answer that unless it is a little more specific. I don't believe I got your meaning.

The CHAIRMAN. I mean by that in what quantities, on an average, would a pharmacist or a drugstore dispense this type drug?

Mr. NOTTINGHAM. Do you mean of a number of given prescriptions, sir, how many of them would fall into these categories we are talking about?

The CHAIRMAN. How many of these amphetamine tablets do you dispense in a day, a month, or a year.

Mr. NOTTINGHAM. I would say, sir, in my pharmacy we would dispense possibly 2,500 or 3,000 doses of amphetamine or stimulant type drugs within the course of a month.

The CHAIRMAN. Within the course of a month?

Mr. NOTTINGHAM. Yes, sir.

The CHAIRMAN. That would be the normal business you would have?

Mr. NOTTINGHAM. Yes, sir.

The CHAIRMAN. Would you say your drugstore was an average or would it be smaller or larger than the average?

Mr. NOTTINGHAM. Slightly larger than average. But it is only slightly larger.

The CHAIRMAN. Would there be a good many drugstores that would dispense a good many more than you do?

Mr. NOTTINGHAM. I do not know why they should, sir.

The CHAIRMAN. Suppose we were to place a limitation on the number to be dispensed, and if anyone gets into the business in a large way then they would come under the inspection provisions. What would you say about that?

Mr. STEEVES. You are saying, for example, that if the physician prescribes 24 or 50 tablets you might put any prescription calling for 100 tablets or more you must maintain a record of? Do I understand you correctly?

The CHAIRMAN. It is an idea.

Mr. STEEVES. The point I make there is that some people going on vacation, for example—and sometimes I hear this from New England pharmacists—when the patient goes to Florida for a winter. They want a 3-month supply of drugs their physician has placed them on.

The CHAIRMAN. Suppose we put in a limitation, say, if a particular

business engaged in the dispensing of drugs of more than average of 3,000 doses a month, that they would have to then keep records?

Mr. NOTTINGHAM. Mr. Chairman, if I may, I think your committee should understand that any time the pharmacist may be suspected of trafficking in these drugs, or others, outside of his professional practice; that is, dispensing them except as exactly under the terms of the law, then he has to have a record to substantiate his conduct. He must have a record to substantiate why he dispensed 5,000 in this particular pharmacy. This is the kind of thing that has happened in other areas of regulation, where purchase records and sales records are maintained at the wholesale and manufacturing levels to alert those who are in the regulatory field to look into certain instances of unusual purchases.

We are already required to have the record to substantiate our conduct. I don't know whether that has been fully understood or not, but that is the case.

The CHAIRMAN. But you want to be darn sure nobody sees them.

Mr. NOTTINGHAM. No, sir, Mr. Chairman; may I disagree. We don't want to be harassed by inspectors coming in without good cause. This can be very, very trying as an experience, sir. I can cite you certain examples.

Mr. STEEVES. There is no objection to inspection as Mr. Nottingham stated in the association statement. For 45 violations a year among the pharmacists, if the enforcement officials could see from the wholesaler or manufacturer records that in my pharmacy I bought 100,000 amphetamine tablets, and they had reasonable grounds to believe that I was peddling the amphetamines, the search warrant procedure exists. They could come in and search the prescription files and prescription room and every other aspect of it on probable cause.

The association would certainly encourage this type of inspection. However, today we have alcohol, the Internal Revenue Service, narcotic, State pharmacy board, Food and Drug, health officials, in some cases local ones, inspecting pharmacies, and any of these inspections can take you anywhere from a half hour to maybe a half day or a day. Just think of the burden on a pharmacist who is maintaining a pharmacy of the average size.

The CHAIRMAN. I can very well understand the fears. My position and record is well known and stated in reports and the Congressional Record. I do not think that the Government ought to be promiscuously and arbitrarily witch hunting all over the lot. I have no intention of anything of that kind.

What we are trying to do is to reach some kind of a formula, or some acceptable way, so that we can give the machinery or the equipment to the Food and Drug Administration to follow drugs after they go on their journey through the illicit traffic.

I don't think I am stretching my imagination that any person engaged in illicit traffic will arbitrarily say that "We will pick out a pharmacy at Williamsburg" or anywhere else and go straight through that. That isn't the way it is done. But there seems to be a vacuum there from the time it goes into what appears to be a legitimate wholesaler's hands and then until it gets into the stream of illegal distribution, where the public can get hold of it.

As I said to the other gentleman, it seems to me that your profession, which is recognized as being a legitimate profession and a very necessary profession, ought to be in here trying to help us devise a way to get to this problem, instead of just coming up and saying, "We want to be exempted outright," and leave it to the States.

We had described to us yesterday that in the State of Virginia three inspectors went around and inspected the records every 30 days. You know how well three inspectors would get along in a State where they had that kind of responsibility.

All we are trying to do is to devise a way to deal with a problem—and there is no one who says there isn't a problem; everyone says there is. Since 1962, I have held the view that the Food and Drug Administration could do more under present law than they have been doing. I have made that pretty clear to them. I am about convinced, though, maybe they couldn't, particularly with some of the descriptions that were given to us yesterday.

I would merely suggest, with all the knowledge that you gentlemen have in your organization and in your profession, that we would welcome all the help you could give to devise the best possible means to do the job that ought to be done, but not interfere with your doing your service to the public.

Mr. NOTTINGHAM. Mr. Chairman, you mentioned Virginia.

I would first like to point out that three inspectors can do a very effective job. In the first place, we consider the vast majority of us, at least, to be law-abiding citizens, and our professional ethics to be on a high scale. We have only about 900 pharmacies in Virginia, and three inspectors, plus an administrative director, can do a pretty good job.

I want to suggest, sir, that the committee may be interested in some of the information from FDA files concerning the truck stops on Route 1 between Washington and Richmond. The board of pharmacy and the State police and the county police have been carrying on a real fine program of disrupting and, to some extent, reducing this illicit traffic.

I think we have put ourselves on record that the American Pharmaceutical Association is supporting this bill. We are very much in favor of reducing the illicit traffic in these drugs, or any other drugs, narcotics or what not. We are very interested in it.

We feel that some of these things we read about are repugnant to us, that they are a reflection on our profession. But that doesn't mean, sir, that the rank and file of us need a policeman coming in our prescription department and disrupting our service for a half day, 2 days, or whatever it takes, and then take my records and try to make me substantiate everything I have done, when, so far as I know, I have done nothing illegal.

But I daresay that none of us would welcome this sort of investigation when it was unwarranted. If it is warranted, then we have to back up what we have done. We have to have the prescription record there to show how we dispense this unusual number. We do feel we are doing a good job. We feel that pharmacists in this country are doing a good job. I know they are doing a good job in Virginia. You have some violators down there, too, but we are trying to apprehend them.

The CHAIRMAN. There is a lot in what you say. It is unfortunate that we have a society where it is necessary, Mr. Nottingham, to have methods and machinery to cause people to desist from doing certain things against society. It would be a wonderful thing if we didn't have to have a murder law. There are very, very few people out of a thousand or a hundred thousand who commit the unfortunate crime of murder. But you wouldn't say to do away with all murder laws because the great body of citizens are good citizens and don't engage in activity of that kind, would you?

Mr. NOTTINGHAM. No, sir, but I don't expect to be investigated for murder until I have committed it or at least am suspected of committing it.

The CHAIRMAN. You don't think, if anyone decides to get into the business wholesale, you don't think there is any way that the Federal Government ought to have any authority under this proposal, as far as the pharmacists are concerned?

Mr. NOTTINGHAM. Did you say "wholesale," sir?

The CHAIRMAN. I use that term in a bigger way. Well, beyond your normal practice. I will put it that way.

Mr. NOTTINGHAM. Sir, in wholesaling and in manufacturing—

The CHAIRMAN. I am not talking about wholesaling. I just used that term. When you get into the business beyond your normal practice of dispensing.

Mr. NOTTINGHAM. Yes, sir. I think we warrant inspection then; yes, sir. The current records would have to support our acts.

Mr. STEEVES. The position that we have taken, here, I think, and in the past, has always been that the FDA may need some additional authority here, and in the Senate in the 87th Congress on S. 1399 we endorsed the approach of the bill, in the Senate on S. 2628 we endorsed the bill in hearings there, on the possession, on getting at the interstate commerce, and on the record of where the drug went, aspects of this type of illicit traffic.

We have always supported the efforts of the Congress to get at the illicit traffic, and we have always tried to guide committees, such as yours on where the problem is. We think that the record shows that imposing this type of control on pharmacists is not warranted for 45 violations a year, considering there are 90,000 or 100,000 pharmacists practicing.

On the other hand, if this type of possession law did not operate properly, and you felt that pharmacists should be included at a later date, you could always include them, add them to the list of people, as you are adding wholesalers and jobbers as a group to keep records in this measure.

We feel that this bill is a good step toward controlling the problem, and have endorsed it as such.

The CHAIRMAN. I would like to remind you that since—when was it, Mr. Younger, that we started making the record?

Mr. YOUNGER. The narcotic records that the pharmacist has to keep, was that in 1957 or 1958?

The CHAIRMAN. It was before that, I think. I would remind you that there is nobody who has taken a stronger position on the principles you have discussed here, and the record is very clear on it.

We have reiterated it again. I did it with a firm belief that this matter could be controlled. Notwithstanding, we slipped a cog somewhere. I am not saying that your profession is responsible, largely, at all. But nobody denies the fact that we have 4½ billion of these illicit pills and capsules that have gone to the public, to youngsters, truckdrivers, to people all over.

I know Mr. Younger and I have entered into a colloquy on the floor of the House several times about this.

Mr. YOUNGER. 1954, Mr. Chairman, was the year.

The CHAIRMAN. Yes. We have entered into colloquies on the principle that this can be met. Well, it hasn't been met. It is getting worse all the time. So whoever is responsible, even though there is only a small percentage of those engaged in pharmacy who seem to have been engaged in this business, we want to get to the real brunt of this thing, wherever it might be.

I think everyone who is interested recognizes there is a problem. What I want to be sure of is that we do the right thing and not leave the gates open any further. Certainly I don't want to encroach upon the prerogatives of the business people of the country who are doing a fine and legitimate job of serving the American public.

I am going to do whatever I can with the other members who are strongly inclined, and I think that includes everyone on this committee, that we do something about it. And we want to do the right thing.

Mr. SPRINGER. Since the Congress enacted the narcotics registration provision, do you feel that pharmacists have been unduly harassed as a result of keeping records? Has it been your experience, in the past 14 years that you have been unduly harassed?

Mr. STEEVES. One aspect of narcotics records, with separate forms and a separate setup under the tax structure, is that the amount of narcotics dispensed through a pharmacy are fractional compared with the number of barbiturates and amphetamines.

I don't have the exact figure, but it is something like 80 million prescriptions in which barbiturate or amphetamine is the principal ingredient dispensed through pharmacies, and something like 18 million narcotic prescriptions through pharmacies.

When you include stimulant and depressant, as it would seem, you would have to broaden it, you can see what a large recordkeeping flow you would have in the average pharmacy and the pharmacies throughout the country, which might be, let's say, 15 times what it would be for narcotic recordkeeping.

Mr. SPRINGER. This happened in my community, and we have had very little of this, but we have had some of it going on. They finally found a druggist who was giving these out and were able to round up enough evidence to trace it to him.

But in talking to the Government about that, it would have been a much easier process. What they had to do was to separate all of the druggists. They finally narrowed it down to this one man running a corner drugstore. But if they had been able to just examine the records, it would have been conclusive in the beginning. As it was, I think it was a several-month investigation and I think they will still have difficulty in convicting the fellow.

Mr. STEEVES. If the FDA enforcement agents could have gone around to the suppliers and if they could have looked at the records and then said "these pharmacies are using on the average of 3,000 or 5,000 amphetamines" and noticed that one or two of these was using a much larger amount than that, they would have at least brought down their field to maybe five pharmacies in the area which were likely candidates.

Mr. SPRINGER. I think what they believed was that he was being supplied by an illicit source which did not show in the records of the manufacturer.

But anyway, this was the problem involved. The man is not convicted as yet. But it did put the pharmacies in the Champaign-Urbana under suspicion, when there would have been no problem, if they had just gone and looked at the records.

We don't know what the answers are, and we just ask a lot of questions to see what you think about it. But some way we have to control it. We are certainly glad to hear your viewpoint on this matter.

Mr. NOTTINGHAM. Mr. Springer, if I may add a little something, the chairman asked for suggestions. We heard, I think, Dr. Smith say something about his 140-odd members constituting about 90 percent of the sales of pharmaceuticals to we pharmacists. This is true. With me it is much higher than that. I don't know how much higher, but with the exception of a few local pharmaceutical firms all of our supplies come from members of his association.

However, in every mail, and I think I can say that without exception—certainly the usual mail—it brings flyers from New York and other places in which so-called generic drugs are advertised at ridiculous prices. The headlines on these sheets are the stimulant-type drugs advertised at a price that to me is a ridiculous figure.

I do not know these houses and they mean nothing to me, for the most part. I throw them in the trash. I never open them any more. I never read them at all. But you asked about a source, Mr. Chairman, and here it is.

All you have to do is look in the U.S. mails and it is there, and it is there in quantity. I think, without knowing—I certainly don't know—I believe if I operated a truck stop on Route 1 I would send it into that character and he would send me whatever I ordered if I had the money with it. That is my opinion.

Your bill, of course, is designed to stop this. That is the reason we are endorsing it. We think this four and a half billion tablets that are going into illicit traffic has to be dried up somewhere near the source.

The CHAIRMAN. That is what we have been talking to Dr. Smith about, and the pharmaceutical people. I think we have to get at it at the truck stops or filling stations as the case may be, and any other source.

I imagine the trucking people are going to say, "We are the victims in this thing. We are not the ones responsible for it. But you should cut it out."

Mr. Nelsen.

Mr. NELSEN. You indicate this bill is too severe in its application dealing with the pharmacists and pharmacies. Is there an area, in your judgment, where we could place in this bill some additional authority

for Food and Drug to do a better job as far as pharmacists and pharmacies, give them the authority in event their needs to be some more surveillance in this area?

Do you have any recommendations to make that would be less stringent, yet would be of some value to Food and Drug?

Mr. NOTTINGHAM. I will try, Mr. Nelsen. We think that FDA has ample authority to inspect me any day they want to for cause. We feel that adding this language merely adds to the harassment. That is an ugly word, and I know the FDA doesn't like me using that, but this is what it amounts to, no matter how gentlemanly the inspectors may be.

Mr. NELSEN. You feel that this language will provide a harassment. Having in mind that this committee will do everything we can to try to write a bill that meets the problem, but yet which is fair to what we think will be the self-policed, legitimate pharmacies.

There may be some area where you would have a provision changed. We are searching for all the information we can get. We don't want to harass anybody. But there may be areas, and we would like for you to give any suggestions you have to the committee.

Mr. NOTTINGHAM. Sir, we will certainly submit it if we can come up with it. We are very much in favor of the bill. We want to see this improved and this illicit traffic blocked out.

The CHAIRMAN. Thank you very much, gentlemen. If we have given you quite a going around this afternoon, I hope you will understand it is for the purpose of trying to develop the record here on which the committee can make a final decision as to how this problem may be resolved.

Mr. GILLIGAN. Mr. Chairman?

The CHAIRMAN. Mr. Gilligan.

Mr. GILLIGAN. In the example given by Mr. Springer a moment ago of a real bad actor in the pharmacy field, suppose the local officers suspected this as a source of supply to college students or whatever else and they went on to his premises and found a supply of these drugs, say 10 times what would normally be expected to be there. He has no records of sale.

He just says "Well, I got a bargain and I just happen to buy it up all over the place, but it doesn't move at all." Short of actually catching him in the act or eliciting a confession from someone, how are they going to nail this fellow? It seems to me that under this act the fact that he would have to register, keep records of supplies, income and outgo, you would have him. I don't see, under the present circumstances, how you would.

Mr. NOTTINGHAM. Sir, I don't know how to suggest that the law be written to accomplish this purpose. But in my lay language that would constitute prima facie evidence of violation and should be confiscated.

Mr. GILLIGAN. Because he has an unusually large supply you would confiscate it?

Mr. NOTTINGHAM. Yes, unless he can defend it with his records. That is where the records come in that he has to keep now.

Mr. GILLIGAN. If he just says, "I haven't been selling it. It has been here on the shelf for months."

Mr. STEEVES. Under the bill as written, H.R. 2, or under the current law, the only change in that situation would be that he would have a record of receipt, plus this. If exempted, as we would have the pharmacist in that case, you would still have the record of sale from the source of supply on this gentleman.

Mr. GILLIGAN. But how many sources of supply are there available to a gentleman of this type in this country?

Mr. STEEVES. You are going to have them all registered. You are going to have all sources of supply registered.

Mr. GILLIGAN. We will not have, presumably, the illicit sources of supply registered because they will not register.

Mr. STEEVES. Then the possession statute would handle him; would it not?

Mr. GILLIGAN. Under H.R. 2 I see where he would be handled.

Mr. STEEVES. That is correct.

Mr. GILLIGAN. I don't understand that there is a possession statute on the books now which would in any way embarrass him.

Mr. STEEVES. This brings up a point, perhaps, for improving it in this type of a situation, where you might put in a section where a pharmacist would not buy from an unregistered source. In other words, make it a violation for him to purchase from an unregistered source.

Mr. GILLIGAN. How could we do that without including the pharmacists under the language of this bill? Aren't you saying, in effect, that we have to get him at least under a portion of the bill to make control effective?

Mr. STEEVES. He is not included under either the inspection or recordkeeping or any other actual possession of the Federal food, drug, and cosmetic law now, and yet the Food and Drug Administration thinks it has pretty good control over prescription drugs. He has the prescription records.

Mr. GILLIGAN. But the same Food and Drug Administration has recommended that we adopt H.R. 2 to bring the pharmacist under control of registration, recordkeeping, and so forth, in amphetamines, depressants, and so forth.

Mr. STEEVES. The three most important parts of H.R. 2, in terms of enforcement as pharmacy would see them, is the possession of these drugs by other than enumerated people is illegal and subject to action; No. 2, that a person may not produce them unless he is registered, a wholesaler may not sell them unless he is registered; and No. 3, the Food and Drug Administration would not have to prove interstate commerce.

They say these are the three troublesome areas. They must first prove interstate commerce, when the drug has no markings. Second, there is no law identifying where these can be manufactured.

They can be manufactured in a bathroom or on a street corner or any other place. If they find them on a person, 100,000 tablets, today they have to buy some from him before they can subject him to a conviction.

These three important points, it seems to me, give them plenty of authority. I say the present food and drug law gives them plenty of authority to cover the distribution through traditional channels.

To cover the situation you mentioned where they buy through an illicit distributor, perhaps you can say it would be a crime for any person to buy amphetamines from a person not registered with FDA. This would then bring the pharmacist under it.

The CHAIRMAN. Or to have them in his possession. How would the inspectors be able to prove where he bought these, whether they were unlicensed or licensed?

Mr. NOTTINGHAM. The record would have to show.

The CHAIRMAN. If the pharmacist is required to keep the record, yes. But you are arguing that he should not be required to keep records, as I understand your argument.

Mr. STEEVES. If you are going to get complete control over amphetamines and barbiturates and recordkeeping down the line, then it seems to me you have to go to the full route of the narcotic law and have every order the pharmacist sends on, whatever form it is, also go to the Food and Drug Administration. That is the way narcotics are controlled.

Mr. GILLIGAN. We don't want to harass you. Just to have them available to the inspectors. You needn't send it in.

Mr. YOUNGER. Will the gentleman yield?

Mr. GILLIGAN. Yes.

Mr. YOUNGER. I am for some kind of record, but I think the question that troubles me is that the crook is not going to keep a record on which they can convict him. That is the trouble with this process, as I see it. The fellow who is going to be crooked in this field is not going to keep a record that somebody can come in and use to convict him. He is not even going to make a record.

That is the trouble with it.

Mr. GILLIGAN. Mr. Younger, if I understand the proposed H.R. 2, that is precisely the point at which you would get him under this law, because he had not kept the records. Under H.R. 2, if he had possession of a sizable supply of these drugs on hand and had no records to indicate where he got them and how he was using them, and at what rate he was dispensing them, then you really have him locked up. If we don't cover the pharmacies in the—

Mr. YOUNGER. I am not against keeping a record. I am just saying that the record system, in my opinion, falls down because you are starting in first with a crook. He ought to be smart enough not to keep a record on which they are going to convict him. Otherwise, he is a stupid man, a stupid crook.

Mr. STEEVES. In the case where he had a record that he received those, with all those tablets, you would still have to make a purchase from the pharmacist to prove an illegal sale.

If he had not sold at that point illegally, he could say "I am going to use these in my practice" and it is a 10-year supply, and possession is authorized by H.R. 2. He can possess them. You would have to prove that he was possessing them for an unlawful purpose, and to do that you would have to make a purchase.

The CHAIRMAN. I am impressed by your proposal to exempt dispensing of these drugs while acting in the course of their professional practice. If they get outside of their professional practices, then the law would cover them.

Mr. STEEVES. Yes.

The CHAIRMAN. Thank you very much.

Mr. NOTTINGHAM. Thank you, Mr. Chairman. We are very appreciative of the opportunity to appear before your committee, and I certainly want to thank the committee members for their patience.

The CHAIRMAN. Thank you very much for your presence and presentation.

(The following letter was later received for the record:)

AMERICAN PHARMACEUTICAL ASSOCIATION,  
Washington, D.C., February 2, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

MY DEAR MR. HARRIS: Since we presented our testimony on H.R. 2, we have given serious attention to some of the points raised in the question-and-answer period and offer the following additional comments for the committee.

As our representatives stated in their presentation, we would hope that the committee would find that the few violations by pharmacists during 1964 involving drugs H.R. 2 seeks to control do not justify inclusion of the practitioners of pharmacy within the proposed law's scope. We do understand the concern that all practitioners obtain supplies of depressant and stimulant drugs from legitimate manufacturers and wholesalers. The American Pharmaceutical Association agrees with this principle and has always advised its members to only deal with persons they know and trust.

To make this explicitly clear, we would support a provision which would prohibit the purchase of stimulant or depressant drugs from any manufacturer or wholesaler that had not complied with the registration requirements of section 510 as amended by H.R. 2. We believe that an amendment to section 301 of the act would accomplish this objective by providing a new subparagraph (r) reading:

"(r) The receipt or purchase by any person of a stimulant or depressant drug from a manufacturer, compounder, processor, wholesaler, jobber, or distributor unless such manufacturer, compounder, processor, wholesaler, jobber, or distributor has complied with the registration provisions of section 510."

With this addition, practitioners of the professions could not lawfully assist illicit peddlers either knowingly or unknowingly. While there is nothing in H.R. 2 which requires physicians, pharmacists, and other professional practitioners to purchase their supplies from sources registered under section 510, we believe that this is a worthwhile amendment for your committee to consider. It also provides better control over the distribution of these drugs if pharmacists were exempted in a manner similar to that provided for physicians, dentists, osteopaths, and other practitioners licensed by law to prescribe drugs. Since all professional practitioners would be required to purchase from legitimate distributors validly registered with the Secretary, FDA would have a complete record of shipments for legitimate medical and pharmaceutical uses at the manufacturer and wholesaler level.

We also note that Commissioner Larrick has asked that the proposed law provide arrest powers for enforcement purposes. We can support this suggestion that FDA officers be given power to make arrests "without warrants for offenses with respect to these drugs when the offense is committed in the officer's presence with respect to these drugs or, in the case of a felony, when the officer has reasonable cause to believe that the person so arrested has committed or is committing the offense."

We recognize that the power to make arrests also carries with it the power to make reasonable searches and seizures of the immediate premises and see that this could be a valuable asset in policing the illicit distribution of stimulant or depressant drugs. We would note that, unlike a general power of inspection, arrest must be based on probable cause and presumably grounds would also exist to support the issuance of a search warrant. Such a power would also apply where FDA officers had reasonable grounds to suspect that a practitioner was distributing drugs outside the bounds of his professional practice.

As you so aptly pointed out, FDA officers would not carry out inspections on a random basis but rather would investigate suspected violations. With only 45 pharmacists violations in 1964, we believe that the arrest or search procedures normally followed to apprehend perpetrators of the most heinous offenses would

not be too burdensome for the Government to employ. The arrest procedure would permit faster action against violators but maintain the usual safeguards afforded to law-abiding citizens.

Let me assure you that the Nation's pharmacists support your efforts to stamp out the illicit traffic in stimulant and depressant drugs. We believe the record shows that pharmacists have been diligent in upholding their responsibilities. The pharmacists of the country are entrusted with safeguarding the distribution of all potent therapeutic medications and medical devices of which stimulant and depressant drugs are but a part. Pharmacists have always stood willingly to accept additional regulation of their activities when warranted.

Of course, we do agree that where a pharmacist or other practitioner unlawfully distributes stimulant or depressant drugs outside of the course of his professional practice, all of the provisions proposed by H.R. 2 should and would apply.

Sincerely,

WILLIAM S. APPLE, Ph. D.,  
*Executive Director.*

The CHAIRMAN. The next witness is the counsel for the American Trucking Associations, Mr. James Fort.

**STATEMENT OF JAMES FORT, COUNSEL, PUBLIC AFFAIRS,  
AMERICAN TRUCKING ASSOCIATIONS**

Mr. FORT. Mr. Chairman, I appreciate the opportunity to be here under somewhat unfamiliar circumstances for the trucking industry, particularly since the chairman has already anticipated my statement.

I would like the opportunity, Mr. Chairman, to file a statement within the next day or so, and I would simply like the opportunity of the committee right now to give you the major two or three points that will be covered in a detailed statement within the next few days.

The trucking industry, as the chairman indicated a few moments ago, is very much interested in the passage of this bill. We do not hold ourselves out, nor do we make any attempt to be regulatory experts in the field of drugs. We don't particularly know whether the bill as it is before the committee will do the job. We are told it will, by the experts.

We have a problem. Our problem is the use of amphetamines by truckdrivers. In our experience we have found it to be a health problem far more than a safety problem. It is for that reason that we ask the control of these drugs.

We have, in the past years, cooperated extensively with the Food and Drug Administration through the distribution of literature and through cooperation in their enforcement methods. The industry and the Food and Drug Administration have cooperated many times by placing of their personnel on our trucks, and through many similar procedures.

Mr. Chairman, those are the principal points that we would detail in our statement which we would like permission to file with you in the next several days.

The CHAIRMAN. You may file your statement, Mr. Fort, with the committee. The committee will be glad to consider it.

However, from your brief presentation today, I understand that you are generally in accord with the proposed bill that is before you?

Mr. FORT. That is correct, sir.

The CHAIRMAN. You say you do have a problem. From your reports of industry, are you in a position to indicate whether the reports that we get that the truckdrivers use, to a very large extent, these stimulant drugs is correct?

Mr. FORT. We have made very serious attempts to find out, Mr. Chairman. Specifically, we wrote in a formal inquiry to the Interstate Commerce Commission last year in preparation for our Senate testimony on a similar bill then, and asked the ICC whether they could specify how many amphetamine-connected truck accidents had occurred in the past 10 years.

The Commission Chairman replied that they had seven years' records and that of the 7 years' records, with approximately 25,000 truck accident reports being filed every year, they felt that they had 13 provable accidents involving amphetamines, and 40 in which amphetamines were indicated to be involved.

So it was, in effect, 13 out of 25,000 a year over a 7-year period. They had 13 in which they felt there were provable connections between amphetamines and the accident. This is the only statistics we have been able to arrive at. There are no facts or figures available. There has been a tremendous amount of sound and fury over the use of amphetamines by truckdrivers.

We know it goes on. We discourage it at every opportunity.

The CHAIRMAN. From your reports, what is the source of their supply?

Mr. FORT. I have no knowledge of that, sir, other than the popular belief and popular statements that you hear frequently that the truck stop is a source of supply for the drivers. We have had no occasion at all to know of any source of supply other than that, let me say.

The CHAIRMAN. You have not pursued the matter to the point of trying to find out if these reports are accurate or not?

Mr. FORT. Yes, to the extent that we have any ability to do so we have. By cooperating with the FDA, we have, we hope, put some limit on it. We really have no one we can go to, and say "What is the source?" other than, potentially, the drivers themselves, and we have not gone that route.

The Teamsters Union and other employee organizations have been extremely cooperative with the management of the companies in distributing literature, putting up posters in drivers' rooms and things of this type.

The CHAIRMAN. Are there any questions, Mr. Younger?

Mr. YOUNGER. Just one question, Mr. Chairman. You said that it was a health problem rather than a safety problem.

Mr. FORT. Yes, sir.

Mr. YOUNGER. In what way is it a health problem?

Mr. FORT. It is a health problem in that the use of any drug, stimulating drug, of these types, habitually used by a person engaged in driving a truck, is bound to be bad. I have no specific information to point to, medically speaking at this moment.

Mr. YOUNGER. That is a statement that is hard to understand, Mr. Fort, because if it is a health problem and involves the health of the driver, certainly it would have something to do with the accidents.

If he is a sick man, he probably cannot react as sharply as a well man.

Mr. FORT. The use of amphetamines, as I understand them, sir, doesn't make a person sick in the accepted sense of the word, in that it dulls his reactions or faculties. In fact, their intended use, as I understand them medically, is just the opposite. They are designed to sharpen a person's reactions for a period.

Mr. YOUNGER. Then why do you say it is a health problem?

Mr. FORT. Continued use of them is very bad for the health, I am told.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Pickle?

Mr. PICKLE. My comment, more than a question, is that it is surprising to me that, if this is a health problem, that you would say that the statistics are exaggerated or that your industry as such has not done something concretely to find out the source of these pills. Why hasn't your organization done something about that?

Mr. FORT. We have done something about it to the extent that we have worked with FDA and we have worked with the Teamsters Union. We have passed out hundreds of thousands of brochures prepared by the FDA with our cooperation. We have no control over truck stops. We have no contact with them, per se. We have no ability to get at a source of these drugs, other than information, other than education.

Mr. PICKLE. You leave the investigation up to the authorities and you keep out of that field entirely?

Mr. FORT. We have no jurisdiction to investigate. We have, obviously, no search warrant authorities or anything like that. As I said a moment ago, through cooperation with FDA we have trained FDA agents as truckdrivers, and as truckdrivers' helpers, and they have ridden many thousands of miles in our vehicles. They have ridden our trucks in order that they could make the necessary purchases and thus enforce the law.

Mr. PICKLE. Do you think their source of these pills comes from physicians by prescription?

Mr. FORT. I know that there have been a lot of arrests of truck stop operators because of sales to truckdrivers. So, my only belief in the matter is that their source is truck stops rather than physicians.

Mr. PICKLE. Then if it is not physicians, would you say that pharmacies are supplying them?

Mr. FORT. Not to my knowledge.

Mr. PICKLE. Then would you say hospitals or clinics?

Mr. FORT. Again, not to my knowledge, sir.

Mr. PICKLE. Then what is the source? Doesn't it leave us the manufacturer or the wholesaler?

Mr. FORT. You are talking about a source beyond the sale to the driver?

Mr. PICKLE. Yes.

Mr. FORT. Rather than the immediate, let us call it, retail sale to the driver?

Mr. PICKLE. Yes, I guess that is what we are talking about.

Mr. FORT. That I would have no knowledge of, Mr. Pickle, I am sorry. The actual retail sale to the driver occurs principally through the truck stop. Who supplies the truck stop I have no knowledge of at all.

Mr. PICKLE. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Nelsen?

Mr. NELSEN. No questions.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. No questions.

The CHAIRMAN. Mr. Curtin?

Mr. CURTIN. No questions.

The CHAIRMAN. Mr. Ronan?

Mr. RONAN. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Cunningham?

Mr. CUNNINGHAM. Of the 13 accidents you had a record of, was it 13?

Mr. FORT. Yes, sir; the ICC reported 13.

Mr. CUNNINGHAM. Were they regulated or unregulated carriers?

Mr. FORT. I would have to check the ICC letter, Mr. Cunningham. I don't recall the answer to that question offhand.

Mr. CUNNINGHAM. You have labor contracts with the Teamsters?

Mr. FORT. In many instances. Of course, not by any means in all instances.

Mr. CUNNINGHAM. And these drivers are only allowed to drive a certain period of time, aren't they?

Mr. FORT. That is not by the labor contract, but by the ICC regulation.

Mr. CUNNINGHAM. I can't understand why any regulated drivers would be tempted to use these drugs, because they are not overly taxed as far as their strength is concerned, since the regulations are designed not to overtax them.

Mr. FORT. That is correct. The ICC current requirement is 10 hours of driving time between minimum 8-hour off-duty periods, with certain weekly limitations. You are entirely correct that if a driver observes these, he should not have to rely upon drugs to stay awake or to perform his normal duties.

Mr. CUNNINGHAM. That was my point. That is why I was wondering whether the unregulated carriers might be more prone, those who are not bound by the limitations on driving time.

Mr. FORT. The unregulated carrier is as bound as the regulated carrier drivers, by the safety regulations.

Mr. CUNNINGHAM. Even a farmer?

Mr. FORT. Yes, sir, even a farmer, provided he is in interstate commerce. I would have to rely upon the ICC to say whether there is better compliance with the ICC requirements by regulated or unregulated motor carriers.

Mr. CUNNINGHAM. If a driver under the ICC regulations—did you say it was 10 hours?

Mr. FORT. The requirement is for 10 hours of driving time.

Mr. CUNNINGHAM. Is there a rest period?

Mr. FORT. Between minimum 8-hour off-duty periods with certain weekly limitations on it, also.

Mr. CUNNINGHAM. Is there any rest period in the 10-hour period, or is that straight driving?

Mr. FORT. There is no prescribed rest time, but normal operations require stops for vehicle servicing, meals, and physical comfort. I would have to check the regulations to tell you exactly, sir.

Mr. CUNNINGHAM. If he is on a run and he can keep going without rest and complete his trip in 9 hours, is the other hour free to him; do you know?

Mr. FORT. I don't know the technical provisions of that either, Mr. Cunningham. There are very specific ICC rules on this.

Mr. CUNNINGHAM. I know there are rules. I thought they were in labor contracts. But you say they are in the ICC regulations. There is the limit on how long they can drive.

Mr. FORT. Yes.

Mr. CUNNINGHAM. I can't understand the reason they would need a stimulus.

Mr. FORT. Provided they comply with the ICC requirements, they should not.

The CHAIRMAN. There are certain occasions where they do drive continuously for a long period of time; don't they? For example, in the delivery of liquid petroleum, they are not, by ICC regulations, required to stop every so often; are they?

Mr. FORT. Mr. Chairman, I will have to plead ignorance of the details of the ICC requirements on those drivers. I am not intimately familiar with them. I know they are spelled out in very great detail.

The CHAIRMAN. And isn't it also true in order to comply with them, that a truck can go on and make its delivery, and, to comply with the regulations, they will pull over to the side of the road and curl up and sleep for awhile and then go on?

Mr. FORT. Not in compliance with the ICC regulations; no, sir.

The CHAIRMAN. It better be looked into, then, because you see them all along the highway.

Mr. CUNNINGHAM. Mr. Chairman, I wonder if we could get the details of these 13 accidents.

Mr. FORT. I would be very pleased to put into the record the letter from the ICC.

Mr. CUNNINGHAM. I would like to know what kind of trucks they were, and that type of detail. Maybe it is a farmer who doesn't come under the safety regulations.

Mr. FORT. I am not certain that the ICC letter detailed very much, but we can certainly check with them and find out.

Mr. CUNNINGHAM. Our staff ought to be able to get the details of those 13 cases.

(The material mentioned above follows:)

Date	Place	Status of carrier	Fatalities	Injuries	Property damage	Drugs circumstances			Description—Discussion
						Admission	Autopsy	Other	
July 24, 1963	Fayette, Ala.	Regulated	1			X			Ran off roadway (unpublished Rept. No. 9). Had written letter regarding use of drugs and drugs in possession.
Feb. 14, 1967	Washington, D. C.	do	1				X		Ran into rear of stopped vehicle at traffic light. Drugs in possession.
Mar. 27, 1968	Callahan, Fla.	do		2	\$10,525	X			Driver claimed blackout, ran off roadway. Admitted taking narcotic pill and he had obtained benzadrine tablets.
June 19, 1968	Mansfield Township, N. J.	do			8,000			X	Truck ran off roadway. Investigation indicated driver had used drugs and was intoxicated.
July 26, 1968	Philadelphia, Pa.	Nonregulated			5,000			X	Struck railroad box car on a highway median, had supply of benzadrine pills in cab.
Dec. 1, 1969	Phoenix, Ariz.	do		1	2,000	X			Vehicle ran off roadway. Driver admitted using amphetamines had drugs in possession, and was also an epileptic.
Dec. 20, 1969	Tucson, Ariz.	do		33	75,000		X		Truck ran into bus. Amphetamine possession of truckdriver. (Published Rept. No. 37.)
Aug. 12, 1960	Hatch, N. Mex.	Regulated			1,500	X			Ran off roadway. Had dexedrine and other drugs in possession. Excess. (Published Rept. No. 45.)
Sept. 16, 1960	Orlando, Fla.	do		1	1,340			X	Truck struck stopped passenger car. Carrier reported driver had been taking "bunnies."
May 2, 1962	Jackson, Miss.	do		1	5,000	X			Driver dozed at wheel, ran off roadway. Had benzadrine tablets in his possession.
Jan. 21, 1963	Easton, Pa.	Nonregulated		4	18,170			X	Truck struck several stopped trucks on highway. Medical examination and tests showed driver under the influence of amphetamine drugs.
June 19, 1963	Lucaas, Iowa	do		1	15,000	X			Truck ran off roadway. Supply of amphetamines found in driver's possession.
July 19, 1963	Tipton, Iowa	Regulated	4		4,000	X			Truck collided with stopped car. Amphetamines in possession of truck driver.
Jan. 8, 1964	Beckley, W. Va.	do	5		50,000		X		Truck collided with post office van. Amphetamines in driver's possession.

The CHAIRMAN. If you want to cover this matter a little more fully in your statement, I think it would be advisable, too, Mr. Fort.

Mr. Mackay?

Mr. MACKAY. Mr. Chairman, I wanted to ask Mr. Fort if he had any statistics other than these 13 accidents in which they relate the use of the drugs that are the subject of this legislation to accidents.

Is this the only statistic you have related to accidents?

Mr. FORT. This is the only compilation of interstate accident reporting that exists. The individual States obviously have varying laws on reporting of accidents. We have not queried the various States on what experience they may have had with this.

Mr. MACKAY. I was also interested in your remark that this is a health problem rather than a safety problem, in your view. Do you have any statistics that would indicate that the drivers of the trucks of America have health problems related to these drugs?

Mr. FORT. I have not, sir. The drivers are required to have periodic medical examinations. I know of no immediate results that have turned up in those medical examinations.

Mr. MACKAY. So the position of your association is simply one of general sympathetic interest with the objectives of this bill and not directly affecting your business.

Mr. FORT. That is correct.

The CHAIRMAN. Mr. Harvey?

Mr. HARVEY. No questions.

The CHAIRMAN. Mr. Gilligan?

Mr. GILLIGAN. No questions.

The CHAIRMAN. Mr. Watson?

Mr. WATSON. No questions.

The CHAIRMAN. Thank you very much, Mr. Fort, for your presentation today. We will be glad to place your statement in the record at this point.

Mr. FORT. Thank you, Mr. Chairman.

(The statement mentioned follows herewith:)

STATEMENT OF JAMES F. FORT, COUNSEL, PUBLIC AFFAIRS, AMERICAN TRUCKING ASSOCIATIONS, INC.

Mr. Chairman and gentlemen of the committee, my name is James F. Fort. I am counsel—public affairs of the American Trucking Associations, Inc., with offices at 1616 P Street NW., Washington, D.C., 20036. The association, as most of you know, is a national federation representing all forms of motor carriers, both private and for-hire, and having affiliated associations in 49 States and the District of Columbia.

We appear today in support of H.R. 2.

In 1954 the trucking industry first obtained concrete evidence that amphetamine drugs were being sold illegally at highway stops and establishments near highways. Since that time we have cooperated with the Food and Drug Administration, we have conducted extensive educational campaigns among our employees, and we have for a number of years sought legislation similar to that before you today to effectively control these drugs.

The committee has already heard testimony as to the detailed provisions of the bill and as to the improper uses which are made of stimulant drugs, so it is not our purpose today to review these technical points. Rather, we think that the committee would be more interested in a brief description of the problems which we have had in this area.

It is our wish initially to make it clear to the committee that the use of amphetamines by truckdrivers is far more of a health problem than it is a safety problem. Further, to whatever extent it is, or may become, a problem

of traffic safety, it must be related to the hour-by-hour and day-by-day physical fitness of all of the millions of drivers of all kinds and sizes of motor vehicles, not just truckdrivers.

It could be pointed out that the side effects of cold remedies of certain types and numerous other medicines can be assumed to detract from some users' driving ability in that they may cause dizziness or other adverse reactions. We know of no figures on this nor of any research into this on a statistical basis.

Any driver can be the cause of an accident, including injury and loss to others who may be entirely innocent of blame. Our industry accordingly is in this regard as much concerned about the health and the driving capabilities of all drivers as it is about those of its own employees.

Our country makes such heavy use of motor vehicles that we Americans have become strongly aware of traffic hazards, as we have long also been conscious of the word "drugs" in its most unpleasant connotation. So if we link the two, we are inclined to jump hastily to a conclusion that if amphetamines are being preferred to truck drivers, this must connote a great highway safety problem. Fortunately, this cannot today be demonstrated to be a fact. But unfortunately, an almost exclusive emphasis upon drivers and highway phases of the amphetamine problem for some years tended to lead attention away from the misuse of these drugs by a much greater number of persons in the general population. Here the problem exists whether or not they ever get behind a steering wheel. We warmly applaud the broader view being taken by this Congress.

We believe that when the general national health problem of misused amphetamines is solved, any particular amphetamine problem concerning our industry directly also will have been solved. We don't think one can be done without the other.

Medical authorities have assured us that there is a body of evidence that misdirected and abusive use of amphetamine drugs can be severely injurious to the health and welfare of many persons. We invite the committee's attention, for example, to the attached copy of a recent article in the British Journal of Addiction entitled "Amphetamine Misuse," which brings something of a world view of the problem.

My industry has been impelled by some of the rather warped publicity from time to time about highway aspects of amphetamine enforcement, to seek all possible facts about these drugs and accident rates. We have had a steadily improving safety record, which seemed to challenge the deceptively easy assumption that the so-called "bennies" must be causing a great many truck accidents.

In inquiring into the safety aspects of this problem, our industry recently inquired formally of the Interstate Commerce Commission whether the Commission could specify amphetamine-connected accidents involving trucks over the past 10 years.

The Commission's Chairman replied that complete records for this decade were unavailable due to storage, but that over the past 7 years it had files of 40 cases in which amphetamines were indicated to be involved and in 13 of these the connection was, in its judgment, provable.

With about 25,000 truck accident reports being filed each year, this makes the 13 provable instances amount to about 7.5 thousandths of 1 percent, clearly a very minor factor. Even assuming that all of the 40 cases were accepted as verified, the number is still far smaller than many other accident causes.

This is not to minimize the problem, for it is a problem and it has been our effort for a number of years to educate our drivers on the dangers to their overall health, as well as to educate them as to the driving hazard which may result from unsupervised or excessive use of these drugs.

According to published reports, the Food and Drug Administration estimates that production of amphetamine drugs annually is sufficient to produce about 8 billion pills or capsules. Commissioner Larrick has stated that a large proportion of these go into illicit channels. Against this background it is obviously illogical to assume that the truckdrivers of the Nation's approximately 700,000 tractor-semitrailer trucks could conceivably be the prime users.

That would mean that every one of these drivers would have to be taking anywhere from 7 to 10 of these pills every day of the year. That is not illogical, it's ridiculous. As a matter of fact the final report of the President's Advisory Commission on Narcotics and Drug Abuse tends to refute both such use and any claim about handling. That report states:

"On the basis of current study, retail pharmacies and pharmacists appear to be a major source for the diversion of dangerous drugs to illicit channels in the

United States. In the 10-year period ending December 31, 1962, there were 1,650 firms and individuals convicted under the Federal Food, Drug, and Cosmetic Act for the illegal sale of amphetamines and/or barbiturates. Of these convictions, 1,298, or 78 percent of the total, involved retail drug firms, pharmacists, or their employees."

The exceptionally fine safety record of the trucking industry further refutes any assertion that truckdrivers are major users of drugs which impair their efficiency as drivers.

National Safety Council and ICC statistics substantiate the fact that truckdrivers, as a group, have the finest safety record of any type of drivers. This record is steadily improving. Let me cite just one statistic to verify this: Trucks constitute a little over 16 percent of all registered motor vehicles. However, they comprise only 11 percent of vehicles involved in accidents. This is involvement, not necessarily fault. A major insurance company several years ago made a study of 100,000 truck-involved accidents and found that in 70 percent of the cases the truck was not at fault, so obviously our record is one of which we are very proud.

The committee knows that under the ICC's safety regulations all interstate drivers must meet, periodically, the strict physical qualifications established by the ICC. They must have in their possession at all times when driving, a copy of the medical certificate issued by a doctor at the time of their most recent examination. Habitual use of amphetamines or related drugs obviously would keep any driver eventually from passing his physical examination. Also, as the committee knows, the ICC has very strict regulations which govern the amount of time which a driver may spend on the road. Currently this requirement is 10 hours of driving time between minimum 8-hour off-duty periods with weekly maximum limitations. Further, every interstate driver must maintain a driver's log to record his hours. In addition to these stringent Government regulations most trucking companies schedule their drivers' runs so that they will be well within the maximum allowable driving time. Thus a driver complying with the ICC's safety regulations and his own company's policies should not need any stay awake type stimulus.

A more detailed summary of the ICC hours of service regulations is attached as appendix A. These regulations are quite extensive and detailed. A copy of the ICC's complete safety regulations is enclosed for the committee's information.

During my brief oral appearance, the chairman asked if there were not different rules for drivers of liquid petroleum vehicles. Upon checking, I find that there are no different rules applicable to these drivers. The regulations are the same for all drivers subject to the Commission's jurisdiction.

The chairman also asked if time spent asleep beside the road in a truck is, in effect, rest time. The answer is no. Such time cannot be considered as a part of the 8-hour rest period required between driving periods. The situation with respect to sleeping in a so-called sleeper cab is covered in appendix A.

Our cooperation with the Food and Drug Administration goes back many years shortly after we first became aware of the problem. The Enforcement Division of FDA has joined with us in our efforts to stamp out illegal sales. Their agents have been trained by our member companies as drivers and helpers in order that they could make purchases and subsequent arrests. Enforcement officers have ridden thousands of miles on our trucks and have made hundreds of arrests while they were posing as employees of trucking companies throughout the United States. This, of course, could only have been accomplished with the complete cooperation of the management of our companies.

This mutual effort between the trucking industry and FDA has resulted in a number of arrests being made at truck stops and other highway type installations, and at the same time it has resulted in a great deal of bad publicity for the trucking industry and its drivers. Our files are replete with lurid, sensational stories based upon suspicion, hearsay, and pure fiction which purport to relate that truck drivers generally use these drugs and thus are responsible for a major traffic hazard. This, as I have stated, cannot be borne out by ICC reports nor any other record we can find.

FDA has also worked with us in producing hundreds and thousands of pamphlets which have been distributed through our members across the country. Attached to this statement as appendix B is the latest publication produced by the Food and Drug Administration with our cooperation. More than 100,000 copies of this pamphlet have been distributed through our industry. A previous pamphlet produced by ATA several years ago had more than a half million distribution in our educational work.

At this point we would like to call the attention of the committee to another great need in addition to this legislation but closely related to it.

In this day and age when Americans have become a nation of pill takers there are many drugs that are known to have side effects that may well interfere with the safe operation of motor vehicles. This suggests that we have in this area a national health problem. To the best of our knowledge, while there are numerous studies of the use of amphetamines in military services and by civilians to extend capabilities beyond normal fatigue, there are no adequate studies covering excessive use of these drugs nor the effect of other widely used drugs upon driving capabilities.

In its pamphlet "Drugs and Driving" the Food and Drug Administration makes this statement:

"The Food and Drug Administration is concerned over the increasing threat to highway safety from drivers under the influence of drugs. The drugs involved range from true narcotics to stimulants, tranquilizers, sleeping pills, and even some cold remedies (e.g., antihistamines). Some are widely used in such common ailments as nervousness, overweight, high blood pressure, and hay fever. Because of these common uses many people do not realize the effects drugs may have on driving ability. They may innocently contribute to the danger on the streets and highways."

It is obvious from this warning that there is pressing need for research work to determine the effects of these drugs on driving ability as well as on the national health. Both are concerns of everyone in this Nation. Too, there is a definite need in the case of amphetamines for research to determine at what point of concentration in the blood stream a person comes under the influence of the drug as has been done with alcohol to determine intoxication. Especially is this need great if there is any foundation for the belief that this particular drug constitutes a real threat to highway safety.

We urge and are most hopeful that the committee will act favorably upon the pending legislation to the end that this problem will be eliminated both for our industry and for the public as a whole.

#### APPENDIX A

##### SUMMARY OF ICC HOURS OF SERVICE REGULATIONS

The regulations permit a total of 10 hours driving time between minimum 8-hour off-duty periods.

The driver may perform other duty such as loading and unloading during his day's tour of duty and accumulate the 10 hours of driving during that tour of duty, but he is prohibited from any driving after he has been on duty for 15 hours. As an example, if a driver spends 6 hours at loading, unloading or waiting to do so, his driving time is cut to 9 hours. After the 15th hour he cannot drive, but he can do other work. He must have at least 8 hours off duty before again driving.

The road or intercity driver may drive 10 hours. No rest periods are required to break this driving period, but normal operations bring stops for meals and physical comfort. In addition most fleets require periodic stops, usually after each 100 to 150 miles for tire and other equipment checks. These are of short duration but the walk around the vehicle and concentration on the vehicle check affords a relief from the build-up of fatigue due to engine noise, road monotony, and eye strain.

For long runs, two drivers are assigned to a vehicle equipped with a sleeper berth. Commission regulations set the size and comfort of the berth. They also set the minimum time to be spent in the berth and prohibit the breaking of the 8-hour rest period into more than two parts.

As an example, one driver generally drives 4 hours while the other rests in the berth after which they change places. Under the regulations this could be kept up until each driver completes a total of 60 hours of driving and other on-duty time, but this is broken up further by meal and restroom stops as well as vehicle checks en route.

In any event, whether the driver operates alone or two drivers operate as a team, each is limited to a total of 60 on-duty hours (driving and other work combined) in a 7-day period or 70 hours in 8 days. After this point is reached the driver may not drive again until the 6 or 7-day period is completed.

Most common carrier runs are set on a 30- to 35-mile-per-hour average and the total run is generally limited to 7½ to 9½ hours driving time. Generally, road drivers can and do complete such runs in less time than allotted although carriers prefer that this not be done. In any event the driver must then be placed off duty for at least 8 hours before being dispatched again.

#### APPENDIX B

##### DRUGS AND DRIVING—SOME PRECAUTIONS FOR HIGHWAY SAFETY<sup>1</sup>

Drugs that produce no unusual symptoms in most people may cause abnormal reactions in some individuals, making it unsafe for those persons to drive. This is true regardless of whether the drug is self-administered or taken at the direction of a physician. No one should drive when taking drugs unless he is certain they will not impair his driving ability.

High on the list of highway killers and traffic safety violators is the drunken driver. But alcohol is no longer the only cause of "intoxication."

The Food and Drug Administration is concerned over the increasing threat to highway safety from drivers "under the influence" of drugs. The drugs involved range from true narcotics to stimulants, tranquilizers, sleeping pills, and even some cold remedies (e.g., antihistamines). Some are widely used in such common ailments as nervousness, overweight, high blood pressure, and hay fever. Because of these common uses many people do not realize the effects drugs may have on driving ability. They may innocently contribute to the danger on the streets and highways.

Dangerous drugs are sometimes obtained without prescription—despite legal requirements to the contrary—by people who use them for their "side effects" or for reasons other than their intended medical purpose. One example is the use of stimulant drugs to keep awake while driving.

Controlled use of drugs by a person under his doctor's care brings with it safeguards that avoid danger. Uncontrolled use of the drugs discussed here is a danger to the health and welfare of the user and the safety of others. Here are the facts about the dangers and precautions to be taken when driving.

#### AMPHETAMINES

Amphetamine drugs have many nicknames, some innocent sounding—"bennies," "pep pills," "thrill pills," "co-pilots"—which conceal the seriousness of uncontrolled use.

The amphetamines are useful in treating certain illnesses when used under medical supervision. Carelessly used they can be very harmful to the health of the user, and make it unsafe to operate a motor vehicle.

Legally, amphetamines can be sold only upon a doctor's prescription, by a licensed druggist. This is for the protection of the user. Anyone who uses "bootleg" channels to avoid the prescription requirement not only contributes to a violation of the law, but also runs the risk of being "hooked" to habitual use, with all the degradation and misery that follow.

Common beliefs about amphetamines are: "They are no more harmful than a cup of coffee," and "you can drive without sleep and never miss it." Both are false and both are dangerous.

Amphetamine may increase alertness and efficiency for a short time, but this effect may be followed by headache, dizziness, agitation, irritability, decreased ability to concentrate, and marked fatigue.

The most important fact for drivers to consider is that excessive, unsupervised use interferes with the body's normal protective symptoms of drowsiness and fatigue. The feeling of exhaustion is short circuited, causing a driver to use up reserves of body energy until a total and sudden collapse may occur. But before collapse there may be a period of decreasing driving ability and alertness, even though the driver thinks he is driving very well.

Another often reported effect is that of seeing things in the road that are not really there—mirages or hallucinations similar to the delirium tremens of the alcoholic. Such "visions" may cause the driver to swerve into oncoming vehicles or off the road. Bennies can kill.

<sup>1</sup>Published by U.S. Department of Health, Education, and Welfare, Food and Drug Administration.

Truckdrivers and many others who constantly use the highways are victimized by unscrupulous and illegal dealers in amphetamine drugs for the enormous profits involved. Such drug bootleggers promote the false belief that bennies are helpful to drivers. They place personal profit above human life.

Rest is the only safe remedy for fatigue. Reliance on stimulant drugs can result in anything from a badly overworked heart to sudden death.

#### BARBITURATES AND OTHER SEDATIVES

Barbiturates are very useful medicines to calm nervousness and produce sleep in persons with medical problems. However, they are habit forming and by law may be sold only upon prescription. Uncontrolled use can lead to addiction more serious in some respects than true narcotic addiction. Barbiturates are often "pushed" by underworld peddlers promoting experimentation knowing it may lead to habitual use, addiction to true narcotics, and another "hooked" customer.

Barbiturates also often follow excessive use of amphetamine drugs, in an effort to slow down and get off the "jag." Amphetamine-barbiturate use may thus become a vicious cycle causing serious emotional and physical damage.

The excessive use of barbiturates produces symptoms similar in some respects to alcoholic intoxication. The person affected becomes drowsy and confused. He cannot coordinate his muscular action when he walks or stands and sometimes reaches the point of collapse. He may experience tremor of his hands, lips, and tongue, and he has difficulty in thinking and talking clearly. A person so affected is obviously unfit to drive.

But even the occasional user of barbiturates will become drowsy and less alert. Effects vary greatly in different individuals. Even if the dose is small and the time under the medication is short, the person should make sure he knows how the drug will affect him before driving. Follow your doctor's advice in the use of these potent drugs. It is up to the doctor, of course, to give the necessary instructions where the drug is not identified to the patient.

#### TRANQUILIZERS

This descriptive term is applied to a group of preparations that are, generally speaking, muscle relaxants affecting some reflexes to relieve mental apprehension. While some of them are also used to reduce high blood pressure, their effect is largely on attitude and outlook.

However, in normal or larger doses, or with other drugs or alcohol, tranquilizers may result in sedation to the point of dizziness or drowsiness. Obviously, these preparations may also pose a danger to the driver and should be taken only under adequate medical supervision, with the doctor knowing that driving is contemplated.

#### ANTIHISTAMINES

These drugs are used for relief of nasal congestion due to colds, to combat allergies, and for other purposes. Some may be purchased without prescription; others are too dangerous for use without medical supervision.

These drugs may also cause side effects such as inattention, confusion, and drowsiness. In fact, some of them are available for use as an aid to sleep. If the drug produces such results in a particular individual, then that individual should not drive or operate machinery. Observe label directions carefully, or follow your doctor's advice about driving.

#### NARCOTICS

Since the true narcotics are used primarily by doctors in seriously ill, usually hospitalized patients, these patients are not likely to be driving at all. In the unusual situation where narcotic medication is indicated and the doctor permits driving, he will undoubtedly advise necessary precautions.

However, a narcotic addict—or a person "experimenting" with the wares of the dope peddlers—is a real threat to highway safety. These drugs affect judgment, produce drowsiness, interfere with concentration, impair vision, and release inhibitions against reckless driving and other improper behavior.

## DRUGS PLUS ALCOHOL ARE ESPECIALLY DANGEROUS

Everyone knows the dangers of driving while under the influence of alcohol. Not so many know how the drugs discussed above threaten driving safety. But still fewer know that the combined effects of these drugs and alcohol may be exceedingly dangerous.

The combined results may be much more dangerous to health and to highway safety than the effects of either the alcohol or the drug alone. The scientific term for the reaction effect is "synergism."

The old adage, "If you drink, don't drive," is still good. But here are some additional rules that may save your life—or the other fellow's:

1. If you are ill, see your doctor.
2. If your doctor prescribes drugs, ask him about driving while on the medication.
3. If you drink, don't drive; but ask your doctor about the combined effects of alcohol and any medicine he prescribes.
4. Don't ask your druggist to violate the law by selling dangerous drugs without a prescription, and don't buy from one who will.
5. Don't allow filling station or truckstop operators to sell you any drugs. These operators may be good mechanics for your automobile or truck, but your body is a much more valuable—and delicate—machine!

The organizations of professional drivers and of persons serving the driving public endorse this policy as being in the best interest of the driver.

If you are offered any of these drugs under circumstances which arouse your suspicions, get in touch with the Food and Drug Administration office serving your area or the headquarters office at Washington, D.C.

(The Food and Drug Administration gratefully acknowledges the assistance of the National Association of Truck Stop Operators, the American Trucking Associations and the National Safety Council in the preparation and distribution of these leaflets.)

The CHAIRMAN. The committee has a communication from Mr. Zablocki, our colleague from Wisconsin, in which he submits a letter from the Pharmacists Society of Milwaukee County, and asks that it be included in the record.

It may be included in the record at this point.

(The material referred to follows:)

HOUSE OF REPRESENTATIVES,  
Washington, D.C., January 26, 1965.

HON. OREN HARRIS,  
*Chairman, Interstate and Foreign Commerce Committee, House of Representatives, Washington, D.C.*

DEAR CHAIRMAN: I am forwarding a letter from the executive secretary of the Milwaukee County Pharmacists Society opposing your bill, H.R. 2.

You will note that Attorney Kaluzny suggests several modifications of your bill. For that reason, I am submitting it to you for your information and possible use.

With best wishes, I am,  
Yours sincerely,

CLEMENT J. ZABLOCKI,  
*Member of Congress.*

PHARMACISTS SOCIETY OF MILWAUKEE COUNTY,  
*Milwaukee, Wis., January 19, 1965.*

HON. CLEMENT J. ZABLOCKI,  
*House Office Building,  
Washington, D.C.*

DEAR CONGRESSMAN ZABLOCKI: Congressman Harris has reintroduced a new version of the "Dodd bill" as H.R. 2. I do not have a copy of H.R. 2, but it is my understanding that it does not exempt pharmacists from its recordkeeping or inspection provisions.

It is the Pharmacists Society's position that H.R. 2 could effectively accomplish its worthwhile objective, namely the curbing of illicit drug traffic, without

subjecting either the pharmacist or physician to its recordkeeping of inspection provisions. I believe that this could be done as follows:

1. Exempt pharmacists from the recordkeeping and inspection provisions, as suggested by the American Pharmaceutical Association in its testimony before the Senate subcommittee last August (see p. 65 of the hearing report). Note: Those persons bent on violating the law would probably falsify their records anyhow, and the provision would thereby be ineffective at the retail distribution level.

2. Retain the application of the recordkeeping and inspection provisions of the "Dodd bill" or H.R. 2 as they pertain to pharmaceutical manufacturers and wholesalers with the addition of a requirement that the drugmakers and wholesalers submit monthly to the FDA duplicate copies of all psychotoxic drug sale records (invoices).

This additional provision would accomplish the following: If a drugmaker sold 5,000 amphetamine tablets to: (1) a dispensing physician, or (2) a hospital, or (3) a community pharmacy—in all these instances the FDA would be put on notice of the sale. It is commonsense that sales to certain types of purchasers would obviously be legitimate while sales to other persons should obviously call for investigation.

The FDA could then pinpoint with mathematical certainty unusual movements of psychotoxic drugs. The suspected persons or places could be "shopped" under present methods or inspected under the present provisions of sections 703 and 704 of the Federal Food, Drug, and Cosmetic Act, or better still, the FDA could immediately report unusual sales to the State law enforcing agencies who are adequately equipped to handle the investigation.

As for the mechanics of the above method, the FDA could utilize data processing equipment and each pharmacy, physician, or other drug outlet could be classified by their IRS employer identification number. Those who don't have such number could obtain it via form SS-4.

Now, it could be said in argument to my suggested amendments to H.R. 2, that a "pusher" could buy 1,000 amphetamine tablets from 50 separate outlets, instead of 50,000 from 1. As a practical matter, 50 different illegal sales would seem difficult in light of the fact that each seller would know that his own purchases were observed by the FDA. However, in either situation apprehension of the "pusher" would seem to be made easier if Federal drug labeling requirements applied to all consumer medications.

Therefore, I strongly recommend that if H.R. 2 is to really aid law-enforcing agencies, then, it must be mandatory that all psychotoxic drugs, whether dispensed by pharmacists pursuant to physicians' prescriptions or dispensed by "dispensing physicians" in the course of their medical practice, should be labeled in accordance with all the labeling requirements of subsection 503(b)(2) of the present act. This requirement was recommended by the Apha to the Senate subcommittee last summer.

There appears to be some doubt as to the application of section 503(b)(2) of the present act to physician dispensing. I have received correspondence from an FDA field office that states it does not. At any rate, I think you will agree that the public health and safety can best be served if all take-home medications are properly labeled.

For example: Besides my law background, I have practiced as a hospital pharmacist for 4 years. In that time I have observed situations in which patients were brought into the hospital with medications which they received from a "dispensing physician." The medical and pharmacy staffs in attempting to identify these medications encountered at times great difficulty and delay because the physician, who originally dispensed the drug, could not recollect what it was that he gave his patients. This was not the case when patients entered the hospital with drugs which they received on prescriptions filled by their community pharmacist. Because of properly labeling in conformity with the law, the community pharmacist has always provided quick and accurate identification.

If, as I suggestion, the bill is modified to require both (1) that the drug manufacturer and wholesaler submit to the FDA duplicate copies of all psychotoxic drug sales, and (2) the proper labeling of psychotoxic drugs dispensed to the public, then the recordkeeping and inspection provisions of the bill would not need to apply to pharmacists.

If the FDA or State law enforcing agencies can pinpoint all unusual purchases of psychotoxic drugs whether by pharmacies, physicians, or other retail drug outlets, then, it should follow that surveillance of such places or persons under present State and Federal procedures of investigation would effectively deter the persons concerned from performing any illegal acts.

We feel as strongly as Senator Dodd in our hope to see illicit drug traffic curbed, but we urge you gentlemen to modify H.R. 2 in a manner which will effectively do the job, and, yet, not impose a severe and unnecessary hardship on the community pharmacist.

Sincerely yours,

Attorney EUGENE L. KALUZNY, R. Ph.,  
*Executive Secretary.*

The CHAIRMAN. These are all the witnesses to be heard today. We have two other witnesses, and possibly three, who have asked for an opportunity to be heard. I think we will come back on Tuesday next at 10 o'clock at which time we will have an opportunity to hear Mrs. Dwyer who has a companion bill, and who has asked the opportunity to be heard or file a statement. If she desires to come down and testify, we will be glad to receive her testimony. If she desires to file a statement, we will be glad to receive that.

Mrs. Sullivan, of Missouri, has a bill. She is away at the present time. I am not sure that she will get back in time. She has asked to file a statement if she does not. We will be glad to have her statement.

I understand a representative from the MacNeil Laboratories would like to have an opportunity to be heard.

Therefore, we will come back next Tuesday to give an opportunity to anyone who wishes to present further testimony. I believe we will ask Commissioner Larrick to come back with us in order that we can ask him some questions about the amendments and some of the matters that have been brought out during the course of these hearings.

Mr. Clerk, I wish you would call the Commissioner and see if it would be convenient for him to return on Tuesday.

The committee will adjourn until 10 o'clock next Tuesday.

(Whereupon, at 3:55 p.m. the committee recessed, to reconvene at 10 a.m., Tuesday, February 2, 1965.)

## DRUG ABUSE CONTROL AMENDMENTS OF 1965

TUESDAY, FEBRUARY 2, 1965

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The committee met at 10 a.m., pursuant to recess, in room 1334 Longworth Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will be in order.

Mrs. Florence P. Dwyer has a companion bill to H.R. 2 which is H.R. 3416 and is also pending before the committee.

Mrs. Dwyer, the committee is pleased to have you with us this morning.

### STATEMENT OF HON. FLORENCE P. DWYER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mrs. DWYER. Mr. Chairman, I greatly appreciate the opportunity to express my views to this committee on the urgent need to enact the legislation you are now considering, the Drug Abuse Control Amendments of 1965.

As a cosponsor of the bill introduced by the chairman this year and as a sponsor of similar legislation in the 87th and 88th Congresses, I am deeply grateful that this committee has given to the drug control bill the high priority evidenced by these early hearings.

Almost daily, Mr. Chairman, and in almost any newspaper, we can read about the devastating effects of the easy availability of barbiturates, amphetamines, and other dangerous drugs—crimes of violence and depravity, widespread delinquency among the young, increased traffic accidents, the graduation into addiction to the hard narcotics, the ruined lives of countless individuals, the misery and heartbreak and dislocation of innocent and helpless families.

The evidence is overwhelming. Local law enforcement agencies in my own State and in other highly populated areas of the country report an alarming spread in the abuse of the stimulant and depressant drugs, especially among teenagers and in middle and upper-middle-class neighborhoods where drug addiction previously has not been a major problem.

In reports to the Juvenile Delinquency Subcommittee in the Senate, the New York City Police Department said that dangerous drug arrests and drug seizures during the first 11 months of 1964 increased by as much as 393 percent in some categories over the same period in 1963; and the California attorney general cited a 75-percent increase in dangerous drug arrests from 1960 to 1963.

In the town of Seaside Heights, N.J., arrests for disorderly conduct, stimulated principally by dangerous drugs, increased 500 percent since 1960. Dangerous drug arrests in Chicago increased by 65 percent from 1963 to 1964; in Baltimore by 60 percent. Arrests of teenagers in Los Angeles for misuse of amphetamines and barbiturates grew from 50 in 1958 to 321 in 1964. In the Oklahoma City area, a 6-month survey recently identified 2,500 pill takers as opposed to a few dozen narcotics addicts.

I could go on and on, Mr. Chairman. The facts and figures are extensive and depressing, but more than that they reveal an unmistakable and startling upward trend both in the rate of addiction and in the rate of crime and other antisocial behavior directly related to drug abuse—and among the groups in our population to which we like to look most hopefully.

Just as the nature and extent of the evil are known and acknowledged, so, too, is the reason why. You cannot have growing addiction to dangerous drugs unless those drugs are readily available. The Food and Drug Administration has estimated that about one-half of the approximately 10 billion amphetamines and barbiturates annually produced by legitimate manufacturers end up in the black market—and these figures presumably do not include other, equally dangerous, stimulant and depressant drugs nor drugs manufactured illegally.

Attracted by the immense profit potential of a racket where pills can be bought for one-tenth of a cent and resold for 10 to 25 cents apiece, organized criminal rings have begun to move into the illicit drug field in a big way, according to the FDA. As an example, Baltimore police broke up one major pill ring after a woman sold undercover agents 200,000 pills during a 7-month period. Nationally, this vicious racket is netting upward of \$500 million a year.

How could this happen? Undoubtedly, there are many methods used to avoid the legal requirement that dangerous drugs be dispensed only by prescription. But one such method—the ridiculously easy direct purchase of wholesale quantities of the drugs by unlicensed, unregistered distributors—may help explain why the problem has become so severe.

Last year, Mr. Chairman, CBS television news inaugurated its fact-finding unit with a report on the dangerous drug menace to demonstrate the frightening ease with which these drugs can be procured. The unit's producer-investigator formed a dummy company, rented a tiny office, printed a few letterheads, contacted 51 drug firms, placed orders for amphetamines and barbiturates with 19 of the companies, and received deliveries on 47 percent of the orders from companies in eight States—none of which bothered to check on the legitimacy of the operation.

For a total cost of \$600.28, this fly-by-night operation—which could be duplicated by anyone—obtained 1,075,000 pills valued on the black market is \$250,000 to \$500,000.

Another channel for illicit trade in the dangerous drugs is the export market, especially to Mexico. The pills, a significant amount of which are manufactured in the United States, are shipped legally to outlets in Mexican border towns and then resold for the purpose of being smuggled back into the United States for sale on the black market.

Counterfeiting has become a further source of illegal drugs. Counterfeiters, who require only a tablet-making or capsule-filling machine and a garage or empty warehouse to be in business, have become so accomplished that industry experts often find it nearly impossible to distinguish fakes from the genuine article.

In the face of this growing tide of illegal traffic in dangerous drugs, the drug industry and Federal, State, and local law enforcement agencies have been virtually helpless in attempting to control the situation. Some individual drug companies have taken extraordinary precautions to prevent their products from getting into the black market, but they have been unable to control other, less responsible, companies or to control effectively every step in the distribution process from manufacturer to consumer. While some States have strict licensing requirements, other do not. State and local authorities have little or no power to get to the sources of supply. And the Food and Drug Administration, under present law, possesses only very limited enforcement and inspection authority, especially when confronted with the difficulty of determining the origin of particular drugs and establishing whether they have been shipped in interstate commerce.

The present bill, Mr. Chairman, would help plug up these big holes in the regulatory scheme of things by means of which the illicit drug trade has been allowed to flourish, and it would provide the means for a concerted attack against the evil at all levels. The bill would require all manufacturers, compounders, and processors of the stimulant and depressant drugs to register with the Department of Health, Education, and Welfare, and to keep records of the quantities of the drugs they handle and the names of those from whom they receive the drugs and to whom they distribute them. Wholesalers, jobbers, distributors, carriers, and sellers of the drugs would also be required to keep such records. All such records would be available for inspection as would the facilities and establishments involved in the distribution of the drugs. Possession of the drugs by unauthorized persons would be prohibited.

The bill would also tighten regulations prohibiting the counterfeiting of drugs and would provide for more effective enforcement.

The penalties included in the bill are aimed especially at those who sell or otherwise supply dangerous drugs to persons under 18 years of age.

I find it particularly encouraging, Mr. Chairman, that there is almost unanimous agreement among those most concerned about the purposes and objectives of this legislation. While there are certain differences of opinion among members of the drug industry about the scope of the bill, these differences can certainly be resolved. Retail druggists, who expressed concern about recordkeeping and inspection requirements in previous versions of the legislation, will find that the present bill involves little more than an extension of existing requirements for maintaining records of prescriptions. Anything less than this would, I believe, seriously jeopardize the objectives of the bill.

As the committee knows, the legislation has also been endorsed by the President, who specifically requested approval of the measure in his health message, by the Department of Health, Education, and Welfare and other departments of the Government, by State and local

law-enforcement agencies, and by individuals and organizations in the field of juvenile delinquency, among many others.

Before concluding this statement, Mr. Chairman, I should like to refer to a problem which the committee's hearings have revealed with regard to the drugs covered by the bill. Although the bill automatically subjects to regulation the barbiturates and the amphetamines there are a number of other drugs which have similar properties and effects, which are known to be subject to the same abuse and to be equally dangerous, and which in some instances are directly competitive with the barbiturates and amphetamines. In the case of these nonbarbiturates and nonamphetamines, however, the provisions of the bill would not take effect automatically and could not become effective until the specified administrative procedures had been completed. In the meantime, manufacturers of the regulated drugs would be placed under a severe competitive disadvantage, and a known public health hazard would be permitted to continue unchecked.

I would hope that the committee, in considering the form in which the legislation may be reported, could agree on language covering all stimulant and depressant drugs which are substantially involved in drug abuse and make them subject to the bill's provisions in the same way and at the same time. It should be noted that the bill already provides a way of taking care of the converse problem, that of exempting those drugs which, even though they may technically qualify of barbiturates and amphetamines, contain so small an amount of the substance that the resultant compound is not subject to abuse.

Mr. Chairman, I greatly appreciate the committee's willingness to consider my views on this vital legislation, and I am grateful for the committee's determination to act expeditiously in meeting the grave threat to our Nation's welfare which is posed by the uncontrolled abuse of dangerous drugs.

The CHAIRMAN. Thank you for a very fine statement, Mrs. Dwyer.

We observe our colleague from Ohio, Mr. Vanik.

Mr. Vanik, we have known of your interest in this field for some time. Do you have a statement you would like to make to the committee? We would be pleased to hear you at this time.

#### STATEMENT OF HON. CHARLES A. VANIK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. VANIK. Mr. Chairman, I have a very brief statement that will not take more than a minute or two.

The CHAIRMAN. You may proceed.

Mr. VANIK. Mr. Chairman, on Friday, November 2, 1962, at about 5:45 in the afternoon, a truck trailer, tractor-trailer unit, operated in intrastate commerce in Ohio, on the Willow Freeway, which is a freeway just south of Cleveland, crossed a 33-foot center strip on a clear, level stretch of the road and went over to the other side of the highway, struck three automobiles which, in turn, pushed these cars into two other cars. In one of the automobiles there were six Akron school-teachers who were attending a teachers' meeting in Cleveland. All six teachers in one automobile were killed.

In addition to the six ladies that were killed, there were four other persons who were injured. A total of six vehicles were extensively damaged.

The driver of the tractor-trailer unit was apparently asleep at the time of the accident, with indications that he was under the influence of amphetamine drugs. He admitted later he had taken amphetamine drugs to keep him awake.

My community has not forgotten this drug-caused tragedy. I am here today to urge that your committee take every step that is necessary or possible to insure that this kind of thing cannot again occur.

Of course, there are other facts in the Cleveland case which relate to the accident. According to the log records, the driver of the vehicle picked up his rig at 2 o'clock in the morning that day, 2:15 a.m. of the day of the accident, and the accident occurred near the end of a 16-hour day, so there are other circumstances. This truck was involved in intrastate commerce, but nevertheless, under Ohio law the driver was permitted to drive after that long period of service.

My community supports the restriction of availability and the use of drugs which can produce such unconscionable harm to innocent people.

Mr. Chairman, if the committee will permit, I will be glad to submit for the record a complete file on this particular case which involves the accident report and the statements of witnesses, if that is of any use to the committee. I have it with me.

The CHAIRMAN. Thank you, Mr. Vanik. We will be very glad to have the information. You may submit it. We will look it over. If it appears to be in order and appropriate, it will be included in the record. If not, it will be retained for the file.

Mr. VANIK. I would like also, if the committee would permit, to urge the committee to permit me to bring in some time before these hearings are concluded Dr. Sam Gerber, our county coroner of Cuyahoga County, Ohio. Dr. Gerber has made a very thorough and intensive study in the use of amphetamine drugs and other drugs in their relationship to accidents. Is it possible?

The CHAIRMAN. When can you bring him in?

Mr. VANIK. Probably within the next day or so, or early next week, some early time at the convenience of the committee. He has indicated that he would like to make a brief statement to the committee if your schedule will permit.

The CHAIRMAN. Could he be here Tuesday of next week?

Mr. VANIK. I will have him here Tuesday of next week.

The CHAIRMAN. We are having some difficulty carrying on the hearings this week without serious conflict all around. I am determined to get these hearings to close, but yet the committee does want to develop a full and complete record.

Mr. VANIK. I believe, Mr. Chairman, this gentleman would make a very worthy contribution. He has gone into this matter very, very extensively, and I think he has information that will be of great value to the committee.

The CHAIRMAN. Mr. Larrick will be unable to come back this week because of some long-standing commitments. We are going to then schedule his return next week, probably Tuesday or Wednesday.

Mr. VANIK. Will Tuesday be a satisfactory day?

The CHAIRMAN. The committee is going to have an executive session on Tuesday of next week to get a report which I have been led to believe the committee should have from a research work that has

been accomplished by an individual who has given a lot of study to this field. We think, because of the nature of it, the executive session would be appropriate.

We would be glad to try to arrange to get your distinguished coroner in during the course of that hearing on Tuesday or Wednesday.

Mr. VANIK. I will have him available.

The CHAIRMAN. By the way, did you develop that the driver of the truck, of the tractor with the trailer, had been taking some of these drugs?

Mr. VANIK. Yes, the record will indicate and the coroner's report will indicate that he had been taking amphetamine pills right along, that he had been using them in order to carry on with the long hours involved with his job.

It isn't developed in the record that I have left with the committee, but Dr. Gerber's report will indicate that the driver had been purchasing them at a regular stop near Columbus, Ohio. It was a regular pickup station. It was not a drugstore. It was a restaurant, a drive-in place.

The CHAIRMAN. What is commonly referred to as a truck stop?

Mr. VANIK. Yes.

The CHAIRMAN. That is where they service trucks.

Mr. VANIK. They service trucks and provide food. He picked up the amphetamine tablets at such a place.

The CHAIRMAN. We had testimony last week from both the Commissioner and a representative of the American Trucking Association that such occurrences were rather rampant all over the country, but it was most general. We would prefer to have some more specific information on it, if you can present it.

Mr. VANIK. I would be happy to see that Dr. Gerber is here next Tuesday.

The CHAIRMAN. We shall be glad to have him come.

Are there any questions from members of the committee of our colleague?

If not, thank you very much.

Mr. VANIK. Thank you.

(NOTE.—Dr. Gerber was unable to testify before the committee.)

The CHAIRMAN. The next witness is our colleague from New Jersey, the Honorable Joseph G. Minish. Mr. Minish, we will be glad to hear you at this time.

#### STATEMENT OF HON. JOSEPH G. MINISH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. MINISH. Mr. Chairman and members of the committee, as sponsor of the Psychotoxic Drug Control Act in the 88th Congress and in the present Congress, I am most gratified at your prompt attention to this highly important legislation. I think it is clearly in the best interests of the country that safeguards be put into effect against the misuse of these "goof balls" and "pep pills" that now constitute our most insidious drug threat.

I can testify from firsthand knowledge of the alarming extent of the use of these dangerous drugs by young people in my own area of northern New Jersey. There have been a number of tragic cases which substantiate the findings of Senator Dodd's subcommittee that the use of these drugs is more and more prevalent among the so-called white-collar youths who have never had prior delinquency or criminal records. The traffic in these drugs is heavier than ever, and vigorous action must be taken to prevent the further toll in ruined lives and serious crime. My bill calls for more severe penalties for those found selling to children and teenagers. Many parents have contacted me about the availability of these drugs to young people and have urged that the Federal Government take vigorous action to eliminate this threat to the health and well-being of their children. The able sheriff of Essex County, N.J., LeRoy J. D'Aloia, has stressed the need for more adequate controls over these drugs.

In citing the alarming growth in the number of juvenile delinquency cases involving psychotoxic drugs, Sheriff D'Aloia has stated:

I think "lesser narcotics" is a serious misdemeanor because barbiturate addiction can lead to death as surely as heroin use.

Police records dramatically illustrate the inadequacy of our present controls to stem the tide of abuse.

It is estimated that one-half to two-thirds of the amphetamines and barbiturate drugs manufactured in this country find their way into illegal traffic. This means that about 5 billion pills a year are going to young people looking for "kicks" and to narcotic addicts and others who depend upon them.

These drugs are dangerous both to the individual and to those around him. Excessive doses of barbiturates induce a state characterized by increasing physical incapacity and lack of coordination. Large doses also lead to disorientation, paranoid delusions, and aggressive behavior. Senator Dodd's Subcommittee on Juvenile Delinquency was informed of at least two homicides done by juveniles under the influence of such drugs. Barbiturates can kill in many ways. Deliberate overdosage is common but it is thought that often overdoses are accidental. Withdrawal symptoms are also severe and may be fatal.

Amphetamines in large doses cause physical hyperactivity and often delusions and hallucinations. It is thought that amphetamines are the cause of many otherwise unexplained motor vehicle accidents. Sometimes pills are even found among the victims' possessions. Under the influence of large doses of these drugs drivers do not realize that they are on the wrong side of the road or they may see "ghost" obstacles and veer off the road to avoid them. Amphetamines such as benzedrine are being sold illegally at many diners and other truck stops.

I believe that the soundest approach to this deplorable situation is to prohibit the manufacture, compounding, or processing of any psychotoxic drug by anyone except regular manufacturers and processors registered with the Secretary of the Department of Health, Education, and Welfare, or by other qualified persons such as wholesale druggists, practitioners, and researchers. Possession should be

limited to those who require such drugs for their personal use or who handle them in the course of their profession or employment.

Furthermore, every person engaged in manufacturing, compounding, processing, selling, or delivering such drugs should be required by law to keep complete and accurate records of all stocks, to which records the Department of Health, Education, and Welfare would have access. Officers and employees of the Department would also have the authority to inspect establishments and equipment pertinent to the manufacture and distribution of these drugs.

Psychotoxic drugs find their way into illegal traffic in many ways. Only by keeping records of every step of their manufacture and distribution can we determine and control the leaks.

Legislation along the proposed lines has been recommended by many groups and individuals concerned with the growing abuse of psychotoxic drugs. The President's Advisory Commission on Narcotic and Drug Abuse favors Federal legislation of this type. The late President Kennedy several times urged the passage of such legislation and President Johnson has called for a higher priority on Government efforts against narcotics and drug abuse.

Drug manufacturers are also concerned with this problem, and have indicated their support of similar proposals.

I believe that this legislation is essential to control a disturbing and rapidly growing illicit traffic in drugs which are extremely dangerous to their users and which are, through the behavior they incite, a threat to the public health and safety. Again, I urge prompt and favorable consideration so that our law enforcement officers at all levels will be better able to cope with this dangerous drug problem.

Thank you for giving me this opportunity of presenting my views on this issue. I am hopeful that the committee will report favorably this legislation which is so clearly needed to protect the public health and well-being of our people.

The CHAIRMAN. Are there any questions? If not, we thank you, Mr. Minish.

Mr. MINISH. Thank you, Mr. Chairman.

The CHAIRMAN. The next witness is our colleague from the State of New York, the Honorable James J. Delaney. Mr. Delaney, we know of your interest in this legislation and we will be glad to hear you at this time.

#### STATEMENT OF HON. JAMES J. DELANEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. DELANEY. Mr. Chairman, members of the committee, I am grateful for the opportunity to present a statement to this distinguished committee in support of legislation to curb the illegal traffic in dangerous drugs. It is my firm conviction that this legislation is needed, and will be a great stride toward preventing abuse of barbiturates, amphetamines, and a host of other drugs which can poison the mind and generate dangerous antisocial behavior.

The arguments in favor of this legislation have been covered in previous testimony, particularly by Mr. George P. Larrick, the able Commissioner of Food and Drugs. My purpose is to recommend amendments to H.R. 2.

The provision requiring the Secretary to exempt any depressant, stimulant or hallucinatory drug when it is combined with one or more substances that do not have a depressant or stimulant effect on the central nervous system or a hallucinatory effect, and the combined drug does not have the effect or the potential for such effect with which the bill is concerned, should be deleted. This provision is a loophole. Ingenuous methods of extracting a depressant or stimulant drug from a combined drug are available, thus opening the door for the illegal sale of the depressant or stimulant drug under the guise of a legitimate sale of the combined drug.

Further, the provision of H.R. 2 which says that no separate records, and no set form or forms for the records shall be required, as long as there are records available with the requisite information, should also be deleted. As Commissioner Larrick pointed out, a firm which manufactures 10 or even hundreds of different articles might have all the required information on depressant or stimulant drugs contained in invoices which may be filed with invoices for all the products the firm distributes. As can be seen, FDA investigators would be unduly burdened if they had to wade through voluminous files checking all the invoices. While I am not advocating that separate forms be required, I do think it should be left to the discretion of the Secretary to prescribe the manner in which the recordkeeping requirement will be fulfilled.

In addition, I suggest that failure to comply with the recordkeeping requirements should be grounds for judicial seizure of the drug or drugs involved. Failure to keep adequate records has been found by the Senate Subcommittee To Investigate Juvenile Delinquency and the Senate Labor and Public Welfare Committee to be one of the principal inadequacies in the present law. If this exemption is not abolished, we are providing a sanction with an ineffective remedy for enforcing it.

With respect to the advisory committee, I feel that referral to this committee should be within the sole discretion of the Secretary. Permitting a petitioner or any other person adversely affected to request referral could be used as a delaying tactic. A person aggrieved by an order of the Secretary has recourse to the courts where an order can be stayed pending judicial determination of the matter.

I urge the committee to incorporate in H.R. 2 the suggestions of Commissioner Larrick with respect to granting FDA investigators the power to serve and execute warrants and other process, the power to arrest, and when the investigator has personal knowledge of a violation or reasonable grounds to believe that the articles are subject to seizure and condemnation, the power to detain and remove the articles prior to the time a libel of information is filed. In conjunction with these powers, I support the Commissioner's position that FDA investigators should be able to seize, and the courts should be authorized to condemn any conveyance in which violative stimulant or depressant drugs or counterfeit drugs have been unlawfully transported, carried, or held; and that provision should be made for the seizure and condemnation of machinery and equipment used in the unregistered or other unlawful manufacture of depressant or stimulant drugs. The clandestine methods of the criminal element who deal in these drugs makes it im-

perative that FDA investigators have these tools to carry out the provisions of this legislation.

Gentlemen, we are confronted with a grave threat to public health and safety through the abuse of these drugs. Recently, I read in the Washington Post that three teenage youths in Chicago fatally shot a 66-year-old man while they were high on "pep pills." One youth told a detective that it was the "pills" that had caused him to do the shooting.

With my amendments, this bill will go a long way toward preventing the repetition of similar situations in the future. I urge your favorable consideration of them.

The CHAIRMAN. Are there any questions? If not, we appreciate your testimony, Mr. Delaney.

Mr. DELANEY. Thank you for the opportunity, Mr. Chairman.

The CHAIRMAN. The next witness is Dr. Lawrence Peters, executive vice president for Scientific Affairs, McNeil Laboratories, Fort Washington, Pa.

I notice you have with you Mr. Stanley Smoyer, counsel.

**STATEMENT OF DR. LAWRENCE PETERS, EXECUTIVE VICE PRESIDENT FOR SCIENTIFIC AFFAIRS, McNEIL LABORATORIES, FORT WASHINGTON, PA.; ACCOMPANIED BY STANLEY SMOYER, COUNSEL**

Dr. PETERS. Mr. Chairman and members of the committee, McNeil manufactures and sells butabarbital sodium, a depressant drug which is a derivative of barbituric acid and which will be automatically covered by H.R. 2. It is one of approximately 25 derivatives of barbituric acid, all of which are called barbiturates.

Among these 25 compounds there is a substantial variation in the length of time required for them to take effect, in addition to other differences. Some of them are quick-acting and short-acting hypnotics, and these are the drugs that have been most attractive for improper use. Others, of which butabarbital sodium is a leading example, are classed as slower acting and longer acting—that is, their effect usually is not felt for about 30 minutes—and are primarily used for mild sedation and tranquilization. Butabarbital sodium has been less attractive to persons who want to use drugs for "spree" purposes.

There are also, on the market, a number of depressant or sedative drugs which do not happen to be barbiturates but which are competitive with butabarbital sodium. They are prescribed by physicians for the same medical purposes as our product; and they have a substantiated record of abuse and as great a potential for abuse as our product. Nevertheless, these products will not be automatically covered by H.R. 2 as it is now written.

We urge this committee to amend H.R. 2 so as to include these non-barbiturate drugs under the automatic coverage of the bill. By doing so, a serious competitive discrimination will be prevented. Furthermore, it goes without saying that if it is necessary in the public interest to provide automatic coverage for drugs such as butabarbital sodium, it should likewise be in the public interest to provide such automatic coverage for all other drugs which serve the same or similar

therapeutic purposes and which have a proven record of and potential for abuse, even though they do not happen to be barbiturates.

Finally, it is recognized by the authorities in the field of drug abuse that those who deal in this illicit traffic will quickly switch to other comparable drugs if their primary drugs are made unavailable through strict controls. In other words, those who have misused barbiturates will quickly switch to the comparable nonbarbiturates unless the latter are also put under the same control.

The nonbarbiturate drugs to which I refer have the following generic names: glutethimide, methyprylon, ethchlorvynol, ethinamate, meprobamate, and chlordiazepoxide.

Some of these drugs are used for the purpose of mild sedation and tranquilization; others are used for their hypnotic effect. Although many of them have been on the market for only a relatively few years, there is already substantial evidence, as we have stated, that they have been used for nonmedical purposes and that they have a potential for abuse.

We are submitting to the committee several representative scientific publications which attest to the foregoing statement. We are also submitting a bibliography listing many other publications describing the characteristics and effects of these drugs. In the publication entitled "Addiction to Nonbarbiturate Sedative and Tranquilizing Drugs" by Carl F. Essig, M.D., of the Addiction Research Center at Lexington, Ky., of the National Institute of Mental Health, the similarity of these drugs is brought out in the following statements from the publication's summary:

Increasing numbers of nonbarbiturate sedative drugs are being introduced into medical practice. Despite their nonbarbiturate chemical structure and regardless of designations other than "sedative-hypnotic," at least six of the newer depressant drugs can cause states of intoxication and physical dependence that are clinically similar to those induced by barbiturates \* \* \*. The behavioral effects of these drugs and their combination with ethanol may become an increasingly important public hazard.

The drugs referred to are the six named above.

In the final report—November 1963—of the President's Advisory Commission on Narcotic and Drug Abuse, exhibit II on page 11, delineates the "Elements of Drug Abuse" such as "antisocial behavior" and lists "meprobamate, glutethimide, methyprylon, chlordiazepoxide, and others" in the same category as "barbiturates." The Commission stated on page 44 of the report that—

Legislation should not be limited to the barbiturates and amphetamines, but should extend to all nonnarcotic drugs capable of producing serious psychotoxic and antisocial effects when abused.

As the committee knows, the bill as it is now written provides that nonbarbiturate drugs which have a potential for abuse because of their depressant effect on the central nervous system or other hallucinatory effect may be brought under the coverage of the law by regulation. This means, of course, that in order to bring such drugs under the law, the secretary will have to pursue the lengthy regulatory procedure involving hearings and possible submission to an advisory committee, as provided in the bill.

Although the Secretary may contemplate that regulations will be issued to cover the nonbarbiturate drugs which I have mentioned,

it is recognized that many months or years may pass before such regulations are issued. In the meantime, butabarbital sodium will be cast in an unfavorable light, competitively, in the eyes of the medical profession, the trade, and the public because of its automatic inclusion under the law; and it will be stigmatized as a "dangerous" drug in comparison with such nonbarbituric competitive drugs. This situation can only result in serious economic damage to our product and discriminatory treatment of all the barbiturates.

Some of the earlier witnesses did not appear to recognize the competitive injury that would result from the automatic, immediate coverage of barbiturates and only possible, later coverage of competitive nonbarbiturate drugs. To illustrate the potential competitive injury, one need only imagine the sales pitch of the sales representative selling the competitive product, which was not automatically covered, when describing to the physician why his product was safer, and hence better, than the barbiturate automatically subject to the strict controls of the Drug Abuse Control Amendments of 1965—H.R. 2.

One or more of the earlier witnesses also stated that it would be difficult now to draw up a list of the nonbarbiturate drugs that should be automatically covered by the bill. We have presented a list of six such drugs, with scientific supporting material. There may be others which should be included. There surely will be new drugs which should be brought in later. But this does not mean that none should be included now.

Where the evidence is now clear that some of these nonbarbiturate drugs are subject to the same abuse as some of the barbiturates, Congress should now take the necessary step to avoid the competitive discrimination and continuing hazard to the health of the public that would result from leaving the decision to an administrative agency under its time-consuming regulation procedure.

The change which we are urging can be accomplished by simply adding a clause (C) to section 201(v)(1) under section 3(a) of the bill and listing the six named drugs therein.

We thank the committee for giving us this opportunity to present our views, and we ask permission to include in the record the scientific publications and bibliography that accompany and support this statement.

The CHAIRMAN. The information referred to may be included in the record with your statement.

The article referred to by Dr. Essig is already in the record.

(The medical bibliography follows:)

MEDICAL BIBLIOGRAPHY PERTINENT TO ABUSE OF NONBARBITURIC SEDATIVES,  
HYPNOTICS, AND TRANQUILIZERS

1. Algeria, E. J., Katsas, G. G., and Luongo, M. A.: Determination of ethchlorvynol in biologic mediums and report of two fatal cases, *Am. J. Clin. Path.* 38:125-130, 1962.
2. Barsa, J. A., and Kline, N. S.: Use of meprobamate in the treatment of psychotic patients, *Am. J. Psychiat.* 112:1023-1026, 1956.
3. Bedson, H. S., and Lond, M. B.: Coma due to meprobamate intoxication, *The Lancet* 1:288-290, 1959.
4. Berger, H.: Addiction to methprylon, *JAMA* 177:63-65, 1961.
5. Billig, O., and Burris, B. L.: Habituation to tranquilizing drugs, *J. Tennessee MA* 49:406-407, 1957.
6. Blakey, H. H., Barringer, T., and Billig, O.: Acute Doriden intoxication, *South. MJ* 49:172-174, 1956.

7. Boyd, L. J., Cammer, L., Mullins, M. G., Huppert, V. F., and Hammer, H.: Meprobamate addiction, *JAMA* 168:1839-1843, 1958.
8. Cahn, C. H.: Intoxication by ethchlorvynol (Placidyl). Report of four cases, *Canad. MAJ* 81:733-734, 1959.
9. Cohen, H.: Primary glutethimide Addiction, *New York State, J. Med.* 60: 280-281, 1960.
10. Darling, H. F.: Acute toxic hypertension due to triflupromazine: Report of a case, *Am. J. Psychiat.* 115:1123, 1959.
11. Davis, P. L., Shumway, M., and Bloom, D. P.: Suicide by meprobamate, *Med. Times* 87:1494, 1959.
12. Davis, R. P., Blythe, W. B., Newton, M., and Welt, L. G.: Treatment of intoxication with ethinyl cyclohexyl carbamate (Valmid) by extracorporeal hemodialysis: Case report, *Yale J. Biol. & Med.* 32:192-196, 1959.
13. Editorial note: Current concepts in therapy sedative hypnotic drugs. V. Nonbarbiturates, *New England J. Med.* 256:314-316, 1957.
14. Ellinwood, E. H., Ewing, J. A., and Hoaken, P. C. S.: Habituation to ethinamate, *New England J. Med.* 266: 185-186, 1962.
15. Essig, C. F.: Addictive and possible toxic properties of glutethimide, *Am. J. Psychiat.* 119: 993, 1963.
16. Essig, C. F.: Withdrawal convulsions in dogs following chronic meprobamate intoxication, *A.M.A. Arch. Neurol. & Psychiat.* 80:414-417, 1958.
17. Essig, C. F., and Ainslie, J. D.: Addiction to meprobamate (correspondence), *J.A.M.A.* 164:1382, 1957.
18. Ewing, J. A., and Fullilove, R. E.: Addiction to meprobamate, *New England J. Med.* 257:76-77, 1957.
19. Greaves, D. C., and West, L. J.: Convulsions following withdrawal from meprobamate: Report of two cases, *Southern Med. Journal* 50:1534-1536, 1957.
20. Haizlip, T. M., and Ewing, J. A.: Meprobamate habituation. A controlled clinical study, *New England J. Med.* 258: 1181-1186, 1958.
21. Hollister, L. E., Motzenbecker, F. P., and Degan, R. O.: Withdrawal reactions from chlordiazepoxide (Librium), *Psychopharmacologia* 2:63-68, 1961.
22. Hudson, H. S., and Walker, H. I.: Withdrawal symptoms following ethchlorvynol (Placidyl) dependence, *Am. J. Psychiat.* 118:361, 1961.
23. Jensen, G. R.: Addiction to Noludar. A report of two cases, *New Zealand M. J.* 59:431-432, 1960.
24. Johnson, F. A., and Van Buren, H. C.: Abstinence syndrome following glutethimide intoxication, *J.A.M.A.* 180:1024-1027, 1962.
25. Kamin, I., and Shaskan, D. A.: Death due to massive overdose of meprobamate, *Am. J. Psychiat.* 115:1123, 1959.
26. Kinross-Wright, V., Cohen, I. M., and Knight, J.: The management of neurotic and psychotic states with Ro 5-0690 (Librium), *Dis. Nerv. System* 21: (suppl.) 23-26, 1960.
27. Lloyd, E. A., and Clark, L. D.: Convulsions and delirium incident to glutethimide (Doriden) withdrawal, *Dis. Nerv. System* 20:1-3, 1959.
28. Luby, E. D., and Domino, E. F.: Additional evidence of the addiction liability of glutethimide in man, *J.A.M.A.* 181:46-48, 1962.
29. McBay, A. J., and Katsas, G. G.: Glutethimide poisoning, *New England J. Med.* 257:97-100, 1957.
30. Mohr, R. C., and Mead, B. T.: Meprobamate addiction, *New England J. Med.* 259:865-868, 1958.
31. Murray, N.: Covert effects of chlordiazepoxide therapy, *J. Neuropsychiat.* 3:168-170, 1962.
32. Phillips, R. M., Judy, F. R., and Judy, H. E.: Meprobamate addiction, *Northwest Med.* 56:453-454, 1957.
33. Powell, L. W., Mann, G. T., and Kaye, S.: Acute meprobamate poisoning, *New England J. Med.* 259:716-718, 1958.
34. Reidt, W. V.: Fatal poisoning with methprylon (Noludar), a non-barbiturate sedative, *New England J. Med.* 255:231-232, 1956.
35. Sadwin, A., and Glen, R. S.: Addiction to glutethimide (Doriden), *Am. J. Psychiat.* 115:469-470, 1958.
36. Schreiner, G. E., Berman, L. B., Kovach, R., and Bloomer, H. A.: Acute Glutethimide (Doriden) Poisoning, *A.M.A. Arch. Int. Med.* 101:899, 1958.
37. Shane, A. M., and Hirsch, S.: Three cases of meprobamate poisoning, *Canad. M.A. J.* 74:908-909, 1956.
38. Swanson, L. A., and Okada, T.: Death after withdrawal of meprobamate, *J.A.M.A.* 184:780-781, 1963.

39. Swinyard, E. A., Chin, L., and Fingl, E.: Withdrawal hyperexcitability following chronic administration of meprobamate to mice, *Science* 125:739-741, 1957.
40. Tobin, J. M., and Lewis, N. D. C.: New psychotherapeutic agent, chlor-diazepoxide, *J.A.M.A.* 174:1242-1249, 1960.
41. Zirkle, G. A., Ott, B. M., and King, P. D.: Meprobamate and small amounts of alcohol, *J.A.M.A.* 173:1823-1825, 1960.

The CHAIRMAN. Are you an officer in the McNeil Laboratories?

Dr. PETERS. Yes, sir.

The CHAIRMAN. What is your position?

Dr. PETERS. My position is executive vice president for scientific affairs.

The CHAIRMAN. Who are McNeil Laboratories? Can you give us a little more information about your company?

Dr. PETERS. Yes. McNeil Laboratories is a pharmaceutical company that, through research, develops new drugs for the prescription drug market.

The CHAIRMAN. Where is its place of business?

Dr. PETERS. Fort Washington, Pa.

The CHAIRMAN. Is its manufacturing plant there, too?

Dr. PETERS. Yes, Mr. Chairman.

The CHAIRMAN. What is its connection with the University of Kansas?

Dr. PETERS. There is no connection, sir. My previous position was that of professor of pharmacology and chairman of the Department of Pharmacology at the University of Kansas Medical School.

The CHAIRMAN. And McNeil Laboratories is in the business of producing prescription drugs?

Dr. PETERS. Yes.

The CHAIRMAN. Any other types of drugs?

Dr. PETERS. Yes. There are some that are not prescription, but the majority of them are.

The CHAIRMAN. Does any other company produce this class of drug, derivatives of a barbituric acid?

Dr. PETERS. Yes, a number of them.

The CHAIRMAN. Do you engage in the production of any of the drugs that you referred to that, in your opinion, should be included?

Dr. PETERS. No.

The CHAIRMAN. In other words, you are asking this committee to include the other drugs which you referred to which were left out on the recommendation of the Department and other witnesses, on the basis of the competitive element involved and the effect it would have, similar to that of barbiturates?

Dr. PETERS. Partially for that reason, Mr. Chairman, and also because of the scientific literature which documents their susceptibility to abuse.

The CHAIRMAN. Do you produce the scientific literature?

Dr. PETERS. Relating to these other drugs?

The CHAIRMAN. Relating to yours as compared to others; yes.

Dr. PETERS. Yes, we have published papers on butabarbital.

The CHAIRMAN. What do you do with the literature? Do you send it to the pharmacists or the doctors, or what general source do you supply?

Dr. PETERS. The published scientific literature on the drugs that we do research on appears in medical journals that are distributed by medical publishers on a national or worldwide basis.

The CHAIRMAN. Since we have you here, and if my colleagues will bear with me for just a moment, what is the procedure your company has of distribution? You manufacture barbiturates.

Dr. PETERS. Yes, sir.

The CHAIRMAN. What is your procedure of distribution?

Dr. PETERS. Our procedure of distribution is mainly through wholesalers, and then we have direct retail accounts.

The CHAIRMAN. Do you have established wholesalers throughout the country?

Dr. PETERS. Yes, we do.

The CHAIRMAN. Do you sell directly to the drug stores, as an example?

Dr. PETERS. I think I would like to ask Mr. Smoyer to answer that question, because I am not too well acquainted in this area, sir.

Mr. SMOYER. I am afraid that neither of us is in the marketing field. I am a lawyer and Dr. Peters is in charge of scientific affairs. But I understand that we do sell directly to some retail outlets.

The CHAIRMAN. Can anybody who wants to come to your place of business and haul away a load of barbiturates?

Mr. SMOYER. No, sir.

The CHAIRMAN. What restriction do you have?

Mr. SMOYER. Well, as I understand it, they are all checked through a credit organization before we will deal with them, and in that way we know that they are in business and doing what they say they are doing. In other words, we know that they are regularly in the business of distributing drugs.

The CHAIRMAN. Does your company give any attention to an unusual order that comes in from someone?

Mr. SMOYER. Yes, I understand we do.

The CHAIRMAN. There has been an allegation here that there were 9 billion barbiturates, amphetamine pills, capsules, whatever they may be, produced in 1963, I believe, 1962 or 1963, the latest information they have, and that half of them went into the legitimate market and the other half the illegitimate market. Would you want to comment on that allegation?

Mr. SMOYER. We don't know whether that is correct or not, but we feel that that is not happening through our distribution except to the extent that some wholesaler or some druggist who is regularly in the business of handling drugs may divert some from time to time.

The CHAIRMAN. Do you have a procedure if a regular wholesaler is doing business with you that when that individual or wholesaler, rather, sends in an order that you fill it without any further questions?

Mr. SMOYER. Yes, with the qualification that if it is in an amount that seems entirely unreasonable, we would question it. But this seldom happens, Mr. Chairman. I don't believe we have had any significant number of such experiences.

The CHAIRMAN. Do You question the allegation that this traffic has been going on?

Mr. SMOYER. No, we don't. There may be many manufacturers of the kitchen and garage variety who are turning out these products

and selling them to the first person who comes along. We just don't know.

The CHAIRMAN. You don't know any of them that are doing that?

Mr. SMOYER. I don't happen to.

I don't know whether you do, Dr. Peters.

Dr. PETERS. No, I am not aware of it.

Mr. SMOYER. I think the Food and Drug Administration probably can advise you on this much better than anyone else, because they have done the checking of this sort of thing.

The CHAIRMAN. I know they have done the checking. They have urged the legislation and stated the need for it. But we are sort of in the position that everyone recognizes there is need for this and it is going on, but everybody says somebody else is doing it. What we want to do is to get down to who is doing this. I am just wondering if the industries, such as yours, without casting any reflection or trying to get unpleasant about it—I don't want to do that at all—I wonder if the industry has been doing its duty in protecting itself.

Mr. SMOYER. We think, as far as our distribution is concerned, the amount that is going into illicit traffic must be very minimal. But we don't know any way that we would have control over the illicit manufacturing and distribution that is being done by these operators that Mr. Larrick referred to the other day.

The CHAIRMAN. But you do think we ought to have such legislation similar to what is proposed here to bring about tighter controls?

Mr. SMOYER. Yes, sir.

The CHAIRMAN. Mr. Younger, have you any questions?

Mr. YOUNGER. Yes.

In your opinion, Dr. Peters, the delineation of these drugs mentioned here would carry the true meaning to those in the industry and these definitions are definitions that will hold water on these drugs that are competitive within it?

Dr. PETERS. Yes, sir.

Mr. YOUNGER. From a scientific standpoint?

Dr. PETERS. Yes, sir.

Mr. YOUNGER. In case the retail druggists are brought in under this bill, do you think that those doctors that dispense and sell drugs from their own office ought to also be brought in?

Dr. PETERS. I personally would think so. I don't see how this could be avoided because they are in exactly the same position with respect to distribution. This represents, incidentally, a small group of physicians.

Mr. YOUNGER. I understand there are very few. I see no reason why, if you can eliminate all the rest of the doctors that do not sell, they would not have to keep any records because they do not sell, that those doctors who do sell and dispense drugs out of their own office are in competition with the retail druggist and the retail druggist has to keep the records so there is no reason why the doctors shouldn't keep records. That is a logical conclusion to my mind.

Do you keep records right now as a manufacturer? Could they go into your manufacturing place and find the records of your manufacturing and to whom you sold?

Dr. PETERS. Yes; those records are available in the company.

Mr. YOUNGER. So this bill would not be a burden on you as a manufacturer or cause you to do something different than you are already doing?

Dr. PETERS. Not from that standpoint I don't believe it would.

Mr. YOUNGER. That is all.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. No questions.

The CHAIRMAN. Mr. O'Brien?

Mr. O'BRIEN. I have a few questions.

Doctor, you support the bill, but you believe that Congress rather than the administrative agency should act now to include the six drugs you have submitted?

Dr. PETERS. That is what we are proposing, Mr. O'Brien.

Mr. O'BRIEN. Is it your feeling that the scientific supporting materials you have supplied is such that without question in your mind the administrative agency in the very near future should include them?

Dr. PETERS. Yes, sir; I do. I feel that way particularly because of the source of some of this information, which is the Drug Addiction Center in Lexington, Ky. These people have as one of their major functions the investigation of the abuse liability of these agents.

Mr. O'BRIEN. I wouldn't want to ask you to look into other people's minds, but why do you think the Department is not recommending the inclusion of these six drugs at this time?

Dr. PETERS. I don't know, sir.

Mr. O'BRIEN. They have the same scientific information you have supplied.

Dr. PETERS. I did hear some testimony here on Thursday, and it was my impression their feeling was that they did not want to name drugs specifically, but rather, name them by classes.

Mr. O'BRIEN. Thank you. That is all.

The CHAIRMAN. Mr. Nelsen?

Mr. NELSEN. In listening to the testimony of the pharmaceutical groups, they felt that keeping the record of the disbursing of these specified drugs would be quite a burden, would be quite a chore. Would it be a great problem for the pharmacists to keep a record of the purchases from the companies, such as your own, for example, the amount they were buying, which would not be as much of a chore as to give a list of the disbursements but it would also give the investigators some idea if there is an unusually large amount purchased.

Do you feel there would be some merit to the exposure of the purchase invoice of the pharmacists?

Dr. PETERS. I imagine this is available at the present time. It is my impression, however, that the pharmacist very frequently orders more than one drug on an invoice. He may order many drugs on an invoice. As a result of this, he doesn't have this material sequestered in a classification under "drugs liable to abuse."

I do believe there are instances in which this would impose a considerable burden, if this material were to be kept separate.

Mr. NELSEN. However, it would be less of a burden to expose the records on purchases than it would be to expose the records on individual sales of these drugs. There might be thousands in one drugstore, while they may be buying all of it from one firm. I was wondering a little about the burden testimony we had from the pharmacists. I

can understand a small drugstore might find it very difficult to keep all these intricate records; however, the purchases would not be difficult, too difficult.

Dr. PETERS. This is probably true, because in terms of his distribution, we are talking about individual prescriptions which he is filling on the orders of physicians. These would run into very large numbers, greater numbers, I would think, than would his invoices. Of course, his suppliers are limited in this field. I would agree that this would be less of a burden.

Mr. NELSEN. It is my understanding that by your testimony you do not dispute the need of this type of legislation, but your main purpose is to be sure that it doesn't put a burden on one type of product to any greater degree than a similar product that falls into another category. You feel that all should be treated the same.

Dr. PETERS. That is correct.

Mr. NELSEN. But you do not oppose the legislation.

Dr. PETERS. No, sir; we do not.

Mr. NELSEN. Thank you. I have no more questions.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Doctor, I am very impressed with your comments this morning, but I note in going through the legislation that there appears to be a distinction between barbiturates and its derivatives, amphetamines and its derivatives on the one hand, and some of the other drugs on the other. I think for purposes of the record it would be useful to have, perhaps, a discussion as to whether there is, in fact, a distinction between these two types of substances, or whether there is not.

First of all, Doctor, are these substances that you have alluded to in your prepared statement, other than the amphetamines and barbiturates, used for thrill purposes or for stimulative purposes by truckers or for sprees and things of this type?

Dr. PETERS. Not to my knowledge at the present time.

Mr. DINGELL. Is there any substantial traffic in drugs of this kind in the illicit channels?

Dr. PETERS. I don't know whether there is at this time. My point was that if there is not—and I don't have information on this point—if there is not, a switch to these drugs with a more rigid control on the barbiturates would be a very logical event.

Mr. DINGELL. Let's discuss very briefly, if we may, the uses of barbiturates and amphetamines as opposed to the symptoms and uses of the other substances to which you alluded in your testimony.

First of all, barbiturates are depressants.

Dr. PETERS. Yes, sir.

Mr. DINGELL. I assume these other substances are also.

Dr. PETERS. Yes, they are.

Mr. DINGELL. But in addition to this, barbiturates have a practical effect, as I understand it, of giving a kick or a pleasurable reaction. Am I correct?

Dr. PETERS. In terms of my understanding of the kick or the spree property of the drugs, some of them do; other do not.

Mr. DINGELL. Do any of the drugs to which you have alluded this morning have that particular—and I am referring to the ones that you

alluded to in your statement this morning—do any of the six drugs that you have alluded to have this potential?

Dr. PETERS. I should say first, Mr. Dingell, that I am not aware of the fact that a potential for spree use—well, that a spree use has been proven.

May I put it that way? I would feel, however, that with some of them, on the basis of the similarity of their action to the barbiturates that are used for spree purposes, it would be logical to assume that they would be.

Mr. DINGELL. It is logical to assume? You referred to glutethimide, methyprylon, ethchlorvynol, ethinamate, meprobamate, and chlordi-azepoxide. Which of the two would be used for spree?

Dr. PETERS. Glutethimide and methyprylon.

Mr. DINGELL. They would have a potential for spree use?

Dr. PETERS. Yes.

Mr. DINGELL. Are any of these strong stimulants of the type that truckers could use to maintain wakefulness?

Dr. PETERS. No, none of these fall into the stimulant class.

Mr. DINGELL. I wish to be as brief as I can in my questioning. However, it occurs to me that if we are to, let's say, regulate additional classes, we should have a strong and compelling reason apart from the economic inconvenience to your company. I happen to feel that we should have as strong legislation as possible in regulating these drugs.

I have gone as carefully as I could in a very brief time through the additional information you have given us in addition to non-barbiturate sedatives and tranquilizing drugs. I have found in the various symptoms that you have alluded to with regard to the six substances you mentioned this morning, no indication of symptoms I could discern as making these attractive for spree uses.

Dr. PETERS. Currently the area into which these drugs fall in the area of abuse are two. One of these is habituation—

Mr. DINGELL. And self-medication? I notice that is sort of alluded to, what appeared to be self-medication. Am I correct?

Dr. PETERS. I don't quite understand what you mean by self-medication?

Mr. DINGELL. Obviously I am referring to a use far beyond what the doctors prescribe.

Dr. PETERS. That is also true with the barbiturates that are abused. But the big factor here that leads one to believe that these drugs would get into this traffic are the fact that they have addiction liability. This has been shown for them. Patients that have been withdrawn from these drugs either because supplies have become unavailable or because they have been deliberately withdrawn, let us say, by a physician, these patients go through withdrawal symptoms which resemble the withdrawal symptoms that one sees with the barbiturates.

Mr. DINGELL. Thank you very much.

The CHAIRMAN. Mr. Curtin?

Mr. CURTIN. Thank you, Mr. Chairman.

Doctor, are these pills which are the subject of this proposed legislation easily put together so that nonprofessionals could manufacture them in a backroom, or are they the type of product that would require special equipment and trained personnel to manufacture?

Dr. PETERS. I would say that in the case of both the drugs which are under consideration in the bill and the drugs which are not, that we are discussing this morning, if one is talking about making the compound, actually synthesizing the compound, this would require technical know-how. It would require a trained chemist to do this.

Mr. CURTIN. The manufacture of these pills could not be readily done by a group of people who didn't know much about medicine, to provide a source for black market pills?

Dr. PETERS. No. The only part of the process which I think someone without training could do and could do very easily is the matter of taking the raw material, that is, the pure compound, having obtained it in some illegitimate way, and simply putting it into a dosage form which would be sellable, such as a hard gelatin capsule, for example.

This is something that would not require training. This is relatively easy to do; inaccurately, I might add.

Mr. CURTIN. Thank you. That is all.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman. I have just a question or two.

Doctor, can you give us your opinion if this would be a reasonable approach: It seems to me, in listening to the testimony, that one of the possibilities of drugs getting into the black market or counterfeit would be when the purchaser goes to the manufacturer without any showing to the manufacturer that he is authorized to deal in these particular drugs.

What would be the objection to requiring, before the manufacturer sells to any person, that he must be registered as a proper handler of these drugs, say with Food and Drug Administration, and simply do it by a registry number, have him include this number to you which you may then check immediately with Food and Drug to see if he is properly registered?

Of course, they would keep their records anyhow as to whom they would sell, right on down the line. Wouldn't this be an aid to the manufacturer and a protection to the manufacturer himself, to see that his product does not get into the wrong hands?

Dr. PETERS. I think it could be, and it certainly would represent an additional safeguard in this area. I would question, to some extent, the necessity of this on the basis of Mr. Smoyer's statement that we know the people that we are dealing with.

Mr. ROGERS of Florida. You say you know the people you are dealing with, and this may be very true, but how are all these drugs getting into this market?

Mr. SMOYER. If I may interject, I think it is done by people who know very well that they are going into the illicit market and that is their intention. The only way you can stop them is to get the law enforcement officers on them.

Mr. ROGERS of Florida. Of course, I assume that is true, but if we have a check where we can tie it to them immediately, certainly this would stop anyone who is not qualified from purchasing from you.

As I understand it, you say you check their credit. But I wouldn't think this is necessarily a very thorough check on whether a person is authorized to deal in drugs.

Mr. SMOYER. A credit check shows you what business they are in. You get a Dun & Bradstreet type of report which shows what kind of business they are in, so you have had an investigation made when you get your credit check.

Mr. ROGERS of Florida. Does every company do that?

Mr. SMOYER. I can't speak for the others, but I assume that the major ones do just as careful a check as we do.

Mr. ROGERS of Florida. Of course, what I am trying to get at is the fact that the bill requires records to be kept, whom you would sell the materials to, and to whom the pharmacists do. But it never gets to the point of trying to prevent the sale to an unauthorized person in the first instance. I would think by putting in a simple addition to the bill, saying that these people who would buy from a manufacturer must have a registered number with Food and Drug, that this possibly could cut off a great number of the drugs that are now getting into improper hands, and would be an aid, I would think, and a protection to the manufacturer.

Of course, they would be checked out. They would have to keep their records. They would be automatically inspected, along with everyone else, by Food and Drug. It seems to me that that would certainly be an aid in stopping, I would think, the biggest possibility of large numbers of pills or drugs getting into the wrong hands in the first instance.

Mr. SMOYER. If I may make another comment, I think that the illicit manufacturer isn't going to care whether his customer has a registration number or not. He is just going to be interested in the money obtained by selling the pills to the customer.

Mr. ROGERS of Florida. I agree with you. It wouldn't help the illicit manufacturer. We will have to catch him in another way. But this would protect the legitimate manufacturer from having his pills or products get into the hands of wholesalers who may not be properly qualified or registered to do this type of business.

Mr. SMOYER. Possibly so, but I really feel that now the checks we make accomplish the same thing without some of the complications that you might have through registration numbers. For example, a new customer, who is just going into business, might not have his registration number for awhile because of the machinery required to be gone through.

Mr. ROGERS of Florida. Maybe he shouldn't until he is properly checked out and qualified.

Mr. SMOYER. But I suppose it is possible that the redtape would hold that back for a period of time after he really was legitimately ready to go ahead in the business.

Mr. ROGERS of Florida. I wouldn't think it would be too difficult to make a showing of a license, with a reasonable check that they could submit to Food and Drug to get their registered number.

Mr. SMOYER. This is just a minor complication that occurred to us.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Cunningham?

Mr. CUNNINGHAM. Doctor, I was wondering how big this business is in the particular pills we are talking about. Would you know industrywide or at least for your company how many pills are produced annually?

Dr. PETERS. I don't know what the figure is for the industry except from remarks that I have heard in these hearings. As I remember it, about 9 million and of these, it was estimated that half went into the illicit traffic.

The CHAIRMAN. Nine billion.

Dr. PETERS. Nine billion. This is the only information I have in that regard.

Mr. CUNNINGHAM. How many of these would your firm manufacture?

Mr. SMOYER. If I may interpose, this is confidential information in the trade as to what our exact sales are. But we are one of the principal manufacturers of pharmaceutical preparations containing derivatives of barbituric acid.

Mr. CUNNINGHAM. These that are named on the second page?

Dr. PETERS. No. Those are not barbiturates. They are nonbarbiturates.

Mr. CUNNINGHAM. Which do you refer to?

Dr. PETERS. Butabarbital sodium is our product and that is one of the principal barbiturates.

Mr. CUNNINGHAM. You are one of the largest producers of that particular drug?

Dr. PETERS. We are the largest manufacturer of pharmaceutical preparations containing that particular derivative and in the whole field of barbiturates we are one of the larger manufacturers. There are several other large manufacturers of preparations containing derivatives of barbituric acid.

The CHAIRMAN. Mr. Kornegay?

Mr. KORNEGAY. Thank you, Mr. Chairman.

Dr. PETERS, you say you are the principal manufacturer of butabarbital sodium. How many, or approximately how many other concerns in this country manufacture similar products, that is, the barbiturates?

Dr. PETERS. I don't have that information.

Mr. KORNEGAY. Do you know approximately?

Dr. PETERS. No, I wouldn't. The reason I wouldn't is because I would know about the major ones, that is, I would know the large drug houses that are involved. I wouldn't know some of the smaller ones there might be.

Mr. KORNEGAY. Approximately how many large houses are there?

Dr. PETERS. I would hazard a guess, sir. There are a dozen.

Mr. KORNEGAY. I wanted to get some idea of whether it was 10, 100, or 1,000.

You state that two of the nonbarbiturates listed on page 2 are in the hypnotic class; is that correct?

Dr. PETERS. That is the prime indication.

Mr. KORNEGAY. Are they quick-acting hypnotics?

Dr. PETERS. Concerning the term "quick acting," perhaps a better term is based on the duration of action, because this is what determines whether a drug is used as a hypnotic or not. If a drug is a short-acting depressant, this is a prime indication for inducing sleep. The reason is that obviously one would like to wake up at the end of 7 or 8 hours refreshed, rather than hung over. These drugs fall into that class.

Mr. KORNEGAY. In other words, as I understand your statement, the quick-acting drugs are more in demand by the illicit trade than the slow acting?

Dr. PETERS. One could say the quick-acting ones and the ones that have a powerful effect. You see, there is a difference here, too, because some of these are not as powerful in their action as are others.

Mr. KORNEGAY. In the six categories of nonbarbiturates, two of those would fall into the quick-acting category?

Dr. PETERS. I would say that; yes.

Mr. KORNEGAY. And they would be more desirable for those persons who are just after a kick; is that correct?

Dr. PETERS. That would be the way I would look at it. I don't have the evidence for this, as I indicated previously, because I don't know that they have been used for that purpose up to this point, but basing it on the pharmacology, my answer would be "Yes."

Mr. KORNEGAY. Thank you.

The CHAIRMAN. Is Seconal a derivative of butabarbital sodium?

Dr. PETERS. No, sir. They are both derivatives of barbituric acid. One is not a derivative of the other. They are both derivatives of barbituric acid, which is the parent substance of the family of drugs.

The CHAIRMAN. Is butabarbital sodium a class?

Dr. PETERS. Butabarbital sodium is an individual chemical, just as secobarbital is an individual chemical, a pure chemical.

The CHAIRMAN. And Seconal is a derivative of barbituric acid?

Dr. PETERS. Yes, sir.

The CHAIRMAN. Is it a barbiturate?

Dr. PETERS. It is a barbiturate; that is correct. Its generic name is secobarbital.

The CHAIRMAN. Mr. Broyhill?

Mr. BROYHILL. No questions.

The CHAIRMAN. Mr. Van Deerlin?

Mr. VAN DEERLIN. Dr. Peters, does your firm do much business with buyers in foreign countries?

Dr. PETERS. We are affiliated with foreign companies; yes.

Mr. VAN DEERLIN. Do you sell many products on consignment to Mexico?

Dr. PETERS. I think Mr. Smoyer could probably answer that better than I.

Mr. SMOYER. I really don't know the answer. I don't think we would sell on consignment, but I don't know. I am sure we do some business in Mexico. I just don't know the nature of it, but I would question that we sold on consignment, because we have affiliates down there through whom we would sell.

Mr. VAN DEERLIN. These are not customers in the sense that you would have customers on the American side on whom you run these Dun & Bradstreet checks?

Mr. SMOYER. Well, I think the distribution would be handled by our Mexican affiliate. I don't know what their system of checking customers would be, but I think it would be similar to ours.

Mr. VAN DEERLIN. Because this is a problem in southern California, do you think we could get more specific information on the methods of selling outside the country?

Mr. SMOYER. Yes, we could. I am quite certain, however, that the distribution down there by our affiliate would be the same as here. We want to know that our customers are in the business and that they are able to pay the bills.

Mr. VAN DEERLIN. How would the drugs physically be transferred into their hands?

Mr. SMOYER. I assume they are exported from this country to Mexico, but I am not sure. I don't believe we manufacture this product in Mexico.

Mr. VAN DEERLIN. What I want to know is in what manner are the deliveries made, so we can get some idea of the security which prevails.

Mr. SMOYER. Through common carriers, I am sure. Through common carriers who would be subject to whatever controls are present in Mexico.

Mr. VAN DEERLIN. And from what points in this country?

Mr. SMOYER. From Fort Washington, Pa.

Mr. VAN DEERLIN. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Harvey?

Mr. HARVEY. Dr. Peters, I have two questions. First of all is McNeil Laboratories, as a manufacturer, a member of the Pharmaceutical Manufacturers Association for whom a representative testified last week?

Dr. PETERS. Yes, sir.

Mr. HARVEY. My second question is, What raw materials go into the manufacture of butabarbital sodium?

Dr. PETERS. Into the manufacture of butabarbital sodium in a form which is available to the consumer? Is that the question?

Mr. HARVEY. Yes.

Dr. PETERS. Or into the making of the compound itself?

Mr. HARVEY. I am just trying to go back one step further. In other words, my next question, after you tell me what raw materials you use, would be, I want to know where you get those raw materials from.

Dr. PETERS. For the manufacture of the chemical?

Mr. HARVEY. Yes. You use barbituric acid, I take it.

Dr. PETERS. No, the way these barbiturates are actually made is that they are made from two chemicals which have no hypnotic or depressant properties in themselves, which are interacted.

Mr. HARVEY. What are they?

Dr. PETERS. They would differ with each of the barbiturates. One of them is urea. The other one would differ for each of the barbiturates in that there would be different chemical groups on one of the atoms in that structure. If we would talk about barbituric acid, itself, the two are urea and malonic acid.

Mr. HARVEY. Are those chemicals used in other barbiturates?

Dr. PETERS. Yes. Not very extensive medicinal uses in modern medicine. Urea in the past has been used as a drug. For example, urea is a normal constituent of excretion by the kidney, and this drug was administered in large doses at one time to promote excretion by the kidney. I am not aware of any other medicinal uses for the substituted malonic acid.

Mr. HARVEY. Where do you purchase chemicals such as these?

Dr. PETERS. I don't have this information, sir. As a matter of fact, I believe that our butabarbital as a chemical is made for us outside of the plant. This is frequently done.

Mr. HARVEY. Could any company, large or small, purchase that particular chemical, butabarbital?

Dr. PETERS. I don't have that information.

Mr. HARVEY. As to whether any company could or could not purchase it?

Dr. PETERS. No, sir; I don't have it.

Mr. HARVEY. I have no further questions.

The CHAIRMAN. Mr. Pickle?

Mr. PICKLE. Thank you, Mr. Chairman.

Doctor, I want to pursue a little further the question that Mr. Rogers had presented to you. You are licensed to manufacture in the State of Pennsylvania, and I assume you have a license from the State to go into business. Is that correct?

Dr. PETERS. Yes, I would say so.

Mr. PICKLE. You would say so?

Dr. PETERS. May I qualify this in this regard? This is outside of the scientific area, you see, so I am not acquainted with it.

Mr. PICKLE. You got a license to manufacture from the State of Pennsylvania; is that correct?

Mr. SMOYER. Do you mean a drug license, a license to manufacture drugs?

Mr. PICKLE. Yes.

Mr. SMOYER. Some States have that requirement, not very many, and I am not sure whether Pennsylvania does or not.

Mr. PICKLE. Are you telling me that you can just set up a business and go into operation and you don't have to get a license from anyone to do it?

Mr. SMOYER. In many States you can. You have to register with the Food and Drug Administration.

Mr. PICKLE. How about Pennsylvania?

Mr. SMOYER. Pennsylvania has a registration law, I understand, and we do have to register there.

Mr. PICKLE. Is this a perfunctory sort of registration?

Mr. SMOYER. No. I believe they inspect. They inspect.

Mr. PICKLE. You mean you don't really know what requirements you have to meet to go into business?

Mr. SMOYER. Mr. Leininger, who is here with me, is familiar with that, and he says we do have to be inspected and get a certificate of registration from the State, but that is not required in many States.

Mr. PICKLE. Apparently, then, and I am assuming this, it is relatively easy to get a license to go into business such as your organization; is that correct?

Mr. SMOYER. I think if you meet certain minimum requirements of the State board of pharmacy or board of health.

Mr. PICKLE. Are those requirements established by the State of Pennsylvania?

Mr. SMOYER. Yes.

Mr. PICKLE. Is this true of every State?

Mr. SMOYER. No. I think many States do not have any kind of a registration law.

Mr. PICKLE. So if there is no registration law in X State, then an organization could go into business and possibly manufacture a lot of these very drugs and put them on the market, put them into distribution channels, without any basic control; is that correct?

Mr. SMOYER. I should point out that the Federal Food and Drug Administration, under the drug amendments of 1962, requires regis-

tration of companies manufacturing drugs, no matter where they are in the country. Then they are inspected at least once every 2 years by the Food and Drug Administration.

Mr. PICKLE. Did your company get a license from the FDA?

Mr. SMOYER. Yes.

Mr. PICKLE. And every organization in the country, so far as you know, who manufactures these or similar drugs, had to have a license from the FDA?

Mr. SMOYER. They are supposed to, but I think many of the illicit ones have not, according to what Mr. Larrick was saying the other day.

Mr. PICKLE. Then the only controls, generally speaking, would be through FDA and not through a State licensing or registration procedure; is that correct?

Mr. SMOYER. I think in some States you would have both of those controls. In other States you would have only the Food and Drug Administration. They might run into the situation where the company maintained that it was in intrastate commerce only and, therefore, not subject to the Federal law.

Mr. PICKLE. Most of the organizations such as yours, though, would almost automatically be classified as an interstate organization: wouldn't they?

Mr. SMOYER. Correct.

Mr. PICKLE. Yet, would you say it would be helpful that a State set up stringent or a more rigid licensing procedure of concerns which manufacture drugs?

Mr. SMOYER. I really haven't given too much thought to it.

Mr. PICKLE. You are an attorney representing this company.

Mr. SMOYER. Yes.

Mr. PICKLE. Dr. Peters said, pursuing Mr. Rogers' suggestion, that any company who buys drugs might have a number issued to them by the FDA, and this, in itself, would be some protection and a guarantee and indication that they were legitimate and were entitled to purchase these drugs. Would you approve of that procedure?

Mr. SMOYER. As I attempted to point out to Mr. Rogers, I think that our controls now are good enough so that we don't have any problem about our products going to illicit distributors, but I suppose this would be another check on that, although numbers could be falsified by the customers.

You would have to check back with the Food and Drug Administration. They would have to keep issuing lists, I suppose, of registered distributors. There would be some delay in getting out proper lists. I can see complications that would result.

Mr. PICKLE. There may be complications but we are trying to improve on a bad situation, so we are looking for some kind of a procedure that would generally improve it.

Would you say that if there are some 9 billion illegitimate pills put on the market that this is loose control somewhere?

Mr. SMOYER. Yes. I think it was  $4\frac{1}{2}$  billion out of 9 billion.

Mr. PICKLE.  $4\frac{1}{2}$  billion; that is correct.

Mr. SMOYER. But I think that the main problem, from what the Food and Drug Administration has said, and others have said, is that the people who are putting these drugs into illicit channels will not pay any attention to whatever law is put out.

Mr. PICKLE. The problem, then, as always is the case, is that the people who go to church are not the sinners, and you manufacture the products but you are not guilty of it. Still we have 4½ billion in circulation. How will we control these illegitimate companies, or these companies that have very small regard for ethics and distribution?

Mr. SMoyer. I think this bill will go a long way toward giving the Food and Drug Administration more power. It, for example, makes it illegal to possess these drugs even though interstate commerce cannot be shown.

Mr. PICKLE. It would seem to me that even going further than the possession, the records would be a more rigid control on the manufacturer. We don't have a problem until these pills are manufactured. From that moment on they get to be a problem.

I have just one other question. This is a general question to either one of you. We are trying to get into the control of these products. Would you say the American people are just using too many pills, too many drugs? You manufacture the products, and you are bound to be interested in the health of our people.

Dr. PETERS. I don't doubt but that there is a certain amount of prescribing that goes on that is not necessary.

Mr. PICKLE. I am afraid that is correct. I think we all share that feeling. It is often said this country is getting to be a nation of goofballs rather than a few people who are goofballs. There must be some additional controls. Would you agree with that?

Dr. PETERS. I would certainly agree that in this area controls are needed.

Mr. PICKLE. Thank you.

The CHAIRMAN. Dr. Carter?

Mr. CARTER. Your company is in competition with the makers of tranquilizers; is that not true?

Dr. PETERS. That is true.

Mr. CARTER. Do you think tranquilizers are potentially as dangerous as the barbiturates?

Dr. PETERS. It depends in which area we are discussing. I would say that in the area of drug addiction this is a good likelihood.

Mr. CARTER. In reading the report from the doctor from Lexington, I noticed that he gave a very good report. In this he gave excessive doses of the particular forms of the six drugs mentioned, and not the usual dosage but far exceeding the dosages that are prescribed; isn't that true?

Dr. PETERS. In that paper, the experiments that were performed, a number of them were on animals and here the doses were excessive.

Mr. CARTER. Yes, and even among the humans, so far as that is concerned, the dosages that were harmful were greatly above dosages ordinarily given by a physician, prescribed by a physician.

Dr. PETERS. Which is the situation that accompanies drug abuse in terms of dependence and addiction.

Mr. CARTER. That is true. They represent that every one of these drugs are potentially dangerous, but almost any other drug is equally so if abused. I think you have a point, but I doubt that the tranquilizers present such a problem as the barbiturates.

That is all, Mr. Chairman.

The CHAIRMAN. As I understand, you say you do not know that they do present a problem at this time. Your contention is that they do present a potential problem equal to the problem that exists.

Dr. PETERS. That is right. They have been shown to possess these properties and have a potential which at the moment one cannot predict accurately. May I point out, Mr. Chairman, that it took many, many years before we recognized the full potential of the barbiturates in this area because the first barbiturate was synthesized and used in humans about the year 1912. Many of the others came along in the 1920's.

The problem of the real abuse of these is something that is considerably more recent, both in terms of addiction and I believe in illicit traffic.

Mr. CARTER. You do have a slight conflict of interest in this area, is that true?

Dr. PETERS. I beg your pardon?

Mr. CARTER. You have a slight conflict of interest in this area, is that not true?

Dr. PETERS. We have an interest in two aspects of it, one of which has been referred to, namely, the competitive angle.

The CHAIRMAN. Of course, what causes me some difficulty about legislating on the basis of a potential hazard is how far you are going to go, where are you going to stop? I have no doubt that you and most members on this committee, most people having an illness, go to the doctor and he might say, "Don't drink any more coffee" for a certain length of time, or "Don't drink alcohol," or "Refrain from taking this or that."

As Mr. Younger says, they tell you to quit smoking. It seems to me that our problem here is to develop the hazards in these fields and then meet the conditions. I don't know that I am capable of passing judgment on everything that might have a potential adverse effect.

Dr. PETERS. I think one problem that comes into this picture, in this same regard, Mr. Chairman, is the fact that within the class of barbiturates, actually, we have drugs which differ in the extent to which they are being abused at the present time.

The CHAIRMAN. I suppose there have been abuses in the use of aspirin. I suppose there can be abuse in most anything, as the doctor said a moment ago.

Mr. Satterfield?

Mr. SATTERFIELD. Thank you, Mr Chairman.

Dr. Peters, is it possible to anticipate with any degree of certainty that a drug, due to its chemical properties, is subject to abuse?

Dr. PETERS. Due to its chemical properties?

Mr. SATTERFIELD. Yes.

Dr. PETERS. Just looking at the chemical structure of the compound? It is possible in some instances to make predictions. For example, one could look at a chemical structure and say, "This has some similarity of chemical structure to morphine. It is, therefore, possible that it might have morphine-like properties." With certainty it would be difficult.

Mr. SATTERFIELD. The six that you mention in your report, do any of them contain chemical properties that would enable you to anticipate abuse?

Dr. PETERS. From the chemistry, itself, one couldn't project this. When any one of these was made for the first time, either this property came up as a surprise or, let us say, a related compound was first shown to have this property, perhaps to a lesser extent. But just to project purely from the chemistry, this is a very interesting speculative science. Medicinal chemists do this all the time with a reasonable batting average, may I say.

Mr. SATTERFIELD. You are in the business of research and development of new drugs as well as the production of those that you have developed. Is there some point in the development when a manufacturer can with some degree of certainty arrive at the conclusion that a particular drug does possess properties that make it a potential for abuse?

Dr. PETERS. Yes, in some instances there would be. For example, if we had a drug which showed, upon injection into an animal, that it would put the animal to sleep at a given dose, then one would say this is a hypnotic agent; the possibility is that if this were given to this animal for a long period of time in doses that don't keep him asleep constantly and when we withdraw the drug, it is possible that this will be a drug that will show withdrawal symptoms.

Mr. SATTERFIELD. Then you attach significance, to drugs that show withdrawal symptoms in terms of those that have a potential for abuse?

Dr. PETERS. Yes, sir; I do, because one of the abuses of drugs, of course, is the fact that there is a dependence developed to them and this is manifested by abstinence symptoms when the drug is withdrawn.

Mr. SATTERFIELD. Isn't it true there are substances classified as drugs for momentary of passing effect that do not become habit forming and yet still have a potential for abuse?

Dr. PETERS. Yes, this is possible.

Mr. SATTERFIELD. In other words, you are not really going to know as to certain drugs except through one experience of people actually abusing the use of them?

Dr. PETERS. In some cases it would require experience with them.

Mr. SATTERFIELD. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Huot?

Mr. HUOT. No questions.

The CHAIRMAN. Mr. Mackay.

Mr. MACKAY. Thank you, Mr. Chairman.

Dr. Peters, as I understand it, your company has no comment on this bill other than the request that these six drugs be added by name?

Dr. PETERS. Right.

Mr. MACKAY. I was not clear in your testimony about the medical literature supporting the possibility of abuse of these drugs. Have there been experiments made that demonstrate these qualities that are adverse to public health?

Dr. PETERS. Some of these experiments have been done in animals which indicate that if the drug is withdrawn, abstinence symptoms occur. The major evidence here is based on case reports of situations in which the drug has been taken in large doses by a patient who is abusing it, and upon withdrawal of the drug he has shown abstinence symptoms.

Mr. MACKAY. There is no question in your mind that this bill could deal with those through the committee process set up in the bill, that they could be brought under it?

Dr. PETERS. Ultimately, I believe they could; yes.

Mr. MACKAY. But you feel the noninclusion of them at this time really is unfair to your company. That is your case, isn't it?

Dr. PETERS. That is right.

Mr. MACKAY. Thank you.

Mr. SMOYER. I think it could be pointed out also that if there is reason to include drugs such as ours under the bill now, there is equal reason, from the public health point of view, to include these other drugs which have the same qualities.

Mr. MACKAY. Except that there is not any record now that the public is being injured.

Mr. SMOYER. Actually, the record of abuse on some of the barbiturates is very slight. If you go entirely on the question of actual abuse, I think that some of the barbiturates, including ours, might well be excluded from the bill. If you do not accept the test of potential for abuse, that is.

Mr. MACKAY. Specifically with reference to highway safety, are the stimulants or the depressants the greater threat?

Dr. PETERS. Mr. Mackay, this question is complicated by the fact that the person abusing the sedatives in the context we are discussing at the present time is usually abusing alcohol simultaneously. That clouds that part of the picture.

I have been more impressed in terms of the highway situation by the acuteness of some of the things that happen with the stimulants. But on the other side, there are a lot of cases where people are driving, I think, using sedatives and alcohol and perhaps getting by. What we hear about are the dramatic situations. The truck stop is a stop for amphetamines. This is what has brought this to the fore.

I would not be prepared to answer your question directly as to which of these two is abused the more.

Mr. MACKAY. Does your company have any recommendations to add to this bill on control?

Dr. PETERS. No, sir; we have none to add.

Mr. MACKAY. That is, how to get to the nonethical manufacturer?

Dr. PETERS. I couldn't, beyond greater diligence on the part of those whose responsibility this is.

Mr. MACKAY. I have no further questions.

The CHAIRMAN. Mr. Gilligan?

Mr. GILLIGAN. Thank you, Mr. Chairman.

Doctor, you say earlier in your statement that McNeil manufactures and sells butabarbital sodium as a present drug, which is a derivative of barbiturate acid. Do you manufacture Butisol Sodium tablets?

Dr. PETERS. Yes, we do.

Mr. GILLIGAN. That is the trade name under which you put this drug on the market?

Dr. PETERS. Correct.

Mr. GILLIGAN. Do you manufacture the drug and sell it as butabarbital sodium tablets?

Dr. PETERS. Our labeling carries both designations.

Mr. GILLIGAN. Do you sell it without the trademark on it?

Dr. PETERS. No, we do not.

Mr. GILLIGAN. So that any butabarbital sodium you produce you produce under that label, Butisol Sodium tablets; is that right, quarter grains and half grains?

Dr. PETERS. Yes, sir.

Mr. GILLIGAN. There are other manufacturers, however, producing this product?

Dr. PETERS. Yes.

Mr. GILLIGAN. And they sell it at one-tenth of the price of Butisol Sodium?

Dr. PETERS. I wasn't aware of that.

Mr. GILLIGAN. This is a catalog put out by an outfit which describes itself as "America's foremost wholesaler of generic drugs," and they have listed Butisol Sodium tablets, quarter grain, McNeil, 1,000 tablets, \$12.60; butabarbital sodium, half-grain tablets, 1,000 tablets, \$1.70, which is very close to one-tenth of the price. This outfit claims that their products pass all standards and tests of the Food and Drug Administration. They sell these things on an order blank, which is contained in the back of the catalog. They will sell it to anybody.

I got this catalog from a druggist in my district on Sunday, who said that anybody could buy, therefore, butabarbital sodium by filling out this order blank. You have no knowledge that this drug is being put on the market in this form?

Dr. PETERS. I wasn't aware of this particular situation, Mr. Gilligan. I am aware of the fact that there are considerable numbers of drugs that are being sold as generics at very low prices.

The situation which I am most acquainted with is the one that relates to the antibiotics, where some of these are being imported from Italy.

Mr. GILLIGAN. They have a whole section in here on antibiotics and another one on vitamins. This happens to be the section in which they deal with name brand drugs. They list the well-known houses that produce the drug and in the same column the drug sold under the generic name for anywhere from a half to one-tenth of the cost.

Part of the bill before us, H.R. 2, deals with counterfeit drugs. Are you aware of a problem in this field, of your drugs being produced in a form which is similar, so far as the layman's eye can detect? The druggist showed me two tablets, for instance, that were exactly identical, which came out of different bottles. One cost him one-tenth of what the name product cost.

Dr. PETERS. I knew that there were others that were selling butabarbital. I did not know the magnitude of the price difference. I don't find this unusual because of the fact that, you see, my area within the company is that of the scientific development. I am sure that the marketing people in my company are fully aware of this.

Mr. GILLIGAN. Is Butisol Sodium required to be dispensed upon prescription only?

Dr. PETERS. That is right.

Mr. GILLIGAN. And it is a barbiturate?

Dr. PETERS. That is correct.

MR. GILLIGAN. These other drugs which are mentioned in the paper you have submitted to us, and I shall not attempt to pronounce the names—do they require a prescription when dispensed?

DR. PETERS. Yes, they do.

MR. GILLIGAN. A drug whose trade name is Librium requires a prescription, but it is not a barbiturate?

DR. PETERS. That is right.

MR. GILLIGAN. The same druggist told me that he felt that this Librium was being sold on the market under generic terms quite widely without prescription. Would you, therefore, feel that H.R. 2 should be broadened to cover the registration and recordkeeping on all drugs sold under prescription?

DR. PETERS. I wasn't aware of the fact that Librium is sold without prescription.

MR. GILLIGAN. It was not. Librium is specifically to be sold on prescription. But he showed me a bottle of Librium on the shelf. He said that he was convinced that Librium, under its generic term, was being sold through illicit outlets, drugstores, and so forth, without prescription.

DR. PETERS. Through illicit outlets. I see.

MR. SMOYER. That is a violation of law, of course, to sell Librium without a prescription.

MR. GILLIGAN. The question that I couldn't solve in discussing this matter with him was why should not all drugs which require a doctor's prescription come under the terms of H.R. 2 rather than just drugs which are listed as barbiturates or amphetamines? Why not include them all? If they are dangerous enough to public health to require a doctor's prescription to dispense them, why should not the drug houses, wholesalers, jobbers, pharmacists, and so forth, be required to keep accurate records of the stocks on hand and so forth, the other provisions of this bill?

DR. PETERS. I think actually there is a gradation here of hazard. The requirement of a prescription, itself, is already a very adequate safeguard for many of our drugs.

MR. GILLIGAN. Do amphetamines and barbiturates normally require a prescription?

DR. PETERS. That is right.

MR. GILLIGAN. But because of their acute effects, you would say they require even more stringent controls?

DR. PETERS. Yes.

MR. GILLIGAN. Mr. Chairman, this next question I think I prefer to direct to the committee or its professional staff rather than to the witness.

On the sections of H.R. 2 which deal with counterfeit drugs, I would like to ask whether these sections are intended to cover the situation of drugs being sold by their generic names, produced in tablets or whatever—they look identically like the drugs that are sold under the trade name and sell for one-tenth the cost—is that in the meaning of this proposed legislation, the counterfeiting of drugs?

THE CHAIRMAN. The technical determination and the legal interpretation, of course, are matters to be discussed when we get into the writing of the bill. When we get to that phase, there will be ample discussion, I am sure.

Mr. GILLIGAN. I have one last question.

The CHAIRMAN. But if the counsel for the company wants to make any comment about it, it would certainly be appropriate.

Mr. SMOYER. I have no comment except that we feel that the provision regarding counterfeiting is beneficial. It prevents a fraud on the public and competitive injury to companies whose products are being counterfeited.

The CHAIRMAN. I will say to the gentleman for his information that we dealt with that subject matter of labeling in the Drug Act of 1962.

Mr. GILLIGAN. One last question: Does your firm produce a catalog like this, with order blanks in it, so people can order drugs from your house by direct sale?

Mr. SMOYER. No.

Mr. GILLIGAN. I have no further questions.

The CHAIRMAN. Doctor, thank you very much for your appearance today, and you too, Mr. Smoyer, for the contribution you have made to the committee. I am sure the committee will give consideration to your suggestions.

Mr. SMOYER. Thank you, Mr. Chairman.

The CHAIRMAN. The committee will adjourn until 10 o'clock Tuesday next. At that time we will have the coroner from Cleveland and Mr. Larrick, I am sure. There may be one, two, or three other witnesses. There will be one other witness, but we will hear him in executive session.

I will say, Dr. Peters, along with the medical bibliography that you referred to, which is included in the record with your statement, you submit substantial information about these various drugs you mentioned. This information will be received for the files, but I think the nature of it and the volume would make it unnecessary to be included in the record.

(Whereupon, at 11:50 a.m., the committee recessed, to reconvene at 10 a.m., Tuesday, February 9, 1965.)

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

...

## DRUG ABUSE CONTROL AMENDMENTS OF 1965

TUESDAY, FEBRUARY 9, 1965

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The committee met at 10 a.m., pursuant to recess, in room 1342, Longworth Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

As we continue the hearings on the proposed legislation on the drug abuse control bill, H.R. 2, we are very fortunate, and pleased, this morning to have as our first witness Dr. Alvin R. Yapalater, of White Plains, N.Y.

Among the qualifications of our distinguished guest, he is presently engaged in private practice in psychiatry and as psychoanalyst in White Plains, N.Y.

He is a lecturer of wide experience, author of several scientific papers; and chairman of the Committee on Alcoholism and Drug Addiction, Westchester County Medical Society of New York. He has been the consultant psychiatrist for Westchester County Penitentiary since 1954. Among other offices, the doctor is the secretary of the New York State Committee of Delegates, American Psychiatric Association, and chairman of the Medical Committee of the Westchester Committee on Alcoholism.

Dr. Yapalater, it is a pleasure to have you with us today. We appreciate your taking the time out of your very busy schedule to come to Washington and give us the benefit of your experiences and such information as time will permit on this important subject matter.

Permit me to say, as background for Dr. Yapalater's presentation, recently I had the television on for the "Today" show of NBC—and I am sure they will not object to the plug—a few days ago, when Dr. Yapalater was the special guest. I do not know if he or the network had in mind the hearings that were underway at the time or not, but I was greatly impressed with the knowledge displayed by our witness this morning, and particularly the things he spoke of relating to this field, although he was on the program discussing primarily another product.

So last week, when I had the privilege of being in New York for a speech to the National Radio & Television Society, I called the doctor and asked if he would mind coming to the committee and giving the committee the benefit of his knowledge in order to help make this record as complete as possible.

I give you this background information to let you know how we happen to have this distinguished guest with us this morning.

Doctor, we would be very pleased to have a statement from you, and probably there will be some questions.

**STATEMENT OF DR. ALVIN R. YAPALATER, WHITE PLAINS, N.Y.**

Dr. YAPALATER. Thank you, sir.

I am glad to be here today because, to my estimation, there is so much confusion in the thinking regarding the whole field of addictions and drug abuse. So much emotion obtains in this field that clear thinking is sometimes hard to find. There is an awful lot of heat generated and very little light.

My experience in this field began about 1952 when I was assistant chief psychiatrist at Grasslands Hospital, Westchester County. At that time, we worked on a small project dealing with drug addicts in conjunction with the FBI.

For a number of months, we examined and tried to treat a few of their cases, selected cases. That was my first contact with drug addiction. Then in 1954 the county board of supervisors decided to start a program at the Westchester County Penitentiary for their alcoholics who constituted upward of 80 percent of the inmate population. I was hired as a consulting director for one morning a week and they assigned to me a full-time psychologist.

That is how we began a program there which I am very pleased to say I developed and at the present time we have a staff of a full-time psychiatrist, psychologist, social worker, supervising psychiatric social worker, and a brandnew building for 130 beds for the treatment of alcoholics there.

We reduced the number of alcoholics by roughly 30 percent as a result of our treatment. This was the skid-row type of alcoholic, primarily, the derelict kind.

Then we applied our treatment methods, which was group psychotherapy, counseling, a total push approach, to the narcotic addicts as well, and have a very promising program going on there for them.

I became a member of the Executive Committee of the Westchester Committee on Alcoholism in 1956 and became chairman of its medical committee. Then, when the medical society started a subcommittee of the public health committee on alcoholism and drug addiction, I was asked to serve as its chairman in 1960, and am doing so until the present time.

In my private practice, I see many alcoholics, since I am fairly well known for that in Westchester, that is, for the treatment of the illness, and get occasional drug addicts in my practice as well, much more occasional drug addicts or drug abusers than alcoholics, because at the present time very few of the drug addicts will seek medical help because of what I feel is the highly repressive, legalistic, and punitive approach that currently prevails.

I mention this background because I have found that alcoholics are very similar to drug abusers. They have certain similarities to the drug addicts, but more similar to the drug abusers, which I will clarify in a moment.

We find that alcoholics will very often resort to pills, barbiturates, or amphetamines when they are trying to avoid alcohol, and then they will find that doesn't work and they will end up with an addiction or habituation to alcohol and barbiturates.

Anyway, there is a distinction to be made between drug usage and drug addiction, such as we find in the use of alcohol. There is alcohol usage and there is alcoholism or addiction or habituation, as the case may be. Roughly, there are 70 million people who use alcohol in the country, and of these there is an estimated 5 million people who have a problem with alcohol. A similar percentage or proportion may prevail in drug addiction and drug abuse. That is my opinion.

It is good to keep in mind that a lot of people use drugs and are not addicted. Again, to my mind, this has a basic relationship to—the use of these things has a relationship—to human nature. Man is an imperfect creature. He has many weaknesses, many failings, one of which is a tendency to regress, that is, not to face up to life's responsibilities. He will tend to revert to infantile dependencies, infantile behavior. He will seek pleasure and seek relief from responsibilities. This is people.

There are the fortunate few who are fully mature and who are able to go along life's path in a very responsible, constructive, and wholesome way. Again, if it comes to figures, I would hesitate to say what percentage of people constitute that group.

We have heard about the vices in general throughout the centuries, and they generally refer to these regressive, infantile tendencies in man. That applies to the use of intoxicating substances, either liquid or powder or pill, to gambling, to sloth, to sexual perversions, and other things of that nature.

To state something very simply, I do not feel that we can legislate out these tendencies toward vice.

Now, to come to something which is more pertinent to what we are talking about here, which I gathered had to do with dangerous drugs, it is good to know that dangerous drugs are either addicting or habit forming, or neither. I mentioned that before. One can use various drugs in a vice-like way and still not be an addict or even have a habit, such as we find in people who use alcohol.

The potential for addiction, however, is higher in some drugs, for example the opium derivatives where a mental and physical dependence is acquired, than it is in others. In some, addiction does not occur. In some drugs, for example marijuana, as far as we know, and the evidence seems unequivocal to date, marijuana can merely become habit forming, and then not necessarily so.

The same thing applies to barbiturates and to benzedrine, in my estimation, as well as other things, like glue sniffing, gasoline sniffing, turpentine sniffing, and various other fads of intoxication that prevail among the youth.

It is interesting to note that in Peru, for example, there are an estimated 2 million coca leaf chewers, which is chewed to derive pleasure from the cocaine contained therein, and of them, an estimated 10,000 addicts, an interesting proportion.

The CHAIRMAN. Did you say 2 million?

Dr. YAPALATER. 2 million coca leaf chewers. In other words, there is a very small percentage of addicts among the coca leaf chewers.

Likewise, I feel that applies to the use of drugs in this country. The number of addicts is probably a small proportion of the number of users, of almost any of these drugs.

Much depends on the way the drugs are used by the user, either to facilitate social relationships on the one hand, or for the drug experience itself; that is, to get "high." The addictive-prone person seeks the drug experience itself. He is immature, has a personality maldevelopment, is maladjusted personally and socially.

Once addicted, this person is as dependent on drugs as a diabetic is dependent on insulin to feel well and to function in relative health. Like a diabetic who may vary in the amount of insulin that he requires, the addict functions similarly. The amount of drug he requires varies from time to time, and is subject to considerable fluctuations.

The incidence of drug addiction and drug abuse to my mind is simply unknown, for two reasons: One is—well, for one reason, that the addicts are driven into hiding for two reasons: One, because of the deep sense of shame they have for this type of perverted behavior; and, secondly, because of the repressive legal measures that have been in existence. It drive addicts and users underground.

There are various estimates ranging from 60,000 on the one hand in the country to 400,000 in the country, of addicts. This is just the addicts. This does not refer to the drug abuse. Even less is known about that. Reports have varied about it. It does appear that there is a disturbing increase in the use of dangerous drugs. We hear about it in the colleges, with marijuana parties; we hear of it in the high schools, the use of marijuana, particularly; and also the barbiturates, otherwise known as goof balls.

The degree of habituation to marijuana is simply not known, and probably is not very great. The degree of habituation or addiction to barbiturates is probably pronounced, but to my mind also probably considerably exaggerated. I do feel there is a problem in this country with these drugs, and still with alcohol. It is something to be concerned with, something to do something about. But the question is how.

There are two problems. One is a moral one and one is a medical one. The moral one would pertain to the use of alcohol or other intoxicating substances, and the other one would refer to the prevention and treatment of habituation and addiction. I don't think we have been very successful in a repressive approach to these things, as I mentioned before.

The Volstead Act, prohibition against alcohol, was an excellent example of that. It just didn't work. It drove people into mildly or severely criminal behavior. It probably created a lot of alcoholics. It made a greater kick out of a forbidden thing. Finally it was repealed.

What happened to drugs? Around the turn of the century, drugs started coming into this country. It was easily obtainable. People didn't know much about it. They took them liberally. These were respectable people. They developed addictions or formed some habits. A lot of do-gooders got concerned about it, and finally laws were passed to prevent the importation of these drugs into this country and finally limit, ostensibly, their use by people.

It has been estimated that about a million cases of drug addiction were in existence around 1910. This compares with the current estimate of as high as perhaps a half million today. We don't know that there are only that many addicts. The other half million, or more, may be completely unknown and invisible because of the current laws.

To my mind, the legal approaches to drug addiction and drug abuse have failed. The claims that drug abuse and drug addiction have been diminished, to me are unfounded. I believe it is a fallacy that urgently needs correction. The only thing that has happened is that the gangsters have gotten enriched, the addicted have been victimized and made into criminals, instead of being treated like the unfortunate people they are, who often need help—often, not necessarily, all the time.

I want to stress that. Just as many alcoholics are living and functioning as respectable, constructive people because of their alcoholism. They can't live any other way. If we take their alcoholism away from them, they are dead pigeons. That is a certain group.

For example, in the penitentiary, when we first started there, I know I, myself, thought that all alcoholics were in penitentiaries, or got there via skid row, or because they were homeless derelicts. I found out that this constituted less than 5 percent of the alcoholic population. The other 95 percent were fairly respectable people, living fairly normal lives, compromised to varying degrees by their alcoholism.

I think that the same thing can apply in good measure to drug addiction and drug abuse. This is a very unpopular viewpoint, I know, but this is the way I feel about it. I am not alone in it, because the Academy of Medicine of New York in 1963 reiterated its stand that drug addiction is a disease, the drug addict is a sick person, and he should be treated medically.

The American Medical Association has come up with compromise ideas to try to retain the legalistic approach and at the same time emphasize the medical approach. I don't agree with that, because I don't think it can be done successfully, not as long as the laws remain as they are.

To me, the person who has drugs in his possession or uses them, or has drugs in his possession for their use, whatever drug it may be, this person should simply not come under the aegis of the law. This is the diabetic, so to speak, that I spoke of before. He has his illness, he has to resort to drugs, he should be allowed to, as far as I am concerned.

Also, such people should be able to get their drugs from doctors on prescription, or even without prescription from pharmacies where they are known. That is my considered opinion on this. You are not going to end up with liquor stores selling, let's say, instead of liquor, selling opium or heroin. There will be some control in the fact that it is available in the drugstore, primarily on prescription, but not necessarily so.

Again, to my mind, this is the approach that is needed, and until we do it, we will be going up a blind alley. I would like to see these people be able to get their drugs inexpensively instead of having to resort to crime to raise the \$15 to \$30 a day that is required to satisfy their habits. I think that legal measures can remain such as to pre-

vent the illegal sale of dangerous drugs or narcotics by unauthorized persons, mainly the underworld.

What other thing would I suggest? That involuntary hospital commitment be made possible for some cases of drug abuse and drug addiction.

I meant to say before about pharmaceutical dispensing of these drugs, by a pharmacy, that, of course, sales to minors would be restricted.

The major approach is one that is a public health one, to my mind, and belongs to the field of education and medical rehabilitation. We often find that once you give doctors a task to do, they are generally people of higher intelligence and great technical skills; if they can put their ingenuity to work on these things, they can usually come up with a fairly good answer.

I would like to see the drug abusers and drug addicts smoked out of where they are, out of their hiding places, freer to come out in the open, to seek help when they need it, and for us to have the facilities to treat them. As long as it is not in medical hands, we just do not have these opportunities sufficiently.

I believe, Mr. Chairman, that will conclude my somewhat prepared remarks.

The CHAIRMAN. Doctor, thank you very much for your very interesting discourse on this subject. I am sure there are in the minds of the members innumerable questions. Time is a factor this morning. I don't know how we could elaborate a great deal on what you have said, even with innumerable questions, but under the circumstances, I think we will probably allow a few minutes for it.

I believe it would be advisable, since you come from the great State of New York to give the committee the benefit of your experiences and suggestions in this field, to first recognize our colleague from New York, Mr. Murphy.

Mr. MURPHY. Doctor, in my district on Staten Island there is a 4-year experiment going on which was funded by the Federal Government. That is to take addicts and put them in a home-type atmosphere, in a group of about 20, and in that way to try to treat them not as a criminal, but to put them in an atmosphere that would be conducive, say, somewhat to a homelife and try to bring them off, I guess somewhat, as you said, maybe in a type of group psychotherapy, or something to that effect.

For over a year and a half now we have had no instances of dope pushers coming down into that area, or these people going out and perpetrating any crime for that purpose.

Is this the type of treatment that you would prescribe as part of the controlled hospitalization of an addict or a user?

Dr. YAPALATER. That would be one type of approach for a certain type of addict. To my mind, there are different kinds of addicts and users, as I have stated, just as there are different kinds of alcoholics, and the treatment would have to be tailored to the particular kind that you are dealing with, some of whom may never respond to help.

Maybe we will never reduce the number of addicts we have in the country, for that matter, but we will be treating them, at any rate, in the proper way, ways which can be devised as we go along, one of which, for example, is that I have been trying, in New York, to get

bill 88 passed, which would provide for involuntary commitment of certain cases of alcoholism, where a person was no longer able to function in a community, due to the use of alcohol. He becomes simply helpless because of it.

We cannot at the present commit such a person involuntarily to a State hospital. The State department of mental hygiene has been one of the leaders in opposition to this. They don't want to spend the extra money to do it, pure and simple. They haven't fully accepted the fact that the alcoholic is a sick person.

There are various ways we can treat these people, a good number of them. As I said, this will be devised by the doctors once it is put in their hands. I feel certain of that. I think you are referring to the Hilltop House in Staten Island, which is one type of facility. Synanon is another type of facility, which is run by an ex-alcoholic or an ex-addict, as the case may be. There is a place for that, too. There is a place for various types of approaches which will be tried and have varying degrees of success.

Mr. MURPHY. Who is going to determine who is going to be considered just an addict or a user of drugs?

Dr. YAPALATER. We don't have to worry about the user so much, as far as I am concerned, as long as they are staying out of trouble and not being forced to be criminals by the current laws. It is just as in the case of mental illness. People are examined by one or two psychiatrists and a decision is made as to whether a person should be certified, or not, to a State hospital.

I think a psychiatrist there would probably play a major role in determining who is a drug user or who is a drug addict and whether or not he needs hospitalization.

Mr. MURPHY. Mr. Chairman, I have no other questions. Thank you.

The CHAIRMAN. I believe it would be appropriate at this time to recognize the medical side of the committee. I would like to recognize Dr. Carter.

Dr. CARTER. Thank you, Mr. Chairman.

Doctor, certainly this is a trend in medical thinking today, and I am in thorough agreement with it. However, there are certain problems that arise. As a practitioner, I have seen many times that many people abuse the use of barbiturates, particularly. Some of these patients consume larger amounts than they are supposed to, particularly in cases of hypertension, and they lose their coordination and so on.

If we just open the door to them, then perhaps we would have lots of wrecks and so on. Don't you think we should limit their use of vehicles and things like that if we are to let them have what they want, and also limit their occupations, where they shouldn't be around dangerous machinery and so forth?

That is the only comment I have. I certainly enjoyed your discourse very much.

Dr. YAPALATER. Thank you, Doctor. I do agree that just as driving while intoxicated with an alcoholic beverage is an offense, driving while one is intoxicated with any substance should be considered an offense. As far as the management of a person who starts to take more of these medications than he is supposed to, under the doctor's

care, the doctor should feel free to admit such a patient to a general hospital, to detoxify him, then to take the patient back into treatment, to get psychiatric help where indicated, to work out the problems that led to the abuse of his medication, et cetera.

But, again, the offenses for which such a person would be charged would then be limited to the types of things, probably, that an alcoholic would be charged with.

Dr. CARTER. I feel as though we would have to have stricter regulations, however, because from the little experience I have had when they use too much of the barbiturates their coordination is such that they would be hazards on the highway, or hazards to people working beside them in certain fields, and so on.

Dr. YAPALATER. Such restrictions I feel should be that a person is committing an offense if he is operating a vehicle on the public highways while under the influence of such a medication. Then just as there is a test for alcoholism in such cases, there can be the various easy tests for barbiturates in the blood, or heroin, for that matter.

Dr. CARTER. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Staggers, have you any questions?

Mr. STAGGERS. Yes, Mr. Chairman. I have several questions, but I think that, as the chairman has said, in behalf of expediency, we will be limited in time.

But with regard to the bill we have before us today, its main purpose is the illicit traffic of the drugs. It defines them and penalties for them.

Do you concur that this committee should do something about that?

I am not talking about the subject from the medical side, because we don't deal with that. We are talking about the illicit traffic in drugs.

Dr. YAPALATER. My opinion regarding that is that we are putting our efforts in the wrong direction. That is my main objection.

Mr. STAGGERS. We are talking about attacking one problem. They can make any kind of drug and sell it without anyone knowing about it, and it can get into any avenue without anyone knowing about it. We are trying to regulate the interstate traffic, the illicit trade. That is what this bill is about. Would you be in favor of that? That is the question I am asking about on this bill.

Dr. YAPALATER. The only reason I am not in favor at the present time is that, as I say, it is in the direction of control and restrictions. Then if it weren't for the fact that all efforts have been in that direction up to the present time, I would be in favor of it.

But to me it is against the spirit of what I feel should be the approach to the problem. People are going to feel that if you have some other restricted measure to control illicit traffic that you are really accomplishing a big part of the job. To me it is a small part of the job. If the drugs were more readily available to people in pharmacies and under doctor prescriptions the further restricted measures on illicit traffic would not, to my mind, necessarily be required.

It may be that subsequently if, let's say, the approach I have in mind were in effect, then some mild degree of restriction on illicit traffic would be required. I would not know to what extent.

Mr. STAGGERS. Doctor, this bill has nothing to do with the sale in pharmacies or those places at all; for your medical advice, from doc-

tors of the country, when they need it, that has nothing to do with it. This is talking about the racketeers and criminals that are making fortunes out of these sales, and the unfortunates they are selling to, where the officers cannot get to them. We are trying to control that.

We are not trying to go to the doctors and say what you should say as a doctor to your patient. We are trying to govern the illicit trade in this country. I think when a country fails to do this, when they don't do it in the State, in the Nation, or in the communities, something is lacking.

I think the separate problem that you are trying to them attack is from another angle than what we are talking about. I would agree with you to a certain extent. As Dr. Carter said, I have come in contact with a lot of things in my career as a law enforcement officer where I have seen that a lot of the crimes in this country are perpetrated by those involved in the illicit trade.

DR. YAPALATER. I believe in the law of supply and demand. Dry up that traffic by making the stuff more readily available at a cheaper price to the consumers.

MR. STAGGERS. We are not arguing with that. We are talking about the criminal element of this country who are doing it and making fortunes out of it, and driving those in the high schools and colleges of this country into addiction because they know they can do it by violating the law or getting around it in some way.

We are not talking about those who are users who go and legitimately buy a prescription.

DR. YAPALATER. I quite agree. I think it is admirable to consider that, that anything against these vicious criminal elements should be done. It is a question of whether it is advisable at this time and whether it would be necessary if the whole approach were changed. That is my question.

MR. STAGGERS. We are not trying to dictate to the medical profession how to treat any addict or any user.

DR. CARTER. Would you yield for one question?

MR. STAGGERS. Yes.

DR. CARTER. Our question is on these people, for instance, who take barbiturates and then commit crimes. We have seen that happen. We read of it regularly. I have seen it. For instance, not too long ago in my community a man had taken seconal. In a short while he stabbed another man in the chest. We see it in truck accidents along our highways where we find benzedrine or a combination of amphetamines-barbiturates so many times of these people's person that we know that it happens too often among the drivers.

The drug must be causing the wrecks and so on that we see. That is what we are trying to do. We are trying to formulate a bill which would control the traffic of these things which do cause, we think, crimes and accidents on the highways and so on.

Thank you.

DR. YAPALATER. I understand that.

MR. STAGGERS. I have no further questions.

THE CHAIRMAN. Gentlemen, that is the very thing I have been trying to avoid, to getting into an argument with a doctor regarding these things. The doctor has made it very clear that he believes that these drugs should be made readily available through proper channels, legitimate channels, and he has made it very clear that the unauthorized

people were the ones that were causing the trouble in the distribution of it. I hope we can avoid getting into arguments, if we can, about it, because we have another important witness that we want to get to in a few minutes, who will show you from his experience, how easy it is in this country to get these drugs through illegitimate channels.

Mr. Macdonald?

Mr. MACDONALD. I just have one question which I hope will cause no argument. But before I get really confused about this, isn't second a so-called sleeping pill that people who want to go to sleep take as a barbiturate?

Dr. YAPALATER. That is quite so.

Mr. MACDONALD. Why would someone who wants to stab someone take a sleeping pill before they will do that?

Dr. YAPALATER. These people who misuse such medication stay awake with them. It is like taking a certain amount of alcohol, not enough to put you asleep but to keep you on your feet, and you are sort of asleep on your feet. But your judgment is affected and any criminal tendencies or antisocial tendencies a person might have may then be permitted to be expressed, because conscious controls and judgment are weakened by the medication. But they take it to get high.

If you stay awake while taking these—one of these hypnotics or barbiturates—you get a high effect. That is what they are seeking.

Mr. MACDONALD. Thank you.

Mr. FRIEDEL. Mr. Chairman, I have a question.

Doctor, I know you have given this subject a great deal of thought. While you were making your statement, I made an observation. You smoke quite a bit; don't you?

Dr. YAPALATER. Yes, I smoke about a dozen cigarettes a day. I would be called a moderate user. Apparently it does not affect my health or my actions.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Doctor, do you dispense drugs yourself, in your practice, through prescription, or do you have them for sale in your own practice?

Dr. YAPALATER. I don't have any drugs for sale. I do dispense various medications for psychiatric use in my practice, tranquilizers, antidepressants. Very occasionally in my limited experience in private practice with a drug addict I will prescribe for brief periods something like methadon which is a narcotic drug, which will help a person get off or withdraw from a more severely narcotic condition.

Mr. ROGERS of Florida. I wonder under your philosophy if a person came to you and wanted a drug you would have no compunction to prescribe?

Dr. YAPALATER. Any patient who wants a prescription from me I have to examine thoroughly and understand and see for what purpose the medication would be prescribed.

Mr. ROGERS of Florida. I thought it was your philosophy that people should be able to get this if they wanted it, and, for instance, should be able to go to a pharmacist.

You would not, then, give it to them, if I understand your practice?

Dr. YAPALATER. No, if they wanted it, I would give it to them. But through my initial contact with them I would consider it a therapeutic contact. I have met with this person. I have tried to establish a professional rapport.

Mr. ROGERS of Florida. What about the pharmacist, where you suggested to let the pharmacist give it to anyone who came in?

Dr. YAPALATER. The pharmacist is also a professional person and has some judgment. He dispenses quite a few pharmaceuticals.

Mr. ROGERS of Florida. If a person just came into the store and asked the pharmacist, do you think he should be able to let anyone have these drugs if they ask for it?

Dr. YAPALATER. Yes; if this is generally the case I feel that a pharmacist should be able to do that.

Mr. ROGERS of Florida. Then in your practice, if anyone wanted a drug, it would not matter if they were examined or not, you would be willing to give it to them?

Dr. YAPALATER. That would be an extreme interpretation.

Mr. ROGERS of Florida. I was just saying according to your philosophy.

Dr. YAPALATER. It is difficult to state that accurately. But I would say that is essentially correct.

Mr. ROGERS of Florida. Thank you.

Dr. CARTER. I believe the doctor meant he would first examine the patient and then determine his needs.

Dr. YAPALATER. That is what I mean, yes.

The CHAIRMAN. Mr. Kornegay.

Mr. KORNEGAY. Doctor, you indicated in the course of your testimony that there is some difference in the medical definition of habit forming and addiction. Do you mind giving us the distinction between those two terms?

Dr. YAPALATER. Yes. Habit forming refers to psychological dependence on any substance, just a need for it from an emotional or mental standpoint. A person is addicted when there is, and in addition to this, a physical need for the drug then so that if the drug is discontinued there are definite categorizable withdrawal symptoms.

Mr. KORNEGAY. Could you accurately state that habit forming is the first stage in addiction? In other words, one moves from habit forming into addiction?

Dr. YAPALATER. In some cases. Again, that would have to be better determined once we are in a better position to explore these matters. But in some cases you have habit formation never leading to addiction. In other cases, it is habit first and then addiction.

Mr. KORNEGAY. In other words, in some cases the use of drugs will never cause a physical impairment of the person.

Dr. YAPALATER. That is correct, and it is not generally appreciated, as a fact.

Mr. KORNEGAY. Thank you, sir.

Mr. CURTIN. Will the gentleman yield?

Mr. KORNEGAY. Yes.

Mr. CURTIN. Do the persons become addicts who so use these pills?

Dr. YAPALATER. I am not sure I understand that.

Mr. CURTIN. Do persons become addicted to the use of these pills if they take them?

Dr. YAPALATER. Again, that is variable. Some people can take them at will, like some people who use alcohol. Others will develop a habit. Others will develop addiction.

Mr. CURTIN. So you can become an addict in the use of these barbiturates?

Dr. YAPALATER. Yes. And that is only realized in the recent few years. It was not realized before.

Mr. CURTIN. Thank you, Mr. Kornegay.

The CHAIRMAN. Are there any further questions by any members?

Mr. Van Deerlin.

Mr. VAN DEERLIN. Doctor, very recently the organizers of Synanon, out in California, complained that the State government was not friendly toward their type of treatment and went so far as to charge that the State narcotics enforcement machinery has a vested interest in the continuance of drug addiction. Would you see any fairness in this charge, any justification for it?

Dr. YAPALATER. I think it is probably a distortion of the facts. If anyone does anything intensely in a period of time they have a vested interest in it.

That is human nature. One develops a preference for one's way of doing something and for the whole approach that one follows. That does not mean that one gets financial gain or one is serving some evil purpose thereby, but that one is just doing what one thinks is right, and it just happens to be wrong.

Mr. VAN DEERLIN. I think the substance of this charge was that if drug addiction were cured, there would be no great further need for drug control, and that the fact that Synanon was purportedly making gains in this direction was pulling the rug out from under the narcotics agents, which is a rather sweeping assertion.

Dr. YAPALATER. I think it is a rather sweeping assertion. There is some truth in it. Of course, they think that drug addiction can be cured. I don't know if it can be. Just as certain types of illnesses can never be completely eradicated, you will have a certain number of afflicted individuals every year, let's say, but better management and treatment can be found for these people. But certainly, again, what you say does fit in with what I feel, that the whole Federal approach and even the local approaches to this are almost worthless, as far as I am concerned.

Mr. VAN DEERLIN. Doctor, would you say that the British legal attitude toward drug control tallies fairly well with the views you have expressed this morning?

Dr. YAPALATER. Of course, there is no British system as such. It is just a way that the British people go about handling various types of problems. It used to be that the British were very barbaric people with their handling of various problems, with hanging in the public square, et cetera. Now they have abolished the death penalty.

Then, I think all the Puritans came to America and left Britain much more liberal and understanding in their viewpoints about many things. The Puritans, I feel, here have directed the repressive approaches, thinking that that will gain the ends that they seek. I think that is false.

So we find that in other countries where there is a very liberal attitude toward drug addiction—for example, in Norway there is a high incidence of drug addiction, but there is very little crime connected with it. In other countries, like Britain, there always has been a low

addiction rate, for reasons that we don't understand. And it still is low.

Mr. VAN DEERLIN. Would you call H.R. 2 an example of puritanism? That is the bill we are discussing.

Dr. YAPALATER. I must say that I have come here not prepared to discuss this bill. I have not read it. I really don't know what it is. I just came to give some general views about these problems from the medical and psychiatric standpoint.

Mr. VAN DEERLIN. For one thing, for illegal, unauthorized possession of prescription drugs, it would impose a fine of up to \$2,000 and/or 2 years in jail, if you prefer.

Dr. YAPALATER. For unauthorized what?

Mr. VAN DEERLIN. The illegal possession of specified prescription drugs. Is this puritanical?

Dr. YAPALATER. I think so.

Mr. VAN DEERLIN. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Mackay.

Mr. MACKAY. Mr. Chairman, I have one question.

My State of Georgia has been very aroused because of a brutal murder that was committed just a couple of days before Christmas, in which a father and husband was killed by two hitchhikers he picked up, who beat him to death with a board while they were under the influence of stimulants. I have not seen the record of the trial, but it seems that they probably picked them up at an illegal source, such as a truck stop. We have been told by the Commissioner of the Food and Drug Administration that he needs this bill in order to eliminate the availability of this type of stimulant by giving a broader definition of interstate commerce and giving him certain powers of search and seizure that he does not feel he has now.

The public feels that everyone's life is risked because of this illegal traffic, which this bill seeks to dry up.

As I listened to your testimony, I did not understand that you were opposed to our trying to crack down on the illegal traffic of barbiturates and stimulants. You were not saying that a truck stop ought to be able to sell to a casual passerby the stimulants and depressants, were you?

Dr. YAPALATER. No, I was not. I spoke of authorized channels, primarily through drugstores.

Mr. MACKAY. Have you any comment on this type of thing? I have read several stories in the paper just recently where brutal crimes have been committed, where the underworld has dispensed these stimulants and depressants.

Dr. YAPALATER. That is an important question. I feel, and statistics bear me out, that crimes against the persons are minimal among the addicts and users.

If these murderers killed this person under the influence of stimulants, to my mind they would have done it anyway, and maybe at some other time. They are vicious psychopaths to begin with, and I don't know that the use of the drugs makes that much difference.

Mr. MACKAY. With reference to amphetamines and barbiturates aren't they easy to get hold of? Wouldn't it be possible for me to go out of this building today and get them?

Dr. YAPALATER. It is fairly easy to do so.

Mr. MACKAY. And you feel that that ought not to be changed?

Dr. YAPALATER. I feel that changing that is not going to make that much of a difference, that the greater efforts have to be toward education, toward orientation of the public about the danger of these things, toward greater controls of parents over their children, the schools over their students, et cetera. These don't have to be legal measures, so far as I am concerned.

Mr. MACKAY. I would like to make a request of the witness, Mr. Chairman. I have been very interested in his general discussion, but since he has said he has not read this bill I would certainly hope he would and give us the benefit of his view, of the approach of this bill, which aims itself at this illegal traffic in the drug.

I don't feel that it is puritanical. I would hope after he has read it that he could tell us whether he feels that the Congress ought to pass this bill.

The CHAIRMAN. I would like to say to my colleagues that we brought Dr. Yapalater here as a professional man, a psychiatrist, a man who has dealt in a professional way with people who have been addicted, who are habitual users or otherwise users of these drugs.

I did not suggest that the doctor come here for the purpose of analyzing the legalistic phases of this legislation. We brought him here in a professional status all together.

I believe we have good lawyers on this committee who are capable of dealing with that end of it.

Are there any further questions?

Doctor, do I get the full import of your testimony to be that there are many users of this type of drug, from your experience?

Dr. YAPALATER. Yes, that's correct.

The CHAIRMAN. There are many young people users of this type of drug.

Dr. YAPALATER. That is probably also correct.

The CHAIRMAN. You mentioned something about the young people using it.

Dr. YAPALATER. Yes.

The CHAIRMAN. For what purpose, from your experience?

Dr. YAPALATER. To get intoxicated.

The CHAIRMAN. Sir, is that what has been commonly referred to here as the desire to go on a spree?

Dr. YAPALATER. Yes, that would be the idea. But not necessarily. That is one form of intoxication. Some of them will just want to get intoxicated in a group and all laugh together, or they think they are having a good time.

The CHAIRMAN. From your professional experience, certain criminal elements are dealing with this type of drug?

Dr. YAPALATER. Yes, I do believe.

The CHAIRMAN. Do you know from your professional experience that there are certain professional people that deal and utilize this type of drug?

Dr. YAPALATER. Who traffic in it, do you mean?

The CHAIRMAN. No, who use it.

Dr. YAPALATER. Yes, there are some professional people who do. It is no respecter of profession, age, or intelligence.

The CHAIRMAN. Our problem here is to try to consider how those who might be engaged in the trafficking of it can be handled. That is our problem and that is the purpose of asking you for your professional experience.

On behalf of the committee, let me thank you for your presentation here this morning, and for your willingness to come to Washington for this purpose.

Dr. YAPALATER. You are quite welcome, Mr. Chairman. It is my duty and my pleasure to have done so.

The CHAIRMAN. You have been very kind. We thank you for it.

Dr. YAPALATER. Thank you.

The CHAIRMAN. At this time, I would like to call Mr. Jay L. McMullen.

For the information of the committee, Mr. McMullen is an employee of the Columbia Broadcasting Co. Mr. McMullen was in charge of the program assigned to his group and was responsible for the program that many people saw last fall. In view of the interesting nature of the program that was presented over the Nation, it occurred to us that it would help this record if we found out just how Mr. McMullen and his group went about getting the information that they presented to the American people.

I had occasion to visit Mr. McMullen in New York when I was there, and he did explain to us very briefly what they did. It certainly is an interesting experience, which I believe should become a part of the record, and all of you should have an opportunity to hear it.

**STATEMENT OF JAY L. McMULLEN, CBS NEWS, NEW YORK CITY,  
N.Y.**

The CHAIRMAN. I think Mr. McMullen, I have at least partially identified you. If you have any other identification that you would like to give the committee yourself, we would be glad to have it.

I think probably I should say that you originally came from Ohio, and you have had a varied experience in the field of broadcasting, and in the last few years in the field of obtaining information regarding the utilization of various types of products in connection with your responsibility.

Mr. McMULLEN. Mr. Chairman, I think you have identified me quite correctly. My title is producer of the CBS news factfinding unit, which is a unit that does investigative reporting. We consider that the McMullen services project would fall in that category.

As some background on that, which I believe you would want, I had worked for almost 2 years prior to presenting this particular program on another program dealing with "The Business of Heroin." That was the name of the documentary. That documentary there took me through the Middle East, into Europe, and back to this country, tracing the route of heroin from abroad into the United States, and then tracing its route within the United States down to the street-corner level, from pusher to addict, et cetera.

When this program was finally completed, a number of experts in the field of narcotics told me that the problem with amphetamines and barbiturates had become acute. Some even said it had become

more acute even than heroin. With that information and that background, I began making some inquiries. These inquiries, in turn, led me to believe that in fact there was a problem.

Part of the problem, if not one of the major parts of the problem, was the diversion of these drugs from legitimate channels. Quite clearly the drugs were being sold in the black market, some at truck stops, some on street corners, et cetera. But the question was, at least in my mind, How could these drugs be diverted from the legitimate channels?

Since if there was, in fact, a considerable market in these pills, then it would follow that there would need to be a considerable diversion of these pills. The question then was what could we do to examine how this diversion could possibly take place. In order to do this, we set up a dummy organization called "McMullen's Services."

We had printed up a letterhead, which merely stated the name, "McMullen's Services" and said, "Export-Import." And it also had our telephone number, which was an unlisted number. Then we began looking to contact various legitimate manufacturers of these drugs.

We went through the Red Book, which has the listing of these companies, and we picked at random the names of some of these companies. We wrote to them first asking for their catalogs. Some of the companies sent catalogs without making any inquiry, either by letter or by telephone.

The CHAIRMAN. You mentioned companies. You are talking about manufacturers of drugs.

Mr. McMULLEN. That is right, sir.

Some of these drug companies, producers, refused to send us catalogs, and wrote us to the effect that they considered it illegal to do so unless we could present them with some evidence of our legality as a drug wholesaler, which is the area in which we were posing.

I think that the film that we have ready to show will really present a picture of what we did.

Rather than go through the whole story now—I might be repetitive—if you would care to look at the film, we could discuss it from there on in.

The CHAIRMAN. Is there objection?

No objection being offered—the film takes about what, 6 or 7 minutes?

Mr. McMULLEN. Yes, sir.

The CHAIRMAN. I think probably you may present it at this time. (Film was shown.)

The CHAIRMAN. Mr. McMullen, that is a very impressive presentation. Certainly it is directly on the point of the problem that we are trying to reach. I assume you decided when the inspectors of the State of New York came in on you, that it was about time to wind up your show.

Mr. McMULLEN. We certainly did, sir. As a matter of fact, we did have some opportunities to buy after that time, but did not think that this would quite be playing the game fairly. That the game was over when the inspectors walked in.

The CHAIRMAN. Do you have any further comment?

Mr. McMULLEN. I should say the experiment was over. I don't like to think of it as a game.

The CHAIRMAN. I think everyone on the committee and probably everyone who is here understands precisely what you had in mind, and the public service that you were attempting to render.

Do you have any further comment that you wish to make?

Mr. McMULLEN. No, sir; I think the film and the background fairly well presents what we did.

The CHAIRMAN. It certainly does vividly portray just what you set out to do.

Mr. Staggers?

Mr. STAGGERS. I have no question, but I would like to commend Mr. McMullen for the great service he performed, and to make the statement that the strength of the land has been that we live under law. Evidently in the movie you have shown there was a laxity in the law somewhere because under the law you should have had a license to buy. Is that correct?

Mr. McMULLEN. If I understand your question, I think you are saying that the program shows that there was a laxity in the law. I am not clear on whether you mean a laxity in enforcement of the law or something that is lax, innately lax, in the law, itself.

Mr. STAGGERS. Perhaps both. But I think perhaps maybe in the enforcement of the law. According to the New York inspectors who came to visit you, you were performing against the law and you stopped that when it was enforced. So perhaps it was a laxity of enforcement.

Mr. McMULLEN. I don't know about laxity, in all fairness to the New York inspectors, because quite soon after we were recorded by one of the drug manufacturers, this visit was made, as soon as they had knowledge of it.

They certainly lost no time in getting there. They did tell me, however, that they were very happy that we were not in business as a commercial outfit, but were merely doing this for educational purposes. They said that they had only eight inspectors for the entire State, and it would be very difficult for them to check up on everybody without having at least some leads there. So I would not want to imply that they were lax, considering the small number of people they have there, and considering the fact that they did act very quickly once they were informed.

Mr. STAGGERS. I would agree with you, Mr. McMullen. All I wanted to show was that there was something wrong someplace, that you were able to do this, and that we should find out what it was.

Thank you very much.

The CHAIRMAN. Mr. Younger.

Mr. YOUNGER. Thank you, Mr. Chairman.

I want to thank you, Mr. McMullen, for I think you have rendered a very good service to the committee in getting this information.

I have one question. Do you think that merely by controlling the manufacturer in his shipments and the mail orders that we could control the distribution of the drugs?

Mr. McMULLEN. I don't know whether I can hypothesize on that or not, sir. Certainly increasing control of the manufacturer I would imagine would result in a greater control of these drugs right down

the line, from the manufacturer to the drugstore and the shipment channels. I would say this, and I think perhaps it ought to be said in fairness to some of the companies that we did business with, so to speak, there did seem to be, and it is my impression, in some ways the Federal law, as presently constituted, is unclear to some of the drug manufacturers that we dealt with, or was at that time.

My impression is that generally there were three groups of manufacturers that we dealt with. One group was primarily the larger companies who were, I would say, quite sophisticated in terms of the law, in terms of the potential danger of these drugs getting out into illicit hands.

I think these were the companies for the most part that wanted to send around a sales representative before even doing business for us. Of course, that stopped us from doing business with them. I would say the second group, which was the larger of the three groups, consisted primarily of companies that were legitimate and had good intentions, but I would suspect from the correspondence were not as familiar with, one, the potential problem; and, two, the law, to the effect that they were either confused by the law or simply were not as well acquainted with the law as they might have been. I would say that the third group might fall in a more nebulous category as to intentions.

They may have known about the law and may have had knowledge of the potential harm of these drugs getting into the wrong hands but were willing to do business anyway.

I would say those are the three groups, I would say that by and large the manufacturers have no desire to effect the release into illicit hands, judging from the correspondence that we had.

Mr. YOUNGER. I did not get your last statement.

Mr. McMULLEN. I would say that the great majority of the companies that actually did business with us did not want to effect, intentionally effect, the release of their merchandise into illicit hands. They did not do this knowingly.

Mr. YOUNGER. How could you come to that conclusion when they would sell you 100,000 pills without any inquiry at all as to whether you were a legitimate dispenser?

Mr. McMULLEN. Well, sir, I am largely basing my statement on their statements made after the program, which were to the effect that some clerical errors had been made, in some cases, and others. Whether you believe this or not but this is what they said—and I happen to believe what many of them said.

Mr. YOUNGER. I think you are very generous with them. We may differ between the two of us as to their intentions.

That is all.

The CHAIRMAN. Mr. Friedel.

Mr. FRIEDEL. Mr. McMullen, that was a very informative film and I think a public service was rendered. You are to be complimented.

Without revealing the name, do you know the name of the company that notified the New York inspectors?

Mr. McMULLEN. Yes, sir.

Mr. FRIEDEL. Was that one of the companies in the third group?

Mr. McMULLEN. That company I think I can reveal, because the company was mentioned in the film. We went by it rather quickly. It was the Kirkman Laboratories.

Mr. FRIEDEL. Were they the ones that notified the New York inspectors, trying to cover up because of their looseness in sending you these pills?

Mr. McMULLEN. No, sir. They did not ship to us. They did what I think the Food and Drug Administration would agree was quite proper. They, having received our request for drugs, then contacted the New York State Board of Health to determine whether we were licensed and, in effect, whether we were authorized to receive these drugs.

When the New York authorities informed this company that we were not authorized, we received a letter from the company stating that they could not ship to an unauthorized wholesaler.

Mr. JARMAN. Would the gentleman yield?

Mr. FRIEDEL. I will.

Mr. JARMAN. Was that the only company that took such precautionary steps?

Mr. McMULLEN. We really don't know. We stated in our broadcast that we do not know how many of these companies attempted to check on us one way or the other. This is the only one that we know about.

The CHAIRMAN. Mr. Devine?

Mr. DEVINE. When did you conclude this experiment, Mr. McMullen?

Mr. McMULLEN. We concluded the experiment when the New York inspectors knocked on the door.

Mr. DEVINE. I know that, but approximately what date?

Mr. McMULLEN. It was August 14.

Mr. DEVINE. About 6 months ago?

Mr. McMULLEN. Yes, sir.

Mr. DEVINE. Do you know whether or not any citations of any type have been issued against any of these companies who shipped without authority?

Mr. McMULLEN. No, sir; I don't.

Mr. DEVINE. You have no knowledge?

Mr. McMULLEN. No. I would say this: We did conduct some surveys with the States trying to ascertain, so far as State law was concerned, whether there would be a breach of State law if a company within a particular State, a drug company within a particular State, shipped to an unauthorized person outside of that State. I do not recall a single instance in the replies of the States to the effect that this would be a breach of State law.

Mr. DEVINE. When the New York inspectors became aware of your operation, do you know whether or not the Food and Drug Administration here in Washington were made aware of your findings?

Mr. McMULLEN. They were certainly made aware of our findings. After we had been in operation about a month, we had still not received any pills, but we had been on a fishing expedition, so to speak. We informed the Food and Drug Administration that we were engaged in this project.

Mr. DEVINE. They had foreknowledge, then, prior to your receiving these pills?

Mr. McMULLEN. Yes, sir.

Mr. DEVINE. Was that kind of an insurance policy for yourselves?

Mr. McMULLEN. I would say that we didn't consider it an insurance policy because the Federal statute, I believe, requires wholesalers who repackage to register with the Food and Drug Administration. McMullen Services did not repackage and, consequently, we were not concerned about breaching the Federal law. However, we did feel that we wanted to inform them.

Mr. DEVINE. I think you should be commended for your effort. Again, I would like to ask you, Do you have any knowledge of any kind whether or not any citations have been issued by either State or Federal authorities in connection with the shipments?

Mr. McMULLEN. No, sir; I am afraid I do not.

The CHAIRMAN. Mr. Macdonald.

Mr. MACDONALD. I just have one question, Mr. McMullen.

In your statement after the film, I thought you said, and I will ask you now if you did say, that after you closed down the operation of the experiment, or the public service, whatever label you want to put on it, that you were solicited to continue to do business with some drug firm?

Mr. McMULLEN. Perhaps I didn't make that clear. We had other orders out, and I felt—that is, before the State inspectors came, we had a number of orders pending; companies had accepted our checks, for example, and our orders, and had promised to ship—I felt that once the State inspectors arrived that our experiment was over and it would not be quite cricket to count the other shipments.

As it turned out, one shipment was enroute at the time the broadcast went on the air, and the particular company stopped that shipment. It was a rather large order for 161,000 pills. But I didn't feel that it was quite proper to count that in, and we did not.

Mr. MACDONALD. At any time did any company, once you put out your feelers, send letters soliciting your business, or did you send letters to each drug company?

Mr. McMULLEN. We were a brandnew company and, fortunately, it wasn't generally known that we were in business. We were not advertising. We, in answer to your question, did all the soliciting to the extent that we asked for price quotations on drugs from various companies. We went to them. They did not come to us.

Mr. MACDONALD. No company ever came to you?

Mr. McMULLEN. That is right.

Mr. MACDONALD. Thank you.

The CHAIRMAN. Mr. Keith?

Mr. KEITH. Thank you, Mr. Chairman.

Are there any other significant areas in which you feel the law is not being enforced, of a parallel nature?

Mr. McMULLEN. I am not quite certain that I understand your question.

Mr. KEITH. I can remember as a high school student a science teacher, Stephen Cote, who had a hobby writing to firms that advertised drugs and had testimonials accompanying the advertisements. He would write to the individuals whose names were used in the testi-

monials to find out if their name was used without their permission or if the individual in fact existed, or whether or not there was misrepresentation of the facts. Is there any law pertinent to that kind of activity that you know of?

Mr. McMULLEN. Insofar as misrepresentation is concerned?

Mr. KEITH. Yes.

Mr. McMULLEN. No, I would think not. One of the things, however—since I think the thrust of your question had to do with the law itself—is that I would say this: Insofar as registration with the Food and Drug Administration is concerned, what seems to be required, presently, is merely stating your name, address, the name of your company.

If I am a wholesaler, and I wish to state that I am a wholesaler, I register with the Food and Drug Administration, state my name, address, and place of business. Within a period of 2 years, the Food and Drug Administration is required, I believe by statute, to check on me. But because of the FDA's limited personnel, conceivably such a check would not be made until the second year, and perhaps in some cases late in the second year. This would mean that an illicit operator could register with the Food and Drug Administration and when the drug companies requested his registration number, he could give them his registration number, and every 6 months or so change his registration number by registering under a new name, going out of business after 6 months and going into business again under another name. Say he did this for a year. It might make it a little difficult for the FDA inspectors.

Mr. KEITH. Did you make any effort to correct this weakness in the law prior to taking the action that you did?

Mr. McMULLEN. Any effort to correct the weakness in the law?

Mr. KEITH. Yes. In other words, did you, by chance, confer with the Food and Drug people and suggest that they might conduct an experiment such as you did?

Mr. McMULLEN. No, sir. We are not in the business of suggesting legislation or enforcement action. I hope that the public service we may offer is in the area of enlightenment in terms of matters the way they presently stand. What action need be taken is certainly up to those who have the authority and the interest to do so.

Mr. KEITH. You pointed out, I believe, the figure of \$670 as a total cost.

Mr. McMULLEN. That is correct.

Mr. KEITH. And the retail value was how much? Not the black market, but the retail.

Mr. McMULLEN. I don't know that we quite broke that down. What we said was that we paid an average of 6 cents per hundred, and that the retail drugstore cost was around \$5 per hundred. That varies to some extent. We took the lowest figure that we found, as I recall. The drug prices in some cases went up to \$8.

Mr. KEITH. Do you believe there is a great deal of significance to that phase of your enlightening process?

Mr. McMULLEN. I do, sir, because I think that it indicates that this is an area where large profits may be made by those who wish to engage in the business, those who wish to engage in an illicit business.

Mr. KEITH. But there are legitimate and large profits that are made in that same area.

Mr. McMULLEN. I, of course, am in no position to speak in terms of the profits that are made because I am not familiar enough with overhead costs, et cetera, and I really couldn't comment on that.

Mr. KEITH. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mr. McMullen, I think you have pointed out very vividly for us the point we were developing with the manufacturers the other day, and that is that in the law it is not now required for the wholesalers to furnish a registry number to the manufacturer before he fills the order. I, for one, plan to offer an amendment to do that.

I wonder if in your studies you went further, without putting it in your film. Did you see where the drugs could be funneled out into an illicit market? Did you make any study along this line? What was your finding there?

Mr. McMULLEN. We did make what I would call a cursory study of that. We contacted numbers of persons who claimed to be barbiturate or amphetamine addicts. We talked with them concerning where they had obtained these drugs. We also began a survey of the States to try to determine from the States whether the problem was increasing in terms of harmful effects within the State.

In answer to that particular question—this is probably rough, but this is my recollection—18 States said the problem was increasing considerably. I think three or four States said they thought it was diminishing. The majority or the remaining States said they simply had no way of gaging.

Mr. ROGERS of Florida. What I was trying to get at is when you talked to these addicts in trying to find out where they were purchasing, I wondered if you had gone into the problem of where a man like the McMullen Services, but operating illicitly, would funnel out those pills. Would they go to truck stops, or what was your finding there?

Mr. McMULLEN. We did find—and I will not take credit for this as it is rather common knowledge—we did find that some of these pills were being sold at truck stops. We found that some of them were being peddled in bars and in nightclubs. Some also were being peddled on the street.

The question would remain: Where did the peddlers obtain these pills? The closest we got to that was that there was a wholesaler of some sort who was providing these, but I did not actually have the time to try to track such an individual down, somebody who was there.

Mr. ROGERS of Florida. So a person who would sell, say, in a bar, or a truck stop, would get his supply from a wholesaler, or is there a regular traffic in that?

Mr. McMULLEN. I think it is, for me, very difficult to make any categorical statements about how it works.

Mr. ROGERS of Florida. I just wondered if you had found any pattern.

Mr. McMULLEN. I would think the answer to that is, "No, I did not find any pattern." I found perhaps a few instances of the way things work, but as for pattern, I don't think that we really did a thorough investigation of that.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Curtin?

Mr. CURTIN. Thank you, Mr. Chairman.

You say, sir, that your research indicated these pills were sold in drugstores for from \$5 to \$8 per hundred, and you say you also found that they were sold illicitly in bars and truck stops and perhaps on the street. Did you find out what these pills were sold for in the illicit market?

Mr. McMULLEN. Not by the same purchasers. The cost in the black market was considerably more and, again, varied, I would say, up to five times or six times. We did not make, again, as comprehensive a survey on that as I would like to have made.

Mr. CURTIN. Are they sold in the black market to these purchasers in quantity, such as 100 tablets, or just in very small quantities, as for example, 2 or 3 tablets?

Mr. McMULLEN. Sometimes they are sold in small quantities of 5 or 10 tablets; other times they are sold in perhaps 100 or 200. Sometimes, as I understand it, they may be obtained in drugstores if the addict has a friend in the drugstore who will sell to him. In that case, the amounts would probably be 25 or 30 tablets, something to that effect. But certainly not 15,000 or such as that.

Mr. CURTIN. Thank you.

The CHAIRMAN. Mr. Kornegay?

Mr. KORNEGAY. Mr. McMullen, let me, with my colleagues, congratulate you on a fine public service.

Pursuing Mr. Rogers' question a little further, is it your feeling or was it your feeling that you would have any difficulty in disposing of this large quantity of barbiturates that you purchased through illicit channels?

Mr. McMULLEN. Of course, I think the only honest answer to that is that I didn't try, so I cannot say that it would have been easy. I do have the impression, as gleaned from talking to addicts and users of these drugs, that a wholesaler would have no problem selling them.

Mr. KORNEGAY. And getting rid of the large quantity that you had in a relatively short time?

Mr. McMULLEN. It is possible that the wholesaler would parcel these out; that is, he wouldn't give any particular peddler a million pills. He might have a middleman who would distribute or who would parcel them out to peddlers in smaller amounts. I would suppose that that is the way this would be handled.

Mr. KORNEGAY. Thank you.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Broyhill?

Mr. BROYHILL. Mr. McMullen, I, too, join my colleagues in commending you for this very valuable information presented to the committee and the American public.

You have just indicated that your investigation showed that certain addicts obtained these pills at the retail drug level. Does your experiment or your investigation show that any great number of pills are getting out of the legitimate channels of trade and into the "black market" at the retail drug level?

Mr. McMULLEN. No, sir; I didn't mean to indicate that we had done an investigation of pills getting out at the level of the pharmacy. We

did not do such an investigation. My statement was based on what we had been told by numbers of addicts and was not based on a comprehensive, firsthand examination.

Mr. BROYHILL. No further questions, Mr. Chairman. Thank you.

The CHAIRMAN. Mr. Van Deerlin?

Mr. VAN DEERLIN. I know, Mr. McMullen, this was not the principal objective of your study, but I think it is extremely noteworthy that if the figures you have offered are correct—and check my inadequate mathematics if they are not—at an increase of \$5 per hundred on retail, from the 6 cents that you were talking about, is a markup of about 8,000 percent, and if your estimate of the black market value is correct, of five times that, then we are talking about a markup of over 40,000 percent in the black market.

We may be putting our finger on the very real motivation that makes this traffic so difficult to eradicate. Those markups would tally with your figures; would they?

Mr. McMULLEN. I believe that is the way it comes out. I would say this: That insofar as the black market price of these drugs is concerned, the Food and Drug Administration is certainly the central authority on this. We did not do any buying of these drugs in the black market, and I cannot testify firsthand as to what their price is.

We did lean pretty much on what not only the Food and Drug Administration said, but what some of the narcotic bureaus and police departments reported to us as the price of some of these pills. It was on that basis that we stated that their black market value might be \$250,000.

Subsequently, I think, as you heard, a spokesman for the Food and Drug Administration said that the value might be as high as a half million dollars. I have no way of knowing specifically whether the value was that high, but that is what they believed.

Mr. VAN DEERLIN. These are largely prefabricated pills? There wasn't any work to be done on them by a pharmacist in most cases?

Mr. McMULLEN. Most of them were, but we did buy some powder. This would be in the raw form. We made inquiries as to how difficult it would be to convert this powder into pills, if this was an extremely difficult process, as, for example, it is difficult to convert morphine base into heroin. This is a very intricate business that requires a good knowledge of chemistry.

If this had been the case, perhaps it would not have been pertinent to buy powder. We were assured that it is not difficult to convert this powder into pills. There are machines that apparently are inexpensive where you can just crank these pills out. That is my understanding.

Mr. VAN DEERLIN. Thank you.

The CHAIRMAN. Gentlemen, I think we will have to go to the House. Is there anyone who cannot be back at 2 o'clock?

Would it inconvenience you to come back at 2 o'clock, Mr. McMullen?

Mr. McMULLEN. No, sir.

The CHAIRMAN. If you will do that, it will let us go over to the House. We will get permission to sit during general debate this afternoon. We will come back and conclude with you at 2 o'clock. Then we will have Dr. Griffith.

The committee will recess until 2 o'clock.

(Whereupon, at 12:10 p.m., the committee recessed, to reconvene at 2 p.m. the same day.)

AFTER RECESS

The CHAIRMAN. The committee will come to order.

Mr. McMullen has resumed the stand.

Mr. Pickle, do you have any questions?

Mr. PICKLE. Mr. McMullen, I wanted to ask you if in your contact with the various suppliers that you mentioned this morning—do you know whether they were required to have a license or be registered within their own State?

STATEMENT OF JAY L. McMULLEN, CBS NEWS—Resumed

Mr. McMULLEN. We made a check on the various State requirements and found that quite a number of States do not require either registration or license number. My recollection is that insofar as the companies who sold to us are concerned, some were in States that did not require either licensing or registration.

Mr. PICKLE. In those States which do require registration or licensing, is it not possible that they could apply for a license and go ahead and operate until some time later before they are apprehended?

Mr. McMULLEN. Sir, I am speaking of the manufacturers and producers. Insofar as wholesalers are concerned—and I gather now that the thrust of your question has to do with the wholesaler rather than the manufacturers—insofar as wholesalers are concerned, the same thing that I said before would apply to them. Some are required to register in some States, that is, wholesalers are required to register in some States, and other States they are not.

Mr. PICKLE. This is true of manufacturers likewise; is that not correct?

Mr. McMULLEN. Yes, sir; that is correct.

Mr. PICKLE. Then, in your opinion, there is a considerable laxity with regard to the licensing or registering of both manufacturers and wholesalers within respective States?

Mr. McMULLEN. I would certainly say there is a discrepancy in terms of some States requiring this and others not requiring it.

Mr. PICKLE. For my own information, what is the requirement with reference to FDA regulations when a manufacturing concern, although it may be perfectly legitimate, goes into business and they are required to register with FDA? Is this a matter of simply writing to FDA and telling them that they are in business and they can operate just the same, or must they get that registration first before they can ever go into business? Do you know?

Mr. McMULLEN. I really do not know the answer to that question. I believe that they must register. I am not certain when this provision went into effect. It is possible that some companies were in business before it did go into effect and, consequently, they would then have to go and register after the fact, so to speak.

Mr. PICKLE. One official testified, I believe, that the FDA would inspect these various establishments on an average of once every 2 years, so it is possible, then, that even though a concern might submit

its registration under FDA, they would have several months to operate and accumulate all kinds of medicine in the meantime, before they were ever visited or inspected; is that correct?

Mr. McMULLEN. In the case of a wholesaler as opposed now to a manufacturer who produces these amphetamines and barbiturates, it would seem, on the basis of our study, that a wholesaler could be in business for a considerable time before he would be checked by the Food and Drug Administration.

Mr. PICKLE. That is all, Mr. Chairman. Thank you.

The CHAIRMAN. Mr. Huot, have you any questions?

Mr. HUOT. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Ronan, have you any questions?

Mr. RONAN. No questions.

The CHAIRMAN. Mr. Gilligan?

Mr. GILLIGAN. Mr. Chairman, thank you.

I have just one question of you. You recounted the story of, because one of these wholesale drug firms had talked to the New York authorities, that two inspectors from the State of New York visited your office, grim faced. Was there any suggestion of what they could do to you, or did they explain it, or do you happen to know?

Mr. McMULLEN. If the circumstances had been entirely different, and if, in fact, we had been operating for commercial rather than educational purposes, there was certain action open to them. Under the circumstances, the inspectors, and in fact the State board of health, expressed considerable gladness that we were not in fact black-market operators, and they also expressed the view that what we were attempting to do would be in the public interest and have an educational nature.

Mr. GILLIGAN. I understand that, of course. But suppose you had said to them that you had bought \$600 worth of pills and you collect pretty pills like some people collect stamps. Short of being able to prove a sale on your part, is there anything under the New York law to forbid your possession of these drugs?

Mr. McMULLEN. Yes. New York has a statute concerning illegal possession. What the inspectors did say to me, however, which may be of interest to you, is that they may have had a good deal of difficulty in proving—assuming that we were a commercial black-market outfit, which we were not—they may have had a considerable difficulty in proving a case because it would be difficult, since wholesalers are not required to keep records, for them to ascertain to what extent we were in business, and if they could not find on our premises the drugs and could not find any records, they would be hard pressed to prove a case.

Mr. GILLIGAN. That is the point I was leading to. This bill before us does require or would require, if adopted, the wholesaler, among others, to keep records of the receipt and disbursement of certain types of drugs, including the barbiturate and amphetamines.

The other question that I had in mind, again using the figures which you gave us of something like \$600 worth of drugs being worth in the neighborhood of a quarter of a million dollars on the black market, is the bill provides, on the first offense, a fine of \$2,000 and/or 2 years in prison, and \$15,000 on the second offense with up to 6 years in prison.

Do you have any opinion as to the balance between the penalty offered under this law and the really astronomical profits which apparently are available to this kind of trade?

Mr. McMULLEN. I am, of course, not a lawyer. I am not sitting in a position of having to make this kind of judgment, with access to information from different sources. I don't consequently, know that I am very qualified to pass on whether that penalty would be sufficient or not. I don't think that I have any particular expertise in that area.

Mr. GILLIGAN. Thank you. No more questions, Mr. Chairman.

The CHAIRMAN. Mr. Murphy, have you any questions?

Mr. MURPHY. Mr. McMullen, I would like to congratulate you on a real public service and a graphic presentation of your program. I noted that one Florida firm that you ordered the drugs from had them shipped from a New York firm to your office. Did it occur to you that that transaction probably did not involve interstate commerce?

Mr. McMULLEN. Did not involve interstate commerce?

Mr. MURPHY. Yes.

Mr. McMULLEN. It did not occur to me. The transaction as I understand it, was basically between McMullen Services and the company in Florida. The company in Florida made arrangements for the actual delivery through, apparently, communications with a firm in New York for actual delivery.

I think I recognize your point, however, which is that, in effect, the materials that we received did not cross a State line. Is that your point?

Mr. MURPHY. That is right. It probably was an economy in transportation costs as well as the fact that none of these drugs did cross a State line, and it probably would not come under this particular act in that type of transaction.

Mr. McMULLEN. That I don't know, but those are the facts of the matter, in any case.

Mr. MURPHY. No further questions, Mr. Chairman.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. No questions.

The CHAIRMAN. Mr. Staggers, have you further questions?

Mr. STAGGERS. No, Mr. Chairman.

The CHAIRMAN. Mr. McMullen, we want to thank you on behalf of the committee for your appearance here and the contribution you have made to this hearing. It has been a very great one and we are grateful to you.

Mr. McMULLEN. Thank you, Mr. Chairman. It is a pleasure to try to be of help to your committee.

The CHAIRMAN. You have been very cooperative and we appreciate it very much.

Mr. McMULLEN. Thank you, sir.

(The following matter was submitted for the record:)

CBS EVENING NEWS WITH WALTER CRONKITE, SEPTEMBER 2, 1964

CRONKITE. One of the unsolved and major evils of our modern American society is narcotics addiction. And today it frequently begins—and ends tragically—in the use of the seemingly innocent pep pills and goof balls—properly barbiturate drugs and amphetamines. Their overuse leads to addic-

tion to them—and withdrawal can be more painful and more dangerous than withdrawal from more notorious drugs. Their overuse leads frequently to the use of other drugs. There overuse leads to crime and debasement. When misused by drivers fighting drowsiness the result has been death on the highways.

Yet pep pills and goof balls are easy to come by. They are peddled at candy stores and filling stations and dozens of other outlets.

The law—Federal and local—is inadequate in most cases to deal with the problem, mostly because the supply of the drug cannot be cut off.

The Federal Food and Drug Administration estimates that at least one-half of the legitimate production of these drugs is being diverted and sold in the illicit market.

We wondered just how difficult it is to secure from legal channels mass quantities of barbiturate and amphetamine drugs—pep pills and goof balls. A CBS news factfinding unit has just completed a 4-month investigation of that question. Here is what they found, reported by Producer Jay McMullen.

McMULLEN. First we found that in many States wholesalers of barbiturates, amphetamines, or other prescription drugs are required to obtain a license and to keep records of purchases and sales. Those who repackage and sell in interstate commerce are generally required to register with the Food and Drug Administration and—according to the FDA—manufacturers should check on the legitimacy of a new wholesale buyer. But to what extent can a would-be wholesaler without registration or license number purchase quantities of amphetamines and barbiturates from legitimate producers or manufacturers?

To find out we created McMullen Services. In New York City on May 4, 1964, McMullen Services rented an office in this building at 35 West 45th Street. In room 605 we began operations. We ordered 250 letterheads and envelopes. The letterhead included our telephone number, which was not listed in the telephone directory, and the words "export-import." At the First National City Bank of New York we opened a regular checking account. Next we bought a copy of the Drug Topics Red Book. This book lists drug manufacturers that sell barbiturate and amphetamine drugs.

Then we sent out letters to 24 companies in 11 States requesting their catalogs. We received price catalogs with no questions asked from 17 of the 24 drug companies contacted. We eliminated five of these because they have sales representatives in the New York area who could easily check on us. That left us with 12 companies—and we placed orders with all of them.

In Philadelphia Richlyn Labs said no sale unless you send us your FDA registration number. But Harvey Labs asked us no questions; promptly shipped us a carton in response to our order for 40,000 phenobarbital tablets. Jan Laboratories—also in Philadelphia—filled our order for 2 pounds of amphetamine sulfate powder and 4 ounces of phenobarbital powder.

In Worcester, Mass., Cowley Pharmaceuticals asked us no questions and shipped us a carton invoiced for 100,000 phenobarbital tablets and 5,000 amphetamine capsules.

In Chicago, Savoy Drug refused to ship without receipt of our license number as did Bates Laboratories, which demanded our FDA registration number. But Maizel Laboratories did not check with us, and filled our order for 5,000 vials of phenobarbital.

In Portland, Oreg., Hack Laboratories responded to our order for 25,000 phenobarbital tablets.

In Baltimore, Md., the Barre Drug Co. asked for our State license number, but Carroll Chemical did not question us and filled the order of McMullen Services for 50,000 phenobarbital tablets.

In Miami, Fla., we placed an order with Zirin Laboratories. Zirin accepted the order without question. But the actual shipment, 5 pounds of amphetamine powder—equal to 441,000 5-milligram tablets, came from Hexagon Laboratories, in New York City. Hexagon—a producer of amphetamine powder—did not question McMullen Services.

By the first week of August 1964, McMullen Services had received total shipments for the equivalent of 297,000  $\frac{1}{4}$ -grain phenobarbital tablets and 628,000 5-milligram amphetamine tablets. They came from 58 percent of the companies with which we placed orders.

In a mood of confidence McMullen Services then wrote to 27 more companies. This time we asked for direct price quotations on generally larger amounts of amphetamines and barbiturates. Only 13 of the 27 companies complied with our requests. We placed orders with seven of them.

From Canton, Ohio, Bowman-Braun Pharmaceuticals shipped a carton labeled 75,000 phenobarbitals. From Buffalo, N.Y., Direct Laboratories also sent us a shipment invoiced as 75,000 phenobarbital tablets. But Barry-Martin Pharmaceuticals in Miami and four other companies refused to ship—unless McMullen Services presented an authorization.

Kirkman Laboratories in Seattle, Wash., went further. It asked the New York State Board of Pharmacy whether a license had been issued to us. The board sent two rather grim faced inspectors to pay a surprise visit to McMullen Services.

The books of McMullen Services are now closed. We have not opened the cartons we received. We have asked the Food and Drug Administration to do that—in order that their contents may be officially inspected and tabulated. We believe that we received the equivalent of 1,075,000 pills. Our total cost: \$600.28 or about 6 cents per 100 pills. Their price in retail drugstores: about \$5 per 100. Experts estimate that the value of 1,075,000 pills sold in the black market is between \$250,000 and \$500,000.

To purchase these pills we had contacted 51 companies; placed orders with 19 of them. We do not know how many of the companies we contacted attempted to investigate us. We do know that by the time the State inspectors arrived, 47 percent of our orders had been delivered by companies in eight States. Just how difficult is it to purchase mass quantities of dangerous drugs? The facts speak for themselves.

CRONKITE. Today the unopened cartons that McMullen Services received were trucked from New York to Washington and were delivered to the Food and Drug Administration.

There they will be opened, and to keep the record clear, the drugs will be analyzed.

Tomorrow we'll report on the results of that analysis and talk with Federal officials and Congressmen who are concerned with this matter.

---

“CBS EVENING NEWS” WITH WALTER CRONKITE, SEPTEMBER 3, 1964

CRONKITE. Last evening, you'll recall, we presented an exclusive film report by the “CBS News” factfinding unit on black market traffic in pep pills and goof balls—or, as properly known, barbiturates and amphetamines. We wanted to find out how difficult it would be to obtain mass quantities of these drugs through legal channels. Producer Jay McMullen set up a bogus company and nine of the firms he contacted sold him the drugs, without any questions. For an outlay of \$600, he got more than 1 million pills, which could be sold on the black market for more than \$250,000. We turned over the unopened cartons of drugs to the Food and Drug Administration in Washington. Reporter McMullen followed the story there and here's his report.

McMULLEN. We are with Mr. Louis Lasher, assistant to the Director of Field Operations Food and Drug Administration. Mr. Lasher, yesterday, on behalf of the FDA, you received the unopened cartons that were delivered by McMullen Services. Obviously you've opened some of these cartons; precisely what steps have you taken?

LASHER. We opened the cartons and determined that the cartons contained a number of containers of drugs. To this point the analysis has confirmed that the drugs are amphetamines and barbiturates, and that the amounts of amphetamines and barbiturates say in each capsule or tablet are, as indicated on the product's label.

McMULLEN. How many pills would be in a bag like that one before us there?

LASHER. That bag probably contains 75,000 to 100,000 tablets.

McMULLEN. Well, we believe and have so stated that we obtained the equivalent of approximately 1,075,000 amphetamine and barbiturate pills. So far, would this seem to check out with your tabulations?

LASHER. Yes.

McMULLEN. Would you think that our estimate of the possible black market value of these drugs totaling perhaps \$250,000 would be out of line?

LASHER. I would say that the black market value of the drugs turned over to us would range from \$250,000 to \$500,000 worth.

CRONKITE. Just as in the case of other drugs, the overuse of pep pills and goof balls can lead to the addiction that turns life into a nightmare. To get a description of the warning signs, “CBS News” Correspondent Dave Dugan talked with

Dr. Robert Baird, a New York physician who spends a lot of time working with addicted youngsters.

DUGAN. Dr. Baird, what are the physical effects on someone who's taking pep pills or goof balls?

BAIRD. Well, the classification of two different things—the pep pills are the amphetamines, such as dexamine and benzadrine, and what the individual goes through in many—they have this fast heartbeat which the youngsters would be aware of, a fast pulse in the knuckles, feels like their heart is trying to get out of their chest. They are extremely apprehensive, very anxious, they are extremely suspicious of people, they can't go to sleep at night, they stay up all night, they lose their appetite, there's tremendous loss of weight. Just by way of illustration, some of those I've seen—I've had them in my office—one particular youngster I recall I had seen thought he saw, right in my office here, red alligators and green rats running around the office. Another fellow told me that every night before he'd go to sleep he would use a knife and stab the sleeping hamper because he was sure there was someone who was staying there. Another chap believed that a red car was following him all day, so they had these delusions of paranoia that someone was chasing them. That is on the dexedrine, the weight-reducing pills.

DUGAN. Yes.

BAIRD. Then with the goof balls—those are the barbiturates—those pills the individuals are extremely sleepy, very lethargic, but before they get to that stage, they go through a stage of being very animated, sometimes very hostile, very suspicious, they pick a fight with individuals.

CRONKITE. The shadow on the office wall is that of a young man who learned about barbiturates the hard way.

DUGAN. Did you have any idea when you started out what the results would be?

SHADOW. No, I didn't. I had no idea of it at all. In fact, I made a purchase from one of the fellows in the neighborhood. I purchased three goof balls for a dollar, and I wasn't aware of what these things would do to me. And I was told to take one, or possibly two and you'd get real high and feel great. I took just that, but I also had a few drinks besides and on the way home I managed to hit two parked cars, and I got into trouble with the police. And this is one of the side effects of goof balls.

DUGAN. How serious did it get? How bad did you feel taking these things?

SHADOW. Well, I felt that I was awake and I knew what I was doing and yet my reflexes wouldn't respond. And when I tried to walk—my equilibrium—I would bump into things and I had no control over myself. And plus the aftereffect, after this drug has worn off is like you're coming off a weekend binge, a hangover.

DUGAN. How does it feel to be clean, as they say, not dependent upon pills any more?

SHADOW. To be in the gutter and to lift yourself up and look the world straight in the face again and live from day to day and know that you're clean and not using drugs and not using any sort of pills. You're just getting up every morning, going to work, eating a good meal and enjoying it, and to be able to communicate with people and—it's great. I can't find words for it, it's really indescribable. It's good to be alive again, let's put it that way.

CRONKITE. A number of authorities are convinced the only way to cut down on this illegal traffic is to give Washington greater supervision over drug manufacture and sale. A bill sponsored by Senator Thomas Dodd, of Connecticut, and passed by the Senate would require manufacturers, among other things, to disclose all sales to the Federal Government. "CBS News" Correspondent Charles Von Fremd talked about the bill's prospects with the Senator.

VON FREMD. What is the progress of this bill now?

DODD. I introduced that bill back in March of 1961. It's passed the Senate; it's now in the House, where it is meeting the undercover opposition, opposition that never appeared when we held our hearings in the Senate. And this makes it very difficult for us to get the bill through this year.

VON FREMD. Have you been aware of the lobbyist strength in this particular field?

DODD. I sure have. I've learned of it in a couple of other fields, too. And it is powerful, it is strong. They don't come forward—we invited everyone who wanted to be heard on this bill to come forward, for over a year and a half we heard witnesses. None of these people ever showed up; that isn't how they

work. They work underneath in a sinister manner, and they block these measures despite the fact that a vast majority, I believe, of our people in this country want this bill, for example, and others like it passed. It's a frustrating experience to fight this kind of opposition. It's just what I said it was, it's a national scandal. Now I'm suggesting, and those associated with me like Senator Hart and other Senators, just give us the simple information, how many are produced, who do you sell them to. What a little thing to ask. And yet we run into a stone wall of opposition.

CRONKITE. Senator Dodd's bill now is in the House Commerce Committee, and up to now, it has been given little or no chance of getting out this year.

But as a result of our story, the situation was brought to the attention of both houses of Congress today.

In the Senate, Ralph Yarborough of Texas took the floor to urge House action so the measure could become law this year. A similar appeal came from New Jersey Congresswoman Florence Dwyer in the House.

CRONKITE. Tomorrow, we'll have a report on the reaction of the firms that sold the drugs to McMullen's bogus company.

Right now, Eric Sevareid has some thoughts about this revealing venture.

SEVAREID. The private enterprise success story of McMullen Services, export-import, proves once again that with imagination, a small amount of capital and hard work, any upstanding young American can become a financial success, if not necessarily a pillar of society.

His \$600 investment could have brought McMullen Services around \$54,000 had he sold his pills at going retail prices; over a quarter million had he sold them in the black market, where the youthful addicts get them.

All done by means of a nice little letterhead. In modern society the letterhead seems to have the same magical power as the king's seal in medieval Europe or the Roman eagle of antiquity.

Six cents per hundred pills at the manufacturer's level; an average of about \$5 per hundred at the retail druggists' level and far more than that at the level of the black market. That's a spread wide enough to accommodate middlemen in the middle of middlemen.

This couldn't happen, of course, without the universal lust to take drugs, one thing that distinguishes man from the animals. And without the careless craving for a new thrill, one of the things that distinguishes adolescents, the real victims here, from mature men and women.

Many years ago, Dr. Oliver Wendell Holmes told the Massachusetts Medical Society that if the whole materia medica were sunk to the bottom of the sea, it would be all the better for mankind and all the worse for the fishes.

He probably overstated his case. But the chemical revolution does seem to be backing up on itself. Chemistry, in the form of medicines and serums, has saved millions of lives and prolonged life expectancies, with many results including a population explosion now engulfing many countries, including our own. Maybe chemistry, by some law of nature or history, is now rectifying this situation—by the careless use of pesticides, the release of breathable fumes into the air of every big city, by polluting the rivers and parts of the sea, and by filling bodies with barbiturates, pep pills, and antibiotics—the final effects of which on the human system the next generation may discover, and may not like.

The CHAIRMAN. Our next witness will be Dr. V. D. Mattia.

I believe you are the executive vice president of Hoffmann-LaRoche Laboratories of New Jersey, Doctor.

**STATEMENTS OF DR. V. D. MATTIA, EXECUTIVE VICE PRESIDENT,  
HOFFMANN-LaRoCHE, INC., NUTLEY, N.J., AND DR. GERHARD  
ZBINDEN, VICE PRESIDENT FOR RESEARCH**

Dr. MATTIA. Yes, sir.

The CHAIRMAN. And I believe you might like to identify the person with you.

Dr. MATTIA. On my right is Dr. Gerhard Zbinden, our vice president for research. He is accompanying me in this presentation on behalf of the company.

The CHAIRMAN. You may proceed.

Dr. MATTIA. I am a physician, as is Dr. Zbinden. I received my training at New York Medical College. I am a fellow of the American College of Cardiology and of the American College of Angiology as well as a member of several other professional groups. Before becoming executive vice president, I served as director of medical research for Hoffmann-LaRoche, Inc.

Dr. Zbinden received his training at the University of Berne, Switzerland, and specialized in experimental pathology and toxicology. He is a member of the American Society of Pharmacology and Experimental Therapeutics, a fellow of the American College of Clinical Pharmacology and the New York Academy of Science, a member of the American College of Cardiology and various other professional societies.

We appreciate this opportunity to appear before the committee to strongly urge passage of H.R. 2. As Dr. Zbinden will discuss in greater detail, our company is perhaps unique in that it has manufactured or now manufactures every category of drugs which has been discussed in connection with this legislation.

Not only do we strongly support this bill, but we generally support the analysis of the problem given by Mr. Larrick, the Commissioner of the Food and Drug Administration. We are in accord, too, with the recommendations for amendments to the definitions made by the spokesman for the Pharmaceutical Manufacturers Association.

We had not originally intended to testify on this legislation. However, we concluded after reviewing the testimony in the first 3 days of the hearings that we were under a public obligation to submit to this committee our views on the problem with which this bill is intended to cope.

We should first make clear that this legislation imposes no responsibilities, requires the institution of no additional controls, and imposes no financial or administrative burden which Hoffmann-LaRoche has not long since imposed on its own operations of its own accord. Few changes in our procedures would be required by the passage of this legislation.

Furthermore, we expect minimal increases in our costs, or decrease in our sales, or change in the share of the market of any of our drugs, whether they are or are not subject to the controls established by this bill.

All these drugs are legally available only on prescription and they are prescribed by doctors on the basis of their suitability for the condition being treated. We expect that they will continue to be so prescribed when they are appropriate. We make every effort to insure that our drugs do not move in illicit channels and our efforts in this regard would be strengthened by this bill.

We want to strongly recommend to the committee that it retain the approach now followed in the bill, and endorsed by the Food and Drug Administration, in classifying the drugs subject to the new controls that are proposed. Scientific opinion supports, almost without dissent, the inclusions of barbiturates and amphetamines as a class in this legislation.

It is equally sound from a scientific standpoint to leave to the Food and Drug Administration the determination as to what other drugs

should be subjected to similar controls, after receiving the advice of an expert advisory committee and subject to the protections of a formal rulemaking proceeding.

One witness before this committee asked that the legislation cover additional nonbarbiturates and nonamphetamines by name. We are not here today to plead for or against any specific compound, but, rather, to point out the hazards of such a course of action.

This committee has one of the broadest fields of responsibility of any in the Congress. We do not believe that this committee will have enough time to assess all the scientific evidence necessary to pass judgment on such specific compounds. It is our opinion that men representing various scientific disciplines will have to be consulted by the Food and Drug Administration prior to passing judgment on the therapeutic agents in question.

This committee on several occasions in the past wisely provided statutory guidelines and then delegated responsibility to the appropriate administrative agency. The precedent has been set in the legislation dealing with pesticides, food additives, and color additives. In these three instances the statutory guidelines, plus the section 701(e) hearings, provided the basis for objective scientific determination so essential in these critical borderline cases.

The mechanics provided by this proposed legislation and supported by Commissioner Larrick and the Pharmaceutical Manufacturers Association will maintain rather than alter the competitive situation. The proposed advisory committee procedures, plus the procedures of section 701(e), provide the established mechanisms by which the Government can determine the scientific facts in the interest of the Nation's public health.

I find it difficult to believe that where there is conclusive evidence to warrant inclusion of a drug under this act that responsible manufacturers will oppose such measures. By the same token, where marginal cases exist, I believe, and believe very strongly, that discussions should be held with outside members of the scientific community and the determination of additional controls be through the procedures established in the bill.

A separate question has been presented to this committee. That is, whether the statutory standards for the inclusion of additional drugs should be a finding by the Food and Drug Administration that they have a potential for abuse, or whether it should require a finding that they are actually abused. In this connection, we would like to have Dr. Zbinden comment briefly on the scientific environment in which this question is presented.

Dr. ZBINDEN. Mr. Chairman, I am grateful for the opportunity to appear before the committee and to take part in this hearing on drug addiction, representing the research division of Hoffmann-La-Roche, Inc.

Our firm has been investigating and selling narcotics since 1909, barbiturates since 1922, nonbarbiturate hypnotics since 1943, and is today the largest producer of tranquilizing agents. It is thus certain that at least part of our products will be affected by this legislation.

Our research on amphetamines dates back to the 1920's. Today, the work on psychotropic drugs, both stimulants and depressants, accounts for more than 50 percent of our total research effort.

Both as research director and as a physician, I am personally responsible for making every effort to insure that our drugs are properly used and that the risk of injuries to patients are minimized. One important harmful effect against which we are constantly on guard is drug addiction, with its many tragic physical, mental, and socio-economic consequences.

It is for this reason that our research is directed toward developing not only more powerful, but also less addictive compounds in the broad field of psychostimulants and depressants.

My discussion will be limited to just two major points: (1) A clarification of the term "drug addiction" as far as the bill is concerned; and (2) a summary of the methods available by which we may determine whether or not and to what extent a drug has addictive properties.

1. Definitions of "drug addiction": In December 1963, the World Health Organization Scientific Group on the Evaluation of Dependence-Producing Drugs reviewed the problem of abuse of drugs—WHO Technical Report Series No. 287—and made the following statement:

Very commonly, both lay and legal language tends to apply the term "addiction" to any and every type of misuse of drugs outside medical practice, with the connotation of serious harm to the individual and to society and often with the demand that something be done about it.

The previous testimony has shown that this is indeed the case.

Since practically all drugs, from aspirin to cortisone, and from cough sirups to laxatives, are occasionally grossly abused by certain individuals, it behooves us to define as clearly as possible the kind of abuse or addiction this bill should cover and prevent. Certainly, the fact that a drug may have been misused to commit suicide, or the presence of toxic symptoms following administration of excessive doses to animals or man, should not be a criterion to include it among the addictive agents.

The experts of the World Health Organization have recognized these facts and stressed the point that the old definition of addictiveness which was developed to describe the addiction to morphine does not adequately characterize effects observed with other drugs. It therefore proposes the substitution of the term "drug dependence" for the term "addiction" with a modifying phrase linking it to a particular drug type and thus differentiating the characteristics of one class of drugs from another.

It is clear that the new bill will cover drug dependence of the barbiturate-type, and the amphetamine-type. The question which remains unresolved pertains to the possible inclusion of drugs which are not barbiturates or amphetamines but which may, due to certain similarities, produce a similar degree or type of drug dependence.

2. Evaluation of addictive properties of drugs: The various parameters which may be considered in evaluating the addictive properties of drugs are:

- (a) Chemical formula;
- (b) Pharmacological properties;

(c) Capability to substitute for a dependence-producing drug in animals;

(d) Direct addiction experiments in man; and

(e) Clinical experience.

(a) Chemical formula: It is generally recognized that it is rarely possible to predict the pharmacological activity and potency of a drug from the chemical formula. Minor changes of the molecular may markedly alter effectiveness and side-effect liability. Even in the series of narcotic drugs, agents have recently been discovered which have a chemical structure very similar to strongly addictive agents, but which have no addictive properties while retaining a marked analgesic effect.

(b) Pharmacological properties: It has been suggested in the medical literature that compounds having the same pharmacological properties as amphetamines and barbiturates are likely to produce similar type of drug dependence. In the group of the amphetamines, this theory has not yet been subjected to a practical test, because there are no compounds clearly different from the amphetamines with identical pharmacological properties.

There are, however, a small number of nonbarbiturate hypnotics which are pharmacologically very close to the barbiturates. Although it is probable that these drugs may produce a similar type of dependence as the barbiturates, the clinical experience today does not permit us to make this statement without reservation.

Our own experience with methyprylon, a hypnotic which has been widely used since 1955, shows that only a very small number of patients have developed psychic dependence—three reports in the literature; no additional reports in our files. This is much less frequent than one would expect with a barbiturate.

As far as the so-called tranquilizers are concerned, it is important to note that they differ very markedly from the barbiturates with regard to the quality of action and the site of attack in the brain. The pharmacological evaluation, therefore, does not give any reasonable and objective criteria which would give an indication of their dependence-producing characteristics.

(c) Capability to substitute for a dependence-producing drug in animals: Applying methods developed for narcotic addiction, investigators have recently tried to study the potential of drugs by testing their ability to suppress abstinence symptoms in animals which were made dependent on barbiturates. A large number of sedative and tranquilizing agents were found which were indeed capable of substituting for sodium barbital in dogs.

This method, however, does not support the claim that these agents have the same dependence-producing properties as sodium barbital, since these effects were attained only by heavy overdosage.

For example dogs were maintained on 100/mg./kg./day of sodium barbital, but required 400/mg./kg./day of chlordiazepoxide for suppression of the abstinence symptom. If one calculates the ratio of the therapeutic dose in man to the abstinence-suppressing dose in dogs, one obtains a figure of 20:1 for sodium barbital but 400 to 800:1 for chlordiazepoxide.

Thus, the physical dependence capacity of chlordiazepoxide is considerably smaller than that of barbital—a conclusion which is borne out by clinical experience. It should also be mentioned in this connection

that the drug "carisoprodol" was able to substitute in dogs for barbital but was absolutely ineffective in a direct addiction experiment in humans despite the use of several times the therapeutic dose.

(d) Direct addiction experiment in humans: It is known that repeated administration of small doses of narcotic drugs to humans will lead to physical dependence demonstrable by severe abstinence symptoms upon acute withdrawal of the drugs. The same technique has been used for barbiturates and related compounds, but with these agents, higher than therapeutic doses must be administered in order to develop physical dependence.

As expected, this repeated administration of excessive doses of these drugs often produces alterations of brain function and metabolism which manifest themselves as typical withdrawal symptoms upon sudden discontinuation of the medication. This does not prove, however, that such a compound has a high degree of addictiveness since its psychic dependence liability may be so low that it is rarely taken voluntarily in the excessive amounts which are necessary to produce physical dependence in the experiment. This, again, is borne out by the clinical experience.

(e) Clinical experience: As indicated above, nonbarbiturate sedatives and tranquilizing agents differ from the barbiturates not only chemically, but often also with regard to their pharmacological effect in animals and men. Often these differences are of a quantitative rather than qualitative nature, but nevertheless in many instances are so pronounced that significant advantages may ensue.

It is impossible to predict the impact of these differences on the drug's dependence-producing properties in man without the benefit of extensive clinical experience.

Prof. L. Goldberg, of the Karolinska Institute in Sweden, a consultant to the World Health Organization on drug addiction, has recently prepared the attached table which summarizes the clinical experience with seven classes of dependence-producing drugs. It is obvious from this table that there are marked differences among these compounds with regard to the risk of developing drug dependence. This risk factor ranges from 70 to 100 percent in the case of heroin, to one one-hundredth to one one-thousandth of 1 percent for amphetamine.

The table also shows that out of 1 million users of barbiturates from 200 to 500 will become dependent on the drug as compared to from 1 to 10 in the case of meprobamate. For some of the newer tranquilizing agents the figure is similar or below the one estimated for meprobamate.

This is unquestionably not due to a lesser availability of these drugs as compared to the barbiturates, but must in some way be related to a different quality of action which makes one type of drug less desirable or pleasurable to abuse than another. The incidence of dependence to psychosedatives should also be compared to alcohol for which Professor Goldberg estimates a figure of 5,000 to 20,000 per 1 million users.

The discussion about the evaluation of drug dependence liability of the various drugs may best be summarized by a statement taken from the report of the Scientific Group of the World Health Organization:

Whatever the agent, the recognition of psychic dependence is, for the most part, a matter of observation and judgment when it is actually used by man.

The experimental approach to the assessment of psychic dependence in both animals and man is just beginning, and no definitive statement regarding techniques or their predictive value can as yet be made.

(The table referred to follows:)

	Dependence created on therapeutic dose	Risk on use	Intensity of dependence -- psychic and physical	Severity of abstinence syndrom	Time to Dependence	Number or Frequency per million users
Heroin	yes	70-100%	++++	++++	1-7 days	2000
Morphin	yes	50-70%	+++	+++	1-2 weeks	50 - 150
Codein	?	0-10%	+ - + +	+	weeks to months	?
Barbiturate	no	0.1%	+ + - + + +	+ - + + +	months	200 - 500
Meprobamate	no	< 0.1%	+ +	+ - + +	months	1 - 10
Alcohol	"no"	2-3%	+ - + + +	+ - + + +	6-12 years	5000 - 20000
Amphetamine	no	0.01-0.001%	+ - + + +	?	months ?	1 - 100

Severe + + + +

Marked + + +

Moderate + +

Slight +

Prof. L. Goldberg, 12/5/1964

Dr. MATTIA. We hope that Dr. Zbinden's presentation will serve to explain why we favor the amendment proposed by the Pharmaceutical Manufacturers Association to require a finding of actual abuse of a drug before it is subjected to these additional controls. We support that position, quite simply, because we know of no basis to accurately determine a nonnarcotic drug's potential for abuse except for clinical experience demonstrating that it is in fact being abused.

But let us make one thing clear. However this issue is resolved by the committee, our company favors enactment of this legislation. Furthermore, however this question is resolved by the committee, it will have little or no competitive impact within the drug industry.

Finally, however this question is resolved by the committee, this bill will not eliminate drug abuse. If the much more stringent regulations of narcotics have been unable to stop illegal importation, it seems obvious that the measures of control provided by this legislation will be subject to similar limitations in the control of illegal importation of depressant and stimulant drugs. This is not an argument against the legislation, but only a plea that we be realistic in our expectations as to what it will accomplish.

This committee is concerned with a serious problem. Its solution will require public awareness, enlightened laws, vigorous enforcement, and the cooperation with governmental authorities by pharmaceutical manufacturers, wholesalers, and distributors, retail druggists, and the medical profession. This committee is making a significant contribution toward this multiple attack on the problem. Within our

more limited capacity, Hoffmann-LaRoche will continue to do everything within its power to contribute to its solution.

Thank you, Mr. Chairman.

The CHAIRMAN. Do you care to describe the table that is attached to your statement?

Dr. MATTIA. Dr. Zbinden touched on it in his presentation, and we wanted it placed in the record at that point, if we may.

The CHAIRMAN. Would you care to describe it a little more fully, Doctor?

Dr. ZBINDEN. This table was prepared to contrast seven different classes of dependence-producing drugs. In the first three lines we see typical classes of narcotic drugs, with codeine a borderline case. In contrast to the barbiturates—alcohols, amphetamines, and meprobamate—the narcotic drugs may cause drug dependence if they are given at the normal or therapeutic dose.

This is a very important difference as compared with the other class of drugs which have to be taken at much higher doses to produce addiction. As the witness this morning mentioned, these drugs have to be really abused in order to become addictive.

You also see in the next column the risk factor involved if these drugs are given over a substantial period of time, which ranges from 70 to 100 percent of the patients becoming dependent with heroin, to a very low figure; namely, one one-hundredth to one one-thousandth of 1 percent for amphetamines.

You also see that all these drugs cause various degrees of psychic and physical dependence symptoms. These are noted on the chart. A very marked difference also is shown in the time required to develop dependence. One can become a drug addict on heroin in from 1 to 7 days. It takes months to become a barbiturate addict and it takes years to become an alcoholic. For amphetamines this has not yet been determined.

Statistical evidence of the number of addicts as compared to the number of people using these drugs for regular use or nonmedical use is also shown. You can see that with heroin 2,000 people will become addicts out of a million users who try this compound once or once in a while. This compares with 5,000 to 20,000 who become dependent on alcohol, with the results with the other drugs somewhere in between.

It is very important to note that barbiturates account for 200 to 500 drug-dependent people in 1 million users, whereas, with meprobamate the number is only 1 to 10. Also, the users for meprobamate are probably lower. This shows that one cannot just talk about drug abuse any more. You have to differentiate from one compound to another. Every compound has to be taken individually.

As I also mentioned in my statement, it cannot be done just because of the chemical formula or the way it behaves in animals. Clinical experience has to tell you really whether the drug will be addictive and dangerous or whether it will not be.

The CHAIRMAN. Your table has already been placed in the record at the point you first referred to it.

Thank you, gentlemen, very much for your joint statement to the committee. It is rather technical, but I think even as laymen we are able to get a great deal out of it. It is a very helpful presentation.

Mr. Friedel, have you questions?

Mr. FRIEDEL. No questions.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

You are representing a manufacturer?

Dr. MATTIA. Yes, sir.

Mr. YOUNGER. You heard the story this morning by Mr. McMullen on what the manufacturers did, did you?

Dr. MATTIA. Yes, sir.

Mr. YOUNGER. Do you think control of the drugs can be handled by control at the manufacturers base alone?

Dr. MATTIA. I think Mr. McMullen demonstrated, and I think previous witnesses have demonstrated, that it can't be done by and through the manufacturer alone.

Mr. YOUNGER. It can or can't?

Dr. MATTIA. It cannot be done through the manufacturer alone.

Mr. YOUNGER. In other words, even though you were careful as to who you sell to, you do not believe that it will prevent the drug from getting into illicit trade?

Dr. MATTIA. No, sir; I do not.

Mr. YOUNGER. Then what do you recommend?

Dr. MATTIA. I am recommending rather strongly the passage of H.R. 2, because I think that the complete channels of distribution must be better controlled. I am also pointing out, however, that even with the enactment of H.R. 2, I don't believe that we will completely eliminate abuse. I think we will reduce it, but I don't believe we will completely eliminate the problem.

You have demonstrated in your hearings thus far, and you have certainly established beyond any doubt as far as I am concerned, that additional controls are necessary.

Mr. YOUNGER. You want the abuse of the drug to be determined before it is included. How, in your opinion, should we determine the abuse of the drug?

Dr. ZEINDEN. We believe that the amphetamines and barbiturates should be included as classes. Any other drug should be investigated by the proper committee of experts, with the help and support of the FDA, and the decision based mostly on its clinical record.

Mr. YOUNGER. So far as the first two drugs are concerned, you are assuming that there is abuse in those drugs already?

Dr. ZEINDEN. Yes, sir; we do.

Mr. YOUNGER. That is all, Mr. Chairman.

Dr. MATTIA. May I add something, sir? I think you asked the question of how we would propose these drugs to be assessed. I think this committee has, in the past, provided the guidelines for such assessments. By establishing such guidelines and using section 701(e), as the administrative procedure, I think this can be done.

The regulatory body, in this case the Food and Drug Administration, can assemble and compile the data submitted by the manufacturer, appoint an ad hoc committee, if it chooses to, and then assess the particular products. I think that without this we will run into the risk of classifying, inaccurately, certain compounds which have not demonstrated any abuse and are not likely to demonstrate an abuse or create a public health problem.

Mr. YOUNGER. Thank you.

The CHAIRMAN. Mr. Jarman?

Mr. JARMAN. No questions.

The CHAIRMAN. Mr. Pickle?

Mr. PICKLE. I want to compliment you for your testimony. I think it is some of the clearest statements and most understanding and co-operative statements we have had on this subject.

I know that Hoffmann-LaRoche is one of the largest manufacturing concerns in the country, manufacturing perhaps as many properly used drugs as are on the market today. I personally have had occasion to contact your company indirectly within the last few weeks, and have found them most understanding.

I want to ask this of you, two or three short questions: One, as I understand your statement, you do not think there would be any competitive advantage given to manufacturers except the amphetamines or the barbiturates; that the others would not enjoy any particular advantage?

Dr. MATTIA. No, sir; I do not.

Mr. PICKLE. You also make the point, and I would like to make a statement to see if this is a correct position: As I recall, the FDA said they would like to have the bill amended to provide, in the field of definitions, that a drug, if it had a potential for abuse, would be classified or would be subject to control under this act.

You say that this would be too general and too difficult to establish.

Dr. MATTIA. Yes, sir.

Mr. PICKLE. This is generally a correct statement?

Dr. MATTIA. Yes, sir.

Mr. PICKLE. What is the FDA, then, to do about the control of drugs? Must they wait until it is proven and lives have been wrecked and established without any question, beyond any question of doubt, that this is harmful, and it is subject to addiction, before they can step in?

Dr. MATTIA. I think the question is a very good one, Mr. Pickle. I think we endeavored to show graphically that addiction to these non-narcotic agents does not occur overnight, and that, by and large, in the development of the various clinical testing programs we are able to assess those compounds which have a greater or lesser record of abuse.

I don't think the Food and Drug will always agree with the manufacturer, and there will be times when the Food and Drug, in the interest of public health, will have to determine that a drug should be under these controls, and when it should not. But I think that the public health problem will not be a serious one if certain compounds are left off for the reasonably short periods of time required to make this determination.

I also think there is enough data accumulated on the compounds in question—and these are the ones that everyone is concerned with, and justifiably—for any impartial group to assess their record of abuse. If you were to ask the question about compounds which are still under experimentation, I think my answer would be a different one.

But you are concerned with the six or seven additional therapeutic agents, many of which have been available for a decade or longer. It would take the regulatory body a relatively short period of time to review our files and the literature and, in concert with an ad hoc committee, make a recommendation and a decision concerning each specific compound.

I don't think that it is necessary for this committee to go into such detail. It could do it, if time were available; it could certainly make such a determination, but you would have to do it for each and every compound under question, and I think time limits you.

Mr. PICKLE. You are fearful of the phrase "potential of abuse."

Dr. MATTIA. Yes, sir.

Mr. PICKLE. Are you saying, then, that you classify the FDA as a potential of abuse?

Dr. MATTIA. No, sir; I didn't say that.

Mr. PICKLE. I know you didn't say that, but this must be in your mind or else you would want to leave with them the right to make a determination as to whether there has been a drug so developed that it is an abusive or addictive drug.

Dr. MATTIA. I have complete confidence in the people in the Food and Drug Administration, and I feel that with their scientific people they can take their accumulated knowledge to date and make such a decision. I think it is the intent of this committee that these decisions be made with the full knowledge of the facts at hand.

I am merely suggesting that rather than incorporate it in this bill, these be taken up individually by the scientific people involved.

Mr. PICKLE. May I ask one further question? Although you didn't touch upon it in your testimony, but you did say in your testimony that this would not subject you to any particular additional keeping of records, that this would not be a bother to you, would you say this would be true of wholesalers?

Dr. MATTIA. Sir, I can't honestly say. I don't know the mechanics of wholesaling, the mechanics of keeping books, and so forth. I do know this: that as far as most manufacturers are concerned, this bill would pose no administrative problem for them.

Mr. PICKLE. But you wouldn't care to comment on whether it would impose any additional obligation on the wholesalers?

Dr. MATTIA. No, sir; I just am not qualified to say.

Mr. PICKLE. Then I assume you wouldn't care to comment on whether that would mean any burdensome problems to the medical profession or to pharmaceutical concerns, drugstores?

Dr. MATTIA. No, sir; I just don't think I am in a position to decide on that.

Mr. PICKLE. That is all.

The CHAIRMAN. Mr. Kornegay, have you any questions?

Mr. KORNEGAY. No questions.

The CHAIRMAN. Mr. Murphy?

Mr. MURPHY. No questions.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Huot?

Mr. HUOT. No questions.

The CHAIRMAN. Mr. Gilligan?

Mr. GILLIGAN. Mr. Chairman, I have just one.

Does your firm sell products under any other name than Hoffmann-LaRoche? Do they sell them under the name of Roche, or Robbins-Roche?

Dr. MATTIA. Robbins is another company. Roche is a name which many pharmacists use to refer to the company. We have a company

which markets our chemicals called the Roche Laboratories Division of Hoffmann-Roche.

Mr. GILLIGAN. If drugs contained under a catalog under the name of Roche, alone, like Gantrisin, these are your products?

Dr. MATTIA. Yes, sir.

Mr. GILLIGAN. There is a long list of drugs, including some of the ones that are under discussion in this bill, that appear in a catalog of a wholesaler. Presumably you provide these drugs to the wholesaler, you sell them to the wholesaler who, in turn, may sell them or distribute them to retail outlets?

Dr. MATTIA. Yes, sir. We sell to approximately 480 wholesalers in the United States. There are about 810 wholesalers all told in the United States.

Mr. GILLIGAN. You say that this bill, for instance, would not require of you any further controls than you already apply to your normal business activities. What controls do you now impose upon a wholesaler who wants your drugs? I have in mind the film we looked at this morning.

Dr. MATTIA. I think that is a good question, and if I may take the time, I would like to outline what we would do in such a case.

If an organization makes application to Hoffmann-LaRoche to seek the right to distribute our products, we would immediately request that a representative of the company visit the activity. The first man who would visit would be our local representative. He would then get information concerning the principals involved, the facilities at hand, the kinds of customers he would service, and the areas he would cover.

Our representative would seek a list of personal references. He would also seek a list of credit references. Based upon his visit, he would make a recommendation to the district or division manager. The district or division manager would then make an additional study and recommendation.

Finally, the regional manager would fly in or drive into this area and review the situation and visit the wholesaler, too, so that three individuals are the minimum number who would be asked by our company to visit with the wholesaler, review his records, and to discuss his prospects.

A recommendation is then drawn up and a report filed with the company. It is submitted to the distribution committee, which consists of a member of the legal department, of the marketing area, the financial department, and the general administrative area. Following this, then the recommendation to management is made as to whether or not this man should be added to the list.

I must say that it is an exceedingly difficult thing for a wholesaler to qualify. We have approximately the same number of wholesalers today that we had 3 or 4 years ago. By and large, it would be impossible for any wholesaler such as Mr. McMullen's experiment or operation to qualify with Hoffmann-LaRoche or any of the other ethical major manufacturers that I am in contact with.

Mr. GILLIGAN. Doctor, are you aware that the drug wholesaler in question advertises a drug which he purports to be the same as Gantrisin at half of the cost of Gantrisin?

Dr. MATTIA. Yes, sir. This can happen. Gantrisin is a product which is without patent. This chemical can be purchased in the

United States or it can be purchased abroad. Any number of people can get this chemical and they can mark it as sulfisoxazole. He can't market it as Gantrisin. So the price of this chemical varies with the various wholesalers and some of the manufacturers or distributors who are handling the product.

Mr. GILLIGAN. You would not, then, regard this activity as an unethical one, or a wholesale house which indulged in it as being an unethical operator?

Dr. MATTIA. I could not call him unethical, simply because his prices were lower than our prices. I think this would depend upon what he did in his distribution practices, and I am just not familiar with this particular operation to know this.

Mr. GILLIGAN. The only reason that I pursued the question is that the retail druggist who gave me this said that it was his personal conviction that wholesalers like this would generally sell the drugs to virtually anybody who asked for them, these fellows who, as he termed it, were engaged in drug piracy, and they were using generic terms in place of the name brand, and they were then supply these drugs or their generic counterparts to anybody who wanted to buy them and who had the money ready.

It appeared curious to me that reputable manufacturers would deal with people who were engaged in this practice.

Dr. MATTIA. In some cases we can't exercise control over what they do. We certainly would hope that this kind of practice would not happen. I can appreciate the position taken by your pharmacist friend.

Mr. GILLIGAN. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. Dr. Mattia, on page 15 of your statement, the last paragraph, you refer to the department requiring public awareness, and so forth, with enforcement by governmental authorities, pharmaceutical manufacturer, retail druggists, and the medical profession. Do you mean by that that they should all keep records?

Dr. MATTIA. I think recordkeeping is part of it, Mr. Friedel, but I think this is a problem which affects the Nation as a whole. I think that we have more or less strayed down rather independent paths in endeavoring to seek solutions to these problems. What I am, in effect, stating is that we must work more closely if we are going to try to correct the menace which exists.

Mr. FRIEDEL. By regulations and records? Do you feel keeping records would be just as important?

Dr. MATTIA. Yes, sir; I think that is certainly part of it.

Mr. FRIEDEL. And you would include all of those that you have in your statement?

Dr. MATTIA. Yes, sir.

Mr. FRIEDEL. One other thing I would like to be enlightened on is where you say you are very much in favor of this legislation, that your company favors it, and you say it will have little or no competitive impact within the drug industry. Finally, however, if this question is resolved by the committee, you say this bill will not eliminate drug abuse.

Do you feel this bill will help to stop a lot of the abuse?

Dr. MATTIA. I think there is no question in my mind that it will certainly reduce the amount of drug abuse. There is no doubt in my mind about this, nor in the minds of any of the people in our company. The unfortunate thing, however, is that we also feel just as strongly that it cannot eliminate it. It will do a great deal to correct the legal pathways of drugs, but the unscrupulous operator, the man who works with a crime syndicate, will be able to get these drugs in various parts of the world and will somehow manage to get them in.

But the fact that we cannot eliminate it, I don't think, should deter us from going ahead to seek enactment of this legislation.

Mr. FRIEDEL. Do you have any suggestions on amendments that would tighten this bill to eliminate these abuses?

Dr. MATTIA. No, sir; I can't at this time make any additional recommendations. I wish I could.

Mr. FRIEDEL. Thank you, Mr. Chairman.

The CHAIRMAN. Doctor, thank you very much for your presentation. We appreciate the testimony of both of you on behalf of your company from your experience in this field.

Dr. MATTIA. Thank you, sir.

The CHAIRMAN. The next witness will be Dr. John Griffith.

**TESTIMONY OF DR. JOHN GRIFFITH, DIRECTOR, OKLAHOMA MENTAL HEALTH PLANNING COMMITTEE, OKLAHOMA CITY, OKLA.**

The CHAIRMAN. Doctor, you came here at our invitation, and it was indicated at the time that we might want to take your testimony in executive session in order to avoid seeming to single out any one area of the country. It has later developed that a great deal of information has already been given with reference to this problem in other cities, such as New York, Chicago, Baltimore, Miami, Portland, and various other places, so that reference to Oklahoma City would not now be isolated.

After consultation, it was decided that we would proceed in open session. I think with that statement, if it meets with your approval, we will give Mr. Jarman, who represents the great district of Oklahoma City, and who is a member of this committee, an opportunity to present you to the committee.

Mr. JARMAN. Thank you, Mr. Chairman.

I appreciate the opportunity to welcome Dr. Griffith here to testify before this committee at this hearing.

Dr. Griffith is associated with the Oklahoma State Health Department. I am advised he has conducted investigative studies in this general field. I am convinced from all I have heard and read that Dr. Griffith can make a contribution to this hearing, Mr. Chairman, and I am pleased to have him here.

The CHAIRMAN. Thank you.

Doctor, we are glad to welcome you here. If you have a statement you can give, we would be pleased to have it at this time.

Dr. GRIFFITH. Thank you, Mr. Harris, and Mr. Jarman, and members of the committee.

I welcome the opportunity to be here, especially since we have already heard from one psychiatrist; one psychiatrist in a man's life is bad, but two in 1 day is a disaster.

I wanted to bring to light some of the facts that we have picked up in a research project on amphetamines which we began even before we knew that Congress was interested in this problem.

Like most things, this research began in a very human way, in that a friend of Governor Bellmon had a daughter who became habituated to the use of these compounds. He asked us to look into this matter.

The CHAIRMAN. Could I interrupt? Some of the members may not have grasped particularly the testimony we will be receiving. For your information, I think it would be appropriate to say that Dr. Griffith, as Mr. Jarman said, is from Oklahoma, and he conducted a research project out in Oklahoma City and areas surrounding Oklahoma City.

Is that true?

Dr. GRIFFITH. That is true.

The CHAIRMAN. The purpose in bringing the doctor here is to give the committee the benefit of his research in these areas with this particular problem. We thought it would be very helpful to have the testimony of a man who has spent a year or more in a particular research project in this field.

It is that situation that he is about to explain to us.

Dr. GRIFFITH. Thank you very much.

The purpose of our research was to find out, first, the size of the problem both in Oklahoma City and in a representative sample of small towns in other parts of the State. Second, we wanted to know how these drugs, amphetamines, and barbiturates were distributed, and last, we wanted to know what was the disadvantage to the user and to society. We were also asked to determine what measures were needed to minimize this traffic.

The first problem I had was to get money to support research of this type. I did not think it would qualify for a Federal research grant, nor could I justify using State money. However, the Oklahoma Publishing Co. and KWTV very generously underwrote the cost of this project. I, of course, did it at night, after hours.

Our first attempt was to disguise medical students as addicts in an attempt to have them move in on the group. The response of the addicts was, "That sure is a funny way for you medical students to dress."

Next we engaged a private detective. Luckily we did not pay him, because we have not heard from him since. Our last attempt was successful even though it was really a "last ditch" sort of thing: I went to a drug peddler and introduced myself, saying, "I am Dr. Griffith. I am a psychiatrist making a study of drug traffic, and I understand you can give me some information."

Then we argued for 3 hours over why he should and should not. Finally he made the proposition that if I could prove that I was a "stupid doctor" instead of a "smart FBI agent", he would talk with me quite willingly. I asked him how I might convince him. He said, "If the police will tell me that you are really a doctor, I will tell you what you want to know."

Accordingly I went back to the police station, picked up an officer who took me out to this peddler's home and introduced me as a doctor. Then the peddler said, "Well, Doctor, when you are not running in such bad company, come back and see me."

For several weeks after that we would spend an evening a week or so sitting out on his lawn with the sprinkler going and the moon filtering through the trees, and he would tell me about his life of crime, and whom I should know if I wanted to learn about the drug traffic.

So I got to know this group. The first thing that we found out was that these people know one another quite well. I at first thought that it would be very difficult to count these people. However, since they know each other quite well, if one knows a few of them, it is very easy to get to know almost all of them, if one has the time.

We had to go to the peddlers and addicts because we found that from a medical standpoint, a physician would see this problem as only the point of an iceberg sticking up above the surface of the water whereas seven-tenths of the iceberg is beneath water. That is, there might be 10 patients admitted to our State mental hospitals each year. Too, doctors we interviewed in Oklahoma City said that they had seen only one or two cases of habituation to amphetamines, barbiturates, or tranquilizers. So from their standpoint it did not appear to be a big problem.

However, we were surprised by certain findings. We were most impressed by the fact that the ratio of people who are habituated to amphetamines and barbiturates as compared to hard narcotics is about 100 to 1 in the Oklahoma City area.

In other words, the number of individuals addicted to "hard" narcotics in Oklahoma City was estimated as something less than 3 dozen. However, the number of people who are habituated to amphetamines and barbiturates is somewhere between 1,000 and 5,000, and we think the latter figure is more correct.

The CHAIRMAN. What is the population of Oklahoma City?

Dr. GRIFFITH. The Oklahoma City metropolitan area is 500,000, and within the city limits, approximately 300,000.

These 5,000 people do not include nonwhites, truckdrivers, or people in the middle and upper socioeconomic level. Most of the illegal traffic; that is, the sales by peddlers are to people in the lower socioeconomic levels. We found, also, that drug traffic causes crime. We thought at first that these drugs warped a person's mentality in some curious way so he turned into a Frankenstein monster. Actually, it is far more simple than that.

Once a person begins to take drugs, he loses interest in working, and since he continues to need money, he will steal or engage in prostitution. Rarely do they go berserk. It occurs, of course, but my experience is that people who have a drug party, for example, are less boisterous than the average medical student at one of his parties. It is a pretty dull time for most of the people around.

However, we could not say that the use of drugs caused an absolute increase in the crime rate. Determining this would be a very sophisticated and expensive research project. That is, if you asked "How many crimes would these people have committed if they not had taken drugs?" Then determining the answer would be very difficult. We know they can commit crimes before they took drugs and presumably afterward.

The average drug user is a person who begins taking drugs during his late teens or early twenties. Almost half of them began when they were less than 19 years of age. Most generally, drugs are not

"pushed" by peddlers. Although peddlers sell to teenagers, they do not need to "push" drugs; that is, encourage others to use drugs. The peddlers who talked to me said that all they have to do is spread the word that they have the drugs and within a week they are inundated with customers. One peddler said that business was so brisk that his customers had a three-car accident in front of his home. The peddler's object is to sell as much as he can in the shortest possible time to make a large profit. Then, when the customer who is an undercover policeman comes to make an arrest, he will have enough money to pay for his bond, his lawyer, and his fine.

Although we found that the bulk of illegal traffic was in pills, traffic in a nasal inhaler was a problem in the Oklahoma City and Tulsa area, as well as other cities in the Midwest. Today, this inhaler was declared a prescription item.

It is an ordinary nasal inhaler which contains 150 milligrams of dl-desoxyephedrine which is equivalent to something like 30 amphetamine tablets. We found a cult of people, numbering between 100 and 200, who extract the contents of this inhaler in water and inject the solution intravenously.

I could not believe it when I first learned about it, and told one of the users as usual. He said, "Well, I will invite you to the next party." With a great deal of fear and trembling, I attended one of these parties where they would sit around and inject this amphetamine solution into the veins. They also allowed me to take their blood pressure. I could corroborate that they were taking a pressor substance. I palmed the inhaler to ascertain if the group had been taking "hard" narcotics. The inhaler was analyzed by the laboratories of Smith, Kline and French Inc., and they said it did not contain narcotics. These people appear and act like individuals addicted to narcotic drugs.

Another thing we did before we knew of Mr. McMullen's project was to have the college students, who were working with us, order drugs from drug wholesalers. We placed orders with four drug companies and three filled the order without question. However, one said they had no record of this person being a physician and refused to fill his order. Of course, when Mr. McMullen's film was put on television, we could see that he was well ahead of us, so we dropped that particular type of investigation. We found, also, that drug traffic is not confined to large cities by any means. We picked three small towns at random in Oklahoma. The smallest had a population of 1,500. We found that some degree of drug traffic was going on in each of these small towns.

We found, too, that habituation to amphetamines and barbiturates occurs in members of all classes of society. It is not confined merely to people who do not take baths or do not go to church. Once I lectured on drugs to a group of teenagers at a fashionable Presbyterian church. The response of the audience: "Tell us something new."

One of the boys who attended the lecture confided to me afterward that he had been taking amphetamine and wondered how he might stop. I offered to drive him home. We drove to a home where the driveway alone cost more than the house that I live in. Here is an example of a boy from the upper socioeconomic levels who became habituated to drugs. We found, too, that the sales of drugs is quite

common on college campuses, and not just college campuses in the State of Oklahoma.

We learned of this campus traffic inadvertently during a mock trial at a law school. Twelve law students were selected to be the jury. The student lawyer asked, as an opening question, "Have any of you taken amphetamine drugs?" Ten hands out of the twelve went up. Then he backtracked and said, "I mean how many have taken amphetamines and have not obtained them through a prescription?" Again 10 hands went up.

This is an indication of how prevalent this traffic is. We feel that one of the big problems in Oklahoma—I don't know how true this is elsewhere—is that the penalties in our State and on the Federal level, too, are much too light. If the penalties are light, the penalties imposed are even lighter. Individuals are arrested for selling drugs quite often. For instance, one drug peddler was arrested twice last year but he was fined only \$100 for each offense. This is less than 1 day's profits, so I did not think that he was going to switch to another business, and, indeed, he did not.

Also, the fact that the penalties are light causes a certain amount of cynicism on the part of police officers who arrest these people, then find them peddling just as heavily the next day. Nor does it please them to get five indictments against a peddler and then have most of the indictments dismissed. However, I want to point out that I am not a lawyer and the last is just an observation.

Thank you, sir.

The CHAIRMAN. Doctor, thank you very much for your very revealing report. Is Oklahoma City your home?

Dr. GRIFFITH. No, sir, I am a mountaineer from Tennessee.

The CHAIRMAN. Being from Arkansas, I welcome you from both sides.

How long did your research project go on?

Dr. GRIFFITH. It took us 6 months to learn how to do it and 6 months to do it, approximately.

The CHAIRMAN. Were there several of you engaged in this project?

Dr. GRIFFITH. Yes. We had two college students, Mr. Ben Henry and Steve Peeler, who helped us, two medical students, Mrs. Wanda Duncan and Mr. Jerry Troy, and also a local reporter, Miss Peggy O'Rear, helped us with a view toward publishing a magazine story.

The CHAIRMAN. Has the magazine story been published?

Dr. GRIFFITH. Not yet, sir. We hope it will be just a matter of a few weeks.

The CHAIRMAN. You are a psychiatrist by profession?

Dr. GRIFFITH. Yes, sir, I am.

The CHAIRMAN. And you are presently the director of the Oklahoma Mental Health Planning Committee?

Dr. GRIFFITH. Yes, sir.

The CHAIRMAN. Is that a committee established by the Oklahoma statutes or by your Governor, or by an association?

Dr. GRIFFITH. The committee was appointed by the Governor. It is financed by the Federal grant through NIMH; and is to help States plan for their future mental health programs. Of course, this problem of amphetamine and barbiturate abuses is certainly a most difficult mental health problem since psychiatrists actually have very

little to offer these patients once they are addicted. The only hope is to prevent the addiction rather than to hope that we can cure these people.

The CHAIRMAN. In other words, this was a cooperative Federal-State project?

Dr. GRIFFITH. Yes, sir.

The CHAIRMAN. And you are directing your time and attention to it.

We have been told that a barbiturate is a derivative from barbiturate acid. That is a class. You are familiar with that, are you?

Dr. GRIFFITH. Yes, sir.

The CHAIRMAN. Is amphetamine a class, too?

Dr. GRIFFITH. It is frequently used to designate a class of drugs. These drugs all have very similar chemical structure and clinical actions. Amphetamine drugs closely resemble the chemical epinephrine or "adrenaline." Adrenaline is the substance that courses through ones bloodstream, speeds up the heart and prepares us, if we become frightened or need a burst of energy, like a runner getting ready to wait for the gun. The amphetamines are very similar to this and possess very common properties.

The CHAIRMAN. But it is not from an acid, such as barbiturate acid? There is no relationship between the two?

Dr. GRIFFITH. No, sir, they are two different things altogether.

The CHAIRMAN. Two different classes, as they have been referred to here.

Dr. GRIFFITH. Yes, sir.

The CHAIRMAN. Mr. Friedel, have you any questions?

Mr. FRIEDEL. I have no questions, but I want to commend him on his research.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. No questions, Mr. Chairman, but I believe the witness had made a great contribution to the hearings.

The CHAIRMAN. Mr. Jarman?

Mr. JARMAN. Mr. Chairman, I have a question or two to ask.

Doctor, how many users would you estimate you contacted in the 6-month period?

Dr. GRIFFITH. Almost 100 users. Of course, the estimates as to the number of actual users was based primarily on the information given to us by drug peddlers. Nor did we attempt to interview every user that was available to us. Information obtained was checked against the impressions of drug peddlers who were in prison, and against police records. The Oklahoma City Police Department has the names of over 1,000 amphetamine or barbiturate users within the city.

Mr. JARMAN. Did you get pretty good evidence as to frequency of use?

Dr. GRIFFITH. This we found ranged from two or three tablets a day, which a prostitute would, for instance, take to keep up with her irregular hours, to one man who said that he took 100 tablets in 1 day. This is a large dose. However, I have observed 1 man taking 25 at one sitting, so it is not beyond the realm of possibility.

Mr. JARMAN. Do you estimate that there are 1,000 to 5,000 users in Oklahoma City?

Dr. GRIFFITH. Yes. One reason we did not try to be more precise was that all we wanted to know, was whether such traffic was a small problem, a middle-sized problem or a big problem. Of course, between 1,000 and 5,000, in our estimation, was a big problem.

Mr. JARMAN. I have one question to ask, particularly to make sure that the records reflect the answer. Your testimony has been particularly with reference to the problem in Oklahoma City, and then in three other smaller communities in Oklahoma. Based on your investigation and the information that you have, does not this same problem exist in many other cities and States throughout the country?

Dr. GRIFFITH. Yes, it is quite ubiquitous, and as a matter of fact there is reason to believe that in very large cities in the United States, it is a much more serious problem.

For example, in Los Angeles, we were told that it was so large that they could not concern themselves with the individual user, or the small peddler. Rather they could only concern themselves with the big peddlers.

Mr. JARMAN. Thank you.

The CHAIRMAN. Dr. Carter.

Mr. CARTER. What were these tablets which you saw the man take 25 of?

Dr. GRIFFITH. They were 10 milligram, DL amphetamine.

Mr. CARTER. It must have blown his head off.

Dr. GRIFFITH. No, as a matter of fact, in extremely large doses, the drug does not seem to be a stimulant. In fact, it seems to be a depressant. This is one aspect of the research with which we are continuing; that is, What is the effect of large doses? We found then it actually slows down mental processes quite markedly.

Mr. CARTER. Of course, we know that barbiturates do that somewhat, and sometimes they stimulate, too. Sometimes they are quite benign and certainly I want to compliment you on your presentation here today.

Dr. GRIFFITHS. Thank you, sir.

Mr. ROGERS of Florida. Doctor, this certainly is an interesting experiment and the results of it are certainly pretty startling, I think. I wonder if you have made any study at all of where the pusher or the peddler was able to get the drugs? Did you go into that problem at all?

Dr. GRIFFITH. Yes, we asked, and were told that they got drugs from people in California and from people who would make a round trip to Mexico.

Mr. ROGERS of Florida. What would this indicate, that there is an organized ring as far as Oklahoma City is concerned, that is bringing this in, or were there wholesalers that they would write to and get the drugs from, or manufacturers?

Dr. GRIFFITH. Well, if they were organized, they certainly don't like one another. They are more like business competitors than they are an organized ring. They seem to have quite intermittent operations. Their biggest problem, they say, is getting drugs. They can sell any quantity they can get, but of course they have trouble getting it.

I might say also that we told some of them about Mr. McMullens "business," and they would say, "I didn't know about that, how does it

work? How do I get a catalog," and things of that nature. Apparently there are very few men who can obtain large quantities of drugs. From then on it is just a pyramid of independent businessmen.

I don't think that there is an organized ring, as yet.

Mr. ROGERS of Florida. What I wondered was this: Did the peddler get his drugs from a wholesaler or a manufacturer, say in California? You said it was in California.

Dr. GRIFFITH. Well, this is rumor. As a person in research I hate to quote rumors, but this is the best we have. They bought from a man who knew a man in a drug company.

Mr. ROGERS of Florida. So it would either have been a wholesaler or a manufacturer, probably?

Dr. GRIFFITH. That is right.

Mr. ROGERS of Florida. Did any of them try to go through the process of setting up themselves as far as you know, as a druggist with stationery, and then go through the same process as Mr. McMullen went through?

Dr. GRIFFITH. No, sir.

Mr. ROGERS of Florida. None would do that?

Dr. GRIFFITH. No, sir.

Mr. ROGERS of Florida. None would do that?

Dr. GRIFFITH. They were not that sophisticated.

Mr. ROGERS of Florida. So far as your research showed, those in Oklahoma, peddlers, received their drugs from outside the State?

Dr. GRIFFITH. Yes, sir.

Mr. ROGERS of Florida. Do you have any drug manufacturers in the State?

Dr. GRIFFITH. No, not of these compounds.

Mr. ROGERS of Florida. Were any of the users that you talked to recipients of prescriptions from their doctors in Oklahoma?

Dr. GRIFFITH. Yes, sir, this is a big problem.

Mr. ROGERS of Florida. Will you explain that problem to us, if you please?

Dr. GRIFFITH. We found that some physicians will write a prescription for, say, amphetamines, for the purpose of helping someone lose weight. They will write a prescription that can be refilled indefinitely, long after the physician has died and the original druggist has died, if we want to choose an absurd example. We found that many of the patients would not return to the doctor or they felt so good taking the pill that they would think it solved all of their problems.

They would then become habituated, and go down hill. Some would then be taken to another doctor, who would help them to recover. I don't want to appear to be critical of my medical colleagues, but we did see this happen.

Mr. ROGERS of Florida. Was this in a number of instances?

Dr. GRIFFITH. Yes. We found that as far as middle- and upper-class people are concerned, that this is the usual route. They do not go to drug peddlers. They obtain a prescription or somebody else's prescription to get a drug.

Mr. ROGERS of Florida. Now, is there any regulation in your State that says a prescription can only be filled once or is there any check on filing of prescriptions?

Dr. GRIFFITH. A doctor can write a prescription that can only be filled once or he may say it can only be filled a finite number of times, but if he does not so designate it, then the prescription can be refilled indefinitely in Oklahoma. And it is refilled indefinitely in many instances.

For instance, we found that this was the favorite way for college students to get amphetamines to study. That is an overweight student, usually a girl, would go to a doctor and complain of being overweight. She would be given amphetamines and pass these out to her friends.

One student, we found, made \$200 a week during finals selling tablets for 50 cents a piece. He used his mother's prescription.

Mr. ROGERS of Florida. What would they do, take them to different pharmacies to be filled, or could they go back to the same pharmacies?

Dr. GRIFFITH. I don't want to be critical of my pharmacy friends either, but they most generally would take it to the same pharmacy.

Mr. ROGERS of Florida. The same one?

Dr. GRIFFITH. Yes.

Mr. ROGERS of Florida. How does the drug affect them, is it in the weight problem, you say?

Dr. GRIFFITH. Yes. They would tell the doctor that is what they wanted it for, but actually it was a pill to help them stay awake.

Mr. ROGERS of Florida. Is it helpful to hold weight down, or what?

Dr. GRIFFITH. The research is conflicting. There is indication it will help people for about 28 days or less, and after that it only has a placebo effect, that is people think that it helps them.

Mr. ROGERS of Florida. Does it cut down appetite, or appear to cut down the appetite, or what effect does it have?

Dr. GRIFFITHS. Actually, it distracts the person from his hunger pains. That is, it makes him feel happy, and happy people are able to forget their unhappy stomach.

Mr. ROGERS of Florida. Do you feel that the penalties that we have on the books and now are not sufficient or should there be some attention given to the problem of prescriptions without end, as far as these drugs are concerned?

Dr. GRIFFITH. I believe that if you were to take a survey of medical school professors, the vast majority would say there is absolutely no reason for a prescription to last longer than, say, 6 months, and most would say that 6 months is too long.

There are two reasons for that. If a person is not sick, then he does not need the drug. If he is sick, he should see his doctor more often than every 6 months while he is taking the drug, because unpleasant side-effects might occur.

So that I think most physicians would support me when I say a prescription should last no longer than 6 months.

Mr. ROGERS of Florida. Is there any checking to see whether a pharmacist in your State has been filling prescriptions that have expired?

Dr. GRIFFITH. Yes, this has been done by Food and Drug Agents. I would hate to speak for them, since they are available.

Mr. ROGERS of Florida. Have you seen any instances of where this has happened?

Dr. GRIFFITH. Yes, sir.

Mr. ROGERS of Florida. This has happened?

Dr. GRIFFITH. Yes, sir.

Mr. ROGERS of Florida. And have you any particular suggestions concerning the penalties? Should there be confinement penalties, are these more effective, or more penalties or what?

Dr. GRIFFITH. It is a little more complicated than that. For instance, in Oklahoma it is considered, by State law, a misdemeanor. This means that after the county attorney has gotten all of his felony cases off the docket, he can go to work on the misdemeanors.

It also means that the judge, when he tries a case, says: "Well, there can't be much of a problem, it is a misdemeanor." So when he sees a poor wretched man coming up before him saying he will never peddle pills again, the judge will administer a very light sentence. The Food and Drug maintains a list of the sentences meted out to people who peddle drugs, and it is quite abysmal. A man might make \$10,000 selling a stock of 100,000 tablets. He is then arrested and fined \$500. Occasionally even this sentence is suspended.

Now, if my research shows nothing else, it shows that the lives of these people are for all intents and purposes destroyed by these drugs, because it hits them during the most productive years of their lives. This is much worse than spitting on the sidewalk, which is also a misdemeanor.

Mr. ROGERS of Florida. Then you don't by any means agree with the philosophy that there should be an easier access to drugs by people?

Dr. GRIFFITH. To be quite frank I do not know how it could be much easier. Every other prescription written in this country is written for a drug which affects the mind. In every large city, we found that poor people who can't afford to go to a doctor, can buy their drugs cut rate through a drug peddler. I think that we have inadvertently experimented with free access to drugs and it is a disaster.

During the past 10 years, we have seen the addiction rate go up astronomically, and I would say that the period of experimentation is over.

Now is the time to try another approach.

Mr. ROGERS of Florida. Is confinement a better punishment than just a fine?

Dr. GRIFFITH. Well, I would have difficulty answering a question like that.

Mr. ROGERS of Florida. I just wondered if you had looked into this to see how it affected those people, who had been taking drugs, if this is more effective there in the punishment?

Dr. GRIFFITH. Every time a peddler is arrested, it costs him approximately \$600. \$500 is for a lawyer and a bondsman, and \$100 is for the fine, and they seem to be worried by that amount.

Mr. ROGERS of Florida. Have there been any confinements because of this, that you recall?

Dr. GRIFFITH. Yes, in 7 years there has been 1 person who has been sent to prison for more than 1 year for this, even though there are 200 cases pending right now.

Mr. ROGERS of Florida. Was this the peddler or just a user?

Dr. GRIFFITH. Both peddlers and users.

Mr. ROGERS of Florida. What was the one that went to jail? Was he a peddler or a user?

Dr. GRIFFITH. He was a peddler and is very well known. He told me he intended to reform and actually went on television to discuss the problem. He was one of our corroborators; he had very little to lose by talking to us. Most of these people would not mind spending 15 days in jail, however, because they do it all of the time anyway.

On the other hand, a stiff fine hurts them. It costs money.

Mr. ROGERS of Florida. Now, I have one last question. You say prescriptions on the overall probably should not be effective for longer than 6 months. What about, say, four refills, or three refills, of this prescription? I think that you mentioned that sometimes they would say that it may be refilled five times past the original figure—the original filling of the prescription?

Dr. GRIFFITH. I don't think that that has much to do with it. It would depend on how much of the drug was prescribed. If you have a poor patient, he might not have enough money to buy a 4-week's supply of drugs. You might have to refill it four times, so that he could afford that one week.

Mr. ROGERS of Florida. That is the way—that is what I was saying. Suppose there was some restriction, to say that drugs of this type should not be prescribed on one prescription more than four times, for three refills or would it be better to say a 6-month period?

Dr. GRIFFITH. For drugs of this type, I don't think that doctors would say that a prescription should be refilled any more often than four times, nor should the prescription last longer than 1 or 2 months. There are exceptions, for instance a patient with epilepsy will require phenobarbital and he might not see a doctor any more often than once every 6 months. But let us take amphetamines. Very, very few clinical indications exist that would require a prescription that was older than 1 month. I could be wrong on that, but certainly not more than 6 months.

Mr. ROGERS of Florida. Do you think under this law as it is proposed, the manufacturer and the wholesaler should keep records of their sales, to whom they sell them?

Dr. GRIFFITH. Yes, sir.

Mr. ROGERS of Florida. And the pharmacist. Now, should the doctors also be required, do you believe, after your study, to keep records of whom they prescribe to?

Dr. GRIFFITH. I think every one agrees that any good businessman, or any good pharmacist or any good doctor automatically keeps such records.

Mr. ROGERS of Florida. For the 3 years, that is the requirement?

Dr. GRIFFITH. That is right.

Mr. ROGERS of Florida. Would you see any objection from the medical profession for keeping such records?

Dr. GRIFFITH. I think that they would go straight up in the air, if they were asked to, not on the basis of any reasonable thing. It would just be that they would hate to have legislated what they will do automatically. We found very few instances of doctors getting involved in drug traffic, on an illegal basis.

Dr. CARTER. The question I wanted to ask, the amphetamines are used in marcolepsy, and they would be used over 6 months in those cases, is that right?

Dr. GRIFFITH. In the treatment of marcolepsy with amphetamines, that is quite true, but the patient should be reevaluated, at least every 6 months.

Dr. CARTER. Well, marcolepsy being a condition which is not really cured and it goes on, more than likely we would have to use that amphetamine over a longer period; is that right?

Dr. GRIFFITH. Yes.

Dr. CARTER. It should not be done without the patient seeing the physician often, much oftener.

Dr. GRIFFITH. The point I was making is that if he has the prescription he might not see the physician.

Dr. CARTER. I agree with you.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mr. KORNEGAY. Dr. Griffith, I want to congratulate you and thank you for coming here with this very valuable testimony, and I want to express to you my appreciation for the fine work you have done in this area.

Let me ask you two or three questions, the first of which is this: To what extent, if any, did you find during the course of your research that these users of barbiturates and amphetamines were using them in conjunction with alcohol, such as whisky, or beer, or other alcoholic beverages?

Dr. GRIFFITH. One of the uses they make of amphetamines is to keep from passing out if they drink too much, so that they will mix amphetamines and alcohol together. If one does not have enough alcohol, sometimes they will mix alcohol with barbiturates because it is cheaper. In other words, a bottle of beer and a seconal tablet is a good drunk, and it is cheaper.

Mr. KORNEGAY. That is exactly the point I am trying to get at. I have heard it said that a bottle of beer and a yellow jacket, which is the common name for seconal tablets, I think, is enough to greatly intoxicate a person.

Dr. GRIFFITH. I have never tried it but I assume that it would be.

Mr. KORNEGAY. I wondered whether you have run into that situation in your experience?

Dr. GRIFFITH. Yes, it was quite common. However, the way to spot a person who takes pills in a bar for example, is to notice the man who orders a coke. Since I could not possibly keep up with the drinking that went on while doing this research, I was forced to order a coke. They immediately assumed that I was one of them.

Mr. KORNEGAY. Now, you spoke awhile ago of the users using anywhere from, say, 3 to as many as 25 in a day. Is that a daily occurrence with them, and do they get on them for awhile or get off for awhile or do they stay on until they seek medical attention or are put away?

Dr. GRIFFITH. With amphetamines, they usually start off with a small amount and then increase the dose over a 3- to 5-day period. Then, regardless of how much they take, they can get no further effect at this point they may begin to have psychotic symptoms, such as hallucinations and delusions. At this point they usually stop taking the drug, and sleep for 24 to 48 hours. Then they start over again. It is a fairly repetitive sort of thing. This explains why they cannot work.

Mr. KORNEGAY. I would say a chronic user, then, is out of commission, is that right?

Dr. GRIFFITH. Exactly.

Mr. FRIEDEL. Would the gentleman yield? If that is the case, wouldn't the parents be the first ones to find out that the children are using these drugs?

Dr. GRIFFITH. I didn't understand the question, sir.

Mr. FRIEDEL. The sample that you just stated, where they use it 1 day and increase it for 3 or 4 or 5 days, and then they would sleep for 24 or 48 hours. Wouldn't the parents be the first ones to find out that their children were using these drugs?

Dr. GRIFFITH. The real young teenagers usually don't do it that way. They will have a party, that is they will take a pill and a beer, and they keep it from their parents. Of course, mothers and fathers who have children of this sort really are not paying very close attention to their children anyway. So the children may escape detection very well.

Of course, since this study came out, we have gotten numerous calls from parents saying, "What can I do about my child?" One doctor called and said, "You were quite right when you said that these people could not be helped."

"I have spent thousands of dollars trying to help my daughter; she is now 30 years old and she is still on drugs."

Mr. KORNEGAY. Now, Doctor, in the case of hard drugs, I have heard that the percentage of cures of addicts, and I am talking about permanent cures of addicts, is not much more than 4 or 5 percent. Is that a fairly accurate estimation?

Dr. GRIFFITH. It is a little better than that.

Mr. KORNEGAY. A little better than that?

Dr. GRIFFITH. Yes, sir.

Mr. KORNEGAY. Well, what are the latest figures if you have them?

Dr. GRIFFITH. Well, the figures depend upon the person's education.

Mr. KORNEGAY. I am thinking in terms of percentages, now.

Dr. GRIFFITH. I think the percentages are around 10 or 12 percent. You see, for some unknown reason, well, when an addict on hard narcotics starts passing 40, he starts dropping off of his habit, and no one knows just why this is, so that finding a really old addict is quite unusual. Therefore one should expect a certain number of cures just because the addicts are growing old.

Mr. KORNEGAY. Now, do you have any figures or any information to compare the cures between those who are addicted to hard narcotics, and those addicted to amphetamines and barbiturates?

Dr. GRIFFITH. No, sir; these are very mobile people, and keeping long-term statistics over a period of years is very difficult. I certainly can't do this, and I am not aware of anyone who has.

Mr. KORNEGAY. Based upon your experience and training and expert knowledge in the field, could you give us any estimation or make any statement with reference to the difficulty of curing one who has been addicted to amphetamines and barbiturates?

Dr. GRIFFITH. It is extremely difficult to treat a person who has become habituated to these drugs, especially if he has been habituated for any length of time. I base this on my own clinical experience, and on the disappointment of other physicians who have also tried to treat addicts.

If everything we needed to know about this condition was an unabridged Webster's Dictionary, we would know the first 10 pages. There is a great deal yet to be learned.

Mr. KORNEGAY. But we do know that once one becomes addicted, even to amphetamines and barbiturates, that they for all practical purposes are lost to society?

Dr. GRIFFITH. Yes.

Mr. KORNEGAY. Approximately how long, Doctor, does it take a user to become addicted, and that is a double-barreled question and a broad question, but can you answer it?

Dr. GRIFFITH. I saw the previous figures on the length of time required to become addicted, and I wondered how these figures were obtained for the reason that this would be almost impossible to compute. It could only be seen in retrospect, and then where would the cutoff be? Does an alcoholic become an alcoholic with the first drink, or the second drink, or the third drink or when he loses his job, or his wife, or his position in society? Is it when he says he is an alcoholic or his friend says he is an alcoholic. This is a very difficult question to answer. We do know, however, that if you take enough people at random and introduce them to the drug, that a certain percentage, for reasons we still don't understand, will become habitual users of these drugs. For this reason drugs should not be used indiscriminately.

Mr. KORNEGAY. I knew that the question would be rather broad, in fact, almost impossible to answer, but I thought if you did have some information it would have some value to us.

The sentencing of a person is an individual matter in each case, depending upon the circumstances which the judges must take into consideration. I would certainly hope that every judge would think in terms of what is the best way to deter this particular individual from repeating the criminal offense. In some instances, of course, a fine and stiff suspended sentence might do it, and, of course, there are many that need to go to jail and ought to go to jail.

The point is, that I quite agree with you, that I think that this type of offense has been too long treated too lightly in our courts. Thank you very much for your appearance here today.

Dr. GRIFFITH. Thank you.

The CHAIRMAN. Now, Doctor, your reference to older people not continuing to have the habit, or to reach that stage, would that have anything to do with life beginning at 40?

Dr. GRIFFITH. Perhaps I can say better when I'm 40.

The CHAIRMAN. I envy you.

Mr. PICKLE. Doctor, this may be too broad a question also, but what is the best thing we could do as a representative of government and in behalf of our society to stop the misuse of these amphetamines or barbiturates?

Dr. GRIFFITH. I think exactly what you are doing is the most obvious, and the most logical step, and that is to make it difficult for these drugs to fall out of legal channels. Once that has been tried, if loopholes appear, go over the problem again and plug up those loopholes.

I know that certain doctors have said that you cannot eliminate this problem by legislation, or by the enforcement of laws, but the fact of the matter is that heroin is almost unknown in Oklahoma City today, and the reason it is almost unknown is that the criminals have stopped

selling it, and the reason they stopped selling it is because they can't get it. It is as simple as that.

We hope to see the same thing occur with drugs of the amphetamine and barbiturate class. I think that there is another thing that you might look into, and that is these compounds being available as a patent medicine. For several years we have been troubled by illicit traffic in an inhaler. There has been absolutely no way that we can handle it as a State. The druggists in Oklahoma all agreed not to sell the inhaler, but now it is being sold by a peddler in Oklahoma City. It sells for \$3 a tube, but its actual retail value is only 79 cents.

Mr. PICKLE. Which inhaler is it?

Dr. GRIFFITH. This is the Valo inhaler that is manufactured by the Peiffer Co., in St. Louis.

Mr. PICKLE. Would you say that we as a people have become too pill happy?

Dr. GRIFFITH. Being a dilettante of history, I can say that almost every major civilization has had a problem with drugs, and I think that there is a great deal of truth in what you say. Perhaps we have become pill happy. But I don't think that this means that we are deteriorating as a society at all.

Mr. PICKLE. Actually, I get to feeling that it is a sort of social status symbol, that the number of pills you have, the better off you are.

Dr. GRIFFITH. Well, that might be true.

Mr. PICKLE. You have a pill for everything, and your medicine closets are so full now that you have a problem in knowing which one to take.

Dr. GRIFFITH. This is an age of instant happiness. We like to get things quickly, and if peace of mind can be obtained with a pill, then this is attractive to a lot of people.

Mr. PICKLE. That is all, Mr. Chairman.

Mr. MURPHY. As all members of the committee have expressed, we find your remarks very illuminating. These 1,000 users, you put them in the addict class?

Dr. GRIFFITH. These are 5,000 people obtaining drugs through illegal channels.

Mr. MURPHY. How many of those are addicts?

Dr. GRIFFITH. I haven't any idea. First, one would have to define an addict. But look at it this way: These people are not buying their pills to lose weight. They are not buying pills to cure an illness. They are buying and using drugs as stimulants. To me, this represents a state of mental illness.

Mr. MURPHY. In your research, did you take people across the board, or did you concentrate on a youth group, or just what type of people did you get to?

Dr. GRIFFITH. We took what we could get, and that was the lower socioeconomic whites between the ages of 18 or 19, to 35 years of age.

Mr. MURPHY. Did you run into any members of the Armed Forces in this category?

Dr. GRIFFITH. No, sir; they wouldn't fall in that socioeconomic group.

Mr. MURPHY. They would be draft exempt because of low qualifications. Did you conduct any research around military installations?

Dr. GRIFFITH. We have a large military installation at Oklahoma City, but we ran into no members of the military who were using it.

However, as an Air Force psychiatrist, I have encountered such patients as clinical problems.

Mr. MURPHY. You wouldn't say there was any problem in the Armed Forces then?

Dr. GRIFFITH. Somewhat of a problem; yes. We see it, but I wouldn't have any idea as to the actual numbers.

Mr. MURPHY. I have no more questions.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. I have one question, Mr. Chairman.

You pointed out the fact that heroin was virtually nonexistent in Oklahoma City. I am sure you understand that under the Federal Narcotics Act, the controls exercised by the Bureau of Narcotics far exceed the controls contemplated in H.R. 2. From your experience, do you think it is possible to meet and control the condition that we are talking about by imposing less positive controls than we find imposed by the Bureau of Narcotics?

Dr. GRIFFITH. I think so. The reason I say this is, the mere fact that I was making an investigation practically dried up the supply of drugs in Oklahoma City. Some people thought that my investigation might get them into trouble, so they just stopped selling for a time. Certainly it would prevent a lot of people who aren't very ingenious from getting drugs. These are very simple criminal types, who don't have the good old American get up and go that it takes to obtain any large quantities of drugs from the drug companies. I think laws such as you contemplate would have a very inhibiting effect on the illegal traffic of drugs.

Mr. SATTERFIELD. That is all of the questions I have.

Dr. GRIFFITH. Might I add something to that?

Another reason that lighter controls would be effective is hard narcotics are not bulky and are quite expensive, but these drugs we are talking about involve large quantities and smaller profit margins. So I don't think you need the same strenuous controls that you need with narcotics.

The CHAIRMAN. You described the type of people, Doctor, that you contacted and you studied in connection with your research, and as I remember, you said it did not include certain classes. What classes was that? Were truckdrivers one?

Dr. GRIFFITH. Truckdrivers and nonwhites—Negroes and Indians. They simply wouldn't talk to me about it. It also did not include middle-class people. In other words, middle-class and upper-class people who are habituated to these drugs do not know one another like the people in the lower classes do, so that there was no easy way that we could identify them unless they saw a doctor.

The CHAIRMAN. Your study and research were primarily in the lower classes?

Dr. GRIFFITH. Primarily; yes.

The CHAIRMAN. And some in the upper echelon, so to speak?

Dr. GRIFFITH. Yes, sir.

The CHAIRMAN. The sophisticated types.

Dr. GRIFFITH. Yes, sir. There is one thing we learned: that neither rank in society nor experience, either professional, or medical, or state of mental health was a good insurance policy against getting habituated to these drugs. We found all of these examples.

The CHAIRMAN. Doctor, did you make any research as to whether it was being used by athletes?

Dr. GRIFFITH. You hit on a very sensitive subject.

The CHAIRMAN. I know it is, and I had this brought to my attention and I am not going to indicate where, because I don't think it would help to do so, not too long ago, when apparently a great many who participated in the event decided among themselves what they would do. I just wondered if you run across anything like that in your research?

Dr. GRIFFITH. To be absolutely frank, we would get second- and third-hand reports, but we tended to reject such reports out of hand anyway. That was from all informants. When we would follow these up, we would find that they were nothing more than rumor in our State. However, the medical literature does contain references to use by athletes.

The CHAIRMAN. Now, as a professional man and a psychiatrist, do you think alcoholism is a disease?

Dr. GRIFFITH. Yes, sir; I do.

The CHAIRMAN. Do the addicts to drugs have a reaction similar to the reaction of an alcoholic?

Dr. GRIFFITH. It is quite similar in many ways.

The CHAIRMAN. Do you think an addict to these drugs then is suffering from a disease?

Dr. GRIFFITH. Quite possibly; yes.

The CHAIRMAN. Then I would assume from what you have said that not only should attention be given to the manufacturer, the wholesaler, and the distributor, but some way of keeping up with the user, if possible.

Dr. GRIFFITH. I don't know exactly what you mean by "keeping up with them."

The CHAIRMAN. Do you think in order to meet this problem it is necessary to go so far as to make possession a violation?

Dr. GRIFFITH. We have this in Oklahoma. It solves a lot of problems in that if you catch a peddler with the pills on him, you don't have to prove that he had those pills to sell. It is up to him to prove that he got it from a doctor.

The CHAIRMAN. Suppose you catch an addict with some. He is the user, and he obtained them from a peddler.

Dr. GRIFFITH. Punishing him is not going to change the situation materially.

The CHAIRMAN. I am inclined to agree with you.

Well, doctor, I want to thank you, along with the other members of the committee, for your very interesting presentation. It is a refreshing thing to have from you your analysis of the problem, and a description of the research work that you have done. We appreciate it very much.

Dr. GRIFFITH. It is equally refreshing to have a distinguished group of Congressmen interested in a very serious medical problem. Thank you, sir.

The CHAIRMAN. Thank you for your appearance.

The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 4:20 p.m., the committee recessed, to reconvene at 10 a.m., Wednesday, February 10, 1965.)

## DRUG ABUSE CONTROL AMENDMENTS OF 1965

WEDNESDAY, FEBRUARY 10, 1965

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The committee met at 10 a.m., pursuant to recess, in room 1334, Longworth Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will be in order.

This morning, as we resume the hearings on the drug control legislation, we are pleased to have our colleague, Mrs. Sullivan. Mrs. Sullivan is the author of legislation on this subject and she has shown a keen interest in the matter over the years.

Mrs. Sullivan, we have conducted hearings for some several days on the subject. Realizing you have been out of the city on very important business, we are glad you did return in time to get your statement before the committee during the course of the hearings.

We are glad to have you this morning. We will be glad to have a statement from you.

### STATEMENT OF HON. LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Thank you, Mr. Chairman. I greatly appreciate your giving me this opportunity because I am interested in this type of legislation, and I consider it of vital importance—vital in the literal sense that our lives are in danger from the continued widespread illicit traffic in barbiturates, amphetamines, and the related central nervous system depressant or stimulant drugs.

We know that many of the head-on crashes on our superhighways, where a car or truck will suddenly careen across the median strip and plow into a car going in the other direction, wiping out entire families, can be attributed to more than just fatigue on the part of one of the drivers. As the work of the Food and Drug Administration has demonstrated, illicit sales of the so-called pep pills at highway stops are so common that the use of such drugs constitutes a real and present danger to everyone who ventures out on a highway.

The barbiturates and the amphetamines serve very useful medical purposes when properly used, and nothing in this legislation, of course, would interfere with the doctor's freedom of action in prescribing such drugs or with the patient's opportunity to buy them through legitimate

channels. But when the Commissioner of the Food and Drug Administration testified, as he did before this committee, that probably one-half of the 9 billion doses of barbiturates and amphetamines manufactured in this country in 1962 ended up on the bootleg market, then, Mr. Chairman, we are compelled by our responsibilities as Members of Congress to wipe out this bootlegging of pills which are major causes of highway homicide, which also serve as handy-dandy little suicide kits, and do-it-yourself instruments of mental illness and delinquency among youth.

Of course, you are not going to wipe out all traffic in instruments of homicide and suicide and crime, no matter what kind of legislation you pass, but I want to point out, before someone raises the question of firearms regulation and we get into a long and emotional controversy on a completely different issue, there is nothing in the first amendment about the right of the public to buy any kind of poison they want to.

In fact, we have many laws, including the Food, Drug, and Cosmetic Act, which severely restrict the manufacture, distribution, and sale of unsafe products in commerce, and we have other laws which prohibit the illegal possession of narcotics regardless of whether they moved in interstate commerce.

We must stop the illegal traffic in nonnarcotic drugs which are frequent substitutes for narcotics and which, when abused, are habit forming and dangerous not just to the user, but to the public. The legislation before you will go far toward accomplishing that purpose. It prohibits unauthorized possession of the pills, permits surveillance of all stages of production and distribution, and establishes criminal penalties for violators, particularly for sales to youths.

#### STRONGER PROVISIONS IN H.R. 1235

Commissioner Larrick pointed out in his testimony certain changes which he would recommend in H.R. 2, the bill introduced by Chairman Harris. Mr. Chairman, I would like to point out that one of the sections of H.R. 1235, my omnibus bill to rewrite the Food, Drug, and Cosmetic Act of 1938, contains all of the provisions of H.R. 2 on control of the dangerous and habit-forming depressant and stimulant drugs, and, in the respects cited by the Food and Drug Administration, also contains language covering most of the additional points raised by Mr. Larrick.

For instance, my bill permits seizure of any drugs for which there are not proper records as required under the proposed law. There are safeguards in the bill to protect legitimate manufacturers, wholesalers, and retailers, of course, but the burden of proof would be placed upon them to prove legal ownership of any drugs for which they failed to keep proper records. Under such tight restrictions, I cannot imagine half of the annual production of 9 billion doses disappearing out of legitimate trade channels.

H.R. 2 would extend to Food and Drug officials the right to carry firearms under certain circumstances in the administration of this new section of the Food, Drug, and Cosmetic Act. H.R. 1235 would go further, as Commissioner Larrick urged, and give such officials the

powers not only to execute and serve arrest warrants, and execute seizure by process issued pursuant to libel, but also to:

(a) Make arrests without warrant for offenses under this legislation—

if the offense is committed in the officer's or employee's presence or if he has probable cause to believe that the person so arrested has committed, or is committing, such offense.

(b) Make, prior to institution of libel proceedings—

seizure of drugs, containers, or conveyances if such drugs, containers or conveyances are, or if he has reasonable grounds to believe that they are, subject to seizure and condemnation under the law, provided, however, that libel proceedings be instituted immediately thereafter.

Mr. Chairman, these are very strong powers, but they are not excessive. They are similar to the powers now held by alcohol tax agents and by narcotics agents. In the case of habit-forming, dangerous drugs so widely bootlegged, we are dealing with criminal syndicates and hoodlums. Without such powers, the evidence can quickly disappear before warrants and libels can be issued.

#### FOOD, DRUGS, AND COSMETIC ACT NEEDS MAJOR OVERHAUL

My purpose in coming here this morning is not just to suggest the substitution of the stronger provisions of section 6 of H.R. 1235 for H.R. 2, as a tighter bill and more inclusive in fighting bootlegging of these dangerous drugs. I am even more brash than that.

Mr. Chairman, I first introduced this barbiturate-amphetamine control legislation more than 4 years ago, so I am very anxious to see such legislation become law. I know that the chairman of the committee has also been a sponsor of such legislation for a number of years. But we both recognize, and I hope all of the members of the committee also recognize, that the situation with regard to these dangerous mind-affecting drugs, while very serious, is only one of a whole series of important problems which now exist in the administration of effective food, drug, and cosmetic regulation.

We have put a lot of blowout patches on the Food, Drug, and Cosmetic Act of 1938 over the years, but the act itself needs a major overhaul. Instead, we have usually taken up one issue at a time, one Congress at a time.

In 1954, we passed the bill on pesticides, but nothing was done on cosmetics, or on food additives, or about other glaring gaps in the law. In 1958, we passed a Food Additives Act, but again did nothing about cosmetics safety, or any of the other deficiencies in the act.

In 1960, when the lipstick makers came rushing in for help, we quickly passed the Color Additives Act, requiring that all coloring matter in foods, drugs, or cosmetics (except hair dye colors) be proved safe before being used, but to this day we have done not a single thing to assure the pretesting for safety of any of the other ingredients in cosmetics except coloring matter.

In 1962, under circumstances I do not have to recall for this committee, which worked a legislative miracle in getting the legislation through under tremendous difficulties, we closed the major loopholes in the clearance of prescription drugs following the thalidomide disclosures, but once again we did nothing about cosmetics, or barbiturates

and amphetamines, or therapeutic devices, or any of the other major loopholes in the basic act which the Secretary of Health, Education, and Welfare, and the Commissioner of FDA have repeatedly deplored.

I included these things in my omnibus bill as long ago as 1961. The chairman of this committee also proposed many of these things in legislation he also introduced in the 87th Congress.

I introduced an omnibus bill in 1961, after having introduced separate bills on cosmetics in four previous Congresses, when I became convinced we were proceeding too slowly by taking up only one phase of the Food, Drug, and Cosmetic Act in each 2-year term of Congress. This is our basic consumer protection statute. It is 27 years old. Many provisions of it are obsolete. Some sections were bad 27 years ago, and are worse today.

Yet we have approached this vast problem a nibble at a time, a Congress at a time, even conceding that some of the acts which you have sponsored in these past 10 years, Mr. Chairman, have been very important and very sizable bites, indeed. But we haven't ever done since 1938 the kind of job done by this committee 27 years ago; that is, take a good, hard look at the entire act on foods, drugs, and cosmetics, and weed out the obsolete portions and replace them with effective provisions which truly protect the consumer in today's economy, rather than that of 27 years ago, when technology and marketing were far different.

#### MAY BE ONLY CHANCE TO AMEND ACT IN THIS CONGRESS

In my remarks in the Appendix of the Record on January 26, I spelled out these necessary and long overdue changes, as called for in H.R. 1235.

With your permission, Mr. Chairman, I would like to incorporate those remarks as part of my testimony today. I would hate to take the time to read it all, but I would like to have the material considered part of my presentation for purposes of this hearing.

THE CHAIRMAN. You may let it be included as part of your remarks.

Mrs. SULLIVAN. Thank you, Mr. Chairman.

In that statement, I went into detail on all of the provisions of my omnibus bill, and the reasons why the health and safety of the public, and the interests of all consumers, require passage of an omnibus bill such as H.R. 1235, rather than another piecemeal approach as in H.R. 2.

My plea is this: Please extend the scope of these hearings to include all phases of the Food, Drug, and Cosmetic Act requiring improvement and amendment. You have made a fine, early start in this Congress on a most important aspect of the problem. But I am fearful that if we pass H.R. 2 by itself, that may be the only part of the Food, Drug, and Cosmetic Act we can get to in this Congress. For I am mindful of the heavy legislative responsibilities of this committee in so many other fields—transportation, aviation, natural gas, power, the Public Health Service program, railroad retirement, communications, the Securities and Exchange Commission and the other regulatory agencies, and the fact that once you put this one aspect of the FDA Act behind you, the press of hearings on other issues may make it impossible to go back to this subject.

Important as are the barbiturates and amphetamines, they constitute only one of the serious gaps in food, drug, and cosmetic control. At the pace which has been followed in the past, it may be years before we can complete action on such major loopholes in the law as those applying to—

1. Therapeutic devices—which can be marketed today without proof of safety and without proof of effectiveness, and which in many instances, are tools for the victimization of the elderly and sick, as Senator Williams' Committee on the Aging reported just last week.

2. Cosmetics—which can also be earmarked without prior clearance for safety, except insofar as the coloring matter is concerned (and in the case of hair dyes, the colors can be virulently dangerous just so long as the label points out they may not be safe for some people to use).

3. Worthless dietary foods—another major source of defrauding the elderly and ill.

4. Factory inspection for foods, nonprescription drugs and cosmetics—the same loopholes in these fields which we closed for prescription drugs in the Kefauver-Harris Act of 1962.

5. Deceptive labeling and packaging—the public is really becoming aroused over the tricks which can be perpetrated under present law. I firmly believe that if we do not solve this problem through the non-controversial features of section 2 of H.R. 1235, you will soon be faced with tremendous demand for much more stringent regulation.

6. Cautionary labeling of foods, drugs, and cosmetics—now exempt under the Hazardous Substances Labeling Act so that no information need be supplied on possible dangerous uses or misapplications, or on first aid steps to be followed in case of mishap or accidental ingestion, particularly by children.

There are many other changes in the basic Food, Drug, and Cosmetic Act of 1938 called for by H.R. 1235, including a proposed ban on interstate commerce in flavored or sweetened aspirin, a major cause of accidental poisoning of children under five. In extending my remarks, I will list all of these provisions. But for right now, I fervently ask that you expand your hearings on H.R. 2 to include all phases of the act, and give our consumers the first real top-to-bottom review in 27 years of the many deficiencies in this statute.

I greatly appreciate, Mr. Chairman, the opportunity to express my views on this legislation.

The CHAIRMAN. Thank you, Mrs. Sullivan. We do appreciate your long-continued interest in this subject matter. We are glad to have the benefit of your views and suggestions and recommendations. The committee, of course, will give serious consideration to them.

With reference to the expanding of the hearings, I doubt that we will be able to do that because we have outlined the schedule and the objective of this particular hearing. I do not pretend to speak for the administration or the agency involved, but I have had it brought to my attention that there will be proposals coming up on many of these subjects in the near future. I am not making promises. I don't know. I am just relating to you what I understand the situation to be. If they do come up with their recommendations, the committee will give consideration to them, of course.

Mrs. SULLIVAN. Thank you, Mr. Chairman.

(Mrs. Sullivan's remarks in the Congressional Record follow:)

[From the Congressional Record, Jan. 26, 1965]

LET'S HAVE MORE, NOT LESS "POLITICS IN THE PANTRY"—AND ALL THROUGH THE HOUSE—BY CLOSING GAPS IN CONSUMER PROTECTION LEGISLATION

(Extension of Remarks of Hon. Leonor K. Sullivan, of Missouri, in the House of Representatives, Tuesday, January 26, 1965)

Mrs. SULLIVAN. Mr. Speaker, I was greatly honored in the last Congress by the chairman of the Committee on Banking and Currency, the Honorable Wright Patman, of Texas, when he named me to the chairmanship of a newly created standing subcommittee known as the Subcommittee on Consumer Affairs, a field to which I have devoted so much of my efforts in the Congress during the past 12 years. And you, Mr. Speaker, further honored me for my work on consumer issues by appointing me as 1 of 5 Members of the House of Representatives serving on the 15-member bipartisan National Commission on Food Marketing, created by Public Law 88-354.

I am therefore always interested in the views of responsible leaders of our food industry and in any discussion of legislation affecting the consumer and the businesses which serve consumers. Consequently, I read with great interest an article in the current issue of *Look* magazine—the one dated today, January 26—written by the chairman of the board of one of our greatest food processing corporations about the fine job the American food industry is performing in making this the best-fed Nation in the world, and at the most reasonable cost.

POLITICS AND THE PANTRY

The article is entitled "Let's Keep Politics Out of the Pantry." In it, Mr. Charles G. Mortimer of General Foods points out that whereas only 19 cents of the American family's take-home dollar goes for food, the average family in Great Britain spends 29 cents, in France 31 cents, in Japan 47 cents, and in the Soviet Union, 50 cents. Furthermore, he tells us, there is a much greater variety of foods here, more convenience foods, and—thanks to Government safeguards and the competitive pressures of America's free enterprise system—Mr. Mortimer says the American housewife is fully protected not only against dangerous and unwholesome foods but also against trickery and deceit in the marketplace.

Nevertheless, this food executive warns, there is an ominous cloud on the horizon, threatening our best-of-all-possible food worlds. Mr. Mortimer declares:

"The machinery of free competition which has made ours the best-fed Nation on earth is in danger of being tampered with. It is being attacked by certain people in Government who have the perverse notion that the Mary Joneses of America need more Government protection than the ample safeguards they already have."

The fears of the General Foods Corp. board chairman grow out of the activities of what he describes as "vote-conscious politicians" who are, as he puts it, "playing politics in the pantry" by "pitching emotion-charged appeals" to consumers. He says that the politicians are indulging in "headlinemaking innuendos" implying that America's food marketing system "needs to be watched and regulated even more closely than it is."

The General Foods executive was directing his fire primarily at Senator Hart's so-called truth in packaging bill, which is aimed at the jungle of confusing sizes making intelligent price comparisons so extremely difficult for the average shopper in the supermarket; at Mrs. Esther Peterson, the President's dynamic and effective Special Assistant for Consumer Affairs; and at the possible recommendations of the National Commission on Food Marketing.

IF THE SHOE FITS—

But although he does not mention me by name, I cannot help but feel that I, too, must be one of his targets in that article. The evils Senator Hart seeks to eliminate in his bill proposing readily comparable sizes of bottles and cans and boxes in easily computed multiples or fractions of pints, quarts, pounds, and so on, are also attached in the labeling provisions of one of my bills, although from a much different approach, and in a less controversial manner. But essentially, Senator Hart and I seek similar goals of better information to the consumer in making price and quantity computations in the stores.

For a second thing, I think Esther Peterson is doing a wonderful job, and I am all for what she is trying to accomplish. I have worked very closely with her through my subcommittee, and I hope to continue to do so. And, for a third thing, I am, as I said, a member of the National Commission on Food Marketing, which Mr. Mortimer of General Foods hopes may do a good job in explaining the necessary roles played by the different levels of our food distribution system, but he fears we may, instead, do a very bad job by merely trying to expose the so-called middlemen as profiteers.

Personally, I have no idea in the world what we will end up doing in that Commission, for we have only just begun our work, and the first job has been to pick capable and unbiased staff experts to do the basic research which will eventually guide us in making our recommendations to Congress.

#### WE NEED MORE CONSUMER POLITICS, NOT LESS

But beyond all that, I am certainly the food executive's target because I must admit that I am a politician—and undoubtedly a vote-conscious one, too. Members of the House of Representatives of the Congress of the United States must win reelection every 2 years in order to retain and enhance their seniority and thus accomplish their objectives. To win elections, you have to get more votes than your opponents, and I have taken my chances in the ballot boxes of my district seven times, so I am certainly aware of the importance of consumers as voters.

Thus, I suppose I must plead guilty to at least some of the counts in the General Foods Corp. board chairman's indictment in today's *Look* magazine against "vote-conscious politicians" promoting what he calls the "perverse notion" that the supermarket customers of this country need more Government protections than the ample safeguards Mr. Mortimer believes we already possess.

If I didn't have such notions—perverse or not, depending upon one's viewpoint—I would undoubtedly feel a bit silly about putting so many bills into the congressional hopper to tighten the safeguards which already exist, or to create new safeguards where none exist.

It is not my purpose here to debate with the General Foods chairman the quality and wholesomeness and comparatively reasonable costs of American food. However, I certainly challenge his theory that there is something ominous or reprehensible about "playing politics" on these issues, or that we should, as he puts it "Keep Politics Out of the Pantry." Instead, I would say: "Let's Have More Politics in the Pantry, and All Through the House."

#### POLITICS IS SCIENCE OF GOVERNMENT

Perhaps the whole argument rests on what we mean by the word "politics." As used in the *Look* article urging us to "Keep Politics Out of the Pantry," it is a somewhat mild and gentle word, implying—in a not too angry fashion—hints of self-seeking, of personal aggrandizement, demagoguery, voter deception, and perhaps a tiny touch of corruption. In this connotation, "politicians" are not necessarily evil, not bad all through, but rather forced by their professions to "play politics" by deceiving the public into wanting things that are not good for them, so that the politicians can stir up enough turmoil in giving these undesirable things to the public to make a lot of headlines and thus get the politicians' names in the paper, the better to gain attention and win votes.

To me, politics is a good many cuts above that level. To me, politics is the science and art of government in which every citizen has not only the right but the solemn obligation to participate to the utmost of his abilities and opportunities. Without politics American-style, the free enterprise system which has made this country great in so many ways could not possibly have grown and developed, for our economy is an outgrowth, and a corollary of our form of government and of the politics which make democracy function.

#### POLITICS AND WHOLESOME FOOD

Even the acknowledged greatness of the American food industry is a direct reflection of American politics at work. For the very safeguards the General Foods chairman referred to in his article as now adequately protecting the American consumer against unwholesome foods and deceptive sales devices were the hard-won—but never completely won—fruits of political effort and political achievement—by Teddy Roosevelt as well as by Franklin D. Roosevelt, and by

other Presidents and Cabinet officers and bureaucrats and Congressmen and Senators doing what the General Foods executive calls "playing politics"—putting politics in the pantry, as it were.

There is a long history of legal enactments—which were all bitterly contested, highly controversial, touch-and-go political issues—when first introduced in the form of proposed legislation in the Congress—but which resulted in today's high food quality and wholesomeness. Each was proclaimed in its time as the fore-runner of doom for the American free enterprise system. Opponents charged in each instance that the "vote-conscious politicians" were "playing politics" with free enterprise.

#### MEAT AND POULTRY INSPECTION

We have had compulsory Federal inspection of meat for wholesomeness in interstate commerce for 59 years. Upton Sinclair and other writer known in their day as "muckrakers" presented such a sickening picture of the conditions in our packing plants that the people demanded that Government take action, and it did. But it was not until 1957—41 years later—that we had the same protections written into law for interstate shipments of poultry. When I first introduced the poultry inspection bill, the poultry industry was alarmed. Today, federally inspected poultry is accepted within the industry as one of its best sales tools, and American poultry has won tremendous export markets around the world, based on the reliability and acceptability of the little seal or tag which says "U.S. Inspected for Wholesomeness." Nevertheless, much meat in intrastate commerce is still not inspected for wholesomeness.

#### PURE FOOD AND DRUG LAW OF 1906

The Food and Drug Act of 1906 was our first foray into protecting the American consumer against adulterated or unsafe American products in the two fields of foods and drugs. It took a scandal involving the sale to the Army of meat treated with formaldehyde, and revelations about tonics and medicines (supposedly for women but consisting mostly of alcohol or opium or other ingredients no lady would have knowingly used), to spur the public into demanding remedial legislation and Congress to pass it.

#### COSMETICS REGULATION BEGAN ONLY 27 YEARS AGO

But cosmetics did not come under Federal supervision until only 27 years ago, in the Food, Drug, and Cosmetic Act of 1938, after numerous women had been blinded by unsafe eye preparations. If you read the old congressional debates on that bill—a milestone piece of legislation then, but terribly outmoded today—you will come across speeches predicting that the measure would bankrupt every business in the field, discourage research in medicines, and make every woman get permission from some bureaucrat in Washington before she could powder her nose or use lipstick.

#### LOOPHOLES IN THE FOOD, DRUG, AND COSMETIC ACT OF 1938

The 1938 act, as I said, was a good law for its time, but time quickly eroded holes in it, through court decisions and changes in technology. Not all of those holes have been repaired. Other loopholes still in the act were deliberately put there when it was originally passed, in order to assure neutrality on the bill on the part of some business interests, like the soap manufacturers, for instance, who otherwise would have joined in the bitter battle to defeat the controversial legislation in 1938. I will mention later a few of those special exemptions dating back to 1938.

But what about the loopholes Congress did not anticipate, and had no intention of creating? One of the first bills I introduced in my first term in the Congress was directed at closing such a gap created by court decisions. The courts had ruled that the Government's food and drug inspectors could not inspect the operations of a plant if the owner or manager did not want to admit them. Well, this was not the intent of Congress at all, so we had to amend the law to make it explicit.

In 1954 we first took notice of the great danger to our food supply which was developing from unregulated use of pesticides on raw agricultural commodities—that was only 11 years ago.

## UNTESTED CHEMICALS IN FOOD

It was only 15 years ago that the Delaney committee in the House, a special committee headed by Congressman James J. Delaney, of New York, first spotlighted the dangers to consumers from a proliferation of new chemical additives being used in food processing without prior testing and certification as to their safety. It took Congress 8 years thereafter to act on the Delaney committee revelations in the Food Additives Act of 1958, which I cosponsored. By then, responsible leaders of the food industry were acknowledging the need for corrective legislation, but the battle over the details of the bill were often bitter ones. The 1958 act was a great forward step. Under it, the manufacturer now has to prove an additive is safe before he can use it in foods. Previously, the burden of proof had been on the Government; if the Government could not provide legal proof that the additive was harmful, the manufacturer could continue to use it, even if the weight of scientific evidence indicated the safety of the product was seriously in doubt.

## BURDEN OF PROOF ON COSMETICS SAFETY IS ON GOVERNMENT

The burden of proof, however, is still on the Government in the law's sections on cosmetics. There is no requirement that cosmetic manufacturers must pretest their products for safety. The consumer thus can easily be a guinea pig on a new cosmetic item. If enough consumers get hurt—burned or scalped or disfigured or scarred or infected from a new and untested cosmetic—the Government eventually hears about it and moves against the product and takes it off the market. But, oh, the agony in the meantime. Remember the false fingernails which caused such anguish several years ago, when it was discovered that removing them could also remove the nails? Or the hair dyes which made women bald? These things can happen under our present law on cosmetics.

So I say to women in this country: "This is an area in which every woman—every woman—had better begin to play politics in every way she knows how, because your skin and your hair and your nails and your eyebrows and your lips and even your lives may be at stake someday."

## COSMETIC COLORS MUST BE SAFE—BUT NOT IN HAIR DYES

The only significant improvement made in the cosmetic sections of the Food, Drug, and Cosmetic Act in the last 27 years has to do with the coloring matter used in cosmetics. How it came about is a long story, and a somewhat ironic one, but color additives must now be proved safe in the manner used before incorporation in a food, drug, or cosmetic. Even if considered safe in the manner used, a color additive can still not be approved if it could cause cancer in man or animal. That is the so-called Delaney clause, which we also wrote into the law on food additives in 1958.

But outside of the coloring matter, no other ingredients of cosmetics have to be pretested for safety or subjected to any preclearance by the Government before use. Only when the Government can produce legal proof that a cosmetic is unsafe or contains unsafe ingredients can it act against it. Legal proof, as you can guess, must go far beyond reasonable doubt as to safety—it must be proof of harm. And often that is impossible to ascertain without years of laboratory research.

In the case of hair dyes, it does not matter how dangerous they are—they can be sold anyway, as long as the label clearly warns the purchaser that the product may be dangerous to use. That is all the law requires. In a beauty shop, how many women ever get to see the labels on the bottles or drums in which hair dyes are shipped?

## GAPS IN OUR FOOD LAWS

So to go back to the thesis in the food executive's article in today's issue of *Look* magazine—that the Food, Drug, and Cosmetic Act already fully protects the consumer of foodstuffs, and that those who would further tighten consumer protections are cynical politicians "playing politics in the pantry," I would say that legislative history of the Food, Drug, and Cosmetic Act in the 12 years in which I have served, and for long before that, shows that it is overoptimistic, and usually premature, to make sweeping defenses of the status quo in consumer protection legislation. Even if we concede the accuracy of Mr. Mortimer's claim that the provisions of the act dealing with foodstuffs are generally adequate—

and on the whole they are very good—it is clear that other sections of the law are terribly inadequate—dangerously so—and that some of the food sections need modernization, too.

For instance, the law we passed in 1960 on cautionary labeling of hazardous household products such as bleaches, paints, insecticides and so on, does not apply to foods, drugs and cosmetics; including those packaged in pressurized containers, which can be dangerous when carelessly handled. Furthermore, the section of the Food, Drug, and Cosmetic Act dealing with informative labeling of foods—giving the consumer information she is legally entitled to have—has been held by the courts to be too vague to prevent some processors from hiding the information in tiny type in a cluttered panel, or in pastel inks on noncontrasting backgrounds, defying the housewife's efforts to find the information on weights, ingredients, and so on.

I am not a lawyer, so I cannot argue with the judges on whether the present language on labeling is too vague. It sounds clear enough to me. It says the required information on a food label must be "prominently placed thereon with such conspicuousness—as compared with other words, statements, designs, or devices, in the labeling—and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

#### READ THE LABEL—IF YOU CAN

As I said, that sounds pretty clear and straightforward to me. But the courts have nevertheless blocked Food and Drug Administration efforts to crack down on some flagrant violators. The law therefore needs a simple amendment authorizing the Government to issue regulations specifying—as is done now in the prescription drug sections of the law—how the required label information must be presented on the label—the location of the data on weights and on ingredients, the comparative type sizes to be used, and so on.

Otherwise, the housewife will continue to find it difficult, if not impossible, to find the net weight on some bags or boxes, or cans or bottles, if only to try to figure out the better buy between different sizes of the same brand. And she will continue to find it a real challenge to find the listing of ingredients to make sure the contents do not include anything to which some member of the family is allergic.

There is not widespread enough violation of the spirit of the labeling law to an extent that it is a serious national crisis, but violations are common enough to constitute an un pardonable nuisance to the careful, label-reading shopper—who must take extra hours to do her marketing. These violations also victimize the casual shopper who is quickly discouraged from making the complex price computations to determine the more economical among competing products or among different size packages of the same product. So she buys the "large economy size" on faith that it is the better buy—and often it is not as good a buy as a smaller size—believe it or not.

#### LOOPHOLES ENDANGERING HEALTH

Much more serious, however, are the gaps in the food, drug, and cosmetic law which affect not your pocketbook and disposition so much as your life and safety. I have described the free and easy manner in which cosmetics can be manufactured and put on sale without pretesting or clearance for safety and the fact that coal tar hair dyes are subject to no regulation, no matter how dangerous, as long as the label warns you of the possible consequences of using them. The cosmetic and hair dye manufacturers won these special exemptions for their products during the battle over passage of the original act in 1938.

They have been successful ever since in fighting off attempts to make them prove the safety of their products before marketing. They apparently want us vote-conscious politicians to keep politics out of the beauty parlor. I hope you agree with me that more politics, not less, is needed in coping with this problem.

#### THERAPEUTIC DEVICES

Let us look at another loophole in the law. Therapeutic devices—medical devices of all kinds—can also be marketed, as cosmetics are, without safety clearance, and can be removed from the market only if proved dangerous or fraudulent. In this case, we should require not only proof of safety but also proof of effectiveness, too—particularly when someone with a serious illness or disability

delays seeking medical attention in the hope some useless machine or device can cure him. But the problem is serious also in the devices and materials used in good faith by physicians and dentists. What a tragedy it has been for some patients who underwent surgery involving the use of artificial bone material only to have the material deteriorate in the body; then they have had to go through the ordeal all over again—merely because the material used had not been sufficiently tested for safety and effectiveness before being put on the market.

H.R. 1235, AN OMNIBUS BILL TO REWRITE THE FOOD, DRUG, AND COSMETIC ACT OF 1938

Rather than catalog all of the possible dangers of living in today's fast-changing world with its amazing new technology, I would like to list what my omnibus bill to rewrite the Food, Drug, and Cosmetic Act of 1938 would actually do. Its number is H.R. 1235. I introduced it originally on the opening day of the 87th Congress, in January, 1961, 4 years ago. Brief hearings were held in June 1962 on the whole range of issues covered in the omnibus bill, after President Kennedy's consumer message that year endorsed most of its provisions. As originally introduced, the bill provided the procedures later adopted by Congress to safeguard prescription drugs, in the historic Drug Control Act of 1962 which was enacted after the thalidomide tragedy came to public attention.

#### IT HAS EVERYTHING IN IT, INCLUDING THE KITCHEN SINK

I revised and reintroduced the bill in the 88th Congress, 2 years ago, but no action occurred in the House on any of its features. I have now reintroduced it in this Congress, bringing it up to date once again. It is 45 pages long and covers everything you eat, all the medicines you use, anything rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for the purpose of cleansing, beautifying, promoting attractiveness, or altering the appearance, to give you the official definition of a cosmetic; it applies also to therapeutic devices, fake cancer cures, worthless ingredients in special dietary foods; over-the-counter drugs, animal foods, sleeping pills, pep pills, and other habit-forming stimulant drugs.

In other words, it has everything in it, including the kitchen sink, along with the refrigerator, the bathroom medicine cabinet, the dressing table, and the nursery. I am going to spell out some of the provisions, Mr. Speaker, so that the Members can decide whether the loopholes which this bill would close are serious enough to warrant action. I also hope that through publication of this material in the Congressional Record, many citizens, particularly women, are able—through newspapers, radio, and television programs, magazine articles, and through their churches and clubs and organizations—to learn more about the need for this legislation, for I am convinced that they then will insist and demand that Congress act.

As I told the women attending the convention of the National Rural Electric Cooperative Association, along those lines, if enough women are made aware of the deficiencies in our basic consumer law and are encouraged to write to their congressional delegation about these deficiencies and the need for corrective legislation, such legislation will be enacted promptly. As I explained, "Congress is like the accelerator of your car—that is, very sensitive to pressure. You make it go by putting your foot down."

#### SECTION-BY-SECTION EXPLANATION OF H.R. 1235

Now here, in the order in which they are covered by H.R. 1235, are some of the things on which all of us, and particularly the women of this country, must put their foot down hard.

Section 1 is the title of bill.

#### MAKING THE LABEL SERVE ITS FULL PURPOSE

Section 2 deals with amendments to the required labeling provisions of the present law—to make sure the consumer can readily find the net weight and ingredients and other information she is entitled to have on food, drug, and cosmetic labels; also to require cautionary labeling on pressurized food or cosmetic containers so as to prevent accidents, and on medicines and drugs to prevent unsafe use by children or by adults with pathological conditions. Labels would have to carry instructions for first aid treatment, when necessary.

For instance, in the case of cosmetics which are frequently swallowed by children, the doctors just have to guess as to what is in the products. This section would also apply to hair sprays, which are usually dangerously flammable—but you see women using them while smoking, and in the beauty shops you see clouds of the spray with no one apparently aware of the fact that they can be dangerous to inhale.

Section 2 also removes a 27-year-old loophole put in by the dairy industry, exempting butter, cheese, and ice cream from having to reveal on the package or label the presence of artificial color. Every other food label must show the presence of artificial color; why not butter, cheese, and ice cream? Of all of the provisions of my bill, I guess this one on artificial color in dairy products is probably the least urgent from the standpoint of health and safety, but I included it because this exemption is typical of how every industry wants to hide from the consumer facts which are perhaps a little embarrassing—such as the fact that the beautiful yellow color which butter claims as its own is often put there with a chemical.

Some consumers, for reasons of their own—and sometimes they are good reasons—want to avoid artificial coloring matter in food whenever possible. The color additives in use in food are proven to be safe in the manner in which they are used, but it should be remembered that the law had to be changed several years ago to repeal a previous requirement that these colors must be absolutely and completely harmless under any and all circumstances. The Government discovered that many of the coal tar colors were no longer able to pass this requirement of the 1938 act because the testing devices, like those used to find pesticide residues in milk, were so much improved and so extremely sensitive.

#### SPECIAL DIETARY FOODS

Section 3 of my bill deals with worthless ingredients in special dietary foods. This is a very controversial issue among health food manufacturers. It prohibits the use in a product represented as a special dietary food of exotic-sounding ingredients which have never been shown to have the least nutritive value, or any dietary usefulness whatsoever. Sale of the ingredients themselves would not be touched; the bill would apply only when the products are represented as having special dietary value.

#### PRETESTING OF MEDICAL DEVICES FOR SAFETY AND EFFICACY

Section 4 applies to the pretesting of therapeutic devices for safety and proof of effectiveness before they can be sold. I covered that earlier.

#### CERTIFICATION OF ALL ANTIBIOTICS

Section 5 requires the certification by the Food and Drug Administration of the purity and potency of veterinary antibiotics, similar to the requirement we wrote into the law in 1962 applying to antibiotics intended for use by man. When these powerful, and often unstable drugs are used on meat animals, we should be certain they are from certified batches, tested and approved by Uncle Sam.

#### THE MIND-AFFECTING DANGEROUS DRUGS

Section 6 deals with the barbiturates, amphetamines, and other habit-forming central nervous system stimulants—the sleeping pills, and the pep pills, the “goof balls” and “bennies,” and other drugs so widely bootlegged as to constitute a national menace. How many deaths on the highways that can be attributed to the use of these pills we can never know. They are dangerous, and doctors who prescribe them treat them with respect.

H.R. 1235 would not interfere in any way with proper medical dispensing of any of these drugs; the targets of the bill are the fly-by-night outfits which obtain and distribute them in the same way that narcotics are sold and whisky used to be sold during prohibition. My bill uses weapons similar to those we use in fighting narcotics; possession itself would be a crime for any except those having a legitimate reason for having the drugs on hand.

We are dealing here with a vast illicit traffic in death-dealing drugs which are major instruments of suicide, and major causes of highway deaths, and major causes of mental injury to youth. A Presidential Advisory Committee called them psychotoxic, or mind-affecting drugs. There is now such widespread

awareness of the dangers from these drugs that the Senate last year passed a bill containing most of the features of this section of my bill.

I oppose the piecemeal approach, however; there are so many deficiencies in the Food, Drug, and Cosmetic Act, of which this is only a part, that I decided in 1961 to seek a single overall solution to all of them at one time, in one bill. That is how my omnibus bill was developed. I got tired of the snail's pace at which we were correcting faults in the old act, like putting blowout patches on an old automobile tube long after it needed replacement for safety. I am sure we could quickly pass a bill dealing with the bootlegging of these so-called psychotoxic drugs, but I am afraid it might be at the expense of early action on other necessary reforms in the Food, Drug, and Cosmetic Act, such as on cosmetics safety and so on. Of course it all depends on the Congress and on the public. If enough Americans insist upon a complete overhaul of the entire act, it can be done. But if Members of Congress are not made more aware of the problems, then the piecemeal approach will undoubtedly continue to be followed.

#### FAKE CANCER REMEDIES

Section 7 of H.R. 1235 deals with fake cancer remedies, and drugs or devices intended for the prevention or cure of cancer. This is an area of widespread trickery and fraud, and it is tragic. On the other hand, we do not want to discourage the search for any really effective treatment for this disease, on which so much research money and time and effort are now being spent.

This is a section of my original bill of 1961 which I have retained in succeeding versions of the measure, even after the passage of the 1962 Drug Control Act which covered the testing of new prescription drugs in comprehensive fashion. I left this section in, however, because I think that in evaluating drugs or devices intended to prevent or cure cancer, the Government must have every possible assistance—the complete facts—everything about the treatment—without any holdback of information, so a determination can be made of the circumstances under which it can be tested and used. This section, by the way, would apply primarily to racketeers in health, not legitimate researchers.

#### PRETESTING COSMETICS INCLUDING A DELANEY ANTICANCER CLAUSE

Section 8 is the basic foundation on which the rest of the omnibus bill was originally built 4 years ago: the pretesting of cosmetics for safety. It contains an anticancer clause such as we have in the food additives and color additives acts—under it no ingredient could be used in a cosmetic if it could cause cancer in man or animal. The law on cosmetics does not now say that. Under the present law, the Government, as I noted, must prove a cosmetic harmful in order to block its sale; under H.R. 1235, the manufacturer would have to prove the product is safe to use, and, in addition, that it does not contain any carcinogens, whether used in a safe fashion or not.

#### THE SOAP AND HAIR DYE EXEMPTIONS

This section would also repeal the old special interest exemption for soap, which, since 1938, has been held by the law not to be a cosmetic. Soap manufacturers are therefore subject to nothing more than their own consciences and the risk of possible damage suits for what they might include among ingredients of a soap, and they do not even have to tell you the net weight of a bar of soap.

More importantly, this section of H.R. 1235 also repeals the hair dye exemption now in the law. Hair dyes, too, would have to be proved safe for use before being placed on sale.

#### FULL DISCLOSURE OF COSMETIC INGREDIENTS

All of the significant ingredients of a cosmetic item would have to be revealed on the label under H.R. 1235. Actually, there are few secrets in the cosmetic industry; most competing products use similar basic ingredients. But for the woman who is allergic, there is no way but painful trial and error—and sometimes it is very painful—in finding suitable cosmetics. When a formula is suddenly changed in a product she has been using, she is back in the dark, and perhaps also back in the doctor's office. Even the Food and Drug Administration sometimes has to guess what is in a particular cosmetic. The Government should be informed about ingredients, and so should the buyer.

## ADMINISTRATIVE SUBPENAS

Section 9 provides for administrative subpena powers, particularly in developing information for the establishment of food standards. Food standards issued by the Government, in cooperation with the processors, spell out exactly what ingredients must be included in a processed food once it is covered by a particular standard. Subpena power may be needed, too, in pesticides hearings.

## CARRIER'S EXEMPTION IS TOO BROAD

Section 10 repeals an exemption enjoyed for many years by the railroads, trucking firms, and other common carriers, which are now relieved of responsibility under the act for transporting adulterated foods, drugs, or cosmetics even when the adulteration occurred as a result of their own actions or omissions. Under my bill, the carriers would continue to be exempt only in those cases where they did not cause the adulteration.

## A TOUGH FACTORY INSPECTION PROVISION

Section 11 is a tough factory inspection amendment, giving to the Food and Drug Administration stronger powers in inspecting facilities used and methods used in the manufacture, processing, warehousing, packaging, and distribution of foods, cosmetics, and nonprescription drugs. The Food and Drug Administration already has these stronger factory inspection powers in checking on prescription drugs, under the 1962 act. These powers include the right to see all relevant files, including complaint files, and to check on the professional qualifications of personnel responsible for performing certain technical functions in the plant. Factory inspection is a vital area of consumer protection, even though food and drug inspectors can still touch only a tiny fraction of the existing plants in the country each year. But when they do go in to inspect, the inspectors must have sufficient powers to determine whether the products are made in a sanitary, wholesome or safe manner and if the production controls are adequate to maintain the necessary standards.

## CANCER-CAUSING COLORING MATTER IN MEAT ANIMAL FEEDS

Section 12 repeals a special-interest exemption in the law for cancer-causing coloring matter used in animal feeds. I have never been able to get an understandable story from anyone on why this exemption was written into the law or what purpose it is to serve. If the Government finds any residue of a cancer-causing feed ingredient in the carcass of meat animals he can order a halt to the use of the animal feed responsible; and it is on this basis that the growth stimulant hormone stilbestrol is now widely permitted to be used in animal feeds. But why should we permit the use of cancer-inducing coloring of animal feeds? The coloring matter serves no nutritive purpose, and no economic purpose. It is certainly not intended to make the feed more appetizing to the steer. It merely helps the farmer to identify different feeds by color. But permitting the use of carcinogenic coloring matter for this purpose is a completely unnecessary and unjustifiable additional hazard. H.R. 1235 repeals this glaring exemption.

## U.S. INSPECTION OF FOREIGN FACTORIES

Section 13 would require foreign manufacturers of foods, drugs, or cosmetics who export substantial quantities of their products to the United States to permit on-the-scene inspection by U.S. officials of their plants overseas. At present, only a small percentage of the food, drug, and cosmetic imports into this country are inspected on arrival—on a sampling basis, but not necessarily a random one—to make sure they are safe, wholesome, uncontaminated, and otherwise eligible for admission under our laws. This spot check at the docks is often concentrated on the exports of firm whose products have frequently reflected a high percentage of violations. Under H.R. 1235, the United States could send inspectors to inspect the plants of foreign firms it has reason to believe are not observing proper sanitary or production control practices on foods, drugs, or cosmetics sold here. We would inspect on the same basis as we now inspect American plants. If the foreign plant cannot pass our domestic inspection requirements, or if it refuses to permit our inspectors to enter on request, its products would be denied admission to this country. I think this is a useful reform.

## A BAN ON FLAVORED ASPIRIN FOR CHILDREN

Section 14 of H.R. 1235 prohibits the sale in interstate commerce of flavored or sweetened aspirin. This is a new provision, just put into the bill this year for the first time. It grew out of a letter from a St. Louis resident on a completely different matter, but in checking into some facts on household accidents in connection with inquiries made in that letter, I discovered to my amazement and horror that candy aspirin, the special baby aspirin, is far and away the leading cause of accidental poisoning of children under 5.

Aspirin poisoning is the most frequent cause of death among young children from accidental ingestions. The children learn to regard flavored aspirin as candy, and thousands of them each year risk death by eating an entire bottle of flavored aspirin in the belief it is candy. If the mother or the babysitter discovers the empty bottle in time, the child's life is saved, but in 125 to 150 instances a year, the child dies.

There is no reason in the world why a parent cannot crush half of a regular aspirin tablet on a spoon, using the bottom of the bowl of another spoon to do the crushing, and then add sugar and water, or jelly or some other sweetener to the crushed aspirin to help push the medicine down, if the child needs aspirin. The child would at least know this was medicine, not candy.

Since adding this aspirin provision to H.R. 1235, I have heard from mothers from different parts of the country telling me of hair-raising experiences in their homes when children or grandchildren found the flavored aspirin bottle, pried off the so-called safety cap, and ate the contents.

If there were no chance whatsoever of the product being misused by preschoolers—who after all, cannot read warnings on labels—my bill would permit certain exemptions and waivers under this provision, but otherwise flavored aspirin could not be sold in interstate commerce, except for stocks manufactured prior to 1965.

## CONSUMERS MUST MAKE THEIR VOICES HEARD

I do not think the aspirinmakers will like section 14 of H.R. 1235, just as the cosmetic manufacturers do not like section 2 or section 8 and other affected interests do not like other sections of H.R. 1235. The big question to me, however, is whether the people of this country like this bill—enough to join me in fighting for it.

Consumer battles can be won in the Congress only when consumers make it clear that they want them won, and will work at it and, yes, "play politics" at it. That is why I say—in contrast to the General Foods executive I quoted—let us have more politics in the pantry, and also in the bathroom medicine cabinet, and all through the house, as H.R. 1235 would require—more politics in the sense of more active citizen interest in more effective safety laws affecting consumers and consumer products.

There are other consumer issues in Congress besides those involving the Food, Drug, and Cosmetics Act, of course, and I hope the people of this country will "play politics" on those, too.

## TIRE SAFETY

In addition to more politics in the pantry, and all through the house, as exemplified by H.R. 1235, we need more politics on the highways, too. Passage of the provisions of H.R. 1235 applying to the mind-affecting drugs which are such frequent causes of highway accidents will certainly save lives, but so also will another bill of mine on highway safety—H.R. 688, to provide for Federal standards for automobile tires, to and the mass murder on the highways from shoddy tires which the consumer purchases in a jungle of price and performance claims, but with no way of knowing for sure what the quality of that tire really is. H.R. 688 was originally drafted and introduced in the last Congress by former Congressman Kenneth Roberts, of Alabama who, as we all know, Mr. Speaker, was our leading expert in Congress on automobile safety legislation. Unfortunately, he was defeated in the Goldwater sweep of Alabama last November. I cosponsored his bill on tires last session, and since he cannot reintroduce it this year, I introduced it on my own and will work for its adoption. The Federal Trade Commission hearings on tire advertising earlier this month certainly proved the need for reliable grades and standards for tires.

## SAFE HANDLING OF INDUSTRIAL MATERIALS

In still another area of consumer safety, let's have more politics in job safety, too. One of my bills this year, H.R. 1179, never before introduced, provides for the establishment by the Secretary of Labor of Federal regulations for the safe handling of hazardous materials in industry and commerce. At present, the Secretary of Labor issues guides and suggestions for worker protection, but he has no powers to enforce safety standards. State laws vary widely in this respect and few if any States have the resources to keep abreast of all of the new solvents, chemicals, bleaches, dyes, and other dangerous materials coming into use each year, sometimes with very limited application. The Federal Government can do this job, and should be given it to do.

## FULL DISCLOSURE OF CREDIT TERMS

What about more politics at the loan company, or department store credit window, or the automobile agency's finance department? As chairman of the Subcommittee on Committee Affairs of the House Committee on Banking and Currency, I introduced on our side of the Capitol, in the 88th Congress, the truth-in-lending bill drafted by Senator Douglas to require disclosure of actual interest rates and the full costs of credit, and I have reintroduced it in the 89th Congress as H.R. 155.

## UNINSPECTED MEAT GOING INTO OUR CITIES

Citizens of urban areas must become more aware of the danger to their health from meat coming into their city from uninspected slaughtering houses located within the same State. If this meat does not cross State lines, it is not subject to Federal inspection. Since President Kennedy first suggested in his 1962 consumer message an expansion of Federal inspection to cover much of this 20 percent of our meat supply which is not now subject to such controls, I have sponsored bills to accomplish this purpose. In this Congress, my bill on Federal inspection of intrastate shipments of meat in certain designated "major consuming areas" is H.R. 149. It follows the same principle in the designation of major consuming areas as we established originally in the Poultry Products Inspection Act of 1957 for poultry moving only in intrastate commerce but burdening or affecting interstate commerce in wholesome poultry.

## PRICE GYRATIONS IN SUGAR AND COFFEE FUTURES

In 1954 an investigation by the Federal Trade Commission revealed the part played by unregulated speculation, and abuses in trading, in coffee futures contracts in bringing about and accelerating the tremendous leap in retail prices of coffee that year. Ever since then, I have consistently proposed placing trading in coffee futures under the Commodity Exchange Act, as the FTC recommended 11 years ago. Investigation in the last Congress into sugar price gyrations convinced me that sugar futures trading should also be regulated under that act. Consequently, I have amended my previous bill on coffee futures trading to include sugar also, and have introduced it in this Congress as H.R. 8. Excessive speculation in futures contracts, usually at very low margin—thus, largely on borrowed money—can send prices of any commodity skyrocketing, if the futures trading is not properly regulated.

## THE NEED FOR POLITICAL ACTION TO ACHIEVE CONSUMER GOALS

Mr. Speaker, I have outlined many of the great glaring gaps in our consumer legislation, and the kind of legislation which is necessary to close those gaps. This legislation can be passed only if a great many more citizens actively "play politics," as the chairman of General Foods calls it, on these important issues. But this is no game. Politics is a serious business, because the stakes of political action—or inaction—are high.

The battles are not won overnight. Sometimes it takes years. But often results are won even before the legislation is passed. For instance, the food processors do not like Senator Hart's bill on packaging—not one bit; but his introduction of the bill and the hearings he conducted in support of it, did a great deal to bring about voluntary reforms in food packaging by the processors themselves.

Many consumers have now begun to do the same thing I do; that is, try to favor those grocery store products which are packaged in pounds or half pounds or quarts or similar standard sizes in preference to competing products which come in sizes such as  $7\frac{5}{16}$  ounces, or  $19\frac{31}{32}$  ounces. I just think it gives the consumer a better basis for judging comparative values, particularly on the two-for-so-much deals, and I show my appreciation to the manufacturer accordingly. So far as this one consumer is concerned, and I think there are now many like me, it is good business for a firm to package its wares in containers using easily understood net weights.

Senator Hart's hearings have made many consumers aware of this method of fighting back, and increasing numbers of manufacturers are therefore paying heed—getting the message—changing their packaging practices accordingly.

But in many of the situations I have described today—involving the safety of the consumer rather than pennies or nickels on a grocery item—we cannot depend merely upon the manufacturer's sense of intelligent self-interest to provide us with the protections we should have. We have had consumer protection laws for many years, but the laws always need updating, because the products they regulate are constantly changing in composition and in manufacturing technology.

As consumers we are far from helpless in solving these problems if—if, that is—we put more, not less, politics into the pantry and into our strategy for achieving consumer protection.

The CHAIRMAN. First, with pleasure and gratification, let me recognize the presence of a fine, and certainly a fine looking group of students, ninth grade students, from Damascus High School of Montgomery County.

We are encouraged by the attendance of students to these hearings. We always welcome you here. We are glad that you sought this committee for your observation and study.

We have at this time hearings underway on a subject involving some young people and that is the use of certain drugs alleged to have been channeled through illegal sources in the country. The effort here is to do something about proper and effective controls. We hope that you will get something out of these hearings.

We are interested in this because of the public interest, particularly from the standpoint of young people and the necessity for protection of the unfortunate people who would become habituated to these drugs.

Our witness at the moment is Mrs. Leonor K. Sullivan, a U.S. Representative from St. Louis, Mo. We will have, in a few minutes, further testimony from the Commissioner of the Food and Drug Administration. You may have the privilege of hearing him in his further testimony to the committee.

Mr. Friedel, have you any comments or questions?

Mr. FRIEDEL. I have no questions, but I would like to compliment this group of students for listening attentively to such an important witness as Mrs. Sullivan. This is very important legislation.

One of the things about this bill is that the enforcement end of it is not strong enough. We hope to go into that in executive sessions and come out with a more forceful provision.

Thank you.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

I want to compliment my colleague for the very fine contribution she has made, particularly in pointing out some of the shortcomings that we have overlooked in the past.

I have one question. On page 2 of your statement, where you are following the recommendation of the Commissioner to make arrests

without warrants, and so forth, have you any idea at all that such a measure would be approved by the Supreme Court?

Mrs. SULLIVAN. No, I couldn't answer that, Mr. Younger.

Mr. YOUNGER. The rules that they are following now, certainly on any bill that we would pass, if it would allow arrest without warrant or with just suspicion, would certainly be turned down, and any culprit so arrested would be turned loose on the public again, as they have been in the past.

That is the only comment I have.

The CHAIRMAN. I think the record should also show that under the law, any citizen is authorized to make a citizen arrest if the citizen so desires and feels compelled to, if that citizen observed the violation of the law. In that particular instance, it has been upheld by the Supreme Court.

Mr. Van Deerlin?

Mr. VAN DEERLIN. Mr. Chairman, I want to express my gratitude to Mrs. Sullivan for opening my eyes to a new phase of the peril here. As the father of three girls, and the husband of one, I find these things in cosmetics are a constantly rising cost item and I am interested in knowing that they are dangerous, as well. I will have new arguments to take home.

The CHAIRMAN. Let me say for the benefit of the gentleman, you wait until the beauticians come before us. They might have another thought. You can look for some reaction in the mail on that subject, too.

Mrs. SULLIVAN. I can tell the chairman they have been after me—not my own people in St. Louis, though, because they know this legislation would protect them from damage suits, rather than hurt them. The hair dye manufacturers and distributors are the most vocal opponents.

The CHAIRMAN. Mr. Broyhill?

Mr. BROYHILL. Mr. Chairman, I want to join my colleagues and welcome Mrs. Sullivan to the committee, and to thank her for bringing to our attention the broad viewpoint which she has so very efficiently and forcefully presented to us.

Mrs. SULLIVAN. Thank you, Mr. Broyhill.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. Mr. Chairman, I would like to join, too, in thanking our colleague for this very enlightening presentation. I have no questions.

The CHAIRMAN. Dr. Carter?

Dr. CARTER. No comments, Mr. Chairman.

The CHAIRMAN. Mr. Ronan?

Mr. RONAN. I wish to compliment our colleague also, Mr. Chairman.

The CHAIRMAN. Mr. Mackay?

Mr. MACKAY. Mr. Chairman, I have no questions, but I think this presentation has been very helpful and has illustrated that there is a broad field of concern here as well as the specific field with which H.R. 2 deals.

Mrs. SULLIVAN. Thank you, and if you find a moment's time, I hope you have the opportunity to read my full statement on H.R. 1235 in the Congressional Record of January 26, which I have also inserted

in this hearing record. It goes into the background of the entire bill.

The CHAIRMAN. Mrs. Sullivan, thank you very much. We shall read with great interest the article referred to which you have included with your statement. If there is sufficient urgency from the proper source, and it appears that it is the thing to do, I will say the committee will go into the broader scope of the cosmetic problem, but this hearing has to do with the drug control problem.

The schedule of the committee will permit any bill that is presented to it to be considered, and that includes the cosmetic problem, too. But I again remind my colleague that the gentlewoman knows we have been into this subject matter before. The committee considered certain phases of it 2 years ago at length, because of the widespread interest throughout the country.

I do know that the Food and Drug Administration has a keen awareness of this problem and they are constantly giving it thought and consideration. The committee is quite concerned and interested in it, and we shall continue to give it our attention, too.

Mrs. SULLIVAN. Thank you.

The CHAIRMAN. Thank you very much for your presence here and for your testimony and information given to the committee.

Mrs. SULLIVAN. Thank you, Mr. Chairman. It is always a pleasure to come before you and before this important committee of the House on which my husband was proud to serve during his years in Congress. From his pride in the responsible manner in which this committee met many serious problems, I came to Congress 12 years ago already conditioned to recognize the importance of your work. The consumers of this country owe this committee deep appreciation for the many bills you have enacted over the years in strengthening the Food, Drug, and Cosmetic Act. But there is still so much which needs doing in this field that I feel only an omnibus bill can now meet the urgent problems on a broad enough front.

The CHAIRMAN. Commissioner Larrick?

**STATEMENT OF GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY WINTON RANKIN, ASSISTANT COMMISSIONER FOR PLANNING, FDA; WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL, FDA; AND THEODORE ELLENBOGEN, ACTING ASSISTANT GENERAL COUNSEL, LEGISLATION DIVISION, OFFICE OF THE GENERAL COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE—Resumed**

The CHAIRMAN. Commissioner, we have in mind the presentation you made to the committee at the outset of these hearings, in which you made a broad statement on the overall problem, with your recommendations concerning this program which has been a part of the responsibility of your agency.

We have had many witnesses since. We have had comments on and reactions to your recommendations. There has been considerable study. There have been suggestions, in addition to the suggestions you have made, about the legislation.

Before we conclude these hearings, we want now to give you an opportunity to give the committee the benefit of your views on more

positive items in connection with this program. If you want to discuss any of the amendments which you have recommended, which are part of the record, or if you want to comment on the amendments proposed by others, we want you to do so.

You have a statement on the testimony that we have received. To start with, we will be glad to give you an opportunity at this time to give the statement.

Commissioner LARRICK. Thank you again, Mr. Chairman.

Several members, both from the bench and in conversations afterward, asked what these pills looked like. We happen to have a series of pictures of these pills that we prepared in 1961 to give to police departments and law enforcement officials throughout the Nation, so that when they found these products in the possession of persons who appeared to be under the influence of drugs, they would recognize them.

I ask that each member of the committee be given an opportunity, if they care to, to look at a copy of this group.

Also, Mr. Chairman, we have prepared a rather lengthy staff memorandum which I believe is too long to read, but which outlines and illustrates the methods of diversion of barbiturates, amphetamines, and related drugs, and it also deals in considerable detail with the various questions raised during the hearings and the amendments proposed by the various organizations.

I will, of course, as always, proceed in any manner that you wish.

The CHAIRMAN. Did you intend for this chart to be included in the record?

Commissioner LARRICK. I will leave that entirely to you, sir. The members wanted to see what the products looked like, and I just brought it along.

The CHAIRMAN. It can be included in the record, but there is a question about the color.

Commissioner LARRICK. I don't believe it would serve any useful purpose without the color.

The CHAIRMAN. Printing difficulties make it impossible to include the colors. Without color it wouldn't serve any purpose?

Commissioner LARRICK. That is correct.

The CHAIRMAN. We will receive it for the files, then.

Commissioner LARRICK. But I would like the memorandum to be included.

The CHAIRMAN. The memorandum, dated February 10, 1965, will be included in the record.

Commissioner LARRICK. Thank you, Mr. Chairman.

(The staff memorandum referred to follows:)

FOOD AND DRUG ADMINISTRATION STAFF MEMORANDUM ON H.R. 2 CONCERNING METHODS OF DIVERSION OF DEPRESSANT AND STIMULANT DRUGS WITH SPECIMEN CASES AND COMMENTS ON QUESTIONS ARISING DURING THE HEARING

This is a collection of some representative examples of our more successful cases which show how diversions covered by the bill occur. These diversions may occur at any point in the complex chain of legitimate drug distribution from the manufacturer of the basic chemicals to the point at which the finished dosage form of the drug reaches the consumer.

There are 7 manufacturers of basic amphetamine and 10 manufacturers of basic barbiturate. These materials are synthesized from intermediate chemicals, many of which have an industrial use. For instance, one of the intermediate

chemicals produced for the manufacturer of barbiturates is also a component for a jet engine starting fuel. The intermediate can be converted to barbiturate powder in a clandestine laboratory with equipment that is readily available.

The distribution of the basic chemicals may be handled in two fashions: (1) Direct shipment to dosage form manufacturers or (2) shipment to chemical brokers, exporters, and dealers throughout the country. There are several hundred such brokers.

#### DIVERSION OF BASIC CHEMICALS

We have found illegal traffickers ordering large quantities of basic depressant and stimulant powder from dealers and brokers by using fictitious names indicating the firms were engaged in research. We have recently prosecuted two firms, Delta Chemical Works, New York, N.Y., and Calbiochem, Los Angeles, Calif., for shipping stimulant drugs to unauthorized persons. We obtained a preliminary injunction in 1963 against the former firm, which was fined \$10,000 in November of 1964 for violating the injunction. The latter firm pled guilty to four counts and was fined a total of \$800. A third case involved another firm that distributes rare and fine chemicals to research and educational institutions. During the past 3 years we received reports that this firm was selling LSD, mescaline sulfate, and amphetamine to persons not entitled to handle the drugs. On checking we found students and a drug peddler order and received quantities of LSD/25 from the firm also that mescaline sulfate was sold to a man in New York City who used a fictitious firm name in ordering the chemical. He used the product for personal nonmedical use. When this firm was given a notice under section 305 of the Food, Drug, and Cosmetic Act, it adopted methods to insure that its future customers had a legitimate use for the drugs they were purchasing.

#### DIVERSION AT THE DOSAGE FORM MANUFACTURER LEVEL

Some companies make direct sales of large quantities of depressant and stimulant drugs to illegal peddlers and there have been a number of convictions under the Food, Drug, and Cosmetic Act for such violations. For instance, the Physicians Drug & Supply Co., of Philadelphia, Pa., and various individuals involved were fined \$8,550 in September of 1962 after pleading guilty to charges involving sales to unauthorized persons. Our inspectors without identifying themselves as Government agents obtained about 11,000 amphetamine tablets without the firm making any attempt to determine if the sales were being made to authorized persons.

William L. Palmer, Jr., a short-line jobber who was involved in counterfeiting and illegal sales of stimulant drugs obtained the following quantities of amphetamines to carry out his illegal business:

- (a) From a Detroit, Mich., firm—8 million amphetamine tablets in a 9-month period in 1962 and 1963.
- (b) From a small manufacturer in Union City, N.J.—over a half million amphetamine tablets between December 1961 and September 1962.
- (c) From a manufacturing firm in Greenville, N.C.—over 2 million tablets.
- (d) About 3 million amphetamine tablets from two firms—one located in Chicago, Ill., and the other in Philadelphia, Pa. The Philadelphia firm also shipped Palmer 150,000 barbiturates.

William L. Palmer, Jr., was convicted of violating the Food, Drug, and Cosmetic Act and was sentenced to 3 years in the penitentiary. A criminal prosecution is pending against the Philadelphia firm.

William L. Palmer, Jr.'s father, William L. Palmer, Sr., was involved with one John McGee, of Nashville, Tenn., who also obtained shipments of these drugs from some of the above firms. The Philadelphia firm shipped McGee about 2¼-million barbiturate and amphetamine tablets during 1962. William Palmer, Sr., was sentenced to 4 years in jail and his conviction was affirmed by the circuit court of appeals; however, he is free on an appeal bond while his motion for a rehearing is pending. McGee, who supplied truck stops throughout the South and who bought many of his drugs from the Palmers, was sentenced to one and a half years in jail.

Diversion at the dosage manufacturer level is also accomplished by theft from the manufacturing plant or by theft from interstate shipments. In April 1964, an informant introduced a Kansas City inspector to Bob Marshall, a known hoodlum. The inspector purchased a bottle of 1,000 barbiturate tablets from Marshall and noted he was driving a particular car. The number plate on the

car was checked as belonging to Eddy Trader, a shipping clerk at a local Squibb warehouse. Marshall made a second sale of 5,000 barbiturates to our inspector during which time arrangements were made with him for a large buy. Because of Marshall's record, his hostility and threats, the Kansas City Police were notified. They raided his apartment where 48 bottles each containing 1,000 tablets of phenobarbital tablets were seized. They were identified as a Squibb product and under questioning Eddy Trader admitted stealing them. Trader was prosecuted in county court and his sentence is currently on appeal. Marshall was also convicted by a county court and is currently serving a 4-year sentence.

We have also encountered diversion of depressant and stimulant drugs from the dosage form manufacturer because of illegal activities on the part of their salesman. We have found salesmen invoicing large quantities of depressant and stimulant drugs to fictitious physicians and druggists, or intercepting shipments to existing accounts when they reach shipping terminals. Another scheme involves shipments to bona fide physicians or drugstores without their permission or knowledge, and later retrieval of the shipment after it arrives.

In June 1962, one of our inspectors was informed by an Internal Revenue agent that an Indiana motel owner was suspected of dealing in drugs. This suspicion was based on a number of checks written to Drug Salesmen Joseph and Richard Faulkner (brothers) who represented Walker Corp., Syracuse, N.Y., a drug manufacturer. The inspector made a number of amphetamine buys from the motel owner while posing as a truckdriver. Through the motel owner he was introduced to Richard Faulkner who made a number of amphetamine sales to him. He was also able to make amphetamine buys from Joseph Faulkner who acknowledged he was acquainted with dealings between brother Richard and the inspector. Over 20,000 amphetamine tablets and more than 20,000 tablets of amphetamine-barbiturate combination were purchased from the two brothers. While negotiating sales, the brothers indicated a desire to supply drums of 25,000 amphetamine tablets at a price of \$625. Joseph Faulkner was given a 1-year suspended sentence and placed on 6 months probation. Richard was fined \$1,400 plus costs. The drug company fired the brothers as soon as it learned of their activity.

#### DIVERSION FROM DISTRIBUTORS

The method of diversion is essentially similar to those employed to divert these drugs from dosage form manufacturers.

Drug Salesman Stephen Kabala, Jacksonville, Fla., was employed by a St. Petersburg wholesale drug house. In the course of his business, he supplied several truck stops in the North Carolina-South Carolina area with amphetamines and barbiturates. He also supplied drug peddlers. One of our inspectors purchased 399,300 amphetamines and barbiturates from Kabala who was subsequently convicted and sentenced to 3 years in jail and 3 years probation. It was ascertained that he ordered the merchandise for his illicit operations direct from the manufacturer in the wholesaler's name. Shipments were made to fictitious drugstores where Kabala would obtain the merchandise from the truck terminal.

DeWitt Clinton Bowman trading as Carolina Drug Associates, Salemburg, N.C., sold our inspector 81,000 amphetamine and barbiturate drugs during a 4-day period. Bowman operated under an expired State license and during the 14-month period prior to March 1961, he purchased 4,196,000 amphetamines from the Philadelphia, Pa., firm mentioned earlier. Over half a million amphetamines were seized in his possession. Bowman was supplying drugs to another large illegal distributor in Georgia and several truck stops and drivers. A \$1,000 fine and 30 months imprisonment was imposed for Bowman's illegal activities.

In June 1963, an FDA district received a call from State police reporting a barbiturate suicide. The victim had been a barbiturate addict, who at one time had committed himself to a New York hospital to overcome his addiction. By representing himself as a medical doctor, he was able to obtain large quantities of barbiturates from a small New Jersey distributor. The final order placed by the victim was for 20,000 phenobarbital sodium capsules. Two of our inspectors ordered drugs from the firm by mail, using an M.D. after their names. In response to their orders, the firm shipped them amphetamines in bottles of 1,000, and other drugs. A criminal action was filed against the firm. Arraignment has not yet taken place.

During FDA investigations of the amphetamine peddling activities of Paul Anness, Covington, Ky., and his associates in 1963, information was obtained that

one of his sources of supply was the Cincinnati Economy Drug Co. Followup investigation of the drug wholesaler revealed that unknown to management, several hundred thousand amphetamine tablets and about 5,000 barbiturate tablets or capsules had been stolen during a period of a few months. Poor security and faulty recordkeeping permitted this situation to exist as long as it did. Complete correction in the firm's operations appeared to have occurred. Anness was charged with violating the Food, Drug, and Cosmetic Act and sentenced to 6 months in jail.

#### DIVERSION FROM RETAIL DRUGSTORES

We have encountered substantial diversion of depressant and stimulant drugs through retail drugstores.

In March 1962 George Graves trading as Graves Drugstore, Tazewell, Tenn., a town of about 1,200, was arrested by State authorities after making sales of amphetamines. Graves was supplying several area truck stops. A Louisville, Ky., drug sales representative purchased 1,371,000 amphetamine tablets from an east coast manufacturer. Most or all of these were subsequently sold to Graves for illegal distribution. Graves was prosecuted in State court and was placed on probation for 3 years. His license to practice pharmacy was also revoked.

Edward M. Harvath, an employee at Western Electric Co., Baltimore, Md., in 1960 engaged in the peddling of amphetamine tablets, barbiturates, and other drugs to other employees. He was assisted by a woman employee, Anna Henniger.

The drugs were surreptitiously obtained by a pharmacist, Manuel Highkin, from a Baltimore drugstore where he was employed. Buys of quantities up to 3,000 amphetamine tablets were made by Food and Drug inspectors. A criminal action, which included conspiracy charges, was filed January 19, 1962, in Federal court. *Nolo contendere* pleas were entered and the defendants were sentenced March 30, 1962. Harvath and Highkin received 3 months imprisonment and fines of \$250 and \$750, respectively. Mrs. Henniger was sentenced to 1 year, suspended, and placed on probation.

We have requested the institution of criminal proceedings against the manager of a New Castle, Del., drugstore for unlawful sales of amphetamine tablets. In December 1963, an undercover FDA inspector purchased 75,000 amphetamine tablets from the owner of a drugstore in Maryland. The Maryland druggist volunteered to introduce the undercover inspector to the New Castle, Del., druggist who could furnish larger quantities of amphetamines. Undercover inspectors made an initial purchase of 16,000 amphetamine tablets from the New Castle, Del., druggist in December 1963, followed by the purchase of 50,000 amphetamine tablets in January 1964.

In May 1964 the general safety manager of a large trucking firm reported to FDA that amphetamines and barbiturates could be purchased at a certain area in Chicago from a woman known as "Big Linda." Two of our inspectors made separate contacts with the woman and made buys of 5,000 amphetamines each at different times. One of the inspectors identified himself to "Big Linda" and she agreed to cooperate. Her source was a drugstore and an order for 100,000 amphetamines was placed with the pharmacist owner through "Big Linda." On October 14, 1964, the merchandise was seized after it had been delivered to two lockers in the Illinois Central Railroad station. Since there were only 98 bottles containing 1,000 tablets each in the delivery the inspector and "Big Linda" went to the drugstore to complain. The owner was not present but an employee when apprised of the situation delivered 2 additional bottles of 1,000 tablets each to them. We are prosecuting the drugstore; the case has not yet been adjudicated.

John D. McCutcheon doing business as North Highland Drug Co., Birmingham, Ala., on May 28, 1964, was fined \$750 on nine counts of illegal sale of amphetamines and placed on 3 years probation in Federal court in Birmingham, Ala. The Federal prosecution was based on the illegal sale of 9,000 amphetamines by John D. McCutcheon in a period of 8 days. A review of the drugstore files covering receipt of drugs for a year's period revealed no invoices whatever to cover the purchase of amphetamines. A review of records of two local drug wholesalers revealed shipments of 407,000 amphetamine tablets to North Highland Drug Co. during a year's period of time. An interview with a former employee of McCutcheon indicated that shipments of large quantities of amphetamines may have been received from other wholesale dealers. He re-

called that McCutcheon had bought amphetamines in lots of 100,000 tablets or more from a Houston, Tex., firm prior to our investigation. This investigation followed leads from the State board of pharmacy, the State department of public health, the State department of public safety, and the Federal Bureau of Investigation which indicated that John D. McCutcheon was engaged in the illegal sale of amphetamines.

#### DIVERSION FROM PHYSICIANS

Diversions of depressant and stimulant drugs also occasionally occur through physicians, other licensed practitioners, and their officeworkers. A few examples of this type of diversion follow.

On August 10, 1961, Dr. Leroy E. Callahan was arrested in a tourist cabin in De Queen, Ark., by a U.S. marshal. The marshal seized, under a Federal court order, 200,000 amphetamine tablets which Dr. Callahan was delivering to an undercover FDA inspector. An additional 150,000 amphetamine tablets were later seized at Dr. Callahan's residence. At the time of his arrest Dr. Callahan was carrying a pistol. In addition, two rifles were found in the automobile used to bring the amphetamine tablets to the tourist cabin. It was later determined that Dr. Callahan had purchased over 360,000 amphetamines from two eastern drug distributors in 1 month. We were unable to determine whether he had also purchased large quantities from other mail-order distributors. Dr. Callahan was later fined \$1,000 and given a suspended 2-year prison term in the Federal district court at Texarkana for the unlawful sale of drugs. The Arkansas State Medical Board subsequently revoked Dr. Callahan's license because of the unlawful sale of amphetamines. This investigation was initiated by FDA after receipt of information through the Treasury Department, the Bureau of Narcotics, and the Federal Bureau of Investigation to the effect that Dr. Callahan was involved in the "dope" traffic.

On May 29, 1963, U.S. marshals arrested Dr. George H. Springstun in his Oaktown, Ind., office as he delivered 16,000 amphetamine tablets and capsules to two undercover FDA inspectors. The marshals seized an additional 273,000 amphetamine tablets and capsules in Dr. Springstun's possession. The doctor was later fined \$1,820 in Federal district court after pleading guilty to six counts of unlawful sales of amphetamines. This investigation was initiated by FDA after information was received indicating that Dr. Springstun was supplying amphetamines to illegal peddlers in the Midwest and as far distant as Texas and Alabama.

The Carroll Chemical Co., of Baltimore, Md., had supplied small quantities of drugs for years to a Baltimore psychiatrist. During the summer of 1964 management at the firm became suspicious when the frequency and size of orders from the psychiatrist's office increased substantially. They reported their suspicions to the Food and Drug Administration which investigated the case with the Baltimore City Police Department. The psychiatrist's assistant, a woman, and her boy friend had illegally obtained 200,000 amphetamines and barbiturates for resale. The doctor's assistant used prescription blanks to order the drugs which she or her friend picked up at the chemical company. Baltimore city police arrested both individuals and charged them with illegal possession and conspiring to make illegal sales. Shortly before the trial, the woman committed suicide by taking an overdose of barbiturates. On September 2, 1964, the boy friend was acquitted since the doctor's assistant could not testify.

Baltimore district FDA office received a complaint from the Maryland State Police and Hagerstown city police that Ralph Young, M.D., Williamsport, Md., was selling "diet pills" to area residents. A 17-year-old son of a Hagerstown policeman was hospitalized following an overdose of these drugs. Police reported a number of other youths and local undesirables obtained drugs from Dr. Young. Our inspectors made frequent buys of amphetamines from Dr. Young in April and May 1962. While making these they witnessed purchases of "diet pills" by teenagers and other individuals. Dr. Young was fined \$5,000 in Federal court.

In August 1962, an informer told one of our inspectors about a physician selling amphetamines. He introduced the inspector to Dr. Pearce Johnson, of Birmingham, Ala., and made a purchase of over 3,500 amphetamines. The inspector later purchased over 35,000 amphetamine tablets during four different contacts with Dr. Johnson. The inspector placed an order for a 50,000-tablet buy of amphetamines with Dr. Johnson. Subsequently a seizure of 40,000 tablets shipped to the doctor was accomplished. In July 1963, Dr. Johnson pled guilty in Federal court and he was placed on probation.

In early 1962 Cincinnati district was advised that a physician, Ambrose Schneider, M.D., was supplying amphetamines through the mail. Through investigation it was determined that a number of university students from Michigan colleges were ordering and receiving amphetamines from Dr. Schneider. During a 6-month period two of our inspectors purchased through the mails and personal visits over 6,000 amphetamine tablets. A check of the doctor's office records disclosed he had purchased and distributed over 600,000 amphetamine tablets during 1962. It was estimated that he had approximately 1,000 customers many of whom were college students. Our investigations uncovered the case of one female student supplied by Dr. Schneider who had become addicted to amphetamines. This necessitated her dropping out of college and subsequent hospitalization. Dr. Schneider pleaded guilty in Federal court on December 20, 1963, and was fined \$1,500 and placed on probation for 2 years.

Iowa Narcotics Board inspectors informed us that a doctor of osteopathy was selling dangerous drugs. They provided a female informant who introduced one of our inspectors to him. Through a series of buys and contacts our inspector, working with a colleague, purchased over 67,000 amphetamines, over 2,000 barbiturates and other drugs from this man. A large order was placed with him and approximately 324,000 pills were seized in his possession. The case has not yet been filed for prosecution.

#### DIVERSION FROM CLANDESTINE SOURCES

FDA must also attempt to locate depressant and stimulant drugs which never enter legitimate channels. Commissioner Larrick described in his statement before the committee on January 27 how two California men smuggled LSD-25 into this country and attempted to distribute it illegally. Counterfeiters also make depressant and stimulant drugs which often never leave the illegal traffic. Further, surreptitious unregistered manufacturers account for a substantial amount of these drugs.

For example, on January 5, 1965, California authorities, acting on an anonymous call and subsequent surveillance, raided a converted grocery store in Berkeley. The authorities found a rather elaborate laboratory and a number of chemicals used in the synthesis of amphetamine powder. The lone occupant of the premises was arrested; the legal owner is now a fugitive from justice. This is but one illustration of several such cases we have encountered.

#### REQUIREMENT FOR PHARMACISTS TO MAKE RECORDS AVAILABLE

As a normal part of their business, pharmacists keep records showing what prescriptions they fill. The question is whether the records relating to drugs covered by H.R. 2 should be available for inspection as a part of the audit system envisioned in the bill.

One argument against having the audit apply to pharmacists is that the audit would in some way invade the professional realm occupied by the pharmacist. But the American Medical Association and the pharmacists themselves raised no question on this point, to our knowledge, about audits of their files made to determine compliance with laws administered by other agencies.

Another claim is that FDA inspectors would not know what they were looking at when they reviewed prescription files. Our inspectors have the type of education, training, and experience that would enable them to examine prescription files intelligently. It has been stated that when the FDA believes a certain druggist may be a point of diversion, we can check wholesalers to see if the druggist is getting unusually large quantities and use this as a basis for obtaining a search warrant.

Our counsel tells us that such evidence most probably would not provide a basis for obtaining a search warrant. The criminal rules, Rule 41 Federal Rules of Criminal Procedure, provide for the issuance of warrants to search for and seize any property designed or intended for use or which is or has been used as a means of committing a criminal offense. Such warrants are issued only when the judge, or U.S. Commissioner has sworn facts before him which establish probable cause to believe that the grounds for issuance exist. This means we would have to be able to establish that the druggist was in possession of pills intended for illegal sale. The mere fact of purchase of a large number of pills from a wholesaler would not establish this, and even if it would the search warrant would have to be sought and obtained within a short time after the

wholesaler made his sale. Evidence of wholesale transaction, even a few days after the sale was made, would ordinarily be considered too remote to establish that the druggist had the pills in his possession with intent to sell them in violation of law.

What is needed here—and what the bill calls for—is accurate and complete recordkeeping at all levels of legitimate trade so that auditing techniques can be applied to determine precisely where the diversions of these drugs into the illicit traffic are occurring. The fact that records have to be maintained and have to be readily available for inspection will itself accomplish a great deal in drying up the supply to traffickers.

The druggist now has many possible suppliers—estimated in the hundreds or even thousands—and we know of no feasible way of applying checks on the diversion of these drugs without access to the complete line of acquisition and disposition. The records are essential to the regulatory plan.

Tightening up the recordkeeping and record inspection provisions at the manufacturing and wholesale levels, without the same improvement at the druggist level would not solve the problem.

One of the pharmacists who testified suggested that there should be a provision for access to records of drugs dispensed outside the scope of the dispenser's professional practice. We do not know how we could determine what was dispensed in the course of professional practice and what was not, without looking at the complete picture of purchases and sales by the druggists.

#### *Section 3 (a) of the bill—Questions about definitions*

It has been suggested that clause (C) of subparagraph 201(v)(2) be deleted as necessary and duplicatory of section 201(v)(3). However, the two sections are not duplicatory and deletion of section 201(v)(2) would narrow the control which the Secretary could exercise over habit-forming drugs.

In reviewing the record of this hearing, we do not find any objection to regulating amphetamines and barbiturates which must be dispensed under the prescription legend. The disagreement centers around section 201(v)(3) of section 3 of the bill, which would define a depressant or stimulant drug as "any drug which contains any quantity of a substance which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect."

Certain groups presented arguments for narrowing the application of this section to any drug "substantially involved in drug abuse because of its depressant and stimulant effect on the central nervous system or its hallucinatory effect \* \* \*" or "having a potential for abuse leading to adverse effect on the public health because of its depressant or stimulant effect on the central nervous system \* \* \*."

It is, of course, scientifically possible to predict the properties of a new drug in reviewing the clinical experience with the drug during its developmental stage. Indeed, LSD-25 has never been cleared for commercial distribution but enough is known of its hallucinogenic properties to require that it be made subject to the provisions of the bill. The Department is required by law (26 U.S.C. 4731(g)) to give technical advice under the Harrison Act as to the addictive qualities of new synthetic narcotic drugs. We also have an arrangement with the Bureau of Narcotics to bring to it any knowledge we obtain through the new drug procedures about the addicting potential of new synthetic narcotics, so that they may place them under narcotic controls before abuse develops. Under the definition offered by the Pharmaceutical Manufacturing Association, we could not promulgate regulations to control the traffic in new drugs subject to H.R. 2 until substantial abuse of these drugs has become established. This suggestion is a clear departure from the preventive theory upon which the Food, Drug, and Cosmetic Act is founded. To allow such new drugs to fall indiscriminately into the hands of the public and then attempt to stop the illegal traffic which is flourishing by the time substantial abuse can be established is unthinkable. Further, the parenthetical language in the proposed amendment would confine "drug abuse" to situations where the drugs involved are used for nonmedical purposes and obtained through illicit channels. This is too restrictive.

The PMA also proposed to amend the definition of "depressant or stimulant drug" to exclude any drug which may be sold without prescription and certain combination drugs. The bill now exempts nonprescription drugs and combinations of depressant or stimulant drugs with other drugs where the combination

does not have a habit-forming stimulant effect or a potential for abuse. So there is no difference in the objective we all have in mind. But if these exclusions were written into section 201(v) as part of the definition of depressant and stimulant drugs, we would have to prove on a case-by-case basis that the drug involved in a violation was not a nonprescription or combination drug. This would involve presenting a complex and difficult medical-scientific question to the jury before it could decide whether the drug was one subject to the new law. As the bill now stands, these scientific questions can and should be decided in advance of enforcement by the FDA. Then all persons involved would know what drugs are subject to the new recordkeeping, inspection, and possession requirements. Also the proposed amendment would exempt a combination the principal effect of which was not depressant, stimulant, or hallucinatory. We are concerned with the depressant, stimulant, or hallucinatory effect, whether it is primary or secondary so long as the effect at which the bill is aimed is achieved.

#### THE TRANQUILIZER PROBLEM

In our testimony of January 27, we stated that "tranquillizers are being increasingly implicated by medical evidence as agents of drug abuse." H.R. 2 is aimed not only at amphetamines and barbiturates, but also at other drugs capable of causing similar or related effects. We believe that sufficient evidence has been presented to show that some tranquilizers, like barbiturates, can cause tolerance and psychic and physical dependence.

A question has arisen whether or not specific tranquilizers should immediately be incorporated, by name, into the scope of section 201(v). If the committee were to attempt to do so, it will be necessary for it to go into the scientific questions involved, in depth, to the extent that we would have to. Moreover, if this were done, it will become necessary for use to come back from time to time to ask that the list be kept up to date by congressional action. And we would have to ask Congress to devote the necessary time to study the mechanism of action and the potentialities for abuse to decide the medical questions involved in keeping the list current with emerging medical knowledge.

We suggested in our testimony of January 27 that the committee may wish to consider shortening such delays by using the rulemaking procedure spelled out in section 4 of the Administrative Procedure Act as a method for bringing depressant and stimulant drugs under the bill's controls. The procedure specified in the Administrative Procedure Act calls for a notice of proposed rulemaking and invitation for comments. After a review of comments submitted, the agency then issues a final rule. This procedure will work properly here, together with the advisory committee's recommendations, to protect the rights of the pharmaceutical industry against arbitrary or capricious action.

We have obtained some information and are prepared to propose a rule on a number of tranquilizers, but at this time we are not in a position to submit to the committee a complete list of specific tranquilizers to be named in the bill if the committee decides to adopt that approach. One reason for this is that we want to be certain that we have fully considered all of the current information available on these drugs. Also, the naming of specific tranquilizers for inclusion in the bill at this time undoubtedly would result in protests by the industry that the initial listing in the bill is incomplete and lends itself to competitive bias. It seems to us that this competitive situation would be greatly magnified if the dangerous potential of each candidate for the list had to be explored as a basis for congressional action.

#### THE ADVISORY COMMITTEE

An amendment to the provision for a minimum number of members of an advisory committee was proposed. Sometimes more than three and less than seven may be necessary. We feel the present provision in the bill is satisfactory as to the composition of the advisory committee. There are specialities in some fields, particularly medicine and science. As new and different compounds are invented and synthesized, we will need to call upon persons representing various specialities. For one drug we may wish to obtain the advice of one group of experts. For another drug, we might well wish another group's counsel. Sometimes we seek the advice of particular individuals. To make the advisory committee a standing committee would restrict the scope of the scientific advice available to us. But we could work with such a committee, perhaps supplementing it with consultants as needed on special problems, if the Congress should decide to call for a standing committee.

## PROPOSED SECTION 511 (A) (4)

It has also been recommended that the proposed section 511 (a) (4) be amended by changing the subparagraph to read: "(4) Practitioners licensed by law to prescribe, administer, or *dispense* depressant or stimulant drugs, while acting in the course of their professional practice." It is said that this would expressly include pharmacists as persons authorized to possess stimulant and depressant drugs. The word "practitioners" as here used is intended only to refer to physicians, osteopaths, dentists, and similar practitioners of the healing arts, rather than pharmacists. Secondly, such an amendment would weaken the bill and is unnecessary since subparagraph (3) of section 511(a) expressly allows pharmacies, hospitals, clinics, and public health agencies maintaining establishments in conformance with applicable local law and which regularly dispense prescription drugs in accordance with State law to manufacture, compound, process, and possess depressant and stimulant drugs, so that there is no problem on that score. We recommend against enactment of the proposed amendment.

Commissioner LARRICK. With that introduction, Mr. Goodrich, on my right, and Mr. Rankin, Assistant Commissioner, will be very happy to try to answer questions the members may have.

The CHAIRMAN. Thank you very much.

In the first place, I want to ask you a question about the Durham-Humphrey Act on the refilling of prescriptions. It was brought to the attention of the committee yesterday that prescriptions were filled and refilled rather promiscuously.

What is your comment on that?

Commissioner LARRICK. The Durham-Humphrey Act provides, as I am sure you recall, that a prescription can be refilled whatever number of times the prescribing physician authorizes. A prescription can be transmitted to the pharmacist by telephone. The pharmacist must record the oral prescription immediately, but this, again, may be refilled, legally, whatever number of times the physician authorizes.

The CHAIRMAN. I know, but I don't think that that was the problem discussed yesterday. The problem discussed yesterday was that some prescriptions are filled innumerable times without the physician re-prescribing.

Commissioner LARRICK. That is illegal if not specifically authorized by the physician, and we bring many cases based on that action each year.

The CHAIRMAN. What about a prescription where a physician says it may be refilled four times or a dozen times?

Commissioner LARRICK. It can be refilled that many times with the amount of drug that the physician originally provided.

The CHAIRMAN. What is the usual procedure?

Commissioner LARRICK. I would think that the average, careful physician limits the number of refills to the period of time that he thinks the patient should continue the medication without returning for a further examination. A great bulk of doctors in this country follow that practice. There are others that do not, and there are some physicians who write on the prescription that it can be refilled indefinitely. We don't like that practice, but it is not illegal under the statute.

In addition to that, there is a great deal of illegal refilling of prescriptions.

The CHAIRMAN. Dr. Griffith was here yesterday, and he had completed a rather interesting research project for a period of about a year. I was very much interested in his very frank and open statement on

this subject. He seemed to pull no punches, regardless of who might have gotten in front of him.

Commissioner LARRICK. I know Dr. Griffith, and I certainly agree with your appraisal of his fearlessness.

The CHAIRMAN. He made the statement that a person who was not sick didn't need a prescription. If they needed a prescription, therefore they were sick, and he didn't think that a sick person ought to go a period of 6 months without seeing a doctor.

There may be some exceptions to that, but I thought there was something to that idea, myself.

Commissioner LARRICK. As the statute now stands, the Durham-Humphrey Act provides no limitation on the number of times that the physician may authorize a prescription's refilling. That was discussed at great length, as you will recall, when we had that bill up several years ago.

The CHAIRMAN. I certainly can well understand the attitude of the doctors, particularly, the medical profession, on Congress endeavoring to place limitations on their better judgment in treating a patient.

I also recognize these abuses that might develop. That is the kind of a problem where you have a hard decision on what to do. You get the public interest on one hand, which must be considered.

I suppose we ought to try to solicit information from the medical profession and the pharmacists on this problem if it continues to grow. There are reported incidences of abuse. I assume that your agency would be called upon to obtain and preserve as much information on the subject matter as is possible.

Commissioner LARRICK. We have a great deal of information on that subject, particularly when people commit suicide and we try to ascertain whether they obtained the barbiturates legally or illegally. I think the great bulk of physicians are careful in this area. There are some, unfortunately, who are not.

The CHAIRMAN. I hope my colleagues will pardon me if I take these things up as they have been presented, but I do want to get them into the record in order to try to get from Commissioner Larrick his reactions.

Have you had an opportunity to consider the suggestion made by the pharmaceutical association on the "potential," so far as your authority is concerned?

Commissioner LARRICK. Yes, Mr. Chairman, we have. When a new drug is proposed to us, under the Harris bill enacted 2 years ago, there is a great mass of data that is submitted. This includes, first, the testing on animals, as we have discussed before.

Second, it includes clinical work of a very substantial nature. If that clinical work shows conclusively that there is a habit-forming drug, like the amphetamines and the barbiturates, or similar in its action, I don't think the American public should have to have a situation develop where major abuses, major tragedies occur before we put that drug on the list.

I would think that in general the drugs that have been on the market, where we have had clinical experience with them, that those that have shown abuses would be the first ones that we should give attention to. But as of now, under the Narcotic Act, as a new drug is discovered, and if in the clinical testing and clinical trials it is shown that that drug has capabilities paralleling narcotics, morphine, opium,

and whatnot, the laws of the land do not provide that it be sold so that the public can take advantage of those addicting properties or, rather, take disadvantage of the addicting properties, but a procedure is set up whereby as the drug goes on the market, it is under the control of the Narcotics Act. Our view is very strongly that that same process should be involved here.

The CHAIRMAN. What would you think about the proposal recommended by the representative of the American Medical Association to include the language "leading to adverse effects on public health"?

Commissioner LARRICK. I don't think we would have any objection to that. We don't think it adds anything to the statute. It is, in our opinion, surplusage, because the whole bill, the title of the bill and everything else, has to do with abuses that adversely affect the public health.

I think that is the sort of thing that you can put into the committee report, if you cared to, but all the testimony and everything else is to the effect that that is what we are aiming at.

The CHAIRMAN. Have you read Dr. Austin Smith's testimony?

Commissioner LARRICK. Yes, sir.

The CHAIRMAN. He is in accord with the legislation. He feels that there is need for it. But he proposed an amendment and I wondered if you would want to comment on his amendment, or have Mr. Goodrich comment.

Commissioner LARRICK. I think in general I have commented but I would be glad to have Mr. Goodrich supplement it from the legal point of view.

Mr. GOODRICH. Dr. Smith made two suggestions. One was that the drug had to be shown to be substantially involved in abuse before it could be put on the list. Mr. Larrick has answered that. He raised the other question about over-the-counter—

The CHAIRMAN. I would like a further clarification of the answer that he has given about the broad term "potential."

Mr. GOODRICH. The situation is simply this, Mr. Chairman, that when LSD-25 was first used in investigational medicine, it was shown pretty promptly to be quite an addictive hallucinogenic drug. It has never been approved for marketing. Its potentiality for abuse has been developed through these investigational trials.

We think if the evidence developed that type of reaction from the drug, it ought to go onto the list before it is shown to be substantially involved in drug abuse.

As Mr. Larrick said, we made an arrangement with the Bureau of Narcotics some time ago where, when new synthetic narcotics are developed, their potentiality for abuse, and this is their action similar to morphine as an addicting drug, is shown through the trials, we notify the Bureau of Narcotics and they put the drug on the list and it is subject to narcotic control before it is ever marketed.

The difference between Dr. Smith and us is whether we try to act in advance on a potentiality for abuse, or whether we wait until a substantial abuse has developed. We would, of course, have to make—

The CHAIRMAN. That is the full effect of his language. He does clarify it with this language:

Drug abuse being deemed to exist when drugs are used other than as therapeutic media prescribed in the course of medical treatment, and when they are obtained through illicit channels.

Mr. GOODRICH. Those added two additional factors are proof that would have to be made that drug abuse could only arise in those two instances. At least that ought to be in the alternative, one or the other.

Also, you have some abuses which arise out of the course of professional practice in abusing a drug which is actually prescribed for you, when you exceed the amount or use it for another purpose. All this bill does, remember, is to require the keeping of records and the maintenance of controls over these drugs so that the points of diversion can be identified. Nothing in this bill puts any such drug off the market or anything of the sort. This is a control bill over the people who manufacture it, and so forth.

The CHAIRMAN. If you decide that a particular drug has a potential for abuse, then you can do something about it.

Mr. GOODRICH. We can make them keep records and we can audit the records, but that is all. We can keep it within the legitimate scope of medical practice.

Commissioner LARRICK. Let me give you a concrete illustration that would perhaps clear it up.

Amphetamine inhalers would be dealt with specifically under this statute, but under our present authority, about 6 years ago we found that these inhalers were being broken open and the contents put in water and the water either injected into the vein or taken orally. The persons would thus get the drug effect of this amphetamine.

Amphetamine inhalers were widely used in penitentiaries. There were all sorts of problems that came out of it. So we put it in the category where it could only be sold on prescriptions, and we have stopped that practice.

Well, then a new drug came along, and this new drug was a modification of amphetamine. It was called methamphetamine. It, too, was put in inhalers. Our doctors and the medical profession generally were well aware that this methamphetamine had virtually the same potential for misuse that the amphetamine had, but there had been no actual abuse.

We did not feel under the law that we now have that we could do anything about it. We kept our eye on it. We knew it was going to come. In 1959 we got reports of six cases where it had been misused. We didn't think that was substantial enough to call it abuse.

The next year there were five, and the next year there were five. In 1963 there were 54. Some of them came to my attention through this document that you referred to. Then, in 1964, they jumped up to 153 people who had abused it. Then we put it on prescription.

If we had had the power to deal with the potential misuse, this drug would have been put on prescription in 1959. Under this new law, the choice would be to put it on when we know it is going to be misused, where it has this potential, or wait, as Dr. Austin Smith has proposed, until there is actual abuse and there has been a lot of damage to the public health.

The CHAIRMAN. What law do you have on the books today by which you put that drug on prescription yesterday that you didn't have in 1959?

Commissioner LARRICK. We felt that we had to have very substantial evidence of a general misuse before we could put it on prescription.

We were so advised by our counsel, and I think there is no question but that our authority was so limited.

Our last contact that brought the number of cases up was when this doctor you spoke of came in to see me on January 11. We have pursued the cases he spoke of diligently, and we have put mesamphetamine inhalers on the list.

The CHAIRMAN. You have done that, and I compliment you for it, but you haven't answered the question. What law do you have today?

Commissioner LARRICK. The Durham-Humphrey.

The CHAIRMAN. The Durham-Humphrey bill was passed in 1951.

Commissioner LARRICK. Yes; but there wasn't the evidence of the generalized misuse. If Dr. Smith's proposal is accepted, we will not have the power to put it, to put the drug, under the additional controls of this Harris bill until there is a substantial enough actual misuse to satisfy the language that he has put forth.

The CHAIRMAN. In other words, if his language here was accepted, it would be more restrictive than the language is in the law today for drugs to be made prescription drugs?

Commissioner LARRICK. Tremendously more, and definitely more detrimental to the public health, in our opinion.

The CHAIRMAN. If you have been as cautious about moving on to something like this under present law, as apparently you have been under the action that you took yesterday, I don't know why the pharmaceutical people would be concerned about it.

Commissioner LARRICK. I don't think they should be concerned about it.

The CHAIRMAN. I believe you started to talk about the other suggestion.

Mr. GOODRICH. The other suggestion, sir, was to bring the exceptions for over-the-counter items up as a part of the definition. We discussed that, you will recall, during Dr. Smith's testimony, but since some of the members were not here, perhaps I should repeat it.

There is no difference of opinion between us and Dr. Smith that the products that are legal for sale over the counter do not come under these special controls, but what he is proposing is that these drugs be made exempt as a part of the definition of stimulant and depressant drugs. We are proposing that they be specifically exempted by name, under regulations, so that there will be no confusing point of medicine involved in a later enforcement case.

If you put that exception in the definition of stimulant and depressant drug, when you find a truck stop that is selling a drug and charge them with possession outside the legitimate channels, you would not only have to prove that, but you also would have to prove that it was not an over-the-counter drug.

When you passed the Durham-Humphrey law in 1951, you will recall, there was a proposal that there be complete and comprehensive lists of what were prescription drugs and what were not. The decision of the Congress was that with a broad definition of what was a prescription drug in terms of any drug which, because of toxicity or other potential for abuse, or collateral measures necessary, and some other language, could only be used on the prescription of a physician, that type drug had to be sold on prescription.

But that leaves it as a factual matter in each case, to prove the type of drug involved. Then it would be up to the jury in the enforcement case on the truck stop, to decide whether or not this was an over-the-counter drug. But in substance, there isn't any difference here. We have handled the low-dosage barbiturates by exempting regulations under the Durham-Humphrey Act itself, as you authorized us to do. There has been no trouble with that.

Over the years, the State of Pennsylvania required a prescription for one drug we allowed over the counter, but other than that there has been no problem at all with handling the problem by exemptions. It would keep out of the enforcement cases medical questions that really don't belong there.

Mr. DINGELL. Mr. Chairman, could I interrupt to ask one question?

You referred to this point, I believe, in your staff memorandum on pages 10 and 11, I believe.

Mr. GOODRICH. Yes.

The CHAIRMAN. I haven't had a chance to read this memorandum. I have, therefore, taken this occasion to try to get some clarification of the proposals made.

I do think this record needs to be brought up to date and some of these problems clarified. I have two or three other things in mind, but maybe some other members will get to them and I won't be using all the time.

Mr. DINGELL. Mr. Chairman, I was just making mention of the fact so that members who may want to could pursue this on those pages.

The CHAIRMAN. I am sure there will be other questions that will be asked, but I will give others the opportunity at this time.

Mr. YOUNGER, have you any questions?

Mr. YOUNGER. Yes; thank you, Mr. Chairman.

Mr. LARRICK, there is one statement in the memorandum that rather bothers me. I take it that when your investigators buy drugs in the illicit market they pay the regular price to the seller, do they not?

Commissioner LARRICK. They are operating as undercover agents, and they do pay whatever it is. They may dicker with them, but they pay what they ask.

Mr. YOUNGER. If that is true, why do you buy in such great quantities? For instance, on page 5 you buy 75,000 pills in one case, 50,000 in another. It seems to me that you are making a great contribution to the illicit seller to get the money by which to hire attorneys to defend himself.

Commissioner LARRICK. Our experience has been, Mr. Younger, that if you buy 50 and take it into court, the judges and juries aren't very much impressed, but if you buy 500,000, which is the amount the man is regularly engaged in selling in the illicit market, you present the court and the jury with a set of facts which they need to help them in deciding what the penalty should be in case of a conviction.

We find it is much more efficient enforcement to proceed in that manner.

Mr. YOUNGER. But there is a tremendous difference between 50 and 500,000. There is a tremendous difference in the profit to the seller between 50 and 500,000.

Commissioner LARRICK. Sometimes we get to the 500,000 point. If you give us this legislation and we have made a buy of 50, paid the

Government's money for it, and you give us this legislation to detain, pending the filing of a libel, the inspector who has offered the 500,000 will take it and seize it and won't pay him the money, but he will have it as evidence.

Mr. YOUNGER. That is all right. I think that might solve the problem.

Commissioner LARRICK. Thank you for the suggestion.

Mr. YOUNGER. I didn't think the Government ought to be in the business of fattening the salesmen in a manner to get evidence of that kind. It is kind of like the overkill problem.

Commissioner LARRICK. I think you have a good point.

Mr. YOUNGER. Commissioner, you have a fund now, some \$300,000, to make a study as to the State enforcement activities.

Commissioner LARRICK. That is right.

Mr. YOUNGER. When is that report going to be ready?

Commissioner LARRICK. That report was actually due on February 1, but the independent agency that is conducting the study asked the Secretary if it might have a little more time to round out the report and get it in good form, so we expect it sometime this month.

Mr. YOUNGER. Do you think it might be well to hold up the report on this bill until we could get that report and get the benefits of that report?

Commissioner LARRICK. I don't think there is anything in the offing that would cause me to recommend that you hold up this bill. We have an abuse, we have a problem, it is an interstate problem, and no matter how much the States pitch in and help on this matter—and I hope they will recommend that they pitch in and help—we need this bill, in my opinion.

Mr. YOUNGER. Can you give us any possible highlights of that report at this time?

Commissioner LARRICK. No, sir. The report hasn't been submitted. I have talked to the people. They have let me see certain parts of it to check for accuracy, but they have not finished their report. I don't think it would be proper for me to discuss it until they turn it in.

Mr. YOUNGER. Then you couldn't advise the committee as to whether cooperative contracts between the States and your Department might help in better enforcement?

Commissioner LARRICK. I could give you my opinion that it would, but I can't tell you what the Public Administration Service will recommend. I don't think there is any question but that this problem is so big that it will require the best efforts of the Federal, the State, and the city people to begin to control it, and that won't control it completely.

Mr. YOUNGER. I have one other question. Yesterday, in Mr. McMullen's testimony, I couldn't understand why all of these manufacturers were able to supply the great quantity of pills that were ordered and nothing was done about it. Apparently no investigation is made of these various concerns except maybe once every 2 years, which I think was the report, as to their records and who they sold to.

A manufacturer is not required to even inquire who the purchaser is, or whether he is a legitimate purchaser, or whether he has a license. What is the status on that?

Commissioner LARRICK. That is what we are trying to fix with this bill.

Mr. YOUNGER. The present law doesn't require you or the manufacturer to inquire as to who the purchaser is or whether he is a legitimate purchaser, or whether he has a license?

Commissioner LARRICK. No. He could be subjected to a penalty if we can prove that he sells a prescription drug in channels which are not in the regular drug trade.

Mr. YOUNGER. But there is no requirement for the manufacturer to inquire even of a prescription drug?

Commissioner LARRICK. No; there is no specific requirement of that sort at all.

Mr. YOUNGER. But there is in this bill?

Commissioner LARRICK. This bill, yes. This bill would require him to keep a record of how much he makes, it would make him keep a record of who he sells to, and make him show those records to us.

Mr. YOUNGER. But is there anything in this bill that requires him to make an inquiry as to the purchaser and whether the purchaser is a legitimate licensee to handle the drug?

Commissioner LARRICK. There is nothing that requires him, that makes it a penalty for failure to inquire, but there is a provision which makes a penalty for failure to keep it in legitimate drug channels.

Mr. YOUNGER. Don't you think it would be well to have a penalty in there and put the burden on the manufacturer?

Commissioner LARRICK. I wouldn't object at all.

Mr. YOUNGER. Don't you think it would be helpful, in the light of the evidence we received yesterday?

Commissioner LARRICK. I think this would be helpful.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Friedel.

Mr. FRIEDEL. Commissioner Larrick, what is the procedure—or the chain from the manufacturer down to the distributor? What kind of records are required to be kept?

Commissioner LARRICK. Under the bill, Mr. Friedel, or the present law?

Mr. FRIEDEL. Under the present law today.

Commissioner LARRICK. None. The only thing that is required under the present law in the way of recordkeeping is that the pharmacist, at the end of the chain, is required by the Durham-Humphrey amendment to keep and make a record of all prescriptions that he fills. But he is not required to let us see it.

Mr. FRIEDEL. Under this bill he will be required to let you see it?

Commissioner LARRICK. That is right.

Mr. FRIEDEL. We had Dr. Mattia here, and he recommended that records be kept by pharmaceutical manufacturers, wholesalers, distributors, retail druggists, and the medical profession. Does this bill take all of those in?

Commissioner LARRICK. Does this bill take them all in?

Mr. FRIEDEL. Yes.

Commissioner LARRICK. No; it does not. It does not take in the physician.

Mr. FRIEDEL. Does it take in the pharmaceutical manufacturer?

Commissioner LARRICK. It does.

Mr. FRIEDEL. The wholesaler?

Commissioner LARRICK. It does.

Mr. FRIEDEL. The distributor?

Commissioner LARRICK. It does.

Mr. FRIEDEL. The retail druggist?

Commissioner LARRICK. It does.

Mr. FRIEDEL. But nothing about the medical profession?

Commissioner LARRICK. That is right.

Mr. FRIEDEL. Why?

Commissioner LARRICK. As we testified in our original testimony, the incidence of violations among the medical profession in the enforcement that we have done in the last 10 years has been very small. We did say, the Department in its letter and in my testimony, that if in the judgment of the committee the physicians should be included, the Department would see no objection to the inclusion of the physician.

Mr. FRIEDEL. Would there be any objection if we put a limitation on time, a limitation, for example, where a prescription could not be renewed after 6 months, when the doctor presently says it can be renewed repeatedly?

Commissioner LARRICK. I haven't consulted with the Department, but I certainly would see no objection to that. On some drugs 6 months would be too long.

The CHAIRMAN. Doctor, there would be quite a lot of objection if we include a lot of stuff in this that would endanger the passage of the bill, wouldn't there be?

Commissioner LARRICK. Yes, sir.

Mr. FRIEDEL. I just wanted to know if doctors should be included.

Commissioner LARRICK. We have tried to be practical and not put in so many things as to reasonably make it unlikely that it would pass.

Mr. YOUNGER. Would the gentleman yield?

Would it not be possible to put in a requirement that those doctors who sell and dispense drugs from their own office would be required to keep records? That is only a small number. If they do not sell and dispense drugs, they wouldn't be covered. Couldn't that be done?

Commissioner LARRICK. As we have said in our letter, if the committee decides that they wished to do that, we have no objection.

Mr. YOUNGER. Thank you.

Mr. FRIEDEL. I have nothing further.

Dr. CARTER. Will the gentleman yield?

Mr. FRIEDEL. Dr. Carter.

Dr. CARTER. Mr. Larrick, we have noticed that over a period of 10 years, I think it was, there were only 13 convictions in the medical profession. Is that true?

Commissioner LARRICK. That is correct.

Dr. CARTER. That shows a pretty good record that we are not, as practitioners, afraid of any regulations concerning this. On regulations that you might want to give those who dispense, I certainly don't think physicians would object to them. Certainly I don't believe many physicians would want to have a prescription be refilled over a period of time of 6 months, as some people have suggested. We would want to see our patients more often than that.

In giving an amphetamine drug for weight reductions, as they commonly are used, rarely does a good physician give more than 15 to 30 of those at a time, and more than likely not more than 15. Certainly you would see that patient within that time, it seems to me.

The CHAIRMAN. Mr. Nelsen?

Mr. NELSEN. I have no questions.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Commissioner Larrick, I am happy to see you before the committee this morning.

Commissioner LARRICK. Thank you, sir.

Mr. DINGELL. There is an exemption given in the bill at the bottom of page 5, dealing with persons who use depressant or stimulant drugs in research, teaching, or chemical analysis and not for sale. That is on lines 23, 24, and 25. Similar exemptions are given in other drug regulatory bills and legislation; isn't that so?

Commissioner LARRICK. That is correct.

Mr. DINGELL. This exemption is, however, somewhat different than the exemptions which are accorded in other legislation of a similar type. Am I correct?

Commissioner LARRICK. I don't know that, Mr. Dingell.

Mr. DINGELL. I have some concern about this. I would like to limit as narrowly as possible the exemption to really sincere and honest researchers and chemical analysts and not simply to those who may so designate themselves.

As I recall the regulatory bill that was passed by this Congress a couple of sessions back, it has quite different language. Can you remember the language, Mr. Goodrich?

Mr. GOODRICH. I don't remember that offhand. If you are talking about the control of investigational use drugs, there was some more comprehensive language there. Under this language, if we could prove that the drug was not being used in the course of research, teaching, chemical analysis, and was for sale, we could still take action. I don't see that it has any loophole in it.

Mr. ELLENBOGEN. Are you referring to the use of the term "bona fide" in the 1962 amendment?

Mr. DINGELL. Yes. It is not limited so narrowly to persons who are doctors of medicine, but to persons who were, I believe, qualified by training, research, and experience.

Commissioner LARRICK. Experts qualified by scientific training and experience.

Mr. DINGELL. Why should the exemption be any different or broader in the case of this bill than the exemption in the previous legislation?

Mr. GOODRICH. That previous language related to the use of the drug in clinical investigations, before the drug was approved, in obtaining the evidence of safety and effectiveness; that is, actual use on man. This is a use in teaching, research, and chemical analysis which wouldn't involve that. It could be made clear that this meant research, teaching, and chemical analysis not involving administration on man, but we think that is implicit in the exemption.

Mr. DINGELL. I don't want to limit it so narrowly. The reason I am concerned is that I remember the college student who got hold of some LSD-25 for use in investigation, and I believe there are other incidents that could be cited to the committee.

Mr. GOODRICH. But in the LSD-25 case, where Copely and his associate claimed they were using it for research, we were able to show that they actually sold it to our agent and were not in any sense involved in teaching or research, so we made that case under existing law.

Mr. DINGELL. Are you satisfied that this exemption is so narrow that you will be able to make a case in any set of circumstances that might arise where someone professed himself to be a researcher, a teacher, a chemical analyst of one kind or another?

Mr. GOODRICH. You can never be 100 percent sure on legislation that passes. The day it passes, we all think we understand completely what it is all about, and then the next day apparently there is a blank on it. But we think this is a satisfactory provision that could take care of these abuses.

Mr. DINGELL. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Curtin, have you any questions?

Mr. CURTIN. Thank you, Mr. Chairman.

Commissioner LARRICK, we were privileged to see a film yesterday that showed certain purchases of these drugs made throughout the United States. Are you familiar with that film?

Commissioner LARRICK. Yes, I am.

Mr. CURTIN. Was there any prosecution on the part of your agency as a result of the disclosures in that film?

Commissioner LARRICK. Do you mean the purchases that CBS News made or the pictures of our agents making buys?

Mr. CURTIN. I mean the picture that CBS showed on various wholesalers, or perhaps, manufacturers of these pills. Did you follow it up in any way?

Commissioner LARRICK. Yes, we followed up every one of those firms and had our own dummy corporation. I suspect largely because the firms had been alerted, we were not able to make any buys. We then undertook to discover whether or not we could use the actual purchases by Mr. McMullen and his associates as the basis of a prosecution under the Federal law.

But it happened that in a letter to me, Mr. McMullen made the following statement:

Presently, under the name of McMullen Services, we have been ordering quantities of the above-mentioned drugs. Letters to the drug companies bear my signature. The district attorney of Manhattan has been informed and has assured us that in taking this action we are not violating the State law since McMullen Services is acting as the temporary purchasing agent of the CBS Medical Office which is, of course, licensed to receive drugs.

I think the action that Mr. McMullen and his group had was very useful, because the firms who made the sales didn't know that he was acting as the agent of a physician. But we could not go into court and prosecute on those sales when the evidence would be that he was acting as an agent for the physician, and the physician is legally entitled to receive the drugs under the present statute.

Mr. CURTIN. Do you mean you could not prosecute the firms from whom McMullen Services purchased on the evidence that they had?

Commissioner LARRICK. Because they wrote me that they were acting as the agent of their doctor in CBS, and a doctor is entitled to buy these drugs. Understand, I am not critical of what Mr. McMullen did. I think it was very dramatic.

Mr. CURTIN. Mr. Commissioner, last week we had evidence as to the number of these pills that get into the illicit market, and my recollection is that it was 4.5 billion pills a year. Is that correct?

Commissioner LARRICK. Yes. It is approximately 4.5 billion 1-grain barbiturates, and 4.5 billion amphetamines.

Mr. CURTIN. It seemed so fantastic, I wanted to verify my recollection. Thank you.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Doctor, we have gone over some of the problems, of course, and have had some discussion about the possibility of having wholesalers who have a registry number with you anyhow—do they not?

Commissioner LARRICK. Some do and some don't. If they engage exclusively in wholesaling, they are not required to have a number with us. If they engage in making drugs and become manufacturers, then they have a number.

Mr. ROGERS of Florida. Do they have to, under this bill, have a number?

Commissioner LARRICK. They do have to register.

Mr. ROGERS of Florida. I thought that would be true, that they would have to register under the provisions of this act.

Commissioner LARRICK. That is right.

Mr. ROGERS of Florida. And you would assign them a number, I assume.

Commissioner LARRICK. That is right.

Mr. ROGERS of Florida. But I don't believe there is any provision in the bill, and I am considering offering an amendment, but I wanted your idea about it, requiring wholesalers when purchasing drugs from the manufacturer to submit their registry number with their order for purchase. What would be your feeling about that?

Commissioner LARRICK. I do endorse that.

Mr. ROGERS of Florida. I think this would be a quick way to stop what we saw in the CBS film, because these numbers can be verified with you after they establish their propriety in obtaining such a number, and this could be checked, it seems to me, very quickly by the manufacturer in contact with FDA.

Commissioner LARRICK. Mr. Rogers, I don't think you ought to set up a situation where the manufacturer's responsibility, moral or legal, would be completely satisfied by getting the number, because we don't get around often enough and it is pretty easy for somebody to make a false representation to us and get the number, and it may be some months before we check him, maybe 2 years, as a matter of fact, and he could operate. This would be a help to him rather than a hindrance.

Mr. ROGERS of Florida. I would agree that this should not take the responsibility away from the manufacturer to go beyond the number, but this would certainly help, in any event, and right off.

What about prescriptions? It is my understanding from testimony we heard yesterday that prescriptions for these types of drugs are often given without an end, so that they are an open prescription, or they may be designated two, three, or four times for refills, without having to go back to the doctor.

What objection would there be to requiring that these drugs sold by prescription may not be sold or those prescriptions filled without a check with the doctor, or whatever language might be necessary, but to require that there be only one filling of the prescription.

It is not that you would necessarily have to go back to the doctor to get another prescription, but it would require the doctor's approval for a refill within the 6-month period.

Commissioner LARRICK. The idea of that is excellent. You have a practical problem here of having a very wide variety of drugs potentially subject to regulation under this statute, and you have also a great variety of different types and kinds of illnesses that may be involved, particularly when you get to the stimulant drugs. Patients will include old people, young people, and babies.

I am very sure that your suggestion would be helpful to us in enforcement. I am not sure but what it would make some problems, some legitimate problems, in medical practice that might outweigh the advantages.

Mr. ROGERS of Florida. I understand this is done in many States. Is that true?

Commissioner LARRICK. It is done in many States, but it is restricted to drugs ordinarily that are specifically designated. If you wanted to give us or delegate to us the power to tailor the restriction to the drug, perhaps make your initial restriction to the amphetamines and barbiturates that are specifically mentioned, maybe if you saw fit to delegate the same general sort of authority, but to tailor it to the problems of that drug, perhaps it would be worth putting in.

Mr. ROGERS of Florida. I would think this study would show how many States have this sort of law. I understand Florida does, for instance; that they cannot retail the prescription unless the pharmacist at least calls the physician and gets his approval. That prevents exactly what we are trying to get at and exactly the thing we had testimony about yesterday, where people will get a prescription perhaps because they are overweight and then they start going around getting it refilled, refilled and refilled, and then they sell it even in the colleges.

Commissioner LARRICK. I think that is very wrong. I don't think that is good medical practice. If it gets refilled and refilled and refilled without the doctor's permission, it is illegal now.

Mr. ROGERS of Florida. It is being done.

Commissioner LARRICK. Of course it is being done, because we have 56 inspectors to cover this whole problem.

Mr. ROGERS of Florida. What makes it illegal?

Commissioner LARRICK. The Durham-Humphrey Act makes it an offense to refill a prescription drug unless the doctor has stated it may be refilled.

Mr. ROGERS of Florida. Suppose he just gives a person a prescription?

Commissioner LARRICK. It cannot legally be refilled at all. The practice that is bad in this connection is for the doctor to write on the prescription that it can be refilled at will. That doesn't happen often, but that does happen. We deplore it.

Mr. ROGERS of Florida. From the testimony we heard yesterday, it happens fairly frequently in one area of the country anyhow.

Commissioner LARRICK. I think that gentleman referred not entirely to the practice of the physician, but to the practice of refilling prescriptions where they had not been authorized to be refilled, which would be a violation of the law.

Mr. ROGERS of Florida. No, I didn't get that from his testimony. Well, we will not argue that.

You see no objection, do you, to try to put some language in, particularly as it concerns these two types of drugs, to say that the prescription shall not be refilled without the permission of the physician?

Mr. GOODRICH. When those laws came out before, when we were considering the Durham-Humphrey, there was a proposal kicked around—and I don't know how far it ever got—like the Florida law and some of the other laws, to allow unrestricted refilling for a period of 6 months.

The decision was that that was very wrong; that each refilling should be on the doctor's authorization, under his supervision. He could indicate one time, two times, three times, or 6 months. But what the State laws tended to do was encourage refilling during the 6-month period without going back to the physician, which could be very dangerous.

For example, if you allow a barbiturate to be refilled for 6 months, a person could get very shortly enough to kill himself.

Mr. ROGERS of Florida. Couldn't we say "Without the permission of the physician?"

Mr. GOODRICH. If he did that, there may be instances where the physician, in his medical judgment, could well authorize the use of the drug in limited amounts for longer than 6 months, with some of these tranquilizers.

Mr. ROGERS of Florida. What I mean is that after the first filling, they must again have the permission of the physician before the pharmacist would fill the prescription.

Commissioner LARRICK. I would think it would be necessary to take care of the medical needs under many circumstances for a physician to authorize at the time that he gives the prescription that it be refilled. For example, I spent the entire month of December in your district. I took my wife with me. She had some medicine. She was going to be gone a month. Before she left, the physician, knowing that, gave her a prescription for a small amount and authorized its refilling twice.

I think that sort of practice is necessary to adequate medical care, but if you were to say that the physician could authorize a reasonable number of refills at the time he writes the prescription—I think you would be repeating what is in the present law—and that no refilling could be had without going back to the physician, unless he has authorized it, I think you would have it in good shape.

Mr. ROGERS of Florida. Would that help to say that, do you think?

Commissioner LARRICK. I think so; yes.

Mr. ROGERS of Florida. What about the penalty? Do you think the penalty is sufficient in the bill as proposed?

Commissioner LARRICK. The penalty, in my judgment, in the statute is sufficient. I think we have a major problem of educating the courts to the relative seriousness of these crimes, and I think that is part of our responsibility to do that.

Mr. ROGERS of Florida. I notice in your proposal that you would allow any officer or employee of the Department of Health, Education, and Welfare, designated by the Secretary, to conduct investigations or inspections under the Federal Food, Drug, and Cosmetic Act. Should it be "Conduct investigations or inspections for particular drugs"? Should we name the drugs there? This is rather a broad authority, to allow the Secretary, not that he would, but that he might, to allow any employee to conduct any investigation?

Commissioner LARRICK. Basically, the statute, as you know, gives no authority by statute to the Commissioner. Everything is delegated to the Secretary. That language simply follows the pattern of the bill as a whole. But there are limitations in the proposal.

It says on page 18 of the statute, under (g)—

officers or employees of the Department designated by the Secretary to conduct investigations or inspections relating to depressant or stimulant drugs.

So it does do what you are speaking of.

Mr. ROGERS of Florida. And you feel that the other does not wipe that out by the amendment to section 1114 of title 18?

Commissioner LARRICK. No, sir; I think it is limited. We are proposing that this be amended to cover counterfeit drugs as well as the drugs mentioned there now.

Mr. ROGERS of Florida. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Broyhill.

Mr. BROYHILL. Mr. Chairman, I just want to say that I certainly appreciate the Commissioner making his second appearance before the committee. His statements have been helpful and constructive, and I know they have cleared up a number of questions in my own mind.

Commissioner LARRICK. Thank you very much, Mr. Broyhill.

The CHAIRMAN. Mr. Kornegay.

Mr. KORNEGAY. Let me pursue the question of penalties a little further, please. I think generally speaking the judges, both State and Federal, view the severity of the offense to some degree with the amount of punishment which the legislative body has prescribed for it. They also say that when a maximum, as is generally the case, is prescribed by the legislation, it was apparently the intent of Congress that the worst possible case should receive the maximum punishment, and they work from there on down.

Human nature being what it is, we say "This is a bad case, but it is probably not the worst case to come along." Do you see what I mean?

Commissioner LARRICK. I see what you mean.

Mr. KORNEGAY. Under section 303 are provided the penalties. For the first offense it is declared to be a misdemeanor, with a maximum punishment of 1 year or \$1,000 fine, and for a second or subsequent offense, you go up to 3 years, and a maximum fine of \$10,000. Of course, under the bill that we have under consideration, there is an innovation which brings into account the situation where a person over the age of 18 years sells, delivers, or otherwise disposes of depressant or stimulant drugs to a person under the age of 18, to take care of the adult-child situation.

That merely provides a maximum term of imprisonment of 2 years or a maximum fine of \$2,000, for the first offense, and increases in the second or subsequent offenses to 6 years and \$15,000.

When you consider all the aspects of punishment and sentencing of a defendant, suppose a first offender got the maximum of 1 year. Under the present statute he would be eligible for parole after he served 4 months, and in most instances where prisoners behave themselves and get along well in prison they get out shortly after they become eligible for parole.

So it just boils down to the fact that if this situation is serious, as it is pictured and painted here before us, it would certainly appear to me that the punishment set forth, both in the existing law and in the bill, is a bit on the light side.

Commissioner LARRICK. I wouldn't disagree with that.

Mr. KORNEGAY. We had testimony yesterday to the effect—and it was not meant as criticism of the judges, and I am not doing that now—that it was sort of a slap on the wrist business, the violation of this statute would be declared to be a misdemeanor, and the prosecuting attorney, of necessity, has to relegate those cases on his docket to positions after the felony cases. Sometimes he gets to them and sometimes he doesn't get to them.

It would be my thought, unless I heard something to the contrary, that the penalty is just too light, that it decreases the severity of this type of offense against the public.

Commissioner LARRICK. I wouldn't disagree with you.

Mr. KORNEGAY. Would you care to make any suggestions? You are familiar with this area. You have watched the prosecution of these cases and the sentencing of violators, and you have seen repetition of sales and so forth.

Commissioner LARRICK. Of course, the second offense already in the statute calls for an increase for each offense with a penalty of \$10,000 maximum and 3 years in the penitentiary. If the committee, in its wisdom, wants to up it, I would certainly see no objection to it. I would recommend against a minimum penalty.

My view is that in putting minimum penalties in statutes where you have some emotional problems involved, like dependents, wives, and so on, when you have juries you may get an acquittal.

Mr. KORNEGAY. I am well acquainted with that problem, and I agree with you.

Commissioner LARRICK. But with that exception, I would be content to leave it quite to the judgment of the committee as to the penalties.

Mr. KORNEGAY. Thank you. I do want to thank you for coming back. I missed you the other day. I had a long-term commitment that took me away from the committee the day you testified. I am delighted to see you.

Commissioner LARRICK. Thank you.

The CHAIRMAN. Dr. Carter.

Dr. CARTER. I want to compliment Commissioner Larrick on his statement. I certainly support his proposal.

Commissioner LARRICK. Thank you, Dr. Carter. I think the committee is very fortunate to have a physician on board.

The CHAIRMAN. Did I understand you to say that you are wholeheartedly supporting this legislation?

Dr. CARTER. Yes, sir.

Commissioner LARRICK. I heard that, too, Mr. Chairman.

The CHAIRMAN. I wanted to understand correctly.

Mr. Van Deerlin?

Mr. VAN DEERLIN. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Pickle.

Mr. PICKLE. I have two questions.

With respect to registration or licensing, since many of the States or some of the States don't require any licensing before they go into business, I am hopeful that this State study would point this out and each State could then take corrective measures, but in your own instance, with respect to the FDA, do I understand that all a man has to do if he is a manufacturer and goes into business is just write you and ask for a registration number, that he has gone into business. Must he have that registration before he can set up his manufacturing concern and start dispensing, or will that approval or registration from you come at a later date?

Commissioner LARRICK. If he is a manufacturer of a drug for shipment in interstate commerce, he must register with us before he engages in business.

Mr. PICKLE. Before he engages?

Commissioner LARRICK. That only applies to the manufacturer. It does not apply to the wholesaler or the retailer.

Mr. PICKLE. Only to the manufacturer?

Commissioner LARRICK. That is right.

Mr. PICKLE. I have another question, and it is for information. We are all agreed, generally, that there ought to be some kind of a bill passed along these lines. No one has testified really strongly against the bill. Surely these controls will be a big help to us, but one physician said we were taking the wrong approach; that these controls will be helpful, but his idea was to just make the drugs more available. I think, in his opinion, and most of the committee members, it is that the big problem is the overuse of these drugs, not just the controls of them.

It seems to me that the American people have developed a dependency on these drugs. They are more of a mental crutch than they are a physical or medical aid to them. I don't know what you could testify or say about that, but if this is so, our big problem is in the field of education.

How can we stop that? Do you have any funds to spearhead a campaign on that? This is our big problem.

Commissioner LARRICK. We have some funds to spearhead a program on that. I think the American Medical Association has recently, or perhaps not recently, taken an increased interest in educating the physician in these fields.

One of my associates in the Department, the head of St. Elizabeths, is chairman of a committee that has prepared a pamphlet to go to all doctors, I understand, on narcotics. I know they are studying these tranquilizers and whatnot.

What I am saying is that I think the medical profession will have to do a great deal of educating itself. I think we can do some. But

I think the actual regulation of the practice of medicine will have to be left with the State governments.

Mr. PICKLE. Is it unfair to say that medical doctors have too quickly prescribed pills?

Commissioner LARRICK. Some have, unquestionably. Doctors, like lawyers, vary.

Mr. PICKLE. The biggest offender is the public generally?

Commissioner LARRICK. The public demands these things. They read about them and demand them. It is pretty hard for the physician to refuse them.

Mr. PICKLE. We have come to think that a pill will cure anything, and we can abuse ourselves in any manner, day or night, and then take a pill and it will be corrected. This is our big problem.

Commissioner LARRICK. You have a basic psychological problem of the kind of people who do become addicted to these drugs.

Mr. PICKLE. That is all, Mr. Chairman.

Commissioner LARRICK. We have put out pamphlets, for example, Mr. Pickle, like "First Facts on Drugs for Schoolchildren." We are getting wide distribution of this throughout the schools. We hope to do more in that area.

Mr. PICKLE. I would hope that the Advertising Council of America, the medical profession, our schools, and our newspaper, all news media, could concentrate and come together on some kind of a campaign that would stress these dangers and turn the direction of the use of these pills.

Commissioner LARRICK. We share your view.

Mr. PICKLE. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Satterfield?

Mr. SATTERFIELD. Thank you, Mr. Chairman.

I have two brief questions.

When a drug is found to have a potential for abuse, will it then be made a prescription drug?

Commissioner LARRICK. Yes, as in the case of the Valo inhalers.

Mr. SATTERFIELD. In other words, there will be no drugs falling within the purview of this act except that they be prescription drugs?

Commissioner LARRICK. This act deals exclusively with prescription drugs.

Mr. SATTERFIELD. When we talk in this act about individuals having possession of these drugs, there is an exclusion which makes possession legal if it is for use of himself or a member of his household. Wouldn't it be well to include an additional provision that it also have been obtained by prescription?

Commissioner LARRICK. That was, we thought, covered, Mr. Satterfield, by saying "legal."

Mr. SATTERFIELD. Wouldn't this require that you actually make a purchase to prove that it wasn't for the possessor's own personal use?

Commissioner LARRICK. I didn't understand your question.

Mr. SATTERFIELD. As this section is drawn, wouldn't it require that a purchase be made in order to establish the proof that possession was not for the possessors personal or household use, whereas, if you included the provision "and obtained by prescription" you could nail

him by the fact that the drug wasn't obtained by the prescription, without having to make a purchase.

Commissioner LARRICK. You would run into some drafting problems which probably could be solved. You wouldn't expect the wholesaler to have a prescription to get the drug that he is going to sell. You wouldn't expect the retailer to have a prescription.

I am not the draftsman, but the draftsman tried to incorporate language which would, in one fell swoop, cover legal possession from the user to the retailer to the wholesaler and the manufacturer.

Mr. SATTERFIELD. Wouldn't your contact, in terms of identifying illicit traffic, normally start with some person who has possession of the pills?

Commissioner LARRICK. It will. Often it comes from complaints from police departments, from mothers worried about their children, husbands.

Mr. SATTERFIELD. Wouldn't you be in a better position from an enforcement standpoint if you could make it illegal to have it in possession without the prescribed prescription?

Mr. GOODRICH. This sort of an idea was considered before. Since we were concerned with commercial distribution, it was decided that it would be best to put it in terms as it is in the bill, rather than make it so wide open that if you got your druggist to give you six pills without a prescription you would be a criminal. That is the idea of this provision.

The CHAIRMAN. What this would do is to get to that druggist and not to the man who may have a half dozen pills for his own use.

Commissioner LARRICK. That is the point.

The CHAIRMAN. But if the man who gets it illegally then proposes to distribute it illegally, it does reach him.

Commissioner LARRICK. That is the point. We could prove it probably by the large volume in his possession as well as by an actual sale.

Mr. SATTERFIELD. I have one other question, and that is in terms of the guidelines set down for potential of abuse. I am still vague as to what the standards would be under this bill. Would it be safe to say that any drug that would affect the central nervous system would have a potential for abuse?

Commissioner LARRICK. Not every drug that would affect the central nervous system would come under this bill. It would have to not only affect the nervous system, but be a drug that is sought for non-medical purposes to produce these escapes from reality.

Mr. SATTERFIELD. Then we come back to the proposition that the only way you can really ascertain this question is through the experience of the actual abuse?

Commissioner LARRICK. No, sir; because nowadays when a new drug comes on the market there has been no commercialization. First is the animal experimentation. Then if it passes, and we approve it, then it goes to the clinics, not as a sale proposition but as a test proposition.

In that process, a great many times the potential for abuse is discovered in these clinics who are investigating the drug to acquire evidence to try to get us to let it go on the market commercially. You could say that that is an actual abuse, but it isn't an abuse in the sense that it has gone through all these illegal channels. It is a drug very

tightly contained, legally distributed only to these few top-flight investigators who, in the course of their work with it discover its potential for harm, its potential for good, also discover that it is addictive, habit forming, or what have you. Then I think it should go on the list.

Mr. SATTERFIELD. One other thing, and it is really not apropos of this bill, but I am told that paregoric, for example, is still obtainable without prescription. It would seem to me that this would fall within the purview of this act.

Commissioner LARRICK. This bill has an exemption in it which provides that anything that is covered under the Narcotics Act shall not be duplicated in this act.

Mr. SATTERFIELD. Paregoric isn't covered under the Narcotics Act, is it?

Commissioner LARRICK. It is covered under the Narcotic Act, but it is exempt. Some States have agreed with the statement you just made and those States have provided that it can't be sold without prescription.

Mr. SATTERFIELD. Those are all the questions I have.

The CHAIRMAN. Mr. Mackay?

Mr. MACKAY. No questions.

The CHAIRMAN. Mr. Gilligan?

Mr. GILLIGAN. No questions.

The CHAIRMAN. Commissioner, some question has been raised by the pharmacists as to whether or not they should be given the same exemption as the doctors.

I wonder what would be your reaction to placing an exemption so far as the pharmacist is concerned up to a certain level that that particular pharmacy might handle on this type of drug?

Commissioner LARRICK. Do you mean you would exempt the pharmacist if he only bought 1,000?

The CHAIRMAN. Or whatever number it might be.

Commissioner LARRICK. How would we ever know whether he was exercising the exemption legally if we weren't permitted to check to see how many he had bought?

The CHAIRMAN. I assume if you get what you are asking here, with what you referred to as 500 inspectors and \$10 million a year, you should obtain that information.

Commissioner LARRICK. 500 employees. There are 1,000 places he can buy them. He can buy 1,000 here, 1,000 here, and 1,000 here. If you can't go in and check his records, you would have a loophole in your bill that you could drive an elephant through.

The CHAIRMAN. Suppose any man you caught in violation of that exemption then would be subject to the penalties of the act?

Commissioner LARRICK. Mr. Chairman, in the final analysis, we will do our best with anything that the committee decides is necessary, as a practical matter.

The CHAIRMAN. If a man is dispensing 5,000 or 100,000, then we know it is getting out of legitimate channels. You are not after, and this doesn't propose to get after, those who are engaged in the legitimate channels.

Commissioner LARRICK. You are quite right.

The CHAIRMAN. What we want to do is to preserve the best we can those who are engaged in legitimate activities and get at those who are abusing this privilege they have, leading to these drugs going into illegitimate channels. If you find coming from various sources—and you will get reports from one source or the other—

Commissioner LARRICK. The bill doesn't require them to report to us, sir.

The CHAIRMAN. I know it doesn't require reports, but you said you are going to get reports if somebody is handling these pills or goof balls, whatever they might be, indiscriminately. That is the purpose of having your so-called police force that you are going to have.

Commissioner LARRICK. I still think it is very necessary to the successful administration of this statute to have the authority to go in and look at the records. If we find the pharmacist is only buying 1,000, and has only gone to one source, we won't be worried.

The CHAIRMAN. I know. That is what you have been trying to get all the time. But why do you want to go in and look at all the records of the pharmacists, and all the prescriptions? You have been trying to do that, I know, for 15 years. I want to know why you want to do that, to meet this problem?

Commissioner LARRICK. Because we think it would be a very important step forward in the protection of the public health.

The CHAIRMAN. In other words, that is the reason you have had this idea in mind all the years, that you want to get into the corner drugstore and go over the records, all the time, any time you want to.

Commissioner LARRICK. Ninety percent of the retail pharmacists of the country that we visit today let us look at them voluntarily, without any objection. The ones that don't are generally the ones that have something to hide. They let the detail men go in, they let them look at their prescription files if the detail man wants to know how his product is selling in comparison with his competitors.

The alcohol tax people have the power to go in and look. The narcotics people have the power to go in and look. The State pharmacy inspector has the power to go in and look.

I can't, in all honesty, see why there should be a handicap placed in the way of enforcing a statute whose drive is exclusively in the public health interest, where permission to see them would advance that.

The CHAIRMAN. I can't either, with the exception of one thing.

Commissioner LARRICK. The practicality?

The CHAIRMAN. No; it isn't. It is abuses by your people who go into these drugstores that leads into problems and difficulties. I think if you go from that side of it, we might see if we can't get this thing to a head one way or another. Actually, in my district, I have had only one case called to my attention, in which such a situation has happened, where there had been objection to an inspection.

But I do know what the pharmacy organization contended and what they say. If they are accusing your agency and those who represent your agency of something that is not true, then we ought to know it. We ought to bring it to a head. If your people engage in the kind of approach to them as they, themselves, complain, then you ought to go and find out why they do it.

Commissioner LARRICK. I agree with that 100 percent. If you will recall, the person who wrote to you and complained was a pharmacy student at the University of Arkansas, and the professor later wrote to you and said that the complaint was completely unjustified.

The CHAIRMAN. No; that is not the case I am speaking of. The case that I am speaking of was a regular pharmacist in a little town in southeast Arkansas. It has been a long time since he was a student in the University of Arkansas.

Commissioner LARRICK. Mr. Chairman, our inspectors are human beings.

The CHAIRMAN. That is the whole problem. We are dealing with human beings on both sides.

Commissioner LARRICK. That is right. And I am sure there are some occasionally where a badge goes to their head. But I will promise you that we will do everything in God's world to try to administer this law with fairness and not take advantage of the tremendous powers that this committee is giving us, except in the proper way to try to enforce the law.

The CHAIRMAN. I think you are just as sincere in that as you know how, and all the rest of us are also, under the circumstances. That is the reason I agree with you. I can't understand why the pharmacist would not object to a narcotic act coming in, to a State agent coming in, to others who do come in and look over the records, and then object to one from your establishment coming in for a given purpose.

I can't understand it. But it is the feeling through the whole organization of pharmacists throughout the United States. They have been talking to us about it now for the last 15 or 20 years. You have been trying to get this authority for that long, or your agency has. I think we ought to see if we can't bring it to a head and find out what is wrong—what is the situation that we are faced with to make a decision here.

Commissioner LARRICK. I agree with that, it puts you in a very difficult position.

The CHAIRMAN. You take 52,000 pharmacists or druggists in the country, and you have a great agency, a big agency, a very important and necessary agency of the country. I have been wondering if there is not some way that we can settle this issue that has been plaguing us now for all these years.

It is as this individual told me. He said, "They came in here and asked for my records. They don't say what they want them for. They don't give me any information about what they are after. They are in here trying to abuse me."

I have never talked to you about it because I did not want to get into it.

Commissioner LARRICK. I wish you would. Let me explain one thing. If the sheriff of the county comes to us and says, "I have so many people that I lock up every Saturday night, and I have found these goof balls in their pockets. I have talked to these people and they tell me they are buying them at this place." The inspector gets the assignment to go into that place. When the man says, "Why do you want to look at that record?" he is not going to tell him, "Your friend Joe Jones, the sheriff, has, in an indirect way, gotten informa-

tion from some people who are hopheads that looks like it puts you in a bad light." The inspector doesn't tell him why he is in there.

The CHAIRMAN. The inspector ought to tell him why he is in there.

Commissioner LARRICK. I don't think he ought to.

The CHAIRMAN. That is where we disagree. I was district attorney for a good many years, and I never tried to mislead anyone.

Commissioner LARRICK. He does not tell him. I don't think he ought to give away the source of his information.

The CHAIRMAN. I did not say he should give away the source of his information. He should tell him the reason he is in there. The narcotic man tells him why.

Commissioner LARRICK. I don't object to telling him, "We are here to see whether or not you are selling drugs without prescription." If that is satisfactory, maybe that will be the solution to the whole thing.

The CHAIRMAN. What you do, according to what they tell me, is you give the impression, when your agent goes in, that the druggist is being accused of something without him knowing what it is, and, consequently, what the inspectors are doing in there is just hunting and pecking. The human element is involved and reports have gone in, and an individual has some kind of attitude of mind against a particular person, and he is going to use the authority he has to go in and abuse and penalize him. That is what the druggist thinks.

It seems to me that there ought to be some way, either through the proposed legislation, or through the enforcement, or the kind of people you have, or maybe a changed attitude in the druggist himself a little bit.

We get this kind of situation where maybe some people are violating the law a little bit and getting by with it and they don't want anybody to know about it. That was pretty apparent here yesterday with Dr. Griffith.

On the other hand, there is this idea that a man gets that "that agent over there has it in for me and he is going to see what he can do to put me out of business."

Commissioner LARRICK. If that comes to our attention, we will surely look into it. If the inspector is misbehaving himself, we will discipline and discipline him severely. These men are all college men. They are all people who have had at least a year's indoctrination and training. One of the things that we try to impress on them is that they represent the Food and Drug Administration to the public and business community. They are the ones that make our image for us, and we want them to proceed decently and fairly with anybody.

I am very happy at any time to sit down with anybody you designate or any representative of the pharmacists to try to resolve our 15-year-old difficulties in this field.

The CHAIRMAN. The man who goes into a drugstore and wants to look at all of them, is there any reason he should be permitted to look at every prescription he had in there?

Commissioner LARRICK. Not under this bill.

The CHAIRMAN. Under what you want?

Commissioner LARRICK. Under what I want, we want to look at all of them. But in this bill we have limited it, because this bill deals only with barbiturates, the amphetamines and other drugs that could be put under it.

The CHAIRMAN. In other words, if he were to keep a separate record, as he does with narcotics, that is all the record you would want to see?

Commissioner LARRICK. He would have to keep the invoices of how much of these drugs he buys, he would have to keep a separate record of the prescriptions that he fills, and he would not have to show us the other prescriptions, under this bill.

I still would probably be pursuing that at a later date.

The CHAIRMAN. I think you are going to pursue it until you get it. It may be soon or it may be a long, long time. But I think 45,000 or 50,000 druggists in the country are going to keep on objecting to it, and I guess the Congress is going to be called upon to settle the differences between you sooner or later if we can.

Commissioner LARRICK. These people are very good personal friends of mine, Mr. Harris, that you are talking about.

The CHAIRMAN. They may be, but I think there is the old saying that it is your friends you have to watch.

A matter that has probably plagued many of us here is the failure of your agency to pursue this matter of distribution. We talk about the pusher and these people who abuse the use of these drugs on the distribution end of it. I believe most everyone has their minds made up here that the real culprit in this thing has been the negligence, or whatever it might be, the attitude, of the manufacturer on wholesale operations, just selling to everybody and anybody they want to.

We had testimony here to the effect that if this mail proposition could be limited, it might help a lot. I think there is a lot to that.

I say again, as I did at the outset, I have a feeling that even your agency, whether it is criticism or not, probably could have been more effective if you had pursued this kind of situation from the manufacturer, where enormous amounts of this have been going into the illicit channels.

I know it takes the first step to be effective. But I also know, Mr. Commissioner, we can write the finest bill that can be put together with the English language, and if it is not adequately, and with adequate spirit, as it should be, administered, then this condition is not going to be reached.

Commissioner LARRICK. We are going to have to have facilities to administer this bill if you want it to be successful.

The CHAIRMAN. But a 10-year-old boy could have gone and discovered that thousands and hundreds of thousands of these amphetamines and barbiturates were going out somewhere and were going into illegal channels. That has been so obvious, from what we have had here.

I just feel that through the activity of your agency, the State people and the local people, a lot better job could have been done in this field. It has gotten out of hand. I do not think there is any question about that.

Commissioner LARRICK. Mr. Chairman, I have been trying for 15 years. I have before me a picture of the testimony that I gave before a Senate committee in 1955, telling that this thing was going to get out of hand. I have been trying for 15 years to get adequate legislation to deal with this problem.

I will grant you, if I could take the entire Food and Drug force that has to regulate 100,000 manufacturers of foods, drugs, and cosmetics in this country, all the problems that grew out of the thalidimide episode, and all the other problems, if we had taken them off those things, of course we could have done a better job in this field.

But to handle this even reasonably well we need a strong law, which is the type of bill you have introduced, and we need the money and facilities to do it. We cannot neglect the safety of our food supply. We cannot neglect the safety and efficacy of the basic drugs that the American public needs to keep well.

I will concede we could have done a better job, but we would have done a poorer job in these other areas. We will always have to balance the activities of the FDA.

The CHAIRMAN. Yes, I know you have a tremendous responsibility, and you keep on asking for more, and you have been getting more. Your agency, as others, has grown—it has grown tremendously so, of necessity. You have asked for more authority, from time to time, and you have been getting more, from time to time.

You do have a tremendous responsibility on your shoulders and your own agency's shoulders. But when there is, Commissioner, a tremendous outflow of production of a product which has been put under the statute on prescription and half of that product when it goes out in illegal channels, then I think it is just as important that you give that problem as much attention as you give to any other problem in the Food and Drug Administration.

I want to say to you that I feel here that when you have 9 billion of these things going out, and 4.5 billion of them delivered anywhere, somebody has failed to do their job.

It may be true that the Congress has not given you everything you want—I grant you that—but it does seem to me that there is a problem here of asking for more and more and getting more and more than has perhaps been absolutely necessary to do the job in the public interest.

I am, for one, willing to go as far as necessary. But I just do not see why you are going to have to set up an FBI force all around this country.

Commissioner LARRICK. Mr. Harris, as far as I am concerned, I would be quite willing to have this whole job undertaken by any other agency of Government that the powers that be decide should undertake it. My initial testimony was that it should not be given to the Food and Drug Administration, way back. The powers that be in the Government, after considering it fully, decided that it should be given to the Food and Drug Administration. So we are supporting giving it to the Food and Drug Administration, and we will do the best job we can, within the limits of our abilities and our resources.

The CHAIRMAN. I think every member of this committee has the feeling that they want to give you every resource that is necessary in order to break up this plague that has come on our society. I sense the feeling that probably most of the members of the committee are probably ready to go beyond what would be necessary, I think, at this time, and probably we are going to run into that difficulty.

What I want to do is to see if we can get together the kind of a program that will do the job and not go overboard, as somebody mentioned about the Volstead Act the other day, in providing you with authority and setting up procedures that would defeat the very purposes we seek out here.

I think probably that is going to be our biggest problem now, in giving you the practical kind of legislation that you should have.

Commissioner LARRICK. Mr. Harris, over the years, this committee has done a magnificent job of implementing the Food and Drug Administration with the basic authority that we have needed. We have come back again and we, as I said before, will take whatever you give us and make the best use of it that our capabilities will permit.

The CHAIRMAN. Thank you very much for your attention to this problem, your testimony, and the good record that has been made, which I think is a very splendid record, on the subject.

When we get together and start writing this legislation, if Mr. Goodrich could make himself available to us, I think it would be very helpful.

Commissioner LARRICK. I am sure he will.

Thank you again, sir.

The CHAIRMAN. I appreciate the willingness you and your associates have shown in providing us with the necessary information to make this record.

The record will remain open for a period of 5 days for the supplementing of any statements, at which time we will have the hearings printed and proceed to executive consideration of this matter.

Thank you very much.

Commissioner LARRICK. Thank you, sir.

The CHAIRMAN. The committee will adjourn.

(The following material was submitted for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
February 16, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: In our report and testimony on H.R. 2 (the proposed Drug Abuse Control Amendments of 1965), we recommended certain amendments to the bill, including a provision which would extend the seizure and condemnation authority provided for in section 6 of the bill to any vehicle or other conveyance in which contraband, stimulant, or depressant drugs are transported, carried, or held.

In the course of his testimony before your committee, Mr. George P. Larrick, the Commissioner of Food and Drugs, stated that the Department of Justice had not yet completed its study of this recommendation with respect to forfeiture of conveyances. Their experts in this field have since advised us that in their view a provision for such forfeiture would not be well suited to promote effectively the objectives of this bill. In deference to that view we therefore suggest that forfeiture of conveyances not be added to the enforcement provisions of the bill.

Sincerely,

WILBUR J. COHEN,  
Assistant Secretary.

HOUSE OF REPRESENTATIVES,  
Washington, D.C., February 16, 1965.

Hon. OREN HARRIS,  
Chairman, House Interstate and Foreign Commerce Committee,  
New House Office Building.

DEAR MR. CHAIRMAN: Though a member of the committee, I am asking that this letter be included as part of the printed hearings on H.R. 2. The problems encountered in Florida by barbiturate and amphetamine drugs is an increasing one and although our State law-enforcement agencies have done an excellent job in policing this problem in Florida, some strengthening of the laws concerning these drugs seems in order.

The public health authorities in Broward and Palm Beach Counties, Fla., have been extremely helpful in my determination of the problem, as have the Jacksonville and Miami offices of the Bureau of Narcotics, Florida State Board of Health. I am also enclosing a letter from Mr. Frank S. Castor, director of the Bureau of Narcotics in Florida, in which he outlines the narcotics problem in Florida very succinctly.

Your including this letter from Mr. Castor in the printed version of the public hearings would be appreciated also.

Kind regards and all good wishes.

Sincerely yours,

PAUL G. ROGERS,  
Member of Congress.

FLORIDA STATE BOARD OF HEALTH,  
Jacksonville, February 10, 1965.

Hon. PAUL G. ROGERS,  
Congressman, House of Representatives,  
Washington, D.C.

DEAR CONGRESSMAN ROGERS: Confirming our discussion by telephone this date, the following is a résumé of our experience dealing with problems concerning amphetamine and barbiturate drugs.

The Florida barbiturate law, chapter 404, Florida statutes, was passed during the 1957 legislature due to an investigation conducted by the Dade County Grand Jury under the direction of Assistant State Attorney Edward Swan. This law was drawn up by Mr. Swan with the assistance of Mr. R. R. Bellinger, inspector in charge of the bureau's Miami office. The passage of this law was steered through the legislature by Senator W. C. Herrell, of Dade County.

The Bureau feels that the major violators who deal with amphetamine and barbiturate drugs are concentrated around truck stops, barrooms and amusement places. We have had some difficulty in our universities. Since the passage of this law, there has been a steady increase in the number of arrests and I might add that the majority of these have resulted in convictions. Since 1957, the barbiturate and amphetamine arrests are as follows:

1957	11	1961	98
1958	28	1962	175
1959	31	1963	108
1960	46	1964	125

<sup>1</sup> There have been some illegal activities on the part of the pharmacists within the State. 38 of the 98 cases made in 1961 were connected with drugstores and 19 pharmacists were ordered to appear before the board of pharmacy to show cause why their licenses should not be suspended or revoked for illegal sale of amphetamines and/or barbiturates. We feel that this action resulted in the decrease in the cases made in 1962.

In our opinion, the illegal drugs in the hands of the traffickers are obtained from three major sources:

1. From the manufacturers: This is accomplished by posing as a professional person or wholesaler. (NOTE.—It has been hoped that Federal law would be strengthened in that the manufacturer would be required to know that he is shipping to an authorized source.)

2. Drugstores: Many of our defendants have advised that their source of supply was from drugs purchased on prescriptions.

3. Physicians: A few defendants have admitted purchasing large quantities of these drugs directly from physicians.

We are enclosing several copies of chapter 404, Florida barbiturate law, a copy of our annual report for 1964, and a copy of motor carrier accident investigation Report No. 37 for your information.

If further information is needed, please advise.

Respectfully yours,

FRANK S. CASTOR, *Director.*

[Prepared for annual report for 1964]

#### BUREAU OF NARCOTICS

The responsibilities of this bureau are quite explicitly defined by statute. They include the enforcement of Florida laws concerning the practice of the healing arts, the sale, administration, and use of narcotics and legally restricted drugs, the registration of practitioners prescribing or administering such drugs, the inspection of drugstores and other agencies selling or dispensing them, and the enforcement of laws concerning the manufacture and sale of drugs and cosmetics within the State. Less specifically defined, but inherent in the spirit of the law, is the mandate to pursue diligently any opportunity to appear before groups of citizens to inform and educate them concerning these problems, for the misuse of powerful drugs is becoming year by year more prevalent and at the same time more dangerous as medical science brings forth even more exotic and dangerous products which affect the brain and the personality of the individual.

Bureau personnel made 103 appearances before civic, collegiate, and law-enforcement groups last year, setting before the several thousand individuals present the gospel of abstinence from the less powerful "party" drugs, the importance of strict adherence to the law, and the reporting to the authorities of suspected violations. The speakers emphasized the importance of this latter point, noting that drug law violations are seldom overt, and that a trained investigator should be contacted in case of suspicion in this field.

With an additional inspector employed during the year, the bureau utilized the services of 13 men in conducting its operations from the central office in Jacksonville and the branches in Tampa, Tallahassee, Orlando, and Miami. These men, all registered pharmacists, have police powers and make arrests. They also cooperate with other city, State, and national enforcement agencies in the field of law covered by the alleged infractions.

A substantial percentage of the effort of the bureau is expended in consultation with the many persons who have become embroiled in the technicalities of the law without criminal intent. However, the hard core of the work is criminal investigations and this consumes most of the time of the personnel. There were 390 arrests made for all violations; these included 211 for narcotics, 125 for barbiturates and amphetamines, 27 for pharmacy, 6 for medical practice, and 2 for drug and cosmetic manufacture. This latter small number reflects the discretion of the inspectors who frequently found that the alleged infraction was related more to the technical nature of the statutes than to do harm to the public. Many thousands of dollars' worth of drugs and cosmetics were found by bureau personnel to have outlived their stipulated shelf-life, to have been subjected to possible damage or contamination by fire or flood, or to have been improperly labeled, however inadvertently. These products were withdrawn from sale, usually with the full cooperation of the owner.

Open inspections, that is unscheduled visits to drugstores, hospital dispensaries, manufacturers, wholesalers, and others handling or dispensing drugs, totaled 1,876. Investigations, examinations made as the result of suspicion or complaint, amounted to 2,396. Of these, 127 resulted in corrections of violations without legal action. The 390 arrests previously mentioned were included in this number of investigations. The remaining inquiries failed to materialize into cases because of lack of sufficient evidence, false rumor, cessation of illegal activities, or other legitimate reason. There were 19 persons sent to the hospitals of the State prisons at Raiford and Lowell for treatment of narcotic addiction. Such persons are wisely and humanely treated by the law as non-criminals, as long as they are involved in nothing more than addiction, and are not charged with crimes.

Amphetamines and barbiturates—"pep pills" and "goofballs"—continue to pose a serious problem. Their acceptance among a sufficient minority of our

youth as adjuncts to social activity is a continuing challenge to our educational efforts. The inspectors arrested 125 persons in connection with the enforcement of this law, but a large amount of illegal activity is known to be continuing in the State and the enforcement of this act is regarded as one of the major problems of the bureau.

Bureau personnel along with medical authorities are continuously intrigued by the tragic fact that most highly trained and sophisticated practitioners are the most likely of all types of people to become addicted to narcotics. Probably the availability of the drug is an important factor here, but the knowledge of the catastrophic effects of self-administration of narcotics is better known to them than to other people. It is supposed that the strain and tension of life in a medical career is the causative factor in most such cases.

The same difficult problems involving the influx of displaced persons from Cuba is reportable for 1964 as for previous years. However, the bureau still feels that these people do not commit a disproportionate number of violations. Those cases which are made are distributed among the various statutes enforced by the bureau.

So far as narcotics are concerned both the enforcement and the educational activities of the bureau deal with diseases which are subtle and elusive—human greed and sensual appetite. To these must be added the factor of the unfortunate victim caught in the toils of addiction through the nature of the drugs which were used and intended for his blessings. The personnel of the bureau are at all times aware of the soundness of purpose, the quality of judgment, and the dedication to principle that must be applied to their work. Punishment swift and sure must be administered to those who have been made sick of mind and body by addiction and, above all, the public must be made aware of the problems and the dangers of narcotics, and the State's youth in particular must be steered in a path clear of this most terrible of follies.

*Summary of activities, Florida, 1964*

Investigations.....	2,396
Open inspections.....	1,876
Arrests.....	390
Violations corrected where no legal action was taken.....	127
Aggregate sentences imposed by courts, 188 years, 7 months	
Aggregate fines imposed by courts.....	\$16,850
Defendants receiving probation, deferred, withheld, or suspended sentences.....	118
Cases discharged or nolle prosequi by courts.....	39
Narcotic addicts confined to State or Federal institutions for treatment.....	19
Persons acquitted by the courts.....	21
Cases placed on absentee docket.....	17
Bonds estreated.....	\$3,000
Talks made.....	103
Drugstores registered for 1964-65.....	1,688

FRANK S. CASTOR,  
*Director.*

KAY-FRIES CHEMICALS, INC.,  
*New York, N.Y., May 4, 1964.*

Re H.R. 10409, psychotoxic drug control of 1964.

Hon. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

SIR: We are quite concerned at what we believe is an unintended inaccuracy in part of the definition for "psychotoxic drug" in H.R. 10409. We refer to section 3(a) of that bill and specifically to the amendment of section 201 of the Federal Food, Drug, and Cosmetic Act designated as (v)(1)(A).

The part of the definition which we question states:

"(v) The term 'psychotoxic drug' means (1) any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid;"

Barbituric acid is a chemical name which describes a specific chemical structure. Salts of barbituric acid are such compounds as sodium barbiturate or ammonium barbiturate and also define a specific chemical structure. They

are not "barbiturates" as the term is commonly or popularly used to describe a class of hypnotic drugs. These hypnotic drugs, known as barbiturates, have the same general structure but have additional chemical groups attached and technically are called substituted barbituric acids.

The seventh edition of 1960 of the Merck Index lists under use for barbituric acid: "Manufacturing plastics, pharmaceuticals."

(It is used in the manufacture of pharmaceuticals other than barbiturates, notwithstanding the similarity in name.)

In addition, the same Merck Index has a note under the description of barbituric acid as follows:

"Unsubstituted barbituric acid has no hypnotic properties."

Ammonium barbiturate is not listed in the Merck Index, which is not surprising since it has only been used as an experimental chemical in industries other than the pharmaceutical. Neither is sodium barbiturate apparently listed. This is also not surprising since, to the best of our knowledge, its main use is in connection with the aircraft industry. To the best of our knowledge, ammonium and sodium barbiturate as direct salts of barbituric acid should show no hypnotic effect and neither of these, nor barbituric acid, are used as pharmaceuticals.

Our interest arises from the fact that Kay-Fries manufactures barbituric acid and sodium barbiturate and, upon occasion, have also manufactured ammonium barbiturate. We manufacture these compounds only for use as intermediates or building blocks in the synthesis of other chemical products.

It would appear that if H.R. 10409 were enacted in its present form, we literally would be unable to manufacture and sell these compounds for their present industrial uses. In addition, our customers, industrial users—including those in defense industries—could not use these materials since they are obviously not pharmaceutical manufacturers. We do not believe that this is the intention of the bill.

We believe that the purposes of the bill will be adequately and completely satisfied by the changing of (1) (A), lines 16 and 17, page 3, to read:

"(1) any drug which contains any quantity of (A) a substituted barbituric acid or any of the salts of a substituted barbituric acid;"

We would greatly appreciate your consideration of these comments. Of course we would be glad to have a representative come down for an informal discussion with your committee staff if you should feel that this is necessary. We also would request, that if further action is needed on our part, that we be given an opportunity to testify if hearings should be called on H.R. 10409.

Thank you very much for your consideration.

Very truly yours,

H. KENT VANDERHOEF,  
*Vice President.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
FOOD AND DRUG ADMINISTRATION,  
Washington, D.C., January 27, 1965.

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in reply to your letter of January 8, 1965, requesting comment on a letter from Mr. Vanderhoef of Kay-Fries Chemicals, Inc., concerning the definition of "psychotoxic drugs" in H.R. 10409, introduced in the 88th Congress. H.R. 2, presently before the Congress, contains similar language. It defines "depressant and stimulant drug" in part, as any drug which contains any quantity of "(a) barbituric acid or any of the salts of barbituric acid."

Mr. Vanderhoef's letter accurately quotes the seventh edition of 1960 of the Merck Index with respect to unsubstituted barbituric acid having no hypnotic properties. The problem here is that unsubstituted barbituric acid can be changed from a substance which does not have hypnotic properties to one which does by relatively simple chemical manipulation using manufacturing equipment that is readily available. Thus, amending the definition, as suggested, would create a serious loophole in the consumer protection afforded by the proposed legislation.

There is no provision in H.R. 2 which should lead Mr. Vanderhoef to conclude that passage of the bill would make his firm "unable to manufacture and sell these compounds (salts of unsubstituted barbituric acid) for their present in-

dustrial uses." The recordkeeping proposed by the bill is (aside from the inventory of stocks on hand which would be required initially) simply the recordkeeping that most responsible firms presently employ.

If we can give you further information, please feel free to contact us.

Sincerely yours,

JOHN L. HARVEY,  
Deputy Commissioner.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
FOOD AND DRUG ADMINISTRATION,  
Washington, D. C., February 17, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This replies to your letter of February 8, 1965, requesting our comments on a letter you received from Mr. Vanderhoef of Kay-Fries Chemicals, Inc., with regard to the effect of H.R. 2 on Kay-Fries Chemicals.

Mr. Vanderhoef will be pleased to know that there is no basis for the confusion which he fears exists with respect to the effect of H.R. 2 on his sales of barbituric acid. In the first place, there is nothing in H.R. 2 which would affect chemical firms that are shipping or receiving unsubstituted barbituric acid for industrial nondrug purposes. In the second place, as indicated in our letter of January 27, 1965, if the firm is shipping unsubstituted barbituric acid for drug purposes, the recordkeeping proposed by the bill is (aside from the inventory of stocks on hand which would be required initially) simply the recordkeeping that most responsible firms presently employ.

As indicated earlier, we believe it would create a serious loophole in the protection intended by the proposed legislation to amend the bill as Mr. Vanderhoef suggests.

Sincerely yours,

JOHN L. HARVEY,  
Deputy Commissioner.

AMERICAN PHARMACEUTICAL ASSOCIATION,  
Washington, D.C., February 12, 1965.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.

MY DEAR MR. HARRIS: Since the Food and Drug Administration representatives commented directly on some of the points raised in APA's testimony on H.R. 2, we would appreciate having the following comments entered in the committee's record. We hope that this letter will aid the committee in its deliberations by clarifying the profession of pharmacy's stand.

As to the question of inspection of records and premises, we can only state that the profession of pharmacy does not object to inspection. We have, however, continually opposed granting such authority to FDA. It is true that pharmacies are subjected to inspection by a number of local, State, and Federal agencies. In the narcotic and alcohol areas, Federal tax officials do not have power to inspect the tax records of pharmacists and pharmacies. Excise taxes are another notable area. These and other inspection powers relate to revenue collection and pharmacists and pharmacies are subjected to the same taxation burdens as are all other individuals and business establishments.

The Federal Government regulates the quality, purity, and branding of drugs through its power over interstate commerce—not taxation. We have no objection to FDA inspecting, sampling, or otherwise assuring itself that drugs in interstate commerce comply with the provisions of the law. Once that drug comes to rest for use in the practice of a profession, the regulatory effort is transferred to the professional practice acts of the States governing their use and distribution. If the State food and drug laws and pharmacy practice acts are to continue to have any purpose or meaning, then this distinction is the only possible justification for their existence.

The profession of pharmacy, like all other professions, is regulated under the police powers of the several States. If the Federal Government is going to obtain the power to police the profession of pharmacy under the guise of regulating interstate commerce, then it is but a short step to establishing guidelines for

pharmacists and pharmacies and requiring Federal registration as is now done with manufacturers. This would be a direct and total usurpation of the role of the States in regulating the professions.

So long as we maintain that in our form of government there is a distinction between the Federal Government and those of the several States and the powers and functions that each possesses, the profession of pharmacy will oppose regulation by FDA. Pharmacists have nothing to hide but protest such an extension of the Federal Government's powers in the interest of preserving a traditional principle of Federal-State relationships. Our objection is not only that such inspection "would in some way invade the professional realm occupied by the pharmacist" as FDA phrased their statement, but that it would also invade the realm of responsibility reserved to the States under the Constitution of this Republic.

FDA further pointed out that "we do not know how we could determine what was dispensed in the course of professional practice and what was not" if the amendments APA suggested were included. This is just not so. FDA has made such determinations and does so today. The conviction of every practitioner licensed by law to administer drugs for illegal sales of amphetamines and barbiturates is based on this very determination. The pharmacist convictions cited by FDA are also for dispensing prescription drugs beyond the scope of the pharmacists' professional practices. Whatever degree of compliance with the Durham-Humphrey amendment FDA has attained has been based on this principle.

FDA commented that "tightening up the recordkeeping and inspection provisions at the manufacturing and wholesale levels, without the same improvement at the druggist level would not solve the problem." This does not accurately reflect the current situation. FDA claims to have good control over the distribution of prescription-legend drugs in this country, and this is essentially correct. But, we would remind the committee that this control does not presently include the power to inspect pharmacies or prescription records. This latter phase is left to State professional practice acts and licensing boards. Since the record with the 30,000 or more dangerous and potent prescription drugs available in pharmacies throughout the land shows that effective control over pharmacists can be achieved without a new grant of power, we submit that FDA has failed in proving that inspection of pharmacies is essential to their enforcement efforts. The record does show that FDA is quite effective in apprehending and convicting the few pharmacists who attempt to divert stimulant and depressant drugs.

Finally, we recognize that the proposed section 511(a)(4) was not intended to include pharmacists. This amendment is necessary whether pharmacists are required to keep records or not. Proposed section 511(a)(3) does provide for pharmacies, hospitals, and clinics, but these are establishments. There is an obvious difference between the pharmacy as an establishment and the pharmacist as a practitioner. It is apparent that FDA did not recognize this distinction and the omission of pharmacists as practitioners authorized to possess stimulant and depressant drugs.

We believe that the data we submitted on the 45 pharmacist convictions during 1964 establishes that pharmacists are not significant diverters of stimulant and depressant drugs. We must let the record set forth during the hearings by all parties guide the committee on this point, and we will not dwell on it further.

We appreciate the courtesy of this opportunity to comment further on this legislative proposal.

Very truly yours,

WILLIAM S. APPLE, Phar. D.,  
*Executive Director.*

STATEMENT OF RANDEL SHAKE, DIRECTOR, NATIONAL CHILD WELFARE COMMISSION,  
THE AMERICAN LEGION

Mr. Chairman and members of the committee, I am Randel Shake, national child welfare director for the American Legion and located at its national headquarters in Indianapolis. My statement is submitted in behalf of the American Legion's National Child Welfare Commission, of which Morris Nooner, Jr., Plymouth, Ill., is national chairman.

My statement is submitted in support of H.R. 2 designed to provide better controls for depressant and stimulant drugs.

The American Legion for many years has concerned itself with the misuse of drugs, especially so by young people. As early as 1950 the American Legion national organization began receiving reports from many of the volunteer workers in its vast child welfare program of an alarming increase in the use of narcotics by juveniles. These reports reached us primarily through our regional conferences held in five different areas of this country.

Following a study of these reports our national convention took official recognition of the serious problem of the use of narcotic drugs by juveniles. Early in 1951 the American Legion sponsored a narcotics crisis conference in New York City aimed at focusing attention on this problem. Nearly 400 individuals, representative of all professions having an interest in the illicit traffic in drugs, attended this meeting.

The same year the national convention of the American Legion, upon recommendation by its child welfare commission, adopted a 15-point program aimed at providing more effective control of the illicit traffic in drugs. Subsequently many of these 15 points were enacted into Federal legislation by the Congress. It is with a feeling of pride that we reviewed statistics of law-enforcement agencies and the U.S. Public Health Service accumulated after the enactment of this legislation pointing to a downward trend of the narcotics problem, particularly among juveniles.

Some 12 years after we first became vitally interested in the complex problem of the illegal use of narcotic drugs by juveniles we again began receiving reports from our child welfare workers of the use of dangerous drugs by high school and college age youth. We found this situation to be true in all parts of the country. Study showed that these drugs were in common use, but taken without medical supervision could be habit forming and harmful even to cause permanent damage.

The barbiturates and amphetamines have proven to be most valuable to the science of medicine, but like so many other drugs they are a paradox. Unsupervised and indiscriminate use of these drugs can produce serious social problems as well as medical problems.

Promiscuous use of barbiturates results in drowsiness, confusion, inability to think and to coordinate. Many youth involved in auto accidents upon examination have been found to be under the influence of barbiturates.

Amphetamines, on the other hand, tend to stimulate and elevate the mood of the user. Consumption of such drugs by individuals in a normal mood produces a state of excitement on the part of the user, often resulting in explosive-like behavior resulting in fighting, criminal acts, and promiscuous sexual conduct. Based on our observations, it is obvious that many young people and their parents are totally unaware of the serious consequences which can occur to them from indiscriminate use of these drugs.

Out of this background, the National Executive Committee of the American Legion in May 1963 adopted a resolution urging that parents and the general public be educated concerning the dangers involved in the use of amphetamine and barbiturate drugs without proper medical supervision. This same resolution also requested strengthening of State and Federal laws to halt illegal sales of such drugs. This action was reaffirmed at the 1963 National Convention of the American Legion. At our most recent national convention held in Dallas, Tex., September 22-24, 1964, the following resolution was adopted.

"Whereas the use of dangerous drugs such as amphetamine and amphetamine-like drugs, barbiturates and other habit-forming and central nervous system stimulants by high school and college students, and by other young people remains at a high level; and

"Whereas more than half of these drugs are obtained illicitly and at exorbitant prices; and

"Whereas these drugs are dangerous to the physical and mental systems; and

"Whereas existing laws governing the sale of these drugs are inadequate and competent medical authority has proved that these drugs can be dangerous when used without medical supervision; and

"Whereas the American Legion has requested the various States and the Congress of the United States to strengthen laws dealing with the distribution and sale of such drugs and little progress has been noted to date: Now, therefore, be it

*"Resolved by the American Legion in national convention assembled in Dallas, Tex., September 22-24, 1964, That it reaffirm that parents and the public be*

alerted concerning the dangers of unsupervised use of these drugs; and be it further

*"Resolved, That appropriate action be taken to secure passage of Federal and State laws which will effectively control the distribution and sale of such drugs."*

Mr. Chairman, we hope that your committee would report favorably and the Congress adopt suitable legislation to more effectively control the distribution and sale of these dangerous drugs. The provisions of H.R. 2 should have the same favorable effects produced by the enactment of more stringent Federal laws early in the 1950's resulting in more effective control of the sale of narcotic drugs.

The American Legion recognizes the various States also have a significant role to play in controlling the distribution and sale of amphetamine and barbituric drugs. At the present time a number of our State organizations are actively engaged in supporting State legislation in those States where present controls are deemed inadequate.

Mr. Chairman, some members of the committee may wonder why the American Legion should concern itself with the matter of dangerous drugs. Since 1925 the American Legion has had a major child welfare program whose primary purpose has been to assure care and protection for children of veterans and improve conditions for all children. Today there are over 70 million children in our Nation, over half of whom are children born of veteran parentage. Obviously, if we are to assure protection for children of veterans, the American Legion must interest itself in improving conditions for all children. We believe the adoption of H.R. 2 will help provide such protection.

Mr. Chairman, may we express to you and the members of your committee our appreciation for the opportunity to present our views on this subject.

---

BROOKLYN, N.Y., February 1, 1965.

HON. OREN HARRIS,  
Chairman, House Commerce Committee,  
House Office Building, Washington, D.C.:

On behalf of 1,100 Brooklyn pharmacy owners, we appeal for your active support or amendment to H.R. 2 and include pharmacists with physicians in the present exemptive language of the bill, thereby giving pharmacists same professional consideration as physicians who also dispense drugs covered in H.R. 2.

BENJAMIN LEVINE,  
President.

MOE WEISS,  
Executive Secretary, Consolidated Brooklyn Retail Pharmacists Association.

---

AMERICAN FEDERATION OF LABOR AND  
CONGRESS OF INDUSTRIAL ORGANIZATIONS,  
Washington, D.C., January 29, 1964.

HON. OREN HARRIS,  
Chairman, Committee on Interstate and Foreign Commerce,  
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The American Federation of Labor and Congress of Industrial Organizations is pleased to register its support of the objectives of H.R. 2, the Drug Abuse Control Amendments of 1965, a bill introduced by you and now under active consideration by your committee.

With the passage of years, remedial legislation to suppress illegal sales of barbiturates, amphetamines, and other depressant and stimulant drugs has become increasingly needful as a public health measure. Testimony before your committee from the Food and Drug Administration, for example, indicates that half of the production of all barbiturates and amphetamines in the United States ends up on the bootleg market and thus in the hands of consumers who abuse them both to their own hazard and that of the public at large.

We believe that H.R. 2 is a significant step forward toward correcting the deficiencies of the present Food and Drug Act with respect to effective policing of illegal sales of these otherwise useful drugs diverted to harmful purposes. Certain additional enforcement amendments have been recommended by the Food

and Drug Administration which we believe would add to the effectiveness of the bill, and we urge that your committee give them favorable consideration.

We are glad to note that the bill covers not only barbiturates and amphetamines specifically, but also any other drugs having a "potential for abuse" because of depressant or stimulant effects on the central nervous system or hallucinatory effects. Adequate authority to police illegal sales of all drugs of this type is necessary to prevent the buildup of additional bootleg operations in drugs inadequately policed and sold as substitutes for the more stringently controlled drugs.

We would hope, however, that procedures for placing additional drugs under the special controls provided by the bill would not be made so difficult and time consuming as to defeat the purpose of the proposed legislation. We also feel some concern over the provision regarding the rights of interested parties to consult with any advisory committee set up to advise the Secretary of Health, Education, and Welfare as to specific drugs which should or should not be put under the special controls authorized by the bill. Our concern runs to the possibility of off-the-record contacts offering undue opportunity for special pleading and influence on the deliberations of committee members by those having an interest in maintaining total sales volume, some of which may derive from illegal markets. A full record should be required of contacts made and of material presented by interested parties.

We also wish to make special note of the bill's provisions for the keeping of records on the specially controlled drugs by commercial producers, sellers, and compounders and the grant of authority to Food and Drug inspectors to inspect these records. Such records are obviously necessary to effective enforcement, as is the right to inspect them. Traditionally, pharmacies have objected to inspection of prescription drug files, but we fail to see how the law can be effectively enforced unless it is possible to check sales records against records of authorized prescriptions for the drugs. We urge that the recordkeeping requirements and inspection authority provided by the bill be retained without impairment.

The bill also provides new authority to deal with the marketing of "counterfeit" drugs, since they frequently constitute a health hazard to users. We fully support remedial measures to suppress the sales of such products.

We are glad that your committee is moving so promptly to act on H.R. 2.

Sincerely yours,

ANDREW J. BIEMILLER,  
*Director, Department of Legislation.*

---

AMERICAN HOSPITAL ASSOCIATION,  
WASHINGTON SERVICE BUREAU,  
Washington, D.C., January 28, 1965.

HON. OREN HARRIS,

*Chairman, Committee on Interstate and Foreign Commerce, Longworth Office Building, Washington, D.C..*

DEAR MR. HARRIS: The American Hospital Association wishes to comment upon H.R. 2, introduced by you and upon which hearings have begun. The measure, when enacted, will be called the "Drug Abuse Control Amendments of 1965."

This association is much concerned with the flow of depressant and stimulant drugs into the hands of those who would use them in an improper manner. We doubt that hospitals have been a source of illicit traffic in amphetamines and barbiturates and the other drugs which are attempted to be reached by H.R. 2. Nevertheless, we feel that America's hospitals will want to do their part to prevent abuses in the distribution of these drugs.

On August 7, 1964, we wrote to Senator Thomas J. Dodd to comment upon S. 2628 which he had introduced. His bill was, in many ways, similar to H.R. 2. We pointed out that his proposal required elaborate recordkeeping on the part of hospitals, records duplicating information already available in hospitals. We noted that most hospitals retain their patient's medical record charts for many years and some keep them indefinitely. Each prescription or doctor's order for a depressant or stimulant drug is written in the chart and the notation of the administration of such drug by the nursing staff is also recorded. Drug procurement and the drug inventory records can be retained for 3 years without undue hardship and usually are kept by hospitals for a considerable time.

We suggested to Senator Dodd that hospitals not be required to alter their traditional recordkeeping process inasmuch as the information desired under his bill is usually available under the conventional hospital recording systems. Many hospitals maintain as tight a control over amphetamine and barbiturate drugs as they do with narcotics. These records are maintained in detail and are retained for a lengthy period. Also, some states require control of these drugs in a manner similar to that necessitated for narcotics. For these additional reasons we think it would be a great waste for hospitals to be required to change their system to add additional forms and files.

We were pleased to read on page 5 of Senate Report 1442, dated August 14, 1964, accompanying S. 2628:

"The committee is also satisfied that, as the committee contemplates the bill will be administered, the recordkeeping requirements of the bill will not require the maintenance of any special records not usually kept by hospitals observing the usual minimum standards. Insofar as drug purchases by hospitals are concerned, the hospitals now maintain records thereof, whether in the form of invoices or otherwise; it would be no hardship to keep such records for the required 3 years. The hospitals also have a record of drugs disposed of, both in the form of prescription or patient order files and in the form of each patient's medical record chart. It is standard hospital practice to retain the patient chart, if not the patient's order file, for many years, thus easily satisfying the 3-year requirement of the bill."

We are equally pleased to read the language of section 3(b) of H.R. 2, especially the last sentence of proposed section 511(d) (1), title 21, United States Code, which provides:

"No separate records, nor set form or forms for any of the foregoing records, shall be required as long as records containing the required information are available."

This wording appears to carry out the sentiment of the Senate Committee on Labor and Public Welfare report quoted above. Thus, the American Hospital Association has no objection to the recordkeeping requirements of H.R. 2. We support the bill and its objective of restricting the illicit traffic in depressant and stimulant drugs.

We respectfully request that this letter be incorporated in the record of hearings on H.R. 2.

Sincerely,

KENNETH WILLIAMSON, *Director.*

MALLINCKRODT CHEMICAL WORKS,  
*St. Louis, Mo., February 19, 1965.*

HON. OREN HARRIS,  
*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives,  
Washington, D.C.*

DEAR MR. HARRIS: This letter is written at the request of Mr. James Menger, of your staff, in order to record certain recommendations made orally to him for technical amendments to H.R. 2, the pending bill to establish special controls for depressant and stimulant drugs.

By way of introduction, it should be stated that this company is engaged in the manufacture of barbiturates which are distributed in bulk to various segments of the drug industry. This company does not manufacture or sell dosage forms of these drugs.

Sections 511(a) (1) and (2) of the bill as presently drafted do not seem to make adequate provision for the situation of the bulk manufacturer, and indeed might even prohibit his continuance in business. At the very least, certain of the language is ambiguous and in need of clarification.

The introductory portion of section 511(a) prohibits the manufacture, compounding, or processing of these drugs, except by those persons whose activities are solely as specified in subsections (1) through (7). Subsection (1) covers manufacturers, compounders, and processors regularly engaged in preparing pharmaceutical chemicals or prescription drugs, but only if they distribute through specified channels to pharmacies, hospitals, clinics, etc. The manufacturer of bulk barbiturates which are distributed to manufacturers of the final dosage forms or to other chemical manufacturers would not meet the conditions of subsection (1) and hence could not legally continue in business. It is recom-

mended therefore that the present clauses A and B be redesignated as B and C, and that a new clause A be inserted, reading as follows: "(A) to other such manufacturers, compounders, or processors, or".

One other ambiguity in this subsection (1) should also be corrected. The requirement of distribution "through branch outlets, through wholesale druggists, or by direct shipment" appears to be unduly restrictive. The legitimate indirect distribution of these drugs is not confined to distribution through "wholesale druggists." On the contrary, bulk quantities are frequently distributed to hospitals or institutions through medical or surgical supply houses, through laboratory distributors, or other jobbers who handle chemicals. These are, of course, perfectly legitimate channels of distribution and the use of such channels should not be proscribed. It is therefore recommended that the quoted language be deleted and the words "directly or indirectly" be inserted in lieu thereof. As an alternative, the words "wholesale druggists" could be replaced by a broader term, such as "wholesalers."

It would seem to follow that a corresponding change should be made in subsection (2). Instead of "wholesale druggists," the more general term "wholesalers" should be used. If this is done, it is also recommended that the requirement "regularly engaged in supplying prescription drugs" be entirely deleted since the legitimate laboratory or hospital supply house may not deal in prescription drugs, but rather in bulk drug chemicals as well as other hospital equipment and supplies.

I wish to thank you for permitting us to express our views on these matters and to express our hope that you will see your way clear to make the technical changes we have suggested in your otherwise excellent bill.

Sincerely,

VICTOR H. KNOOP,  
*Secretary, Mallinckrodt Chemical Works.*

---

JEFFERSON COUNTY JUVENILE COURT,  
*Louisville, Ky., February 9, 1965.*

HON. OREN HARRIS,  
*Chairman, House Commerce Committee,  
U.S. House of Representatives,  
Washington, D.C.*

DEAR MR. HARRIS: Concerning the recent reference to the introduction of a bill controlling barbiturates and other harmful drugs in the House of Representatives may I take this means in urging that such legislation be introduced and passed. I believe such legislation also should control amphetamine drugs and that provisions should provide penalties for the improper sale by druggists and others who might distribute these various drugs contrary to law. The problem of enforcing legislation in this area will be greatly complicated if control of the manufacturer and distributor are not included in the legislation.

It is most unlikely that any voluntary self-policing in the manufacture and distribution would be effective and materially affect the flow of these drugs for improper usage.

Trusting the above to be in order, I remain,

Respectfully yours,

CHARLES C. DIBOWSKI,  
*Chief Probation Officer.*

---

SMITHSON DRUG STORE,  
*Clayton, N. Mex., February 8, 1965.*

Re House Commerce Committee and bill H.R. 2

HON. CLINTON T. ANDERSON,  
*Senate Office Building, Washington, D.C.*

DEAR MR. ANDERSON: This bill unjustly discriminates against the profession of pharmacy and Congress over the years has always rejected FDA request for prescription file inspection authority. The medical profession, which dispenses large quantities of drugs, including stimulant and depressant drugs, is exempted completely from this bill.

This bill broadly duplicates State drug enforcement activity and it is unneces-

sary, since almost all druggists voluntarily cooperate with FDA agents and search warrants are available to deal with the others whenever probable cause exists.

Besides the small businesses have enough extra bookwork they are now doing for the Government, without adding all of this extra which would be required if this bill is passed.

Please use your influence against this bill with the members of the House Commerce Committee.

Thanking you very much, I remain,

Sincerely yours,

MALCOLM D. SMITHSON,  
*President, New Mexico State Board of Pharmacy.*

---

NATIONAL PHARMACEUTICAL COUNCIL, INC.,  
*New York, N.Y., February 5, 1965.*

Re H.R. 2.

HON. OREN HARRIS.

*Chairman, Committee on Interstate and Foreign Commerce,  
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: The National Pharmaceutical Council, Inc., takes this opportunity to express its views on section 9 of H.R. 2 relating to the counterfeiting of drugs, and requests that this letter be incorporated in the record of hearings on this bill.

The National Pharmaceutical Council, Inc., is an association composed of 25 companies engaged principally in the manufacture and distribution of prescription drugs. Among its purposes are to benefit the public interest by promoting the highest professional standards in the manufacture, distribution, and dispensing of prescription medication and other pharmaceutical products and to promote the interests of the public, physicians, pharmacists, and others in the pharmaceutical industry by encouraging the highest standards of ethics and integrity in the manufacture, distribution, and dispensing of such medication and pharmaceutical products.

Since its incorporation in 1953 the council has deemed the manufacture, distribution, and sale of counterfeit drug products to be dishonest, vicious, unlawful, and dangerous to the public health. Its aim is and has been to join with ethical pharmacy organizations, regulatory agencies, and others to combat it.

The council, therefore, endorses section 9 of H.R. 2 and sincerely urges its enactment.

In the interest of clarifying and strengthening this bill, however, the council suggests an amendment, not substantive in nature, to the definition of counterfeit drugs appearing at lines 11-16 on page 20. It is believed that the text of line 14, in particular, is not clear, and it is therefore suggested that lines 11-16 on page 20 be changed to read as follows (the italicized words indicating new material and the words in parentheses indicating material to be deleted):

"(2) The term 'counterfeit drug' means a drug which, or the container or labeling of which, bears the trademark, trade name, or other identifying mark, imprint, *design*, or device of a person (other than the person or persons authorized), *without proper authorization (to) for its use, (it) on such drug, container, or labeling, or which bears any likeness thereof.*"

It is the council's conviction that the amendment to the bill hereinabove suggested will clarify it and enhance its effectiveness, and earnestly requests that this suggestion be given the careful consideration of the committee before the bill is reported out.

Respectfully submitted.

NEWELL STEWART.

FLORIDA STATE PHARMACEUTICAL ASSOCIATION,  
Fort Myers, Fla., February 4, 1965.

HON. PAUL ROGERS,  
Member of Congress,  
House Office Building,  
Washington, D.C.

DEAR PAUL: There has been introduced into the Congress H.R. 2, on depressant and stimulating drugs.

While we as pharmacists realize the importance of control of these drugs, we also feel that the bill goes too far in allowing FDA agents the right to inspect our business and professional records including our prescription files.

We feel that pharmacists should be exempted in this bill the same as physicians. The main traffic in these drugs is through peddlers and truck stops. These should be stopped, but pharmacists keep records, and these records can be opened if necessary by court action and should not be opened indiscriminately. There is a relationship between the physician, the patient, and the pharmacist that should be protected, and this relationship should be inviolate.

I note that you are a member of the committee that will hold hearings on this bill, and I hope that you will take our side and see to it that pharmacists are exempted the same as physicians.

Assuring you of our appreciation and with best wishes,

Sincerely,

R. Q. RICHARDS, *Secretary-Manager.*

---

STATEMENT OF DR. WILLIAM BALDWIN, JR., ON BEHALF OF THE AMERICAN  
OSTEOPATHIC ASSOCIATION

I am William Baldwin, Jr., D.O., medical director, Memorial Osteopathic Hospital, York, Pa. I am a former member of the Panel for Evaluation of Therapeutic and Medical Agents, American Osteopathic Association; former professor and chairman, Department of Physiology and Pharmacology, Philadelphia College of Osteopathy; certified by the American Osteopathic Board of Internal Medicine, and fellow of the American College of Osteopathic Internists.

It was my privilege to be among those invited to attend the first White House Conference on Narcotic and Drug Abuse, September 27-28, 1962, where I served as representative of the American Osteopathic Association. The published proceedings of the Conference contain valuable background material supportive of the pending bill, H.R. 2, the Drug Abuse Control Amendments of 1965.

I am pleased to record the American Osteopathic Association in favor of the bill.

The bill imposes additional controls on certain depressant and stimulant drugs, including increased penalties for disposal of these drugs to juveniles, and strengthens the enforcement processes available to the Food and Drug Administration in combating the serious problems of counterfeit drugs.

Manufacturers and others engaged in receiving or disposing of depressant or stimulant drugs, defined in the bill (other than licensed practitioners handling the drugs in the course of their professional practice) would be required to keep a complete record of the quantities of such drugs they handle, and make these records available to food and drug inspectors who, in addition, would be given authority to inspect establishments and vehicles, inventory stocks, etc. Disposal of these drugs would be forbidden except through legitimate channels, and their possession would be prohibited if not for the personal use of the possessor or a member of his household or for administration to an animal owned by him or by a member of his household.

Under the bill, depressant or stimulant drugs include barbituric acids and amphetamines and any drug which the Secretary of Health, Education, and Welfare determines to have a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinatory effect.

The Secretary would have the benefit of an advisory committee which, on the initiative of the National Academy of Sciences must be chosen from a panel submitted by that body. While the National Academy of Sciences is highly respected, we question the public policy of so circumscribing the appointive power of the Secretary.

In addition to the necessity for the pending legislation, we hope a public education campaign can be stepped up and sustained. Our schools should recognize the problem of drug abuse and provide instruction of equal quantity and quality with that provided for other health hazards.

---

STATEMENT OF FEDERATION OF HOMEMAKERS

Chairman Harris and members of the committee, I am Ruth Desmond, president of the Federation of Homemakers, a nationwide organization of public-spirited housewives. The federation appreciates this opportunity to submit a statement for the record with respect to H.R. 2 and related bills to curb and control illicit traffic in amphetamine and barbiturate type drugs and to control illegal sales of drugs of a similar effect in the future if deemed necessary in the public interest.

Through the years the public has become increasingly aware that misuse or overuse of the barbiturates could lead to accidental death—apparently through confused and unintentional overuse. The many intentional deaths through deliberate abuse of barbiturates is also well known. Only recently has the public become aware of the tragedies which can result from abuse of the amphetamines. At first only a rise in blood pressure seemed to be the serious side effect to guard against. Even while these hearings were being conducted three youths in Chicago, high on amphetamines stolen from the car of a peddler known to them, murdered an elderly man solely to obtain his pocket change, a mere \$11. Traffic accidents caused by drivers relying on amphetamines to keep awake over many hours has caused considerable concern to the public.

In Arlington, Va., where I reside, juvenile delinquency, amongst young people from comfortable homes and never previously in trouble, rose to alarming proportions. A citizens committee was formed to get to the root of the cause or causes of this sudden increase in delinquency. The chairman of this committee informed me that both amphetamines and barbiturates contributed to the shocking misconduct of many of these young people. Happily this delinquency problem in Arlington seems to be decreasing as a result of the efforts of the committee and others. Reliable sources have also informed me that the ring-leaders of the student riots at Ocean City, Md., used drugs and liquor for thrills. One can only wonder if these drugs helped spark riots at other beaches?

It is difficult for homemakers without legal training to discuss specifically the legislation under study except in a general manner. It is apparent that recordkeeping will curb the legitimately manufactured drugs from being sold on the black market if manufacturers, distributors, pharmacists, and physicians all comply with the regulations being considered. The CBS programs last summer emphasized the ease with which an individual could purchase huge quantities of legally manufactured pills and powders merely by pretending to be a firm engaged in legitimate distribution of said drugs. The profits are so huge that this type of loophole must definitely be plugged. But what about checking the sales from another country to distributors here? It is disturbing to learn of the large amount of drugs sold by U.S. manufacturers to firms in Mexico which apparently sell to other U.S. distributors—so that many of these same drugs return to the United States and black-market operations the same day. Will Mexican firms cooperate with the Federal regulations and furnish the names of U.S. distributors who buy back these amphetamines and barbiturates?

The fact that these drugs can easily be counterfeited by chemists using plentiful and cheap raw materials should be a cause of grave concern. It has been testified to that a chemist could produce these pills in a garage or shed or other small building. Should chemical companies check to whom their raw supplies go in large quantities?

To argue this would be complicated perhaps is not justified when one reflects on the lives that are ruined through easy, illicit access to these damaging drugs—misused for thrills, on dares—for kicks. The temptation to produce these inexpensive drugs through counterfeiting could be most enticing when legal channels are closed—especially for such enormous profits.

It was commendable and encouraging to have one of the largest manufacturers of these stimulant drugs appear before this committee as its public duty to testify in support of the registration features of H.R. 2. Earlier in the hearings

a large manufacturer of barbiturates and related substances testified it was not possible to give the amount of its products manufactured that year. Although this firm ships drugs out of the country (Mexico was named) the details of these transactions seemed very vague. Let us hope H.R. 2 will clarify such vagueness.

It was revealing to learn how light the sentences can be for peddlers of these addicting drugs in certain States. Frequent violations by the same peddler does not always seem to result in substantial increase in fines or in a jail sentence. This must result in a discouraging situation for the arresting officers. Certainly those who sell these drugs to children and teenagers should have to face severe penalties. These peddlers in drugs cannot be treated as pickpockets and shoplifters—but should be considered capable of destroying the future leaders of this country. A menace.

Several years ago our local newspapers quoted from a report of Dr. Ratner prepared for the Ford Foundation which indicated the U.S. citizens were becoming pilltakers. They take pills for headaches, stomach aches, colds, coughs, toothaches—they take pills to pep them up and later other pills to put them to sleep. When problems become difficult—they cry for tranquilizers. Our question: If pills and drugs are mass produced, isn't it then necessary for them to be mass consumed?

Expert testimony presented before this committee by a New York psychiatrist indicates that certain individuals seem to be more sensitive to these particular drugs than others; more prone to addiction. Should not FDA have the labels on these drugs remind doctors to closely observe the tendencies of individual patients to be more sensitive to said drugs and guard against prescribing same again? And is there research on the effects of these drugs on unborn infants whose mothers took amphetamines during pregnancy to control weight problems? Would these infants later in life be more sensitive to the drugs—more prone to become addicts? By now we must have teenagers whose mothers took these drugs during pregnancy. Could addiction to amphetamines or barbiturates by young mothers result in child abuse? Child murder? Should not statistics be compiled on this? Prescribing amphetamines for the overweight is general. What percentage can be deemed to become addicted as a result? It was disturbing to learn of college students who obtained their parents' prescriptions for these drugs and had them filled to sell these pills to fellow students at exam times and for great profits. Cannot this type of loophole be plugged? Some students might use their parents' prescriptions for personal thrills and kicks with resulting irrational behavior. Should physicians encourage their patients with mild ills to adopt good habits of living—moderate outdoor exercise and sensible diets of wholesome food instead of relying on the crutches of pep pills, sedatives, and tranquilizers to mask the sluggishness of self-indulgence?

Mr. Chairman, it seems to members of this federation the primary concern in enacting legislation to curb and control the serious problem which has arisen from misuse and abuse of relatively cheap and easy to obtain addictive drugs must be to protect the public rather than to spare the manufacturers, distributors, wholesalers, and dispensers the necessary chores of keeping accurate records which will aid in strict enforcement.

(Whereupon, at 12:25 p.m., the committee adjourned subject to call of the Chair.)





