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[DOCID: f:95190.wais]

S. Hrg. 108-684

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

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HEARINGS

before the

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

of the

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

JUNE 17 AND JULY 22, 2004

Printed for the use of the Committee on Governmental Affairs

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER

THE INTERNET

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U.S. GOVERNMENT PRINTING OFFICE
95-190 WASHINGTON : 2004

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BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

THURSDAY, JUNE 17, 2004

U.S. Senate,
Permanent Subcommittee on Investigations,
of the Committee on Governmental Affairs,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:02 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Norm Coleman,

Chairman of the Subcommittee, presiding.

Present: Senators Coleman, Levin, Lautenberg, Collins, Pryor, and Carper.

Staff Present: Raymond V. Shepherd, III, Staff Director; Katherine English, Counsel; Mark Greenblatt, Counsel; Jay Jennings, Investigator; Mary D. Robertson, Chief Clerk; Katherine Russell, Detailee, FBI; Claire Diegel, Intern; Elise J. Bean, Staff Director/Chief Counsel to Minority; Jason Hill (Senator Levin); Priscilla Hanley (Senator Collins); Marianne Upton (Senator Durbin); Tate Heuer and Gita Uppal (Senator Pryor); and Demian Moore (Senator Dayton).

OPENING STATEMENT OF SENATOR COLEMAN

Senator Coleman. This hearing of the Permanent Subcommittee on Investigations is called to order.

Americans are increasingly turning to the Internet for access to affordable drugs. In 2003, consumer spending on drugs purchased over the Internet exceeded $3.2 billion. Unfortunately, rogue Internet sites have proliferated and rake in millions of dollars by selling unproven, counterfeit, defective or otherwise inappropriate medications to unsuspecting consumers. Even more dangerously, these sites are profiting by selling addictive and potentially deadly controlled substances to consumers without a prescription or any physician oversight.

In today's technological environment, it is essential that we understand the forces at work here. Internet pharmacies have the potential for bringing important and, in many cases, lifesaving drugs to our homes in a way that we have never before imagined. But, unless we understand the safety issues surrounding the use of the Internet and the delivery of prescription drugs, what should be about improving our lives may very well end up costing lives. I believe we have an obligation to develop coherent public policy that addresses these safety concerns.

As Chairman of the Permanent Subcommittee on Investigations, I endeavored to provide an objective snapshot of what drugs are available to consumers on the Internet--the good, the bad, and the ugly.

Our first inspection was at the JFK International Airport, in New York, home to the largest International Mail Branch (IMB) in the United States. Senior Customs officials at JFK

estimate that 40,000 parcels containing drugs are imported through that airport on a daily basis. During last summer's FDA/Customs blitz, 28 percent of the drugs tested were controlled substances. This means that as many as 11,200 drug parcels containing controlled substances, like the painkillers Vicodin and OxyContin, are imported daily through JFK; 78,400 weekly; 313,600 monthly, and 3,763,200 annually.

Top countries of origin include Brazil, India, Pakistan, the Netherlands, Spain, Portugal, Canada, Mexico, and Romania.

On March 15 and 17, 2004, PSI discovered at least 2,000 boxes from a single vendor in the Netherlands that contained hydrocodone and generic Valium or Diazepam.\1\ In addition, Customs regularly seizes shipments of OxyCodone, a codeine-laced product, GHB (the date rape drug), and morphine.

\1\ See Exhibits 1, 2, and 3 which appear in the Appendix on pages 286, 287, and 288.

With PSI present, FDA uncovered a number of boxes of fake Lipitor--the real Lipitor is the last bottle on the right in this slide.\2\

\2\ See Exhibit 4 which appears in the Appendix on page 289.

FDA and Customs regularly seize and inspect packages containing: Counterfeit Viagra from India,\3\ injectable steroids from China,\4\ and boxes of unidentified drug product.\5\

\3\ See Exhibit 5 which appears in the Appendix on page 290.
\4\ See Exhibit 6 which appears in the Appendix on page 291.
\5\ See Exhibit 7 which appears in the Appendix on page 292.

FDA and Customs often discover packages of drugs without any of the required inserts that lack labeling and have directions for usage in foreign languages. An example of this is Lupron, an injectable hormone used to treat prostate cancer.\6\ I will note that I was with former Mayor Giuliani when we looked at the Lupron, and he looked at it and said, ``I know that drug''--he has suffered from prostate cancer and was well aware of it. He turned to me and said, ``You know, this is something that needs close physician supervision,'' and there it is, without any instructions, something that is clearly very

dangerous when individuals use it without physician supervision. Unfortunately, all the labeling and directions for usage of this product are in Spanish.

\6\ See Exhibit 8 which appears in the Appendix on page 293.

Unfortunately, we found similar problems at Chicago O'Hare International Airport, which is home to the Nation's fifth-largest International Mail Branch. Approximately 16,600 parcels are imported through the Chicago IMB each day. Of those parcels, 4,300 are estimated to contain drug products imported for personal use by consumers. Customs estimates that 75 percent of the parcels that contain drug products are imported from Canada. Other top countries of origin include Great Britain, the Netherlands, and Mexico.

While inspecting the Chicago IMB, PSI discovered packages of: Injectable steroids,\1\ counterfeit Viagra from Mexico,\2\ growth hormone from Mexico,\3\ codeine-laced products injectable insulin from Canada, which was not properly refrigerated,\4\ and a large box of unidentified and unlabeled white pills from Mexico.\5\

\1\ See Exhibit 15 which appears in the Appendix on page 300.
\2\ See Exhibit 16 which appears in the Appendix on page 301.
\3\ See Exhibit 17 which appears in the Appendix on page 302.
\4\ See Exhibit 18 which appears in the Appendix on page 303.
\5\ See Exhibit 19 which appears in the Appendix on page 304.

The same dangerous conditions are present at the Miami IMB. Senior Customs inspectors at Miami IMB estimate that as many as 30,000 parcels that contain drug products are imported through Miami each day. This means that as many as 6 million parcels containing drugs are imported annually through this one IMB. Of the 30,000 daily imports, a couple thousand are dangerous controlled substances, including Valium, Ritalin, Bromazepam, Zolpidem, and steroids. Other types of drugs that FDA and Customs inspectors routinely see include fake Viagra from Belize, antibiotics including Ciprofloxin, and unknown drug products identified as vitamins or dietary supplements. Top countries of origin include Great Britain, Honduras, Mexico, Canada, Costa Rica, and the Bahamas.

During the same period, at my request, the General Accounting Office made purchases of pharmaceuticals from both

domestic and foreign Internet Websites. Their results confirmed what we discovered at JFK, Chicago and Miami--when consumers log onto the Internet to purchase their pharmaceuticals, it is truly ``buyer beware."

GAO demonstrated just how easy it is to purchase these drugs over the Internet. GAO used the Internet to purchase numerous prescription drugs-- including highly-addictive narcotics and other controlled substances. Notably, GAO purchased 66 percent of these pharmaceuticals, including narcotics, without a prescription and without visiting a doctor.

GAO also used the Internet to purchase from foreign pharmacies counterfeit versions of American drugs, pharmaceuticals that have not been approved by the FDA, counterfeit drugs that lacked the active ingredient, damaged products, and drugs without proper packaging, no warning information, or instructions for use.

The GAO investigation does reveal some encouraging news for those of us who use bona fide established domestic Internet pharmacies and those of us who support the safe importation of Canadian drugs to ease the cost of prescription medications. The preponderance of problems uncovered by GAO investigators with virtual pharmacies was associated with drugs that came from foreign countries other than Canada. All of the drug samples that GAO received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels that generally provided patient instructions for use. None displayed evidence of mishandling, and most included warning information.

However, most disturbingly, GAO's Office of Special Investigation found that: Anyone, including children, can easily purchase the highly addictive painkiller hydrocodone from the Internet without providing a prescription or being examined by a physician; the Internet pharmacies from which GAO purchased hydrocodone charge significantly higher prices than walk-in pharmacies, regardless of whether a patient has health insurance; and some Internet pharmacies focus exclusively on selling hydrocodone. GAO has concluded that these sites are in the business of profiting from illegal drug use rather than providing a safe, inexpensive alternative source for consumers lacking health insurance.

In order to put a human face on this dangerous and potentially lethal situation, we will hear testimony from two individuals who lost family members because of overdoses of

drugs procured through rogue Internet sites.

Francine Haight will tell us about her son, Ryan, who died from a mix of hydrocodone, morphine, and Valium. Ryan obtained these highly potent narcotics from Internet pharmacies. For some of these drugs, Ryan did not have a prescription; for others, Ryan had a prescription from a doctor that he had never met.

Elizabeth Carr's husband, James Lewis, a tri-athlete, died of an overdose of Darvon on April 10, 2003. He purchased the Darvon, as well as other drugs from Internet pharmacies doing business in South Africa, Thailand, and Spain. Some of the websites that James used required him to fill out a short questionnaire before he could order the medication, while others required nothing.

I cannot tell these witnesses how appreciative I am of their brave decision to come here and tell your story to Congress. I promise that I will do whatever is in my power to prevent the same tragedy from befalling other families.

I also look forward to hearing testimony concerning his assessment of the U.S. pharmaceutical system from my friend, former New York Mayor, Rudy Giuliani. Lastly, I am eager to hear the results of the study performed by Dr. Marv Shepherd of the College of Pharmacy at the University of Texas at Austin that details the Canadian drug market.

Now that PSI has identified some serious problems in the Internet pharmacy industry, we must start fashioning solutions. That is why I introduced S. 2464, the Ryan Haight Act, and S. 2465, the Todd Rode Act. Taken together, these bills: Empower Customs to immediately seize and destroy any package containing a controlled substance that is illegally imported into the United States; provide new disclosure standards for Internet pharmacies; bar Internet sites from selling or dispensing prescription drugs to consumers who are provided a prescription solely on the basis of an on-line questionnaire; and allow State Attorneys General to go to Federal court to shut down rogue Internet pharmacies.

Surely, we do not want to play what some correctly call ``Rx roulette'' with the health of American consumers by blindly ignoring real safety concerns of the drugs we allow to be imported from the vast unregulated Internet pharmacy. Ignoring those concerns can have tragic consequences, like the tragic stories of Ryan Haight and James Lewis.

With that, I will turn to the Ranking Minority Member,

Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator Levin. Thank you very much, Mr. Chairman, and thank you for your focus on this very critical issue and for your commitment to trying to see if we cannot get at the real fundamental problem here that you have just identified.

As prescription drug prices in the United States continue to skyrocket, American consumers have become increasingly desperate to find the cheapest drugs available. In recent years, consumers are turning to the Internet to comparison shop and buy the lowest cost drugs online. The problem is that many Internet pharmacies are dispensing medicine illegally and, in some cases, selling counterfeit or unsafe drugs.

Because U.S. enforcement efforts are currently inadequate to stop the illegal operators, the high cost of U.S. prescription drugs is driving increasing numbers of Americans to play Russian roulette with Internet pharmacies, gambling their safety on the lure of more affordable prices.

Over the past 4 years, U.S. prescription drugs have increased an average of nearly 20 percent annually. Today, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than Germans, and twice as much as Italians. For poor and middle class individuals suffering chronic illnesses, high drug costs are forcing some to choose between taking their medicine on any given day, paying their bills, and even buying food.

The GAO report before us today leads me to two conclusions. First, Internet purchases of illegal pharmaceuticals are out of control, and we need to increase enforcement. Second, medicines purchased from Canada are as safe or safer than those purchased in the United States.

Now, I say that because 100 percent of the medicines purchased by the GAO on the Internet from Canadian pharmacies required patient prescriptions compared to only 5 out of 29, or 17 percent of U.S. pharmacies.

In addition, none of the Canadian medicines was counterfeit. That was also true of the U.S. medicines.

Internet pharmacies are a relatively new response to the problem of high-cost medicines. Some Internet pharmacies are completely legal operations, set up to offer clients

convenience and cost savings. They required patient prescriptions and deliver medications from U.S.-approved facilities.

Other Internet pharmacies operate illegally, selling medications without prescriptions and using unapproved manufacturers either in the United States or offshore. Some shadowy operations send unsolicited offers to millions of Internet users, hawking medications like junk food bargains. These illegal operators have begun to capture attention as a health and safety threat requiring criminal and civil enforcement action. And again, I commend our Chairman, Senator Coleman, for focusing on this problem and holding this inquiry today.

Pharmacies and pharmaceutical sales involve a complex web of State and Federal regulation to protect the public from unsafe or improperly prescribed drugs. In the United States, the practice of pharmacy is regulated by State boards which license both pharmacists and pharmacies. To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented with a valid prescription from a licensed health care professional before delivering the drug to the purchaser. On the Federal level, the Food and Drug Administration (FDA) is charged with ensuring the safety, effectiveness, and quality of domestic and imported drugs; the Bureau of Customs and Border Protection (Customs) is supposed to screen and stop unauthorized controlled substances at the border; and the Drug Enforcement Agency (DEA) is responsible for combating illegal narcotics and the abuse of controlled substances.

To get a better sense of the enforcement problems associated with Internet pharmacies, at the request of this Subcommittee, the General Accounting Office (GAO) spent several months earlier this year buying prescription drugs online, tracking the Internet pharmacies and drugs delivered in response to their on-line orders, and then testing the delivered drugs to ascertain if they were actually the medications ordered. GAO efforts focused on buying popular medications such as Celebrex, an anti-inflammatory pain reliever; Lipitor, a cholesterol lowering drug; Viagra, a medication for sexual dysfunction; and Zoloft, an antidepressant.

GAO found that buying medications from Internet pharmacies was not difficult. GAO placed 90 on-line orders for

prescription drugs and received 68 samples, a success rate of 75 percent. Of those 68 medications, 45 were shipped illegally because there had been no patient-provided prescription. Many were also shipped without FDA-required precautions such as patient instructions and temperature-controlled packaging. Of the 68 samples, 48 were from the U.S. or Canadian-based Internet pharmacies, 18 were from foreign or Canadian sites, and two could not be determined. Of the 18 foreign samples, three were found to be counterfeit, including two that contained incorrect but not necessarily dangerous chemical compositions, and one that had no active ingredients at all. Again, GAO determined that none of the U.S. or Canadian samples was counterfeit, evidence indicating that medications delivered from other foreign countries were less safe than those originating in the U.S. or Canada.

The Subcommittee also examined operations at three U.S. ports of entry, in New York, Chicago, and Miami, to evaluate how Federal agencies screen parcels containing pharmaceutical products and originating from foreign countries. The investigation determined that tens of thousands of dangerous and addictive controlled substances are streaming into the United States on a daily basis from overseas and that, at ports of entry such as the John F. Kennedy International Airport, Miami International Airport, Customs agents are being overwhelmed as they attempt to prevent potentially hazardous materials from entering our borders.

At JFK Airport, Customs officials estimated that over 40,000 parcels containing pharmaceutical products pass through its facility every day. Miami Intentional Airport saw 30,000 packages a day. Neither facility had sufficient personnel to screen those parcels. For example, JFK had an average of 50 Customs agents and just six FDA inspectors working at its facilities during the course of a day, which meant that every person was responsible for screening more than 700 pharmaceutical parcels every day--and remember, these agents and inspectors have lots of other responsibilities, too. They are charged, for example, with screening packages for firearms, nuclear material, counterfeit currency, and other contraband items.

Millions of packages containing pharmaceutical products were imported into the United States last year and in 2003, and an estimated $1.1 billion worth of prescription drugs were imported into the United States solely from Canada. Internet

pharmacies have contributed to this increase and to the ongoing strain on our enforcement resources. While some of these Internet pharmacies are based in the United States, many others are based in foreign countries which makes them harder to investigate, inspect, and shut down. Recent research indicates, for example, that the top countries of origin for imported medications include Brazil, Canada, India, Mexico, the Netherlands, Pakistan, Portugal, Romania, and Spain. While Federal agencies such as FDA, Customs, DEA, and the Department of Justice have successfully taken enforcement actions against both domestic and foreign Internet pharmacies and associated physicians in the past, these agencies face a host of enforcement issues with scarce resources. In an age of global terrorism where these same agencies are charged with protecting the public from dirty bombs, heroin sales, and chemical and biological weapons, it is tough to believe that stopping Internet pharmacies will become a top priority.

There is also, again, the larger issue of drug reimportation. The importation of prescription drugs happens every day in this country, whether it is through private individuals purchasing drugs through the Internet, or a busload of seniors traveling to Canada to buy cheaper drugs from their drug stores there.

It is the exorbitant price of prescription drugs in the United States that is driving Americans to buy low cost medicines from foreign countries. Folks are doing what they have to do in order to find and buy more affordable medicine.

It is an ironic but comforting fact that the GAO study found no counterfeit drugs among the medications imported from Canada, since so many Americans are now shopping there, including thousands of my constituents from Michigan. And I am one of the Senators who favors legalizing the importation of drugs from countries such as Canada as a way to bring down prices here at home and stop the current practice of forcing American taxpayers alone to bear the burden of subsidizing research and development costs for drug companies.

While I support stronger enforcement action--and I very strongly support enforcement action--to shut down illegal Internet pharmacies and to confiscate unsafe medications at the border, those actions will not cure the larger problem of overpriced drugs here in the United States. It is my hope that Congress will have an opportunity this year to vote on a real proposal, such as the Dorgan-McCain Pharmaceutical Market

Access and Drug Safety Act, S. 2428, that will legalize the importation of drugs and begin to address the real issue of high drug prices for Americans.

Again I commend you, Chairman Coleman, for taking on this important and complicated safety issue.

Senator Coleman. Thank you, Senator Levin.

It is my great pleasure to have with us the distinguished Chairman of the Committee on Governmental Affairs, Senator Collins.

OPENING STATEMENT OF CHAIRMAN COLLINS

Chairman Collins. Thank you, Mr. Chairman.

Let me start by commending you for holding these very important hearings to highlight the safety concerns that can be associated with the purchase of prescription drugs over the Internet.

I also want to echo Senator Levin's comments that one of the greatest challenges facing American consumers is the high cost of prescription drugs. Soaring drug costs have placed a tremendous strain on family budgets. They have also imposed a heavy burden on employers, both public and private, who are struggling to provide affordable health insurance coverage to their employees.

It is therefore no wonder that American consumers throughout our country are looking across the border and into their computer screens in search of more affordable prescription drugs.

It is well-documented that the average price of prescription drugs is much lower in Canada and in Western European countries than in the United States. The price differential we are particularly aware of in my home State of Maine, because consumers often do go across the border to Canadian drug stores to get the prescription drugs that they need.

For example, a drug commonly used to treat Type II diabetes costs $124.65 in the United States and just $26.47 in Canada. It simply does not seem fair that American consumers are footing the bill for the remarkable yet costly advancements in pharmaceutical research and development, while our neighbors just across the border receive exactly the same medications at substantially lower prices. And that is why I have long supported legislation to allow American consumers to benefit

from international price competition on prescription drugs by permitting FDA-approved medicines to be reimported into this country.

But I am also concerned that we make certain that reimportation is done safely and responsibly. As Senator Levin mentioned, this is not likely to be a problem when we are dealing with a country like Canada, but as the evidence that Senator Coleman has outlined in his opening statement, it can be a very serious problem in dealing with imports from other countries.

Today's hearing focuses on a closely-related issue, and that is the safety challenges posed by the sale of prescription drugs over the Internet. The Internet offers many advantages for on-line shoppers--convenience, competitive prices, privacy, and easy access to health and medical information. Moreover, through the Internet, individuals with disabilities, the elderly, and patients living in remote areas can more easily obtain the information, medicines, and services that they previously could acquire only with great difficulty.

It is not surprising, therefore, that the number of on-line pharmacies has increased dramatically from the 190 identified by the General Accounting Office in October 2000 to an estimated 1,400 sites in April of this year.

While on-line drug sales by reputable pharmacies can have many advantages for patients, they nevertheless present unique challenges for regulators, law enforcement, and policymakers. Years ago, when I was in State Government, I was responsible for the Board of Pharmacy, so I am well aware of how State regulators inspect pharmacies, something that is very difficult to do if you are dealing with an on-line entity.

Much more problematic, however, are rogue on-line pharmacies that sell unsafe or counterfeit drugs that can be a prescription for disaster for unwary consumers. I have been particularly alarmed by recent surveys which have found that more than 90 percent of on-line sites do not require a prescription or even validate that there is a legitimate patient-physician relationship behind the prescription.

The avenues for drug abuse that are provided by such pharmacies are painfully obvious and have caused much heartache to the family members who will be testifying before us today.

I believe we need legislation to protect consumers from these rogue Internet pharmacies, and that is one of the reasons why I have joined with the Chairman in cosponsoring Senator

Gregg's Safe Import Act, which establishes Federal licensing requirements for all Internet pharmacies. It also requires the verification of a legitimate patient-prescriber relationship and establishes verification procedures for all prescriptions. No longer could a teenager go online without having a valid prescription and be able to get powerful addictive drugs sent through the mail via the Internet pharmacy.

Mr. Chairman, while I believe that we must do all that we can to make prescription drugs more affordable--and that includes passing a reimportation bill this year--we must also ensure patient safety. These hearings are a very important part of that process and will help ensure that we reach that goal.

Thank you for your leadership.

Senator Coleman. Thank you, Senator Collins. Senator Lautenberg.

OPENING STATEMENT OF SENATOR LAUTENBERG

Senator Lautenberg. Thanks, Mr. Chairman, and my compliments for the work you have done thus far. It is really critical to focus on what the problems are that would have people who in many cases desperately need these materials, these drugs, these products, and often are forced to make choices between food and medicine. That is a terrible place for anyone to be, and we ought to do what we can. We certainly do a lot to help people afford food in this country, with food stamps and things of that nature; yet the pharmaceutical needs are often unable to be met, and people resort to anything they can do to get their hands on these products. And it is understandable, whether you feel pain or you have other effects of illness that can be relieved, we certainly have a responsibility to deal with it, and I think you are doing it in a forthright fashion, and again, I commend you for it.

I noticed a coincidence here, my three colleagues sitting on this Subcommittee with me all have borders that touch Canada. Accessibility to the marketplace is quite interesting, and people are pushing very hard.

I come from the ``medicine chest State'' in the country. New Jersey is the place where so much is manufactured. These are responsible companies that invest huge sums in research, and many of these research attempts turn out to be fruitless after years and millions of dollars. But that in no way excuses the fact that you have different pricing structures in one

place, radical differences that are avoided in another place. And we have got to do what we can to get these prices down.

Again, I am pleased that we are examining what the problems are with importation, or reimportation as it is called, because when we heard Senator Levin's commentary about the safety of products coming from Canada, it starts to question the rationality of saying, well, the safety issue, because we have lots of problems within our own society with mixes of drugs that produce terrible effects, including death in many cases. So we have to be aware of that and scrutinize it very thoroughly.

Unfortunately, the FDA does not have the funds available to it to provide the kind of monitoring that we need, and when we look at what is out there in front of us, and we see that on-line pharmacies offer advantages--lower prices, easier accessibility, improved privacy--and many of these on-line pharmacies are legitimate businesses that do offer safe and convenient services and products similar to those provided by traditional pharmacies, and other on-line pharmacies engage in practices that are illegal, such as selling unapproved or counterfeit drugs, or dispensing drugs without a prescription. But the question is how can we protect consumers and regulate rogue pharmacies that peddle counterfeit medications, sell drugs without a doctor's prescription. There is a constant search. I use a local pharmacist, and he tells me about the number of times that suspicious prescriptions have come across his counter.

So this is not a problem that is exclusively of on-line companies or reimportation. Since 2000, the number of counterfeit cases that the Food and Drug Administration has investigated has quadrupled, and it is obvious to me that the trend is going to continue. Americans looking for cheaper drugs online, especially from pharmacies abroad, are taking some gambles with their health, but again, if it is a choice that is so desperately motivated, then people do take risks in those conditions.

Last November, the New York Times reported that Internet pharmacies have recently sprung up that claim to be based in Canada and do business from another country, using a Canadian domain name. We need to investigate these on-line pharmacies, but we also need to consider, as has been said, the underlying issue--what is driving consumers to risk their health by purchasing drugs from sources that they are not familiar with.

The answer is obvious--the lower price that they can get these products for is very appealing. And we have got to protect consumers from fake drugs and unscrupulous on-line pharmacies. But we also must recognize that consumers, particularly the elderly on fixed incomes or modest-income families, are flocking to the Internet because it is the only way they can afford to buy these essential products. Prescription drugs in this country cost much more than people can generally afford to pay.

Today we are looking at ways to regulate on-line pharmacies, protect consumers more effectively, but we cannot ignore the real problem, which is that prescription drugs in many cases are way too expensive, and ultimately, we have got to find ways to lower prescription drug costs for all Americans.

Here, I will say that I have invited, and I extend the invitation again to those in the pharmaceutical industry to come forward and offer their ideas about how we can modify these prescription drug prices and equalize them, whether they are purchased in Canada or purchased here. Yes, we want to avoid price-fixing as is done in Canada, but the fact of the matter is that when the difference can be as much as 50 percent, you are talking about sums of money that are really very tough for people to pry.

So, Mr. Chairman, once again, my compliments for doing this, and I look forward to hearing from our witnesses.

Senator Coleman. Thank you very much, Senator Lautenberg.

I would note that Senator Levin, before he left, and I were also reflecting on the fact that he, Chairman Collins and myself all represent States that border Canada, so this is a very personal issue for the folks that we represent.

I would also note that Senator Levin is managing the Defense Authorization Bill right now on the floor of the Senate and could not stay, but he is deeply committed to this issue of ensuring access to safe, affordable prescription drugs for his constituents and for all Americans, and I applaud him for that.

I would now like to welcome our first panel to today's hearing. I welcome Marcia Crosse, Director of the Health Care Team at GAO, and Robert J. Cramer, Managing Director of GAO's Office of Special Investigations.

As I mentioned in my opening statement, this morning, GAO is here to release the report of its investigation of Internet pharmacy website drug sales. The purpose of this hearing is to

examine the extent to which consumers can purchase pharmaceutical and controlled substances over the Internet without a medical prescription or medical diagnosis and whether the pharmaceuticals that are pouring into the United States from foreign countries are counterfeit, unsafe, or legitimate.

I appreciate your attendance at today's important hearing, and I am anxious to hear the results of your investigations.

Before we begin, pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn in. At this time, I will ask you to rise and please raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. Crosse. I do.

Mr. Cramer. I do.

Senator Coleman. We will be using a timing system today, so when you see the amber light come on, you know it is time to wind up. If you have full written statements, they will be entered into the record at your request.

I understand, Ms. Crosse, that we will have you go first, followed by Mr. Cramer. After we have heard all the testimony, we will turn to questions.

Ms. Crosse, you may proceed.

TESTIMONY OF MARCIA CROSSE,\1\ DIRECTOR, HEALTH CARE--PUBLIC HEALTH AND MILITARY HEALTH CARE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Ms. Crosse. Thank you, Mr. Chairman. I am pleased to be here today as you discuss the safety of prescription drugs sold by Internet pharmacies. Various types of pharmacies offer prescription drugs over the Internet, including those that require a patient to provide a prescription, and other pharmacies that issue a prescription based on an on-line medical questionnaire or have no prescription requirement. My testimony will summarize the findings of a report that we are releasing today that examines issues surrounding the availability and safety of prescription drugs sold over the Internet as well as the business practices of certain Internet pharmacies.

\1\ The prepared statement of Ms. Crosse with an attachment appears

in the Appendix on page 109.

My colleague Mr. Cramer will provide additional details on our purchases of narcotics.

At your request, Mr. Chairman, we examined the extent to which certain prescription drugs can be purchased over the Internet without a prescription; whether drugs sold by Internet pharmacies are handled properly, are FDA-approved and are authentic; and the extent to which Internet pharmacies are reliable in their business practices.

With respect to the availability of drugs, we were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples, each from a different pharmacy in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, the Philippines, Spain, Thailand, and Turkey.

The samples included drugs with special safety restrictions that require close physician supervision. We also purchased addictive narcotic painkillers.

Some U.S. and all Canadian pharmacies where we purchased drugs required the patient to provide a prescription, but the majority of U.S. and all other foreign Internet pharmacies where we made purchases either issued prescriptions based on their own medical questionnaires or did not require a prescription.

With respect to the safety of the drugs, we identified several problems with the handling, FDA approval status, and authenticity of the drug samples we received from foreign Internet pharmacies outside the U.S. and Canada, but fewer problems among the samples received from U.S. and Canadian Internet pharmacies. None of the samples from these other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information.

As you can see in this first figure,\2\ some samples arrived with no labeling of any kind. As you can see, there is no information as to even what drug is supposed to be contained in the bottle much less how many pills to take or how frequently.

\2\ See Figure 1 of prepared statement of Ms. Crosse which appears

in the Appendix on page 121.

In our second figure,\1\ you can see that we also received products with no warnings in English. All of the information that came in this package was printed in Spanish.

\1\ See Figure 2 of prepared statement of Ms. Crosse which appears in the Appendix on page 122.

A majority of these samples displayed other problems associated with the handling of the drugs, such as three samples of a temperature-sensitive drug that were sent in envelopes without insulation. The product shown here requires refrigeration but was shipped from abroad in a regular envelope without any temperature control.

We also received five samples containing tablets enclosed in punctured blisterpacks, potentially exposing the tablets to damaging light or moisture. You can see in this figure \2\ that this product arrived damaged, and this is a moisture-sensitive product.

\2\ See Figure 2 of prepared statement of Ms. Crosse which appears in the Appendix on page 123.

Some of the samples we received from these other foreign pharmacies arrived in unconventional packaging, in some instances with the apparent intention of concealing the actual contents of the package.\3\

\3\ See Figure 1 of prepared statement of Ms. Crosse which appears in the Appendix on page 124.

These are two unique shipping containers we received--one with the product packaged inside a CD case--as you can see, it was wrapped just in brown tape. Another product that we received was placed inside a sealed pop-top can and packaged in a box with a misleading label. This, as you can see, says ``Gold Dye and Stain Remover Wax.''

Manufacturers who tested the drugs for us reported that almost all of the drug samples from these other foreign pharmacies were unapproved for the U.S. market because, for example, the labeling or the facilities in which they were manufactured had not been approved by FDA. However, they

reported that the chemical composition of all but four of the other foreign samples was comparable to the product that we had ordered.

Among the exceptions, two samples were found to be counterfeit versions of the product we had ordered--Viagra--containing a lesser amount of the active ingredient, and two samples had a significantly different chemical composition than that of the product that we had ordered--OxyContin and Accutane.

In contrast, all of the drug samples that we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels; almost all including warning information; and none displayed evidence of mishandling.

Like the samples from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market. However, manufacturers determined that the chemical composition of all of these samples was comparable to the product that we had ordered.

With respect to business practices, some Internet pharmacies, mostly other foreign pharmacies, were not reliable in their business practices. We did not receive six of the orders that we placed and paid for, five of which were placed with other foreign Internet pharmacies and one of which was placed with a pharmacy whose location we could not determine.

Also, we found that several of the drug samples were sent from locations that raised questions, such as from private residences.

We also observed Internet pharmacies that obscured details about the drugs sold, such as other foreign pharmacies from which we ordered brand name drugs but then received a generic or foreign version of the drug.

Finally, about 21 percent of the Internet pharmacies that sent us samples were found to be under investigation by DEA or FDA. Reasons for the investigations included allegations of selling adulterated, misbranded, or counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these pharmacies were from the United States, one from Canada, and four from other foreign countries.

In summary, Mr. Chairman, consumers can readily obtain many prescription drugs over the Internet without providing a prescription, particularly from certain U.S. pharmacies and from foreign Internet pharmacies outside of Canada. Drugs

available include those with special safety restrictions, for which a patient should be monitored for side effects, and narcotics, where the potential for abuse is high.

For these types of drugs in particular, a prescription and physician supervision can help ensure patient safety.

In addition to the lack of prescription requirements, some Internet pharmacies can pose other safety risks for consumers. Many foreign Internet pharmacies outside of Canada dispense drugs without instructions for patient use, rarely provide warning information, and in four instances provided drugs that were not the authentic product that we ordered.

Consumers who purchase drugs from foreign Internet pharmacies that are outside of the U.S. regulatory framework may also receive drugs that are unapproved by FDA and manufactured in facilities that the agency has not inspected.

Other risks that consumers may face were highlighted by the other foreign Internet pharmacies that fraudulently billed us, provided drugs we did not order, and provided false or questionable return addresses. It is notable that we identified these numerous problems despite the relatively small number of drugs we purchased, consistent with problems recently identified by regulatory agencies.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of the Subcommittee may have.

Senator Coleman. Thank you very much, Ms. Crosse. Mr. Cramer.

TESTIMONY OF ROBERT J. CRAMER,\1\ MANAGING DIRECTOR, OFFICE OF SPECIAL INVESTIGATIONS, U.S. GENERAL ACCOUNTING OFFICE

Mr. Cramer. Thank you, Mr. Chairman and Members of the Subcommittee.

\1\ The prepared statement of Mr. Cramer appears in the Appendix on page 130.

I am pleased to be here today to report on some of the results of our investigation of the sources of hydrocodone that we purchased without a prescription from eight U.S. on-line pharmacies. hydrocodone is an addictive narcotic pain medication, and illicite use of this drug has increased significantly in recent years.

We found that one can purchase hydrocodone from Websites on the Internet without providing a prescription or being examined by a physician, and the Internet pharmacies from which we made our purchases charge prices that are 3 to 16 times the prices charged by local retail pharmacies at which we inquired.

We concluded that those who participate in these Internet drug operations appear to be in the business of knowingly servicing and richly profiting from individuals who may purchase narcotics for illicit purposes.

We ordered and obtained hydrocodone from eight domestic Websites. Six purchases, each from different Websites, were dispensed by a single pharmacy. The two remaining purchases were ordered from two separate Websites and were dispensed by two other pharmacies.

We obtained the hydrocodone by completing on-line questionnaires in which a GAO staff member, whom I will refer to here as ``the customer,'' claimed that he had pain.

In an attempt to determine the relationship between the Internet site and the pharmacy that dispensed the drug, we contacted one of the pharmacies that sent us hydrocodone. This purchase was made from a Website that claimed that customers had to undergo a complete physical examination in order to receive the narcotic. However, the customer obtained the hydrocodone without undergoing a physical examination or seeing or even speaking to a physician.

Instead, a physician's representative telephoned the customer and offered two options for satisfying the physical examination requirement. For $199, the customer could visit a physician at one of two clinics in the area where the customer lived, or for $49, the representative said that she would send paperwork that the customer could take to his own physician to fill out and return to them; and if the customer chose and paid for one of those options right then and there with a credit card, the physician would immediately issue a 30-day prescription.

The customer chose the $49 option and gave the representative his credit card information and subsequently paid an additional $190 for the hydrocodone.

After we received it, a GAO investigator posing as a relative of the customer contacted the pharmacy listed on the return address of the package in which it was delivered. The pharmacist confirmed that he had sent the drug and explained that he has a business relationship with a Website and with a

physician who had sent him a prescription for it.

The investigator then telephoned the physician, who confirmed that he had prescribed the hydrocodone. The physician claimed that he never writes prescriptions for new medications for patients and that he always confirms that the patient has been on the medication in the past. But when the investigator asked the doctor whether he had actually spoken with his relative, the doctor responded that one of his associates had in fact spoken to the relative. He said that he has a staff of several people who make such telephone calls. He repeatedly asserted that the staff calls and speaks with the customer's physician who previously prescribed the medication, but he confirmed that the telephone number his staff had called with respect to our purchase was the telephone number of the customer himself, not that of a physician.

The physician indicated to our investigator that his Internet drug business is run from a clinic that he operates, but when asked the name of the clinic, it indicated that it is part of a health care network and gave a name that does not correspond to the name of any existing health care network we could find or to any medical practice with which this physician is in fact connected.

He said to our investigator, ``Ninety percent of our business is for hydrocodone.'' He also said that he currently provides prescriptions for five different Internet drug sites and that he previously wrote prescriptions for two others that have been shut down.

During our visit to the site where the physician purports to operate a clinic, we saw no evidence of a health clinic. The site is a one-room storefront set up with several computers and telephones. The only individuals that we saw going to or leaving the location appeared to be employees, and there was no sign on the premises indicating that the business there was health-related. When one of the employees was asked what kind of business is operated at the location, she responded that they do ``computer consultations.''

When asked about the possibility of children buying narcotics through him, the physician claimed that the need for a credit card is the ``safeguard to prevent that from happening,'' and ``a kid should not have a credit card.'' However, he admitted that, in his own words, parents call him ``all the time, saying that their children have gotten hold of their credit cards.''

The physician repeatedly stressed that his on-line pharmacy offers a service for patients who do not have insurance. However, this assertion is patently false. To the contrary--the customer paid a total of $190 and an additional $49 consultation fee for 60 hydrocodone pills that can be purchased for an average price of about $26 at local retail pharmacies at which we inquired. Thus, we paid nearly 10 times the ordinary retail price of this drug because we did not have a prescription.

The street price, or illegal sales price, of hydrocodone that we bought online is about $5 to $6 per pill. Thus, we paid slightly less than the street price for this drug from this source.

Indeed, as I mentioned earlier, the prices that we paid for hydrocodone at all eight of the Websites from which we ordered it were 3 to 16 times the ordinary retail price charged for it at local pharmacies.

In sum, these Websites appear to purposely cater to hydrocodone customers who are willing to pay a substantial markup for the narcotic because they do not have prescriptions. Claims that these Websites provide a safe, inexpensive, alternative source of drugs for customers are bogus. Instead, they appear to be in the business of profiting from illicit drug use.

That completes my prepared statement. I will be happy to answer any questions that you may have.

Senator Coleman. Thank you very much, Mr. Cramer.

To both Ms. Crosse and Mr. Cramer, I am very appreciative of the work that the GAO has done. In a very short period of time--and as Ms. Crosse noted, this is a small sample here; we have not fleshed all the concerns or all the challenges facing the importation of drugs from Canada or other countries--but in a short period of time, you have done outstanding work, and this Subcommittee and this Congress is very appreciative. So I want to start by saying thank you.

Let me talk a little bit about the universe which we are dealing with, and there is some good news and some bad news in this. I am the optimist. The good news is that among those Canadian and American pharmacies that were sampled, the business practices were pretty solid?

Ms. Crosse. Yes, Mr. Chairman. The problems that we had with the fraudulent billing were with other foreign pharmacies or in one case from a pharmacy where we could never determine

the actual location of the pharmacy. We did not have that difficulty with pharmacies in the United States or in Canada.

Of course, some of the narcotics purchases are from U.S. pharmacies. All of our hydrocodone purchases are actually from pharmacies that are located in the United States.

Senator Coleman. But the concern is that you can get those narcotics by simply filling out a prescription online, at a minimum.

Ms. Crosse. That is correct. Three of the sites also telephoned back to the customer with some follow-up questions, but at five of those sites, all that was required was to fill out the questionnaire online.

Senator Coleman. Let me take you back a step. You described in your testimony a counterfeit sample, and I believe this purports to be OxyContin, which is a very addictive narcotic.

Ms. Crosse. That is correct.

Senator Coleman. One, do we know what country it was sent from?

Ms. Crosse. We have been requested because of an ongoing investigation not to reveal that publicly. I would be happy to inform your staff.

Senator Coleman. Let me step back. From the consumer's perspective, if I am going online, attempting to do a Google search for ``OxyContin,'' and I get a list of Websites, is there anything that--let us say hypothetically that this came from Pakistan or Turkey--is there anything that requires that Website to be identified as coming from Pakistan or Turkey?

Ms. Crosse. No. For Internet pharmacies located outside the United States, they are totally outside any regulatory framework that we have in place. They can identify themselves or not identify themselves. In some instances, Websites identify themselves. We sought to try to trace to where their servers were located, to trace to where the payments were made; we also used the return address information on the packages when they arrived to help us identify where the pharmacies were actually located--but it is not a requirement, and it was not always there.

Senator Coleman. And weren't there some instances in the investigation where, even looking at return address or other information, there was an effort to disguise where the pharmacy was actually located where the drugs came from?

Ms. Crosse. Yes. There were discrepancies between information on the Websites and the shipping addresses for the

packages that arrived.

Senator Coleman. So for all we know, this Website could be AllAmerica.com or it could be RoyalCanadianMountedPolice.com, and it could come from Bangladesh or Turkey or Pakistan, and the consumer would not know.

Ms. Crosse. Our information is that it is from abroad.

Senator Coleman. But the consumer, sitting there, as he types in----

Ms. Crosse. The consumer cannot necessarily tell.

Senator Coleman. Thank you.

One of the suggestions that Chairman Collins and I have supported would be having the FDA, even for extraterritorial pharmacies, give some kind of seal of approval which would mean they would investigate and check it out. Do you think that would be helpful to the consumer?

Ms. Crosse. I think it would certainly be an extra layer of protection for consumers that currently does not exist.

Senator Coleman. What is contained in here is called Crixivan.\1\

\1\ See Exhibit 30, which appears in the Appendix on page 315.

Ms. Crosse. Crixivan, yes, Senator. It is a drug for HIV and AIDS patients. Interestingly enough, it was packaged--that can had a sealed pop-top on it. When it arrived, we opened it and found inside an actual manufacturer's bottle of Crixivan. The manufacturer reports to us that it is the actual, authentic product, and that product, even though it came from abroad, was manufactured in an FDA inspected facility and is approved for distribution in the United States.

Senator Coleman. And in fact, it notes that it comes from New Jersey, where it is manufactured.

Ms. Crosse. It took a long route to get here.

Senator Coleman. But what is fascinating is that the ``Gold Dye and Stain Remover Wax free promotion sample'' does say it is a product of Bassick Pharma and Chemicals in Istanbul, Turkey.

Ms. Crosse. Yes, sir.

Senator Coleman. Do we know if that is where this came from?

Ms. Crosse. We believe that this came from Turkey. The Website and the shipping information led us to believe that the pharmacy we ordered from was in Istanbul.

Senator Coleman. Again, I want to get back to the consumer's perspective and what they are looking at, because we are working backward. We get the product, and we trace as best we can where it came from, but from the consumer's perspective, can you help us understand how a consumer would somehow make contact with this particular drug seller?

Ms. Crosse. They could find it by searching on the Internet for a particular brand name drug. We checked for pharmacies that sold Crixivan. We were specifically looking for pharmacies--for each of the drugs we purchased, we looked for pharmacies that sold them in the United States, in Canada, and in other foreign countries to the extent we could identify that from Website information. This Website, I believe, did identify that it was located in Turkey, so it was one that met our requirements for an ``other foreign purchase.'' But a consumer could not always tell.

Senator Coleman. I believe you showed in one of your charts Roaccutan, which is a foreign version of Accutane.\2\

\2\ See Exhibit 28, which appears in the Appendix on page 313.

Ms. Crosse. That is correct. It is a foreign version of Accutane, which is an acne treatment.

Senator Coleman. And this is one where the instructions came in Spanish?

Ms. Crosse. Yes, that is right. All of the information included with this package was in Spanish. This was a product that came from Mexico. It had no pharmacy dispensing label information on it, and anyone who could not read Spanish would not be able to read the warning. It is also a product that the FDA warns against purchasing over the Internet because it has severe side effects and requires close monitoring by a physician.

Senator Coleman. And particularly for women who are pregnant, this is a very dangerous drug.

Ms. Cross. That is right. It is something that causes birth defects. It is a very dangerous drug for women of childbearing age.

Senator Coleman. Mr. Cramer, the physician--I was stunned as I listened to you recount the conversation with the physician, who indicated that parents had in fact called him to raise concerns.

Mr. Cramer. Yes. His words were: ``Parents call me all the

time, saying that their children have gotten hold of their credit cards."

Senator Coleman. I am amazed your investigator restrained himself from asking about conscience.

Mr. Cramer. He did. We wanted to encourage him to keep talking rather than turn him off, and as a result, he did give us a lot of very good information which we have been able to present to you today.

Senator Coleman. And it is clear that there is nothing in place that would stop a child age 16, 17, perhaps 13 or 14, who had dad or mom's credit card from purchasing hydrocodone?

Mr. Cramer. It seems that the key thing here is having a credit card. Five of the sources of hydrocodone never made any phone calls to the customer, so that all you had to do was get on the Internet, fill out the questionnaire and have a credit card number, and that was it for those five, and the three made phone calls, but as I explained with respect to our transaction, in which it appears that there actually was a physician involved, the phone call is a window dressing rather than any kind of true consultation.

Senator Coleman. I think you were being generous in your testimony when you stated that the folks involved in these particular pharmacies that were subject to your investigation--you used the words ``appear to be'' in the business of profiting from individuals seeking to illegally obtain drugs.

Would you go further than that, not that they ``appear to be,'' but that your investigation demonstrated very clearly that the individuals here were generating great profit from providing drugs to folks whom they had no idea whether they in fact had a prescription or who they were--they simply had a credit card.

Mr. Cramer. Certainly based on the prices alone, it is clear that there is big profit in this business.

Senator Coleman. I will turn it over now to Senator Lautenberg.

Thank you, Mr. Cramer.

Senator Lautenberg. Thank you very much, Mr. Chairman, and I apologize for not having been in the room when these very credible witnesses were testifying.

We are looking at situations here that almost extend beyond the fact that there is some risk in obtaining these products outside normal channels, and the price differences are driving much of this discussion, but if there is an addicted person in

the house, and that person is obtaining his drugs over the Internet or across the borders, the fact of the matter is that this person, if he is truly an addict, is going to find other means, and it has little to do with whether they are rogue pharmacies on the Internet or, again, cross-border transactions.

So we are not doing a review of addiction and the problems that follow in that kind of situation, but it is part of the overall problem. And when we look at the results of these investigations and we see that in many cases, these products are delivered in the kind of packaging that we see as original packaging right here in our own country, that in many ways, the safety is practically assured, but the price differential is still going to be enormously attractive to people--here is a product where they can see the container, the packaging, often the instructions are in there as they are if we buy the product in an unopened container--so the problem that results is how can we possibly monitor all of these things.

Should the FDA be more involved? They are terribly short of funds. Which agency do you think should be taking the lead apart from your investigatory responsibility? Should the FDA be more involved? Should we be looking to increase their funding in the interest of the consuming public here? What do we do about this enormous problem?

Ms. Crosse. Well, Senator, in the United States, the FDA is the Federal agency with the lead responsibility for ensuring the safety of the prescription drugs that are sold to consumers, and their jurisdiction currently does not extend to these foreign Internet sites and the drugs sold there.

Some of the products that come in through these Internet sites are in facilities that are inspected by FDA either because the manufacturer has shipped U.S.-made products to Canada for sale there, or in some instances, because the manufacturer has a facility offshore where the manufacturer imports to the United States, so they have a facility offshore that the FDA already inspects.

So there is some cross-border activity that is covered by the FDA. They could speak to you in greater detail about the extent of that coverage. However, they are certainly currently the most qualified to take on this issue if you want to extend Federal oversight to pharmaceuticals coming in from other countries.

Senator Lautenberg. The question that arises is if there is

a discount of approximately 37 percent on average by buying drugs in other countries, can we convince people that the risks of ordering from outside the U.S. boundary or an Internet pharmacy outweigh the financial benefit to these consumers?

Ms. Crosse. I think it depends on the product that you are buying and where you are buying it from. I think it is very difficult right now for a consumer to make that determination, however.

Senator Lautenberg. But that is not necessarily going to curtail their search for a cheaper product.

Ms. Crosse. No, sir.

Senator Lautenberg. Thanks, Mr. Chairman.

Senator Coleman. Thanks, Senator Lautenberg. Chairman Collins.

Chairman Collins. Thank you, Mr. Chairman.

Ms. Crosse, how did the GAO select the Internet sites from which you purchased these drugs?

Ms. Crosse. It is not a random sample. There is no list of Internet sites that exists from which one can make a random selection. We had certain criteria in mind that we were looking for. As I mentioned, we were searching to find Internet sites in the United States, in Canada, and abroad, in other foreign countries, for each of the drugs that we were seeking to purchase.

We also searched to find sites that required prescriptions, those that had on-line questionnaires, and those that had no prescription drug requirement.

So we had certain criteria that we were trying to fill. We began with a list of over 1,400 Internet sites that the FDA passed along to us. This was not their list of sites under investigation; it was a list that they had developed, and some of the information had been provided to them from others who have conducted such investigations.

In addition, we conducted our own Internet searches using a variety of search engines such as Google and Yahoo! and Excite to try to identify different Internet sites that would meet the criteria that we set forth.

Chairman Collins. Thank you.

Mr. Cramer, it seems to me that we have two serious problems. First, we have consumers who are looking to save money by shopping for their drugs over the Internet who may be at risk of receiving unsafe, contaminated, or even counterfeit drugs; and then we have a second serious problem of consumers

with problems with addiction or teenagers who are looking to experiment who are not particularly concerned about price but rather are looking for a way to get drugs, narcotics, for which they are not entitled.

I want to take you through your testimony to illustrate the second problem.

In any of the cases, did you have to submit a prescription in order to get access to the hydrocodone?

Mr. Cramer. No. We provided no prescription with respect to any of the eight purchases we made.

Chairman Collins. And did a physician interview you to make sure that it was an appropriate medication for your investigator?

Mr. Cramer. In five instances, there was absolutely no telephone contact with anyone. We filled out the questionnaire, gave the credit card information, and got the drug. In three instances, we received a return phone call. We know in the one instance that we looked into very carefully that it was not a physician who spoke to our customer. In another instance, the individual identified herself as a customer sales representative of a physician. And in the third instance, it is unclear whether that person was a doctor or not. That was left very ambiguous during the course of the conversation.

Chairman Collins. In none of the eight cases was there a physical examination by a qualified health care provider?

Mr. Cramer. That is right. There was never a physical examination.

Chairman Collins. And as I understand it, in the six purchases from six different Websites, you were able to trace the prescription back to a single pharmacy?

Mr. Cramer. That is right.

Chairman Collins. So a single pharmacy in a southeastern State was supplying the drugs that were ordered on six different Websites; is that accurate?

Mr. Cramer. That is correct.

Chairman Collins. How did you determine that? Was it obvious when you received the drug, or did you have to do some investigative work to determine that?

Mr. Cramer. In three instances, it was obvious from the return address identified on the package. In three other instances, although it came from the same pharmacy, there was an intermediate delivery channel so that particular pharmacy was not in fact identified, and we had to do some further

investigation to track down through the intermediary who in fact the source was.

Chairman Collins. And I assume that southeastern State in which this pharmacy is located has a typical law that would require a prescription to be presented at the pharmacy before the drugs could be dispensed. Is that a correct assumption?

Mr. Cramer. I believe that is the case here, yes.

Chairman Collins. Was there any referral by the GAO, or has there been a referral yet by the GAO, to the State licensing board?

Mr. Cramer. We have been in touch with both law enforcement authorities as well as State authorities with respect to our findings to date, to advise them of what we found and to refer to them so they could take further action.

Chairman Collins. Thank you.

Mr. Chairman, I think this is an excellent example of how one rogue pharmacy can use the Internet to reach so many people and to actually be involved in six different Websites--and there may be many more, since obviously, you did not look at all 1,400. So I think you are really doing a valuable service in examining this problem. Thank you.

Senator Coleman. Thank you, Senator Collins. Senator Pryor.

Senator Pryor. Thank you, Mr. Chairman.

I concur with Chairman Collins' analysis. You are doing a great job here in getting us focused on this issue.

When I was the Attorney General of my State before I came to the Senate, we had responsibility for the consumer protection in Arkansas. We would always recommend to people in Arkansas that when they purchased drugs, they do it through their local pharmacist, because they are dealing with a licensed professional, they are dealing with someone in their community, and if there is a problem, they know who to go to, they have recourse. And certainly we felt better because local pharmacists always require a prescription, etc., so we just felt like all the consumer safeguards and the integrity in the system was there.

But given the high prices of prescription drugs in this country, certainly there is a lot of incentive for people to get online and go elsewhere, and in that industry, on-line pharmacies are now a reality.

I would like to ask you a few questions, and either of you can answer. First, if you know, what percentage of on-line pharmacies that you have experience with or have dealt with are

legitimate, following all the rules, going through all the procedures that we would hope and expect--how many of these are really operating in a way that we would feel satisfied that the integrity of the system is being protected?

Ms. Crosse. I think we really cannot answer that. There is no known universe of Internet pharmacies. They change constantly. We observed in our searches that some of the Websites that were on the 1,400 that FDA provided to us had already closed when we went to look there to make a purchase.

There is a very small number of pharmacies participating in a program where they seek certification from the National Board of Pharmacies, but I believe that is a handful of pharmacies, fewer than 20, I understand.

However, I do not think that alone is the signal of whether or not they are dealing honestly and meeting requirements. I am sure there are other pharmacies out there who just have not sought certification who could meet those requirements.

Senator Pryor. All right. Let me ask that, because this is something that Chairman Coleman mentioned a few moments ago. It seems to me that maybe there should be some kind of seal of approval or some process that these companies go through, and when they meet certain criteria, they get a seal of approval or whatever you want to call it that they can display on their Website so the consumer knows that they have met all of these thresholds.

What you are saying is that only a very small percentage of the on-line pharmacies are participating in such a program?

Ms. Crosse. That is right. This is a voluntary program from their national association. As you may be aware, pharmacies are regulated at the State level, so each State has its own controlling statutes and regulations. There is currently no Federal regulation of pharmacies, and there is no Federal body that would be empowered to provide such certification of a pharmacy. This is something that is regulated by the States.

Senator Pryor. Personally, I think that the industry or some independent nonprofit group could provide a seal of approval to give the consumers the comfort level and assurances that they need to go online.

Let me ask about some of your findings. As I understand it--and I do not want to put words in your mouth--but as I understand it, you found repeatedly that prescriptions were not required, a visit to a physician was not required. Were some of these drugs out-of-date as well?

Ms. Crosse. Of the samples that we received from the manufacturer testing, none of those that we had could be determined to be out-of-date by the manufacturer. That certainly is true for some of the products that the FDA has investigated, but in our small number of samples, we did not find any that were out-of-date.

Senator Pryor. OK. But there were other problems?

Ms. Crosse. There were a number of other problems.

Senator Pryor. I am about to run out of time, but I do want to ask you about the testing and the cost of the testing, because I think that is an important factor for us to consider.

First, on the testing, let me ask a two-part question, because I am almost out of time. Who did the testing, who paid for it, and also, could you give us a sense of the cost that is required in testing these products?

Ms. Crosse. For each of the products that we purchased, we sought initially to buy brand name drugs. We made a decision midcourse to accept generic products for the hydrocodone because of the difficulty of finding enough sites where we could place orders of the brand name narcotics. The generics were much more readily available. However, for the other drugs--Lipitor, Celebrex, Crixivan--all of those drugs, each was tested by its manufacturer. We entered into an agreement with each manufacturer to conduct the testing for us, because they have the specs on their products, they could make the determination of what the chemical composition was, what it was supposed to be. They have the lot number information to know if it was a valid lot number, to know if it was outdated, to know if it was fully potent. So they conducted the testing for us.

I cannot speak to the price. They did it at their own expense for us and in service to us and to the Subcommittee and this investigation.

Senator Pryor. Did we have anyone present there when they were doing it?

Ms. Crosse. No, sir, we did not have anyone present in the laboratories. However, as part of this process, one of the reasons we were seeking to make purchases from what we call control pharmacies, these on-line pharmacies that are associated with big-name retail pharmacies such as Walgreen's or CVS, was to have a control sample. These were blinded to the manufacturers. They did not know which sample came from which country, which type of on-line pharmacy, which on-line pharmacy the product came from. So they had no knowledge; they only had

a code number for each product when they did the testing.

Senator Pryor. Thank you.

Senator Coleman. Thank you, Senator Pryor.

I have three very brief follow-up questions. One, Senator Collins in her line of questioning spoke about a single pharmacy that supplied multiple Websites. Do we know where this pharmacy got its drugs?

Mr. Cramer. No. We do not have that information. This particular pharmacy has now been shut down, and we are unable at this point to probe any further with respect to that particular one.

Senator Coleman. Is there anything that prevents the principals involved in that pharmacy from getting back in the business?

[Pause.]

Senator Coleman. Ms. Crosse.

Ms. Crosse. Not to my knowledge, unless they were prosecuted and perhaps jailed.

Mr. Cramer. It is my understanding that there are pending proceedings with respect to that pharmacy and the principals.

Senator Coleman. That was my other question. I presume the results of your investigation have been turned over to the appropriate authorities for further criminal or any other type of enforcement actions?

Mr. Cramer. Yes, and we will see what happens. But it is now being handled by law enforcement authorities who have taken action.

Senator Coleman. Thank you very much. Do any of my colleagues have questions?

[No response.]

Senator Coleman. If not, I will thank the witnesses again for outstanding work in a short period of time. We are very appreciative. Thank you very much.

Mr. Cramer. Thank you.

Senator Coleman. I would now like to welcome our second panel to today's important hearing.

I welcome the distinguished former Mayor of New York City, the Honorable Rudy Giuliani, currently Chairman and CEO of Giuliani Partners. Mr. Giuliani brings with him his expertise in border security and public safety issues.

We appreciate you lending your expertise in security and international terrorism to assist us in developing recommendations to control the illegal flow of these

unregulated rugs.

And finally, I would like to welcome Dr. Marvin D. Shepherd, Director of the Center for Pharmacoeconomic Studies at the University of Texas at Austin. Dr. Shepherd will discuss his study concerning the Canadian drug supply.

As previously mentioned, the purpose of this hearing is to examine the extent to which consumers can purchase pharmaceuticals and controlled substances over the Internet without a medical prescription or medical diagnosis; what role FDA, the Bureau of Customs and Border Protection, the U.S. Postal Service, and DEA play in preventing the illegal importation of scheduled pharmaceuticals or pharmaceuticals that are violative of the Food, Drug, and Cosmetics Act, and whether the pharmaceuticals that are pouring into the United States from foreign sources are counterfeit, unsafe, or legitimate.

I appreciate your attendance at today's hearing and am anxious to hear your observations on the current state of affairs.

Before we begin, pursuant to Rule 6, all witnesses before this Subcommittee are required to be sworn in. I would ask you to please raise your right hand and repeat after me: I swear that the testimony I am about to give is the truth, the whole truth and nothing but the truth, so help me, God.

Mr. Giuliani. I swear that the testimony that I am about to give will be the truth, the whole truth and nothing but the truth, so help me, God.

Mr. Shepherd. I do.

Senator Coleman. Thank you.

You understand the timing--when the yellow light goes on, if you can sum up your testimony. Your full testimony will be entered into the record.

Senator Lautenberg. Mr. Chairman, just a side comment. The Mayor knows that when you see a red light, it does not mean stop--it means speed up.

Senator Coleman. I thought it ought to be a suggestion.

Mr. Giuliani, we will have you go first, followed by Dr. Shepherd, and after we have heard all the testimony, we will turn to questions.

Mr. Giuliani, you may proceed.

TESTIMONY OF HON. RUDOLPH W. GIULIANI,\1\ CHAIRMAN AND CHIEF EXECUTIVE OFFICER, GIULIANI PARTNERS, LLC, NEW YORK, NEW YORK

Mr. Giuliani. Mr. Chairman and Members of the Subcommittee, good morning, and thank you very much for the opportunity to present the results of the report that we are in the process of doing.

\1\ The prepared statement of Mr. Giuliani appears in the Appendix on page 136.

The availability of safe, effective, and reasonably priced medications for all Americans is without doubt, as you have all noted, a very important and very crucial issue for us. Individuals and even State and local governments have sought many different alternatives to see if they can find access to medicines for everyone at reasonable cost, and this is something that has to be pursued, and I commend you, the Members of the Senate and the House, who are trying to do that and to accomplish that.

But pricing, which is the principal driver and motivation for this, although extremely important, can overshadow the dangers that are created or could be created and actually exist now for the integrity of our medicine supply in the United States. So whatever solution we find has to be one that does not pollute the supply of drugs in the United States, or further pollute it, because there is already a pretty serious issue.

Under the current system, from what we have seen so far, there are already significant risks given the importation that takes place with regard to the dangers that are created for Americans, and based on what we have learned so far, there are serious concerns about the present quality of the medicines that people are buying and using. The FDA has warned repeatedly that if people continue to order prescriptions over the Internet or from foreign sources, it will create the danger not only for them but for the entire drug supply in this country that it will be polluted and not properly regulated.

In this regard, my firm, Giuliani Partners, has been retained by the Pharmaceutical Research and Manufacturers of America to conduct a study, of which we are about one-third completed, and we presented our preliminary views to you in a report which I hope you all have and have a chance to look at, and also to the Department of Health and Human Services' Task Force on Drug Importation which has been charged with the

responsibility of determining how safe is the present system and what kinds of safeguards would be necessary if there were to be any expansion of the current system.

Let me very briefly state some of the things that we found and some of our preliminary observations--and I emphasize they are preliminary because we are about one-third of the way through the process of investigating this.

It is evident that the existing pharmaceutical system right now, as it presently exists, before you consider any further expansion of it, is open to significant exploitation for counterfeit medication and diluted, adulterated drugs. The limitations on the system that we presently have are significant.

The U.S. Surgeon General and the Health and Human Services Task Force are considering all of these issues, and the task force really has to complete its analysis before we have a basis on which we can figure out what to do about the present system realistically to make it safe, as safe as the American people deserve, which is a lot safer than it is right now, and then, what would be needed to expand that system and the safeguards that would have to be put in place.

It really is important--and I commend the Chairman and the Members of this Subcommittee for conducting this hearing--because part of the process also has to be putting the public on notice so that we deal with people honestly about the risks they are taking if they use the Internet or if they go to the alternative of seeking drugs from a foreign source. If people make that choice, they should at least be armed with the information that it is significantly different than, as Senator Pryor pointed out before, buying medicines at your local pharmacy. You are taking a risk. It may be a calculated one, but it is only a calculated one if you are on notice and you know the risk that you are taking.

The system has many problems. There is a lack of standardization, a lack of oversight of wholesalers; there is no chain of custody, no pedigree. The volume almost cannot be described. The testimony that you just heard from GAO was very instructive, very valuable, very important, but it talked about 68 samples, I believe. That is a minuscule percentage of what is coming into this country. It is something like 10 million packages a year. At the John F. Kennedy International Airport, where Senator Coleman and I had a chance to inspect the mail facility--which I believe is the largest or second-largest in

the country for the receipt of any parcels as well as medications--they receive 40,000 packages a day allegedly containing medicines--40,000 a day. Their capacity--and again, this is one of the largest facilities in the country--allows them to inspect at best between 400 and 600 of those packages each day. So 99 percent are moving through totally uninspected, no one looking at them, no one having any idea of what is in them, and then they are able to inspect, in a fairly cursory way because of the lack of resources, only 500 a day. And that inspection has to be a very quick one and a very brief one.

When we visited there, which happened to be on March 17 of this year, they described it as a ``fairly slow'' period because there had been some delay in the obtaining of medicines, yet the facility was overwhelmed with medicines of all different kinds. We saw Xanax, Valium, and Vicodin. As Senator Coleman pointed out, we saw Lupron that had been sent in from a foreign country--I have forgotten which country now, but not the United States, not Canada--it had been sent in from a foreign country. Lupron is a hormone that is administered to people with prostate cancer, and it has to be, should be, administered by a doctor, by injection. This packaging was adulterated. It had apparently been tampered with. There was Lupron, and there were the facilities and the devices for people to self-inject it, which would be extremely dangerous.

We also saw medicines that were expired--you could see it right on the label--I believe it was antibiotics--that were expired by 2 and 3 years, and all you had to do was examine it, and in many cases, antibiotics that are expired by a year or 2 years or 3 years are useless.

We saw what appeared to be adulterated medicines--the coloration appeared suspicious and strange; the packaging was unusual--and medicines from 14 or 15 different countries, including Pakistan, Spain, Greece, Italy, and some from Canada.

So the sheer volume that comes in--40,000 a day in one facility, 10 million a year in the United States--makes the ability to inspect under the present system, without any further increase in methods of foreign importation or Internet use--the present system is overwhelmed at this point, and it presents a threat. It presents a significant threat to the individual who is ordering by that method, because the percentage chance that they are going to receive the wrong medication or adulterated medication is significant. But it also presents a broader threat to this country. It presents the

threat of polluting our drug supply because these medicines can also find their way into what appear to be more legitimate sources of medications. It offers an opportunity for organized criminals and for drug traffickers to take advantage, and for terrorists to take advantage.

Here we are going through a period of time in which we are trying the best way can to deal with our borders in a more orderly and a more secure way, consistent with being a country that is open to people coming here, people feeling that they can come here, and also open to doing commerce correctly. But we are trying as best we can to secure our borders. The whole idea of the Department of Homeland Security is to do that, have the Customs Service and the Immigration Service work together more effectively. And this is an area in which our borders are right now, I think it would not be unfair to say, wide open. If you have 1 percent or less of what is coming in inspected, the odds are that if you are operating in Pakistan, or you are operating in Spain, or you are operating in Greece, or you are operating in Turkey, you can calculate that there is a much better than 9 out of 10 chance, and maybe greater than that, that what you are sending into this country is not going to be inspected by anyone even if it purports to be a dangerous medication.

So from our analysis, our summary of our findings at this point, there is already a situation that needs further regulation, further technology, a lot more investment of resources so that significantly more inspection can be done at the vital, crucial point. Things are all going to go through mail facilities whether they are ordered by phone or by mail or over the Internet. They are all going to end up in these mail facilities to be distributed to different parts of the United States in most cases. And at that crucial point, a great deal more has to be invested in inspecting properly, inspecting with modern technology, and creating a lot more safety for people in the United States.

The results of our preliminary study and the work that we are continuing to do are really no different than studies that have been done in the last 2 or 3 years by the FDA, U.S. Customs, and Border Protection. We have reviewed blitzes that they have done back in the fall and early winter of 2003. In the first one they did, 88 percent of the medicines they had a chance to inspect--that the FDA got a chance to inspect--were not approved by the FDA, and the drugs came from countries such

as India, Thailand, and the Philippines. In the second examination, it was 87 percent that were coming in that were not approved, 16 percent of those shipments coming from Mexico. And a recent review of the Miami facility, which is very similar to the one at JFK, showed roughly the same percentages--no better than 1 percent being inspected, and the ones that were inspected, the overwhelming majority being unapproved either for technical reasons or for very serious and dangerous reasons.

So, given that, it seems to me that the focus of the Congress should be on how do we take the present system that we have and make it much more effective in terms of affording safety to anyone who is seeking to buy drugs from a foreign source or an Internet source. And then, after we have accomplished that, and we have accomplished that for some appreciable period of time--2 years, 3 years--then to take a look at how we would open things up to further foreign sources of medicines coming into the United States, because the present situation, without being an alarmist, is probably, even if you understate it, very dangerous and an area in which there can be, if there is not already, significant exploitation.

We would be happy to answer any questions about what we have found or any suggestions about how you would accomplish that.

Again we commend the Chairman and the Members of the Subcommittee for looking at this, because this is a very complex issue, and it has very big implications for individual Americans who are seeking medicines and access to them, but for all of us. Thank you.

Senator Coleman. Thank you very much, Mr. Giuliani. Dr. Shepherd.

TESTIMONY OF MARVIN D. SHEPHERD, Ph.D.,\1\ DIRECTOR, CENTER FOR PHARMACOECONOMIC STUDIES, COLLEGE OF PHARMACY, THE UNIVERSITY OF TEXAS AT AUSTIN, AUSTIN, TEXAS

Mr. Shepherd. How are you all doing? Mr. Chairman, Members of the Subcommittee, I want to thank you very much for the invitation to come here today.

\1\ The prepared statement of Mr. Shepherd with an attachment appears in the Appendix on page 150.

I have been studying drug importation mainly out of Mexico since 1994, and recently, in the last 3 years, have been looking at it coming out of Canada. I have been pretty active in the area and nationally, trying to figure out what is a sound way of doing this thing on drug importation or reimportation, and how can we best go about figuring out how to do it.

There have been several congressional bills--and by the way, I have a written statement, and my report is also part of the record, on the Canadian market, but I am going to vary from my written statement because I do not want to be redundant of what has already been said, and I have inserted some new things.

We have had three bills, I believe--maybe four now--that have been introduced to make drug importation a safe practice and to make drug importation, most importantly, a safe and cost-effective alternative for Americans.

In addition, the legislative efforts of the Medication Prescription Drug Improvement and Modernization Act of 2003 has charged HHS to make a thorough examination of drug importation.

And as stated, as we stand right now in this country, I am absolutely opposed to any type of methodology to figure out how the drug importation is unless we change and get safety back into the issue. It is a huge risk for the American public. There are no doublechecks in the system. There are no prescription drug accuracy checks from pharmacists. There are no drug interaction checks from pharmacists. There are no drug-disease checks from physicians or pharmacists. There is virtually no counseling on the drug therapies coming in. You have lost total access to health care professionals.

To Senator Collins, who mentioned the two classes of people who are using the Internet, I will say there are three classes of people. You have the drug abusers; you have the people shopping for price; and you have the people who have the money, but they do not want to see a physician, and they want simple access. They want access because I can get anything I want without a prescription, and they can go out and buy whatever they want. I have seen that in Mexico--because in Mexico, they do not require prescriptions unless it is a controlled substance--so you see thousands of people cross that border every day, bringing controlled substances back, but they also bring back all kinds of other medications. It is straight access. Plus it is price there. It is cheaper in Mexico than it

is in Canada, a lot cheaper. But it is both issues. So you have three types of people going down there to get pharmaceuticals.

The potential problems are very serious for those who obtain prescription drugs via the Internet--very serious, as already pointed out--and I am not so sure on the Canadian market, as some people have already purported in this room. Right now, we have one Canadian Internet site forwarding prescriptions to England. They are being filled there, and Americans are getting their prescriptions out of England and not out of Canada.

I am also aware that a Scrip article reported that one Canadian Internet pharmacy provider is shipping pharmaceuticals which are made in Mexico to U.S. residents. The article goes on to say that the products of Mexico coming in through Canada as a drug diverter have not been approved by Health Canada and have not been approved by FDA.

Furthermore, my research--and in this report, I point out to you that in 2003, Canada imported pharmaceuticals from over 80 different countries. Now, Canada has good manufacturing agreements with 18 different countries, mainly Western Europe, and you would expect Canada to import from Ireland, Scotland, France and Germany. You would expect that because they have mutual recognition agreements. But I did not expect to find Canada importing drugs from Ecuador, Chile, Brazil, and all the other countries that make up the 80.

From 2002 to 2003, Canadian imports from India increased by 109 percent, or have doubled; Singapore, they are up 72 percent; Mexico, they are up 50 percent; and Italy, they are up 283 percent.

Even U.S. pharmaceutical exports to Canada have increased. From 1999 to 2003, our exports to Canada have gone up $1 billion. I think that is a significant amount of drugs going into Canada. But what is interesting is that our portion of the total imports that Canada gets is shrinking. In the year 2000, U.S. drugs comprised 55 percent of all Canadian imports for drugs. In the year 2003, it is down to 43 percent of all imports to Canada. So the Canadian market is decreasing for U.S. drugs in the source chain, and other countries are taking hold of that source of pharmaceuticals.

I understand the plight of individuals having a 91-year-old mother-in-law or an 80-year-old father or mother struggling with prescription drug prices. I understand that completely.

However, I am not too sure that the anticipated savings

from importation will justify all the procedures that goes along with importation to make it safe. I am not convinced of that. And some one has to do some studies--either GAO or the FDA has got to look at this very seriously and ask what would it take to import drugs and how cost-effective that would be.

There are 250,000 drugs manufacturers worldwide. You have 1,400 just in Bombay. You have 6,500 in China. To bring all those products in and inspect from what country they are coming from and make sure they are safe is a tremendous task. You have got to do some modeling, hire some people to do some kind of statistical modeling, to figure out what would be the cost impact. If we are only talking about a 30 percent savings, I have a feeling that the intermediaries in the process will take it all away, and the consumer will have nothing in the end. That is not what we want. We want to get prescription prices lower. We do not want the wholesalers and the intermediaries to take off the cotton, and we are left with the stem at the end. That is not fair to the American public. But before we embark on that, we need to seriously look at that and go after it in some kind of modeling.

One potential negative consequence of the program that permits pharmacies and wholesalers to import pharmaceuticals is that it may develop a two-tier pricing system in the United States. I am speaking now as a pharmacist--a two-tier system where you have some pharmaceuticals imported in a store, and you have some pharmaceuticals that are U.S.-made. That has me scared, because a lot of third-party pay plans, including Medicaid reimbursements programs or whatever it is, will gradually shift to the imported product because it is going to be less. I do not know how a pharmacist is going to deal with these two-tier programs if you have a differential in the price of U.S.-made products and imported products in a store. I do not think that has been mentioned. I raised it with the HHS Task Force on Drug Importation that it needs to be looked at seriously.

The last point I want to raise is that it will definitely hurt the generic drug industry. I cannot see the generic drug industry developing new drugs when the imported drug is probably 20 or 30 percent below the brand name drug. I am not so sure they will invest the money for that generic drug industry product when it comes down to that end. I do not know the answer to that, but it just raises that question--how can you foster the generic drug industry and at the same time bring

imported drugs that are cheaper than the generics?

I want to close in the last 38 seconds and say I really believe that more data are needed. The likely impact of importation and the cost of drugs needs to be looked at in a really sophisticated manner. I am opposed to proposals that would allow importation of prescription drugs that leave the safety issue out.

I really urge you and others to let the professionals at the FDA do what you charged them to do in the Medicare bill--let them look at the issue thoroughly, run the numbers, answer some questions, and come up with a proposal for everybody to look at.

I thank you very much.

Senator Coleman. Thank you, Dr. Shepherd.

Dr. Shepherd, let me start with you. You mentioned Health Canada. Does Health Canada have any regulatory authority or power over Internet drug sites?

Mr. Shepherd. Each province has regulatory authority over each Internet site, and you will see differences from Ontario all the way to Manitoba. Ontario is pretty strict with them and basically does not allow them, versus Manitoba, where it is a free-for-all with 60 to 80 Internet sites out there.

What is really important is that the Canadian rules and regulations do not require approval by Health Canada for drugs exported out of Canada. That is the clincher. If we can get Canada to say we will approve those drugs that are exported, that would be all right.

Coming from the Detroit area originally, I had no problem going across to Windsor to buy a drug at a store, but I do have some serious concerns with going to the Internet in Canada to buy a drug.

Senator Coleman. And just on that last point, these Canadian providers are not your neighborhood Canadian pharmacy. In fact, would it be fair to say that for many of them, their sole business is exporting to the United States rather than meeting any Canadian needs?

Mr. Shepherd. Yes. There are a half a dozen where that is their main business.

Senator Coleman. And you did not testify, but it is in your written report, that clearly, the Canadian market does not have the capacity in itself to supply American drug needs, so is the conclusion from that that they will have to turn to other countries and in effect be a flow-through to satisfy U.S.

market needs?

Mr. Shepherd. Yes. Can I explain that in just 2 minutes?

Senator Coleman. How about 30 seconds?

Mr. Shepherd. Thirty seconds, OK.

The Canadian market right now as it stands would only take care of U.S. needs for 38 days. That means that if the United States wanted to buy all its drugs out of Canada, it would last 38 days, and that would be the total annual consumption by Canadians. They only have 300 million prescriptions. We dispense 3 billion. They could not handle it.

So now, with a shortage of supply of drugs coming into Canada--and you get conflicting reports on that--they are going to other countries and other sources to buy their product, and the numbers seem to point that out. They have gone to other sources for their product.

Senator Coleman. Mr. Giuliani, I want to get right to the issue of terrorism, and you touched upon it. Just an observation--we see one cow infected with BSE, mad cow disease, from Canada, and we literally shut off the importation of any Canadian beef. We have in this hearing seen drugs coming in from other countries, foreign countries, but nothing to prevent a pass-through, yet we are talking about expanding the importation of drugs, and some of us have been very emphatic about the safety issues.

I will say it publicly--is there anything to stop a terrorist from setting up an Internet site, giving it a red, white, and blue label, providing prices that are so low that consumers concerned about price would think they were getting the best buy ever, and somehow adulterating those medicines with some substance that could have a disastrous impact on the lives of citizens in this country--is there anything today to prevent that?

Mr. Giuliani. Well, I hate to answer that question, because----

Senator Coleman. I hate to ask that question.

Mr. Giuliani [continuing]. You do not want to suggest anything to anyone--but the reality is that I do not think we are suggesting anything that they could not figure out themselves.

It is pretty much right now a wide-open system with, as I said, 10 million packages a year coming in. The ability to inspect--I am not even sure what the overall percentage is; the percentage at Kennedy is about 1 percent, and I suspect the

percentage nationwide is even less than that. So for 99 percent or more of what is coming in, you can rely on the fact that it is not going to be inspected.

There is no really good field test. My experience in my early life before I was mayor was as a U.S. Attorney, an assistant U.S. Attorney and Justice Department official, where we often dealt with the problem of heroin, cocaine, and the traditional narcotics. And at least for those, there is a field test so that if you suspect that there is heroin or cocaine, you can open the package, and you have a fairly reliable field test that will tell you whether it is or it is not.

For most of these, as GAO demonstrated, there is no really good field test. It requires extensive and very expensive analysis by the pharmaceutical company to determine whether or not this is in fact the medication that is ordered, whether it is safe, whether it is the right dosage. So this is a system that is open for exploitation.

Global Options, Incorporated did a study that is now at least a year old--it may be 2 years old--in which they looked specifically at the potential threats to America in its medical supply and concluded that the threats were very significant and demonstrated what they think they are. I really recommend that. They actually looked at three possibilities--the ability of terrorists, of organized criminals, and of drug traffickers to take advantage of this system.

And then there is one general concept that is enormously important. If the borders of this country are porous in any way, that is the area in which people can take advantage. If you are going to secure our borders, you have to secure them. We have to be more secure in determining the people who are coming into this country, but if we are more secure in determining the people who are coming into this country but not the things that are coming in, we have not accomplished anything, because then, people do not have to come in--all they have to do is send things in. And in an era in which we are trying to figure out a better way to regulate our borders, it would be counterproductive--we would be moving in the opposite direction--if we were to say, well, let us open our borders even more to foreign importation of medicines, which is a way, frankly, as you are asking me, Senator, of attacking us.

Senator Coleman. Thank you. I am going to turn to Senator Lautenberg, since he has been here since the beginning. Senator Lautenberg.

Senator Lautenberg. Thanks very much, Mr. Chairman.

Mayor, welcome. We have had a lot of contact over the years, and I am glad to see you at work on this project. Your concern about the lives and well-being of our citizens is well-known, and that is also something that is considered here as you pursue this research.

I have enormous respect for the pharmaceutical industry. As a matter of fact, at my stage in life, rather than turn to the sports pages, I turn to the Federal pages and see what is coming along and urge them to hurry up. So we want this research to go on, and we want to make sure that the products that our people buy are safe.

But the cost factor is an enormous difficulty for lots and lots of people. There are people, as I said earlier, who would do without food at times so they can continue to have the drugs they need, whether it is to get rid of the tremors or preserve memory or have their hearts continue to function as they should--all of these things. It is a desperate search for relief. And, unless we understand that, we are kind of fooling ourselves. That is an overriding consideration.

So, why do you think, Mayor, given all the risks that you have highlighted, people continue to buy their drugs over the Internet or from unreliable sources as they seem to be?

Mr. Giuliani. I think, Senator, you have hit on one of the reasons. Obviously, it is the pressure of lack of access and high cost. There is no question that your efforts, those of Senator Coleman, all of you on this Subcommittee and in the Congress, to try to find ways to reduce the cost will also ease some of this pressure. That is a very important component of this.

But you said something in your opening statement that occurred to me. You said that we do a lot in this country to create access to food for people who are hungry and starving; there are all kinds of programs that we have to feed people--I am very aware of them in New York City, but they are all over the country. But when we do that, we do not look for programs that are going to make the supply of food more dangerous. We do not look for programs that will pollute the food supply in this country. And the pressure of accomplishing this cannot lead to creating even more danger for the American people. That is why taking a realistic look at the way this system operates now and what can be done--some of the approaches--and I think it is for absolutely the right motivation, which is how do we lower the

cost of medicines--some of the approaches are very unrealistic about the dangers, because there is such a desire to produce the result of low cost.

Dr. Shepherd raised the issue whether we will actually even produce that result, but that is the motivation. And you just cannot wave a wand and create the safety. It is going to need significantly more resources. It is going to need a period of time in which we can take the system that we presently have and make it work better before you can figure out how to expand it.

And from Canada, the experience we had, which I neglected to mention earlier in my statement--which I would have liked to ask GAO, but I imagine you can ask them this--we found that the Internet pharmacies in Canada required a waiver signed by an American. I find that extraordinary.

Senator Lautenberg. I would like to ask Dr. Shepherd, how is your research being funded?

Mr. Shepherd. By me.

Senator Lautenberg. By you, personally?

Mr. Shepherd. Personally, yes with the help of the University of Texas. My group of graduate studies--I have 38 graduate students, and I chose four of them, and we did this study in 3 months.

Senator Lautenberg. You indicated that you were concerned about the supply of drugs that would be left in Canada if we just opened up this importation process of ours. We could ship more, we could export more. You talked about the exports growing, and then you talked about the percentage of reimportation shrinking. I do not know what that signifies except that maybe there is arithmetic ratio here that we are not looking at. If the export supply is growing, then perhaps it is faster than the reimportation factor.

So I do not think that is really the key issue here. I would ask you this. If we could bolster--you are concerned about safety, and you have a professional background that indicates that you have been in the field--if we could deal with the safety factor, would you say open the doors to reimportation?

Mr. Shepherd. Yes. I would say you could probably do it if you could assure the quality of the product and assure that people understand how to take the product.

There are two safety issues. You have the commodity, the product, and then you have the safety issue--do people understand how to use the product properly. You have to

incorporate both of them together.

Senator Lautenberg. I will close, Mr. Chairman, with an observation and a question. That is, with the flow of illegal drugs into this country that kills people, that disrupts our society totally, and we have devoted enormous amounts of resources to stopping that flow, but we cannot do it. And here, with this, we are not spending anywhere near enough time looking at these products to really determine what the efficacy of the product is. I thank you, Mr. Chairman.

Senator Coleman. Thank you, Senator Lautenberg. Senator Pryor.

Senator Pryor. Thank you, Mr. Chairman.

Mr. Giuliani, let me say at the outset that sometimes the industry may perceive that here in Congress, we are just beating up on the industry all the time, but certainly I recognize--and Senator Lautenberg just mentioned as well--the advances that the pharmaceutical industry has made, and some of the things they have done are just absolutely amazing. But I assume you would agree with me that some of the prices for pharmaceutical products in this country are too high?

Mr. Giuliani. There is no question about that, and that is one of the driving forces in what is going on here.

Senator Pryor. Yes. And I am glad to know that--I am sorry, I did not quite catch who funded your research----

Mr. Giuliani. PhRMA.

Senator Pryor. I am glad to know that PhRMA is doing this, because it indicates to me that they are starting to get serious about this issue. Can you tell the Subcommittee how much PhRMA is investing in your study?

Mr. Giuliani. I do not know how much they are investing in my study. The cost of it is insignificant in comparison to the amount of money they are investing in trying to figure out a safe way of doing this and the amount they invest in research. Some companies put $4 and $5 billion into that.

Senator Pryor. One thing I would encourage you to do as a representative of the pharmaceutical industry is to just encourage the industry to get very proactive on this issue. It is something that is of very grave concern to me and I know to the Subcommittee and to the country. We need to try to get a handle on this.

One thing you mentioned in your testimony is you talked about inspections--repeatedly, you talked about inspections. Is it your view that government inspections are essential to

protect Americans, or can we follow more of a market model where the industry kind of regulates itself--in other words, can the industry inspect itself--and put market conditions in there that give them the incentive to do that.

Mr. Giuliani. I think you need both, Senator. I do not think you could ever have a system where there would not be some degree of inspections. Think of it as how do you create safety with regard to the cargo coming into the United States, where we have great concerns about packages or shipments coming in. There has to be a combination of market conditions and some degree of analysis and intelligence, but then you also have to have a certain basic number of inspections so you have a fail-safe point.

And when you are dealing with dangerous medications--one way that we can get to a better stage is to develop better technology and better pedigrees so that you know where it is coming from, who the manufacturer is, and all of that can be done--the problem is that it costs enormous amounts of money, and we are not doing it effectively--I think we have to be honest about it--we are not doing it effectively right now.

So it seems to me the best approach is how do we improve the current system, how do we get better control over it, and then, once we have done that, how do we open it up even more, rather than just opening it up and creating a totally unrealistic situation.

Senator Pryor. We talked a few minutes ago about this concept of a seal of approval--Chairman Coleman was the first to mention it--and someone said that the National Pharmacy Association----

Mr. Shepherd. The National Association of Boards of Pharmacy.

Senator Pryor. [continuing] Has something in place right now that is voluntary. Are they the proper group to do this, or should we somehow broaden that and really force more participation somehow?

Mr. Shepherd. It is called the VIPP Program, the Verify Internet Pharmacy Provider, and it is a very strict inspection and certification program.

Senator Pryor. Is that why a lot of firms will not comply and will not go through the process?

Mr. Shepherd. I believe that last week, only 14 pharmacies had VIPP certifications. I was talking to Carmen Cattezone--they have offered the VIPP certification to Canadian Internet

pharmacy providers, but none of them has taken them up on the offer.

Senator Pryor. Do you know how long that offer has been outstanding?

Mr. Shepherd. It has been out there for at least 3 months.

Senator Pryor. Let me ask you, Dr. Shepherd, while we are talking about it--a few moments ago, in your testimony, I got the impression that if it were up to you today, just under the current conditions which exist today, you would ban all on-line pharmacies.

Mr. Shepherd. Right. As of today, I would. Without any regulation and what is going on right now, I would stop it from coming in.

Senator Pryor. Because the safety protection is not there?

Mr. Shepherd. Safety.

Senator Pryor. You also talked about importation. But here in the Congress oftentimes we talk about reimportation, and we use the word ``reimportation,'' the way we usually mean it is drugs that are made in this country or made in FDA-approved facilities that may go to Canada or another country and be reimported back in.

Is that one of the safeguards that you would like to see if you were able to set up your own system here that we should only be able to reimport, or import, however you want to look at it, drugs that are made in FDA-approved facilities?

Mr. Shepherd. That is one approach that you could use. I have problems with the reimportation unless I have the pedigree paperwork that the mayor talked about, figuring out where that drug has been, how many times it has been sold, and how it has been stored, because it may have passed through six different countries before it comes back in.

Senator Pryor. In other words, in the prosecutor's terms, you need a chain of custody.

Mr. Shepherd. You need a chain of custody.

Senator Pryor. You need to know where it comes from. One last clarification--you mentioned that you pay for your research out of your pocket?

Mr. Shepherd. My group does, yes.

Senator Pryor. What do you mean, your ``group''? Tell us about that.

Mr. Shepherd. My group--the Center for Pharmacoeconomic Studies is comprised of 12 faculty members and 32 some-odd graduate students.

Senator Pryor. So this is part of the University of Texas.

Mr. Shepherd. Part of the University of Texas, right.

Senator Pryor. Do you know where that funding comes from?

Mr. Shepherd. The Center's funding comes from the University of Texas primarily, and then it also comes from grants or contracts that we get from pharmaceutical firms, foundations, grants, and contracts from State Government. The State of Texas provides us a lot of money, the Health Department.

Senator Pryor. Thank you.

Senator Coleman. Thank you, Senator Pryor. Senator Carper.

Senator Carper. Gentlemen, welcome. Mayor, it is good to see you. Dr. Shepherd, thank you for your testimony.

You know how this place works--we have multiple hearings going on at the same time, and I have been off at another one of those, and I apologize for missing your testimony.

Let me ask both of you, if you were in our shoes, how would you approach this issue?

Mr. Giuliani. I would approach it from the point of view of first addressing the current needs that the FDA and some of the other agencies have for more resources, more of an ability to inspect, create better pedigrees, work on developing technology. I would look at the current situation that exists and say it is a dangerous situation. Ninety nine percent of the medicines that are coming into this country, no one is inspecting, and no one has any idea what is in them. Any time anyone has had a chance to look--FDA, Customs, anyone else--at least FDA, when they do these ``blitz'' analyses, and our own analyses--shows that somewhere between 70 and 90 percent of those medicines are unapproved, some for serious reasons, like they are expired or they are the wrong medications, some for technical reasons, but for whatever reason, they are unapproved.

So I would say let us see if you can create legislation, give FDA and the other agencies the help that they need to make that a better system, a safer system, and then take a look at it over a year or two or three and see if it has actually accomplished that--have some of those percentages gone down; is it safer.

I think it is unrealistic to think you will ever have a perfectly safe system, but it has to be a lot better than this. And once that is accomplished, then take a look at are there ways that you can expand importation--but now that you have a

better system in place. That is the way in which I would do it.

Senator Carper. Dr. Shepherd.

Mr. Shepherd. You could work with qualified pharmacies, Internet providers; inspect them, come up with a list of products, drugs, that could be reimported or imported, and work with a small pilot project to see how it flies, and make sure that provider provides it.

You could do it a couple of ways. You could do it not only for personal importation, but you could also do it with a U.S. wholesaler. That U.S. wholesaler works with another wholesaler in another country, gets the U.S.-approved products, comes in and distributes to pharmacies. But they would have to be FDA-approved in quality products.

That is one approach. And I think a pilot project on that would probably be worth looking at to be sure the standards are upheld.

Senator Carper. Thank you.

Do you have any idea how the purchase of drugs from Canada via the Internet compares with, say, Internet purchasing from countries in the EU?

Mr. Shepherd. No.

Mr. Giuliani. We could find out for you, Senator. We could take a look and find out.

The question that I raised before, which I really would suggesting finding out from GAO--because I am sure this is part of their material, but I have not had a chance to look at the report clearly enough--is the pharmacies in Canada that we have had a chance to look at so far all require waivers. So if you want to buy medicines from them, you have to sign a waiver that if they send you the wrong medication, you have no resources. To me, that is extraordinary.

If I went into my pharmacy to buy the medicine that my doctor prescribed for me, and my pharmacist handed me a document that I had to sign in which I waived any recourse if he gave me dangerous medicine, or he gave my children dangerous medicine, I would not deal with that pharmacist.

So I wonder if the pharmacies that they looked at in Canada have those disclaimers or waivers. And part of this process would have to be that you really should only deal with pharmacies that do not require that, pharmacies that are willing to stand behind the product that they are selling you--if you are ordering Lipitor that it is actually Lipitor, whatever it is. This idea of having recourse is part of the way

in which we assure that pharmacists are acting legitimately.

Senator Carper. Why do you suppose people are willing to take that extraordinary step of signing that kind of waiver?

Mr. Giuliani. For all the reasons that Dr. Shepherd mentioned, some of them just purely because they are desperate, because medicines are too expensive, and they are seeking--even though it may not be less expensive--they are hoping that they will find a source that is less expensive; some of them because they are drug abusers; some of them because they may actually be drug dealers, and this is an easy method of getting significant quantities of medicines that they can then resell on the black market. I think that would be particularly true with some of the medicines that are painkillers.

Senator Carper. Thanks to both of you.

Senator Coleman. There is so much more that we could explore here, but we do have a very important third panel that we do want to hear from. We have not even touched the issue of wholesale and that system, which you touch on, Mayor, in your report and some of the challenges that we face there and the opportunities for fraud that has been unearthed in some of the reports that have been done.

So I think we have just touched the surface here, but as I said, we do have a third panel that I want to get to, so I want to thank you, Mayor, and thank you, Dr. Shepherd, for your very important testimony.

Mr. Giuliani. Thank you, Mr. Chairman and Members of the Subcommittee.

Mr. Shepherd. Thank you.

Senator Coleman. I would now like to welcome our final panel for today's important hearing--Elizabeth Carr, whose husband died from taking illegal prescription drugs he purchased over the Internet, and Francine Haight, whose son died as a result of taking illegal prescription drugs he purchased over the Internet.

Ms. Carr and Ms. Haight, I want to thank you for your courage in coming forward to testify about what I know are very difficult circumstances to talk about in public. I offer my personal condolences for your loss.

As I mentioned in my opening statement this morning, we are here to address problems that are facing American consumers, the individuals who have been most directly, and unfortunately, affected by this growing phenomenon. So again, I appreciate your willingness to tell your personal stories.

Before we begin, pursuant to Rule 6, in this Subcommittee, we do require the witnesses to be sworn.

I would ask you to please stand and raise your right hand. Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. Haight. I do.

Ms. Carr. Yes, sir.

Senator Coleman. Thank you.

As you have seen, we are using a timing system, so when the yellow light comes on, it is time to conclude your testimony. If you have written statements, they will be entered into the record in their entirety.

Ms. Carr, we will have you go first and then proceed to Ms. Haight, and after that, we will go to questions. Ms. Carr, you may proceed.

TESTIMONY OF ELIZABETH CARR,\1\ SACRAMENTO, CALIFORNIA

Ms. Carr. Thank you. Good morning, Chairman Coleman and Subcommittee members. Thank you for the opportunity to speak today.

\1\ The prepared statement of Ms. Carr appears in the Appendix on page 172.

My name is Elizabeth Carr, and on April 10, 2003, I lost my husband to an overdose of Darvon, a controlled substance. My husband Jim purchased this drug and others over the Internet from rogue pharmacies located in India, South Africa, Thailand, Spain, and other foreign countries.

Jim and I were married in 1996. He moved from Los Angeles to accept a job in Sacramento, California. This was a significant climate change for him, as he was used to the mild temperatures of Los Angeles. He was a former tri-athlete and a marathon runner, and he loved to mountain bike. Through these activities, he had dislocated a hip and had to have operations on both knees.

By 2002, it was painful for him to even take a brisk walk, and he said it was always worse during the winter. In January 2003, Jim told me he was going to purchase codeine over the Internet for his pain. I did not think much about it at the time, because when I was growing up, codeine was in cough

syrup. He never told me how much he was taking, and because he was working from home, I never saw the packages arriving. However, by the end of March, I grew concerned about a change in his demeanor, and I confronted him about it and asked him to stop, which he agreed to do.

On the day before he died, he was behaving very disoriented when I got home from work. When I quizzed him about it, he explained that he had turned to Darvon to wean himself off the codeine. This was the first time that I knew he had taken the Darvon. He went to sleep that night, and he never woke up.

The autopsy showed that Jim had eight times the recommended dosage of Darvon in his system. After he died, I received five packages in the mail that Jim had purchased in the weeks before he died. By looking at his credit card statements and the dates posted on the packages and when the packages arrived, I could tell that the time from order to receipt from these pharmacies took several weeks. In fact, all packages were from overseas, and none had a pharmacy label. Some had instructions, but most of the instructions were not in English. One of the packages even had a little green tag attached on the outside that looked to me like it said ``Sweets.''

As I continued to go through his things, I found all kinds of empty pill containers. I also looked at his computer activities and discovered that he had done research into the different drugs and how to get them. Some Websites required him to fill out a short questionnaire before he could get the medication, while others did not require anything. All the overseas pharmacies required payment in credit card form and were shipped via U.S. mail.

After his death, I worked with the California Medical Board to try to hold someone accountable for the delivery of these substances to my husband. However, there was nothing that the California Medical Board could do because the only documents I could provide them did not implicate doctors that were licensed in California. They told me something needed to be done at the Federal level.

So that is why I am here today, Senator Coleman. I am here to tell you what is happening to real people--not just numbers or statistics on a piece of paper. This problem affects everyone in one way or another in our society, and something needs to be done to stop these companies from making money off of people's trust, their need, or their lack of awareness.
Thank you.

Senator Coleman. Thank you, Ms. Carr. Ms. Haight.

TESTIMONY OF FRANCINE HAHN HAIGHT,\1\ SACRAMENTO, CALIFORNIA

Ms. Haight. Good morning. My name is Francine Hahn Haight. My daughter Natalie and my son Jeremy are present and sitting behind me. I am very grateful for this opportunity to speak before this Subcommittee and share what has happened to our family.

\1\ The prepared statement of Ms. Haight appears in the Appendix on page 174.

I am the mother of three beautiful children. I am extremely sorry to say that one of them died. I am here to tell you about my son, Ryan Thomas Haight.

Ryan was born on December 28, 1982 and died on February 12, 2001. Ryan died of an overdose of narcotics he had easily purchased on the Internet. A medical doctor, Dr. Robert Ogle, that he never saw, prescribed them to him over the Internet. An Internet pharmacy, Clayton Fuchs of Mainstreet Pharmacy, mailed them to our home. He was only 17 when he purchased the narcotics, and he was only 18 when he died.

Ryan was an incredible boy. From the time he was little, I always believed that he would make a difference in our world. He was very intelligent and excelled in school. He loved math and science. He was always at the top of his class, was a Gate student in the elementary years, and then went on to take honors classes. He was an A student, maintaining a 4.0 or above during his years in high school. He was looking forward to going to college. He loved his family, and we did many things together.

Ryan loved to travel. He loved to hike. He loved the National Parks. He always looked forward to the holidays and gatherings of the family.

He was athletic. In elementary school, he played little league baseball, starting with T-ball, and ended up being a top player in the majors and making the all-star team. He also played open junior tennis tournaments, and went on to play varsity tennis for 3 years in high school. Had he not died in his senior year, he would have been a 4-year varsity letterman in tennis.

He loved to snow ski, snowboard, water ski, kneeboard, and

attempted all sports with great enthusiasm. He loved to play billiards, go bowling, and play ping pong. He was competitive and competed on a swim team when he was young and loved to play Nintendo and other video games.

Ryan loved to use the computer. He used the computer to play games against his friends, to compete in fantasy baseball, where you pick your teams, and he loved to chat with his friends online. He loved to trade baseball cards on E-Bay.

Ryan was taking a computer graphics class in high school. He was considering a possible career designing software or doing something with computers. But all of his hopes and dreams died when he discovered that he could buy drugs on the Internet.

He was curious about the party scene, went to Rave parties with friends, and started to experiment with drugs. He was encouraged to experiment with drugs from an Internet chat room. Someone in this chat room told him where you could buy drugs and how to buy them on the Internet. He found that you could buy powerful narcotics on the Internet very easily, right out of his own house. It was like buying candy in a grocery store.

On February 11, 2001, Ryan had worked a full day at a retail store. He came home at around 8 p.m. and said he was hungry. I made him his favorite chicken soup in the crockpot. He told me his back was hurting because he had been moving plants at the nursery.

It was cold and raining outside. He asked if he could use my spa. He used my bath at around 10 p.m. for about 30 minutes, got out, and we chatted. We talked for a few minutes, and then he said he wanted to relax in his sister's room and play video games. His sister Natalie was away at college. He missed her, and he felt comfortable using her room for the television and video games.

About an hour later, just after midnight, I went to say goodnight to him in his room. He was just getting into bed and said he was going to listen to some music. Ryan loved all kinds of music--rap, techno. We share a common interest in our love for classic rock. I loved it that he loved listening to the Eagles and the Beatles with me. I told him I loved him, as I do every night, hugged him, and he said, ``I love you, too, Mom."

The next morning was a holiday, President's Day, so it was not unusual for Ryan to sleep in. I had 12 women showing up for dinner that night, so I had to go out and shop. My housekeeper was there, and I told her to call me if there was anything she

needed, and that Ryan would be sleeping in.

I got home about 3 o'clock that day and noticed Ryan's car still in the driveway. It had not moved, and I immediately felt something was wrong. I ran into his room and found that Ryan was not breathing.

I could not believe what I saw. I knew he was dead. I called 911 and tried to do CPR. I screamed and I cried, and I screamed and I cried, and I prayed for him to come back to life. I remember a paramedic pulling me off of him and looking into my eyes and saying, ``Oh, my God, I am so sorry. There is nothing we can do."

I thought how, how, how, could this happen? What happened?

The next thing I know, a sheriff is showing me a bottle, a bottle of hydrocodone, Vicodin. On the bottle, it says ``Mainstreet Pharmacy." He also shows me a bottle of morphine. I thought, no way. These are controlled prescription drugs. He said he found the drugs after searching his room. These are drugs under lock and key in hospitals. How did he get them--how?

We parents often worry about our children. When they are little, we worry they will fall and get hurt. But as they become teenagers, we worry even more. We worry that they will drink alcohol and drive and get into a car accident. We worry that they will smoke cigarettes and marijuana. We worry that they will try illegal street drugs such as cocaine, LSD, heroin, and others. We worry about porn and strangers that might hurt them on the Internet. But never did I worry about buying prescription drugs on the Internet.

After Ryan died, a friend of Ryan's called and told us that he got drugs off the Internet. Never did I think you could easily get prescription drugs on the Internet. I was in shock. Being an RN, I always thought that controlled substances were under lock and key.

Ryan was encouraged to obtain these powerful narcotics that required nothing but filling out a simple questionnaire on the Internet.

That week, Ryan's dad gave Ryan's computer to the DEA, and the investigation started. I have assisted in helping with the prosecution of these Internet drug dealers. They are just as bad if not worse than the drug dealers on the street.

Since then, from the evidence they got from the Internet, Clayton Fuchs and Dr. Robert Ogle were found guilty and pleaded guilty of selling drugs illegally on the Internet. They said

they did it just for the money.

An autopsy report showed that Ryan died from a drug overdose of hydrocodone, Vicodin, which was prescribed by Dr. Ogle and sent to him from Mainstreet Pharmacy. Why did they sell these drugs to my son? They both said they did it for the money.

Dr. Ogle had been to prison twice. Once, he served 3 years in a Federal penitentiary for illegally prescribing Quaaludes, a hypnotic sedative. Another time, for theft. But he still got his medical license back. He should have never gotten his medical license back.

I think Ryan, as most kids would, thought that since a doctor was prescribing the drug, it is a legal drug obtained with a prescription, then it must be safe. The drug was delivered to our home with no instructions, no safety precautions, no adverse reactions attached. Ryan received these drugs without ever seeing the doctor, and never had any follow-up.

The pharmacy delivered these controlled substances with no instructions and no questions asked. These money-hungry drug pushers of doctors and pharmacies have got to be stopped. They are making millions of dollars and are only concerned about the money. They do not care about the person ordering them.

There are over 500 rogue pharmacies on the Internet as I speak. Tighter regulations on our Internet need to be enforced with high penalties. I continue to receive emails from these pharmacies on a daily basis.

What our public do not know is that just because it says ``United States pharmacy'' does not mean it is coming from the United States. In fact, when you click on the site, it goes to other countries. They can buy from Canadian pharmacies and save money. But what they do not know is the risks that they are taking. Drugs are being distributed daily, like candy, and it is very dangerous.

RyansCause is an organization I have started--Reaching Youths Abusing Narcotics. Saying no to drugs is not enough. We are losing this war against drugs. President Bush in his State of the Union Address a few months back mentioned that drug use in our youth is down. He might be right about street drugs, but he did not mention the increased usage of prescription drugs. Prescription drug usage is up.

My hope is that with tighter restrictions on the Internet and more public awareness, we can save lives. I want to get

RyansCause brochures into every high school classroom. I want to talk and educate our youth and parents. This tragic death could have happened to anyone. Ryan was the boy nextdoor. We need to fight this war against drugs and save others.

With tighter regulations on the sale of prescription drugs on the Internet, it will make our increasingly technological world more safe.

I want to thank Senator Feinstein and Senator Coleman for introducing legislation to improve the safety of buying prescription drugs on the Internet. Internet pharmacies should be required to identify their business.

Our grief continues and extends beyond the immediate family. Ryan's grandparents, aunts and uncles, cousins and friends feel Ryan's death very deeply. Ryan will never see Jeremy play his clarinet, or take him out for ice cream. Ryan will never be able to sit for long hours and talk to his sister about what happened during his day. I will not see him graduate from college, attend his wedding, or be a grandmother to his children.

But we continue to water our white roses and drink our sprite with no ice in his memory. Ryan will be forever missed and will remain in our hearts forever.

Thank you for honoring my son Ryan by naming the important legislation you introduced after him.

Thank you for allowing me to tell my story in front of the Subcommittee.

Senator Coleman. Thank you, Ms. Haight and Ms. Carr. Again, my deepest personal condolences for your loss.

As the dad of an 18-year-old who loves the computer, your pain is more than an abstract story; it is very personal for a lot of people. So I do want to thank you for coming forward.

And Ms. Haight, I think in a very tragic way, but Ryan will make a difference in our world, and certainly I am committed to that, Senator Feinstein is, and many of my colleagues. So I hope that provides a little glow of warmth in what is a difficult situation.

Ms. Carr, I think you have with you some of the drugs that were received after your husband's death. Let me back up--did he have prescriptions for Darvon to be taken through a local pharmacy? Do you know what kind of prescriptions he had for painkillers?

Ms. Carr. At the time, I do not think he had any. He had not, as far as I know, been to a doctor for that. As a tri-

athlete and a mountain biker, he had had painkillers all his life, because he was always hurting himself--but not at the time that I know of.

Senator Coleman. Can you show us what you received?

Ms. Carr. OK. This is one of the packages that came after he died. I could tell immediately it was not a normal U.S. package. It has a little label on it from New Delhi, and it has all the weird stamps with the different kind of writing on it.

Do you want me to open this?

Senator Coleman. You can take it out.

Ms. Carr. And it was kind of strange when I first opened it. It comes in this wrapping, with scarves or something underneath it, and then you pull it out--professionally wrapped, you see--and it has a newspaper that is probably an Indian newspaper, and then more of that professional look, the cardboard, and then there is the pills.

Senator Coleman. No description of dosage or what it is?

Ms. Carr. No. This one did not even have--well, it has some label or something on there. But as far as----

Senator Coleman. But no instruction booklets or anything like that.

Ms. Carr. No instructions.

Senator Coleman. Did you have a chance to look at the Websites? I think you indicate that you saw some of them.

Ms. Carr. I did, because he not only used it on his computer, but he used it on mine, so I was able to go to a couple of the Websites--although by the time I got around to doing it, some of the Websites, you could not get to anymore, and you got the screen that says they are no longer available. But yes, I did look at some of them to see what was required to get something through them.

Senator Coleman. And there was another package you received, you said, or a series of some others?

Ms. Carr. Yes. This one was from Bangkok, just a small, little package. I did not even think it was prescription drugs, but it was one of the five packages that came. I opened it up, and it was really scary, because it looks like that was done in a garage somewhere--no labeling on it at all, nothing. I do not know why anyone would even put this stuff into their body. And it has some word on it, and I could not even quite read it, except it looks like it has a ``D'' and maybe a ``V'', and I am thinking maybe that was the Darvon; I do not know. But it was very scary.

Senator Coleman. Do you know if, on the Websites that you had a chance to look at, there was a discussion about prescription or anything of that nature?

Ms. Carr. No. The ones that I looked at did not mention anything about a prescription, and I am sure that--I mean, he had done a lot of research, and he was probably looking for places where he did not have to fill out a prescription.

Senator Coleman. And law enforcement's response in terms of your desire to deal with this, to shut it down, to impact it in some way--what kind of response did you get from law enforcement?

Ms. Carr. The only law enforcement I dealt with--I talked to the California Medical Board, and they had an investigator who was really good with the computer stuff. I gave him my husband's laptop, and he looked into it as much as he could. I gave him what documents I could. He wanted to find something, but he could only deal with doctors who were licensed in California. That was the extent of what he could do.

Senator Coleman. They had no other jurisdiction or control over anything.

Ms. Carr. No other jurisdiction. That is why he told me--he said something has to be done at the Federal level.

Senator Coleman. Thank you.

Ms. Haight, how was Ryan able to pay for the Vicodin and the morphine from this Internet pharmacy? Did you ever trace that back?

Ms. Haight. I believe he purchased it with a money order.

Senator Coleman. Money orders. Do you know if any credit cards were used at all?

Ms. Haight. I was told that there is a possibility that he bought it with a credit card, but I have not seen that. I believe it was a money order.

Senator Coleman. Did you ever talk to Dr. Ogle?

Ms. Haight. No.

Senator Coleman. Do you know whether he was subject to any criminal proceedings or any actions after your son's death?

Ms. Haight. Yes. He is actually in prison right now as we speak, awaiting sentencing.

Senator Coleman. What about the folks who own Mainstreet Pharmacy--did you ever identify them?

Ms. Haight. The pharmacy has been shut down, and Clayton Fuchs is also in prison at this time.

Senator Coleman. And Clayton Fuchs is the principal in

Mainstreet Pharmacy.

Ms. Haight. Mainstreet Pharmacy, yes.

Senator Coleman. Do you know anything about his background?

Ms. Haight. I do not know anything about his background.

Senator Coleman. You are reaching out with RyansCause. You are trying to reach youth that way. What do you recommend we do? If you had a list of one, two, or three things that we could do, both in dealing with the plague of predators that allow young people and others to buy quantities of narcotics that have deadly impact, without any conscience, but beyond that, are there other things that we can do to assist in your cause and the cause that you have dedicated yourself to?

Ms. Haight. I think by passing this bill, having tighter regulations, would definitely help, and being able to go in and make sure that these are legitimate pharmacies, legitimate doctors, that they have actually been seen by the doctor. I do not think any controlled substance or any mind-altering drug should ever be sold on the Internet--I do not care if you have seen your doctor or not--I think it should be done within a doctor's office.

Senator Coleman. Thank you.

Senator Pryor. Thank you, Mr. Chairman. I really just had one question for Ms. Haight, and that is a clarification.

Mainstreet Pharmacy was a U.S. company. Was that in California--where was that?

Ms. Haight. Texas.

Senator Pryor. And it was just a rogue pharmacy that was giving out drugs to whomever could pay for them?

Ms. Haight. They had actually made millions of dollars selling drugs throughout the United States and other countries.

Senator Pryor. That is all I have, Mr. Chairman. Thank you.

Senator Coleman. Thank you.

Again I want to thank both of the witnesses--Ms. Carr?

Ms. Carr. Could I just say that if you go ahead with setting up the safe pharmaceutical sites, I know that the way the Internet is, there will be other sites that are going to pop up out there, and people like my husband would have gone to those--they would have bypassed the safe ones. So on these safe ones, if you have some way of recognizing when the packages are coming in, because they are just coming in through the U.S. mail, so you have some special package that comes in, and all the other packages that come in, if you can detect drugs in them, they just do not get shipped, they do not get to their

destination.

Senator Coleman. You raise an issue that we are struggling with here. There will be a second hearing. I will have a hearing on July 22, and we will have representatives of the Postal Services, United Parcel Service, and FedEx there, to try to figure out how to deal with this.

The problem that we face, as you heard from the other witnesses, is the extraordinary volume. We have heard about millions of packages coming through--in single mail production operations in New York, 40,000 a day. And I have been there, and what they do at the post office is actually have a list of identified countries that they know are most problematic, so they are going to prioritize what they try to pull. But I just have a sense that we are trying to find needles in haystacks here. So it is extraordinarily challenging.

But at a minimum, we should do what we are doing in the Ryan Haight Act, which is requiring pharmacies that ship to be FDA-approved, require them to be subject to inspection, require that individuals have a patient-physician relationship and ensure that you cannot get prescriptions by filling out a form online. That is a joke. It is a sad joke. It is a terrible joke. It is a tragedy.

So we can do some of those things, but we are struggling with this, Ms. Carr. This is not something for which there is an easy answer.

You should know that I will be speaking with DEA Administrator Tandy next week, and I am going to follow up on what the DEA can do in dealing with your case, and Ms. Haight, we are certainly committed to the act named in memory of your son.

So I want to thank the witnesses, I want to thank my colleagues.

The record of this hearing will be kept open for 10 days.

Again, I want to thank the witnesses, and this hearing is now adjourned.

[Whereupon, at 11:38 a.m., the Subcommittee was adjourned.]

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET--FEDERAL AND PRIVATE SECTOR RESPONSES

THURSDAY, JULY 22, 2004

U.S. Senate,
Permanent Subcommittee on Investigations,
of the Committee on Governmental Affairs,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:05 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Norm Coleman, Chairman of the Subcommittee, presiding.

Present: Senators Coleman and Levin.

Staff Present: Raymond V. Shepherd, III, Staff Director and Chief Counsel; Katherine English, Counsel; Jay Jennings, Investigator; Mary D. Robertson, Chief Clerk; Elise J. Bean, Staff Director/Chief Counsel to the Minority; and Clare Diegel, Intern.

OPENING STATEMENT OF SENATOR COLEMAN

Senator Coleman. This hearing of the Permanent Subcommittee on Investigations is called to order.

Good morning and welcome to the Subcommittee's second day of hearings into the dangers associated with purchasing pharmaceuticals over the Internet.

According to a 2003 University of Michigan study, the painkiller Vicodin was second only to marijuana in illicit use by 12th graders. Federal statistics estimated that 6.2 million Americans misuse prescription drugs in 2002, compared with 2 million who use cocaine and 700,000 who use Ecstasy.

It is all too easy. Go online with your favorite search engine and type in ``purchase Vicodin,'' \1\ click onto a Website and you can purchase your Vicodin or the generic equivalent, hydrocodone, with a variety of credit cards including MasterCard, Visa, or American Express.\1\ No prescription is necessary. All you need to do is have an on-line consultation and your medication will be FedExed to you.

\1\ See Exhibit No. 24 which appears in the Appendix on page 309.

\2\ See Exhibit No. 26 which appears in the Appendix on page 311.

The first Internet pharmacies began on-line services in early 1999, and FDA estimated that 104 businesses were selling prescription drugs on the Internet by July of that year. In

1999, Americans spent an estimated $160 million on prescription drugs purchased over the Internet. By 2003, spending on Internet prescription drugs had grown to $3.2 billion.

By November 2000, the FDA had identified between 200 and 400 Internet pharmacies, as well as other Websites, where drugs were accessible with the click of a mouse. A new study by the National Center on Addiction and Substance Abuse at Columbia University identified 495 Websites advertising controlled prescription drugs during a one-week analysis. Of these, 157 sites that sold opioid-based drugs such as OxyContin, Percocet, and Darvon. Only 6 percent of the sites selling drugs required a prescription, and none took steps to prevent the sale of drugs to children.

Other evidence suggests the number of Internet pharmacies is much larger. The firm Cyveillance has identified 1,009 Internet pharmacies that purport to be Canadian pharmacies. Earlier this year, the FedEx brand appeared on 12,200 unique websites selling at least one of the 22 top-selling pharmaceuticals in a search by Nameprotect of its 400 million web page database estimated at one-tenth the size of Google's database.

At our first hearing on June 17, we heard the tragic story of two men who died from taking drugs they had purchased over the Internet. Seventeen-year-old Ryan Haight of La Mesa, California was an honor roll student and avid baseball card collector about to enter college. How did a healthy 17-year-old obtain prescriptions for painkillers without a medical exam? He got them from Dr. Robert Ogle, an on-line physician based out of Texas. With the bogus prescriptions from Dr. Ogle, Ryan was able to order hydrocodone, morphine, and Valium and have then shipped via U.S. mail to his front door. In February 2001, Ryan overdosed on a combination of these prescription drugs. His mother found him dead on his bedroom floor.

James Lewis, a tri-athlete, died of an overdose of Darvon on April 10, 2003. He purchased Darvon, as well as other controlled substances, from Internet pharmacies doing business in South Africa, Thailand, and Spain. Some Websites required James to fill out a short questionnaire before he could order the medication. Others required nothing.

Our investigation found that these are not isolated events. At my request, the General Accounting Office made purchases of pharmaceuticals from both domestic and foreign Internet Websites. With disturbing ease, GAO used the Internet to

purchase numerous prescription drugs, including highly addictive narcotics and other controlled substances. Notably, GAO purchased 66 percent of these pharmaceuticals, including narcotics, without a prescription and without visiting a doctor.

GAO also used the Internet to purchase from foreign pharmacies counterfeit versions of American drugs, pharmaceuticals that have not been approved by the FDA, counterfeit drugs, damaged products, and drugs without proper packaging, no warning information, or instructions for use.

As Chairman of the Permanent Subcommittee on Investigations, I endeavor to provide an objective snapshot of what drugs are available to consumers on the Internet by inspecting the operations at the JFK International Airport in New York, home to the largest international mail branch, IMB, in the United States.

Senior Customs officials at JFK estimated that 40,000 parcels containing drugs are imported through the airport each day. During last summer's FDA-Customs blitz, 28 percent of the drugs tested were controlled substances.

This means that as many as 11,200 drug parcels containing controlled substances, like the painkillers Vicodin and OxyContin are imported through JFK daily, 78,400 weekly, 313,600 monthly, and 3,763,200 annually. Top countries of origin include Brazil, India, Pakistan, Spain, Portugal, Canada, Mexico, and Romania.

FDA and Customs officials also regularly seize and inspect packages containing controlled substances like hydrocodone and generic Valium or Diazepam;\1\ counterfeit Viagra from India;\2\ injectable steroids from China;\3\ boxes of unidentified drug products;\4\ and drug packages without any of the required inserts that lack labeling and have directions for usage in foreign languages.

\1\ See Exhibit No. 3 which appears in the Appendix on page 288.

\2\ See Exhibit No. 5 which appears in the Appendix on page 290.

\3\ See Exhibit No. 6 which appears in the Appendix on page 291.

\4\ See Exhibit No. 7 which appears in the Appendix on page 292.

PSI staff made similar findings at the IMBs in Chicago and Miami.

Simply put, we are drowning in a flood of imported drugs of unknown composition and origin, as well as potentially lethal

controlled substances.

Given the overwhelming volume of drug products imported daily, FDA cannot fully process all the packages containing drugs. For example, at JFK, FDA inspectors can only inspect 200 packages daily. As a result, there is a significant backlog of product waiting to be screened by FDA.\5\ Because of the sheer volume of drug product, the FDA acknowledges the vast majority of prescription drugs that are illegally imported into the U.S. through JFK are not screened or regulated in any manner.

\5\ See Exhibit No. 10 which appears in the Appendix on page 295.

Unfortunately, the same is true for Customs. Despite yeoman efforts, because of the sheer number of controlled substances being imported, Customs can screen only a de minimis number of the packages that contain controlled substances.

In conjunction with Senator Levin and John Dingell, the dean of the U.S. House of Representatives, who was the author of the Prescription Drug Marketing Act, I asked the GAO to assess the steps taken by the Federal Government to address this problem. This effort is emblematic of the fact that this issue is not only bipartisan, it is bicameral. GAO confirmed what the Subcommittee has documented at five other sites:

There is no uniform approach to screening and processing imported pharmaceuticals, the quality and health risks associated with imported prescription drugs is unknown, there is no reliable estimate of the quantity of drugs being imported, and most disturbingly, more prescription drugs are released without ever being inspected.

The Federal Government has been on notice about this issue for at least 5 years. On July 30, 1999, representatives from FDA, Customs, and the Department of Justice testified at a hearing entitled, ``Drugstores on the Net: The Benefits and Risks of Online Pharmacies,'' before the House Oversight and Investigation Subcommittee. At that hearing, FDA announced that along with DEA and Customs they had formed an interagency working group to address the problem of on-line pharmacies. In addition, FDA testified that they had purchased a web crawler so they could have ``surveillance over the Internet.'' We will be able to refer controlled substances illegally offered for sale to the appropriate enforcement people.

Many of the initiatives that we will hear about today sound eerily familiar. I am concerned by the apparent lack of

progress in getting our arms around this glaring problem. Those charged with the responsibility to protect the American consumers from the illegal importation of controlled substances and counterfeit or unsafe drugs cannot allow themselves to fall victim to rapidly advancing technology.

Interestingly, in comparison to the Federal Government's response, the response of much of the private sector has been swift and proactive. For example, in response to news reports about the availability of controlled substances on the Internet, in November 2003 Yahoo! blocked all search terms related to prescription drugs for approximately 2 months while it determined what action to initiate. Yahoo! then contracted with a private company to ensure that Internet pharmacies which buy ad space on Yahoo! are legitimate and properly licensed.

Likewise, of its own accord, MasterCard initiated a campaign to identify sellers of OxyContin and Vicodin. MasterCard identified Internet sites that were offering these drugs and made dummy transactions. These transactions allowed MasterCard officials to identify the member bank where the merchant maintains an account. MasterCard then contacted the appropriate member bank and advised the bank of the need to, one, exercise due diligence to identify illegal activity; two, deny the use of MasterCard services if an Internet site was engaged in illegal activity; and three, to require the Internet site/merchant to demonstrate that its sales are legal.

Last, UPS is proactively identifying Websites that offer prescription drugs without a written prescription and that advertise the services of UPS. UPS provided PSI with a list of 105 such Websites. The same information was provided to DEA and FDA on February 20, 2004, with a request that they identify and address the sites that are offering illegal pharmaceuticals. Of these 105 Websites, 89 are still selling pharmaceuticals. I look forward to hearing what measures DEA and FDA undertook with this information.

The potential problems associated with the importation of controlled substances and drugs of unknown origin and composition are far-reaching. Teenagers are getting unfettered access to controlled substances. Patients are self-medicating and receiving medication that could be sub-potent, super-potent, stored in unsafe conditions, or even counterfeit. And unscrupulous drug dealers are getting rich preying on unsuspecting consumers in dire need of affordable medication.

We as a government must do all we can to ensure access to a

safe and affordable drug supply. DEA Administrator Tandy will testify that for consumers buying drugs over the Internet without a legitimate prescription are no safer than taking drugs offered to you by a street corner hustler. We have developed multiple strategies for controlling and shutting down the street corner hustler. We must approach Internet drug sales with the same vigor.

With that, I would look forward to a statement by my Ranking Member and distinguished colleague, Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator Levin. Mr. Chairman, thank you, first and foremost, for not just convening a second day of hearings into a very important subject, but also for your dogged determination to determine the extent of a real problem, which is the purchase of pharmaceuticals and prescription drugs over the Internet, as you have outlined, and to pursue solutions to this real problem. You are taking a leadership role here in the Senate. As you point out, it is both bipartisan and bicameral. There is strong support in the House for action, as well, for the reasons that you have given.

Last year alone, U.S. consumers purchased over $3 billion in prescription drugs from Internet pharmacies. Now, there are many reasons that consumers do this. Some of them are improper reasons, kids trying to get drugs they otherwise aren't going to be able to get and other inappropriate efforts to obtain pharmaceuticals and prescription drugs over the Internet in ways that can accomplish those goals for the people who are seeking those drugs.

But there are also appropriate efforts being made to obtain prescription drugs over the Internet. One of those appropriate reasons is the high cost of prescription drugs that drive Americans to take drastic measures to pursue lower-cost medications, including buying medicines from unfamiliar and sometimes shady Internet pharmacies.

Right now, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than the Germans, and twice as much as Italians. For average Americans suffering chronic illness, high drug costs are forcing some to choose between taking their medicine on any given day, paying their bills, or even buying food.

At the last hearing, the Subcommittee released a report by the GAO describing key problems that are created when people buy medicine from Internet pharmacies. The highlights of that report have already been reviewed by our Chairman, and I will leave my statement for the record to give some of the specifics of the GAO study.

But the picture that was painted raises a host of concerns and today's hearing examines what the Federal and the private sector are doing to protect the American public from unsafe and illegal prescription drugs purchased over the Internet. In its testimony, GAO is going to state that it concludes that very scarce resources in our agencies that are supposed to enforce our laws only selectively target packages by country of origin and other means, and they state that FDA officials acknowledge that tens of thousands of packages are allowed to reach U.S. consumers that violate current laws and pose public health risks.

Our agencies have a key role in overseeing pharmaceuticals which are shipped into the United States. Under one law, the FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. Under another law, the Drug Enforcement Agency is responsible for combatting illegal narcotics and the abuse of controlled substances. And under a third law, the Bureau of Customs and Border Protection is supposed to screen and stop unauthorized controlled substances at the border along with a wide range of other contraband. And the Postal Inspection Service is also charged with investigating the distribution of narcotics through the mail.

So we have got a number of Federal agencies that have a responsibility to protect Americans from unsafe and illegal pharmaceuticals, but as a matter of fact, we know that they are overwhelmed. They are flooded. They are unable to do the job which they must do to protect our people.

The Subcommittee staff that did this field work did not see a single FDA inspector during a 6-hour shift, even though the FDA is charged with helping Customs to look for unsafe and illegal pharmaceuticals. Customs agents interviewed by the staff indicated they had never met their FDA counterparts, even though the two agencies are tasked with coordinating their efforts to identify incoming drug shipments that could be seized and inspected more closely.

Mr. Chairman, because of the number of witnesses that we have, I am going to ask that the balance of my statement be

inserted in the record, but I want to just reinforce one point that our Chairman made about the risk to our children.

Right now, a 12-year-old juvenile can use a parent's computer to log onto an Internet search engine, as the Chairman has outlined, type in the parent's credit card number, and direct illegal controlled substances to be shipped to an address via commercial carrier the next day.

We have private organizations and businesses that are here today to help us understand what efforts they are making--and many of them are making great efforts to combat Internet sales of unsafe and illegal prescription drugs--and they will inform us as to how together we can more aggressively work to protect the public.

These responsibilities are vast. We are falling down in terms of carrying out these responsibilities. Our Chairman is taking a leadership role in trying to get us back on track, but more importantly to address a new kind of a problem and a challenge which is represented by the Internet. So Congress has some responsibility, and I congratulate you, Mr. Chairman, in helping us to understand where we are falling short and how we can carry out those responsibilities.

Senator Coleman. Thank you, Senator Levin, your entire statement will be entered into the record, without objection.

[The prepared statement of Senator Levin follows:]

PREPARED STATEMENT OF SENATOR LEVIN

Unapproved, misbranded, counterfeit, and adulterated prescription drugs are making their way into the United States, and I commend you, Mr. Chairman, for holding a second day of hearings to examine what we can do to reduce the various threats to the health and welfare of people buying pharmaceuticals over the Internet. Last year alone, U.S. consumers buying prescription drugs from Internet pharmacies spent more than $3 billion.

The high cost of prescription drugs continues to drive Americans to take drastic measures to find lower-cost medications, including buying medicines from unfamiliar and sometimes shady Internet pharmacies. Right now, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than Germans and twice as much as Italians. For average Americans suffering chronic illness, high drug costs are forcing some to choose between taking their medicine on any given day, paying the bills, or even buying food.

At the last hearing, the Subcommittee released a report by the Government Accountability Office (GAO) describing key problems created when people buy medicine from Internet pharmacies, and I'd like to recap a few of the highlights. GAO found that buying medications over the Internet was not difficult. GAO placed 90 on-line orders for prescription drugs and received 68 shipments, a success rate of 75 percent. Of those 68 medications, 45 were shipped illegally, because there had been no patient-provided prescription. Of those Internet pharmacies based in the United States, only 5 out of 29, or 17 percent, had required GAO to provide a patient prescription. Many of the shipped medications also arrived without Food and Drug Administration (FDA) required precautions such as patient instructions and temperature-controlled packaging.

Of the 68 shipments received by GAO, 48 were from U.S. or Canadian based Internet pharmacies, 18 were from foreign sites, and 2 could not be determined. Of the 18 foreign shipments, 3 were found to contain counterfeit medications, including 2 with incorrect but not necessarily dangerous chemical compositions, and one with no active ingredients at all.

Today's hearing examines what the federal and private sector are doing to protect the American public from unsafe and illegal prescription drugs purchased over the Internet. In its prepared testimony for today, GAO concludes that scarce resources have forced our enforcement personnel to ``selectively target'' pharmaceutical packages for inspection, and that most shipments reach the public without any federal oversight at all. GAO also states that federal officials acknowledge that tens of thousands of pharmaceutical packages that are allowed to reach U.S. consumers may violate current laws and pose public health risks.

Three federal agencies have key roles in overseeing pharmaceuticals shipped into the United States. Under the Federal Food, Drug and Cometic Act, the FDA is responsible for ensuring the safety, effectiveness and quality of domestic and imported drugs. Under the Controlled Substances Import and Export Act, the Drug Enforcement Agency (DEA) is responsible for combating illegal narcotics and the abuse of controlled substances. And under the Homeland Security Act, the Bureau of Customs and Border Protection (Customs) is supposed to screen and stop unauthorized controlled substances at the border--along with a wide range of other contraband. In addition to the FDA, DEA and Customs, the U.S. Postal Inspection Service is charged, among other tasks, with investigating the distribution of narcotics through the mail.

Each of these federal agencies has a responsibility to protect

Americans from unsafe and illegal pharmaceuticals, but it is clear that they are being overwhelmed by an increasing flood of pharmaceutical imports. Earlier this month, for example, the Subcommittee staff visited the Memphis International Airport in Tennessee to get a first-hand view of incoming shipments of pharmaceuticals. This visit follows earlier ones described at the last hearing to international airports in New York City, Miami, and Chicago. The Memphis airport is the primary commercial hub for Federal Express (Fed Ex), a commercial company that operates a major shipping business, including shipments from over 200 foreign countries. The Subcommittee staff observed the key 6-hour shift for incoming Fed Ex packages, from 9:30 p.m. to 3 a.m.

The Subcommittee learned that, at this commercial hub at the Memphis airport, approximately 740,000 packages arrive during a single night shift. Only 24 Customs agents were present at the hub to view these incoming packages. That meant each Customs agent had 6 hours to review about 30,000 packages. Those numbers made it impossible for the agents to give more than a cursory glance to pharmaceutical shipments, while also searching for such high priority contraband as narcotics, weapons, and terrorism-related materials.

The Subcommittee staff did not see a single FDA inspector during the 6-hour shift, even though the FDA is charged with helping Customs to look for unsafe and illegal pharmaceuticals. Customs agents interviewed by the staff indicated that they had never met their FDA counterparts, even though the two agencies are tasked with coordinating their efforts to identify incoming drug shipments that should be seized and inspected more closely. One Customs agent stated that he got his seizure directives from the FDA website, instead of communicating directly with an FDA agent. The FDA later told the Subcommittee that develops these directives by reviewing manifests for incoming shipments, and identifying about 25-30 packages per day to be held by Customs at the hub. The FDA indicated that it inspects these packages at a later time and determines how each should be handled. The FDA also indicated that, beginning in the fall, new funding would enable it to assign 2 FDA inspectors to help with incoming shipments at the Fed Ex hub.

It is also unclear whether federal agencies are working as effectively as they could with the private sector such as the Internet search engines that direct Internet users to particular on-line pharmacies, the credit card companies that approve payments to these pharmacies, and the shipping companies that move pharmaceuticals from Internet pharmacies to American consumers.

Right now, a 12-year-old juvenile can use a parent's computer to log onto an Internet search engine, type in the parent's credit card

number, and direct an illegal controlled substance to be shipped to an address via commercial carrier next day air. We need to learn from the private entities represented here today what steps they are taking to combat Internet sales of unsafe and illegal prescription drugs and how they can engage in more aggressive efforts with federal agencies to protect the public.

The agencies here today have vast responsibilities to protect Americans from illegal narcotics, weapons, human trafficking and terrorism. They are also charged with protecting the public from unsafe and illegal prescription drugs. That's a tall order, and Congress needs to exercise our oversight responsibility to determine what is being done, what can be improved upon, and how we can enable these agencies to do their jobs more effectively, including leveraging help from the private sector.

Congress also needs to bring down the escalating cost of prescription drugs in the United States. Chairman Coleman and I both represent northern border States, in which thousands of our constituents are already crossing the border to get their prescription medications from Canada--either in person or over the Internet. Folks are going to continue that conduct until prices become reasonable here at home.

Legislation has been introduced by Senator Dorgan and others to tackle this problem, but there is no sign that the Senate Health, Education, Labor and Pensions Committee plans to take up this legislation in the near future. The latest setback came yesterday, when that Committee postponed action on a more modest drug importation bill that had been scheduled for consideration. While weaker than the Dorgan bill, that legislation included some useful provisions, inspired in part by this investigation, authorizing the FDA to regulate the licensing of Internet pharmacies.

I look forward to the testimony today.

Senator Coleman. I would now like to welcome our first witness for today's hearing. I welcome Richard M. Stana, Director of the Homeland Security and Justice Team at the Government Accountability Office. Welcome, Mr. Stana.

Mr. Stana. Thank you.

Senator Coleman. As I mentioned in my opening statement this morning, in conjunction with the Subcommittee's June 17 hearing on this matter, GAO recently released a report on GAO's investigation of Internet pharmacy drug sales. The purpose of these hearings is to continue our examination of the extent to which consumers can purchase pharmaceuticals and controlled

substances over the Internet without a medical prescription, a medical diagnosis, and whether the pharmaceuticals that are pouring into the United States from foreign countries are counterfeit, unsafe, or illegitimate.

My distinguished Ranking Member talked about the issue of children. It is almost as if there is a candy roll out there for kids who want to get this, and not only is no parent not around, but if you have got Mom and Dad's credit card, you have access to it. Can we do something about that? We need to.

The purpose of today's hearing is to examine the Federal response and the private response to the problems highlighted at our June 17 hearing and to learn what Internet search firms, credit card companies, and package delivery services, whose participation is needed to complete these transactions, are doing to address the problem.

I appreciate everyone's attendance at today's important hearing and am anxious to hear the testimony this morning.

Before we begin, pursuant to Rule 6, all witnesses before this Subcommittee are required to be sworn. At this time, Mr. Stana, I ask you to stand and please raise your right hand.

Do you swear that the testimony you give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. Stana. I do.

Senator Coleman. Thank you, Mr. Stana. We will have a timing system today. When you see the light change from green to yellow, you have about a minute left. We will enter your complete statement for the record. So at that point, please summarize your testimony and then we will go to questioning after that. You have 5 minutes. You may proceed.

TESTIMONY OF RICHARD M. STANA,\1\ DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Stana. Mr. Chairman, Mr. Levin, I am pleased to be here today to participate in this hearing on prescription drug importation.

\1\ The prepared statement of Mr. Stana appears in the Appendix on page 178.

As you know, American consumers are increasingly drawn to the convenience, privacy, and cost advantages of purchasing

drugs over the Internet. But at the same time, there is growing concern that prescription drugs from Internet pharmacies are risky because they may be compromised or not the authentic product that you think you are going to get.

Further, consumers may also be violating the law unknowingly or intentionally by having these drugs shipped to the United States through international mail and private carriers. It is primarily the responsibility of U.S. Customs and Border Protection and the Food and Drug Administration to inspect and interdict prescription drugs and controlled substances that might be illegally imported into the United States via the mail or private carriers.

My prepared statement discusses these issues in detail and I would just like to summarize four main points.

First, as you mentioned in your opening statements, the amount of unapproved drugs illegally entering the country is said to be large and increasing. Owing to the popularity of Internet drug sales, large numbers of parcels arrive each day at the 13 international mail branches and 29 express consignment carrier facilities operated by private carriers like DHL or FedEx. Even though they are purchased from some sites that might be considered safe, the overall safety and quality of imported drugs, particularly those purchased from foreign-based sites, is not assured.

CBP did an analysis which demonstrates this, and Mr. Chairman, you also mentioned our previous work which showed that about 45 of 68 purchases we received were made without a prescription and 29 had labeling, packaging, and handling or other chemical composition problems. Some who feel they are getting reliable drugs at bargain prices might unknowingly be putting themselves at risk.

My second point is that many packages known to contain prescription drugs are released to the addressees with or without inspection. CBP officials told us that certain packages were targeted for inspection, but packages not targeted typically bypass inspection and are released to addressees. Many packages that were targeted by FDA and subsequently inspected were also later released to addressees. FDA officials acknowledge that they release tens of thousands of packages that contain drug products that may violate current laws and pose health and safety risks to consumers. This is because available staff are not able to process the volume of packages turned over to them for inspection.

For example, at one IMB, CBP targeted its efforts on packages arriving from 78 countries and forwarded to the FDA packages arriving from the eight countries it targeted for inspection. Packages coming from countries not targeted by CBP or FDA were not routinely inspected, and most continued in the mail. Further, FDA released to addressees some packages containing drugs that were not considered a priority and packages with drug amounts deemed for personal use.

At another IMB, if CBP's x-ray inspection revealed prescription drugs, FDA's instructions to CBP were to fill eight bins of packages twice each week, which would total about 3,000 packages. Once the capacity of the 16 bins per week was filled, other packages would continue on without inspection. At this site, FDA had the capacity to inspect about 140 of the 3,000 packages set aside each week and the remaining packages, 2,800 or so, were released without inspection, as were some of the 140 which were deemed not suitable for holding.

At another IMB, CBP officials told us that they usually released packages containing prescription drugs that appeared to be a 90-day supply or less, which they felt was in line with FDA's personal importation policy. At this facility, FDA officials told us that each week, CBP turned over to them hundreds of packages for inspection, but FDA had the capacity to inspect about 100 of them. They returned many of the other packages without inspection and CBP, in turn, released them to the addressees.

At the express consignment facilities, CBP and FDA relied mainly on reviews of manifests of incoming packages to determine which to inspect. Packages could avoid inspection if manifest information was not accurate. Further, as you mentioned, FDA officials are not on site to coordinate with CBP on targeting activities or random inspections.

My third point is that processing requirements are time consuming and can hamper enforcement efforts. CBP and FDA typically have about two to three staff each to perform the inspections and prepare the paperwork at each location. Processing for these packages can strain available staff, and staff are tied up processing as opposed to inspecting. An average inspection can take anywhere from about 10 to 15 minutes if there is not much to inspect or it is a known product, to 2 or more hours to fully investigate what is in the package. Similarly, CBP's seizure processes are time consuming, and because I need to sum up, I will not go into much detail on

those.

I do want to mention one other thing here which I think is very important. At one IMB, as an alternative to seizure, CBP headquarters approved returning 123 bins containing roughly 40,000 packages of Schedule IV controlled substances, including Valium, pain killers, and antidepressants, to the sender. The 123 bins amounted to a processing backlog of a year or more. According to CBP officials, most of these packages were sent by two companies located in two countries. This stop-gap action avoided the need to fully process the packages and store them for possible forfeiture and destruction, but it is not consistent with policy. We plan to pursue this further in the coming weeks and to see how widespread this action might be.

The last point is that, and I think you made this point, Mr. Chairman, purchasing prescription drugs from Internet pharmacies isn't new and concerns about importation have existed for many years. Action to mitigate this issue are still evolving.

There have been task forces created in the last year in response to Congressional mandates. CBP created a task force which looks very similar to the task forces created in the late 1990's that you have mentioned in your opening statement. It is too soon to tell whether these new task forces will have any better success than the old task forces in addressing this problem.

In closing, CBP and FDA are charged with the responsibility of inspecting and interdicting these drugs and they both have many dedicated staff that try their hardest to do what they can with limited resources. Although initiatives are underway to help either interdict the drugs or prevent their importation, it is too soon to tell whether these are going to have any better success than those that were started in the late 1990's.

This completes my oral statement. I would be happy to address any questions you or other Members of the Subcommittee may have.

Senator Coleman. Thank you very much, Director Stana.

As I read the report and listen to the testimony, it is somewhat mind boggling that we have a system of substances coming into this country, many of which we know are legal. We know from spot checks and searches that there is a substantial volume of material that is counterfeit, dosages not correct, and instructions not there, particularly as we deal with foreign countries, certainly countries outside the U.S. and

Canada. The information is a crap shoot. You don't know what you are getting. And yet we really don't have an effective system for monitoring and controlling that, do we?

Mr. Stana. The system that we have in place has simply been overrun by the volume of drugs coming in due to Internet purchases. There is a system in place as you are well aware. You have seen it at the mail branches and at the carrier facilities. But there just aren't enough people to manage it properly.

Senator Coleman. And I am not directly criticizing our folks who are out there making an effort. Now, I am going to talk about some areas where I do have concern a little later this morning, but I sense it is kind of like sand castles against the tide. It can be as pretty as--I have seen some pretty nice sand castles on the beach, but the tide keeps coming in and just overwhelms it and overwhelms it. Is that a fair assessment?

Mr. Stana. Well, one of the frustrating things is that this is a problem that has been known for many years, and as I pointed out and you mentioned, we started in the late 1990's to focus on the issue, but for too long we have been discussing what needs to be done and not taking appropriate action. Now the problem is much larger and much more difficult to----

Senator Coleman. That is where I want to go next. Help me understand the period from 1999 to today. In 1999, there was testimony before a House Subcommittee, Dr. Janet Woodcock discussing FDA actions dealing with the sale of illegal drugs over the Internet. There are discussions of something called the web crawler. Let me back up. What is a web crawler?

Mr. Stana. I believe, and I am not a technical expert, but what a web crawler does is it identifies certain sites that shouldn't be used for illegal purchases.

Senator Coleman. Are you familiar with FDA's results from using the web crawler?

Mr. Stana. No, I am not. I think you might better address that to FDA.

Senator Coleman. Do you even know if a web crawler was actually accessed?

Mr. Stana. My understanding is they tried to use it, but it didn't meet with the success that they anticipated.

Senator Coleman. And clearly, we go from 1999, when we raised this issue, to today, in which certainly the volumes has increased exponentially, the volumes of access to illegal

drugs. I am trying to understand what happened. I am trying to understand whether we started fast out of the gate and just slowed up, or whether we turned our attention elsewhere. Can you give me a kind of overview or summary of what happened in the efforts from 1999 and at what point it slowed up and what happened? Why aren't we in a better place today?

Mr. Stana. In 1999, FDA started with two task forces that looked similar to what was created just in the past few months. One had a working group on legal and regulatory issues. One had a working group on legal issues. Another had one on public education. And these are very similar to the kinds of working groups we have now.

On the positive side, what they did is they brought affected agencies together and they talked and to some extent coordinated, but there really was very little action taken there. It was more of a talking exercise, a coordination exercise. So not much has happened. And those efforts, while may be well intentioned, really didn't have much impact at the incoming facilities.

The more recent task forces have so far had maybe a little bit more impact in that there were a couple of blitzes done at three IMBs. They also did one at the border for incoming travelers. They posted Public Service Announcements. I was at a Giant a few days ago. There is a notice posted near the pharmacy there about the dangers of using Internet pharmacies. So it is having some impact. But the fact remains that if you need to stop this importation of dangerous and risky drugs, these approaches, while useful, aren't having the kind of impact that is needed to really mitigate the problem.

Senator Coleman. My question or comment is probably better directed to the agency heads, but as a policy maker, I have to reflect upon the question of why I should have confidence today on the formation of a new task force and efforts when we walked down that path 5 years ago and the problem is worse today than it was then.

Mr. Stana. Well, there is so much that we just don't know about the size and nature of this problem. We knew that we didn't know it 5 years ago. We still don't know it today. We don't know how many packages are coming into the country. We don't know how many are getting by without inspection. We don't know how many resources it is going to take to mitigate the problem. One estimate I saw, although I didn't get behind the numbers so I can't vouch for its accuracy, stated there are

about two million packages a year of illegal drugs coming into the country. That is a sizeable amount.

There is another estimate that each IMB site where FDA has its resources, instead of having three staff on each shift, needs ten staff on each shift. We haven't examined the basis for that figure, but it demonstrates that, clearly, there is a resource problem here.

Senator Coleman. Even if we were to increase the resources from three to ten, would it be fair to say that we would not have the capacity to investigate or review each and every parcel that came into the country, are the numbers simply too vast?

Mr. Stana. I don't know how many resources it would take to do that. Clearly, the law states that these packages are not to come into the country unless there are certain very careful prescribed exceptions that are met. But I don't have the number, whether 10 is the right number, 15 is the right number, or if it is a problem that 100 people couldn't solve.

Senator Coleman. I am just trying to look at the system we have, which is not unsystematic. Countries are highlighted that are known to be of greater risk, so it is targeted.

Mr. Stana. Right. It is a risk management issue.

Senator Coleman. You have got a risk targeted approach. But unfortunately, if a country is not a targeted country----

Mr. Stana. Right.

Senator Coleman [continuing]. You could be the worst business operator, the worst crook in the world, but if you are operating out of a country that is not targeted, you are essentially free from review at this time. Is that a fair statement?

Mr. Stana. That is correct at some mail branches, at some IMBs. It is totally targeted initially by country. That is the first cut. You might get picked up on a random search.

Senator Coleman. Talk to me about the random search. Are we talking needles in haystacks?

Mr. Stana. Yes, you are.

Senator Coleman. What are the chances of getting----

Mr. Stana. You are talking about gut feelings----

Senator Coleman. What is the mathematical chance of getting picked up in a random search?

Mr. Stana. Very small. I don't have the exact number, but very small.

Senator Coleman. Infinitesimal. Microscopic.

Mr. Stana. It would be very small, certainly less than 3 percent.

Senator Coleman. I would think less than perhaps----

Mr. Stana. One percent, perhaps.

Senator Coleman. Maybe a percentage of 1 percent.

Mr. Stana. But to amplify your underlying point, even in areas where CBP and FDA target countries, just because you are in one of the 70-some countries that CBP targets at one facility, that doesn't mean your package is going to be fully inspected because there are limits to the capacity. At the other IMB where inspection is a function of volume, if your package is in the 16 bins, it might be inspected, but the fact of the matter is, on average, of those 16 bins, your package in one of the bins is going to be inspected. The other ones are going to be returned without inspection.

Senator Coleman. What is your response to, or your analysis of, the different approaches per IMB? Would you suggest that it would make better sense to have a more uniform approach for the agency?

Mr. Stana. Yes. I think it would be beneficial to use a more consistent and uniform risk management approach from IMB to IMB that focuses in inspections, based on inspection statistics and experience--what are the more important packages to look at. Right now, we have an inconsistent policy.

FDA has just come up with an SOP which is intended to provide a uniform inspection process. The problem is, without more resources, all you are doing is creating a uniform process which in the end returns packages to the mail without inspection.

Senator Coleman. At one point, you talked about a situation, I forget the company, with a number of bins that were returned to sender.

Mr. Stana. Yes. That was that one IMB where there was about a year or more backlog of controlled substances. These were Schedule IV controlled substances. The staff at the facility felt that in the interest of the government they would not spend time processing these packages. As an alternative to seizure, they sent them back to the originating pharmacy. Clearly, a controlled substance is supposed to be seized. It is not supposed to be returned to sender without proper processing. They phoned headquarters and headquarters approved the return of the packages to the senders.

Now, by doing this, they missed a couple of opportunities.

One, they missed opportunity to gather further intelligence on exactly who the sender, receiver, and shippers were. And second, when they do seize a package, they are supposed to tell the person who ordered it--the addressee--that he or she was performing an illegal act and the next time they do this the CBP will take action on it. That could act as a deterrent for future purchases. So they missed that opportunity, too.

Senator Coleman. When you talk about missed opportunity, was there anything they did in returning it to the sender that would have precluded that sender from reselling it, from reintroducing those drugs back into the marketplace?

Mr. Stana. Not that I am aware of.

Senator Coleman. So the sender sold it and made their money, I presume. There is no COD here. You are paying up front. So they made their money and then they received back the goods with the complete freedom to resell them again.

Mr. Stana. There is a possibility, unless there is something that happened that I am not aware of, there is a possibility they could be reintroduced to the market.

Senator Coleman. When you say something happening, was there any coordinated enforcement action against these sellers? Was there anything that identified this list of sellers and then asked folks to go back and to proceed with some action against them?

Mr. Stana. I am not aware of any. Records were not kept on these 123 bins and the 40,000 packages in them. What I know is they were predominately from two countries and they were from two companies within those two countries.

Senator Coleman. I find that of concern. It is like busting a drug dealer and giving him back his drugs without any follow-up. And I understand administratively we are faced with what to do with these things. But on the other hand, giving it back to somebody who is already breaking the law----

Mr. Stana. As you know--you visited the New York facility--there are seizure rooms with dozens and dozens of seized goods waiting for some sort of disposition. These were over and above that. But I didn't want to leave the impression that all controlled substances were returned to sender.

Senator Coleman. But there were. We are looking at a picture \1\ taken at JFK. Approximately 20,000 boxes of suspected controlled substances seized by Customs are awaiting processing.

\1\ See Exhibit 14, which appears in the Appendix on page 299.

Mr. Stana. Right. It would look like that. There were 123 bins in an open area with bags in them that looked similar to those.

Senator Coleman. And we clearly don't have the resources to do those inspections, to process that.

Mr. Stana. Well, they said that it was a year, maybe 2 year's worth of processing backlog given the current required procedures and available staff.

Senator Coleman. Let me ask you a question. You talked about express facilities at one time. Are you talking about private operators?

Mr. Stana. Right, FedEx, DHL, UPS, those facilities.

Senator Coleman. And their representatives will be here and I appreciate that. They have manifests. Now, manifests means that somebody is declaring that this is a controlled substance----

Mr. Stana. Someone is to declare what good is inside, and certain characteristics like weight, volume, and so on.

Senator Coleman. So the sender, the wholesale, whoever is selling the drugs, would typically have to declare.

Mr. Stana. Yes.

Senator Coleman. But if they don't declare, then we are stuck with the same situation we see with Postal. There is no way to readily identify.

Mr. Stana. Well, again, they may be picked up in a random search, but it is not likely. The other thing is, because FDA is not on site at the same time CBP is--they work different shifts, FDA works primarily during the day and CBP works at night--they can't be there side-by-side to coordinate what these random searches might focus on.

Senator Coleman. But you are depending upon the credibility, the good word, the willingness of somebody to subject themselves to review and investigation by the nature of declaration, knowing that if they don't declare, then all they have got to do is gamble, and the odds are substantially in their favor because the odds of getting picked up in a random search are so small.

Mr. Stana. Any kind of cargo, whether it is ocean-going cargo, air freight, whatever, is subject to the same risk here. The veracity of manifests is a longstanding problem.

Senator Coleman. And particularly in an area where it would

be different if there are manifests where you are not dealing with substances that are subject to seizure, that are potentially illegal. In fact, in the kind of spot searches that we have done, we have seen significant percentages of drugs which are controlled substances which are not in this country legally. So it is almost as if going across the border, you are telling the drug dealer, tell us what drugs you have.

Mr. Stana. Well, that is true, but in reviewing the manifests, the FDA people are also looking for other things, like certain structured shipments or a certain address they received a tip on. CBP inspectors might also have a gut feeling about a shipment where the weight doesn't match the description of the goods. So it is not strictly on the declared item, but that is a big part of the targeting.

Senator Coleman. I am looking, just trying to figure out if there are solutions here, trying to sort out the purpose of what we are doing here. One of the thoughts is to give Customs the ability to seize and destroy. So in other words, instead of sending back these 123 bins, if they could be identified as controlled substances which are, per se, illegal, they could have the ability for on-site destruction. Your reaction to that proposal?

Mr. Stana. Obviously, it would require a change in law. But at the same time, if that were enacted, it would certainly reduce the backlog and make the whole process more manageable. We haven't really examined all the pros and cons to it, but on the face of it, it would solve one problem. I don't know if it would create another.

Senator Coleman. I would, at some point, like you to be able to do that. Again, I am looking for solutions.

If there were a few other obvious things based on your study and your review, changes in the law that would improve our ability to provide a greater measure of safety for American consumers in this area?

Mr. Stana. Well, I think some of the initiatives that are underway are going to help, like consumer education, alerting people to the fact that this is just not getting the same drug at a bargain price, that there are health risks. Having looked at the table at the John F. Kennedy International Airport and saw what was on it, I would never put that stuff in my body. I think just getting that kind of word out is very important.

On the enforcement side, we talked about several options, including more people and maybe a summary destruction of

illegal shipments. Another option is a summary return to sender; that wouldn't take the drugs out of the commerce chain, but it does make it more expensive for an Internet pharmacy to operate. There are other options that have been proposed that we are trying to get more information on, like working with the credit card companies, as you mentioned, to stop purchases from seemingly illegal sites, and identifying those sites that appear to be in safe countries but are actually located elsewhere and are selling dangerous drugs.

Senator Coleman. Aren't we also faced with the problem today of sites that are located in safe countries, located in Canada----

Mr. Stana. Or in the United States.

Senator Coleman [continuing]. Or the United States, but are getting their drugs from unsafe countries.

Mr. Stana. I don't know if U.S. pharmacy outlets are getting from third countries, but when we made our purchases of drugs from U.S.-based Internet pharmacies, we also found problems with the drugs. But your point is correct. There are Internet drug sites that mask their actual locations. I read about one site that posed as a Canadian site with Canadian flags on the web page but the orders were filled by a pharmacy in China.

Senator Coleman. And the consumer has no way to distinguish between an all-American Drugs-dot-com coming from Fiji or Thailand----

Mr. Stana. Not without a lot of sophisticated research. They can be pretty well masked. Of course, there are two dimensions to this problem and you mentioned them both. One is the well-intentioned consumer like you or me that just wants a bargain drug. The other involves, for example, the kid who wants to get high and sees ordering from the Internet pharmacies as an easy way to do it. Too often, we focus on the former, and that is part of a great national debate about trying to lower drug prices. But the latter is also very important and plays right into this issue.

Senator Coleman. In 1999, this issue was reviewed. Folks came before a House Committee, talked about task forces, talked about reviews, talked about web crawlers. We had a series of hearings. I believe Judiciary had a hearing just a couple weeks ago. What advice or direction would you give to some of the other witnesses who are coming before us from the FDA and Customs and Postal and the private folks? What advice do you

give them to help raise the prospect of not coming back in another 5 years, because if we come back in another 5 or 6 years and I am still here, I am going to be very angry.

Mr. Stana. Well, I think that this problem grows exponentially. It doesn't grow on a straight line. With the growth on the Internet, I think you would not see anything but a tremendous growth in the future.

I think really that the core solution is getting a consensus and a commitment to address this problem and do what it takes to get on top of it. I don't know if FDA and Customs and now CBP have asked for more resources or if they haven't, whether any requests for more resources have been denied either by the past couple of administrations or by appropriators. But clearly, there has to be a demonstrated commitment to address the problem. There are a lot of really hard-working people that are trying to do the best that they can with the resources they have. We don't want to create a cynacism because they are being put on the line with an impossible task that they are never going to have the resources to adequately addrss the problem.

Senator Coleman. I appreciate that, Director Stana. Thank you. Your testimony has been very helpful.

Mr. Stana. Thank you very much.

Senator Coleman. I would now like to welcome our second panel to today's hearing. Our second panel is comprised of representatives of the law enforcement and regulatory community, the Drug Enforcement Administration, the Bureau of Customs and Border Protection, the U.S. Postal Service, and the Food and Drug Administration.

I would like to welcome the Hon. Karen P. Tandy, the Administrator of the Drug Enforcement Administration; Lee R. Heath, Chief Postal Inspector for the U.S. Postal Service; Jayson P. Ahern, Assistant Commissioner at the Office of Field Operations at the Bureau of Customs and Border Protection; John M. Taylor III, the Associate Commissioner for Regulatory Affairs at the Food and Drug Administration; and finally William Hubbard, Associate Commissioner for Policy and Planning at the FDA.

As previously mentioned, the purpose of this hearing is to examine what role the FDA, the Bureau of Customs and Border Protection, the U.S. Postal Service, and DEA play in preventing the illegal importation of scheduled pharmaceuticals and pharmaceuticals that violate the Food, Drug, and Cosmetics Act, and whether the pharmaceuticals that are pouring into the

United States from foreign sources are counterfeit, expired, unsafe, or illegitimate. Again, I appreciate all of your attendance at today's important hearing and am anxious to hear your observations on the current state of affairs.

But before we begin, pursuant to Rule 6, all witnesses that testify before the Subcommittee are required to be sworn. At this time, I would ask you all to please stand and raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. Tandy. I do.

Mr. Heath. I do.

Mr. Ahern. I do.

Mr. Taylor. I do.

Mr. Hubbard. I do.

Senator Coleman. I think all the witnesses here are aware of the timing system. When the lights go from green to yellow, you have about a minute left to conclude. Your complete written statements will be entered into the record.

Administrator Tandy, we will have you go first, followed by Mr. Heath, Mr. Ahern, and finish up with Mr. Taylor and Mr. Hubbard. After we have heard all your testimony, we will proceed to questions. With that, Administrator Tandy, you may proceed.

TESTIMONY OF KAREN P. TANDY,\1\ ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

Ms. Tandy. Thank you, Chairman Coleman. The DEA appreciates your leadership on this issue, Mr. Chairman, as well as the other Members of the Subcommittee, and I thank you for the opportunity to discuss what is clearly a growing threat of on-line purchases of pharmaceuticals.

\1\ The prepared statement of Ms. Tandy appears in the Appendix on page 202.

In the 21st Century, the Internet is becoming the cyber street corner where dangerous and addictive drugs are bought and sold. Pharmaceutical drugs are peddled by multi-million dollar organizations, albeit the same as Internet drug lords, who are as sophisticated as traditional drug cartels.

Prescription drugs are not the only drugs being peddled by criminals on the web. I want to share with you an operation that just concluded. It was conducted yesterday, and successfully so, by DEA along with my colleagues at this table from Homeland Security, Immigration and Customs Enforcement, FDA, U.S. Postal and Inspection Service. Together, we targeted on-line sellers of illegal designer drugs in Operation Web Trip. We arrested ten Website operators who were distributing highly dangerous designer drug analogs. DEA issued one restraining order, executed one search warrant, and obtained three voluntary terminations of five targeted Internet domains. Users refer to these analog drugs, designer drugs, as Foxy, Methoxy, or DIPT, and too many young people tragically believe that these designer drugs are legal substitutes for Ecstasy or LSD.

In reality, these drugs are research chemicals with no medical use, and when consumed, they produce hallucinogenic effects and users often exhibit violent behavior. These are volatile, powerful drugs that are not meant for human consumption. If users ingest as little as five milligrams too much, fatality can result.

The Websites that were targeted in Operation Web Trip sold substances that led to the fatal overdose of at least two people and many more non-fatal overdoses. This operation demonstrates that we together will shut down these Websites and arrest those behind them.

Rogue Internet pharmacies have also claimed too many unsuspecting victims. DEA's investigations have discovered 14 deaths or overdoses and 15 people who have entered treatment or sustained injuries from drugs obtained over the Internet. With the click of a mouse, consumers are buying controlled substances over the Internet without a legitimate prescription. Physicians associated with these Websites almost never establish a proper diagnosis through the use of accepted medical practice. In short, there is no authentic doctor-patient relationship. Visitors to these pharmaceutical Websites are, in essence, helping themselves to controlled substances. Consumers are subject to habit-forming drugs, dangerous drug interactions, and counterfeit or tainted products.

The Bush Administration has implemented a coordinated strategy announced this past spring to deal with the abuse of prescription drugs. For our part, DEA is targeting the diversion of drugs using the Internet by utilizing additional

tools that Congress has given to us. Appropriations for this fiscal year included 63 additional positions dedicated to our Internet initiative, which targets rogue pharmacies and affiliated doctors and has resulted in 91 active investigations involving the diversion of pharmaceutical controlled substances using the Internet, and those investigations cover some 537 Websites currently.

This fiscal year, we have shut down 25 Internet pharmacy organizations. Over $3.3 million has been forfeited, and 3.2 million dosage units have been seized. Eleven million dollars in assets are pending forfeiture currently.

In addition, Congress provided $6.3 million to DEA to put into place sophisticated technology to track down these rogue Internet pharmacy Websites. We are also using the Internet itself as a tool. DEA is working with major search engines and Internet service providers to warn consumers searching for controlled substances of the dangers, and we have recently established a link to DEA's home page that allows citizens in this country and others who access that home page to report suspicious Internet pharmacies, which is an initiative that has also brought us investigative leads.

The scope of this problem is too broad for DEA or any one of the single agencies before you to tackle alone. We are enlisting the support of the private sector, the legitimate businesses essential to the on-line trade in diverting pharmaceutical drugs through the Internet.

For example, we are working with FedEx and UPS, who are acutely aware that their businesses are being exploited and alert us with any unusual patterns. Similarly, consistent with my emphasis and this administration's emphasis on taking away the proceeds of the illicit drug trade, both Visa and MasterCard are assisting us in investigations and with financial leads. Both shippers and credit card companies have agreed to shut down sites determined to be conducting illegal activities.

And as this Subcommittee has noted, a significant aspect of the pharmacy problem is located abroad. The DEA is cooperating with our Federal and foreign counterparts and we have assumed a leadership role in the international forum on Internet diversion.

We look forward to working closely with you, Mr. Chairman, and with the Congress to ensure that the Controlled Substances Act addresses illegal Internet pharmacies as vigorously as we

intend to address them through our enforcement efforts, and I would be happy to answer questions at the appropriate time. Thank you.

Senator Coleman. Thank you very much, Administrator Tandy. Mr. Heath.

TESTIMONY OF LEE R. HEATH,\1\ CHIEF INSPECTOR, U.S. POSTAL INSPECTION SERVICE

Mr. Heath. Good morning. As Chief Postal Inspector, I appreciate you giving me the opportunity to present the views of the U.S. Postal Service regarding this growing concern and the role the Postal Inspectors play in combatting it.

\1\ The prepared statement of Mr. Heath appears in the Appendix on page 206.

The responsibility for safeguarding approximately 200 billion pieces of mail a year and ensuring America's trust in the Postal system falls on the shoulders of the U.S. Postal Inspectors. I have submitted a written statement which highlights what we have done and continue to do with regards to illegal narcotics, child pornography, and other dangerous mailings. It outlines what we are doing and will do to better address today's issue.

There are numerous items prohibited from being sent through the mail under various sections of Title 18 of the U.S. Code. For instance, it forbids the mailing of lottery tickets or other gambling instruments. Customs agents open suspected foreign lottery mailings upon entry into the United States and then refer the mailing to us, since we have the primary enforcement jurisdiction. Using our existing authority, Postal Inspectors obtain destruction orders for this lottery mail to disrupt the operation.

We have met with the Postal Service General Counsel to explore applying our existing statutory authority to declare illegally mailed drugs in violation of the prohibition against dangerous mail. This strategy would enable us, working with FDA and Customs, to handle these items in a manner similar to what we do with lottery mailings.

To be successful, we must rely on the cooperative efforts of Customs and the FDA. Controlled substances may be mailed if they are not otherwise banned by Title 21 of the U.S. Code and

are packaged in accordance with the Controlled Substance Act. Prescription drugs may be sent through the mail as long as the inner packaging is labeled to show the name and address of the dispenser and the label conforms to the other requirements. The outer wrapper has to be free of content markings.

This requirement creates an enforcement difficulty for Postal Inspectors acting alone. However, I am confident that we can overcome such challenges with the assistance of Customs and FDA using their existing authorities. Without these agencies, it is difficult, if not impossible, for us to articulate the probable cause necessary to secure a Federal search warrant based solely on the exterior appearance of the package or the mailing or the country of origin.

Since meeting with the Subcommittee on June 18, Postal Inspectors have met with our law enforcement and regulatory partners. We asked to be included in the standing working groups focusing on on-line drug sales.

We also conducted an assessment of the extent of the problem at the Miami, New York, Los Angeles, San Francisco, and Chicago International Mail Service Centers to develop strategies to address this problem with the interagency task forces. We proposed to the task force our intent to host a conference of the interested agencies from each of the International Service Centers to develop a strategy to combat this problem.

Finally, as the Chief Postal Inspector, I also serve as the Chairman of the Postal Security Action Group of the Universal Postal Union. The Universal Postal Union is the regulatory organization for all postal administrations, and the Postal Security Action Group is made up of approximately 75 international postal administrations. One of our major efforts since September 11 has been to promote and adopt measures which are designed to keep the mails of the world free from dangerous goods. I will obtain the necessary information from Customs and the FDA with regards to target countries and raise this issue with the other foreign postal administrations.

The Postal Inspection Service will do whatever it can to better address the problem of illegal drugs and illegally imported drugs in the mail. We remain greatly dependent on those agencies which have the primary jurisdiction in these matters and I am confident that we can work with them to overcome any obstacles.

I appreciate your recognition of the importance of this

issue and the support shown by all of you. Thank you.

Senator Coleman. Thank you very much, Inspector Heath. Mr. Ahern.

TESTIMONY OF JAYSON P. AHERN,\1\ ASSISTANT COMMISSIONER, OFFICE OF FIELD OPERATIONS, BUREAU OF CUSTOMS AND BORDER PROTECTION

Mr. Ahern. Good morning, Mr. Chairman, and thank you very much for the opportunity to testify here today. I would like to discuss with you CBP's ongoing efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products and controlled substance into the United States.

\1\ The prepared statement of Mr. Ahern appears in the Appendix on page 218.

Although the main focus of CBP has shifted to protecting the United States from terrorist attacks, CBP also enforces over 400 requirements from more than 40 agencies at our U.S. borders. These include the laws that prohibit the importation of illegal and unapproved pharmaceuticals that fall under the jurisdiction of the FDA, as well as those controlled substances that are under the jurisdiction of the Drug Enforcement Administration.

The issue of U.S. consumers buying prescription drugs from foreign sources have become a significant concern to CBP, and a growing number of Americans obtain their medications from foreign locations, often seeking out suppliers in Mexico and Canada, as well. However, the safety of the drugs purchased from these sources cannot be ensured.

CBP is concerned with several ways that pharmaceuticals are imported, including those that are purchased through the Internet and shipped through our international mail or express courier facilities, those carried by individuals across the U.S. borders, and also bulk shipments of adulterated or counterfeit pharmaceuticals. During the course of the past year, we have taken some steps to address each of these areas of concern.

Millions of packages, though, come through our mail and express courier facilities each year and thousands of these packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. Additionally, we have

found bulk pharmaceutical shipments that were attempted to be imported through the mail, potentially indicating that these products could be making their way to pharmacy shelves.

The volume of the imported material brought into the United States via the mail is overwhelming. The international mail poses also several unique challenges to CBP, since it is not accompanied by any electronic manifest information.

While we do not have statistics on the total number of imports of controlled substances or pharmaceuticals that enter the country each year, the U.S. Postal Service estimates that over 400 million pieces of mail enter the United States through our international mail branches each year. It is also significant to note that during fiscal year 2003, Customs and Border Protection made over 24,000 seizures of mail, and during this period, of those 24,000, 12,353 were pharmaceutical and controlled substances.

At the express consignment facilities that we staff, there are over 46 million packages arrive, with Customs and Border Protection making over 4,900 seizures, of which 1,543 were related to pharmaceuticals or controlled substances.

In order to address some of these challenges, we recognize certainly there is a significant threat growing to the public's health and CBP has been working very cooperatively with the DEA, the FDA, the U.S. Immigration and Customs Enforcement, ICE, and the U.S. Postal Inspection Service, and now the offices of the National Drug Control Policies have become involved, as well. We have directed these issues related to the importation of prescription drugs and miscellaneous pharmaceuticals. The goals of this interagency working group are to create a strategy for enforcement, interdiction, and disposition of unlawful pharmaceuticals entering the United States and to develop proposals for joint enforcement operations at our ports of entry and mutually agreed upon policies to unauthorized importations.

Since a large percentage of pharmaceuticals and controlled substances arrive through the mail and by express consignment, a separate working group has also been created to address these areas. The working group was charged with reviewing and revising procedures used at international mail and express consignment operator facilities in addition to assessing resources used at these locations. CBP is currently working with the FDA to develop standard operating procedure for mail operations.

On the concrete results of the mail and express task force is the coordination of the effort that is being conducted at all of our international mail branches this year. The operation's goals, called Operation Safeguard, is to identify the type and the volume and the quality of the pharmaceuticals imported into the United States. This enforcement effort found the volume of pharmaceuticals shipped through the international mail to be enormous. We have also found that a significant number of these do not contain any active pharmaceutical ingredient but merely contain substances such as starch and sugar.

The latest blitz that was conducted in June uncovered a substantial volume of controlled substances, and of the packages that were examined, 46 percent are suspected to contain controlled substances and these products were seized.

The working group has also conducted regular meetings since January 2004 and several key accomplishments have also been created through the reimplementation of Operation Safety Cap, which is designed to look at passenger importations of pharmaceuticals from Mexico. Safety Cap was an agency-wide plan to enforce laws related to the importation of prescription drugs at the border. Both FDA and ICE also participated in this enforcement operation and this plan continues to develop for further locations along the Southwest border, which we have done four to date. We will also turn to the North and look at crossings coming across the Northern border from Canada.

In conclusion, it is clear that the importation of the pharmaceuticals and controlled substances remains an overwhelming problem for Customs and Border Protection. We are committed to continue to work with the FDA, the DEA, ICE, and other regulatory agencies to develop a more practical and workable approach to solving this problem.

I want to thank you and the Members of this Subcommittee for including Customs and Border Protection in your review of importation of pharmaceuticals and I will be happy to take any questions later.

Senator Coleman. Thank you, Commissioner. Mr. Taylor.

TESTIMONY OF JOHN M. TAYLOR, III,\1\ ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. Taylor. Mr. Chairman, before I begin, I would like to

ask that some additional and updated enforcement cases be included in the record along with my written statement.\2\

\1\ The prepared statement of Mr. Taylor appears in the Appendix on page 227.

\2\ Additional FDA Enforcement Actions appears in the Appendix on page 283.

Senator Coleman. Without objection.

Mr. Taylor. Thank you, sir. Mr. Chairman, I appreciate having this opportunity to discuss with you issues related to on-line pharmacies and importation of prescription drugs to the United States. Despite the many proposals that would legalize the importation of prescription drugs, FDA continues to have serious public health concerns about the importation of drugs outside the current safety system established by Congress under the Food, Drug, and Cosmetic Act.

When it comes to buying drugs absent our existing regulatory protections, FDA has consistently concluded that it is unable to endorse a ``buyer beware'' approach. Currently, new drugs marketed in the United States, regardless of whether they are manufactured here or in a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must be produced in inspected manufacturing plants that comply with good manufacturing practices, and the shipment and storage of these drugs must be properly documented and, where necessary, inspected.

Unfortunately, the drug supply is under unprecedented attack from a variety of progressively more sophisticated threats. For example, FDA's counterfeit drug investigations have risen fourfold since the late 1990's. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs.

For example, FDA recently worked with domestic and international authorities to shut down a Website advertising FDA approved and safe European birth control pills and other drugs, but they were actually importing ineffective counterfeit products. FDA believes this Website and the four Websites that FDA knocked out in February 2004 that were selling contraceptive patches are indicative of the dangers consumers face when they purchase drugs over the Internet.

Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that

are not operated by pharmacies properly licensed under State pharmacy laws. When consumers take such medications, they face the risk of subpotent, contaminated, counterfeit product, dangerous drug interactions, and/or suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, patients may suffer complications from the illnesses that their prescriptions were intended to treat without ever knowing the true cause.

Due to the huge volume of drug parcels entering the United States through international mail facilities and courier services, the requirements for notice and hearing, and FDA's limited resources, it is difficult for FDA to obtain and refuse the many mail imports consisting of individual small quantity shipments. As a consequence, tens of thousands of parcels that FDA is not able to review as a result of its limited enforcement resources and competing priorities are eventually released by FDA and the Bureau of Customs and Border Protection, even though the products contained in the parcels may violate FDA statute.

While we do not believe that this is an acceptable public health outcome, it is one which presents a significant challenge to the agency. We have responded to this challenge by employing a risk-based enforcement strategy, the refinement of which is ongoing, to target our existing resources effectively in the face of multiple import priorities, including homeland security and food safety.

To enhance our ability to effectively carry out this task and to assess the extent of the problems posed by imported drugs, CBP and FDA conducted import blitzes at four international mail facilities last summer. We found that 88 percent of the drug products we examined were unapproved or otherwise illegal. Examples of the potentially hazardous products encountered during the blitz included drugs never approved by FDA, drugs requiring careful dosing, drugs withdrawn from the market, drugs with clinically significant drug interactions, drugs with inadequate labeling, drugs inappropriately packaged, drugs requiring initial screening and/or close physician monitoring, and controlled substances.

CBP and FDA performed another round of blitzes at four international mail facilities and at several courier hubs in November 2003, resulting in similar findings. CBP and FDA continue to perform blitzes which help quantify the type of drugs coming into this country, identify the public health

issues surrounding these products, and identify trends in illegal importation of unsafe drugs. The results enable us to strategically focus our investigatory and regulatory resources and drive our efforts to reevaluate, refine, and improve the programs and procedures used to ensure the availability of safe and effective drugs to U.S. consumers.

As a result of these efforts, the agency has finished drafting procedures that encompass the best and most effective practices identified from our operations around the country. These procedures will be used by all FDA personnel responsible for handling mail at the international mail facilities and at the air courier hubs. We have implemented these new mail procedures in a staggered approach, starting with the international mail facilities located at JFK Airport and Carson, California. The air courier procedures will be implemented in a similar manner next month starting with the air courier hubs in Memphis and Louisville.

The completion of these procedures is significant because it represents a strengthening in the programs and procedures that are used to ensure the availability of safe and effective drugs to U.S. consumers. The procedures increase efficiency and consistency by providing well-defined steps for targeting packages for inspection and detention, and they also help CBP, DEA, Postal, and our other partners because they provide a better understanding of what products are of greatest concern to the agency, and they also make the process more transparent.

In closing, a large and growing volume of parcels containing foreign prescription drugs ordered by individuals from foreign sources are entering the United States. This volume represents a substantial challenge for the agency to adequately assess and process these parcels, resulting in an increased workload for agency field personnel. The new procedures, however, will help the agency target its limited resources in a manner that will best protect the public health from unsafe, illegal imported drugs, and drugs purchased from overseas Internet sites.

Thank you for this opportunity to testify. I look forward to responding to any questions that you may have.

Senator Coleman. Thank you, Mr. Taylor.

For all the witnesses, there is a lot of information in your prepared statements and 5 minutes doesn't do justice to the range of concerns that you have identified and some of your suggestions for addressing those. So I just want you to know I

appreciate that. I don't know if the audience, listening to 5 minutes, knows the extent to which you have been looking into these problems and trying to figure out a way to deal with them. But I do appreciate that.

Commissioner Hubbard.

TESTIMONY OF WILLIAM HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. Hubbard. Thank you, Mr. Chairman, and on that note, I am going to race through some exhibits that FDA has that I believe complement the very findings that you and GAO have made and also give you some results of some recent investigations that we have done.\1\

\1\ See Exhibit No. 33 which appears in the Appendix on page 351.

As you saw in New York, Customs is the initial screening organization for these drugs that turns it over to the FDA. We get presented with these huge bins----

Senator Coleman. Mr. Hubbard, I will let you take your time a little bit, too. I will extend your time.

Mr. Hubbard. Great. Thank you. [Laughter.]

Senator Coleman. I grew up in Brooklyn, New York, spending my last 4 years in Minnesota, but the good news about growing up in Brooklyn is that you can talk fast. The bad news is, nobody understands you. [Laughter.]

Mr. Hubbard. Thank you very much, Mr. Chairman. So FDA is presented with these huge bins of packages, and I have got some here before me. These are actual orders that patients have made, and let me just make up a scenario here.

They send me to New York and become one of these inspectors, and I have an M.D. degree and a pharmacy degree and a law degree, and I begin to open these packages, and maybe I can get through one bin in a day, but I can't make any reasonable judgments about these drugs. I can look at the name. I can look at the pill. But it doesn't tell me very much.

So I think to answer the question that you raised about more resources--a visual inspection with more resources will not actually solve this problem, we fear. And we are also very concerned that controlled substances are finding their way through with the prescription medications because of the

difficulty of finding those, and as you saw in New York, there is a mountain of those sitting there waiting to be dealt with, as well.

Now, one of the things that we have recently done is ask a local computer security firm named Cyveillance to look at some of the sites that purported to be Canadian, which are generally believed to be the best of these pharmacies. So they use a web crawler, as you asked about, to examine sites and found 1,000 sites--1,009--that appeared to be Canadian. And then we did a random deeper analysis of 10 percent of those and found that almost half are offering controlled substances. Two-thirds or more are selling prescription distribution drugs. These are drugs like Accutane or something that FDA would only approve under very restricted use by certain doctors and pharmacists. They also lie and they say the drugs are FDA approved when, in fact, they are not, and they have liability disclaimers that say to the patient, we are not responsible if you are injured.

As an example, here is one, Discount Drugs of Canada. It appears to be very legitimate. We asked, where is it? They say they are in Manitoba. Who is the registrant of it? It is a Mr. Thuy. Where is he? He is in Vietnam. That concerns us. Why is the registrant of this site in Asia? They are selling not only drugs from Canada, they are offering drugs from Australia and Britain. So we see this almost inexorable dimunition of the source, and there are reports now of drugs coming from Chile, from Israel, from South Africa, and so the whole system, we fear, is degrading. And, of course, they are offering controlled substances like Meridia and restricted distribution drugs like the Somatropin that you see here.

And then lastly, these sites are essentially saying to the patient, sign away any right to sue us and attest to the fact that if you are injured, it is your responsibility, patient. No American drug store would ever do that.

We are also worried about an even slippery slope. As you see, this is a communication from a Pakistani drug manufacturer who is saying essentially to Canadian pharmacies, when you start running short of your supply of the good Canadian or American drugs, let us know. We will fill your pipeline with drugs that we make here in Pakistan.

One site that we and the DEA have been investigating is this one that offers to sell generic versions of Canadian drugs, and we have actually made some buys there and explored where they are. They are actually registered in China. But the

postmark was Dallas, Texas. The return address was Miami, Florida. The credit card was billed to a business on the Island of St. Kitts. And the listed phone number for this site when we began to investigate where it really is was the South American country of Belize. Again, why if this is legitimate are these things all over the place?

And, of course, it is not legitimate. We actually bought drugs and tested them, Lipitor, Viagra, and Ambien, Ambien being a powerful sleep aid. We tested for potency. They failed. We tested them for so-called dissolution, to see if they would dissolve in the body and go into the bloodstream. Two failed. And they had impurities in most cases. In fact, in some cases, their potency was half-potent or double-potent. So, for instance, a senior citizen could take this Ambien thinking one pill was what he was supposed to take. It is double-potent. It could sedate him to the point of death, a very serious public health concern.

Now, as you know, part of the problem, Senator, is that the public officials are telling people to go buy these drugs because they are cheaper, and this is the Wisconsin site that Governor Doyle has put up. They use three Canadian pharmacies in British Columbia, in Alberta, and in Manitoba, as you see, Canada drugs, Granville Pharmacy, and Total Care. So recently, the Pharmacy Society of Wisconsin has been examining the actual purchases from those sites and they are finding that a third of the prescriptions from that site, and this is supposedly the site has been checked out by the State. It is supposed to be one of the better ones. A third of the prescriptions are not meeting the State's agreement. Two-hundred-and-thirty-seven impermissible drugs have been dispensed. Many of them were non-FDA approved drugs. And they had a specific requirement not to ship refrigerated drugs because that had been a problem.

So FDA then did its own examination to determine if, in fact, the Pharmacy Society results were accurate, and in fact, we found even worse, that in the case of Total Care Pharmacy, two-thirds of their prescriptions violated the State agreement. But unfortunately, Mayor Thomas Menino of Boston just yesterday announced a program to give employees of Boston drugs from Total Care Pharmacy, the very pharmacy that has been found to be violating the standards that had been established.

And even worse, in many cases, they are selling Americans generic drugs that they could have gotten here in the United States at a corner drug store cheaper than in Canada. So they

could have gotten the regulated, FDA-approved drug here, and they are being sent to Canada to buy a drug that is actually more expensive and less regulated.

Last, I will just close with a couple of mentions of counterfeiting. These are two counterfeit drugs that are virtually identical in appearance and very difficult for the patient to distinguish between.

This is a Viagra die that a counterfeiter had been using. As you can see, it is quite filthy. You can see the Pfizer name upside down on the reverse side of the pill, the Viagra imprint.

This is a tableting machine. This is not what you would see in a licensed manufacturing organization.

This is how they dry the pills using light bulbs, as you see.

Now, this is the Viagra--this is their sophisticated packaging process. The blue pills on the bed are the Viagra and the bottles in the large plastic bags are to be inserted. I am not sure what the microwave oven is for.

This is again a packaging machine.

And then lastly, I will point out that a toilet is an effective porcelain vessel to make drugs. As you can see, that toilet is filled with them. But I don't think any of us believe that is the way to make good drugs, and so we are very worried that the counterfeiters will be able to use this mechanism, as you have pointed out, Mr. Chairman, to get these unsafe drugs into our system.

With that, I will end my presentation. Thank you.

Senator Coleman. Thank you very much, Commissioner Hubbard.

Let me start, and I am going to have questions for the panel, but just a statement about the work that the line folks have done. I have had a chance to be out at JFK, Customs and the FDA--I do have great respect for the work that your folks are doing out there. They are faced with a challenge of overwhelming proportion. I do have concerns about our ability to get our hands around this, whether in the 5 years from 1999 to today, did we move quickly enough in that period of time.

But I just want to say thank you to the folks on the front line. We have some issues that we have to deal with in terms of resources, whether this Congress is providing enough resources and whether we have worked in a coordinated enough approach. But I do want to let the folks on the front line know that we appreciate what they do.

How do you deal with the comments out there? And by the way, let me back it up and say I note you looked at Wisconsin's site. Minnesota has a similar site, and perhaps you are being kind to the Chairman and my governor by not commenting on the Minnesota site. I do recall in my review for this hearing that even the Minnesota site was one where one of the issues there was that site was providing drugs that were actually from another country. Now, apparently they provide notice to the customer that they are not getting Canadian drugs, but can somebody comment on that phenomena, that even those ``legitimate'' Canadian operations are at this point in the process of going elsewhere for their drugs? They are not American and they are not Canadian. They could be produced anywhere in the world. Any reflections on that?

Mr. Hubbard. I think you are right. We pointed that out substantially because the sites often promise FDA-approved, U.S.-made drugs sold through Canada, and this trend of going to other countries is a slippery slope that we are very concerned about. And, in fact, it is happening. And while some do say that, others don't even say that. They just send the drug.

We had a case recently of a gentleman from Michigan who had ordered a drug from a Canadian pharmacy and was told he was going to get the U.S.-made, FDA-approved, Canadian-sold drug and it came from India. So he was lied to, and that is a concern, that in this case a senior citizen was duped into believing he was going to get the good drug and he didn't.

Mr. Taylor. It is directly attributable to supply and demand. One of the reasons why we conducted the blitzes is because there often is a lot of conjecture about what is out there and there is also a lot of conjecture about all the products being perfectly safe or all the products being harmful. And one of the things we have noticed is that, obviously, as the American consumers purchase more and more products over the Internet or through storefront pharmacies, the supply is dropping, and so these suppliers are having to look to other countries to backfill that supply. Our concern is that as they look at these other suppliers, that additional quality issues will arise, we will know even less about the origin of the products and how the products are manufactured.

Senator Coleman. How do you respond to the quip, ``Where are the dead Canadians?''

Mr. Taylor. I am sorry, the----

Senator Coleman. How do you respond to the quip saying,

``Where are--"

Mr. Hubbard. Well, first of all, there are----

Senator Coleman. ``Where are the dead Canadians?" With all of the concerns that we are raising here, we are not seeing lives being lost.

Mr. Hubbard. There are injuries that have occurred from drugs bought by Americans from Canada. It is not a long list. But part of the problem, Mr. Chairman, is that there is no system in place to track injuries from these drugs. These drugs shouldn't even be here. So the health care system doesn't track them. And we have learned from patients, they tend not to tell anyone they are buying these drugs. They feel that maybe they have done something a little wrong and they don't admit it.

So let us say a patient gets a drug for his high blood pressure, it doesn't work, he has a stroke. They ask his doctor later and he said, ``Well, my patient had the high blood pressure and he was stroke-prone," but maybe didn't know that the patient was getting not the legitimate drug but the foreign drug that wasn't working and caused his stroke.

Mr. Taylor. I think that is right. I mean, I think there is an additional facet to it, which is we don't always expect, quite frankly, to see gross negative health outcomes. However, our overarching concern is that a person is purchasing a drug with the expectation that it will treat or control the condition that they have, and if a drug is without any active ingredients, like the products that CBP tested, or like the counterfeit Lipitor that we dealt with last year, or like the contraceptive patches that were in my oral testimony, then the person's condition is not going to be treated or their depression is not going to be controlled. So that might not lead to mortality, but it certainly has a negative health impact that is not desirable.

Senator Coleman. I would also note at our last hearing where we dealt with the instance of dead Americans, a young man's family was involved in the testimony, and a tri-athlete whose wife didn't know that he was getting these drugs until he died. Perhaps she might not have known if certain information hadn't shown up. So I hear that quip again and again.

A question I would like you all perhaps to respond to. Knowing the extent of the problem or the extent of the challenge, was it 200 billion pieces, right, billion pieces of mail coming through this country? The percentage of stuff coming in from other countries, what was the figure there? Was

it 400 million? Does anyone here envision, if you had access to whatever resources you needed, within reason, a system whereby we truly get our hands around this problem? Ms. Tandy.

Ms. Tandy. Mr. Chairman, if you liken this flow of pharmaceuticals coming into the United States as water through a faucet, my panel colleagues are at that downstream of the faucet trying to catch it all. What we are doing with DEA with the resources that were committed to us in the 2004 appropriation, we are focusing on turning the spigot off, which is attacking the organizations that are responsible for that flow.

It requires very sophisticated technology which we have in place now and are refining to identify these hundreds of rogue pharmacy Websites, many of which are outside this country. It is critical in order to truly get our hands around this to stop the spigot at the top and put those Websites out of business and those organizations that are responsible for that, put them in American jails for sending those drugs here.

Senator Coleman. Let me, before others respond, just to follow up on that. It has been highlighted here that you have sites that purport to have FDA approval, that have seals of approval. There have been some proposals to, in fact, require FDA approval in order for folks to operate. But assuming, do we have the authority today? Do we have the laws on the books today? If we were to put in place a system whereby there was bona fide FDA approval but you had folks who were counterfeiting that approval, who were fraudulently stating that they had FDA approval, do we have in place the legal mechanisms to go after and shut down these rogue operations?

Mr. Taylor. So far, a lot of our discussion has surrounded the issue of resources, but for FDA, it is not just resources. It is a question of adequate authorities. As Mr. Hubbard said, mere visual inspection of the product at the border is not going to--it is just not that useful in determining in a dispositive way whether a product is safe or not or whether it is approved or not. An important part of knowing the content of a product is knowing where it comes from and knowing its origins.

And yet when people ask, well, why doesn't FDA go and do a foreign inspection of some of these overseas pharmacies or overseas sites, what people don't understand is we don't have the jurisdiction to do those inspections. In order for us to do our foreign inspections, even the foreign inspections we do now

as part of a new drug approval, we need the company to invite us in, and the incentive is that they invite us in and we do the inspection and their product will get approved, and we need the country to allow us to come in, and there have been instances where we have been on a plane on our way to a facility and either the country or the company has decided they are not ready and we have had to turn around--so it is a question of resources and authorities that are necessary to really do a better job of controlling this problem.

Senator Coleman. Do you currently have the authority to, if you have a site that is fraudulently proclaiming that it has FDA approval, to shut down that site and to prosecute those for some sort of false representation?

Mr. Taylor. We do not have that authority. Sometimes we will--what we will do is sometimes we will talk to the Internet service provider and they will do it for us, depending on the evidence that we have in hand. Other times, we work with our partners at DEA or at ICE and they might have the administrative authority to shut down a site. But FDA does not have the authority to shut down a site. What we often do is we will either enjoin an operation, which will lead to the site shutting down, or we will indict or convict the people who are behind the site. But we don't have express authority to shut down the site.

Senator Coleman. Talking about authority, Commissioner Ahern, do you have the ability at this point to seize controlled substances? We have seen boxes of this stuff, there was one discussion of those being sent back, literally sent back to the illegal purveyor of this. What kind of increased authority do you need to immediately seize and destroy, and would you want that kind of authority?

Mr. Ahern. Thank you, Chairman. I would also like to answer the previous question, too, about the resource impact of this and is resource an acceptable solution to this problem.

I think, certainly, I am not certain you can throw enough resources given the volumes that we are dealing with, and I am not sure a resource response is the appropriate response for the government agencies. I think we need to take a very layered approach. I think it certainly is very appropriate to look at taking out the Websites, taking out the profiteers of this, and also I think a very layered approach with interdiction, investigation, intelligence, and public outreach. I think those are very key components that certainly is part of the task

force, and by adding ONDCP recently onto the task force, we are getting that outreach part along with FDA.

But certainly to the question of authorities and to the referenced parcels that were returned to sender at JFK, I would like to respond to that directly. That is true, that there was the shipments up in JFK that were returned to sender. Most of those were Schedule IV as well as a lot of pharmaceuticals, as well. That was a 5- to 6-month backlog of detentions and seizures that were made at that point in time.

The people at JFK did not respond to policy of this organization and we have made the corrections with them to make sure that they know that they do not send return to sender on seizures. It should be affected at the borders.

However, I would like to state that for each one of those seizures that does occur, it requires about one hour of front-end processing at the mail facility to process those seizures, and that is why when you had your opportunity to go up and take a look at the JFK mail facility, and what has been depicted here today in the hearing shows the volume actually of what is being stored and detained in our storage facilities there for processing, not all for FDA determination, or for Customs and Border Protection processing.

We have to do the same level of processing of that seizure because of the due process the individual importer is afforded under current law and procedure. We have to do the same long-form enforcement report as we would for if it was ten pounds of heroin or cocaine. We need to find a way to do consolidated seizure reports that could take the time involved with this processing down significantly, as well as move to a very efficient and effective summary forfeiture proceeding where we don't need to send the notice out but we can destroy these things on site and continue with the interdiction mission as part of that layered strategy.

Senator Coleman. In order to find that way, is that something that requires administrative changes or does it require legislature changes?

Mr. Ahern. For the summary forfeiture authority, we certainly need to have the legislative change to support that.

Senator Coleman. I look forward to working with you on those proposals.

Also in your testimony, you talked about interagency working groups. I reflected earlier in my opening statement, there were working groups formed in 1999. What is the

difference between the working groups we have today and those that we had 5 years ago?

Mr. Ahern. I can't reflect back to 1999 and what might have not occurred under the group that was put in place at that point in time. I was not directly involved with that. I will tell you, looking back in history, shortly after this group was created, there were some operations that were conducted, not many. We also then had the 9/11 tragedy which certainly took the focus of the Border agency, certainly the agency that I am part of, and redirected our focus to preventing terrorists or implements of terrorism from coming into this country, and I think that was a very appropriate response from us for us at that time.

However, within the last several months, we have created these additional task forces to try to rejuvenate the collaboration that is necessary to achieve the layered approach with stopping this problem. It is not just a border interdiction problem. It is not just an investigative problem or a regulatory problem. We need to tackle this on all fronts.

I believe that the five working groups that are part of this have some comprehensive plans, and I would also submit that with the actions that have come out through the task force, special operations and blitzes that have been conducted as well as the laboratory and scientific services sampling reports, have shown the level of concern and I believe we will take these and continue to move forward with our action.

Senator Coleman. I would hope there would be some objective ways to measure progress here so we are not coming back in 5 years and asking the same question.

Mr. Taylor. Mr. Chairman, one objective measure is the work that we have done on procedures. One of the subgroups is just devoted to mail procedures and targeting. As part of our staggered approach, we have shared the procedures with DEA, Postal, and CBP. We welcome their comments. But more importantly, the information that was used to provide the framework for those procedures is part of our collaborative working relationship.

I agree with Jay. I think that the working group, and I wasn't around in 1994 either, but I think the working group has proven to be a springboard, if for no other reason we have a--it has made our working relationship here in Washington closer. If I need something, I can call Mr. Ahern or I can call Ms. Tandy's people inside or outside those meetings. It has been

easier to involve more headquarters people as part of the subgroups.

And so one objective measure is the fact that after realizing the need for these mail procedures, we have introduced them. We will continue to refine them with the help of our partners. And then we will introduce the air courier procedures, again, in conjunction with our partners. So those are two small hallmarks that signify the robustness of what we are doing now.

Senator Coleman. And I would, Mr. Ahern, suggest a terrorist threat to what we are dealing with here, and we talked about this at the last hearing with Mayor Giuliani. You don't want to give anybody ideas, but it doesn't take rocket science to figure out that we are using extraordinary measures to protect our borders, to protect particularly people coming in, and we are doing things with cargo and other areas, understanding some of the challenges, to take a look at what is coming in. We are concerned about radioactive devices.

But the reality is that any terrorist network could set up an American A-Plus Number One Internet Drugs at bargain basement prices and flood this country with materials and drugs that could have a devastating impact and raise the level of fear. We shut off access to Canadian meat with the identification of one cow with BSE, and yet clearly we have a system here that is without controls, without the ability to, at this point, sufficiently prevent something like this from happening. So I would maintain there is a national security aspect to the availability of or the ease of getting these types of substances into the hands of American consumers.

Mr. Ahern. My comment to that is certainly I don't disagree with you. However, we certainly have to take a very risk-based approach and we know that there are concerns with people crossing our borders, coming into this country, as well as the threat posed by sea containers, as well as other cargoes coming into this country. So we do take a very risk-based, intelligence or information driven approach in our response with our resources.

To this point, there has been no active intelligence that indicates that this would present itself as a threat. Certainly, all the 400 million mail shipments coming into this country, as well as the half-a-billion people that cross our borders legitimately, as well as the sea containers and cargo opportunities, we look at as windows of opportunity and we take

a very risk-based approach with addressing those threats. But certainly we haven't disregarded this as a potential at this point in time. There is no active intelligence that indicates that threat is present.

Senator Coleman. There is a system, is it VIPPS? There is a system that the pharmacy organizations have set up to provide some measure of bona fide, legitimate. Can someone talk a little bit about that?

Mr. Hubbard. It is established by the National Association of Boards of Pharmacy and it has very high standards, and it basically says, if you want to sell drugs over the Internet and you meet all the requirements that a brick-and-mortar pharmacy would meet, you can receive this Good Housekeeping seal called a VIPPS seal. We believe it is a good idea.

There are two, of course, flaws in it. One is that the bad guys can fake the seal. And second, VIPPS cannot reach out into other countries. It is really for domestic Internet sites.

Senator Coleman. Is there anything that would preclude Canadian pharmacies from voluntarily adhering to the VIPPS standards?

Mr. Hubbard. No. In fact, the National Association of Boards of Pharmacy has proposed to Minnesota that they work with them on inspecting Canadian pharmacies and making that very consideration. I don't believe we have heard back from the Minnesota officials on that recently, but FDA has expressed a willingness to be helpful in any way we can in that process.

Senator Coleman. Mr. Taylor.

Mr. Taylor. It is a good consumer outreach and education tool. A consumer can look at the site and know that the product is being dispensed pursuant to a legitimate State pharmacy license and that the products are FDA approved.

Senator Coleman. Help me understand this issue again. We have talked about how you can fake the seal. What are the consequences of falsely advertising FDA approval? Or what is the level----

Mr. Hubbard. If you are a foreign Website, there is not much that can be done because your server is in another country. The business is in another country. I don't think any of us can reach to that country in any effective way. We try to work with other governments, but our actual legal authority doesn't reach there.

Mr. Taylor. Yes. If--I am sorry, Bill.

Mr. Hubbard. There have been proposals in the past,

bipartisan proposals, to at least require Websites to disclose who they are and where they are by both Republicans and Democrats in the House and Senate, and we have felt that concept has generally been a good one.

Mr. Taylor. That is because even though the overseas site might fall outside our jurisdiction, if there is a U.S. agent or a U.S. entity that is part of the business, then we can take action against them.

For example, we brought an injunction last year against RX Depot, which was a storefront pharmacy that was advertising FDA-approved products. In that case, we enjoined the American operation, which was essentially roughly about 80 other storefront pharmacies, and enjoined them from doing business. So even though we couldn't necessarily bring an action against the Canadian entities, we did deal with the domestic entity.

Senator Coleman. I would hope we would look at some way to substantially enhance the penalty and the ability to get compliance, even those who are operating extraterritorially, that some action could be taken. I would anticipate that we are going to reach a point, I would hope, and certainly a proposal that Senator Gregg has offered and Senator Smith and I cosponsored that would require those who want to sell, Canadian and other pharmacies, to, in fact, be subject to FDA review and authorization and the same standards and that there be very strong penalties for those who fraudulently claim to have that kind of approval.

Let me ask, I just want to focus a little bit on some individual cases, and this goes to the enforcement actions for Mr. Taylor and Mr. Hubbard. Can you tell me who Eric Kaiser is? Does that name ring a bell?

Mr. Taylor. No, it does not, sir.

Senator Coleman. I am told that he is a registered owner of numerous Internet pharmacy Websites that offer Accutane, Prozac, Zocor without a prescription. Do you have any information on his actions and his response or lack of response to cease and desist letters, E-mails, etc.?

Mr. Taylor. Actually, it does--I know him in the context of some things that JFK has recently discovered and is looking into. It wasn't specifically with those products, but it was in another context.

Senator Coleman. I raise the question, using him as an example, and I may have one or two others for some of the other witnesses here, but again, it goes back to this ability to

track down, to have some sort of effective control over folks who are operating illegally. If you identify somebody as the owner of an Internet pharmacy but they don't respond to letters, E-mails, etc., then you check down as you have shown here. You show them a Website registration that says it is registered in one place, but it doesn't correspond to a particular name. How do you follow up on this stuff? What are you doing to track down those people that you get a clear sense that they are abusing this process?

Mr. Taylor. Let me use the two examples in my oral testimony. For the contraceptive patches, that Website first appeared to be a U.S. Website. And by the way, this is a product that was brought to our attention by a consumer who received the contraceptive patches in a clear plastic bag, which caused warning bells to go off in her head. So she contacted the manufacturer who contacted us. There were tests and there is no active ingredient.

From there, we looked at the Website that she purchased the product from and had to, with the help of Immigration and Customs Enforcement and use of administrative subpoenas, and by working also with the Internet service provider, track the fact that there were actually five or six different levels--five or six additional Websites between the one that she was using and the one that was registered in India, where the products came from.

So to answer your question, there is a lot of interim investigatory work that is time consuming and requires not only good web crawling, but also good analytical skills to figure out the various links.

Once we realized that--and this case is still ongoing, so I don't want to go into a lot of detail--but once we realized where it was registered, we contacted the Customs officials overseas and the local authorities to enlist their aid. In some cases, the local governments have been helpful in helping us figure out where the person we are seeking is. In other cases, people have been less cooperative. We also utilize the in-country expertise of either Customs or DEA.

Now, I don't want to suggest this is easy. It is not. It is actually very difficult. And in some cases, we have people who are in countries where there is no extradition. But that is the general steps that we use to try and determine the location of someone who is operating outside the country.

Senator Coleman. I appreciate that.

Administrator Tandy, if I can just turn to one or two examples, and I think we have Exhibits 1 and 3,\1\ over a 2-day period at JFK, our staff and I observed a shipment of 3,000 parcels of controlled substance from Amert, a single vendor in the Netherlands. That is one of the things that I noticed, that there were a number of parcels from single vendors containing illegal prescription drugs. When you see something like that, when you see massive quantities coming from single vendors, and I think that is Exhibit 1? I think there is another exhibit there which shows the same thing, single vendor, massive quantities.

\1\ See Exhibits 1 and 3 which appear in the Appendix on pages 286 and 288.

What can you do to stop that company from continuing with these illegal drug transactions? What is your authority and what kind of action do you take?

Ms. Tandy. The process that we follow, once these vendors are identified, is to work with our foreign counterparts in law enforcement in the Netherlands or wherever the country is from whence these drugs have been shipped and to have our foreign counterparts assist us in the foreign-based piece of that investigation.

We do have long-armed jurisdiction under Title 21 as to Schedule I and Schedule II controlled substances. Schedules III, IV, and V, which often are what you see over the Internet, are not included under that long-armed jurisdictional statute.

Senator Coleman. And could you, for the record, describe the difference between Schedules I and II versus III, IV, and V.

Ms. Tandy. I say Schedule I, because under the statute it is covered, but Schedule I, of course, these are not medically accepted drugs. So you can set aside Schedule I.

Schedule II, there is a high risk of abuse of drugs in Schedule II. These are typically opioids.

Schedule III, which is where you have seen some of the deaths, would be Vicodin, which is not pure hydrocodone but is a mix of hydrocodone and acetaminophen.

So those schedules, the penalties are tiered by those schedules. Our authorities are cabined by the statute under the schedules.

Essentially, we have to rely on our foreign counterparts to

assist us in further identification of these Websites because these are not brick-and-mortar locations and require sophisticated investigation in order to identify where they are really operating from. And then our foreign counterparts, we rely on to shut down those sites that are outside of our long-armed jurisdiction. We can always bring charges against these institutions, these Website companies, even though they are outside the country, for what they send into our country under the standard Title 21 process.

Senator Coleman. I believe that hydrocodone is pictured in this photo. Do you know if there was any follow-up with this, what are they, a Dutch operation, Amert, a Netherlands operation? Do you know if there was any follow-up on----

Ms. Tandy. I can tell you that we have a number of foreign-based Website investigations underway now, but I wouldn't be in a position to tell you any specifics about those investigations at the risk of compromising them.

Senator Coleman. Let me just introduce a last area of inquiry for you, and that is we talked about the web crawler. My understanding was in 1999, FDA purchased a web crawler. We are talking about it today. Help me understand why you believe the web crawler today will be more successful than the web crawler in 1999.

Ms. Tandy. I can't speak to FDA's web crawler. DEA just received funding in 2004 for what has been colloquially referred to as a web crawler. It is to conduct these on-line investigations. We have worked very diligently to put into place an on-line investigative tool that, as it is refined, is going to be the equivalent of essentially six Google search engines together that will go through these on-line pharmacies using specific information to try to connect the links to the various Websites to specific targets. So I don't know how this differs from what FDA attempted to do in 1999----

Senator Coleman. You have your own web crawler then?

Ms. Tandy. We have our own web crawler, which after today I won't refer to as a web crawler anymore. It will be the on-line investigations tool.

Senator Coleman. Mr. Heath, you talked about rogue pharmacies getting increased legal private scrutiny, and I believe some of the private operations, Google and Yahoo!, have been doing some things in regard to that. Does the Postal Service work with the private sector to address this issue of illegal sale of pharmaceuticals over the Internet? What kind?

Because our next panel is going to be the private sector and I want to segue into that. Can you talk a little bit about that relationship?

Mr. Heath. Absolutely. I think we have an excellent working relationship, especially with FedEx and UPS, not only to work on the illegal pharmaceuticals, but we share our intelligence and our methodologies with them, whether it is in the mail or in the private courier system, to target illegal narcotics, to target child pornography, and we certainly will do the same things with them with regard to this issue.

There is one other point I would offer up when we look here. Administrator Tandy has talked a lot about the highlights of the investigative effort they put in to addressing the problem. When we look at mailings or shipments, as would be reflected in this, if they are fresh, that is pretty good for an investigative and evidentiary purposes. I know at Miami and at JFK, there is a significant dated backlog of materials that were seized months and months ago.

I would suggest that along with Customs and Border Protection, FDA, that we take a look at using our enforcement authority with the destruction methodology to attack that backlog. If we can, in fact, demonstrate that there are multiple mailings from the same supplier, due to the dated nature, it is probably not going to be of much benefit from an investigative nature, but I think we should try out our methodologies to try to destroy that.

As you mentioned, it does not make good sense to return it to the sender because it is only going to be sent back either to this country or to another country again.

Senator Coleman. Let me talk a little bit about your authority. Does the Postal authority have the ability to open packages without a warrant?

Mr. Heath. No, sir.

Senator Coleman. So you have to turn to who in order to----

Mr. Heath. We rely, especially on the international, the ones coming in from the foreign countries, we rely very heavily on Customs and Border Protection. They open the materials at the point of entry, and then for an enforcement process, once they have determined that it is an illegal product, then we can seek the destruction order.

Senator Coleman. What about the possibility of cross-designation to make it a little easier for you?

Mr. Heath. Yes, sir, it definitely would.

Senator Coleman. I think it is something worth exploring.

I want to thank the members of the panel. We could go on and on. I do appreciate your efforts and your understanding of the nature of a growing problem and the importance of working together to address it. So again, I want to thank you for appearing before the Subcommittee.

I would now like to welcome our final panel to today's hearing. This panel is composed of representatives of the private sector.

I would like to welcome John Scheibel, Vice President for Public Policy at Yahoo!; Sheryl Sandberg, Vice President for Global Online Sales and Operations at Google; Joshua Peirez, Senior Vice President and Assistant General Counsel at MasterCard International; Steve Ruwe, Executive Vice President of Operations and Risk Management at Visa U.S.A.; Robert Bryden, Vice President of Corporate Security at Federal Express Corporation; and finally, Daniel Silva, Vice President and Director of Security at United Parcel Service.

The purpose of this panel is to examine the extent to which consumers can purchase dangerous and often addictive controlled substances from both domestic and international Internet sites and the role that Internet search firms, credit card companies, and package delivery firms can play in identifying rogue sites and preventing them from utilizing their services. I do appreciate everyone's testimony at this important hearing and am anxious to hear your testimony.

Pursuant to Rule 6, all witnesses before the Subcommittee are required to be sworn. At this time, I would ask you all to rise, raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. Scheibel. I do.

Ms. Sandberg. I do.

Mr. Peirez. I do.

Mr. Ruwe. I do.

Mr. Bryden. I do.

Mr. Silva. I do.

Senator Coleman. As I am sure you are aware by now, we do try to have a timing system here, and for such a large panel, I would like to hold people to that. I will ask that folks limit their oral testimony to no more than 5 minutes, but I will make sure that your entire written testimony is entered into the

record. When the light turns from green to amber, it gives you about a minute to sum up, so please follow that.

We will begin with Mr. Scheibel--we will have you go first this morning--followed by Ms. Sandberg, then Mr. Peirez, Mr. Ruwe, Mr. Bryden, and finish up with Mr. Silva, and after we have heard all the testimony, we will turn to questions. So with that, Mr. Scheibel, you may proceed.

TESTIMONY OF JOHN SCHEIBEL,\1\ VICE PRESIDENT, PUBLIC POLICY, YAHOO! INC

Mr. Scheibel. Chairman Coleman, thank you for the opportunity to testify on an extremely serious issue, prescription drug sales over the Internet.

\1\ The prepared statement of Mr. Scheibel appears in the Appendix on page 255.

Yahoo! is a leading provider of comprehensive on-line products and services to consumers and businesses worldwide. Yahoo! is the number one Internet brand globally and the most trafficked Internet destination worldwide.

Mr. Chairman, we appreciate your leadership in this critical area and we share your concern with protecting consumers. That is why, beginning in 2002, Overture, which later became a wholly owned subsidiary of Yahoo!, took its first preliminary steps to address this issue. At that time, Overture prohibited on-line pharmacies from advertising that prescription drugs could be purchased without a prescription.

Then in November 2003, we took industry-leading actions to better ensure that our sponsored search listings of on-line pharmacies meet high standards of integrity and accountability. Sponsored search is a program under which advertisers bid on search terms in order to get placement in search results. Only those listings relevant to a search term are permitted to enter or remain in the active database. These listings are clearly labeled ``Sponsor Results'' throughout the Yahoo! site.

As you mentioned, in November 2003, Yahoo! took the unprecedented action of removing all sponsored search pharmacy listings for prescription drugs as an interim step to developing a more comprehensive program that would maintain our commitment to providing consumers, advertisers, and partners with the best on-line experience possible. Our message was

clear. Until we could create a safer environment for such on-line advertising, there would be no sponsored search listings for prescription drugs on Yahoo!.

Beginning in February 2004, we launched our more comprehensive program, which was the first of its kind. Our goal is to enable a more trusted marketplace for legitimate on-line pharmacies to competitively offer consumers access to prescription drugs. The on-line pharmacy qualification program employs a five-facet approach to enhance consumer trust in participating on-line pharmacies.

First, we determine whether an advertiser is participating in the sale of prescription drugs. If it is, Yahoo! requires the advertiser to join the program and comply with its terms in order to participate in the sponsored search marketplace.

Second, the advertiser is directed to Square Trade, a leading on-line trust infrastructure company, which verifies whether the appropriate governmental body where the company is located has licensed both the pharmacy itself and its associated pharmacists. Unless Square Trade determines that the advertiser and its associated pharmacists are currently licensed, Yahoo! will not allow the pharmacy to advertise.

Third, the advertiser is required to certify that it engages in a set of industry best practices that have been approved by the National Community Pharmacists Association, the NCPA, including certification that it will not provide prescription drugs without verifying the existence of a valid prescription from the person's health care practitioner and such prescription was not obtained solely by means of an online or telephone consultation.

Fourth, Square Trade, in a program administered in conjunction with the NCPA, regularly monitors the licensure status of participating pharmacies as well as responds to any complaints it receives regarding these pharmacies. Any negative action taken by the licensing entity or any complaints that are substantiated by Square Trade are reported to Yahoo! and the advertiser will be removed, as appropriate. Complaints will also be forwarded by Square Trade to the appropriate government licensing authority.

Finally, Yahoo! prohibits on-line pharmacies from advertising the most dangerous and abused prescription drugs, FDA Schedule II prescription drugs, in the Yahoo! marketplace.

Yahoo! believes that this five-pronged on-line pharmacy qualification program complements our mission of aligning the

interests of consumers, advertisers, and Internet destination sites.

Prior to finalizing the terms of our program, we briefed officials at the Food and Drug Administration on its terms. They warmly received our program and were very encouraged by the fact that we were taking a leadership role in this area.

Mr. Chairman, you have also asked for our comments on pending applicable legislation. S. 2464, introduced by Senators Coleman and Feinstein, precludes the sale of prescription drugs over the Internet absent disclosure by the site of identities and licensing information of the seller, pharmacist, or medical consultants. It also prohibits the sale of prescription drugs over the Internet absent a valid prescription, as that is described. This is a very thoughtful piece of legislation.

The bill would follow the lead of the Communications Decency Act by providing that an interactive computer service provider would not be liable under this bill on account of another person selling or dispensing prescription drugs, provided that the interactive computer service does not exercise corporate control over such person.

Senator Coleman, we applaud you for including this critical provision. It recognizes that telephone companies, Internet service providers, and Internet portals should not be liable for what others place on their sites or send over their lines.

Mr. Chairman, we at Yahoo! are proud of the steps that we have taken to create a safer environment for the on-line advertising of prescription drugs. Thank you for the opportunity to appear before you today.

Senator Coleman. Thank you, Mr. Scheibel.

Ms. Sandberg, I will take your testimony, and then I am going to have to recess. We have three stacked votes. So we will do Ms. Sandberg, recess for 45 minutes--I think that is what it will take--and be back here at noon, so if you can just plan your schedules accordingly. Ms. Sandberg.

TESTIMONY OF SHERYL SANDBERG,\1\ VICE PRESIDENT, GLOBAL ONLINE SALES AND OPERATIONS, GOOGLE, MOUNTAIN VIEW, CALIFORNIA

Ms. Sandberg. Good morning, Chairman Coleman. Thank you for inviting me to testify on this very important issue.

\1\ The prepared statement of Ms. Sandberg appears in the Appendix on page 259.

Google shares your concerns about the risks of on-line pharmacies and some of the unsafe products they sell. In my written testimony, I provided a detailed account of our policies and programs on this matter, so in view of the vote, will keep my oral comments very short.

Senator Coleman. Your testimony will be entered into the record as a whole, without objection.

Ms. Sandberg. Thank you very much. Google's mission is to organize the world's information and make it universally accessible and useful. When a user, defined as someone who visits our site, goes to Google-dot-com or one of our 95 other domains, the user is able to search for information on over four billion web pages and over 880 million images.

We are dedicated to preserving the trust our users have placed in us. We always place the interests of our users first and their search for information, and that is the core value on which our company is built.

Like our search results, the goal of our advertising program is to provide users with useful information. Our users want information about pharmaceuticals and we know that providing relevant information from trusted sources can be critically important. We have received numerous E-mails from Google users who have found life-saving information through our Website.

We believe that advertising by licensed pharmacies, treatment and detox centers, and pharmaceutical manufacturers helps consumers locate services, compare options, and make cost-effective informed choices about their health. Our belief is supported by research showing that pharmaceutical-related advertising is strongly positive for consumers. However, we share your concerns that there are disreputable Internet sites, some of which are on-line pharmacies.

In response to the increasingly complex on-line pharmaceuticals market, we have taken proactive and aggressive steps to make sure that our advertising program provides users with relevant and safe information. In order for on-line pharmacies to advertise with Google, they must be certified by Square Trade, a leading third-party trust infrastructure company. Square Trade's licensed pharmacy program has been approved by the National Community Pharmacists Association.

By working with Square Trade, we require pharmacies that advertise on Google to be licensed, to maintain licensed

pharmacists, to obey all applicable laws, rules, and regulations, to not provide prescription drugs unless they receive and verify a valid prescription, to make sure that prescription is not obtained online and not obtained over the phone, and also guarantee that they are only delivering medications through a provider that requires an adult signature for delivery.

Square Trade regularly monitors the licensure status of these pharmacies and we require that advertisers have a valid and current Square Trade ID before participating in our program. Through this process, we strive to permit only licensed pharmacies and pharmacists to advertise with Google. We are pleased to provide a means of connecting individuals with valid prescriptions to licensed pharmacies that can provide them cost-effective and convenient service. We are also proud that our Website helps people find information they need, information on education, rehabilitation, or other medical needs.

Thank you again for this opportunity to share our views. We are grateful for your leadership on this important issue.

Senator Coleman. Thank you very much, Ms. Sandberg.

Again, because of the three stacked votes, I will have to recess the hearing until approximately 12 o'clock. We may get started a little bit before that. This hearing is now recessed.

[Recess from 11:13 a.m. to 11:32 a.m.]

Senator Coleman. I am going to reconvene the hearing at this time. I apologize for the confusion but we have a series of three stacked votes and I probably have another 15 minutes in between this vote and the next vote. We do not have the entire panel in front of us but we have two of the witnesses, the carriers, here and I think it would be very helpful to get their testimony on the record. I am just not sure what time we are going to have for questioning but I think it is important to get the testimony on the record.

So with that, why don't we begin. Mr. Bryden, please begin your testimony.

STATEMENT OF ROBERT A. BRYDEN,\1\ VICE PRESIDENT, CORPORATE SECURITY, FEDERAL EXPRESS CORPORATION, MEMPHIS, TENNESSEE

Mr. Bryden. Thank you, Mr. Chairman. Pleasure to be here with you today to talk about this important topic. I have submitted a statement and I would ask that you accept that for

the record and I will make some short summary comments.

\1\ The prepared statement of Mr. Bryden appears in the Appendix on page 266.

Senator Coleman. Without objection.

Mr. Bryden. Thank you, sir.

FedEx has been working with members of your staff and members of another committee in the House on this issue for almost 2 years now. We have met many times with the staff, and met with many of the Federal agencies numerous times. I feel like the research that we have done and the meetings that we have had have given us a good understanding of the scope of the problem and where our company fits within that problem.

I also think we have identified ways that we can assist the law enforcement agencies in doing, as you heard in earlier testimony, the virtually impossible task that they face in keeping these illegal drugs out of our country and out of the hands of children and people that should not have them. I think that we have discovered ways in this 2-year journey that we have been on that we can enhance our cooperation with law enforcement organizations. We have made those offers to law enforcement. We think we have something to offer to their investigations.

At the end of the day, we believe it is a law enforcement issue and that the technical issues involved in getting to the bottom of who is doing this shipping does require law enforcement power authority and through the use of subpoenas and so forth. But we are happy to cooperate in any way we can. We appreciate you having us here today and I look forward to answering questions that you may have.

Senator Coleman. Thank you Mr. Bryden. Mr. Silva.

STATEMENT OF DANIEL J. SILVA,\1\ VICE PRESIDENT, DIRECTOR OF SECURITY, UNITED PARCEL SERVICE, ATLANTA, GEORGIA

Mr. Silva. Chairman Coleman, my name is Dan Silva. I am the corporate security manager for UPS, and in that capacity I am responsible for security activities worldwide for the organization. I would like to thank you for the opportunity to participate here today.

\1\ The prepared statement of Mr. Silva appears in the Appendix on

page 269.

You asked us to comment on three questions and I will do those in order. First, you asked about efforts that we have undertaken to preclude the delivery by UPS of illegal controlled substances and other pharmaceuticals purchased over the Internet. Let me first state that it is the clear policy of UPS as stated in our tariff that illegal products of any type are prohibited from being transported through our system. We have a long history of working with law enforcement agencies at all levels to enforce legal requirements. While our company privacy policy prohibits us from disclosing customer information in general, we regularly provide law enforcement agencies with information required by lawful subpoena.

Additionally, since 2001 we have conducted an on-line pharmacy monitoring program. Through our outside counsel we conduct weekly searches of the Internet to identify on-line pharmacies that use the term UPS. We send cease and desist letters and are prepared to follow up with appropriate legal remedies to on-line pharmacies that offer UPS services and offer to sell pharmaceuticals without a prescription, and second, that display a UPS trademark or logo, so to avoid any appearance of sponsorship or endorsement.

We have shared information about Internet pharmacy sites that we have gathered through our monitoring program with the FDA and DEA. Since much of the concern in this area arises from imported pharmaceuticals I would like to mention efforts we have undertaken with the Customs Service and FDA. First of all, UPS identifies to Customs and FDA all packages it delivers into the United States that are declared to be pharmaceuticals. Customs and FDA have the ability to pull any of these packages for further examination and enforcement action.

Additionally, in conjunction with our new automated international air hub in Louisville, Kentucky, we developed a computer program called Target Search for the use of Customs. This is a sophisticated and flexible tool that enables Customs to search manifest information for all imported packages passing through that facility. Customs can use this system to help identify illicit shipments by screening for a wide variety of data.

Your second question relates to current efforts with the DEA and FDA to address the issue of illegal purchases of controlled substances. On an ongoing basis we respond to many

subpoenas with information requested in support of ongoing investigations by these agencies.

Additionally, we have met twice this year with officials of FDA and DEA here in Washington to discuss ways in which we might further our cooperation concerning illegal pharmaceutical shipments. As I have already indicated, we have shared information about Internet pharmacies that we have identified through on-line pharmacy monitoring program with these agencies. These meetings with FDA and DEA officials have been productive and we will continue to meet as needed in the future.

The third question seeks our views on pending legislation regarding Internet pharmacies. We support legislation that would establish clear requirements for Internet pharmacies. In particular, we like provisions of the Coleman bill, S. 2464, that would require Internet pharmacies to be licensed. The requirements of S. 2464 are appropriate for ensuring that requirements for the safety and efficacy of drugs are met when U.S. consumers make purchases in this new marketplace. From the standpoint of a package delivery company, these requirements would provide more certainty that the products we are carrying meet the requirements of law and therefore meet our own tariff requirements.

We also support the goal of S. 2465. The criminal use of the Postal Service and carriers like UPS to unwittingly deliver fraudulently declared prescription drugs into the United States is an enforcement problem for Customs, FDA and DEA. UPS alone ships more than 3 billion packages a year, about 15 million of which are imported into the United States. We and other carriers have a limited ability to look behind the declarations supplied by the shipper in the manifest. S. 2465 would direct the attention of Federal agencies to this problem and we would gladly work with them, as we are already doing under the current law.

Thank you for the opportunity to share the views of UPS and I look forward to any questions that you may have.

Senator Coleman. Thank you, Mr. Silva.

For both you gentlemen, do Websites selling pharmaceuticals advertise the service of either Federal Express or UPS without authorization?

Mr. Bryden. They do.

Mr. Silva. Yes, they do.

Senator Coleman. Help me get a better understanding of what

you do to combat those situations where you have Websites selling. For instance, is there a way not to accept packages from these groups? What kind of ability do you have to react to or respond to folks that advertise selling pharmaceuticals with authorization?

Mr. Bryden. We have a group of attorneys who spend their full time every day looking for those types of infringements and then trying to find the right person to send cease-and-desist letters to. As you well know from this investigation, the problem of Internet pharmacies presents a particular problem because, in the main, people that are selling illegal drugs illegally into this country are not going to put their right name and address on the E-mail, on the Website. We have found Websites, as you saw testimony this morning where you would have a pharmacy pretending to be located in Canada and it would be linked to servers in several different countries, so there is no way for us to send cease-and-desist letters to that.

At the same time, it is very difficult to list shipping information with our customers because those Websites are not the ones that are shipping the drugs. They are putting in an order at another location, in the main, and then we are picking up at a completely different location not associated with a Website. So it is a difficult problem for us and, frankly, without subpoena power it is one that we are not finding we can make much headway into.

Senator Coleman. I believe Slide 26 \1\ is that one that had FedEx?

\1\ See Exhibit 26, which appears in the Appendix on page 311.

Mr. Bryden. Yes, sir, that is FedEx.

Senator Coleman. I believe this is one that was done without authorization. Do you have any knowledge----

Mr. Bryden. My written testimony which I submitted will substantiate for you, there are no Internet pharmacies that have the authority to use the FedEx logo.

Senator Coleman. Mr. Silva.

Mr. Silva. The same is true for us. We have had some success with cease-and-desist letters. Eric Kaiser, a gentleman that you mentioned earlier, had somewhere in the vicinity of 30 sites. We have sent cease-and-desist letters. We have done that electronically. We have done that through certified mail. The

mail got returned to us as undeliverable. But at the end of the day, all but one of his sites no longer mentions UPS.

Senator Coleman. What kind of assistance do you get from law enforcement? Use the Kaiser case as an example. What kind of assistance did you get?

Mr. Silva. We provided the information to FDA and DEA. They were aware of Mr. Kaiser's existence through other sources. In that particular case they were already investigating it.

Senator Coleman. Mr. Bryden, you have had experience with the DEA; is that correct?

Mr. Bryden. Yes, sir, I spent 24 years with DEA.

Senator Coleman. Could you give an honest assessment from this side, now looking from the private sector, DEA's response to these matters, these issues?

Mr. Bryden. I can honestly say I am glad I was not a member of the law enforcement panel today. I just think they have a real uphill battle to climb.

I will say this, when I listened to all of the testimony from the law enforcement agencies today it struck me that we may be looking at the forest and not seeing the trees. What I mean by that is, on every one of these shipments that has been destroyed in New York and other locations, and the ones that are seized and are let into the country, there is data point that we are not doing much with. That is the recipient of the package. Anyone who ordered that drug over that Internet site committed an illegal act. I chagrin the fact that in this country we seem to have drifted away from holding people responsible for their actions. That may be an opportunity for the law enforcement agencies.

I am not suggesting, sir, that we put everybody in jail that bought drugs over the Internet. I am suggesting that they should perhaps get a letter from one of the law enforcement agencies saying, we have a package here. It has been seized. You violated the law when you did it. You are on notice. Then you can have a stair-step ladder of increasing penalties including fines. Because I just cannot--the testimony I heard today, I do not know how much resources it would take to get a handle on this, whether it is DEA or FDA, but if we start holding people accountable, that changes behavior. I have always believed as a law enforcement officer and I believe it now. That may be an opportunity.

Senator Coleman. We will get the credit card companies here, but it would occur to me, if somebody has got a series of

credit card transactions, single individuals with multiple Internet pharmacies, there should be some way to deal with that.

Can you talk to me a little bit in the couple minutes I have left here, talk about the tracking systems. I raised the question about you are asking people to be honest. Maybe I have become cynical in my almost 2 years here, that if folks are sending illegal pharmaceuticals I doubt there is any incentive for them to honestly list on a manifest. Help me understand why you believe the manifest provides some way to control the system. You both use manifests; is that correct? Mr. Silva, why don't you start.

Mr. Silva. Yes. When we are referring to Target Search, it is a targeting tool that enables Customs to use a number of data fields off of the manifest to search for any packages that travel into our facility. The value of it is intelligence. You heard some of the earlier testimony revolve around intelligence and that there seems to be a lot of intelligence out there. I do not know how much of it is actionable. I do not know how effective we are in fully utilizing the tools that have been deployed in some of the private courier companies to the maximum. The Target Search tool and the second brokerage operation support system tool afford these law enforcement agencies some tremendous resources. We do, believe it or not, get shipments that come in that have either the generic name of the drug or are identified, and they do get picked off.

Mr. Bryden. Let me also say that the tracking and tracing capabilities that both UPS and FedEx have in order to help law enforcement can be used in other ways as well. For instance, if law enforcement comes to us with a name or an address, we can research that name and address and tell them how many previous times shipments have occurred. That helps them build conspiracy investigations.

The other thing that we use the manifest information for is if we get something that is manifested and it is supposed to weigh--let us say, it is a VCR. It is supposed to weigh 10 pounds, and it weighs one pound. That is a potential targeted package, we probably would open that package and take a look at it. We heard people refer to random searches. In FedEx, we do not like to do random searches. It is largely a waste of time. We like to do targeted searches, and I think my counterpart here at UPS feels the same way from a security standpoint. That is not to say we do not do random searches from time to time,

but we teach our employees to look for suspicious packages. Weights that are different to the manifest, something that rattles when it should not rattle, quickly filled out shipping data on a bill of lading. Things like that enable us to catch more drugs and illegal things than a random search does.

Senator Coleman. I appreciate that.

Gentlemen, I will now recess till 12 o'clock. I do appreciate fitting your testimony in. It has been very helpful to me.

So this hearing is now recessed till 12 o'clock.

[Recess.]

Senator Coleman. This hearing of the Permanent Subcommittee on Investigations is called back to order.

I would note that during the recess, I actually got back between votes, reconvened the hearing for a brief period of time, had Mr. Bryden and Mr. Silva give their testimony, so we will now turn to Mr. Peirez for your testimony. You may begin.

TESTIMONY OF JOSHUA L. PEIREZ,\1\ SENIOR VICE PRESIDENT AND ASSISTANT GENERAL COUNSEL, MASTERCARD INTERNATIONAL, PURCHASE, NEW YORK

Mr. Peirez. Thank you, Chairman Coleman. My name is Joshua Peirez and I am Senior Vice President and Assistant General Counsel at MasterCard in Purchase, New York. It is my pleasure to appear before you today to discuss the important issue of the sale of pharmaceuticals over the Internet.

\1\ The prepared statement of Mr. Peirez with an attachment appears in the Appendix on page 271.

MasterCard is a global organization that has licensed more than 23,000 financial institutions to use the MasterCard marks in connection with the issuance and acceptance of MasterCard cards. MasterCard requires that all licensees conduct business in accordance with all applicable laws. Any failure to comply with the law empowers MasterCard to assess stiff financial penalties and ultimately to suspend or terminate the licensee.

MasterCard deplores the use of its systems for any illegal purposes, including for the illegal sale of pharmaceuticals. As you highlighted in your opening statement, Mr. Chairman, MasterCard has recently taken a number of steps to help prevent Internet pharmacies from accepting MasterCard cards for illegal

pharmaceutical sales.

These steps include, first, issuing a global bulletin to all our licensees around the world, reminding them of their obligation to comply with all applicable laws and specifically highlighting Internet drug sales as risky transactions.

Second, working with our licensees to shut off more than 370 Websites from accepting MasterCard cards for the illegal sale of pharmaceuticals over the Internet.

Third, exploring new ways to protect the MasterCard system against use for any illegal activity.

And fourth, working with the DEA and the FDA in a collaborative fashion, as we always do with law enforcement.

The efforts we have undertaken to date represent important steps in demonstrating MasterCard's commitment to play an appropriate role in addressing this issue. These steps began about 8 months ago when we met with staff of this Subcommittee, as well as with staff of the House Energy and Commerce Committee. The meeting with your staff, Mr. Chairman, was particularly helpful in highlighting the scope of this problem and in clarifying some of the legal issues surrounding the Internet sale of pharmaceuticals, particularly the issues as they relate to controlled substances. We also met with staff of the DEA and the FDA at that time to exchange information and to explore ways in which MasterCard could be helpful to them in their efforts to enforce the law.

Since the time of our initial meeting with the Subcommittee staff, MasterCard's Merchant Security Team has been searching the Internet for Internet pharmacies that purport to accept MasterCard cards for illegal sales of controlled substances. We are pleased to report that, to date, these efforts have been successful in shutting off the acceptance of MasterCard cards at over 370 Websites.

Despite our success, the task has been made more difficult because it is not entirely clear that all these transactions are illegal, although the vast majority likely are. The lack of a clear prohibition has made it more difficult to educate our licensees around the world on this issue.

Additionally, because the DEA informed us that MasterCard and its employees are prohibited by law from knowingly making illegal buys, it has been difficult to identify the true nature of sales on a Website in some circumstances.

If Congress adopts a legislative solution to this issue, it would be helpful to reduce the confusion regarding a number of

legal issues surrounding the sale of pharmaceuticals over the Internet. In particular, requiring pharmacies to be licensed or approved to sell over the Internet would be helpful in providing a clear understanding of whether particular pharmacy merchants are engaged in legal or illegal activities.

MasterCard requests that any statutory obligations on payment systems be carefully crafted to ensure they function appropriately without creating undue liability on the payment systems for simply meeting their obligations under the law.

Mr. Chairman, thank you again for the opportunity to discuss these important issues and for the help your staff has provided to us. I would be glad to answer any questions you may have.

Senator Coleman. Thank you, Mr. Peirez. Mr. Ruwe.

TESTIMONY OF STEVE RUWE,\1\ EXECUTIVE VICE PRESIDENT, OPERATIONS AND RISK MANAGEMENT, VISA U.S.A., INC., FOSTER CITY, CALIFORNIA

Mr. Ruwe. Chairman Coleman, my name is Steve Ruwe. I am Executive Vice President of Operations and Risk Management for Visa U.S.A., Inc. Thank you for the invitation to participate in this hearing. Visa fully supports the Subcommittee's efforts to prevent illicit sales of prescription pharmaceuticals over the Internet.

\1\ The prepared statement of Mr. Ruwe appears in the Appendix on page 280.

The Visa payment system consists of Visa, which performs communication and settlement services for its member banks, and Visa's member banks that issue Visa payments cards or that acquire transactions from merchants that have accepted Visa payment cards. Visa and the Visa member banks that only issue credit cards do not have direct relationships with Internet pharmacies or other merchants that accept Visa payment cards. On the other hand, Visa member banks that acquire transactions from merchants do have a direct relationship with the merchants and the Visa rules require that these acquiring banks assume responsibility for certain aspects of their relationship with the merchants.

Because Visa cards are accepted worldwide, many of these banks, like the merchants that they service, are located in

foreign countries.

Visa believes that the Visa payment system has responded effectively to the challenges posed by Internet transactions. Visa rules prohibit the use of Visa cards for illegal transactions. Visa has a long history of working with law enforcement, including the Secret Service, the Federal Bureau of Investigation, the Federal Trade Commission, and State and local law enforcement.

In the specific area of illicit sales of prescription pharmaceuticals over the Internet, Visa has met with representatives of the DEA and the FDA to discuss approaches to the problem of illicit transactions with Internet pharmacies. In March 2004, Visa reminded its member banks of their responsibilities to ensure that only legal transactions enter the Visa payment system and directed their attention to the list of controlled substances and problematic drugs maintained at the FDA and DEA Websites. Visa advised its member banks to consider relying on a reputable seal program, such as the VIPPS operated by the National Association of Boards of Pharmacy, as a means of identifying reputable Internet pharmacies.

In June 2004, Visa used the services of an outside firm to search the Internet for Websites selling controlled substances and accepting Visa payment cards. As a result of this monitoring effort, we have had discussions with some of our member banks regarding their merchants who appear to be involved in selling controlled substances. These member banks have conducted their own investigations and have terminated or restricted the activity of merchants found to be selling controlled substances.

In May 2004, Visa updated its consumer Website to provide safety messages regarding the dangers of purchasing pharmaceuticals over the Internet and to provide links to the Websites of the DEA and the National Association of Boards of Pharmacy and to remind consumers that they should only use their Visa cards for legal purposes.

We understand that S. 2493 would place additional responsibilities on the operators of payment card systems to prevent the use of payment cards in illicit Internet pharmacy transactions. Visa believes that, in many cases, the only parties that can actually determine the legality of the transactions are the parties in the transactions themselves.

Accordingly, telephone companies, payment systems, and delivery services typically are not required to know whether

transactions that are effected using their facilities or services are legal. Historically, it has been only in those circumstances where the use is so unusual as to suggest illegality in its own right, such as transactions that trigger suspicious activity reports or currency transaction report requirements, or where the illegality is so overt and egregious, such as child pornography, that Congress and law enforcement have enlisted the aid of third-party intermediaries to monitor the use of their facilities or services for policing illegal transactions.

In this regard, I note that imposing the cost of acting as law enforcement on financial institutions, communication channels, or other intermediaries for public purposes is effectively a tax on all the members of the public who use those services. In choosing alternatives, that tax must be measured against alternate expenditures that might accomplish the same purpose, such as hiring more law enforcement personnel.

With respect to S. 2493, we have reviewed this legislation and suggested technical changes. If these provisions are adopted, Visa will move aggressively to see that the Visa payment system compiles with any and all applicable requirements. Visa will continue to work with law enforcement to fight against illegal activity, including those involving Internet pharmaceutical sales. We will also continue to monitor the Internet for Internet pharmacies selling controlled substances.

We appreciate the opportunity to appear before you today and would be happy to answer any questions you may have.

Senator Coleman. Thank you, Mr. Ruwe.

I do want to compliment the folks here. You have clearly made an effort to try to deal with this situation. Unfortunately, as you listened to the prior testimony, it is simply not enough. We continue to be overwhelmed, and it is the nature of technology, nature of the ease of use of technology, and so we are presented with a challenge.

But Mr. Ruwe, you made the comment that it is helpful--let me step back. You made the comment that it is companies like Visa, MasterCard, the search engines, the folks that provide the transport, they are not required to know something is illegal. With all the commerce that you do, it may be difficult to do.

But what if, in fact, you knew that certain activities were

not legal? So, for instance, if there were to be a requirement that pharmacists be licensed or approved to sell over the Internet and you have a list of those that you could easily enter. If you knew then that others were operating illegally, how would you respond to that and do you have any other examples of that kind of situation, where you know something is illegal but they are still using Visa, MasterCard? And I turn to our friends at Google and Yahoo! with the same question.

The question is, let us assume we had a situation where it would be illegal to sell drugs over the Internet unless you were licensed by the FDA, and we can get you a list of those groups that are licensed by the FDA. How would you respond to transactions from companies that are not licensed by the FDA which then are, per se, illegal operations?

Mr. Ruwe. I believe if we had a list of the pharmacies that you believe to be legal and be registered and be approved, that we could manage that within our system, to make sure that they were the only ones that would be permitted to operate.

Senator Coleman. I am just trying to think, is there anology to something else you do today where you do those kind of runs, you have a list of these legal organizations and anything outside that is something that you wouldn't accept the transaction?

Mr. Ruwe. I cannot think of an example that parallels that exact situation today. I mean, we do deal with the continual search for illegal activities, but nothing of the nature that is being proposed here.

Senator Coleman. Mr. Peirez.

Mr. Peirez. I am also not aware of such a list. However, we think that such a list could be highly effective and would be useful to us. I think it is the nature of the Internet that causes the problem in that activities may be perfectly legal in one jurisdiction and not in another. So by having a list like that we could provide to the banks located outside of the United States and tell them, look, if someone is not on this list, you cannot provide them the service to sell pharmaceuticals over the Internet to persons in the United States with a MasterCard card, we believe that is a very clear guideline and something that could be very effective in our system.

Senator Coleman. Another area, and again, I am trying to find analogies to things that you do already that would then be applicable to these kinds of situations. I know you have the

capacity if a series of purchases are made, that generate some sort of suspicion that I have gotten a call about, was your card used so and so, and if the answer was no, you would take action. That has been proactive on your part. I didn't inquire, but you have gotten those kind of calls. So you have the ability in some way to monitor. I don't want to inquire into your security operations, but I presume you have that capacity.

On this issue of buying prescriptions over the Internet, in the instances where we had the tragedies or folks have died, often what you see is multiple sales over the Internet, multiple pharmacies within a short period of time of a range of prescription drugs, clearly something that would raise an eyebrow. Do you have the capacity to kind of spot that kind of stuff and would that raise any red flags?

Mr. Ruwe. I think the example you are referencing, Chairman, has to do with fraud. When I say fraud, I mean not fraud in the sense that the Internet pharmacy is doing something illegal or selling an illegal substance, but where these are unauthorized transactions where the true card holder did not initiate the transaction. In those cases, we have been successful at trying to identify those patterns, but those things are based on other factors, such as the amount of the transaction, where the transaction is taking place, and factors that would indicate patterns of unauthorized use as opposed to authorized use where they were buying something illegal.

Senator Coleman. And I understand the difference, but what I am trying to understand or to see if I can envision is where you could use the same process. You are looking at the activity of an individual card, and from whatever signals you have, things that raise a red flag, you are all of a sudden saying, hey, this may be fraud.

If we are dealing with the purchase of controlled substances in massive quantities from a range of different sites which then, if one checks back, are illegal sites, would you have the capacity to do the same thing, to raise a question about that and then perhaps deal with it?

Mr. Peirez. Mr. Chairman, you are asking a question about something we have thought quite a bit about. There are a couple of things I think that are important to understand. The examples you are raising are activities that are undertaken by the bank that has issued you your card in looking at your purchasing patterns, not an activity undertaken by MasterCard because we have no relationship with you. We don't even know

who you are when your transactions run through our system.

Typically, the information that is contained in a transaction record does not include information on what is being purchased. It is simply where it is being purchased, which is not necessarily the name that you would see on a Website or on a URL. Typically, it would not be that type of a name through the system.

So it is something that we would like to explore a little more, but we think that it would not be nearly as effective as the list of registered pharmacies that we have spoken about previously.

Senator Coleman. Can I go back to the previous slide \1\ that showed the Internet drug site that had the FedEx label and I believe had Visa or MasterCard.

\1\ See Exhibit 26, which appears in the Appendix on page 311.

This is a site, hydrocordone-dot-com, etc. What do you do here? They have got major credit cards accepted. This is one which we have concern about selling drugs illegally. And you have got masses of these. If something like this is brought to your attention, what can you do? Mr. Peirez, then Mr. Ruwe?

Mr. Peirez. Sure. Mr. Chairman, the first thing I will say is obviously we did see this exhibit earlier and we have already contacted our Merchant Security Team and asked them to begin an investigation into whether this site is still live and whether, in fact, it accepts MasterCard cards. Our experience has been sometimes the logo is there but the card cannot be used. What we can try to do is identify the bank that has contracted with this type of a merchant and if we can find that bank, we then follow up swiftly with the bank and have them either confirm that this is only legal activity, which in this case they will be highly pressed to do, or to shut off this merchant from accepting MasterCard cards, and that is the process we have used that has resulted in the successes I highlighted earlier in my testimony.

Senator Coleman. Mr. Ruwe.

Mr. Ruwe. I think the process Mr. Peirez describes would be very similar to the one we would follow, as well. It would be necessary to reach out through the Visa member who signed that merchant to initiate the remediation.

Senator Coleman. Mr. Scheibel and Ms. Sandberg, I would like to inquire a little bit about Square Trade. That is your

process for certifying vendors who are meeting certain standards. First, have you had a problem with unauthorized use of the Square Trade logo?

Mr. Scheibel. Not to date.

Ms. Sandberg. No, not to my knowledge, not to date.

Senator Coleman. You have a system in place if there is unauthorized use to then deal with that?

Mr. Scheibel. Yes. In fact, it is a live seal, so it is harder for somebody to steal that seal than others.

Senator Coleman. If we can go to Slide 24,\1\ please. On Slide 24, it is a Google site, no offense to Yahoo!. What you see is on the right hand side, that is your sponsored links. Those are the ones in which you have some controls, is that correct, Ms. Sandberg?

\1\ See Exhibit 24, which appears in the Appendix on page 309.

Ms. Sandberg. That is correct.

Senator Coleman. And again, explain that to me the nature of what makes this sponsored link versus--I think in this search there were, if I can recall----

Ms. Sandberg. A search listing.

Senator Coleman. Yes. If you look at a Google search for Vicodin, for instance, you will get 147,000 results. But then you have a listing of sponsored sites. Explain the difference.

Ms. Sandberg. Sure, and everyone can see it on here. If you look on the left side, those are search results. Those are the result of our computers crawling the web, looking for information on over four billion web pages. On the right, noted as ``Sponsored Links,'' and when you look at it online, they are colored, so you can tell that they are sponsored links, those are the results from our advertising program.

Senator Coleman. Just so I understand kind of how your system works, if somebody goes to a sponsored site, do you get something out of that? Is there a payment simply for visiting the sponsored site?

Ms. Sandberg. Yes. It is an advertising relationship with the partner. The partner is signing up, registering as a Google advertiser. In the case of pharmaceuticals, they would need to be Square Trade verified. And then we are in a business relationship with them. They pay us for clicks to their site.

Senator Coleman. There are, I think, 147,000 results for Vicodin. If one visits any of the unsponsored sites, does

Google get anything there?

Ms. Sandberg. No.

Senator Coleman. So the control you have is just over that limited number of sponsored sites, but there is nothing you can do to channel customers to go to the sponsored sites in which you have then some basis for checking credibility, whether they are using a process that would meet with concerns of law enforcement?

Ms. Sandberg. We don't have any control. You are correct, Chairman, that we don't have any control over the search results. However, we do take proactive steps to let people know that we have the Square Trade program in place and let consumers know that these are verified, licensed pharmacies. We display that information on our Website and you can read about the program by clicking on those links.

Mr. Scheibel. Mr. Chairman, in addition, on Yahoo!, the first links that a user will come to will be the sponsored links. So in this case, the most trusted parties, the people who we have worked with to try to create a safer environment for consumers will be the first links that a consumer comes to.

Senator Coleman. But for the massive number, the 140,000 or 149,000, what are those, alogarithmic searches?

Ms. Sandberg. Yes.

Senator Coleman. In other words, if you have a word in there, this is the universe and Yahoo! and Google lets people access the universe.

Ms. Sandberg. That is exactly right.

Senator Coleman. The known universe. That is it.

Ms. Sandberg. That is right.

Senator Coleman. Do you have, just hypothetically, do you have the ability to block portions of alogarithmic searches?

Ms. Sandberg. We do have the technical capability to remove things from the index, but given that we are an information company trying to provide all information to the world that is universally useful and accessible, that is done in only very limited circumstances.

Senator Coleman. What about child pornography?

Ms. Sandberg. That is one example where it is done. The content there is illegal and it is removed from the index when we find it.

Senator Coleman. But is the issue of the illegality of the content or is illegal content here, too? I am trying to understand how you draw that line. I know these are tough

questions. Can you help me understand how you draw that line? Clearly, you have illegal content, but there is something else. There is almost a moral equation that you are putting in here that says, this goes so far beyond the standards of what we can accept that you are willing to do that. Help me figure out how you draw that line.

Mr. Scheibel. Two points, Mr. Chairman. The first is that when it comes to child pornography, the simple display of that information is illegal per se, as opposed to what we are dealing with here, which is commercial.

The second point is that when you type in a search term for many of these drugs, you will get as part of your results treatment centers, antidotes, information about the drug, problems with use and abuse of the drug, much of which is obviously very useful to consumers. So as to both Yahoo! and Google, we are search engines. We are in the business of facilitating access to information, and that is part of the information that we provide access to.

Senator Coleman. Let me go to Slide 25.\1\ This shows the results from a research, again on Google, to purchase Vicodin last month. I think there were 129,000 hits on this. If you look at the sponsored links, you have, ``Order Vicodin Online, $44.94 shipped, you save, 100 percent legal purchase.'' We don't know if this is a legal purchase, do we?

\1\ See Exhibit 25, which appears in the Appendix on page 310.

Ms. Sandberg. Well, this advertiser that you are pointing to, the first one on the right, was verified by Square Trade as a licensed pharmacy and meets all of the requirements of Square Trade.

Senator Coleman. So from a Square Trade perspective, it is like whether--we get back to that basic question. Let me back it up. Does Square Trade then screen out those folks, for instance, who try to use--who fill out prescription on line?

Ms. Sandberg. Square Trade----

Senator Coleman. Do they filter out----

Ms. Sandberg. They make sure that you do not accept prescriptions obtained solely online or through the phone. That is part of their verification process.

Senator Coleman. Are there legal products that Google or Yahoo! refuses to accept advertising for?

Mr. Scheibel. Yes. The Schedule II drugs, FDA Schedule II.

Those search terms are not available, nor are the generic equivalent of those search terms.

Senator Coleman. Anything else?

Ms. Sandberg. Yes. There are several legal products that we don't accept advertising for. We don't accept advertising for tobacco, as an example.

Senator Coleman. Can you tell me a little bit about your relationship with law enforcement? Have they approached you with guidance or assistance in this area? One of the challenges we have is technology is moving faster than the law, and obviously you are on the cutting edge of that. Can you help us understand a little bit about the relationship with law enforcement, what kind of assistance they have been seeking from both of you?

Mr. Scheibel. Generally, Mr. Chairman, we work closely with law enforcement. We try to be responsive to their requests and it is a relationship that is evolving.

Senator Coleman. Ms. Sandberg.

Ms. Sandberg. As well, we have worked closely with law enforcement on a number of issues. This is one of them. We were in conversations with the FDA as we were thinking through what to do in this area.

Senator Coleman. How does Square Trade deal with foreign Internet sites, for instance, Canadian Internet sites? Can you talk a little bit about what they do with them?

Mr. Scheibel. Well, there is a distinction here. One is if you are other than a U.S. or Canadian company, you are not eligible for the sponsored search program on pharmaceuticals. With respect to Canadian companies, the requirements are just the same as in the United States. They have to be licensed by the regulatory body that would license them. And then there are several self-certification measures which we also require as part of the Square Trade program.

In addition, Canadian sites are not allowed to target U.S. consumers, and there is also a requisite statement, and I can read it to you, Mr. Chairman. ``The FDA, due to the current state of their regulations, has taken the position that virtually all shipments of prescription drugs imported from a Canadian pharmacy by a U.S. consumer will violate the law."

Senator Coleman. Let me just back up one question. You talked about, I thought you said, Mr. Scheibel, about Schedule II drugs. Is hydrocodone a Schedule II?

Mr. Scheibel. I believe it is.

Senator Coleman. And does either Google or Yahoo! block out or accept ads from Internet pharmacies selling hydrocordone?

Mr. Scheibel. I don't believe we do. Now, let us draw a distinction. We do not allow pharmacies to bid on the search term. If they bid on another search term and that same pharmacy is selling the Schedule II, then we would go to DEA and verify that pharmacy is licensed to sell that drug.

Senator Coleman. Ms. Sandberg.

Ms. Sandberg. We do allow licensed pharmacies to advertise on the majority of Schedule II terms. These are legal to be prescribed with a valid prescription and we make sure that they are done in accordance with the law.

Senator Coleman. One of the problems we confronted in our last hearing was young people using mom and dad's credit card and getting these drugs with a devastating impact. What are the type of things you can do to deal with that, if anything? Mr. Peirez, Mr. Ruwe, is that a problem that you see?

What I am trying to figure out is if there is--I keep coming back to whether you have the capacity to somehow look at the use of credit cards in dealing with on-line pharmacies that we know aren't legal or where they have the capacity to deal with large numbers of purchases of prescription drugs using your credit cards from operations that you know are questionable that have to raise a red flag. Just as you have the capacity to question large numbers of purchases for the sake of checking fraud, that seem to be suspicious, I am just trying to kind of hone in from a technical perspective. Are there ways in which you can work with us more effectively to stop some of the abuses of sale of drugs over the Internet to either young kids or to addicts?

Mr. Peirez. Mr. Chairman, we heard earlier the analogy to a running faucet and people talking about how difficult it is to try to control. I think the administrator from the DEA was discussing how difficult it is to try to deal with the water once it is coming out of the faucet, and MasterCard's focus on this particular issue has been on turning the faucet off. We are focused on the suppliers. We are not looking at individuals.

Frankly, there is no way for us to tell when a particular card is being used, if it is being used by the person who the card is issued to, their spouse, their child. We certainly would hope that parents don't make their cards available to their children. That is certainly something that they are

educated on on a regular basis.

But in general, on this particular issue, we believe where we can be most effective is trying to control the suppliers from getting into the commerce stream using our cards. Obviously, there are other payment means that they will then turn to and can turn to, but we draw a very clear line on the legal and illegal activities. If it is illegal, we don't want it and that is where we are focused.

Senator Coleman. Mr. Ruwe.

Mr. Ruwe. I think it does go back to the basic question of whether the transaction is legal or not. In terms of the individuals, I mean, there are now products in the market where a teenager could legitimately have a credit card in their possession, whether it might be a gift card, or in the case of Visa we have a ``Bucks'' card program. So it would be very difficult to manage it from that perspective, I believe.

But I would totally agree that there are further things that we could explore in terms of technology and working together with law enforcement to do our part and we would be most happy to entertain any of those things going forward.

Senator Coleman. How do you deal with gambling, for instance? Gambling sites present similar problems--not legal, overseas operations. For all of you, Mr. Ruwe, Mr. Peirez, do you accept transactions or do you screen any of those out?

Mr. Ruwe. Gambling is a little easier, Chairman, because it is just illegal. So in our system, if they are coded as a gambling institution and they are coded as an Internet gambling institution, those transactions can be blocked, period. There is no distinction between a legal gambling institution and an illegal gambling institution, such as we are dealing with in the pharmacy example.

Senator Coleman. Mr. Peirez.

Mr. Peirez. It is pretty much the same answer as Mr. Ruwe. In that scenario, U.S.-based banks are able to recognize those codes for the Internet form of transaction and the gambling transaction and then block it. If they were to do that in this scenario, they would be blocking perfectly legal transactions, like if somebody is buying drugs on the Internet from Merck, Medco, or from Duane Reade or some other big pharmacy that does sell on the Internet. So you would be blocking legal transactions, which nobody wants in that scenario.

Senator Coleman. So if the FDA again were to have the capacity to distinguish between specifically approved legal

versus illegal, you would have the capacity to block out the illegal?

Mr. Peirez. If we were provided with that list, frankly, it wouldn't have to be blocking transactionally. We would be blocking them from getting into the system in the first place.

Senator Coleman. I would be interested with FedEx and UPS. The problem there may be a little different in that your source of pickup may be different from the Website. But would that make a difference, if you had a list of places that are legal and anything outside of that, any sites or anything that are illegal, would you have the ability to somehow on your system figure that out or filter that out?

Mr. Bryden. Mr. Chairman, I think a list would be useful if it was a list of the distribution sites offshore. If it were a list of the Internet sites without some linkage to the place that we would pick up a package, it would be less useful to us, but I think it would be useful to solving the overall problem.

Senator Coleman. Mr. Silva.

Mr. Silva. I would agree with Mr. Bryden, but I would also say that might be valuable information for targeting.

Senator Coleman. I want to thank the witnesses here. This is a difficult area. It is a universe that is growing and expanding. I have a great respect for technology. I think it is the key to America's economic future. I respect what Yahoo! and Google do overall, but I am still troubled by the ability of folks to access clearly illegal operations with such ease. Perhaps the more that we can do to help consumers distinguish between the legitimate and the illegitimate, between the bona fide and the false, I think we would all be well served.

So I would encourage you to continue working with law enforcement, looking at your systems and seeing what we can do to ensure that we are not facilitating a process here that really has the potential and the reality of inflicting great harm on consumers in this country.

So again, I want to thank you for appearing. We will keep the record open for a period of 2 weeks for any additional questions.

With that, this hearing is now adjourned.

[Whereupon, at 12:37 p.m., the Subcommittee was adjourned.]

A P P E N D I X

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