AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2015

THURSDAY, APRIL 3, 2014

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:01 a.m. in room SD–138, Dirksen Senate Office Building, Hon. Mark Pryor (chairman) presiding.

Present: Senators Pryor, Merkley, Blunt, Cochran, and Collins.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. DR. MARGARET HAMBURG, COMMISSIONER

ACCOMPANIED BY:

WILLIAM TOOTLE, DIRECTOR, OFFICE OF BUDGET

NORRIS W. COCHRAN, DEPUTY ASSISTANT SECRETARY, OFFICE OF BUDGET

OPENING STATEMENT OF SENATOR MARK L. PRYOR

Senator PRYOR. I'll go ahead and call our hearing to order here. And let me just say welcome everyone to the subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. And today, we are talking about the Food and Drug Administration (FDA).

So I'd like to thank everyone for being here today, especially Commissioner Hamburg who has done great work over there, as well as Mr. Tootle and Mr. Cochran. Thank you for your time and your preparation. And I know that you have to deal with a set of very complex issues not just in what you do normally, but also in the budget environment this year, one that we're all living in right now. And you're working hard to honor the responsibilities of the FDA and we appreciate your efforts on that.

BUDGET

I'm not going to take up a lot of time with an opening statement, but I would like to say that this budget is quite a change from the budgets we've seen from FDA over the past few years. For an agency that regulates products, representing more than 20 cents of every $1 that Americans spend, with a budget of over $2.5 billion,

the increase you're requesting is minimal; less than 1 percent. And on the one hand, I think people appreciate that, but on the other hand, we recognize the challenges that that presents, as well.

And I know that you will talk about a larger request, but it is important to note that that's beyond the jurisdiction of our subcommittee because it's based on user fees. And we'll focus mostly on what the subcommittee has control over. But, certainly, if you want to talk about user fees, you're certainly welcome to do that.

FOOD SAFETY MODERNIZATION ACT

It's often pointed out that FDA's responsibilities are incredibly vast; certainly they continue to grow and to evolve. Currently, you're in the middle of the implementation of the Food Safety Modernization Act (FSMA) which, I'm sure, we'll hear more about this morning. You're also continuing to respond to issues about compounded drugs and implementing the Drug Quality and Security Act (DQSA) which was signed into law last November.

So here, again, you have your plate full. We appreciate the challenges you face. Look forward to hearing about your budget.

And also, one thing I think that we need to recognize is the world continues to become smaller. And you really are in charge of regulating a global marketplace; it's not just the U.S. market but really the, because the United States is such an important part of the global economy, in your areas of jurisdiction, you really are, in some ways, managing or overseeing a global marketplace. And that brings its own set of responsibilities and challenges.

New medical treatments are coming onboard. We're going from, kind of, a one-size-fits-all in the world of medicine to finding drugs and treatments and cures that are very, very personalized. And, even though this is exciting, once again, it creates a whole new set of challenges for you to have the right science and the right methodology and the right approach to get the best results we can possibly get while always being safe, of course.

And so that's obviously a big picture overview. Your agency has a lot of supporters not just around the country and around the world, but also in the Senate. But we also know that there's a lot of expectations on this agency because the FDA has, really, a long track record of getting it right and we appreciate that.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

So we can talk about the funding for the National Center for Toxicological Research (NCTR). In Arkansas, I know that there's a cut there. We'll talk about that. They continue to do groundbreaking research in nanotechnology and a number of other places. So, we'll talk about that during the question period.

And you also have a very small increase in your budget proposed for implementing the FSMA and with a much larger sum proposed in new user fees. And, again, we'll talk about that, too.

So, with all that said, what I'd like to do is turn it over to my ranking member, a great leader on these issues, Senator Blunt.

STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. Well, thank you, Chairman Pryor. And thank you for your extraordinary leadership of this committee and your partnership in the issues we deal with.

Dr. Hamburg, we're pleased you're here. Mr. Cochran and Mr. Tootle, thank you for everything you do. I have a statement for the record, but let me mention a couple of things in that statement.

First of all, the impact of the agency is significant. Twenty cents out of every spending $1 goes to things that FDA one way or another is involved in. Americans expect that the food they eat to be safe and the drugs they take to be safe and effective. Your private sector partners also expect you to be that; a partner in trying to make those things work and, to those conclusions, in the best way for everybody involved, and, ultimately, the best way for the consumer. And, of course, part of that means getting products to the consumer as quickly as we can but no more quickly than we can.

It's like somebody once said, "Everything should be as simple as possible but no simpler." And, that's sort of what we want to see happen at the FDA. We want this done as quickly as we can get it done, but obviously it's important that it be done in the right way.

In the last 3 years, the FDA has been given significant new responsibilities: The Food Safety Modernization Act; the, what sounded easy but turned out not to be so easy, menu labeling legislation; the drug compounding legislation that just gave you new responsibilities in the last year. And in all of those, and everything else you do, I think we need to be careful.

And our job is to be insistent that we don't get into a one-size-fits-all mentality because one size almost never fits anybody. And small businesses really suffer from procedures that are designed for businesses that are much bigger than the job that they're trying to do.

FOOD SAFETY MODERNIZATION ACT

Under the Food Safety Modernization Act, the FDA is tasked with implementing the most sweeping changes in food safety in over 70 years. There's a lot of anxiety in the agricultural community about the implementation of this act. And, back to the one-size-fits-all concept of how this act would work, and something that Senator Shaheen and I in a letter signed by others brought to your attention and you've responded to in the last few weeks. And we see that there's a handful of setbacks already in addressing this law as people say, "Well, this really doesn't work for us. And here's why we want you to understand better that this doesn't work in all of the environments that now the Food Safety Modernization Act would take today's FDA."

But we're glad you're here. I look forward to the chance to ask questions about this budget and about the ongoing work of the agency.

And, Mr. Chairman, again thank you for your leadership and for calling this hearing today.

Senator PRYOR. Well, thank you.

And we really only have one witness today, although, she has, can I say, two wingmen up there with her. Is that fair to say? The wingmen are Bill Tootle, who is the Director of Office and Budget at the FDA; and also we have Norris Cochran, he is at Department of Health and Human Services (HHS), Office of Budget; and of course, the star of the show today is going to be Dr. Margaret H. Hamburg.

Welcome. And I don't think we're necessarily going to put a timer on yours. We'd love for you to—you understand you can submit your full statement for the record. If you want to summarize it, that's up to you.

And, what we're going to try to do here is probably 7-minute rounds, is probably what we're going to do here.

So, go ahead, Dr. Hamburg. Thank you for being here.

SUMMARY STATEMENT OF HON. DR. MARGARET HAMBURG

Dr. HAMBURG. Great.

Thank you so much. And I, of course, would like to submit my full statement for the record.

But, Chairman Pryor and members of the subcommittee, I do appreciate the opportunity to come before you today and to discuss our fiscal year 2015 budget. I also want to thank you for the subcommittee's past investments in FDA. Really, your unflagging support for FDA's work to promote and protect public health, even in these challenging budgetary times, is deeply appreciated. And the recent work you've done to help us around some of the sequester issues also has been very meaningful.

As you know, FDA's mission is far-reaching. We're tasked with ensuring the safety, effectiveness, and quality of human and animal drugs, biologics, medical devices, and other medical products; as well as the safety of our blood supply, safety and quality of some 80 percent of our Nation's food supply, and, most 0recently, the responsibility to regulate the manufacturing, marketing, and distribution of tobacco products.

Today, FDA must respond to ever more complex challenges. We must stay at pace or ahead of the rapid advances in science and technology that are driving product developments and innovation. And globalization is dramatically increasing the volume of imported goods, as well as the complexity of their supply chains.

I'm happy to report that last year FDA moved forward on many fronts to address these and other significant challenges. We took major steps towards implementing the Food Safety Modernization Act, or FSMA, which will enable FDA to build a modern prevention-focused food safety system, protecting Americans against foodborne illness from both domestic and foreign sources. We approved novel medical products in cutting-edge areas of science to address critical medical needs. We've made progress in reducing drug shortages. And working with members of Congress and industry, we reached agreement on an approach to pharmacy compounding and set a timeline for a National Track and Trace System for prescription drugs that, when fully implemented, will further bolster the safety of the drug supply chain.

BUDGET

Looking ahead to next year, FDA is requesting a budget of $4.74 billion for fiscal year 2015. This represents a modest increase of 8 percent overall, or $358 million, to help fund our highest priorities.

In 2015, as noted, proposed and current user fees account for a significant proportion of our total budget request, 46 percent, with budget authority dollars comprising the rest. We recognize the larger pressures on the Federal budgets. So our budget request focuses on our most urgent needs; the safety of medical products including compounded drugs and the safety of our food supply. We're also asking for a small increase for infrastructure.

More specifically, the 2015 budget provides a program level of $2.6 billion to continue core medical product activities across FDA programs, which is $61 million above the fiscal year 2014 enacted level. And, importantly, this budget includes $25 million in budget authority to enhance pharmacy compounding oversight activities.

COMPOUNDING PHARMACIES

The 2012 fungal meningitis outbreak that killed 64 people and sickened some 750 others across 20 States in this country, demonstrated the critical need for improved oversight of compounding pharmacies. To better protect the American people, FDA quickly stepped up activities within available resources, and then Congress passed the Drug Quality and Security Act, in November 2013, giving us new responsibilities and authorities; though without commensurate resources.

FOOD SAFETY

FDA's 2015 budget also requests an increase of $263 million for food safety including resources to continue implementing FSMA. Implementation will reduce foodborne outbreaks which continue to cause preventable illness, hospitalization, and deaths. Implementation will also minimalize the market disruptions and economic costs inflicted by these outbreaks and significant contamination incidents.

This is a crucial time if we're to realize the vision and mandate of FSMA. While we'll still be able to issue the FSMA rules without increased funding, it will be impossible to effectively implement these important rules and to reduce or prevent serious and costly foodborne disease.

New resources are required in fundamental areas: Training; the provision of guidance and technical assistance to industry especially small growers and producers; support to build and strengthen partnerships with States; and the creation of a modern import safety system.

In conclusion, I want to underscore that FDA is a unique and essential agency. What we do matters for health and quality of life of individuals, families, and communities across our Nation. And it matters to the health and vibrancy of our economy, jobs, and our global economic competitiveness, as well. Yet the FDA budget is, in fact, a remarkable bargain.

As has been noted, the products we regulate account for more than 20 cents of every consumer dollar spent on products in the

United States. Yet, individual Americans pay a scant 2 cents a day to support our work; a small price to pay for life-saving medicines approved as fast, or faster, than anywhere in the world; a food supply that is among the safest in the world; and confidence in a vast array of important products that Americans rely on each and every day.

So I thank you for your past support and I look forward to our ability to discuss these important issues this morning.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF HON. DR. MARGARET A. HAMBURG

Good morning Chairman Pryor and Members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration (FDA). Thank you for the opportunity to appear before you today to discuss FDA's fiscal year 2015 budget request. I would like to thank the subcommittee for its past investments in FDA, which have helped us meet the demands of our broad and increasingly complex mission. For fiscal year 2015 FDA is requesting $4.74 billion, which represents a modest increase to address our highest priorities.

FDA PLAYS A VITAL ROLE IN AN INCREASINGLY COMPLEX ENVIRONMENT

FDA is a science-based, regulatory Agency with a public health mission. Our Agency is charged with an enormous and significant task: to promote and protect the health of the American people, and increasingly, people all over the world. This includes efforts to ensure the safety, effectiveness, and quality of human and animal drugs, biologics, medical devices, and other medical products, as well as the safety and wholesomeness of four-fifths of our Nation's food supply. It also includes working to foster the scientific innovation that will lead to tomorrow's products, and more recently, regulating the manufacturing, marketing, and distribution of tobacco products while seeking to reduce the use of tobacco products by minors.

The medical and food products we regulate have the potential to sustain life, reduce suffering, treat previously untreatable diseases, and extend lives. They are products that range from those used daily, such as fruits and vegetables or medicines to treat other chronic conditions, to products that may be needed once in a lifetime, such as an automated external defibrillator, to save someone's life. FDA has a duty to make safe and effective products available as quickly as possible, while at the same time protecting citizens from products that may cause harm. It is this dual responsibility to public health that highlights the critical nature of the Agency. The ability to prevent the outbreak of a foodborne illness is very different but just as important as fast approval of a life-changing medical product. The health of the citizens of the United States depends on both.

Many of the products we regulate are more complex than ever. Gone are the days when treating patients was based on signs and symptoms alone. Rapid developments in science and technology are making it possible for physicians to truly personalize diagnosis and treatment. For example, just last May, FDA approved two drugs for melanoma along with companion diagnostic tests that use the genetic characteristics of the patient's tumor to help determine whether a patient will respond. The ability to evaluate remarkable products like these requires FDA to stay ahead of the curve.

Scientific innovation is also driving remarkable advances in medical device development. For example, we are working hard to support the development of an artificial pancreas which would represent a huge advance in the management of diabetes. Products such as these offer great promise in reducing the burden of disease by tailoring interventions more effectively.

In addition to becoming more complex, the environment in which FDA protects and promotes the health and well-being of the American people is becoming increasingly global. Over the last 10 years, the number of imported shipments of FDA-regulated products has skyrocketed—in 2013, approximately 29 million shipments of imported food and medical products entered the United States. Imports account for 50 percent of fresh fruits and 20 percent of fresh vegetables, 80 percent of seafood, and 40 percent of the drugs on our shelves. Most of this increase in imports is coming from countries with limited regulatory oversight.

A strong FDA is critical not only to the domestic and global public health, but also to the U.S. economy, the balance of trade, and homeland security. The imple-

mentation of FDA's mission promotes innovation in the industries it regulates and affects costs in the broader economic and healthcare systems. Innovations not only create jobs, they position the domestic industries to compete in the global marketplace. Our history shows that when there is public trust in FDA's oversight, our industries flourish. Conversely, when food and medical products cause serious harm, the result is often severe economic damage across the industry involved—to offenders and non- offenders alike.

WE MOVED FORWARD ON MANY FRONTS THIS YEAR

This past year's accomplishments on behalf of public health have been as substantial as any in FDA's recent history. There were too many significant actions to list here; below are just a few of the highlights of fiscal year 2013.

Food Safety.—FDA published seven major proposed rules that form FSMA's central framework for moving to a comprehensive 21st Century food safety system. These science-based standards are designed to keep produce safe, implement modern preventive controls in human and animal food/feed facilities, modernize oversight of imported foods, guard against intentional contamination, and help ensure the safe transport of food and feed. In August, FDA issued a final rule defining "gluten-free" for food labeling, to help the estimated 3 million Americans who have celiac disease make food choices with confidence to better manage their health. In November, we took further steps to reduce the amount of artificial trans fat in processed foods.

Nutrition.—FDA recently proposed updating the Nutrition Facts label on food packages to reflect new public health and scientific evidence about nutrition, obesity, and chronic disease. Serving size requirements would be updated to reflect the amounts of food people are actually eating and drinking, and the format of the label would be refreshed, with key parts of the label such as calories, serving sizes, and percent daily value displayed more prominently.

Breakthrough Therapies.—In 2012, FDASIA created a powerful new tool to facilitate the development and review of "breakthrough therapies." In 2013, FDA's Center for Drug Evaluation and Research (CDER) received 121 requests for breakthrough therapy designation, and has already granted the designation to 36 potentially innovative new drugs that target both rare (epidermolysis bullosa, and Waldenstrom's macroglobuilnemia) and common (cystic fibrosis, breast cancer, and hepatitis C) conditions.

Drug Shortages.—In 2013, FDA helped to prevent 170 drug shortages. In October, the Agency issued a "Strategic Plan for Preventing and Mitigating Drug Shortages," outlining the Agency's strategy for improving its response to early notifications of a potential shortage, as well as identifying long-term initiatives that the Agency is considering or that stakeholders could take to address the underlying causes of shortages, such as opportunities for drug manufacturers to promote and sustain quality manufacturing.

FDA also issued a proposed rule that, if finalized, will expand the early notification requirements.

Unique Device Identification.—On September 20, 2013, FDA announced the final rule requiring that most medical devices distributed in the United States carry a unique device identifier (UDI). The system will be phased in over several years, focusing first on the highest risk medical devices. Once fully implemented, the UDI system will enhance the ability to quickly identify devices when recalled, improve the accuracy of adverse event reports, and help prevent counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems.

Drug Quality and Security Act.—On November 27, 2013, the Drug Quality and Security Act (DQSA) was enacted. Within days of enactment, issued three draft guidances for industry related to how the Agency intended to implement the new requirements.

As of March 6, 2014, 32 firms had registered as outsourcing facilities—and inspections have begun, focusing first on facilities that have not had a recent FDA inspection. A list of the facilities and information about what it means to register as an outsourcing facility is publicly available on FDA's website and is updated weekly.

New Molecular Entities.—Last year marked another strong year for FDA approvals of novel new drugs (NMEs). In 2013, FDA approved 27 NMEs—about the same as the 26 average annual approvals since the beginning of this decade. Some of these medications offer new hope to patients who previously had few or no treatment options. Examples of NMEs approved this year include a "game- changing" virtual cure for Hepatitis C, a drug that attacks breast cancer cells like a "smart bomb" reducing damage to normal tissues, and four new drugs to treat diabetes. Of

the NMEs approved in 2013, one-third were identified by FDA as "first-in-class," and one-third were approved to treat rare or "orphan" diseases. Almost three-quarters (74 percent) of the NMEs approved by FDA in 2013 were approved first in the United States before any other country.

Public Health Preparedness.—We continued our efforts in 2013 to work with U.S. Government partners and product developers to facilitate the development and availability of medical countermeasures for responding to potential public health emergencies. This has resulted in the recent approval of several medical countermeasures to help protect the Nation from chemical, biological, radiological and nuclear threats, including an inhalational anthrax therapeutic, a botulism antitoxin, a next-generation portable ventilator, and several influenza diagnostic tests. For emerging infectious disease threats, such as the avian influenza A (H7N9) virus and the Middle East Respiratory Syndrome coronavirus (MERS-CoV), FDA issued Emergency Use Authorizations for diagnostic tests using new authorities created under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. In addition, FDA recently approved several seasonal influenza vaccines—including a vaccine manufactured using modern cell culture techniques and a vaccine made through recombinant DNA technology.

Family Smoking Prevention and Tobacco Control Act.—In 2013 we made significant progress in implementing the Family Smoking Prevention and Tobacco Control Act. We signed contracts with state and local authorities to enforce the ban on the sale of regulated tobacco products to children and teens. By January 31, 2014, approximately 258,300 inspections were conducted resulting in about 13,400 Warning Letters being issued, and over 1,200 Civil Monetary Penalties were imposed. We launched a significant research initiative, and issued the first-ever determinations on whether certain new tobacco products were or were not "substantially equivalent" to products already on the market. Just last month we launched a national public education campaign aimed at reducing the number of young people who use tobacco products.

In addition we took important steps towards fighting the development of antibiotic-resistant bacteria, decreased the backlog in medical device applications, and exceeded our new ADUFA and AGDUFA performance goals. Our emphasis on product quality is accelerating, with the Center for Devices and Radiological Health (CDRH)'s Voluntary Compliance Improvement Program pilot, and CDER's new Office of Pharmaceutical Quality.

FDA accomplished all this and more while costing Americans only about $8 per person a year. FDA is a bargain—the products regulated by FDA account for more than 20 percent of every consumer dollar spent on products in the U.S., but individual Americans only pay about 2 cents a day to ensure that those products are safe and effective. This is a small price to pay for life-saving medicines approved as fast or faster than anywhere in the world, confidence in medical products that are relied on daily, and a food supply that is among the safest in the world.

FDA'S FISCAL YEAR 2015 PRESIDENT'S BUDGET REQUEST

The fiscal year 2015 President's budget request for FDA is $4.74 billion for the total Program Level, which is $358 million above the fiscal year 2014 enacted level. Of the total funding, $2.58 billion is budget authority and $2.16 billion is user fees. The fiscal year 2015 increase consists of $23 million in budget authority and $335 million in user fees. The growth in user fee funding stems from several new programs, along with increased collection authority for many of FDA's existing programs.

We are mindful of the larger pressures on the Federal budget, and have focused our request on the most urgent needs for fiscal year 2015. Serious product safety and quality lapses in recent years have caused serious public health situations, most notably those involving foodborne illness and the compounding of unsafe drugs, so FDA is seeking increases in order to strengthen oversight of the pharmacy compounding industry and to support food safety and implementation of FSMA.

In addition, FDA must continue to advance medical countermeasures and maintain the integrity of operations and infrastructure, and is asking for small increases to support these activities as well.

MEDICAL PRODUCT SAFETY

The fiscal year 2015 budget provides a program level of 2.6 billion, which is $61 million above the fiscal year 2014 enacted level, to continue core medical product safety activities across FDA programs. Within this amount, FDA will invest $25 million in budget authority to enhance pharmacy compounding oversight activities in

fiscal year 2015, which will significantly benefit public health and safety. It also includes $4.6 million for proposed International Courier user fees.

In 2012, a fungal meningitis outbreak associated with a compounded sterile drug resulted in 64 deaths and over 750 cases of infections across 20 States. Since September 26, 2012, 28 firms ceased sterile operations. Since that time, FDA has learned of at least 20 compounders that may have shipped contaminated drug products, and has received at least 125 reports of adverse events, including serious infections, associated with drugs produced by compounders. As of March 6, 2014, FDA is aware of 40 recalls by compounding pharmacies, including some recalls overseen by FDA, and others overseen by a State.

These statistics demonstrate the magnitude of the problems with compounders' sterile operations.

FDA intends to continue risk-based, follow-up, and for-cause inspections of compounding pharmacies to identify pharmacies with deficient sterile compounding practices.FDA is also encouraging purchasers of compounded products to buy from registered outsourcers, a new category of compounder created by the DQSA and that will be subject to enhanced FDA oversight and Federal quality standards.

FOOD SAFETY

The fiscal year 2015 budget provides a total program level of $1.48 billion for food safety, which is $263 million above the fiscal year 2014 enacted level. Within this amount, FDA will invest $24 million in budget authority to further advance recent gains in food safety modernization through implementation of FSMA. A majority of the increase is the result of new user fees, including $60 million in Food Facility Registration and Inspection fees, and $169 million in Food Import fees.

With the requested increase in budget authority, FDA will be able to develop guidance and provide technical assistance for industry, provide technical support for FDA inspectors, and begin to implement training for FDA and state inspectors. If the proposed user fee revenue is authorized and appropriated, FDA will be able to undertake the wider array of activities needed to fulfill the food safety modernization goals of FSMA, including retraining of the Federal and state inspection force, training and technical assistance for small and mid-size growers and processors, and building the modern import oversight system mandated by FSMA. The implementation of the broad preventive controls framework mandated in FSMA will reduce instances of foodborne illness seen recently as a result of E. coli O157 contamination of pre-packaged salads, Salmonella and Listeria contamination of cheese products, and Listeria contamination in cantaloupe, and minimize the market disruptions and economic costs inflicted by illness outbreaks and significant contamination incidents.

INFRASTRUCTURE

Within the funding for medical product and food safety, and medical countermeasures, FDA requests a program level increase of $5.8 million for infrastructure. Infrastructure includes GSA Rental Payments, Other Rent and Rent Related costs, and White Oak Consolidation.

CURRENT LAW USER FEES

Within the funding requested is a $75.4 million increase for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The user fees collected will support the review and surveillance of human and animal drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases for many existing programs, which will expand the available options for treating and curing diseases and will fund strategies to prevent and reduce the use of tobacco products by young people and reduce the burden of illness and death caused by tobacco products. Some of the amount requested supports infrastructure costs associated with current law user fee programs.

CONCLUSION

FDA's oversight of our food and medical products supply is indispensable to the health and well-being of every American. We carry out our broad public health responsibilities effectively and with few taxpayer dollars—even as those responsibilities are expanding as a result of new legislation, technological advances, and a globalized marketplace. Our fiscal year 2015 budget targets our spending efficiently, on programs that are essential to providing Americans with the safe foods and effective medical products they expect. We look forward to answering your questions today and to working with you in the coming year.

Senator PRYOR. Thank you. And thank you for your testimony.

Let me go ahead and jump in with the first question. Again, we'll do 7-minute rounds.

E-CIGARETTES

Dr. Hamburg, on Monday of this week, I sent you a letter about e-cigarettes, e-liquids, or some people call them liquid nicotine. There was a recent New York Times article that stated that nationwide poisoning linked to e-liquids jumped to 1,351 in 2013, and that's a 300 percent increase over 2012. And it looks like, based on the current numbers, that the 2014 number will probably be double what 2013 was. So obviously this is an exploding problem. And I think one of the reasons it is exploding is because of these little bottles right here.

This is a product called "J Juice." And this one is, believe it or not, the flavor is "Scooby snacks;" okay? This one over here, the flavor is "sour apple." And this one over here, the flavor is "moon pie." And so, the thing that concerns me is really the packaging and the attractiveness to children. They're actually—you can go to the candy aisle at a convenience store or a grocery store and you will see something very similar to this except it's candy.

And I see the numbers and I, obviously, one of the first things that concerns me about this is the marketing to children, when you have a little friendly, colorful packets like this, and then, the packaging itself, it's not childproof. Childproofing probably helps the toddlers and the small children; it really doesn't help teenagers.

And we can talk about some of that in just a moment, but I do think that at least there's probably a whole range of issues to talk about with these, legal and others, but also I do think that probably the first priority should be to try to keep these out of the hands of children.

And when I look at Arkansas and I look at our statistics in our State, there've been almost 80 cases of poisoning. And, of those, about one-fourth were kids age 5 and under. So, again, it's not limited to them but you see this really strong tendency to kids age 5 and under. And of the more than 1,300 exposures nationwide in 2013, about 90 percent of them were pediatric cases.

So I know that you're concerned about this, I've talked to you and your staff has told us some of the things you're doing. So if you don't mind, if you could just walk through with the subcommittee some of the things you're doing. I know you're in a process and some things you really can't talk about it in great detail but the subcommittee would like to hear what you're doing with this liquid nicotine.

Dr. HAMBURG. Well, we share your concern about the potential risks of these e-cigarettes and liquid nicotine exposure and do feel that this is an area that requires greater attention, action, and concern.

At the present time, we do not have the authority to regulate e-cigarettes and some of these other products you're describing unless they make a therapeutic claim, in which case then they can be regulated as a drug.

But in the absence of that, we do need to pursue what we call the "deeming rule," which is something that was laid out in the 2009 Family Smoking Prevention and Tobacco Control Act. That really gave us authority to go beyond what was explicitly in the law, which was the oversight of tobacco, roll-your-own, and smokeless tobacco—cigarette tobacco, roll-your-own, and smokeless tobacco, to other products that are increasingly in the marketplace. And we've been working hard on that. And we hope, some of you have heard me say this before, but we really are making progress and hope that that proposed deeming rule will be put forward very soon so that we can have broader comment in the input. And that is a critical building block for our ability to address what you were describing and other products in the marketplace, as well.

I would also say, though, that while we have been working hard on that, we have also been investing in an important scientific research that will give us new information so that we can most responsibly regulate these products. And we've been doing that within our agency and with partners in the Federal Government, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC); as well as providing grants to academic institutions to help us build the knowledge base about both the behaviors associated with these products and their health impacts, and also to better understand some of the constituents of these products and the public health implications and medical implications of those, as well.

Senator PRYOR. Yes. I know part of what you're striving to do is to be very science-based and understand that. But I also do think that when you look at the numbers, especially if you take one issue here that, to me, would seem fairly easily to tackle, at least in the beginning, would be just the packaging of this.

I'm curious, like you mentioned a deeming rule, do you have to go through that process on a deeming rule just to work on packaging? And then, how long does that typically take? I know you said very soon you'd allow for comment but how long does that process typically take?

Dr. HAMBURG. Well, we do need to have authority over these products in order to regulate them and take certain actions. So that is why the deeming rule is so important. It's foundational to so many other things that we need to undertake.

I will be honest with you that I think it has taken too long to move the deeming rule forward and we are pushing very hard to get it out as a proposed rule for broader discussion and then for finalization so that we can take these actions and provide the regulatory oversight; always science-based, that is crucial. But we need to be able to address these other important products that weren't directly covered in the original legislation.

Senator PRYOR. Yes. And I'm not trying to just single out J Juice because the truth is there are dozens of these different companies and labels. And I think, right now, this is such a new development, I'm not sure that we really know where all this is being made, and what all is in here, and who would regulate it and things like that.

It's a little bit of a Wild West out there but I am seeing what we call "vapor shops." Those are starting to spring up in Arkansas. And I didn't know this until the other day. I was talking to our Alcohol Beverage Control guy in the State that does that and he was saying that this is a real challenge, is these vapor shops.

But also online. That's a whole new thing. Again, I had some of my staff look at this online. And literally, you say, "Oh, yeah, I'm 18," or "I'm 21." Click. And then you can get just unlimited stuff. And some of the flavors, again: "tutti fruity," "fruit punch," "grape," "cherry," lots of other choices; lots of brands.

So I'm not really trying to single out just one brand. And I'm not even saying that this is all completely horrible, but it's a challenge especially with young people that I think it's, again, it's a complicated set of issues that I know you're focused on. I'd like to continue to work with you on that.

I've exhausted my time for the first round. So, Senator Blunt.

Senator BLUNT. Thank you, Mr. Chairman.

We'll have more than one round, too; won't we? So we'll have time to ask questions we want to ask today.

And again, Dr. Hamburg, thank you for being here.

PREVENTIVE CONTROL RULE

As I may have mentioned in my opening statement, Senator Shaheen and I sent a letter in November of last year about the Food Safety Modernization Act and certain sections in Produce Safety and Preventive Controls for Human Food Rules. You're re-proposing part of those rules. Why aren't you just re-proposing all of the rules so that people can see the new changes in the context of the rest of the rule that's out there?

Dr. HAMBURG. Well, this has been a very open process where we have tried to reach out and really get input on all of the different rules. There are seven foundational rules for implementation of this important new law. Congress gave us some very rigorous deadlines for implementation and the courts have also weighed in as well. So we are really pressed to move forward. At the same time, we want to get it right.

And so, what we have been trying to do is to listen carefully, including going out to farms and food producers across the country for meetings, visits, and listening sessions to understand where the concerns are. And there are a set of clear, targeted concerns in the area of preventive controls for human and animal feed as well as in the produce area. And that's where we think that by re-proposing, we can make a real difference.

We agree with your earlier comment about this is not an arena where the one-size-fits-all model can work. We want to find practical, workable, solutions that will matter to make it feasible for industry to implement these important new rules and the spirit of the Food Safety Modernization Act. But that will also make a difference for improving public health in reducing preventable foodborne outbreaks.

So I think we're moving forward on the path that makes sense that enables us to reach our common goals but in a timely way that will matter for both consumers and for industry.

ADMINISTRATIVE PROCEDURES RULE

Senator BLUNT. Well, I do think there's some significant merit to, when you re-proposed certain rules, other rules that were in that package may be impacted by that as well. But I know in the Health Committee, in the last month or so, a number of our colleagues were concerned that you might not be totally adhering to the Administrative Procedures Rule. And you addressed that to some length.

What I'd really like to know today is, as you re-propose the Preventive Controls Rule, that you intend to adhere to the Administrative Procedures Rule and ensure that any new testing requirements would be subject to economic analysis and full notice.

Dr. HAMBURG. Well, we certainly are committed to adhering to the Administrative Procedures Rule. And we're committed to really listening to the various stakeholders as they raise issues and concerns. So, I take your comments to heart. And we will take them back to the agency to review what we're doing and also as we shape the re-proposal.

Senator BLUNT. And that will include an economic analysis?

Dr. HAMBURG. Yes. I——

Senator BLUNT. I think that's——

Dr. HAMBURG. Probably multiple economic analyses.

ANIMAL FEED RULE

Senator BLUNT. All right. You just mentioned the part of the rule that related to what, I believe, the rule may have referred to as "waste." "Byproducts" would be another term that I would have more traditionally, I think, seen used because the waste could wind up in places it doesn't need to wind up in if you really, truly, decide that this is just material that is to be discarded as opposed to material that can be re-purposed, I guess, as we re-propose these rules.

Last night, FDA announced that brewers' grains would be addressed in the re-proposal of the animal feed rule. You and I talked about that part of the rule the other day. And, since then, I thought about this with some greater thought to what we're really doing here. And, I think the issue is larger than brewer's grains. I think there are lots of products that, from burnt potato chips to orange peels that are re-purposed to animal feed and other things, and under all of the restrictions that we would want to have there, I'm a little concerned that the only thing that FDA appears to be revisiting right now is the brewer's grains part of the so-called waste. I think it's a bigger issue than that. And any response you'd like to have, I'd be glad to hear.

Dr. HAMBURG. Well, I think, I mean, I'll be honest with you, that this was an issue that was only recently brought to my attention in terms of the agricultural practices. And, in discussing it with the team at the FDA, there was a strong sense that this is an area of importance that we want to support sustainable agriculture practices. And it makes enormous sense. We do believe that it can be addressed in a practical, sensible way. After our conversation about distillers' grains, I took that back and we're looking at that. So I think we will be looking at it more broadly.

Senator BLUNT. I think you really need to because the place that these things will wind up if we don't make the most out of products we can make the most out of, it's going to be in a landfill somewhere; nobody benefits from that until you truly are at the point that there's no economic or societal purpose to be served by getting more out of what we have. World food needs are going to increase dramatically. That means that not only do we need to think about how we produce more food but how we more effectively use the food and food products we have. And I think this is a big issue and I'm glad that you're going to go back and look at it again.

This is everything from leftover seeds that aren't used that are then mixed into animal feed. I think one of the major, maybe all of the companies that have orange peels and citrus peels, pelletize those, and then they have found good and productive purposes for those. And again, they go somewhere that nobody benefits from more things in the landfill, particularly if there's real value left in these products. And I'm hopeful that you're going to look much more in-depth at what all that really means industry-wide.

Chairman, I'm out of my time, too.

Senator PRYOR. Thank you.

Senator Merkley.

DEEMING RULE

Senator MERKLEY. Thank you very much, Mr. Chairman.

And thank you for all of your testimony.

And I want to continue the conversation that the chair began regarding the deeming regulation. We passed this act in June 2009. And it took 4 years and 4 months for the FDA to send it to OMB which, to me, is an egregious amount of time.

At the beginning of that period, we had products being test marketed in Oregon and elsewhere in the country that were dissolvable tobacco products. We had dissolvable tobacco formed into toothpicks like this. We had it being formed into mint-tobacco candy with caramel and mint flavorings. We had dissolvable tobacco being formed into breath strips, as ironic as that might seem. Here is some mint breath strips that you might want to try made out of tobacco. And we had an explosion in the flavors of cigars and cigarillos and so forth. Just a little sampling here; we've got "sweet cherry," "Captain Black." We've got the "grape" cigar; we've got the "strawberry" cigar. Make sure we get some "apple" cigars. And the list would go on and on.

The whole point being that the tobacco industry understands that you have to addict children because adults don't pick up tobacco products and start using them. Essentially, it has to happen before the age of 21.

And all of this, I am told, and have been told repeatedly by the FDA, would be covered through the deeming regulation. But as you point out yourself, you have to get the deeming regulation done to get that authority. And all we're talking about now is the draft regulation. It's only the draft regulation that's been sent to OMB. And then, OMB has been sitting on it the last 4 months. I find this really embarrassing, disgraceful, and it's harmful to the children of America that the FDA has been sitting by for years with this

power, enacted in 2009, and not even getting the first step in the regulatory process completed which is to get out of draft regulation.

I would like for you and your team to wake up every morning, visit the OMB, and get that thing out there, because people's lives are being impacted. We've had a huge conversation about healthcare in our Nation. Well, this is healthcare. This is about the addiction to products that cause all kinds of disease over the course of one's life. And it's not just the quality of life. It is also the cost to the healthcare system treating all of these diseases.

Now the chair beat me to the punch in talking about the next phase of this and you may have started seeing the emergence of vape shops. This is a picture of a vape shop. It's called "DC Vape Joint," and it has a little underground entrance to it here just a few blocks from our Capitol. Inside of that "vape joint" shop, you find various displays of liquid nicotine of all kinds. You find a rack of dozens and dozens of different flavors.

And I brought two of these today because I think they demonstrate an insidious strategy to addict our children to nicotine. This one, and the chair had a similar bottle, called "Scooby Snacks." Now, if that's not designed to appeal to a child, I don't know what is. And, if you look at it closely, it says, "Zero milligrams of nicotine." Oh, there's no nicotine in this. Is this a bottle of juice? We're not sure. There are no ingredients listed on this. It's designed to go into an electronic cigarette, but this is one of those many vials of products that are out there being displayed. And the other bottles look the same. And, here, we have "gummy bear." Now, "gummy bear," if you look closely, doesn't have zero milligrams of nicotine. It has 10 milligrams.

And so here you have the starter kit, called "gummy snacks," to get kids using this stuff in electronic cigarettes that look like this. They sell these little starter kits in that vape shop. They're hoping kids will start with this zero milligrams, but they'll soon be using the other. And if this one with 10 milligrams, is flavored "gummy bears?" That's obviously marketing to children.

The "gummy bear" one, actually, you can read the ingredients on it. And it notes it contains nicotine, so on and so forth, keep out of reach of children. This one, it's printed in white on black. It's virtually impossible to read so I had the expert eyes of my staff tell me what this actually said. And, let's see. Where do I have that? Right here. This fine print that is in the block that normally would have the ingredients says, "Stay weird, challenge the status quo, everybody love everybody and, above all, enjoy yourself." That's the starter bottle for this line of nicotine products.

You all have got to get this deeming regulation done. You have a responsibility to the health of American citizens, our children, and 4 years and 4 months to get the first draft over to OMB is unacceptable. And for OMB to be sitting on this now over the last few months is unacceptable.

I had a timeline done of all the times I've contacted the FDA about this. It was signed into law in June 2009 and, about 8 to 10 different times I've either sent letters, met with you, or met with Lawrence Deyton who was Director of the Center for Tobacco Products, and time and time again it was said, "We're working on it,

we're working on it, we're working on it. We want to make it, kind of, iron-solid."

Well, there's no making anything that can't resist a lawsuit. Of course there are going to be lawsuits. There are teams of lawyers that've been preparing their cases over the last 4 years. I'm sure they'll attack every angle once it's done. But, to never get through the gates and get that process started of getting a draft regulation, it's completely absolutely unacceptable. And I have no idea—we've done letters, we've done meetings, with you, we've done meetings with folks that work for you.

How do we possibly convey the importance of this to the future of America, to healthcare, and actually get some action?

Dr. HAMBURG. Well, as I said, it has taken far too long. We have been working very hard on this. It has been a complex challenge for many reasons.

I do believe that very soon I will be able to call you and say that the deeming rule is out. It will just be the first step in a process, though. As you noted, it's a proposed rule. But it is essential we get it out. I could not agree with you more that this is a vital issue that these products represent very real threats to health and to the future of our children. We have to get it done and we have to get it done soon.

Senator MERKLEY. Well, I'm just asking you to make your agency as visible as possible with OMB for their review to be completed. If you can advise on how we can be helpful. It's just, let's not let another month pass with this thing gathering dust in some bureaucrat's closet.

Dr. HAMBURG. I think we're almost to the point of the proposed rule. And I promise you, you will be among the very first calls that I make. But we have to respond, and your criticisms are fair. This is one of the most important public health challenges before us. And we have this unique responsibility in terms of oversight of these products. And we are committed to moving forward on this.

Senator MERKLEY. Thank you very much.

Senator PRYOR. Thank you.

Senator Cochran.

Senator COCHRAN. Mr. Chairman, I may have not appreciated the practical part of the question that we just heard and the answer to it.

I was going to ask about the Modernization Act public comment period and whether or not that was going to be extended. There's some concern as I understand it that because of overlapping and maybe other factors among the new rules that the Food and Drug Administration intends to implement, whether or not there isn't sufficient comment period.

PRODUCE SAFETY

According to one piece of information I have in front of me, it says there was less than a month between publication of the Feed Safety Rule and the comment deadline for the draft rules on produce safety and preventive controls for human food. Is that something we need to worry about or provide advice and counsel to how do you do this and still recognize the fairness to your consumers that this contemplates?

Dr. HAMBURG. Well, thank you for your questions. And it follows nicely on an early question.

As was noted, this is a sweeping transformation of the food safety system in our country recognizing both domestic and global needs. The law that was passed by Congress really laid out a very ambitious agenda for us including a schedule for a set of important rules.

The comment period is still open on two of the seven foundational rules. But on the other ones we have tried to extend comment periods to have a broad outreach and opportunity for comment and input through, various mechanisms; an open docket, public meetings, a range of discussions, etc.

We are currently continuing our interactions with the range of stakeholders. And we are anticipating that we will re-propose certain aspects of some of the critical rules; the preventive controls for animal and human feed and produce where there have been areas where the concerns have been very clear and where we feel that we do need more opportunity to find the right regulatory pathways to really develop the right approaches that will make a difference. Make it a law that is feasible for industry to implement, but achieve the goals of reducing foodborne outbreaks for American consumers.

Senator COCHRAN. One of the joys of the community where I lived back in Mississippi are the farmers' market outlets where produce farmers bring in their wares and provide opportunities for the general public to come look and buy fresh fruits and vegetables, particularly.

And this is a very popular avenue for good diet habits. Families go to the farmers' market on Saturdays and get up early. And I can remember as a young boy my grandparents who had truck farming interests in Mississippi, taking items from the farm that had been grown there or the farm for display and for sale. It was a very exciting thing. And, thinking back on it, it was a real tradition that has carried forward even to the present day. People really enjoy the opportunities that this provides even if you're living in the city and not on a farm like my family was when I was small.

What exemptions, if any, or differences, if any, should be recognized and made available for small family farms to provide their vegetables and fruits that's grown on their places, to be seen and sold without fear of running afoul of some Federal official coming and saying, "You violated some rules and you shut down this operation."

And, to what extent do you think that the Federal Government should be involved in that? Or should we let State and local governments manage the Saturday morning visits to the farmers' markets?

TESTER AMENDMENT

Dr. HAMBURG. Well, we all enjoy, I think, those local farmers' markets and they play an important role in the community and for health. The law does include some explicit recognition of that; the so-called tester amendment gets at some of those issues about small growers and producers.

We also feel that the implementation of this new law has to be done in partnership, importantly, including with State and local agencies and organizations so that really it will reflect and build on what is already being done and what works for promoting and protecting the safety of the food supply. Whether you're a big grower or a small grower, I think everyone wants to produce great, high-quality food. But in terms of the application of aspects to the Food Safety Modernization Act, there is a recognition of the special needs of small farmers and producers. And that is certainly reflected in how we are addressing it and will be implementing it.

Senator COCHRAN. Does this mean there'll be exemptions for State and local governments to regulate and monitor and inspect, rather than having the Federal Government?

Dr. HAMBURG. That there will be extensions; did you say?

Well, we're working closely with USDA and the agricultural extension service as we try to implement this.

And part of what we are seeking in our budget request is moneys that will enable us to actually give seed money to State agencies as well as technical assistance and training so that they can be full partners in implementation.

Senator COCHRAN. Thank you.

Senator PRYOR. Thank you.

Let me just, one last comment on what Senator Merkley and I asked you about earlier. And that is, I'll just say we can't wait for another tragedy to act. And I know that you're trying to act. But just count me in to work with you and industry to try to facilitate moving this through as quickly as possible. And, to me, it seems like the childproof packaging is a commonsense first step. I think there's a lot of other things we need to do but I would love to work with you on that and continue to move that down the tracks as quickly as possible.

Dr. HAMBURG. Thank you.

COMPOUNDING PHARMACIES

Senator PRYOR. Let me change gears, if I can.

You mentioned compounding pharmacy in your opening statement. And I guess what I heard you say is that the status report on that is you're making progress. Kind of moving through the various things you need to do there. But are there any particular challenges? I mean is there a problem with the law that was passed? Or is there something going on that you didn't anticipate that the subcommittee needs to know about?

Dr. HAMBURG. Well, I think that the passage of the DQSA is a very important step. It clarifies one component of the prior existing law that related to compounding pharmacies for the FDA's so-called 503(a) which had been interpreted differently in different courts. And so, we had sort of a patchwork in terms of its application. So that is now clarified and it will be uniformly applied across the Nation.

It also created a new category under 503(b), which allows compounding pharmacies that are making certain high-risk products, sterile injectables, to register with the FDA and be subject to our oversight. And I think, to promote safer, better quality products for patients, our challenge there is that this is a voluntary pro-

gram and some compounding pharmacies will appropriately register with us. And actually, I think about 35 have to begin that process of coming under our regulatory oversight for these very important, medically important products, but high-risk products.

But there may be many other compounding pharmacies that are, in fact, making these high-risk products that don't choose to register with us, don't choose to become part of this new regulatory framework. And we are concerned that some of those manufacturers and the products they produce may not be adequately safe for patients and medical care in our communities.

So we need to maintain a very proactive posture here. We need to continue to monitor who's out there doing what, which is hard if they don't have to register with us. We need to work closely with States who have the primary responsibility for traditional compounding pharmacy regulation. So there are a lot of challenges. And we think it's very, very important to protecting public health that we maintain a very strong presence in this arena and continue to build a strong program.

Senator PRYOR. And, back to your budget, and looking at the cost to you of implementing this and rolling this out and doing all the things you need to do, as I understand the budget, in order to find the resources you need, you're paying for that with some unspecified cuts to other medical products' safety activities. And do you know what those are yet? And do you know how it's going to work?

WHITE OAK

Dr. HAMBURG. Well, it is the case that the $25 million for this new initiative is not new money but it is coming from elsewhere within the agency. We have the opportunity to reallocate $15 million that would have been used for White Oak, our Washington headquarters' consolidation activities, that will go unutilized because, sadly, the General Services Administration (GSA) is not funded to do the construction necessary to continue to build out our master plan for that campus. And the rest of the moneys will be taken from other efficiencies that we can find within the agency and really trying to leverage resources as best we can.

This is so important to the health and safety of the American public that we feel we need to have resources to build a program that will make a difference. And, over time, I think we're going to have to find other budget mechanisms to support these crucial activities. And it is my guess, based on what I see as the need out there and the demands on FDA that likely we will have activities and responsibilities that outstrip the available resources.

FOOD SAFETY MODERNIZATION ACT

Senator PRYOR. And let me change gears here, again, on the Food Safety Modernization Act.

Mr. Tootle here, at some point, wrote on his blog, an FDA blog, that "With current resources, we will still be able to issue the FSMA rules but we won't be able to effectively implement them." And, obviously, I have that concern. I think a lot of people have that concern just about resources and how we're doing here. But are you requesting enough money to issue these rules and to implement them?

Dr. HAMBURG. This is a crucial time in terms of implementing the program itself. We can complete the process of finalizing the rules as we've been discussing, but what really matters to the public and to safety is that we put these programs in place in fiscal year 2015 and subsequent years are going to be crucial to that effort.

And we need the moneys that we have requested in order to fully implement and realize the potential of this program to undertake certain critical activities that are vital to success including building the modern Import Food Safety Program that we need; including building the important partnership with the States, that Senator Cochran and I were just discussing, in terms of the seed money States need to build capacity and the training and technical assistance that are necessary to be able to ensure that they can be full partners in this effort. And we need resources so that we can work as effectively as possible with industry in terms of training and technical assistance as they move to implement this important new law.

So, it is essential that we have these resources. And I think that with those resources, we can really make this law work and achieve the vision that Congress had when they passed it.

Senator PRYOR. But are you requesting enough for fiscal year 2015 to get done what you need to get done in fiscal year 2015?

USER FEES

Dr. HAMBURG. Well, the amount of money that is in the budget request reflects our thoughtful and serious assessment of what we would need and, I think, mirrors other assessments that have been undertaken.

The Congressional Budget Office (CBO) came out with a somewhat higher budget number for the overall implementation needs of the Food Safety Modernization Act. We took another look and tried to be a little bit more conservative. But, we do need money to implement this.

We also realize that the user fee request is a challenge that the user fee option is one that has been utilized in other arenas of the FDA but not so much in the food space. And so, as we look at fiscal year 2015, we see a budget need and the pathway to get there is a complicated one. And we look forward to working with you on that because, I think, we all share a recognition that being able to really implement this law matters to the health and safety of the American public and it really matters to the food industry that plays such a crucial role in our food safety system.

Senator PRYOR. Senator Blunt.

Senator BLUNT. Commissioner, I think this is the fourth year in a row that the budget has requested these fees. And I think now they're around $220 million in new and repetitive registration and import fees. I think it's unlikely that those fees are approved.

Given the choice, would you rather just have appropriated money from general revenue or have this financed on a fee basis?

Dr. HAMBURG. Well, what matters to me as Commissioner of the FDA and to the team that's been working so hard on food safety and what ultimately matters, I think, to our country, is that we get the job done; that we successfully implement this important law.

And from my perspective, we need the dollars and we need the money if fiscal year 2015 is a critical year for implementation.

And we need a sustainable funding stream as well. Too often, we have been in a position where there's a focus on an issue and we get some resources and then they get cut back when the attention shifts somewhere else. So we need a level of funding that is both adequate and sustainable. And if it comes from budget authority, that would be terrific.

Senator BLUNT. Do you know anything that we don't know that would make this request for fee increases more likely this time than the precious three times you asked for it?

Dr. HAMBURG. Well, I think that it is true that you've seen this request before. We have had discussions with industry and components of industry are more supportive than others in terms of user fees. It will be a discussion that we'll continue. Meanwhile, we are trying hard as an agency to implement this important law and I think we have to be realistic about the need for resources.

Senator BLUNT. On the compounding resources, the CBO's score, the Congressional Budget Office score was about half what—was $12 million and declined pretty dramatically after the first 3 years of getting you up to where, I guess, to initiating the program.

I have two questions, really. One is why is this amount twice as big as what the Congress anticipated it to be? And two, the budget proposes reductions of $3.685 million in money that previously would have gone to looking at human drugs, $1.628 million reductions in biologics, a $2.88 million reduction in medical device programs without any real understanding on, any explanation on how those amounts of money that previously we thought we needed in these areas could be shifted now to compounding?

So why the bigger number? And is there any explanation for the several millions of dollars shifted around internally; why you don't need it there now and did need it there before?

Dr. HAMBURG. Well, first, with respect to the CBO question. We are really trying to better understand their estimates because we don't think that they actually match what the needs are. And this has been an evolving area of focus, but we also think that there are some timing issues in terms of how and when they did their assessment. And so we're going to be working with them to better understand.

As far as the moving money around, the reductions that you note are not because they're being redirected towards the pharmacy compounding issue, we're going to be really looking across the agency and looking to find efficiencies rather than taking from other programs. But we are operating in a very constrained budget environment. And, if you ask me, do we have what we need in each of these critical program areas to do the job that we've been asked to do and I think we must do, in most cases, I do believe that the demands outstrip the resources.

So it's a very challenging time. And we are trying to really look at programs in as clear-eyed a way as possible; focus on the critical needs and priorities; and to try to build strength in other ways. In certain instances, through partnerships and collaborative activities, through economies of scale and other efficiencies, and by really focusing on what are the most critical and urgent needs.

SEQUESTERED FEES

Senator BLUNT. In the fee area, one, our committee tried to do all we could to be sure you had access to the fees that you were able to collect, some of which were set aside by the sequester process. And, from an authorizing point of view, Mr. Pryor and I both have been very interested to see that happens again. But did happen. We got those fees back. But I think you've got another $79 million worth of fees that were collected prior to 2010 that the Office of Management and Budget says can't be spent.

Do you have any advice here, Mr. Cochran or Mr. Tootle, on what we could do about that so that that money could actually be used to advance the purposes it was collected for?

Dr. HAMBURG. Well, first, let me thank you for the work that you did to help address the problem of the sequestered fees, the user fees, which was very worrisome and we're grateful for the leadership that you brought to that.

With respect to the outstanding user fees, in terms of past collection, you are right. I think the number is $79 million and I think you've created a framework in terms of language that enables us to engage in discussions with the Office of Management and Budget (OMB) and we're actively in that process because we would—as I was saying, in answer to your last question, we do have critical needs and those resources could make a difference.

Senator BLUNT. Right. Well you do have critical needs and you do have this money that's been collected for the purposes of some of these needs specifically.

And I'd certainly be willing to, and have been willing to be as helpful as I could be to convince the Office of Management and Budget, or whoever needs to be convinced. Maybe we need to do that with some further language again this year, but we want to work with you on that. There's no reason to have that money collected as fees for a purpose not to be somehow fenced off from ever serving that purpose. So——

Dr. HAMBURG. Thank you.

Senator BLUNT. Thank you, Mr. Chairman.

Senator PRYOR. Thank you.

Senator Cochran.

Senator COCHRAN. I've already——

Senator PRYOR. Senator Collins.

Senator COLLINS. Thank you very much.

I thank the Senator from Mississippi and the chairman and ranking member.

OFFICE OF FOODS AND VETERINARY MEDICINE—SPENT GRAINS

Commissioner, I understand that Senator Blunt has brought up already the issue of spent grains. Grains that have been used to make beer and serve no further purpose to the brewer and are now being used for animal feed. I have to tell you, but I think the FDA's approach is a perfect example of a solution in search of a problem. This practice has been going on for literally centuries where brewers have donated or sold, often for little money, their spent grains to farmers.

In Maine, we have an emerging craft beer industry that now employs over 1,000 people and 90 percent of spent grains produced by craft brewers are disposed of as animal feed. To me, this makes great sense. It recycles the remainder of the spent grains. And there simply is not evidence of problems.

I understand, and agree, that it's essential that we ensure the safety of our Nation's food supply. But this is an example of regulatory overreach that will hurt both the small employers, that our craft brewers are, and the farmers that are working so cooperatively with them. So I want to just second the concerns that Senator Blunt has raised and urge you to take a really hard look at what the impact of that rule is and whether you're really solving a problem or creating one.

Dr. HAMBURG. Well, thank you.

And you were not present when we had the early discussion.

Senator COLLINS. Correct.

Dr. HAMBURG. I'll just reiterate that we have heard these concerns. Senator Blunt actually raised some additional ones around this notion of sustainable agriculture and recycling of product. We actually do think that this is an arena where there are sensible, reasonable solutions and we're committed to working towards those. And we think that this issue can be effectively addressed when we put forward a re-proposal this summer of some of the components of the human and animal feed preventive controls rule and the produce rule.

ARTIFICIAL PANCREAS

Senator COLLINS. Good. I hope we will see a significant change.

I know that you're also aware, well aware, of my strong interest in the development and approval of an artificial pancreas, which would help people living with type 1 or juvenile diabetes to achieve dramatically better control over their blood glucose levels until a biological cure is found.

And I want to start by commending you and your team for all your work to advance these critically important technologies by streamlining the review structure in improving outpatient studies in a timely manner. An extremely important step was taken last year when your agency approved a Low Glucose Suspend system which is considered, in many ways, to be the first generation of an artificial pancreas technology.

I can tell you from the long years of work that I've done with families with children with type 1 that they are so eager for a breakthrough in this area. I know you're collaborating closely with the families and with stakeholders like the Juvenile Diabetes Research Foundation and with medical researchers outside the agency. But could you give me an update on your timeline, your strategy, for ensuring that these very promising new technologies reach patients as soon as possible?

Dr. HAMBURG. Well, thank you for the question and your appreciation of how hard we've been working in this area. I do think it's really a model for the importance of FDA working in full partnership with the scientific search community, medical care community, and importantly patients and families.

The development of an artificial pancreas would transform the health and the quality of life of individuals living with type 1 diabetes and of course to their families as well. And it's not yet available anywhere in the world but we are really working hard to make it a reality.

We put forward final guidance several years ago to really lay out what would be the regulatory pathway to try to encourage manufacturers to move in this direction and ensure the right research and study. We now also have, I think, 12 clinical studies, some community-based studies, including one at a summer camp, to try to really understand how the current prototypes would work and, we want to move this as swiftly and surely as possible.

We want to make sure that the product is safe and effective because if you are relying on this for the assessment of your glucose levels, in a continuing way and the delivering of insulin, it needs to do it right. But we think the science and technology is coming together with an acute and currently unmet medical need. And it's a very exciting and promising undertaking.

And I would just add that it also, I think, is a model for other areas of medical product development as well; the partnership with key stakeholders and really trying to leverage the opportunities in science and technology today with critical unmet medical needs.

Senator COLLINS. Thank you.

Mr. Chairman, could I do one more? Or—thank you very much.

SEIZURE MEDICATION—CANNABIDIOL

Commissioner, I recently had a very poignant meeting with a family in my office in Maine whose daughter had suffered for years, since she was age 11, from uncontrolled seizures. And she had been unable to control her convulsions with regular seizure medications and her family finally decided to have her try a tincture extracted from marijuana with a high cannabidiol (CBD) value, which does not cause the psychogenic effects of smoking marijuana. And, just so my colleagues don't misunderstand, I'm opposed to the legalization of marijuana the way that Colorado has done.

But, for this young girl, the results have truly been remarkable and life changing. She's now a college freshman. She has not had seizures in many, many months whereas before she was having them all the time. And she's not, obviously, experiencing any kind of high because of the tincture that she is taking; so it's not interfering with her in that way.

I know that a drug containing highly purified CBD, similar to the tincture being used by my constituent, is currently under investigation by the FDA under its expanded access Investigational New Drug program to help treat a few children with intractable epilepsy or other kinds of seizures.

Could you tell me where you are in this process? Has consideration been given to expanding the number of young people who could participate in the program? And, as a physician, do you have any preliminary thoughts on whether this may, in fact, be a promising treatment for children who have uncontrollable seizures?

Dr. HAMBURG. Well, you raise many important issues.

With respect to a specific product that might be under review by the FDA, without permission from the sponsor I can't speak to that. But what I certainly can say is that, number one, I think it's very important that we really study potential medical applications of marijuana and marijuana components. The active ingredients in a controlled way so that we can really understand what works, how, and for what conditions. So I think that is a very important undertaking. And certainly, this issue of that class of product for epilepsy has been brought to my attention as an area where there are scientists and medical providers who believe it holds great promise.

With respect to expanded access while a drug is under study, we are very responsive to applications or requests that come. At the end of the day, it's the company that has to decide with affirmation from us to make the product available. But that is something where, over a period of many years now, we have had an active program. And, the majority of requests for expanded access that come before us are supported by the FDA.

Senator COLLINS. Thank you very much.

Thank you, Mr. Chairman.

Senator PRYOR. Thank you.

FEED RULE

I have about four or five questions left. I'm just going to try to run through these very quickly.

One is to follow-up on a question by Senator Blunt and Senator Collins, on the feed rule, the feed rule. And actually, mine is a little different take on that. I know that under the current rule, as I understand it, feed mills are exempted in situations where the owners of the mill are feeding animals it owns, on land it owns. Animals it owns on land it owns. And that's probably a sensible exemption or exception. But the question is should it be extended because in the poultry world and in the pork or swine industry world, oftentimes they own the animals and they own the mill but they contract out to independent farmers to do that. Or do you know are all considering extending that exemption?

Dr. HAMBURG. What I would like to do, with your permission, is take this back to the experts within the FDA because this is an important question, but it's at a level of detail that I really can't answer.

[The information follows:]

Section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires the registration of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the U.S. These requirements are implemented in Title 21 of the Code of Federal Regulations, part 1, subpart H, Registration of Food Facilities. Some facilities, e.g., farms, are not required to register as a food facility under this subpart. The definition of furm is found in 21 CPR 1.227(b)(3):

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. [The preceding sentence would be deleted under the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," 78 Fed. Reg. 3646, 3795 (Jan. 16, 2103).] The term "farm" includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Section 103 of the FDA Food Safety Modernization Act applies only to facilities that are required to register under section 415 of the FD&C Act and its implementing regulations. At this time, FDA is not intending to extend/change the definition of "farm" to include farms providing animal food to other farms. The feed mill in the scenario presented would probably be required to register as a food facility as the feed is not being consumed on a farm under the same ownership as the feed mill.

Senator PRYOR. Sure. Okay. That's great.

DRUG SHORTAGES

And another one, I'm totally changing gears here as well, is on drug shortages. And I think we kind of barely touched on that in testimony or in questions. But, I know that there are drug shortages and there have been some Government Accountability Office (GAO) recommendations. And I'm just curious about the status of that and if you're working with industry to try to make those drug shortages less frequent and less severe?

Dr. HAMBURG. Yes.

Well, it's a really important area. And, as you know, over the years there have been shortages in medicines that are really critical to the practice of medicine and the care of patients. We have seen some very significant progress. We went from, I think it was 251 shortages a couple of years ago, to 44 this past year. But we're seeing another trend that we're paying attention to which is we're seeing some of the shortages sustained for a longer period of time.

A number of things are making a difference as we respond to shortages and helping us really grapple working with industry, of course, who on the frontlines of this to address the problem. One is that through the Food and Drug Administration Safety and Innovation Act (FDASIA) we got new authorities to require companies to report to us not just if they were going to discontinue a medically important product within a 6-month timeframe, I think it was, but if there was reason to believe that there was an imminent threat to a product, a supply chain disruption, et cetera. So that's given us an opportunity to engage much earlier with companies that might have emerging or real shortages.

We work closely with companies to try to address the cause of the shortages whether it's quality or lack of availability of a product so that we can keep that product in the marketplace. If it's a quality issue that requires them to actually stop manufacturing for a while, we work with them to try to fix the problem as quickly as possible.

We also try to identify other manufacturers making that same kind of product and encourage them and work with them to actually ramp up the manufacturer. Or sometimes identify a manufacturer who might not be making that specific product but could make that product and, again, we would work with them to quickly move them towards an ability to make that product.

And when necessary, we also will look oversees to see if there's an equivalent product that's available and approved in another country but not here and then we will move to make that drug available through importation to address a shortage need.

So we have a range of tools. We have tried to be very proactive and responsive and flexible working with companies. There are some fundamental problems in that the majority of these shortages are in the arena of generic sterile injectables which are drugs that have a low return on investment but high requirements in terms of manufacturing capability and upkeep to keep the manufacturing at the appropriate quality level. There are, in many of these areas, limited manufacturers who are still making these products. So if one has a problem either in quality or supply chain, it puts at risk the national supply.

So, it is something that we need to continue to work on. We do believe we have made progress. We do believe that working with companies around a broader quality agenda and really modernizing manufacturing as part of that will make a long-term difference.

DRUG APPROVAL DUCHENNE MUSCULAR DYSTROPHY

Senator PRYOR. Okay.

And we talked about before the wide range of topics that you have to deal with. Here's another topic: Duchenne muscular dystrophy. My understanding is there's a new therapy that's in the pipeline that shows some promise. And, apparently, it's not a cure but it just maybe will delay the onset of some of the symptoms of the disease. And my question really is, is this going to be a good candidate for accelerated approval or is that not a consideration right now?

Dr. HAMBURG. Well, again, I can't really speak to the specifics of a product that's under review. But what I can say here is that we all know that Duchenne muscular dystrophy is a devastating disease for patients and their families.

We also recognize that advances in science and technology are really opening up huge new opportunities to find meaningful treatments. Maybe even someday a preventive or a cure. And we are working hard with the scientific research community, as well as the patient community, to try to find a pathway to realize the promise of science for these patients.

There has been a huge effort around this disease and the products that are in development. I would say that it's an area where some of the top scientists and leaders in FDA have committed a huge amount of time and effort. And I think we are making progress. And, I really hope so because it's such a devastating disease. But the science and product development is very promising.

Senator PRYOR. Senator Blunt.

Senator BLUNT. Well, on that topic, I know we've had a number of Missouri families and clearly the individuals involved want to find the best help they can find and they want to find it as quickly as they can. And I'm glad you're pursuing that and hope we can find the answer to some of these possible cures, this one particularly, as quickly as it's possible to do and to safely do.

MENU LABELING

On menu labeling, when do you expect the final rule to come out?

Dr. HAMBURG. Well, sadly, this is a conversation that we've had before.

Senator BLUNT. We have.

Dr. HAMBURG. It has been a long undertaking. And as you, I think, noted in your opening remarks, what had initially seemed like a relatively straightforward undertaking, menu labeling the nutritional content, especially calories, has been much more challenging than expected. But we are moving towards a final rule. And I do believe that I will not have to come to another budget hearing and have this discussion with you. But, no, I take very seriously——

Senator BLUNT. Well, depending on the ruling, you might. You might have to have this discussion.

Dr. HAMBURG. But you have raised a number of important issues over time and issues that have also been reflected in other comments on the proposed rule. And, you know, we have received lots of comments and undertaken a thoughtful, considerate analysis. And I think many of your concerns will be reflected back in the final rule.

Senator BLUNT. Some of those, as you know, would include, like, prepared food is a very small part of what a grocery store might do, a drive-through location, a delivery location where very few of the customers would ever see what was posted on the wall no matter how many things you posted on the wall.

Do you have any anticipation, once you propose the rule, how long the compliance period would be?

Dr. HAMBURG. You know, I actually don't know the answer to that.

My colleague Mike proposed a year.

But the other thing I might just mention, I think you're probably aware, is that the menu labeling requirement applies to restaurant or restaurant-like establishments that are chains of 20 or more and have consistent menus. So that helps to narrow the focus. Not all restaurants will be asked to implement this menu labeling.

Senator BLUNT. Okay, good.

MITOCHONOLNAL DISEASES

As the chairman has prefaced many of his questions on a very different topic, the FDA recently held a public meeting on reproductive technology. The purpose of the meeting and quotes was for the prevention of transmission of mitochondrial diseases ended those quotes, which involves cryoembryo using DNA from three parents.

The advisory committee, the FDA briefing for the committee, said "that the FDA recognizes that there are ethical and social policy issues related to genetic modification of eggs and embryos and that these issues have the potential to affect regulatory decisions; however, such issues are outside the scope of this meeting."

My view of that would be that the ethical questions associated with the procedures should be considered before we have a lot of discussion about how you do this. I'm just wondering if the ethical bridge is outside the scope of FDA. When do you think we should have that ethical discussion?

Dr. HAMBURG. We think those discussions should be ongoing and we are working to make sure that those discussions are engaged. We don't believe that we are the right agency to lead those discussions and it needs to be a broader societal discussion as well as

bringing important expertise to bear. But research is going on in this area of what's called "oocyte modification" in assisted reproduction to address mitochondrial disease.

And we undertook this public meeting in order to begin to understand what is the nature of the science and what is being done. I would add that research is being done in this country and in other countries and is being looked at as a policy matter in other countries of the world as well. But it's a very preliminary discussion and we do feel strongly that the broader social and ethical context has to be addressed.

And, as I said, we are working to make sure that that happens as we also make an effort to understand what's really happening in terms of the scientific research. And, of course, mitochondrial disease is a serious problem. It affects a limited number of people in this country, but for those who it affects it is a very serious concern. And so, there's an eagerness to understand what kinds of scientific opportunities might exist to address it. But we are not unaware of all of the other issues that are raised and feel that those need to be addressed as a high priority.

Senator BLUNT. And I think you said you were working to ensure that the ethical questions are being addressed, though, not by you.

Dr. HAMBURG. Well, we would take part just because I think this is an issue that needs broad engagement. And, you know, certainly we would not move forward. We don't think that the science is ready to move forward based on that public meeting in terms of moving to clinical studies. But I think that we understand the importance of these issues and the broader context for this kind of scientific research. And so, as I said, we want to make sure that all of the issues; scientific, social and ethical, are examined fully.

Senator BLUNT. Well, I would hope so. And I hope you continue to use some of you efforts and the ongoing discussions with groups who should be talking about this to do so. You know, if the purpose of looking at this in the very narrow way you did was to see if it was just so dangerous that nobody should even being talking about it, I might understand that. But when you begin to talk about things that are this different from the way humans have always procreated and the potential of what might happen unknown, there is an ethical bridge here that we all understand that we're crossing that somebody should be in charge of that discussion or ensuring that that discussion happens before agencies of Government decide, well, this is the only thing we really have to do with this, so we should step forward and do our part of this before society has had the kind of discussion they need to have about the ethics of this kind of science and this kind of activity.

But, Dr. Hamburg, I'm always really impressed by both your broad understanding of what you do and your willingness to look at things that you realize you don't understand yet because this is a huge portfolio. And the worse person we could have doing this job is somebody who thought they had all the answers on every topic. And I think today, again, you've expressed your interest and willingness to look at things that have broader context than maybe the agency initially thought they had. And I appreciate you and your responses to the questions today.

Dr. HAMBURG. Thank you.

Senator BLUNT. Thank you, Chairman.
Senator PRYOR. Thank you.

ELECTRONIC DRUG LABELING

I have two final questions for you and they're going to be quick. One is something I didn't know about until recently and that is the electronic distribution of prescribing information that goes along with drugs.

My understanding is that this is the paper insert that you kind of get in there and unfold and look at it if you ever want to. By the way, I probably throw mine away more often than I read it. But every now and then, I want to see it and I want to have it. But I can think of lots of examples where that information could be and should be included to the end user. But anyway, we can talk about those if you want to. But regardless of my personal feelings about it, my understanding is that there's a possible rule change on that ending with the Office of Information and Regulatory Affairs (OIRA), and so I was wondering if you have an update on that or a status report on that?

Dr. HAMBURG. Well, I think we are looking towards making information more available on the Web. Some of us are slower to fully adapt. But, you know, there is a sense that that is, in fact, how many people get their information and if it's on the Web it's there. As you pointed out, many people just throw away their labels, their insert information, and I think that is a concern.

In addition, I think one of our critical goals is manifested across various aspects of what we do is how can we communicate the important information in a way that's more understandable, accessible, and useful to consumers. And so, I think the move towards the electronic here is really an effort to try to make the information, in fact, more available to consumers.

Senator PRYOR. I think, again from my standpoint, I think of maybe seniors don't, typically don't always have the technology other people do. Rural people sometimes have challenges connecting to the Internet. You know, you think of scenarios: People traveling; people with kids and the kids are having a sleepover somewhere. I mean, I can just sort of see where that paper, from my standpoint, should continue to follow the—we'll see what comes out there.

And the last thing, of course, I want to do, I've heard you sing the praises and you've heard me sing the praise of the NCTR many times. And I know that we were able to get them some additional money. And you obviously care about NCTR. And could you just give me a little update on what you're seeing down there and how things are going at the National Center for Toxicological Research?

Dr. HAMBURG. Yes.

NANOTECHNOLOGY

Well, we do have a shared interest in NCTR and it really does represent a unique resource for FDA and for the Nation as a research organization that is really solely based on studying really important issues about toxicology, safety, and risk of a range of products that we regulate. And we have been able, I think, to accomplish some remarkable things there and have been very grate-

ful for the interest and support that you have provided over the years.

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Most recently, I think we've really done some groundbreaking work in the area of nanotechnology, including in partnership with the research universities in Arkansas and the State of Arkansas. Through a research alliance and collaboration we've been able to really build important programs to deepen our understanding of the toxicology of various components of products to develop new tools; to assess potential toxic effects more effectively and swiftly and earlier in a product development process, which is important in terms of saving time and saving costs; and developing new models that whether it's biomarkers or bioimaging that enable us to have new models rather than relying on what our increasingly outdated approaches as well, where you just try to study something in an animal model which isn't really adequate for a human model, and then when you try to make the translation it may not work.

So really trying to apply cutting-edge science and technology to better and improve toxicology assessment technologies. They've also been a leader for us and more broadly in terms of the area of bioinformatics and how do we really harness the tools of computers and information technology to deepen our understanding of existing data, our collection of new data, and our analysis of critical problems for health. So they really are a very, very important resource.

And, we have been able to, in recent years, undertake some important new projects. And we appreciated the one-time money that we were provided with last year that went to support some of the important activities I just mentioned.

Senator PRYOR. Well, thank you for that.

And also, let me say, thank you for this hearing. We've kept you here for 95 minutes. You've been on the hot seat for that entire time. But thank you for being here and doing this.

What we're going to do is we're going to leave the record open here for the subcommittee members to submit additional questions if they have them for another week, which is Thursday, April 10, and then we'll allow you all three or four weeks to respond to those.

CONCLUSION OF HEARINGS

But anyway, thank you again for your leadership and for the FDA and all the things FDA does. And, with that, we'll conclude this hearing.

Thank you.

Dr. HAMBURG. Thank you.

[Whereupon, at 11:36 a.m., Thursday, April 3, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]