STATEMENT OF MARGARET A. HAMBURG, M.D.

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE SUBCOMMITTEE ON AGRICULTURE,

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Introduction

Chairman Kohl, Senator Blunt and members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2013 budget request for the Food and Drug Administration (FDA).

I want to begin by thanking you for your efforts over the past few years to shrink the gap between the FDA's budget and its vast and evolving responsibilities. We have made every effort to spend those funds responsibly – to reinforce core functions and obtain the most public health value for the dollar.

As a science-based regulatory agency of global scope, FDA's mission is both exciting and daunting. Our core responsibilities are evolving and expanding to include additional product areas such as tobacco, to accommodate scientific and technological advances, and to step up to the global leadership role that FDA must play if we are to promote innovation and protect American consumers.

Our recent spending and new budget requests reflect this evolution. We are embracing these changes in several important ways – by deploying smarter and more flexible regulatory approaches, by identifying efficiencies and innovative approaches to deliver our core mission, improve outcomes, and better target our resources, and by using collaborations to leverage expertise, data, and experience. Through these approaches, we are already improving efficiency and achieving concrete results. While the challenges loom large, we are confident that we have identified investments and approaches that will allow us to continue this evolution and to protect and promote the public health.

1. FDA Investments and Results

With the funding you have provided, FDA has delivered significant and quantifiable benefits for the American people, and we are very proud of these achievements.

In the area of drugs, FDA now has the highest first action approval rate for new drugs we have ever achieved, and we continue to look for ways to improve the predictability, consistency and transparency of our drug review process. During FY 2011, we approved 35 innovative drugs, many of them ground-breaking. This was the second-highest number of approvals in the past decade. These drugs represented real advances for patients, including breakthroughs in personalized medicine. They include two novel drugs that were developed and approved with diagnostic devices that will allow doctors to target the drug to those patients most likely to respond, as well as new drugs to treat important medical conditions.

To achieve these results and to speed access to the American people, we demonstrated regulatory flexibility, using, for example, accelerated approvals and innovative clinical trial designs. Of note, we lead the world in the number and speed of drug approvals. Of the 57 novel drugs approved by both FDA and the EU between 2006 and 2010, 75 percent were approved first in the United States. Furthermore, between 2003 and 2010,

all 23 cancer drugs approved by FDA and the EU were approved first in the United States by FDA.

During FY 2012, we continued our strong performance. Since October 1, FDA approved 15 innovative drugs and biologics. Of the 15, 11 (or 73 percent) were approved in the United States first. Fourteen of these products had PDUFA deadlines, and we met the PDUFA deadline for 13 of the 14 products (that is, we met the PDUFA deadline 93 percent of the time). Just as important, of the 15 innovative drugs and biologics, 12 were approved on the first cycle, for an 80 percent first-cycle approval rate.

Some specific information on individual drug approvals will provide context for the importance of these actions. During January, 2012, FDA approved a truly breakthrough product in the field of personalized medicine, a drug to treat a rare form of cystic fibrosis. Known as ivacaftor and sold under the trade name Kalydeco, this drug only works for patients with a certain genetic mutation. But, thanks to advances in personalized medicine, physicians can identify patients with this mutation. This allows doctors to use Kalydeco only for patients where the drug will be effective. For patients who respond to this drug, it can keep their lungs clear, help them breathe, and make an enormous difference in the quality of their lives.

The FDA drug review process normally takes about 10 months. But in the case of Kalydeco, a drug of great importance for patients in need, this drug was approved in less than four months.

FDA approved another drug in January 2012. Known as vismodegib and sold under the trade name Erivedge, it is the first FDA-approved drug for metastatic basal cell carcinoma, the most common type of skin cancer. This new drug interferes very little with the growth of healthy cells, but works by disrupting the molecular pathway in the body that causes cancer cells to grow. Given there were no available treatments at the time, FDA took measures to expedite its approval. As a result, Erivedge was approved in less than 5 months – or half the time of a typical FDA approval.

We have also been working aggressively to address and prevent drug shortages and to implement important Presidential directives. On October 31, 2011, the President issued an Executive Order that directed FDA to take action to help further reduce and prevent drug shortages. In 2011, FDA successfully prevented at least 195 drug shortages. During the first three months of 2012, FDA prevented 22 shortages. FDA has sent letters to pharmaceutical manufacturers, reminding them of their legal obligations to report certain discontinuances to FDA, and urging them to voluntarily notify FDA of all potential disruptions of the prescription drug supply, even when not required by law. This has resulted in a significant increase in the number of potential shortages reported to FDA, and thus enhanced our ability to take action. In February of this year, we announced a series of steps to increase the supply of critically needed cancer drugs that were in short supply, including exercising enforcement discretion for the temporary importation of an alternative drug and approving a new manufacturer on an expedited basis.

We are also playing our part to address the rising costs of health care, by implementing a new approval pathway for biosimilar biological products and a user fee program to support review and evaluation of biosimilar products. We are also proposing a new generic drug user fee program that will support faster, more predictable reviews for generic drugs, effectively eliminate the current generic application backlog, and help assure quality by providing resources for regular surveillance inspections of manufacturers of generic drugs.

In the area of medical devices, in 2011, FDA released the Plan of Action for Implementation of 510(k) and Science Recommendations, which contained 25 specific actions that we would take in 2011 to improve the predictability, consistency, and transparency of our premarket programs. Seventy-five percent of those actions, plus eight additional actions, are already completed or well underway. We issued guidance on FDA's regulatory expectations for personalized medicine diagnostic devices that are developed along with a therapeutic product, to target that therapeutic product to the appropriate population. We launched the Innovation Initiative, which proposed actions that FDA could take to help accelerate and reduce the cost of developing and evaluating innovative medical devices, using science-based principles to maintain or improve patient safety.

In the area of food safety, the most sweeping reform of our food safety laws in more than 70 years was signed into law by President Obama on January 4, 2011 – the FDA Food Safety Modernization Act (FSMA). We issued an interim final rule describing the criteria for administrative detention of food when there is reason to believe the food is adulterated or misbranded, and we have used this authority several times. We met the one year FSMA mandate for inspections of foreign facilities, and are well on the way to meeting the 5-year inspection frequency mandate for high-risk domestic food facilities. We also issued an updated guidance for the seafood industry on food safety hazards. We anticipate issuing several proposed rules called for in FSMA shortly. We post regular progress reports on implementation milestones on our web site.

In the area of tobacco, we have been working to achieve a number of significant public health goals since enactment of the Tobacco Control Act of 2009. These include restricting youth access to cigarettes and smokeless tobacco, encouraging youth and adults who use tobacco products to quit, providing accurate information on the contents of tobacco products and the consequences of tobacco use to the public, and using regulatory tools to protect kids from initiating tobacco use and to begin to reduce the public health burden of tobacco in the United States.

We also have been aggressively and systematically addressing challenges that affect all products that FDA regulates. In June of 2011, FDA issued our "Pathway to Global Product Safety and Quality" report, describing the challenges of regulating in the globalized world in which FDA now operates, calling for a paradigm shift in how we approach our duties in light of such challenges, and describing the concrete actions we will take in four areas:

- assembling global coalitions of regulators dedicated to building and strengthening the product safety net around the world
- developing a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets
- expanding FDA's capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities
- effectively allocating FDA resources based on risk, leveraging the combined efforts of government and industry.

The essence of this strategy marries creative international coalitions with cutting-edge investigative tools to continue to provide the consistently high level of safety and quality assurance the public expects—and deserves.

2. Maximizing the Impact of FDA Funds

At this time of fiscal restraint, FDA is focusing on its core responsibilities and working to identify opportunities to streamline activities and leverage human and financial resources.

I have instituted a series of reorganizations designed to ensure that FDA better reflects its evolving responsibilities, but that also recognizes our responsibility to make the most efficient use of our limited resources. Early in my tenure, I appointed a new Deputy Commissioner for Foods, to ensure coordination of our growing and rapidly evolving responsibilities for oversight of the domestic and global food supply chain.

Last year I created the new position of Deputy Commissioner for Global Regulatory Operations and Policy, to fully address the need to integrate domestic and foreign inspections, streamline procedures, and seek greater harmonization and opportunities for collaboration with our counterparts in other countries. I also appointed a new Deputy Commissioner for Medical Products and Tobacco, reflecting our recognition that the review of medical products increasingly cuts across Center boundaries and that a new framework was necessary to address challenges like personalized medicine and combination products. Together, these changes build efficiencies into our organizational structure from the ground up and will make it easier to identify new opportunities for streamlining in the years to come.

We have made significant progress in consolidating our IT infrastructure into modern data centers. Simultaneously, we have modernized and standardized our hardware and software infrastructure, resulting in savings in power consumption and the ability to use FDA equipment and IT support resources more efficiently. You will see savings from this consolidation reflected in our proposed budget for FY 2013, as well as additional proposed savings.

Another key area for improved efficiencies is improved targeting of inspection resources. We have been working hard to ensure that our import inspection programs are risk-based, targeting imports at port-of-entry more efficiently. We are redeploying current food

inspection resources and pursuing efficiencies to support initial implementation of FSMA.

3. Preparing FDA for the Challenges Ahead

FDA's mission is challenging, even in the best of times, with scientific advances occurring at breakneck speed and the pace of globalization accelerating. Our responsibilities are vast and growing, a trend that will only continue. We receive thousands of medical product submissions each year, and serve as the watchdog for tens of thousands of products on the market, ensuring that they continue to meet the highest standards.

We have evolved from a country that once consumed simple, primarily domestically-produced goods to one that consumes complex products manufactured in every corner of the globe. We enjoy a greater variety of products from a greater range of places than ever before. The complexity of the products we regulate and the complexity of the supply chains by which they reach the eventual consumer has only increased. All of this means that FDA's job has gotten more complex and the stakes have continued to increase.

As our FY 2013 budget notes, FDA regulates more than $450 billion of domestic and imported foods. Nearly 40 percent of the drugs Americans take are made overseas, and about 80 percent of active pharmaceutical ingredients are imported. Food imports have increased nine-fold since 1993. These food imports come from more than 250,000 foreign facilities in 200 countries. About seventy percent of seafood and about 35 percent of fresh produce consumed in the United States comes from foreign countries.

We are grateful that Congress has begun to help give FDA the tools needed to effectively regulate in a modern, complex, globalized environment. We are on the right path, but the road is long and challenging. The proposed FY 2013 budget, described in more detail below, will continue the forward motion that you have supported.

FDA Fiscal Year 2013 Budget Request

1. FY 2013 Summary

The FY 2013 budget recommends $4.5 billion for FDA, a 17 percent increase from FY 2012. The FY 2013 increase for user fees, including increases for current law user fees and amounts for seven new user fee programs, accounts for 98 percent of the FDA budget increase.

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices, and other FDA-regulated products. Fees also allow FDA programs to achieve timely and enhanced premarket review performance. Finally, fees support the programs and operations of the FDA Center for Tobacco Products.

For FY 2013, FDA is proposing savings in two areas – information technology (IT) and the FDA Buildings and Facilities (B&F) account. In addition to these budget authority reductions, FDA is also absorbing more than 80 percent of the inflationary cost of rent activities.

After accounting for these savings, the net increase in budget authority is $11.5 million for FY 2013. Our increases support import safety, medical countermeasures, White Oak laboratory facilities, a portion of the increased cost of our rent activities, and the military pay raise that FDA Commissioned Corps officers will receive.

The federal investment in FDA is small compared to the breadth of our mission and the $2 trillion in products that we regulate. The investment in FDA is also an investment in the economic health of two of the largest sectors of America's economy: the U.S. food industry and the medical products industry.

2. FDA Budget Authority

A. FY 2013 Budget Reductions

FDA made significant progress in recent years to consolidate our IT infrastructure into modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an FDA computing environment that reduces our costs and provides agility not previously possible. The result is savings in power consumption and more efficient use of FDA equipment and resources for IT support.

Under this FY 2013 initiative, FDA will realize savings that flow from the consolidation effort. FDA will generate additional IT savings by streamlining other data management activities, reducing redundant IT devices, and reducing other IT costs, for a total savings of $19.7 million. Finally, FDA will also save $3.5 million by deferring repair and maintenance projects supported by our Building and Facilities account.

B. Food and Drug Imports from China

FDA is requesting a budget authority increase of $10 million to strengthen the safety of foods, drug products, and ingredients exported from China to the United States. From FY 2007 to 2011, the number of shipments of FDA-regulated products from China increased by 62 percent. This represents a fundamental change in our economic and security landscape, a change that requires FDA to alter its approach to protecting the health of the American public. To address this change, FDA must strengthen its capacity to inspect Chinese facilities that ship products to the United States and strengthen its ability to perform risk analysis on FDA-regulated products from China.

The addition of $10 million will strengthen FDA's ability to protect American consumers and patients in important and fundamental ways.

- FDA will improve its food and drug inspection and analytical capabilities with 16 additional inspectors in China, and by adding three U.S.-based analysts.

- FDA will broaden the range of its inspections. In addition to inspecting Chinese facilities that manufacture food and medical products for export to the United States, FDA will inspect sites of clinical trials.

- FDA will strengthen the understanding of Chinese regulators and the exporting industry about U.S. safety standards through targeted workshops and seminars. This process will foster a constructive dialogue on improving the safety and quality of food and medical products.

With these resources, FDA will develop more robust knowledge about the complexities of regulatory pathways and supply chains within an increasingly globalized environment. This understanding will allow FDA to make better evidence-based decisions and allocate FDA resources based upon risk.

C. FDA Medical Countermeasures Initiative

The FDA Medical Countermeasures Initiative (MCMi) is designed to help meet America's national security and public health requirements for medical countermeasure (MCM) readiness. MCMs include drugs, vaccines, diagnostics, and other medical products needed to respond to chemical, biological, radiological, nuclear (CBRN) threats and emerging infectious diseases.

Thanks to the efforts of this subcommittee, FDA received an appropriation of $20 million in FY 2012 to provide a base of funding for FDA's MCMi. For FY 2013, the FDA budget includes an additional $3.5 million for FDA medical countermeasures activities.

With the FY 2012 base funding and the additional FY 2013 resources, FDA will support partnerships with industry, academia, and government partners to improve the development timelines and success rates for MCMs. FDA will also expand technical assistance to developers of the highest priority MCMs.

The top priorities for these MCM funds include FDA action teams to support the development of MCMs to address the following MCM needs:

- warfighter care for American soldiers exposed to trauma or CBRN threats
- diagnosing and treating the multiple manifestations of acute radiation syndrome
- meeting the special needs of pediatric patients and pregnant women
- developing next generation in vitro diagnostic tests for CBRN threats
- working closely with HHS to establish flexible manufacturing capacity in the U.S.

Since the announcement of the FDA MCMi in August 2010, FDA and its drug, device and biologics programs have worked aggressively to ensure that the United States has access to high-priority MCMs during a public health emergency. Although less than two

years old, FDA's MCMi has an impressive list of accomplishments, made possible by the resources that this subcommittee approved.

D. FDA Regulatory Science Facilities

On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction is well underway.

An FY 2013 increase of $17.7 million will allow FDA to outfit the new CBER-CDER Life Sciences-Biodefense Laboratory complex that will support FDA's core regulatory science needs. FDA must make this investment now to ensure that all laboratory biosafety hazard systems are operational and the laboratory is ready for occupancy during FY 2014.

E. Pay and Rent

The FY 2013 budget also contains $1.5 million to support the military pay increase for Commissioned Corps personnel serving at FDA and $2.0 million to pay a portion of the inflationary rent costs for FDA for FDA programs. Funding these elements of the FY 2013 budget will help ensure that FDA can retain the professional staff to perform our mission of protecting patients and consumers and improving public health.

3. FDA User Fees

A. Prescription Drug User Fees

In January 2012, the Administration submitted legislation to Congress to reauthorize the Prescription Drug User Fee Act (PDUFA). The proposed legislation recommends $713 million in PDUFA fees for FY 2013. The current law expires on September 30, 2012, and FDA is ready to work with Congress to ensure timely reauthorization of this vital program. To sustain and build on our record of accomplishments, reauthorization must occur seamlessly, without any gap between the expiration of the old law and the enactment of PDUFA V. The resources in PDUFA V will allow FDA to review and approve new and innovative therapies for patients, without compromising the FDA's high standards for demonstrating safety, efficacy, and quality of new drugs prior to approval.

B. Medical Device User Fees

For more than a year, FDA met with stakeholders and held discussions with the medical device industry in an effort to develop a package of recommendations to reauthorize MDUFA. On February 17, 2012, FDA reached an agreement with representatives from the medical device industry, and published draft recommendations to reauthorize MDUFA on March 15. The agreement would authorize FDA to collect $595 million in user fees over five years, an amount that is subject to inflation increases. The agreement would also result in an FY 2013 MDUFA fee amount is $97.7 million.

The agreement strikes a careful balance between what industry agreed to pay and what FDA can accomplish with the proposed funding. We believe that it will result in greater predictability, consistency, and transparency through improvements to the review process.

Key features of the agreement include:

- Earlier, more transparent and more predictable interactions between FDA and applicants, both during the early product development stage as well as during the review process

- More detailed and objective criteria for determining when a premarket submission is incomplete and should not be accepted for review

- More streamlined FDA review goals that will provide better overall performance and greater predictability. This includes a commitment to provide feedback to an applicant if FDA's review extends beyond the goal date, so that the parties can discuss how to resolve any outstanding issues

- Additional resources to support guidance development, reviewer training and professional development, and an independent assessment of the pre-market review process to identify potential enhancements to efficiency and effectiveness

- More detailed quarterly and annual reporting of program performance

- A commitment between FDA and industry to reduce the total average calendar time to a decision for PMAs and 510k applications.

C. New User Fees for Generics and Biosimilars

In addition to recommending the reauthorization of PDUFA and MDUFMA, the FY 2013 Budget recommends new user fee programs to support review and related activities for generic drugs and biosimilars. The proposed user fee programs for generic drugs and biosimilars are modeled on the successful PDUFA program, but are tailored to reflect the unique challenges and needs associated with regulating generic drugs and biosimilars.

Generic Drug User Fees: As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, America's generic drug industry has been developing, manufacturing, and marketing – and FDA has been reviewing and approving – lower-cost versions of brand-name drugs for more than 25 years. This legislation and the industry it fostered are a true public health success.

Last year, approximately 78 percent of the more than three billion new and refilled prescriptions dispensed in the United States were filled with generics, yet those drugs

accounted for only 25 percent of prescription drug spending. In the last decade alone, generic drugs have provided more than $931 billion in savings to the nation's health care system.

The number of generic drug submissions sent annually to FDA has grown rapidly, reaching another record high during FY 2011, including nearly 1,000 ANDAs. The current backlog of pending applications is estimated to be more than 2,500. The current median time to approval is approximately 31 months, although this includes time that the application is with the sponsor to address FDA questions about the application.

The Generic Drug User Fee Act (GDUFA) proposal submitted to Congress in January 2012 will put FDA's generic drugs program on a firm financial footing and provide $299 million in additional resources to ensure timely access to safe, high-quality, affordable generic drugs.

Biosimilars User Fees: A successful FDA biosimilars review program will spark the development of a new segment of the biotechnology industry in the United States. To advance this opportunity, the FY 2013 budget includes a proposal for biosimilar user fees of $20.2 million.

The proposed biosimilars user fee program will generate fee revenue in the near-term and enable sponsors to have meetings with FDA early in the process of developing candidates for biosimilar biological products. With these fees, FDA will develop the scientific, regulatory, and policy infrastructure necessary to review biosimilar biological product applications.

D. Implementing FSMA – The FY 2013 Food Establishment Registration Fee

Food Safety remains a critical program area for FDA. FDA's FY 2013 proposal for food safety aims to advance the vision of a strong, reliable food safety system that Congress enacted in the landmark FDA Food Safety Modernization Act of 2011 (FSMA). The FY 2013 budget proposal builds on the food safety increases that the subcommittee appropriated for FY 2011 and FY 2012 and calls for user fee revenue to allow FDA to establish a prevention-focused domestic and import food safety system, consistent with FSMA.

FSMA set out a vision for a modern food safety system that shifts the focus to preventing food safety problems, rather than relying primarily on reacting to problems after they occur. Implementing Congress' vision for a strengthened food safety system represents a dramatic expansion of FDA's workload. However, the simple truth is that FDA cannot meaningfully deliver on these mandates without the funding contained in the FY 2013 budget.

The fee will support:

- establishing new, effective, and comprehensive food safety standards
- establishing a new program for import safety

- increasing the number and efficiency of inspections
- launching an integrated national food safety system with states and localities
- expanding research activities, which will include improved data collection and risk analysis
- improving FDA's capability to conduct risk-based decision-making.

These fees will allow FDA to reduce the risk of illness associated with food and feed and decrease the frequency and severity of food- and feed-borne illness outbreaks. With these fees, FDA can reduce instances of contamination and greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events. Without sufficient and reliable fee revenue, we can expect the unacceptably high human toll of foodborne illness to continue, with the resulting disruptions to the food system and the economic burdens to the food industry that result from foodborne illness outbreaks.

E. Tobacco Product User Fees

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. Since 2009, the user fees authorized in the statute have allowed FDA's Center for Tobacco Products (CTP) to hire Center leadership and enable those leaders to initiate the scientific, educational, enforcement and regulatory activities needed to accomplish the public health goals of the Tobacco Control Act. By the end of FY 2011, the CTP had a staffing level of over 230 FTEs, and the center anticipates meeting projected staffing goals in FY 2013.

The FY 2013 budget request for the Tobacco Program, including resources for CTP, is $505 million, an increase of $28 million above the FY 2012 enacted budget. The amount requested is specifically authorized in the Tobacco Control Act and comprised entirely of tobacco user fees. FY 2013 priorities include protecting youth from tobacco, encouraging current users to quit, and making existing tobacco products less harmful.

F. Other New User Fee Proposals

Cosmetics User Fee: The proposed cosmetic user fee of $18.7 million will strengthen FDA efforts to protect public health by preventing harm to consumers, ensuring the safety of cosmetics and removing unsafe cosmetics from the market. With this fee revenue, FDA will develop necessary guidance and standards for industry. The fee revenue will also allow FDA to identify research gaps, such as gaps related to the safety of novel ingredients used in cosmetics.

Medical Product Reinspection User Fee: The FDA Food Safety Modernization Act, which Congress enacted in December 2010, authorized fees for reinspections of food and feed establishments. FDA is proposing to expand this fee authority to medical product establishments. With this change, medical product establishments will pay the full cost of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs)

or other important FDA requirements. The FY 2013 estimate for Medical Product Reinspection user fees is $14.7 million.

Food Contact Notification User Fee: FDA has statutory responsibility for the safety of all food contact substances in the United States. The Food Contact Notification (FCN) program supports applications for innovative food contact substances that help mitigate microbial food contamination and provide consumers with more healthful and safe food choices. The proposed user fees of $4.9 million will support FDA efforts to increase the availability of safe food contact substances, to prevent unsafe food contact substances from reaching the market and to apply the most modern regulatory science to the review of food contact substances.

International Courier Use Fee: For FY 2013, FDA is proposing a new International Courier User Fee of $5.6 million. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the increased cost of its international courier activities through user fees.

Conclusion

The resources in this budget will allow FDA to perform its fundamental public health responsibilities in new and more efficient ways. Our budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

My goal with this proposed FY 2013 budget is to position FDA to seize these opportunities. The resources in this budget will allow FDA to perform its core public health responsibilities in more efficient ways, to address these and the many other challenges at the heart of our mission. This budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

Thank you for the opportunity to testify. I am happy to answer your questions.