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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

U.S. HOUSE APPROPRIATIONS SUBCOMMITTEE ON

AGRICULTURE, RURAL DEVELOPMENT,

FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

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Good morning Chairman Aderholt, Ranking Member Farr and members of the Subcommittee. I appreciate the opportunity to discuss the Food and Drug Administrations (FDA) priorities and provide an overview of the Fiscal Year (FY) 2014 budget request. I would also 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.

I. FDA plays a vital role in the health of our citizens and our regulated industries

Congress has given FDA responsibility for a vast range of products that are central to the health and well-being of every American. From spinach and frozen dinners, to vaccinations that save millions of children's lives, to new medicines for the treatment of major killers like cancer and heart disease, Americans rely on products overseen by FDA every single day. A short list of what FDA oversees includes:

1. The safety of most of America's food supply;
2. The safety and effectiveness of drugs, biologics, vaccines, and medical devices;
3. The safety of the blood supply;
4. The development of medical countermeasures to address chemical, biological, radiological, and nuclear threats, and infectious diseases;
5. The safety of products that emit radiation;
6. The quality of mammography facilities services;
7. The safety of dietary supplements and cosmetics;
8. The nutritional quality of infant formula;
9. The safety of animal food and feed as well as the safety and effectiveness of drugs for use in livestock, pets, and other animals;
10. And most recently, FDA has been charged with reducing harm from tobacco use.

The products we oversee are capable of producing great benefits: sustaining human life, reducing suffering, treating previously untreatable diseases, and extending lives. FDA's recent approval of the first drug to treat one of the causes of cystic fibrosis, as well as the first bionic eye system for a rare genetic condition, illustrate the ability of these products to transform lives.

Without proper oversight, however, many of these products are also capable of causing great harm. We need only look at the recent outbreaks of foodborne illnesses from peanut butter or the newest report of counterfeit cancer drugs being imported into the US to understand those risks.

FDA has a dual responsibility to the public health—to make safe and effective products available to Americans as quickly as possible, while at the same time protecting our citizens from those products that injure or kill. Our citizens' health depends on both.

We also recognize that the producers of our nation's food and medical products are vital to the health of our economy—and a strong FDA is vital to their health as well. 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.

II. FDA carries out its far-reaching responsibilities with few taxpayer dollars

FDA is a true bargain among Federal agencies. Added together, the products we regulate represent more than 20 cents of every consumer dollar spent on products in the U.S. Americans each pay about $8 a year for FDA's appropriations, which is substantially less than the amount Americans spend each year on snack chips alone.

And putting money into FDA is a smart investment. For about two cents a day, Americans get an extraordinary array of public health benefits, including: (1) life-saving medicines approved as fast or faster than anywhere in the world, (2) confidence in the medical products they rely on daily, and (3) a food supply that is among the safest in the world. But maintaining this level of performance for the American public, especially related to food safety, demands a fully-funded FDA.

Although FDA continues to be an effective and efficient investment, our job has become increasingly demanding. We are in the midst of dramatic technological and market-based changes in the way that foods, drugs, biologics, and devices are produced—from personalized medicine and nanotechnology to the globalization of our food and medical product supplies. Congress has also continued to pass new laws and expand our responsibilities. While we welcome these new responsibilities, they don't always come with added resources. These changes force us to stretch our limited resources, while finding ways to ensure the safety of a

global supply chain. Our scientists must also adapt to, and even drive, new science and technology so that we can accelerate medical product innovation rather than impede it.

Let me say a few words about the impact of globalization, which I believe to be among our greatest current challenges. Not that long ago, FDA's job was to oversee a largely domestic market of food and medical product suppliers. Most of the facilities in which these products were stored and manufactured were within our borders and relatively easy to inspect and oversee. Most of our producers and manufacturers were accustomed to operating under the rules of a modern regulatory system and most lived up to our high standards.

We have now entered a brave new world—a world in which, very soon, the majority of our food and medical products will come in whole or in part from foreign countries. In the last ten years, the number of imported shipments of FDA-regulated products has skyrocketed – in 2012, approximately 28 million shipments of imported food and medical products crossed our borders. That includes 50% of our fresh fruits and 20% of our fresh vegetables, around 80% of our seafood, and 40% of drugs on our shelves. Eighty percent of the manufacturers of active drug ingredients are located outside the U.S., and more than half of medical devices are imported. Most of the increase in imports is coming from China and India, countries with limited regulatory oversight. Many other imports are from developing nations with even less regulation.

The vast increase in imported foods raises the risk of contamination and illness. Of the imported produce and seafood refused entry at the border, 70-85% is for potentially dangerous violations, including the presence of disease-causing organisms and chemical contamination.

The global marketplace also increases the threat of deliberate adulteration, fraud, and counterfeiting. Criminals exploit how hard it is to inspect and track products through the global supply chain. Chinese suppliers of heparin, a critical drug to prevent blood clots, substituted a lower-cost, adulterated raw ingredient in their shipments to U.S. drug makers, causing deaths and severe allergic reactions. Chinese suppliers of wheat gluten substituted melamine, an ingredient used in making plastic, which was toxic when it was used in U.S. pet food and dairy products. The contaminated food sickened and killed pets across the U. S. and put many people at risk.

The global supply chain itself is becoming increasingly complex. Each product may pass through a number of foreign links in the chain, and each additional link increases the risks to

American consumers. Consider canned tuna. Once primarily canned in the U.S., tuna processing and canning is now outsourced to foreign facilities, and tuna often takes a circuitous journey through processors and canners in Southeast Asia, Africa, and/or Latin America, before it is ultimately shipped to the U.S. for distribution to our grocery store shelves.

The world has changed and our historical regulatory approaches and tools—such as hoping to intercept products at our borders—are outdated and often inadequate. Border inspections will remain important but they cannot guarantee the safety of even a small fraction of our 24 million food and medical imports a year. Globalization demands a major change in the way FDA fulfills its mission. If we are to continue to promise Americans a safe food and drug supply, FDA must continue to transform itself—from a primarily domestic agency to one that uses innovative global strategies to secure a vast global supply chain. Although challenges lie ahead, we have already made strides toward this goal using the resources you have provided.

III. We are delivering results that help Americans every day

A. Implementing Major New Laws.

We are partners with Congress in implementing the policies in three major new laws and several smaller ones that add to FDA's responsibilities in advancing the health of Americans.

1. The Food and Drug Administration Safety and Innovation Act (FDASIA). With the passage of FDASIA last year, Congress granted us important new authorities, reauthorized human drug and device user fees, and authorized new user fees for generic human drugs and biosimilars. These authorities and fees are intended to increase the speed and predictability of medical product reviews, better protect the drug supply chain, reduce drug shortages, and speed the review of more affordable versions of drugs that are essential in holding down health care costs. We are working hard to implement FDASIA and achieve these important goals.

Drug approvals. We continue to run a state-of-the-art drug approval process that brings important new drugs to Americans quickly and safely. In 2012, FDA approved 39 novel medicines, and the great majority were approved in the U.S. before any other country in the world. The drugs included 13 treatments for cancer patients, 13 orphan drugs, and the first brain imaging agent to help rule out Alzheimer's Disease. Recognizing the need to bring safe, life-saving drugs to Americans as quickly as possible, FDA approved some of them in as little as 3½ months.

Medical Device Approvals. Over the past decade, important indicators of the efficiency of the FDA's medical device review program, including the average length of review and the size of the backlog of overdue applications, had steadily worsened. Since 2011, FDA has worked intensively to turn this around. Almost every major indicator has now reversed: review times are getting shorter and backlogs are shrinking. This important turnaround will allow the industry to bring safe and effective devices to market more quickly and at lower cost.

Drug Safety. FDA has also used your investments to improve our oversight of the safety of marketed drugs. The new Mini-Sentinel system allows us to quickly assess potential drug safety problems using data from over 130 million patients. FDA used Mini-Sentinel to assess reports that a new blood thinner, Pradaxa, was causing more bleeding than similar drugs. The results gave reassurance that bleeding rates were not higher with Pradaxa than with the other drugs.

Drug Shortages. FDA prevented 282 drug shortages in 2012—87 more than in 2011. Early notification to FDA of potential shortages has made a huge difference in our efforts. In 2012, we cut the number of new shortages by more than half (117 v. 251).

Affordable drugs. FDA is working to provide Americans with better, quicker access to affordable generic drugs and is also implementing an abbreviated pathway for approval of biological products shown to be "biosimilar to" or "interchangeable" with an FDA-approved biological product. Biosimilars are products that are similar to approved biologics, and while biologics are among the most important drugs Americans use today, they are also the most complex and expensive. We are developing a science-based process for bringing safe and effective biosimilar and interchangeable products to market, which should increase competition and create substantial savings for patients, healthcare providers, and insurers.

2. The FDA Food Safety Modernization Act (FSMA). Even though the U.S. food supply for humans and animals is among the safest in the world, the current rate of foodborne illness remains too high—according to CDC estimates, roughly one in six Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases each year, leading researchers to estimate a cost of more than $75 billion due to medical expenses and lost productivity. This does not include costs to the food industry or public health agencies. These are preventable human and economic costs, and they reflect an outdated food safety system. FSMA, the most sweeping reform of our food safety laws in more than 70 years, creates a modern food

safety system that shifts our traditional focus—responding to contamination after it occurs—to preventing it before it happens. This new prevention strategy involves all participants in the food system, domestic and foreign, government, industry, and consumers, doing their part to minimize the likelihood of harmful contamination.

FDA is working on regulations on the kinds of risk-based measures food producers and importers should put in place to reduce the risk of contamination. We take pride in our release earlier this year of two proposed rules that set science-based standards for the prevention of foodborne illnesses – one on safe growing and handling practices for produce and another on prevention practices in facilities that process, handle, and store food. Before drafting the proposed rules, FDA conducted extensive outreach with farmers, manufacturers, consumer groups, state and local officials, and the research community. We have just completed three public meetings across the country to get additional input from stakeholders.

The proposed rules are built on existing voluntary industry guidelines and recognized best practices for food safety. Many producers already follow these guidelines, so compliance will be less of a burden. For those who need to add new food safety practices to their operations, FDA, in collaboration with USDA, will offer technical assistance and guidance.

FDA is committed to working with industry members to provide the support they need, especially the smallest businesses. We know that our rules and oversight practices must be responsive to the diversity of operations covered by FSMA, be risk-based and flexible, and address small business concerns. That's why we've included a number of exemptions for small businesses, including one for farms. The produce rule would also exempt low-risk products, like potatoes that are rarely consumed raw, or that will be further processed with a step that kills bacteria—like vegetables that will be canned. We've also proposed that small farms and other small business be given extra time to come into compliance with both rules.

3. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act gives FDA responsibility to reduce death and disease caused by tobacco and to lessen tobacco use, especially the initiation of smoking, by children and teens. This program is entirely supported by tobacco industry user fees. Since enactment, FDA has worked to enforce a ban on cigarettes with candy and fruit flavors, to make them less appealing to kids; prohibit claims like "light" or "mild" that misleadingly imply products are safer; and

enforce new smokeless tobacco warnings. FDA has also joined with States and Territories to enforce laws against under-age sales. We have conducted over 131,000 retail inspections and sent over 6,800 Warning Letters and 420 Civil Money Penalty complaints to retailers.

4. Other New Authorities

FDA is also implementing other recently enacted laws. Last month Congress passed the Pandemic and All-Hazards Preparedness Reauthorization Act, strengthening FDA's authority to prepare for chemical, biological, radiological, and nuclear threats, as well as infectious disease emergencies like pandemic flu, and to support rapid deployment of medical countermeasures. FDA is also carrying out new requirements in the Affordable Care Act, including provisions on biosimilars and nutrition information on menus.

B. Safeguarding the Global Supply Chain

Using the public's investments, the agency is working to transform itself into a public health agency capable of preserving the safety of our food and medical products in a complex global marketplace. We are developing better enforcement and regulatory tools, encouraging greater industry responsibility, increasing transparency and accountability in the supply chain, and increasing collaboration with international regulatory counterparts and other third parties.

1. Foreign posts. To enhance our ability to oversee import safety, we now have 12 permanent FDA overseas posts in key locations around the world: three in China, two in India, three in Latin America, two in Europe, one in the Middle East, and one in South Africa.

2. Foreign inspections. FDA conducted over 2,700 foreign inspections in FY 2012, the largest number ever, exceeding last year by 23%. We are on track to surpass that record this year.

3. Border screening. To make the most of our limited border inspection resources, FDA developed PREDICT, a sophisticated computer screening system that uses intelligence from many sources—such as intrinsic product risks, past inspection results, and information about such threats as extreme weather that could spoil a shipment—to flag the riskiest imports before they arrive. This allows FDA to focus its border resources on those imports that are most likely to pose a danger, and at the same time easing entry of low risk products. PREDICT has helped stop many contaminated products at the border. Recently, PREDICT flagged a large shipment of cucumbers from the Dominican Republic, which were contaminated by *Salmonella*. PREDICT has also identified products with illegal pesticides, heavy metal contamination, filth, and

decomposition, as well as substandard medical devices and improperly canned food.

FDA also developed mobile handheld devices that allow our investigators to immediately identify products that may be counterfeit or adulterated. The counterfeit detection device uses light waves to detect irregularities in the chemical composition or labeling of a drug, while the chemical detection (IMS) device identifies inappropriate chemical compounds in a product. The IMS recently identified an unlawful prescription drug—one taken off the market because it can cause heart attacks and strokes – in a large number of imported dietary supplements for weight loss. We hope to fund the development and use of more such mobile handheld devices.

4. Collaboration with other nations. To address the vast number of imports successfully, we must build a global public health safety net by partnering with other nations. FDA has signed over 120 international arrangements with foreign counterparts to create mechanisms for information sharing and collaboration. We are actively using information from, and conducting joint inspections with, trusted foreign counterparts, and engaging in harmonization efforts on foods and medical products. For example, we have signed an arrangement with Brazil, Canada and Australia to implement a Medical Device Single Audit pilot program under which a medical device inspection done by one regulator can be relied on by other regulatory agencies. Such programs can cut duplicative requirements for industry and allow us to better allocate our resources.

C. Supporting Biomedical Innovation

The U.S. food and biomedical industries are among the most successful and respected in the world and FDA plays a key role in that. FDA is sometimes viewed as a barrier to the economic success and innovation of both industries, but that does not take into account the benefits FDA regulation brings them. Public confidence in a strong FDA fosters consumer trust in the safety, effectiveness and quality of the products we regulate. This, in turn, helps producers build their markets. For example, as FDA became the model for science-based drug approval around the world, its high standards spurred decades of medical advances and turned the U.S. pharmaceutical industry into the world leader in innovative medicines.

As you know, I have made it a priority to help U.S. biomedical companies maintain their status as world leaders in innovation. It is well known that advances in biomedical research are not being translated into real world products as swiftly and surely as we all would hope. The

time and costs of developing new drugs has been increasing. Yet despite increases in research and development, the pipeline of new, innovative drugs remains disturbingly limited. Serious public health needs, such as treatments for autism and Alzheimer's disease, are not yet being met, despite years of research and investment. And many drugs are not revealed to be unsafe or ineffective until the last stages of development, wasting valuable time and resources. Through its regulatory science programs, FDA is committed to helping to develop new knowledge and tools that can help translate basic scientific discoveries and approaches into life-saving medicines, and reducing the time, complexity, and cost of drug and device development.

Investment in FDA allows our scientists to support innovation through a range of activities, including:

(1) The Innovation Pathway, which cuts the time and cost of developing and reviewing breakthrough device technologies—the first to benefit from the Pathway was a robotic arm controlled by a microchip in the brains of patients with spinal cord injuries or amputations;

(2) Greater use of genetic data to advance personalized medicine, especially in cancer therapies;

(3) New scientific tools and partnerships to learn earlier in development whether a drug or device will work and be safe, saving time and money now wasted on late-stage product failures;

(4) More guidance to industry early in technology development to help bring important new products, like the artificial pancreas, to market more quickly; and

(5) More collaboration with companies earlier in development. When companies come to us for help early in the process of testing their products, experience shows that they can shave up to five years off their development time. That's a dramatic shortening of the path to market.

D. Stretching Budget Dollars

We have also made belt-tightening a priority. We have consolidated our information technology infrastructure and administrative functions across FDA, and put in place controls to cut the cost of travel, training and conferences. We are avoiding additional rent costs by making better use of existing office space through tele-work and office-sharing, and we are reviewing contracts to cut service and product duplication.

IV. Current Budget Requests

The budget includes $4.7 billion, an $821 million increase from FY 2012. Of this requested increase, user fees account for 94% ($770 million). Mindful of the need to reduce

spending, we seek a reduced budget authority in several areas, including a $15.4 million decrease for human drug, biologic, and medical device programs. We are also asking for a small number of increases, which are necessary to meet our growing duties and preserve the safety of our food and medical products:

1. An additional $43 million to carry out our responsibilities under FSMA and to modernize our food safety system. These resources will go to building prevention-based food and animal food and feed safety systems, to reduce the toll of foodborne illnesses.

2. An additional $10 million, above FY 2012, for overseeing the safety of goods from China. This increase will add 16 new inspectors in China, who can conduct more inspections and train Chinese counterparts, strengthening our ability to prevent safety problems before products reach the U.S.

3. An additional $3.5 million, above FY 2012, to improve the development timelines and success rates for medical countermeasures intended to protect against chemical, biological, radiological and nuclear threats and new infectious diseases. The top priorities for these funds include care for U.S. soldiers suffering from traumatic brain injury, treatment of acute radiation syndrome, and supporting rapid deployment of critical medical countermeasures in emergency situations.

4. An additional $17.7 million to permit us to equip and obtain certification for four already-constructed buildings, including two labs, on the White Oak campus, so that they may begin carrying out research to support biomedical advances. Without these funds, the labs cannot be used and the $300 million cost of constructing them will have been wasted. Moreover, we will need to continue to pay rent for the old space occupied by FDA staff.

Under agreements negotiated with industry, we seek an increase in current law user fees of $500 million to support our drug, device, animal drug, animal food and feed, color additive, export, and tobacco product programs. We also seek $269 million in proposed user fees, including $225 million for food facility registration and inspection, and imports, $31 million for animal drug application fees that are up for reauthorization this year, $19 million to strengthen our oversight of cosmetic safety, and $15 million for reinspection of medical product facilities.

I know that some of you have expressed concern that proposed user fees for food producers will impose unexpected burdens, especially on small producers. Please be assured that

food-related user fees, if authorized, will be developed in close cooperation with stakeholders.

V. 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 FY 2014 budget targets our spending efficiently, on programs that are essential to providing Americans with the safe foods and effective medical products they expect. I look forward to answering your questions today and to working with you in the coming year.