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**BEFORE THE SUBCOMMITTEE ON AGRICULTURE,
RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION,
AND RELATED AGENCIES
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Introduction

Chairman Kingston, Ranking Member Farr 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 2012 budget request for the Food and Drug Administration (FDA).

For today's hearing, I am joined by Patrick McGarey, FDA's Assistant Commissioner for Budget.

In my testimony today, I will outline the important initiatives in FDA's FY 2012 budget request to Congress. My testimony also highlights FDA's unique role in protecting public health and the value that FDA delivers for American taxpayers.

Unique Role of FDA

At FDA, our responsibility and reach are enormous. We are responsible for overseeing products that people need, products they care about, products that are fundamental to their health, safety and well-being.

FDA must do its job well because there simply is no other agency to fall back on, no one to backstop us. Our role is unique, and FDA must fulfill this unique role completely and responsibly.

Fulfilling our mission is a difficult task under any circumstances. But these are especially challenging times. We live in a time when powerful forces shape our world. We live in a globalized world, and the reality of globalization affects everything we do at FDA. We live in a time where new threats – whether accidental or intentional – constantly emerge and pose new risks to the products FDA regulates and to Americans who rely on them.

And fortunately, we live in a time when there is an explosion of knowledge in the life sciences. This offers industry new opportunities to invest, innovate, create new markets and strengthen our economy. These new opportunities offer the promise of new products and important benefits for all Americans.

FDA Innovation, Accountability and Results

The dedicated professionals that I work with at FDA have a deep commitment to the health of American patients and consumers. At FDA, we also recognize that innovation is essential to progress in public health.

Innovation is the foundation of the successful industries that we regulate. Innovation is responsible for remarkable advances across all of the product areas within FDA's jurisdiction.

Innovation is also critical to maintaining U.S. global leadership in many areas, including medical product development. Currently, most new drugs are approved in the U.S. before they are approved in Europe. In fact, FDA approves more new drugs each year than all other countries combined. In addition, according to a recent industry study, we either are ahead of or tied with Europe for approval of medical devices that fall into the lower-risk category, which represents 90 percent of medical devices.

In my testimony, I highlight some of the recent FDA actions that allow the food, drug, biologic and device industries – all engines of innovation – to bring new products and technologies to market.

We also recognize that just as FDA supports the ability of industry to innovate, FDA itself must innovate and become more efficient. In FDA's FY 2012 budget, we highlight more than 100 examples where FDA centers and offices are improving the efficiency of their programs. In many of these examples, FDA also is supporting industry efforts to develop new products. Examples of FDA innovation include the recent launch of the Innovation Pathway, a program to stimulate new, breakthrough technology and advances for medical device manufacturers. Another example is FDA scientific collaboration with industry to develop novel technologies to detect new and traditional foodborne contaminants and to develop safe food packaging. These efforts reduce the risk and expense of recalling products that fail to meet safety standards.

FDA is also committed to being accountable. During the past year, we developed and implemented FDA-TRACK, an agency-wide system to monitor key performance measures for more than 90 FDA programs. Through FDA-TRACK, we are systematically monitoring FDA's progress as we work to achieve our performance measures. FDA-TRACK also allows FDA stakeholders and the public to witness our progress through the quarterly reports that we post on FDA.gov.

But the best measure of the value that FDA delivers is the opportunity to reduce costs and achieve measurable savings in areas that are important to America's health. One example is FDA support for the generic drug industry, which markets drugs that save American patients and taxpayers \$140 billion per year.

A second example is FDA's food safety program, which is making significant progress to reduce foodborne illness that costs the U.S. health care system \$88 billion annually. A third example is the FY 2012 Generic Biologics Initiative, which will generate significant savings for the federal government and for private sector health plans.

FDA Accomplishments

Thanks to the support of this Subcommittee, FDA is achieving important public health milestones. Since early 2010, FDA has supported industry efforts to innovate and bring many new products and technologies to market. These products touch the lives of countless Americans in very profound ways.

During the past year, FDA –

- approved new drugs to treat diabetes, hypertension, osteoporosis, bacterial infections, chronic pain, rheumatoid arthritis, preterm birth, gout, immune deficiencies, schizophrenia, major depressive disorder and pulmonary disease
- approved five new therapies to treat rare diseases
- conducted four workshops to stimulate new orphan drug development
- tentatively approved its 126th anti-retroviral drug under the President's Emergency Plan for AIDS Relief (PEPFAR)
- approved vaccines for seasonal and pandemic influenza
- approved new donor screening tests for HIV and Chagas disease
- cleared a new test to support kidney transplant patients
- approved new medical devices to treat hearing loss, severe asthma and vision loss, and to perform 3-D mammography screening
- cleared technology for physicians to view diagnostic images on iPhones and iPads
- identified measures to prevent radiation overdoses during CT scanning
- permitted the marketing of the first test to identify norovirus, a common foodborne illness
- applied genome sequencing to trace foodborne illness outbreaks
- collaborated with the National Oceanic and Atmospheric Administration (NOAA) to develop tests to re-open Gulf Coast fisheries
- formed public-private partnerships to improve produce safety
- launched a new system that identified 100 food safety problems in first seven months of operation.

FY 2012 Budget Summary

As the President emphasized in his FY 2012 budget message, “The fiscal realities we face require hard choices.” However, the 5-year freeze on federal spending announced in the FY 2012 budget is not an across-the-board cut. Although it represents a freeze in the aggregate, it also contains investments in areas critical to sustain and grow the American economy.

FDA is one of the critical areas where the Administration makes key investments for FY 2012. As you can see from FDA’s FY 2012 priorities – food safety and nutrition, medical countermeasures, patient safety and FDA regulatory science – an investment in FDA is an investment in the economic health of two of the largest segments of America’s economy: America’s food and medical products industries.

Our FY 2012 budget is also an investment in America’s health. The budget includes \$4.4 billion in budget authority and user fees to protect and promote the health of the American public every day, and through every stage of life.

Contract and Administrative Savings

Although FDA’s FY 2012 budget is an overall increase for FDA, it also contains savings that contribute to the Administration’s deficit reduction goals. FDA is proposing \$29.7 million in contract and administrative savings designed to achieve reductions and cut costs across all FDA program areas.

To achieve these savings, FDA will reduce administrative staff by 46 FTE. FDA will also lower contract costs by increasing competition. We will expand the use of blanket purchase agreements and other agency-wide approaches to reduce contract costs. Where possible, we will use technology to improve how we manage our contracts and the contracting process and thereby achieve savings. Finally, in some program areas, FDA will reduce the cost of employee training by replacing traditional classroom training with online training.

Transforming Food Safety and Nutrition

For FY 2012, FDA proposes an increase of \$326.0 million for the Transforming Food Safety and Nutrition Initiative. This increase includes \$225.8 million in budget authority and \$100.2 million for user fees, including the four new user fees enacted in the FDA Food Safety Modernization Act.

With this increase, FDA will begin to implement the landmark food safety legislation that Congress enacted last December. Under this initiative, FDA will empower Americans to make more healthful food choices through menu and vending machine labeling and develop a stronger, more reliable food safety system.

FDA Food Safety Investment: The passage of the FDA Food Safety Modernization Act (FFSMA), the first major overhaul of our food safety law in more than 70 years, is transforming FDA's food safety program. In FFSMA, Congress enacted new safeguards and enhanced tools to protect America's food supply. The central thrust of FFSMA is to protect public health by preventing food safety problems, rather than reacting to problems after they occur.

In its FY 2012 budget, FDA is organizing its food and animal feed safety programs and investments to implement FFSMA. Our detailed budget documents display the specific amounts that FDA will allocate to implement 22 separate sections of FFSMA.

FFSMA closes significant and longstanding gaps in FDA's food safety authority. For example, FFSMA gives FDA important new tools to ensure that imported foods are as safe as domestic foods. The new law also directs FDA to build an integrated national food safety system in partnership with state, local and tribal authorities.

FDA will use these resources to establish a prevention-focused food safety system that leverages the valuable work of FDA's state and local food safety partners. The result will be a stronger, more reliable food safety system to protect American consumers.

Regrettably, foodborne illness is pervasive across America. Each year, nearly one of every six Americans gets sick due to foodborne illness. Some cases are severe. One hundred twenty-eight thousand require hospitalization, and 3,000 Americans die from foodborne illness.

In addition to yielding profound public health benefits, the focus on prevention in FFSMA offers the opportunity for a dramatic return on the resources that this subcommittee invests in food safety. According to recent studies and the latest estimates of foodborne illness, the health care cost due to foodborne illness exceeds \$88 billion each year. This estimate does not include the significant costs to the food industry when outbreaks occur.

Nutrition: As part of this initiative, FDA will also begin an \$8.8 million program to improve nutrition labeling on restaurant menus and vending machines so that consumers can construct healthier diets. This small but significant initiative also offers a big return on investment. A 2009 analysis estimated the medical costs of obesity at \$147 billion per year [Finkelstein, et al., Health Affairs].

Controlling obesity goes hand-in-hand with controlling health care costs and reducing a significant burden on our economy. The investments in this initiative will empower consumers to make better nutritional choices and will motivate food producers to develop healthier foods.

Advancing Medical Countermeasures

For FY 2012, FDA proposes \$70 million for the Advancing Medical Countermeasures (MCM) Initiative. Medical countermeasures include drugs, vaccines, diagnostic tests, and medical equipment and supplies to respond to deliberate biological, chemical, radiological and nuclear (CBRN) threats and emerging infectious diseases, such as pandemic influenza.

The Advancing MCM Initiative will strengthen FDA's ability to support development of MCMs to respond to these national security threats. The MCM Initiative will allow FDA to enhance the review of MCMs by working interactively with product developers and government partners from very early in the development process. FDA will anticipate and resolve bottlenecks in MCM development and accelerate development of MCM products for pressing public health and national security needs.

MCM Gap: Today, our nation lacks the range of MCMs required for emergency response. For example, there are no countermeasures to treat acute radiation syndrome that would afflict millions in the aftermath of a nuclear event.

Moreover, no FDA-cleared, rapid, point-of-care diagnostics exist for any of the biothreat agents of greatest concern. Such diagnostic tests are essential to guiding the public health response, to ensure that patients receive the most appropriate treatment, and to ensure appropriate use of the limited supplies of MCMs available during a public health emergency.

Analysis of the Need for MCMs: In December 2009, on the heels of the influenza pandemic, HHS Secretary Sebelius called for a comprehensive review of the nation's readiness to defend against CBRN threats. The HHS review was prompted by recognition that influenza vaccine became available only *after* pandemic influenza was already widespread across the United States. The HHS review called on the expertise of the scientific leadership of all federal agencies that work with medical countermeasures, as well as state and local health departments, the National Biodefense Science Board, and the Institute of Medicine.

The review, released on August 19, 2010, identified the barriers to MCM development as well as significant opportunities to improve the path for successful MCM development. The review identified FDA as critical to the success of the MCM Enterprise, primarily because FDA evaluation of product safety and efficacy can significantly affect the course of product development.

The report further recognized that robust FDA engagement from the earliest stages of product development can significantly increase the odds of successful approval. Increased support for FDA MCM activities is one of the most critical steps the Federal government could take to transform the MCM Enterprise.

Threat Assessment: Dozens of reports since September 2001 and the October 2001 anthrax attack have affirmed the clear risk of terrorist groups wielding biological weapons and the suffering, death, and social and economic disruption that would result. Therefore, the FY 2012 investment in FDA medical countermeasure development and review offers the potential for a very strong return on investment.

The analysis of the National Security Strategy warns that the effective dissemination of a lethal biological agent within a U.S. population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, social, and political consequences. The National Security Council warned in 2009 that the economic cost of a well-executed bioterrorist attack on American soil could exceed one trillion dollars.

Clearly, such an attack would have profound consequences for our way of life, for trust in government, and for our society and political order. Without this investment, America's public health and national security will continue to be at risk.

Protecting Patients

For FY 2012, FDA proposes an increase of \$123.6 million for the Protecting Patients Initiative. This increase includes \$64.8 million in budget authority and \$58.8 million from three new user fees. FDA is proposing new fees for reviewing generic drug applications, paying the cost of medical product reinspections, and inspecting imports that arrive by international courier.

Generic Biologics: With the FY 2012 increase in budget authority, FDA will establish a pathway for approving generic biologics. Generic biologics are biological drugs shown to be highly similar to an FDA-approved biological product. In some cases, generic biologics may also be interchangeable with the FDA-approved biological product.

Biological products include many life important therapies to treat certain cancers, rheumatoid arthritis, age-related macular degeneration, and HIV. These therapies cost \$15,000 to \$150,000 or more per patient per year and represent a significant share of Federal government and private sector pharmaceutical costs.

Approving biosimilar versions of these products offers the potential for substantial savings for the federal government and private sector health plans. However,

these savings will not materialize unless FDA has the resources to implement a clear regulatory pathway for approving generic biologics. FDA is seeking these funds for FY 2012 because the timing of the investment in this initiative will determine the how soon the savings from generic biologics begin to flow.

Other Medical Products: In addition to investing in generic biologics, the Protecting Patients Initiative also invests in new scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, vaccines and other biological products. For example, the Protecting Patients Initiative also strengthens FDA efforts to modernize and improve safety throughout the supply chain of medical products. FDA is launching this initiative at a time when the number of medical products manufactured abroad is increasing dramatically, which presents great challenges for product and manufacturing safety.

Safer medical products not only benefit patients, but also benefit the manufacturers of drugs, biologics and medical devices. Safer products reduce health care costs and allow manufacturers to avoid the expense of product recalls.

With the resources in this initiative, FDA will modernize its approach to ensuring safety across the supply chain for medical products. The initiative also expands FDA's capacity to conduct medical product safety assessments and to strengthen the safety of vaccines and the blood supply.

The proposals in this initiative offer a high rate of return for the investment of federal dollars. They can reduce the cost of care and promote safe, high quality and accessible health care that Americans deserve. In addition, the Administration is proposing additional measures for FY 2012 designed to reduce costs and increase the availability of generic drugs and biologics.

FDA Regulatory Science and Facilities

For FY 2012, FDA proposes an increase of \$48.7 million for the FDA Regulatory Science and Facilities Initiative.

The FDA Regulatory Science and Facilities Initiative will strengthen the core regulatory scientific capacity that supports all elements of the FDA mission. Regulatory science focuses on developing tools to properly assess the safety, effectiveness and quality of products that are being developed or are already on the market.

Specifically, this initiative will help modernize and streamline the regulatory pathways that industry relies on to bring new, innovative products to market.

This initiative will also modernize the FDA review and approval process for products that rely on new and emerging technologies. The result will be promising new opportunities to diagnose, treat, cure and prevent disease.

The resources in this initiative will also allow FDA to outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex. On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction work is underway. Without this investment, FDA must pay double rent: once for the new lab it cannot occupy and a second time for the old lab it cannot vacate.

The new laboratory complex will have an essential role in fulfilling FDA responsibilities for drug and biologic safety, MCM development, annual influenza and other threats. FDA must make this investment in FY 2012 to ensure that the laboratory is operational and ready for occupancy in FY 2014.

FDA Current Law User Fees

For FY 2012, FDA proposes an increase of \$634.5 million for 12 current law user fee programs.

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices and reviews of 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.

Existing user fee laws authorize fee increases for many FDA user fee programs. The increases expand the available options for treating and curing diseases and addressing other important public health needs.

Conclusion

The FDA budget for FY 2012 contains important investments for essential public health priorities. With these resources, FDA will transform food safety and support the development of urgently needed medical countermeasures. We will protect American patients by assuring that the drugs and other medical products that they rely on are safe, and we will advance regulatory science, which serves as the foundation for science-based decisions at FDA.

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