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**BEFORE THE SUBCOMMITTEE ON AGRICULTURE,  
RURAL DEVELOPMENT,  
FOOD AND DRUG ADMINISTRATION,  
AND RELATED AGENCIES  
UNITED STATES SENATE**

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## **Introduction**

Chairman Kohl, Ranking Member 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 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 and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

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**

FDA is charged with ensuring the safety, effectiveness, and wholesomeness of products that Americans rely on in fundamental, sometimes lifesaving, ways – drugs, vaccines, medical devices, our nation's food supply, and more. These are products that people need; products they care about; and products that are critical to their health, safety, and well-being. Our role is unique and if we don't do our job completely and responsibly, there is simply no other agency or entity to backstop us.

Fulfilling our mission – to promote and protect the public health – is a difficult task under any circumstances. But these are especially challenging times. Today, the powerful forces of globalization are reshaping our world. We face complex threats – both accidental and deliberate – that pose new risks to FDA-regulated products and the Americans who rely on them. And we have been forced to rethink the way we do our job.

But we also live in a time of great advances in science and technology. Breakthroughs in the life sciences have provided industry with new opportunities to invest, innovate, create new markets, strengthen our economy and – most important – deliver new products and benefits for the American people.

## **FDA Innovation, Accountability and Results**

My dedicated colleagues at the FDA are deeply committed to the health of American patients and consumers – and they recognize that innovation is essential to progress in public health.

Innovation is the foundation of the successful industries we regulate, and innovation is responsible for remarkable advances across all of the product areas within FDA's jurisdiction – which is why we must work proactively to foster the scientific innovation that will lead to tomorrow's breakthrough products.

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. And 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 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 in which FDA centers and offices are improving the efficiency of our programs, and, in many of these examples, we are also 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 as well as a 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 accountability. 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 and allowing stakeholders and the public to witness our progress through 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 continues to achieve important public health milestones. Since early 2010, FDA has supported industry efforts to bring new products and technologies to market – and to think creatively about how to promote and protect the health of the American people in meaningful and sustainable 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 the 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**

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

FDA is one such area of critical investment. 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: our food and medical products industries.

Our FY 2012 budget is also an investment in health – in the health of individuals and the public health of our nation. As a result, 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, lower contract costs by increasing competition, and expand the use of blanket purchase agreements and other agency-wide approaches to reduce contract costs. Where possible, we will also save by using technology to improve how we manage our contracts and the contracting process. Finally, in some program areas, FDA will reduce the cost of employee training by replacing the traditional classroom model 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 to build a stronger, more reliable food safety system that will protect American consumers. 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, which Congress enacted last December. Under this initiative, FDA will also ensure – through menu and vending machine labeling – that American families have the information they need to make more healthful food choices.

**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, will transform FDA's food safety program. Through FFSMA, Congress enacted new safeguards and enhanced tools to protect America's food supply by preventing food safety problems rather than reacting to problems after they occur.

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.

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 and 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. In addition to yielding profound public health benefits, the FFSMA focus on prevention 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 of foodborne illness – not including costs to the food industry – exceeds \$88 billion each year.

The combined result of these actions will be a stronger, more reliable food safety system that protects the American people.

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 dollar amounts that FDA will allocate to implement the 22 separate sections of the law.

**Nutrition:** As part of the Transforming Food Safety and Nutrition Initiative, FDA will also begin an \$8.8 million program to improve nutrition labeling on restaurant menus and vending machines so that consumers can adopt healthier diets. This small but significant initiative offers powerful return on investment. A 2009 analysis estimated the medical costs of obesity at \$147 billion per year [Finkelstein, et al., Health Affairs], which means that 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 respond to these national security threats by supporting the development of MCMs as well as enhancing review by allowing FDA to work interactively with product developers and government partners from early in the development process. With this investment, FDA will be better able to 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, which 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; ensuring that patients receive the most appropriate treatment; and promoting 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 substantially increase the odds of successful approval. In other words, increased support for FDA's MCM activities is one of the most critical steps the federal government could take to transform the larger MCM Enterprise.

**Threat Assessment:** Dozens of reports since September 2001 and the October 2001 anthrax attack have affirmed the risk of terrorist groups wielding biological weapons and the suffering, death, and social and economic disruption that would result in the case of an attack. Therefore, the FY 2012 investment in FDA medical countermeasure development and review offers the potential for a 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 \$1 trillion.

Clearly, such an attack would have profound consequences on our social and political order, and, more broadly, our way of life. 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 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 requesting these funds for FY 2012 because the sooner we make this investment the sooner we will see savings from generic biologics.

**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 will strengthen FDA efforts to modernize and improve safety throughout the supply chain of medical products at a time when the number of medical products manufactured abroad is increasing dramatically, which presents real challenges for medical 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 ensure safety across the supply chain for medical products. The initiative will also expand FDA's capacity to conduct medical product safety assessments and 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 the knowledge and 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.

It 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.

Finally, 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 currently underway. Without this investment, FDA must pay double the rent: the first for a new lab we cannot occupy and second for the old lab we cannot vacate.

The new laboratory complex will help FDA fulfill our scientific responsibilities to promote drug and biologic safety and MCM development and prevent threats, including annual influenza. 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 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 critical public health priorities. With these resources, FDA will transform food safety; support the development of urgently needed medical countermeasures; protect patients by assuring that the drugs and other medical products they rely on are safe; and advance regulatory science, which serves as the foundation for all science-based decisions at FDA.

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