

Message from the FDA Commissioner



I am pleased to present the Administration's FY 2012 budget request for the Food and Drug Administration (FDA).

FDA protects and promotes the health of all Americans through every stage of life. The breadth of this mandate means that FDA responsibilities continue to grow. For example, in December 2010, Congress enacted important new food safety authorities and instructed FDA to establish a new system for food safety oversight.

The FDA FY 2012 budget supports many urgent public health priorities. It contains the needed resources to achieve fundamental public health responsibilities entrusted to FDA. The budget recommends new resources for FDA to transform America's food safety and nutrition, speed the development of medical countermeasures to meet critical national security priorities, protect patients, and advance FDA regulatory science. The FDA FY 2012 budget includes the following priorities:

Transforming Food Safety and Nutrition: The Transforming Food Safety and Nutrition Initiative allows FDA to implement the landmark Food Safety Modernization Act. FDA will establish a prevention-focused food safety system and leverage the valuable work of FDA's state and local food safety partners. The resources in this initiative will also empower Americans to make more healthful food choices through nutrition labeling for menu and vending machine items.

Advancing Medical Countermeasures (MCM): The Advancing MCM Initiative strengthens FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear threats, and to respond to naturally emerging diseases such as pandemic influenza. With this initiative, FDA will enhance the review of MCMs and develop new tools and standards to speed the development of MCMs. To improve public health response, FDA will also strengthen the legal, regulatory and policy framework that governs MCM development and availability. These efforts will accelerate development of MCM products for pressing public health and national security needs.

Protecting Patients: The Protecting Patients Initiative allows FDA to develop a pathway for approving biosimilars. Establishing a pathway for biosimilars offers the potential of significant savings for government and private sector health care systems that provide care to millions of Americans. This initiative also strengthens FDA efforts to modernize and improve safety throughout the foreign and domestic supply chain of medical products and includes other measures to assure the safety of medical products.

FDA Regulatory Science and Facilities: The FY 2012 budget will allow FDA to strengthen its core regulatory scientific capacities. The Advancing Regulatory Science Initiative will help FDA review and approve products that rely on new and emerging technologies and that offer promising new opportunities to diagnose, treat, cure and prevent disease.

FDA is responsible for overseeing more than \$2 trillion worth of foods, drugs, biologics, medical devices, cosmetics, dietary supplements, tobacco products and consumer goods. As I quickly learned since coming to FDA, our role in protecting public health and overseeing these products is unique, and there is no one to backstop us. The initiatives and resources that FDA recommends for FY 2012 will allow us to act more quickly and strategically to protect consumers from food safety threats and help deliver safer, more effective medical therapies to the American people.


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