

Executive Summary

Statement of FDA Mission

FDA is responsible for protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

The Scope of Our Mission is Vast and Complex

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. FDA oversees the safety of most of America's food supply, the safety and effectiveness of drugs, biologics, and medical devices, the purity of the blood supply, the development of medical countermeasures, the safety of animal feed as well as the safety and effectiveness of drugs for use in livestock, pets, and other animals, and most recently, reducing harm from tobacco use. Together, the products we regulate represent over 20 cents of every consumer dollar spent on products in the US. Public trust in FDA oversight breeds confidence in our regulated industries, at home and in the global market place.

A strong FDA is critical not only to the public health, but to the United States economy, the balance of trade, and homeland security. Our work has ripple effects on innovation in the industries we regulate and on costs in the broader economic and health care system. For example, on January 16, 2013, FDA proposed regulations on manufactured food and produce safety that outline new, innovative means for ensuring that a factory or warehouse's food is safe and for eliminating potential contamination of fruits and vegetables. FDA estimates that the cost of foodborne illnesses associated with FDA-regulated foods covered by these two rules is nearly \$4 billion per year. The proposed rule for produce safety alone is estimated to reduce illnesses by \$1 billion annually.

FDA is a Bargain

Every American pays about \$8 per year for the vast array of protections and services FDA provides. The return on this investment is remarkable. For this amount, FDA assures that the food that Americans serve their families every day is safe to eat and that Americans have access to life-saving medicines that are approved as fast or faster than anywhere in the world. For this amount, Americans can have confidence that the medical products that they rely on, ranging from toothpaste to cancer drugs to artificial organs, will provide the expected health benefits. FDA is a sound investment for the American people.

FDA Delivers Results

FDA is delivering significant, quantifiable, results that help Americans every day. FDA's drug approval system continues to lead the world in both quality and speed. In FY 2012, for the second year in a row, FDA approved 35 novel medicines. About 75% of those drugs were approved by FDA before any other country in the world. Among the FY 2012 approvals was a groundbreaking treatment for cystic fibrosis, approved in only 3.5 months, and the first drugs to treat advanced basal cell carcinoma and bone marrow disease. FDA prevented 282 drug shortages in 2012 and cut in half number of shortages in the prior year. FDA achieved significant reductions in medical device application review times and application back logs. FDA issued the first two new major proposed rules to implement the Food Safety Modernization Act, rules on preventive controls for human food and produce safety, so we can prevent contamination rather than respond to adverse events after they occur.

We are finding ways to leverage our scarce resources, through both domestic and global collaborations, ranging from partnering with foreign governments to improve the quality of imports to the United States, to partnerships with the nonprofit Medical Device Innovation Consortium to work on regulatory science initiatives.

The Scope of FDA Mission is Evolving Rapidly

We are in the midst of dramatic technological and market-based changes. The food and drug supply chains we oversee are not only increasingly global, but increasingly complex. The scientific underpinnings of the products we regulate are advancing at a dizzying pace — from personalized medicine and nanotechnology to tissue engineering and vaccine manufacturing. We must harness new science and technology so that we can be active partners with American industries to accelerate medical innovation.

To address these challenges, we are partners with Congress in implementing significant new authorities to safeguard America's food supply, modernize medical product safety and innovation, and reduce the harms of tobacco use. These new authorities reposition FDA on key fronts. The Food and Drug Administration Safety and Innovation Act (FDASIA) is intended to increase the speed and predictability of medical product review

while enhancing safety and fostering innovation, and better protect the drug supply chain. FDASIA also established two new user fee programs that will bring more affordable therapies to patients. FSMA creates a modern food safety system based on prevention. The Family Smoking Prevention and Tobacco Control Act provides FDA with new authorities to address one of the most important preventable public health problems. The Biologics Price Competition and Innovation Act, part of the Patient Protection and Affordable Care Act, established a new regulatory pathway for biosimilar biologic products. Together with ongoing initiatives to advance regulatory science and innovation and to transform FDA into a globally-facing regulatory authority, these Acts establish the foundations of a modern, science-based public health agency.

These changes are driving us to stretch our limited resources and find innovative, global-facing approaches to preserving the safety and quality of our nation's food and medical product supplies. These changes also drive our budget request for FY 2014 – carefully targeted investments to support food safety and FSMA implementation, medical product innovation and FDASIA implementation, and to build agency capacity for oversight of the global supply chain.