



FDA Facts: Biomedical Innovation

The U.S. Food and Drug Administration plays an important role in fostering the development of promising new treatments. The agency is taking an active part in identifying and overcoming unnecessary delays in the development and review of innovative new drugs and technologies.

Investments in basic biomedical research and development (R&D) steadily increased during the past two decades. In 2010, investments in biomedical R&D reached more than \$95 billion in combined R&D by industry and the National Institutes of Health. And yet, these investments have not translated into a significant and sustained increase in applications for novel new drug products submitted to the FDA for review.

The FDA's focus on biomedical innovation is reflected in two of its strategic priorities:

1. Advance Regulatory Science and Innovation
2. Advance Medical Countermeasures and Emergency Preparedness.

Key Points

In October 2011, FDA Commissioner Margaret A. Hamburg, M.D., released recommendations to advance biomedical innovation. Titled "Driving Biomedical Innovation: Initiatives for Improving Products for Patients" (www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm), the report launched the FDA's Innovation Initiative to address the most pressing concerns facing public health.

The blueprint provides the vision for implementing the following actions:

- rebuilding FDA's small business outreach services;
- building the infrastructure to drive and support personalized medicine;

- creating a rapid drug development pathway for important targeted therapies;
- harnessing the potential of data mining and information sharing while protecting patient privacy and complying with applicable law concerning proprietary information;
- increasing consistency and transparency in the medical device review process;
- training the next generation of innovators; and
- streamlining and reforming FDA regulations.

Overview

In July 2011, the FDA issued draft guidance on how the agency proposes to define and view companion diagnostics, tests that are essential for the safe and effective use of a corresponding therapeutic product. For example, they may be used to determine whether a particular therapy may work based on the patient's genetic characteristics. The goal of the guidance document is to ensure that the tests steering patients toward targeted therapies are accurate and reliable and that the right patients receive the right drug, promoting the basic tenets of personalized medicine.

As part of its focus on innovation, the FDA is developing a Virtual Physiological Patient—a collection of functional computer models that include both normal human anatomy and diseased tissues. Once completed, the Virtual Physiological Patient may allow personalization so a device can be redesigned to suit an individual patient's anatomy, physiology, and disease state.

The FDA continues to advance regulatory science—the scientific tools and methods used to evaluate the safety and effectiveness of regulated products—as part of its focus on innovation. For instance, in 2011 the FDA's National Center for Toxicological Research entered into an agreement with the state of Arkansas to establish a Center of Excellence for Regulatory Science at the University of Arkansas for Medical Sciences School of Public Health in Little Rock, Ark.



The agency also awarded \$2 million to support regional Centers of Excellence in Regulatory Science and Innovation at the University of Maryland and Georgetown University.

FDA's Innovation Reforms

- **Outreach to Small Business:** Innovation often begins with small firms, but many do not understand the FDA's regulatory processes. The FDA will establish a Small Business Liaison Program to train FDA staff to help small businesses and a Young Entrepreneurs program to provide start-up businesses with access to information about the FDA's product review and approval processes. The agency will partner with the Small Business Administration to find better ways to support the needs of small businesses.
- **Support for Personalized Medicine:** The FDA's new Deputy Commissioner for Medical Products oversees the FDA's three medical product centers—the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. These centers will work together to get safe and effective personalized treatments to patients as quickly as possible.
- **Expediting Drug Development:** The FDA brings together academic investigators, patient groups, drug developers, statistical and methodological experts, and ethicists to discuss strategies that can be used when an investigational drug being studied for a serious disease with no acceptable treatment option shows exceptional promise.
- **Data mining and information sharing:** The FDA has the largest known repository of clinical data pertaining to the safety and effectiveness of medical products. The ability to analyze these data sets could revolutionize the development of new treatments. Therefore, the FDA is rebuilding its information technology and data-analytic capabilities and establishing science enclaves that will facilitate the analysis of its large, complex datasets, while preserving patient privacy and complying with applicable law concerning proprietary information.
- **The Future of Medical Devices:** The CDRH Medical Device Innovation Initiative aims to accelerate and to reduce the time and cost of development, assessment, and review of innovative medical devices. The FDA is also working with

its partners in the public and private sector to increase its awareness and understanding of emerging technologies.

- **Training Future Innovators:** The FDA is designing a Future Innovators Program in which candidates who show promise in their fields will be hired for short-term positions during which they will be trained in multiple disciplines. The goal is to qualify these candidates for highly technical jobs either in the government or the private sector.
- **Improving FDA Regulations:** The agency is reviewing its regulations to identify burdensome, unclear, obsolete, ineffective, or inefficient regulations that hinder innovation.
- **The Entrepreneurs-in-Residence (EIR) program:** The FDA has built Innovation Pathway 2.0 with support from the White House's EIR program. The program allowed CDRH to bring in leaders in business process innovation, decision science, medical device innovation, venture partners, and information technology to work alongside agency staff and leadership to develop Innovation Pathway 2.0.

Driving Innovation Within FDA

The FDA employs thousands of the best and brightest in the science, engineering, and medical fields, creating a fertile ground for ideas for new inventions. Federal agencies are allowed by law to patent inventions. A number of FDA inventions have been licensed and are currently being developed. For instance, the FDA's National Center for Toxicological Research recently filed a utility patent application for a variation of a Magnetic Resonance Spectroscopy that potentially can reduce the need for brain biopsies.

For More Information

Go to www.fda.gov/AboutFDA/Innovation/default.htm for additional resources on the FDA's Innovation Initiative, including the latest news and developments.

Created: May 2012