

FDA

The U.S. Commitment to Global Health R&D



THE U.S. FOOD AND DRUG ADMINISTRATION regulates most of the food supply, monitors the safety and efficacy of drugs and other consumer products, and prepares comprehensive and coordinated responses to emerging public health threats. The FDA also engages in global health efforts to combat the cross-border nature of infectious diseases. By implementing rigorous standards of health and safety in both the U.S. and abroad, the FDA is committed to keeping Americans healthy.



Global Health Research and Development:
working to improve lives at home and abroad.

FDA BY THE NUMBERS

- Nearly **25 cents** of every dollar spent by Americans are on products regulated by the FDA. Source: FDA
- FDA's seven product and research centers and two offices are staffed by more than **12,000** employees around the world. Source: FY 2012 FDA Congressional Justification
- The FDA has **106** formal arrangements with regulatory counterparts in 29 countries. Source: FDA

The FDA first began to create regulatory standards to ensure the safety and integrity of foods, medical products and cosmetics over 100 years ago. Today, the FDA remains the worldwide "gold standard" for ensuring safety, based on strict science-based evidence.

Source: FDA Strategic Priorities

"By instilling confidence in American products and technologies, the FDA stimulates economic growth, creating jobs at home and opening markets overseas."

MARGARET HAMBURG, MD Commissioner, FDA

SMART COLLABORATIONS IN GLOBAL HEALTH

Product Development Partnerships



MICHAEL BRENNAN, Ph.D.
SENIOR ADVISOR
GLOBAL AFFAIRS
Aeras

The FDA launched their **Critical Path Initiative** program in 2004 to address the steep decline in the number of innovative medical products being submitted for their approval. As part of this Initiative the FDA funds treatments for tropical disease, with an emphasis on new tuberculosis treatments. TB affects a combined 11 million people each year, and the threat of an untreatable pandemic due to rising rates of drug-resistant TB demands that new combinations of treatment be explored. Source: Critical Path Initiative

Aeras is just one of the global health organizations supported by the Critical Path Initiative. Aeras is a nonprofit product development partnership dedicated to the development of effective TB vaccines and other prevention technologies. Aeras has a robust TB vaccine portfolio that currently supports the research and development of six vaccines. In October 2010, the FDA awarded Aeras a three year grant to support research that addresses key scientific questions for TB vaccine clinical trials. These vaccines have the potential to virtually eliminate TB, a disease that kills more than two million people annually. Source: Aeras

Global Health R&D

A SMART THING FOR THE U.S.
THE RIGHT THING FOR THE WORLD.

PARTNERING TO SAVE LIVES

Global health R&D partnerships foster success at home and abroad

PARTNERS Food and Drug Administration and Duke University
LOCATION Worldwide
GOAL To make clinical trials safer and more effective

The **Clinical Trials Transformation Initiative (CTTI)** was established in 2008 by the FDA and Duke University as a public-private partnership to identify practices that have the potential to increase the quality and efficiency of clinical trials. Today more than 60 organizations comprise CTTI, including government agencies, private sector, academic institutions, and other interested parties. These partners are working together to explore new methods and tools to make the current clinical trials system more efficient so that drug therapies can reach patients quicker, and patients can be assured that the benefits of these products outweigh the risks. The research findings and recommendations are intended not only to help U.S. patients, but to identify improvements that can be applied around the world. Source: Trials Transformation

Global Health Research and Development Progress

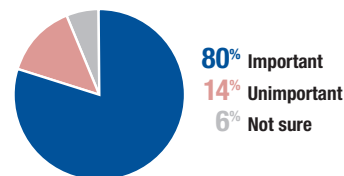
The U.S. Food and Drug Administration supports global health R&D that stimulates job growth at home, promotes a stable global economy and ensures a safer, healthier world. FDA's global presence helps maintain and improve product safety and the health of people worldwide.

- ▶ Under an innovative FDA program, companies that develop a treatment for a neglected tropical disease become eligible for a voucher that can be used to obtain "priority" (expedited) review, allowing companies to bring products to the market faster.
Source: BVGH Priority Review Vouchers
- ▶ In April 2011, FDA approved the first test to help diagnose people with symptoms of dengue fever (the test was developed initially by the Centers for Disease Control and Prevention). Recent dengue outbreaks have been reported in Hawaii, Texas, and Florida and globally this disease infects 100 million globally a year.
Source: FDA press release April 8, 2011
- ▶ A successful public-private partnership with the FDA during the 2009 H1N1 influenza pandemic brought about the development and approval of safe and effective vaccines in record time.
Source: FDA
- ▶ In 2009, FDA issued the first priority review voucher to Novartis for an anti-malarial drug. In clinical trials it cured 95% of patients, even in areas where there was drug resistance.
Source: BVGH Priority Review Vouchers
- ▶ The FDA Office of International Programs is the focal point for the agency's international efforts. This office coordinates and facilitates the agency's capacity building program, including offering technical assistance to national regulatory systems in 29 other countries.
Source: FDA International Programs
- ▶ Since December 2004, FDA has approved or tentatively approved 82 antiretroviral therapies to treat HIV/AIDS under their President's Emergency Plan for AIDS Relief (PEPFAR) expedited review program.
Source: FDA International Programs

What Americans are saying about the FDA and R&D

It is important to increase funding for FDA.

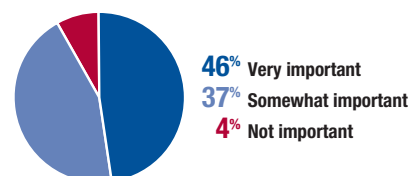
The U.S. Food and Drug Administration plays a role in improving the health of Americans by evaluating the safety and effectiveness of medical treatments and monitoring the safety of most of the foods we eat. Should funding for FDA be a priority in the federal budget?



Source: Your Candidates-Your Health Public Opinion Poll, October 2011, JZ Analytics for Research!America

It is important for Congress to Support Funding for Improving FDA Approval.

Some people say the FDA needs to fund university-based experts to help improve the approval process for pharmaceuticals and other medical products. How important do you think it is for the U.S. Congress to support this funding?



Source: Research Enterprise Poll, February 2010
Charlton Research Company for Research!America

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Less than one penny of every U.S. health dollar goes toward global health R&D.