RESEARCH AMERICA
AN ALLIANCE FOR DISCOVERIES IN HEALTH

Food and Drug Administration

By the Numbers:

:: The Food and Drug Administration (FDA) ensures the health of all Americans by overseeing the approval of safe, effective drugs and medical devices as well as monitoring the safety of food and cosmetics.*

:: In FY17, the FDA budget was $4.6 billion, with 40.5% paid for by industry user fees.*

:: FDA oversees the regulation of 11% of imported goods into the U.S. *

:: FDA oversees more than $2.4 trillion in medical product, food and tobacco spending, accounting for 20 cents of every dollar spent in the U.S.*

:: In 2016, the FDA approved 22 novel drugs, 91 medical devices and 11 biologics.*

:: Between 2009 and 2013, 76% of the new drugs released in Japan, the EU and the U.S. were first approved by the FDA.#

FDA in Action

Organs-on-chips

In 2017, the FDA announced it will begin to evaluate the accuracy of the promising organs-on-chips technology, which was developed through a funding partnership with FDA, Defense Advanced Research Projects Agency (DARPA) and the National Institutes of Health (NIH). These micro-engineered chips recreate human organ-like structures, potentially simulating the human response to new drugs. Experts hope this new technology will provide scientists with precise information, including the identification of unsuccessful drug candidates, prior to the risky and expensive clinical trial process.*

Vaccine Conjugation

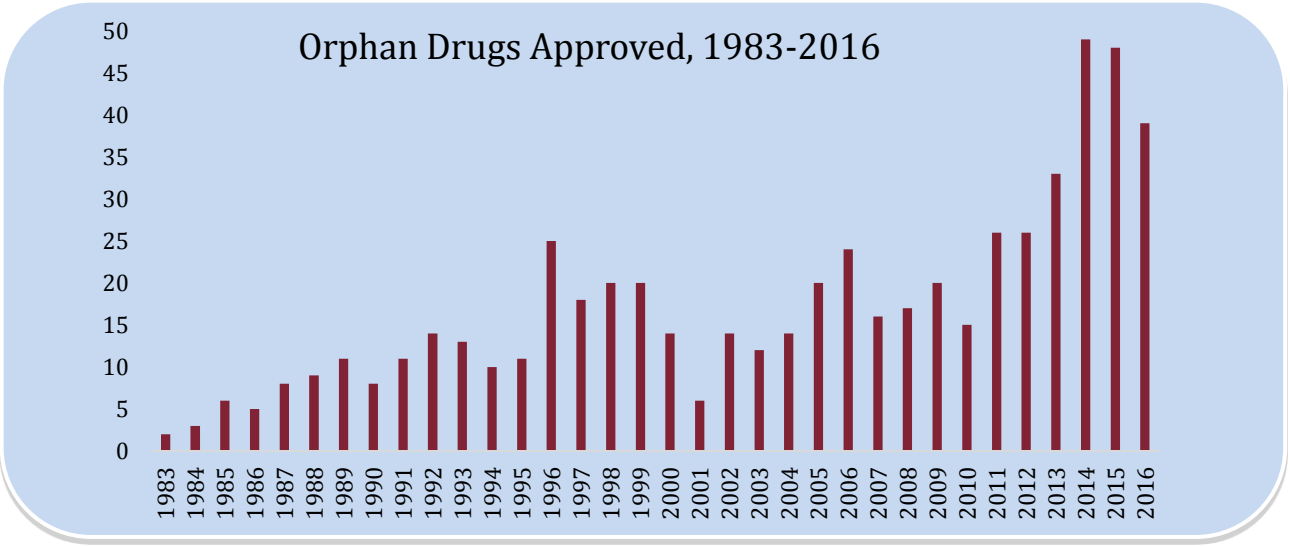
In 2003, two FDA scientists created a new method to efficiently develop vaccines. Known as conjugation, the method improves the ability to link multiple vaccine ingredients, improving production. The World Health Organization, PATH and the Bill & Melinda Gates Foundation utilized conjugation in the development of MenAfriVac, a meningitis A vaccine developed for use in Africa. By 2020, MenAfriVac is expected to protect 400 million people, prevent 100 million cases of meningitis A, 150,000 deaths and 250,000 cases of severe disability.*

The National Evaluation System for Health Technology (NEST)

In 2014, the FDA began a public-private partnership to set up a national medical device surveillance system. NEST will aggregate real-world data to inform and empower patients, accelerate medical device innovation, and improve health care outcomes. NEST will evaluate and analyze risk to ensure more effective regulatory decision-making by the FDA.@

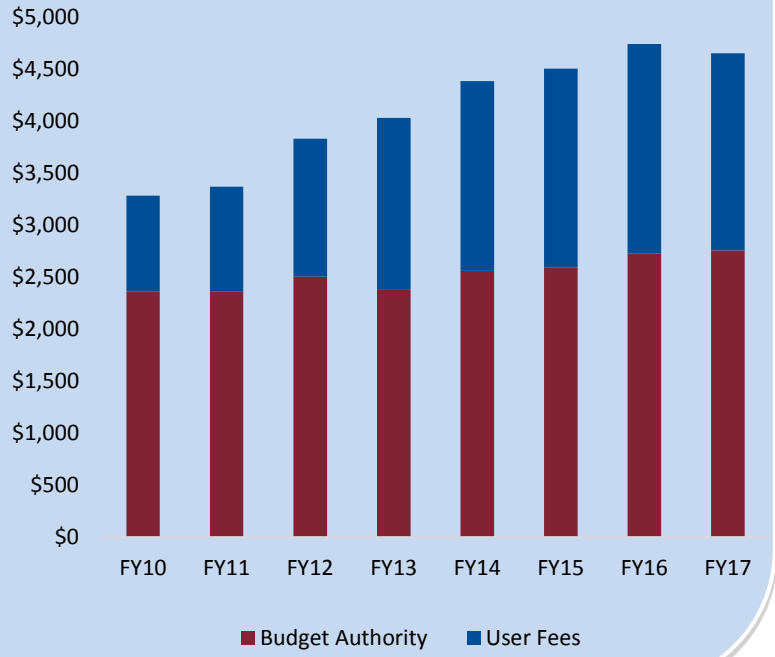
Rare Disease Spotlight:

There are 7,000 rare diseases that affect more than 30 million Americans. Historically, the challenge of small target populations hindered rare disease research and development, limiting clinical research and access to funding. Fewer than 10 industry-developed products created to treat a rare disease were approved by the FDA between 1973 and 1983. The Orphan Drug Act of 1983, and the subsequent formation of the Office of Orphan Product Development, resulted in policy changes that incentivized the development of treatments for rare diseases. Since 1983, the FDA approved more than 600 drugs and biologic products for rare diseases. *,^



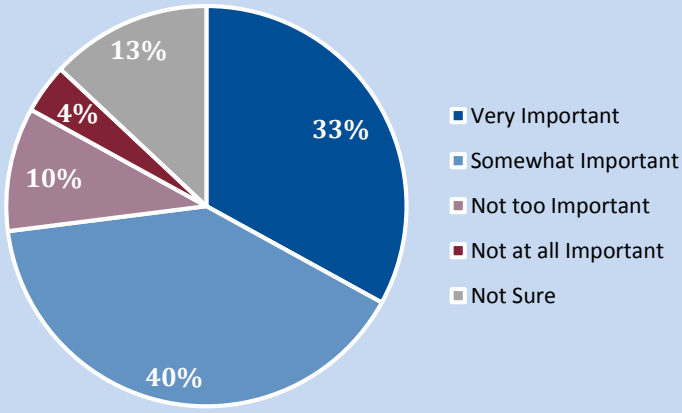
The FDA is one of the nation's primary defenders of the public health and we must continue to support it as we move into a 21st century health care system.

Total FDA Funding, FY2010-FY2017 (in millions)



Majority say Important to Boost FDA Funding

The Food and Drug Administration (FDA) is the agency responsible for the safety and effectiveness of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics and products that emit radiation. How important is it to increase funding for the FDA?



A RESEARCH!AMERICA SURVEY OF U.S. ADULTS CONDUCTED IN PARTNERSHIP WITH ZOGBY ANALYTICS IN JANUARY 2016.

SOURCES: *FOOD AND DRUG ADMINISTRATION ^ GLOBAL GENES # CENTRE FOR INNOVATION IN REGULATORY SCIENCE @ DUKE MARGOLIS CENTER FOR HEALTH POLICY

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