

Frequently Asked Questions About the Reagan-Udall Foundation

1. What is the Reagan-Udall Foundation for the FDA?

The Reagan-Udall Foundation is a private and independent nonprofit organization that advances the mission of the Food and Drug Administration (FDA) to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety.

The Foundation was created through bi-partisan action in Congress in the [FDA Amendments Act of 2007](#). Many members on both sides of the aisle believed that the Foundation was needed for a critical role at this time of rapid scientific progress and innovation in such areas as genomics and proteomics, information technology, and other technologies that could protect and improve the health of Americans.

The Foundation supports activities that promote better science and better technical capabilities that can advance the FDA's mission. The Foundation does not advise the FDA on regulations or approvals. In its unique statutory role, it creates and facilitates public-private partnerships, which include all stakeholders – patient groups, academia, government, health care providers, industry and others – seeking to develop better science and evidence.

2. What are the reasons for creating the Reagan-Udall Foundation with the FDA as an active partner?

As a regulator, the FDA should not conduct stakeholder collaborations when the scientific information produced may come to the Agency for evaluation. Rather, the FDA's role is to evaluate this scientific information along with all of the other scientific information it considers, from public and private sources, in fulfilling its mission. However, FDA experts have many insights about the most important gaps in the science available to support the FDA's mission. To help fill these gaps, the Foundation can organize complex scientific collaborations that need a neutral third party to convene the participants, negotiate complex working and data sharing agreements, and help resolve disputes among participants.

In the end, the goal is to produce better science that can be used by the FDA and the public and private sector on issues that are important to FDA, and thus to the American public. Congress recognized that the Reagan-Udall Foundation could help advance this critical but unmet goal.

3. What are some examples of the kinds of projects that the Reagan-Udall Foundation will conduct?

As part of its innovation strategy, the FDA has identified several high-priority scientific areas that FDA would like to engage in with the Foundation. Examples of projects that can fulfill scientific and technical gaps relevant to the FDA mission include:

- Exploring opportunities in the areas of food safety.
- Novel approaches for developing therapies and diseases. Example: [Combination drug regimens to treat tuberculosis](#).
- Methods to enhance the FDA's ability to use clinical data sets from private insurers and other sources for active post-market product surveillance.
- [Academic fellowship programs](#) that bring experts to FDA in emerging scientific issues where the FDA seeks to develop more expertise.
- Studies that bring together data from different companies to help determine the association between genetic and other variations and important drug toxicities, where the FDA has concerns but data from individual companies are not adequate.

All of these initiatives require collaboration between different experts and organizations in the public and private sector. They are intended to provide better scientific evidence and better technical capabilities to support the FDA's mission.

4. **Why Is the Reagan-Udall Foundation a Public-Private Partnership?**

The Reagan-Udall Foundation was created to develop scientific evidence and technical expertise that is too complex and expensive for one group to accomplish. The Reagan-Udall Foundation will conduct activities that can only be accomplished through partnerships of multiple stakeholders, including patient groups, government, academia, and industry, and that have not been addressed by other entities. Private sector participation was [mandated by Congress](#), because important scientific work and knowledge resides within private sector companies, as well as within government and academia. One important benefit of the Reagan-Udall Foundation is its ability to incorporate these stakeholders in its scientific work. The Foundation works hard to get balanced input from all stakeholders. This along with a proactive system of disclosure requirements and on-going [transparency](#) will ensure that there will be no undue influence by any one sector or group.

5. **What are some other examples of Public-Private Partnerships?**

Today, there are many other private-public partnerships across many industries, working with many parts of government. Some examples:

- Foundation/pharma collaborations such as the Global Alliance for Vaccination (GAVI) www.gavialliance.org/about/partners/the-partnership-model/, an international public-private partnership that includes the World Health Organization (WHO), UNICEF, the World Bank, and others to facilitate research, development, and use of vaccines.
- The Foundation for the NIH (FNIH) <http://www.fnih.org> supports public-private collaboration on basic and translational research.
- The Centers for Disease Control and Prevention Foundation (CDCF) <http://cdcfoundation.org> connects the Centers for Disease Control and Prevention

(CDC) with private-sector organizations and individuals to build public health programs that make our world healthier and safer.

As long as we rely on a private-sector model to bring drugs, devices and food to market, and as long as much of the information related to the use of these products is held by private health plans, health care organizations, and other private companies, the knowledge and experience of the private sector will be a resource that must be tapped.

6. How does the Reagan-Udall Foundation determine its priorities?

All of the Foundation's projects and programs must be approved by the Board of Directors and the FDA Commissioner before they are undertaken.

The Foundation takes guidance from the FDA on the important scientific issues that FDA feels are inadequately addressed. As part of its innovation strategy, the FDA has identified several high-priority scientific areas that FDA would like to engage in with the Foundation, such as exploring opportunities in the areas of food safety, novel approaches for developing therapies to [fight TB](#), and methods to enhance the FDA's ability to use clinical data sets for active post-market product surveillance. The work and evidence that comes out of Foundation efforts is considered by FDA, and everyone else, as part of what is a greater body of useful scientific evidence.

7. How is the Reagan-Udall Foundation funded?

The Reagan-Udall Foundation is supported by both public and private funds. When Congress created the Foundation, it authorized transfers of FDA funds to the Foundation for general operations in the amount of \$500,000-\$1,250,000 annually. Prior to 2012, no funds were appropriated for the Foundation. Projects can be funded by [grants and charitable giving](#). These contributions are integral to helping the Foundation fulfill its mission. All contributions are reviewed by the Executive Director and the Board of Directors, including for possible and potential conflicts of interest. The Foundation maintains discretion to accept or refuse contributions.

8. Do the Reagan-Udall Foundation Board of Directors and staff have any particular FDA expertise that sets them apart from existing foundations or nonprofits?

The Reagan-Udall Foundation is managed by an executive director, and is overseen by a 14-member [board of directors](#). As required by [statute](#), the Board includes representatives from patient/consumer advocacy groups, academic research institutions, the general, pharmaceutical, device, food, cosmetic and biotechnology industries, health care providers and at large representatives with relevant and diverse expertise and experience.

Additionally, two leading government scientists - the Commissioner of the FDA and the Director of the National Institutes of Health are ex-officio members of the Board.

As [executive director](#), Jane Reese-Colbourne has experience across an array of FDA matters, including food manufacturing standards and drug development. She also has extensive experience in patient advocacy and in projects that involve bringing together diverse groups of stakeholders to work together on common goals that support FDA and regulatory science.

In addition, for specific projects, the Foundation relies on experts in the relevant subject areas. For example, in its work on the regulatory science relevant to the [CPTR Project](#), the Foundation has employed an experienced regulatory scientist with expertise in tuberculosis.

9. How does the Reagan-Udall Foundation protect against conflicts of interest and undue influence?

The Reagan-Udall Foundation has numerous provisions in place to protect against [conflicts of interest and undue influence](#). For example, Board members are prohibited from participating in Foundation matters in which they (or close relatives or entities in which they have an interest) have a financial interest and must disclose their financial interests in entities doing business with the Foundation and in entities regulated by the FDA, and their involvement in entities with interests that may conflict with the Foundation's best interests.

Similarly, annual financial disclosures submitted by Foundation employees and Board members are reviewed by the Foundation's Outside Counsel, who is responsible for identifying conflicts and determining what actions are necessary to ensure that an employee or director does not participate in matters in which such a conflict would or could exist. Regulated industry representation on the Board is limited to four of the fourteen voting members.

All projects must be reviewed and approved by the Board and can be subject to independent peer review. Finally, the Foundation is prohibited from participating in regulatory matters or offering advice to FDA on policy matters. The Reagan-Udall Foundation does not advise the FDA on regulatory or other decisions. Rather, the scientific and technical information developed by the Foundation go into the public domain, where they can be used by the FDA and others.

10. How does the Reagan-Udall Foundation maintain transparency?

The Foundation is committed to transparency and is in the process of posting critical information on its web site. As the website is built out further and as new projects are considered, the Foundation will continue to post additional information. Please check back for new information.

- The Foundation [Bylaws](#).

- The amount of [each donation and the identity of the donor](#), including in kind donations.
- Information about each [project](#), including:
 - An Executive Summary.
 - A list of organizational project participants and their role.
 - The identity of all funders.
- A way to ask questions, and give feedback and public input:
Comments@ReaganUdall.org