

The Reagan-Udall Foundation for the Food and Drug Administration — an independent, non-profit organization — was created by Congress in 2007 to advance the FDA’s mission to modernize medical, veterinary, food, food ingredient and cosmetic product development; accelerate innovation and enhance product safety. The Foundation advances safety and innovation by building unique partnerships between experts, consumer advocates and researchers to improve scientific evidence relevant to the development and use of medical products, manufacturing and food safety.

Collaborative Innovation with the FDA

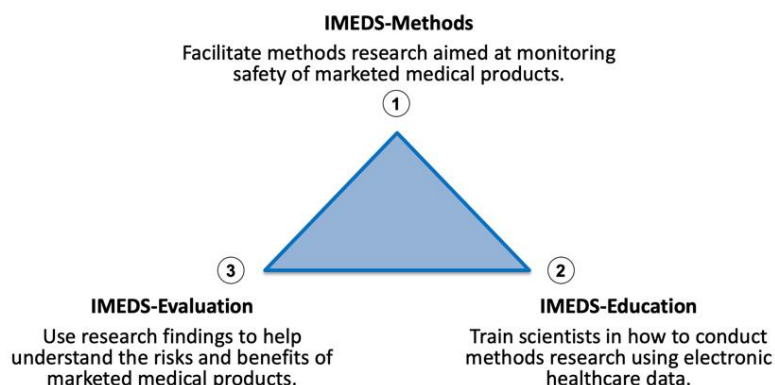
As required by Congress, FDA provided financial support for the Foundation’s ongoing operations and infrastructure. A critical milestone, this initial appropriation, combined with project grants, put the Foundation on the path Congress envisioned — to provide the FDA with additional scientific thinking about its regulatory activities.

"The Reagan-Udall Foundation is an important partner in advancing the FDA's public health mission and embodies the agency's vision for collaborative innovation to address the scientific challenges of the 21st century. We are pleased to work with the Foundation on major public health concerns, such as tuberculosis and cancer, and we look forward to future activities that bring the best possible science in support of our regulatory activities."

— FDA Commissioner Margaret A. Hamburg, MD

Innovations in Medical Evidence Development and Surveillance

Throughout 2012, the Foundation continued to build the infrastructure and secure the needed resources to institute a new pillar project, Innovation in Medical Evidence Development and Surveillance (IMEDS) — taking over for the Observational Medical Outcomes Partnership (OMOP), a public-private partnership involving the FDA that informs the appropriate use of observational healthcare databases in studying medical products’ effects. Ultimately, IMEDS endeavors to fully transition the OMOP data into IMEDS and expand access to private sector stakeholders, like industry, academia and health care providers.



This year, the Foundation began that migration and designed an operating model to serve as the IMEDS north star. The Foundation also instituted governance to oversee IMEDS’ design. A newly formed organizing committee comprised of representatives from the Foundation, FDA, OMOP, Mini-Sentinel Operations Center and the Brookings Institution honed the IMEDS mission and vision and developed action and recruitment plans. In the end,

the operating committee organized IMEDS around three components: methods, evaluation and education — all overseen by the Foundation’s Board with support from its Executive Council and Advisory Boards.

In October 2012, the Foundation held IMEDS’ inaugural annual meeting in Washington, D.C.

Critical Path for Tuberculosis Drug Regimes

The Foundation collaborated with a broad array of stakeholders to reduce tuberculosis’ global burden by developing shorter-duration, more effective and safer TB drug regimens than currently available. The Critical Path for Tuberculosis Drug Regimens (CPTR), under the auspices of the Bill and Melinda Gates Foundation and with support from the Critical Path Institute and TB Alliance, accelerates the development of multidrug treatments for TB by creating consensus, sharing new regulatory science tools and developing new drug combinations.

2012 BOARD of DIRECTORS & LEADERSHIP

Chair: *Mark McClellan, MD, PhD, 18th Commissioner of the FDA*

Vice Chair: *Ellen V. Sigal, PhD, Chair and Founder, Friends of Cancer Research*

Treasurer: *Georges Benjamin, MD, Executive Director, American Public Health Association*

Secretary: *Kay Holcombe, Senior Vice President for Science Policy, Biotechnology Innovation Organization*

Directors: *Pamela G. Bailey, President and CEO, Grocery Manufacturers Association*

William W. Chin, MD, Executive Dean for Research, Harvard Medical School

Helen Darling, President, National Business Group on Health

Sally J. Greenberg, JD, Executive Director, National Consumers League

Garry Neil, MD, Corporate Vice President of Science and Technology, Johnson & Johnson

Phillip Sharp, PhD, Professor of Biology and Member, Koch Institute

Tadataka Yamada, MD, Executive Director, Global Health, Bill and Melinda Gates Foundation

Diana Zuckerman, PhD, President, National Center for Health Research

Ex officio: *Francis S. Collins, MD, PhD, Director, National Institutes of Health*

Ex officio: *Margaret Hamburg, MD, 21st FDA Commissioner*

Executive

Director: *Jane Reese-Coulbourne*

As a 501(c)3 nonprofit, the Reagan-Udall makes all of its [audited financials](#) and [990 forms](#) available at www.reaganudall.org/about-us/annual-reports.
