Annual Report

2019

Advancing Collaboration

REAGAN-UDALL FOUNDATION FOR THE FDA

Letter from the Board Chair


Ellen V. Sigal, PhD

At the Reagan-Udall Foundation for the FDA, we are charged with helping to advance the mission of the U.S. Food and Drug Administration to modernize product development, accelerate innovation, and enhance product safety. We do that by creating and fostering collaborations that help move regulatory science forward.

We are advancing collaboration in research and analysis by building real-world data alliances that add depth and dimension to traditional scientific study.

We are advancing collaboration through patient, provider, and consumer services that translate regulatory science into meaningful patient and public impact.

And we are advancing collaboration through education and engagement that connects science to the stakeholders who create it, benefit from it, and are protected by it.

As you read through this annual report, you will see that we are expanding our partnerships to more fully reflect the breadth of FDA's mission. In 2019, we began to explore how the Foundation could support FDA's work in food safety and nutrition. And we began partnering with FDA's patient affairs staff in the Office of Clinical Policy and Programs to coordinate Patient Listening Sessions across FDA Centers. Of course, moving forward does not mean abandoning the work that has come before; we have also transformed our flagship public-private partnerships, Innovation in Medical Evidence Development and Surveillance (IMEDS) and Expanded Access Navigator, to help move innovation to patients.

We appreciate the partners, old and new, who join U.S. in our mission. Your collaboration, support, and insight propel U.S. forward in helping Americans live longer, stronger, and healthier lives.

Wishing you good health,

Ellen V. Sigal, PhD
Board Chair | Reagan-Udall Foundation for the FDA

> ...for more than a decade, we have worked closely with the Reagan-Udall Foundation for the FDA through a unique statutory partnership. This relationship serves many of our Agency's goals, but more importantly, it serves the American public.

STEPHEN HAHN, MD | 24th Commissioner of Food and Drugs

Stephen M. Hahn, MD

Message from the FDA Commissioner

At the Food and Drug Administration (FDA), we are required to be as modern and as innovative as the products we regulate. New discoveries, new opportunities, and new technologies require us to use visionary regulatory approaches to help speed innovations that could make medical products safer, more effective, and more affordable to help the public get the most accurate, science-based information.

We are not alone in our mission to keep America safe. For example, for more than a decade, we have worked closely with the Reagan-Udall Foundation for the FDA through a unique statutory partnership. This relationship serves many of our Agency's goals, but more importantly, it serves the American public. With the Foundation, we have made the innovative methodologies and resources of our Sentinel network available as a national resource for medical evidence generation. But we have accomplished more than that. We have worked together to stimulate dialogue, demonstrate relevance, and validate the role of real-world data as a tool for rapidly learning about patient characteristics, treatment patterns, and health outcomes.

In addition, we have partnered with the Foundation to amplify both the voice of patients and the impact of patient experience in the regulatory process. In 2019, we laid the groundwork to partner with the Foundation in patient listening sessions to inform our processes. We continue to work side by side with the Foundation to get innovation to the patients who need it most by improving physicians' understanding of expanded access and by clearing pathways to help patients access investigational therapies that could positively change the course of their disease progression.

We are excited for the Foundation's growth and look forward to pioneering partnerships in new sectors — some of which we are already pursuing in 2020. Science is evolving at an unprecedented pace, presenting more opportunities than ever before to advance innovation and deliver on our promise to protect the nation's public health.

Sincerely,

Stephen M. Hahn, MD
Commissioner of Food and Drugs | U.S. Food and Drug Administration

Reagan-Udall Foundation for the Food and Drug Administration

REAGAN-UDALL FOUNDATION FOR THE FDA

Created by a nonpartisan act of Congress, the Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization charged with advancing regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The Foundation works to improve America's public health through public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today's rapidly evolving science.

Results from our programs and activities inform FDA by conveying patient and public insights, identifying stakeholder concerns and priorities, detailing process barriers and potential solutions, and making FDA methodologies and tools accessible to external partners.

In 2019, the growth of the Foundation led the Board of Directors to adopt a Strategic Framework. The framework demonstrates how the mission, vision, and values of the Foundation are supported by four pillars:

- Research & Analysis
- Patient, Provider & Consumer Services
- Education
- Engagement

The Foundation was named for two federal leaders who battled incurable neurodegenerative diseases: President Ronald Reagan, who died of complications from Alzheimer's, and Congressman Morris "Mo" Udall, the 14-term Democratic congressman from Arizona who had Parkinson's disease. **The name of the Foundation illustrates both the need for new cures as well as the bipartisan nature of our work.**

REAGAN-UDALL FOUNDATION FOR THE FDA STRATEGIC FRAMEWORK

MISSION	VISION	CORE VALUES
Advance the mission of the Food and Drug Administration to modernize product development, accelerate innovation, and enhance product safety	A world where regulation informed by science improves product innovation and public health	Engagement Innovation Evidence

3-YEAR OUTCOME STATEMENT: Progress Toward Our Vision

The Foundation manages a suite of programs that assist the FDA to engage with external stakeholders, facilitate innovative research, advance the vitality of its workforce, and deliver improved health outcomes.

Goals			
Encourage innovative research & analysis	Improve public understanding of the risks and benefits of FDA-regulated products	Support education and training in regulatory sciences	Facilitate multi-stakeholder collaboration
Strategies			
Provide data assets and analysis tools to examine the risks and benefits of regulated products	Identify priority areas for consumer, patient and provider education in areas of emerging science	Identify and develop training opportunities in areas of emerging science	Enable expert analysis and candid discussion on issues relevant to the FDA mission
Mission Pillars			
Research & Analysis	Patient, Provider & Consumer Services	Education	Engagement

Advancing Collaboration

Innovation in Medical Evidence Development and Surveillance (IMEDS)

IMEDS Network Partners

Aetna

Harvard Pilgrim Health Care

HealthCore, Inc.

HealthPartners Institute

Humana/Humana Healthcare Research

Kaiser Permanente Washington Health Research Institute

Marshfield Clinic Health System

Meyers Primary Care Institute

Sutter Health Systems

Vanderbilt University Medical Center

The Reagan-Udall Foundation for the FDA's Innovation in Medical Evidence Development and Surveillance (IMEDS) program mobilizes healthcare networks, drug manufacturers, researchers, and the FDA Sentinel network to leverage real-world data to accelerate research and help answer critical product safety questions.

In 2019, IMEDS grew in both breadth and depth, enhancing our public-private partnership framework to support new research modalities. With the addition of two new network partners, Kaiser Permanente Washington Health Research Institute and Sutter Health Systems, IMEDS now includes healthcare data on more than 117 million people, including children, pregnant women, and Medicare/Medicaid populations.

2019 IMEDS Studies

IMEDS launched three new studies in 2019 while continuing work on several multi-year projects and creating new annual queries with each of our Network Partners to characterize the IMEDS population by age, sex, and other meta data. We also consulted with advisors and partners to cultivate a suite of pre-competitive research proposals entitled "Network Evaluation of Claims-Based Algorithms for High Priority Clinical Endpoints" (Algorithm Evaluation). These studies will establish new methods and metrics to identify high value, claims-based algorithms to inform real-world data studies.

The Algorithm Evaluation is an early step in framing a new Foundation venture: a consortium of organizations interested in advancing tools and methods to produce real-world evidence. In 2019, we conducted a detailed Landscape Analysis to better understand the needs of organizations that generate real-world data and the entities who need such data in order to respond to safety signals or conduct post-market research. Our goal was to identify how IMEDS can further leverage Sentinel data and tools with a broader set of stakeholders — such as academic institutions, clinical societies, and smaller biopharma companies.

The Foundation also looked internally in 2019, strengthening the charge of our IMEDS Steering Committee, creating the position of Vice Chair, and expanding representation to a greater variety of real-world data stakeholders.

The IMEDS network engages a subset of the Sentinel network and includes more than **117 million patient-lives** with access to medical, pharmacy, and laboratory claims data. Medical records, including electronic health records, are accessible for approximately 80% of the IMEDS population.

IMEDS GOALS

Through IMEDS, the Foundation makes FDA-quality data available by adhering to the same rigorous methodological standards developed by the Sentinel Initiative. IMEDS is built on the following goals:

- Make the analytic tools, methodologies, and expertise of FDA's Sentinel Initiative a national public resource to help researchers conduct medical safety surveillance and find answers to previously unanswerable questions
- Help drug manufacturers fulfill regulatory obligations, conduct population characterization studies (even for hard to reach populations like those with rare diseases), and engage in comparative effectiveness analyses
- Leverage real-world evidence to inform critical areas of public health
- Maintain a single-entry point to healthcare data on millions of patients in a secure environment that protects patient privacy

2019 IMEDS Steering Committee

Jacqueline Corrigan-Curay, JD, MD
Director, Office of Medical Policy
U.S. Food & Drug Administration

Peter Doshi, PhD
Assistant Professor/Associate Editor,
Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy/The BMJ

Sascha Dublin, MD, PhD
Senior Investigator
Kaiser Permanente Washington Health Research Institute

Carlos Garner, PhD
(Committee Vice Chair)
Vice President, Global Regulatory Affairs
Eli Lilly and Company

Solomon Iyasu, MD, MPH
Vice President and Head of Pharmacoepidemiology
Merck

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
U.S. Food & Drug Administration

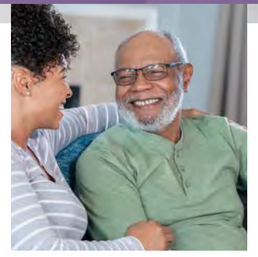
Vinit Nair, BPhar, MS
Health Plan Research Network Principal Investigator
Humana

Sally Okun, RN
Vice President, Policy and Ethics
PatientsLikeMe

Marcus Wilson, PharmD
(Committee Chair)
President
HealthCore, Inc.

Research & Analysis

Expanded Access Navigator



The cornerstone of the Foundation's expanded access portfolio is our Expanded Access Navigator, a comprehensive web-based tool that provides critical guidance for accessing investigational medications. Literally putting potentially life-saving information at the fingertips of stakeholders, the Navigator provides:

- Step-by-step guides for patients, physicians and other prescribers, and biopharmaceutical companies
- Detailed company listings including expanded access policies and contact information
- Extensive resources, such as templates and videos, to guide physicians and other prescribers through the request process

FDA has designated pathways that allow physicians **to request use of an investigational product to treat patients with serious, often life-threatening, diseases.** These mechanisms include single patient, intermediate-size, and large population expanded access programs or protocols.

EXPANDED ACCESS NAVIGATOR GOALS

The Expanded Access Navigator serves as a roadmap to help patients and physicians move through the single patient expanded access process and connect directly with companies providing investigational therapies. The goals of the Navigator are to:

- Increase understanding of expanded access by filling information gaps and clarifying misconceptions
- Reduce the burden on physicians and patients of finding expanded access information
- Increase willingness of physicians and other prescribers to explore expanded access for their patients
- Facilitate and expedite the request process
- Increase equity by ensuring that every patient is aware of expanded access as an option
- Improve physician and patient experience
- Assist FDA and industry in helping physicians better navigate the expanded access process

2019 Enhancements

In 2019, the Foundation collaborated with ClinicalTrials.gov to import expanded access listings into the Navigator and enhance search functionality to include free text searches — allowing users to simply enter a condition or disease, drug name, or other detail to search for expanded access options. Not only did this integration reduce the need for the user to move back-and-forth between sites, it also allowed the Navigator to display information in an easy-to-follow format for patients and physicians. The Navigator earned nearly 16,000 unique page views and doubled the number of companies in its Company Directory.

Additional 2019 enhancements to the Navigator include:

- Publishing the "Guide for Companies" to help new or smaller biopharma companies develop their own expanded access policies
- Releasing the "Leveraging Real-World Treatment Experiences from Expanded Access Protocols" report from our Fall 2018 public convening
- Posting FDA's new four-part Drug Info Rounds video series walking physicians through the process of submitting single patient expanded access requests for investigational drugs and biologics

> Our alliance with the Reagan-Udall Foundation and Project Facilitate is an excellent one...
>
> RICHARD PAZDUR, MD | Director, Oncology Center of Excellence, FDA

Michael Menefee, MD | FDA

Project Facilitate Partner

PROJECT FACILITATE

In late Spring 2019, the Foundation partnered with FDA's Oncology Center of Excellence (OCE) on the launch of Project Facilitate, a pilot program that created a single point of entry to help oncologists explore and submit expanded access requests for patients with cancer. Oncology healthcare providers are guided to the Foundation's Expanded Access Navigator to identify investigational therapies, pharmaceutical companies, and forms prior to completing the expanded access request for their patient. The Navigator also contains webinars and other training tools produced by the Project Facilitate team.

To learn more about the gaps in patients' and healthcare professionals' knowledge of the current system for expanded access requests and to gain feedback on plans for the Project Facilitate pilot, the Foundation co-coordinated a May 2019 public workshop with OCE. The event allowed us to demonstrate the increased search functionality and new resources on the Navigator and to hear directly from stakeholders on the usability of the website and database. Project Facilitate was formally launched in June when Foundation Board Chair Ellen V. Sigal, PhD, joined OCE Director Richard Pazdur, MD, for a press briefing at the American Society of Clinical Oncology Annual Meeting in Chicago. News coverage of the pilot program earned more than 100 million media impressions. Our staff also joined OCE in subsequent educational events such as webinars for the National Cancer Institute's National Community Oncology Research Program and the Maine Cancer Genomics Initiative. In its first six months, Project Facilitate saw a 20% increase in oncology expanded access applications demonstrating the need — and patient benefit — in helping providers navigate the expanded access process.

Expanded Access Stakeholder Roundtable

Amar Bhat, PhD

In October 2019, the Reagan-Udall Foundation for the FDA again partnered with FDA's Oncology Center of Excellence (OCE) to convene more than 25 stakeholders from healthcare systems/provider groups, biopharmaceutical industry, Institutional Review Boards, and academic medical centers to explore obstacles that too often cause unnecessary delay in getting an investigational product to the patient. Among the many points raised was the perception (real or not) that the request process is complicated and difficult to complete. Also highlighted were questions about the Institutional Review Board process and difficulties in negotiating contracts between provider organizations and biopharmaceutical companies.

Next Steps

As a result of the daylong roundtable, the Foundation established working groups to address two pressing recommendations (with completion anticipated in early 2020):

1. Publish a best practice "white paper" with templates showing what is most needed in the Letter of Agreement between healthcare systems and biopharmaceutical companies for single patient expanded access
2. Submit recommendations to FDA on clarifying the role of and criteria for Institutional Review Boards when reviewing single patient expanded access requests

2019 Annual Public Meeting

Leveraging public-private partnerships was the theme as 150 stakeholders convened for the Reagan-Udall Foundation for the FDA's Annual Public Meeting of the Board of Directors on May 2, 2019. Top FDA leadership — including then-Acting Commissioner Dr. Norman "Ned" Sharpless and Principal Deputy Commissioner Dr. Amy Abernethy — shared challenges and priority issues that Dr. Abernethy said, "will take the entire ecosystem coming together to solve."

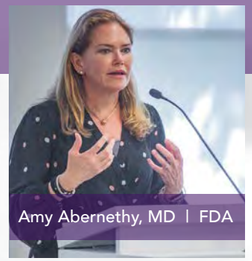
Dr. Abernethy went on to highlight the role of the Foundation as the "place we can strike partnerships to move regulatory science forward," a task all the speakers agreed is needed as science and innovation are moving so quickly.

The need for partnership to keep pace with the speed of science was echoed by four Center Directors: Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER); Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN); Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health (CDRH); and Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER).

Dr. Marks told panel moderator Michael McCaughan of Prevision Policy, LLC, that FDA needs "less formal, less traditional public-private partnerships that can keep pace with development and new ways of acquiring information," citing the fast-developing field of cellular and gene therapies as examples. Both Drs. Mayne and Shuren shared that the same challenge holds true with food and device technology advancements. Dr. Shuren emphasized the need for collaboration in figuring out how to make new science "less costly and more efficient," while Dr. Mayne reinforced the need for "partnership in science communications to keep the public informed." Dr. Woodcock highlighted the ongoing need for real-world data and partnerships that address "the challenges in the quality and completeness of that data," pointing to the Foundation's IMEDS program as a successful example. "We're building a national resource there," she said in highlighting the Foundation's collaboration with the Sentinel Initiative.

Then-Acting FDA Commissioner Sharpless talks with Foundation Board Chair Ellen Sigal

Following the panel, Foundation Board Chair Dr. Ellen V. Sigal sat down with then-Acting Commissioner Sharpless for his first public discussion since taking the post. He immediately picked up the thread of real-world data calling such partnerships "the way of the future" while acknowledging challenges such as privacy protection, aggregation, and interpretation of data sets. He noted a goal of addressing the challenge of real-world evidence so that FDA's work is fully informed by evidence, experience, and stakeholder input, stressing the agency's commitment to being patient/consumer driven: "we're making that the driving priority."



Amy Abernethy, MD | FDA

> Dr. Abernethy highlighted the role of the Foundation as the 'place we can strike partnerships to move regulatory science forward.'

REPURPOSING OFF-PATENT DRUGS:
Research & Regulatory Challenges

Christopher P. Austin, MD | NIH

Today, the world faces more than 6,500 identified rare and neglected diseases, but only about 250 of those have available treatments. Repurposing existing therapies may be a mechanism to get more treatments to more people quickly and safely, yet the pathway is not always simple.

On December 5–6, 2019, the Foundation partnered with the National Institute of Health's National Center for Advancing Translational Science (NCATS) and the FDA Center for Drug Evaluation and Research to explore the research and regulatory challenges in repurposing off-patent drugs. The two-day, interactive workshop engaged more than 300 participants — online and in-person — representing nearly every facet of the drug repurposing process: academics, funders and philanthropists, health economists, patients, pharmaceutical developers and manufacturers, patent/intellectual property lawyers, payors, regulatory policy experts, and scientists.

> History will show that this was the start of the change we all want to see, and all know is possible.

CHRISTOPHER P. AUSTIN, MD | Director, National Center for Advancing Translational Science, NIH

Panelists and participants explore the challenges of off-patent repurposing and work to identify potential solutions

Together, these experts worked to identify solutions to the often non-scientific, systemic challenges — such as lack of economic incentives, few regulatory options, labeling challenges, and lack of ownership — that prevent drug repurposing from occurring. The goal was to prioritize potential solutions and help identify ideas that could be used to develop an actionable research agenda to overcome the challenges of repurposing drugs that lack commercial and regulatory incentives.

While crafting that agenda may take some time, Dr. Christopher P. Austin, Director of NCATS, closed the workshop by saying he believed "History will show that this was the start of the change we all want to see, and all know is possible." Day one of the conference can be viewed online, and a comprehensive white paper will be released in 2020.

Patient Listening Sessions with FDA

There is a lot to be learned from patients. Their unique, first-hand experience with a disease or symptom set is undoubtedly a priceless source of knowledge, insight, and understanding. In late 2019, FDA's patient affairs staff in the Office of Clinical Policy and Programs asked the Foundation to partner in organizing ongoing Patient Listening Sessions.

These interactive, informal discussions with patients, caregivers, and advocates are designed to provide insights to FDA reviewers to inform their regulatory decision-making, guidance development, or public meeting preparation. Foundation staff observed sessions in September and October and began integrating into program coordination by year end. Foundation responsibilities will grow in 2020.

PATIENT LISTENING SESSIONS

Foundation staff supported five FDA Patient Listening Sessions in 2019

September 17, 2019 | Osteogenesis Imperfecta

October 17, 2019 | Sanfilippo Syndrome — Pediatric

November 6, 2019 | Cerebral Cavernous Malformation

November 13, 2019 | Childhood Cerebral Adrenal Leukodystrophy

December 2, 2019 | Gastroparesis

Big Data for Patients (BD4P)

To ensure the voices and needs of patients are central drivers of big data research efforts in biomedicine, the Foundation's BD4P training program was established four years ago to help patients and patient advocates understand the science of big data so they can participate more fully and effectively in patient-centered and real-world data initiatives.

In health, big data is patient data, so patient participation is vital in creating beneficial and patient-centered research initiatives. BD4P training empowers patients and advocates by enhancing data science literacy and critical appraisal skills. Graduates of BD4P report being more prepared and comfortable communicating on big data issues with policymakers, scientists, physicians, and other patients. Training materials, including lesson plans and case studies, can be downloaded free of charge from the Foundation's website.

BD4P GOAL

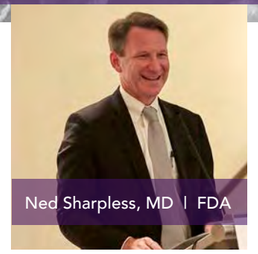
Ensure patient voices and patient needs are central drivers of big data research efforts in biomedicine

OBJECTIVES

- Increase awareness of big data research and how these efforts affect patients
- Enhance scientific literacy in the basic concepts and key vocabulary of big data
- Develop a community of informed and empowered patient advocates
- Build a community of practice that encourages patient participation and information exchange

Celebrating the 25th Anniversary of FDA's Office of Women's Health

FDA Office of Women's Health celebrates 25 YEARS 1994-2019 Promoting and Advancing the Health of Women



Ned Sharpless, MD | FDA

On October 10, 2019, the Foundation hosted an anniversary reception to celebrate 25 years of accomplishments and advancements through FDA's Office of Women's Health (OWH). Foundation Chair Dr. Ellen V. Sigal welcomed nearly 100 partners and collaborators who have worked with the office as well as FDA leadership, including then-Acting FDA Commissioner Dr. Norman "Ned" Sharpless, Principal Deputy Commissioner Dr. Amy Abernethy, and Acting Associate Commissioner of OWH Dr. Kaveeta Vasisht.

Kaveeta Vasisht, MD | FDA

Amy Abernethy, MD | FDA

The group highlighted the leadership, policy direction, and scientific expertise OWH has provided to the FDA and external partners in identifying the needs in women's health and ensuring inclusion in scientific research and clinical trial recruitment. Dr. Sharpless praised OWH for helping to "strengthen and inform regulatory decision-making and innovation at the FDA — and to further understanding about women's health."

Dr. Vasisht acknowledged the growth of OWH's responsibilities and activities along with the expansion of scientific understanding about the impact of gender, sex, and diversity in health. She closed the event by announcing the creation of a time capsule to be buried this year and opened on OWH's 50th anniversary in 2044.

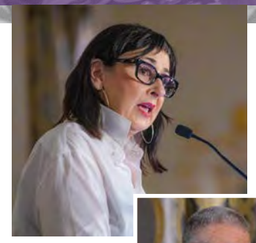
Exploring a Foundation Role in Nutrition and Food Safety

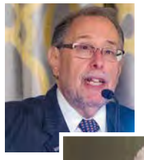
Food plays a significant role in public health from nutrition to the quality and safety of the food supply. FDA's Center for Food Safety and Applied Nutrition (CFSAN) safeguards more than $1.5 trillion worth of food, cosmetics, and dietary supplements.

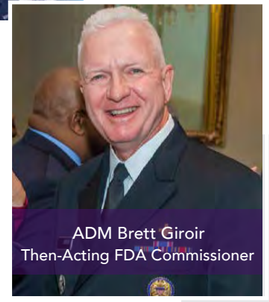
In late 2019, the Foundation began exploring how we could contribute to regulatory science in the food sector. At CFSAN's request, we met with food stakeholders, listened to the needs of regulators, and interviewed leaders across the field on topics such as nutrition, nutrition-related chronic disease, food safety, and food technologies to gauge the need and opportunity for public-private partnership. We also reviewed our Board of Directors structure to assess our strengths and needs in food expertise.

Our groundwork identified that we could bring value to the sector, and we began to plan for expansion. At the end of the year we were interviewing potential Board members and planning an early 2020 focus group to explore public-private partnership opportunities in the food space. Our anticipated first collaboration will be helping CFSAN amplify education around the new Nutrition Facts Label.

Innovations in Regulatory Science Awards







ADM Brett Giroir
Then-Acting FDA Commissioner

One way to advance innovation is to recognize it. The Innovations in Regulatory Science Awards celebrate the achievements of today's innovators and hope to inspire tomorrow's.

The 2019 Innovations in Regulatory Science Awards honorees reminded us what innovation is really about — improving the lives of patients. Each awardee contributed to science in ways that directly impact patients, incorporating their experiences, ensuring they have equitable access to promising investigational therapies, and supporting research that gives patients effective treatments as well as hope for a cure.

Leadership Award: The Foundation's Leadership Award was presented to Dr. Theresa Mullin whose 20-year career at FDA exemplifies exceptional leadership and a passion to elevate patient experiences into medical research enterprise. As Associate Center Director at the Center for Drug Evaluation and Research, Dr. Mullin's vision for FDA's Patient-Focused Drug Development Initiative is creating culture change at FDA as well as the entire regulatory field by using scientific methodologies to incorporate patient perspectives into the drug development and evaluation process.

Innovation Award: Innovation is often created when you have a problem to solve. A few years ago, Johnson & Johnson partnered with the New York University Langone Health's Division of Medical Ethics to develop an objective review process independent of commercial interest. Now, the Compassionate Use Advisory Committee, or CompAC, ensures a more equitable, consistent, and transparent pathway for individuals seeking access to investigational therapies. The program is now transforming how expanded access requests are evaluated across the industry.

Policy/Advocacy Award: 2019 saw introduction of the Reagan-Udall Foundation for the FDA's Policy/Advocacy Award, created to recognize significant policy achievements that advance regulatory science and have a direct impact on the public. The inaugural presentation honored the life-changing advocacy of the Cystic Fibrosis (CF) Foundation. The CF Foundation is the world leader in the search for a cure for cystic fibrosis, and nearly every cystic fibrosis-specific drug available today was made possible with their financial support. Their advocacy has helped to advance the regulatory science agenda and has accelerated innovation and modernization in regulatory practice and policy.

The Reagan-Udall Foundation for the FDA thanks our presenting sponsor, **Alexandria Real Estate Equities,** for supporting the 2019 Innovations in Regulatory Science Awards Dinner. We also appreciate the contributions of our Innovations sponsors — Deloitte, Johnson & Johnson, and Merck — and the 27 other organizations and individuals whose donations helped make the Awards program possible.

ALEXANDRIA
Building the Future of Life-Changing Innovation™

AWARDS

LEADERSHIP
Theresa M. Mullin, PhD

INNOVATION
Compassionate Use Advisory Committee
Accepted by
Joanne Waldstreicher, MD and Arthur L. Caplan, PhD

ADVOCACY/POLICY
Cystic Fibrosis Foundation
Accepted by
Preston W. Campbell, III, MD

Selection Committee

Garry Neil, MD
(Committee Chair)
Board Member, Reagan-Udall Foundation for the FDA
Chief Scientific Officer, Cerecor Inc.

Robert T. O' Neill, PhD
Senior Statistical Advisor, Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (retired)

Richard Pazdur, MD
Director, Oncology Center of Excellence, U.S. Food and Drug Administration

Pamela Tenaerts, MD
Executive Director, Clinical Trials Transformation Initiative

Andrew C. von Eschenbach, MD
20th Commissioner of the FDA
Board Member, Reagan-Udall Foundation for the FDA
President, Samaritan Health Initiatives

Financial Highlights

Financial Highlights for the years ended December 31, 2019 and 2018

REVENUE AND SUPPORT	2019	2018
FDA Direct Funding*	$1,250,000	$1,250,000
Grants and Contributions	350,450	474,720
Contracts	920,539	573,125
Fundraising Event	222,488	133,607
Miscellaneous and Interest Income	35,993	9,172
Total Revenue and Support	**2,779,470**	**2,440,624**

EXPENSES AND CHANGES IN NET ASSETS	2019	2018
Program Services		
Critical Path to Tuberculosis Drug Regimens	–	–
Innovation in Medical Evidence Development and Surveillance	2,068,059	1,450,103
Expanded Access Navigator	92,237	111,158
Big Data For Patients	–	18,780
Total Program Services	**2,160,296**	**$1,580,041**
Supporting Services		
Management and General	208,030	145,059
Fundraising	152,921	122,561
Total Supporting Services	**360,951**	**267,620**
TOTAL EXPENSES	**$2,521,247**	**$1,847,661**

CHANGE IN NET ASSETS	2019	2018
	$258,223	$592,963

*The Reagan-Udall Foundation for the FDA's operations are supported by direct funding from the U.S. Food and Drug Administration. (21 USC CHAPTER 9, SUBCHAPTER VII, §379dd(n))

Sponsors | Donors

The Reagan-Udall Foundation for the FDA fosters expert collaborations that can inform the FDA's work to ensure the food we eat, the medicines we take, and the products we rely on are safe, effective, and secure. We appreciate the financial contributors who help support our efforts.

INNOVATION IN MEDICAL EVIDENCE DEVELOPMENT AND SURVEILLANCE (IMEDS)

Research Study Sponsors

AbbVie, Inc. | Merck Sharp and Dohme Corp | Novartis Pharma AG

INNOVATIONS IN REGULATORY SCIENCE AWARDS

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Biotechnology Innovation Organization
Bristol-Myers Squibb Company
Buchanan Ingersoll & Rooney Life Sciences
Deloitte Services LP
Eli Lilly and Company
EMD Serono, Inc.
ExGloH, a Leidos Company
Friends of Cancer Research
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