2023
ANNUAL
REPORT

Advance Engage Inform

REAGAN-UDALL
FOUNDATION
FOR THE FDA

STRATEGIC FRAMEWORK

Helping the FDA do more to protect and promote the public's health

MISSION

Advance the mission of the Food and Drug Administration to modernize product development, accelerate innovation, and enhance product safety.

VISION

A world where regulation informed by science improves product innovation and public health.

3-YEAR OUTCOME

Progress Toward Our Vision: The Foundation manages a suite of programs that assist the FDA to engage with external stakeholders and that facilitate evidence generation, improve public understanding of the FDA, and deliver improved health information to the public.

VALUES

- Engagement
- Innovation
- Evidence
- Patient and Consumer Centered

GOALS

- Encourage innovation in regulatory science and career development
- Improve public understanding of the FDA and the risks and benefits of FDA- regulated products
- Support inclusion of all affected populations in research
- Facilitate multi- stakeholder collaboration to accelerate evidence generation and dissemination

PILLARS

Advancing Regulatory Science

Facilitating Engagement and Information Exchange

Supporting Development and Dissemination of Reliable Information

STRATEGIES

- Provide data assets, evaluation tools, and career development opportunities to help FDA assess the risks and benefits of regulated products
- Identify priority areas for consumer, patient, and provider educationin areas of emerging science
- Improve provider, patient, and consumer access to regulated products throughout product life cycles
- Enable expert analysis, candid discussion, and actionable recommendations on issues relevant to the FDA mission

2023 Foundation **Leadership Message**

The ability to adapt to changing circumstances is an essential part of science and leadership. As part of our continuing evolution at the Reagan-Udall Foundation for the FDA, we refreshed our strategic framework this past year to see how we might better support the mission of the FDA. One of our modifications: to elevate the 'patient and consumer centered' focus to our value statement. Strengthening this commitment will better guide our work.

In 2023, the Foundation initiated new activities and built on existing programs to better address the myriad challenges and opportunities facing the FDA. Our new work included recommending strategies to improve public understanding of FDA and FDA-regulated products, examining post-market evidence generation for both medical products and food, and more specifically, how FDA and other stakeholders can better support post-market studies that address gaps in clinical evidence.

The Regulatory Science Accelerator helped the Agency and the private sector examine emerging technologies in the development and monitoring of FDA-regulated products. We launched RAISE, the Real-World Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care. This is an important step toward the development of safe and effective medical products and equitable care delivery for all patients; improving real-world data is essential to strengthening health equity in clinical trials and ensuring that study results are applicable to all individuals for whom the product is intended.

We also developed our Regulatory Science Fellowship program, welcoming our first full-year fellow. We engaged with new sponsors and launched a partnership with Howard University to identify our candidates. These continuing collaborations will help grow the program and help build a more diverse regulatory science community one graduate at a time.

The Foundation could not do this alone. We are grateful to the many partners who join us in our mission. As you read the pages of this report, please know that your collaboration and guidance have been instrumental as we support the FDA to help Americans live longer, stronger, and healthier lives.

Sincerely,

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Chair
Reagan-Udall Foundation for the FDA Board of Directors

> Having a partner like the Reagan-Udall Foundation for the FDA… allows the agency to be more effective, to keep pace with and promote innovation, and to better protect the public's health and safety.
>
> Robert M. Califf, MD, MACC

FDA Commissioner Message

Every day in our work at the FDA, we are asked to examine and review groundbreaking new products to ensure their safety and effectiveness for the public that will use them. The developers of these products often use state-of-the-art science, and it is essential that we apply regulatory approaches that stay ahead of emerging science and technology. For us to be effective protectors of public health, we must embrace these developments, not only to keep pace with the industries we regulate, but also to advance innovation, and ensure that our regulatory oversight will be applied effectively, consistently, and fairly.

Having a partner like the Reagan-Udall Foundation for the FDA — an organization that exists to help us do more — allows the agency to be more effective, to keep pace with and promote innovation, and to better protect the public's health and safety. Over the years, the Foundation has provided us with important research and thoughtful analysis on a broad range of essential and challenging issues we face.

For instance, one of the FDA's most essential responsibilities is to provide and disseminate reliable information to the public to help people make informed decisions and choices about their health. We currently face a growing proliferation of health misinformation, which I consider to be one of the most serious threats to public health today. The Foundation's work to prepare a report on strategies for improving public understanding of FDA-regulated products was an essential and invaluable first step toward combatting this threat.

They've provided that kind of critical support and analysis in so many different areas, including tobacco regulation, evidence generation, and how to strengthen our Human Foods program. We've partnered with Reagan-Udall to encourage dialogue and advance the role of real-world data as a tool for rapidly learning about patient characteristics and improving health outcomes. We work side by side with the Foundation to speed innovation to the patients who need it most by improving understanding of expanded access and clearing pathways to help patients access investigational therapies that could positively change the course of their disease progression. Our collaboration to address the devastation of substance use disorder is making a difference, particularly in understanding patient needs. And we're pleased to continue our work with the Foundation in patient listening sessions, to further incorporate the voice of patients, patient advocates, and consumers to inform our processes.

In short, the work that the Reagan-Udall Foundation does in support of the FDA is, like the responsibilities of the FDA itself, diverse and challenging. We are grateful for our ongoing partnership with the Foundation and look forward to building on this relationship through the exploration of new avenues of research and stakeholder engagement. There is still much work to be done that is integral to our public health mission and it's important that we have partners we can rely on.

Sincerely,

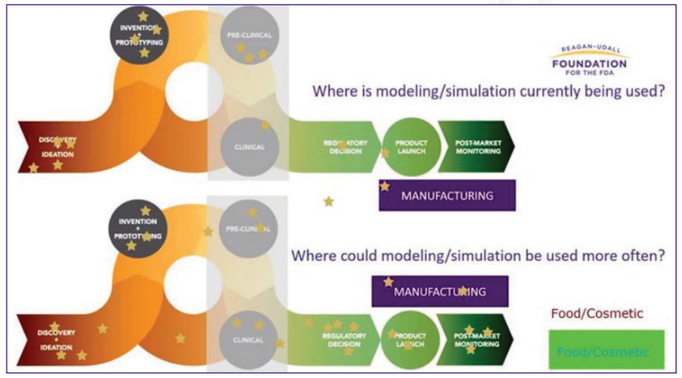
Robert M. Califf, MD, MACC
Commissioner of Food and Drugs
Food and Drug Administration

Regulatory Science Accelerator

The Foundation's Accelerator model, first developed with the COVID-19 Evidence Accelerator, provides a forum for key stakeholders across the health care ecosystem to share real-world experiences, help advance regulatory science, and address critical health issues. Stakeholders meet regularly to present ideas and work toward solutions.

In 2023, the Foundation, working with the FDA's Office of Regulatory Science and Innovation, launched the Regulatory Science Accelerator to examine emerging methodologies and technologies.

In Silico Alternative Methods:
Researchers presented proposals describing various In Silico Alternative Methods, which can be used to replace traditional animal testing with non-invasive methods or substitution, using in silico (computational) approaches.



In Silico Alternative Methods can be used to replace traditional animal testing with non-invasive methods or substitution, using in silico (computational) approaches.

Good Simulation Practices:
The Good Simulation Practices/Computational Modeling & Simulation (GSP/CM&S) cluster began by discussing whether there was a need for GSP guidelines that mirrored other "good practice" documents. Over the course of the cluster discussions, participants concluded that, rather than a GSP guidance document, the CM&S field needed a document describing how the practices might be more thoroughly adopted in FDA-regulated product development and regulation. Cluster members identified elements missing from the current literature and outlined content areas for a document to address. Work in 2024 will focus on developing a paper to communicate how CM&S is complimentary to other methods and mechanisms of evidence generation across FDA-regulated product areas.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Advance
Regulatory Science

Examining emerging technologies in the development and testing of FDA-regulated products.

Engage

More than 100 stakeholders took part in the two-meeting series, 10 animal/method pairing presentations were discussed.

Inform

The project produced one Summary document on In Silico Alternative Methods and began developing a second on Good Simulation Practices. A third and final paper to promote the adoption of computer modeling and simulation in the development of FDA-Regulated Products is expected to be completed in 2024.

RAISE

Incomplete and inconsistent capture of information about race and ethnicity in real-world data (RWD) limits understanding of the distribution, safety, and effectiveness of FDA-regulated products, which impacts the public health. That's why the Foundation, working with FDA's Office of Minority Health and Health Equity (OMHHE), launched the **Real-World Accelerator to Improve the Standard of collection and curation of race and Ethnicity** data in health care (RAISE).

The project unfolded in two phases:

Phase One included a series of 10 workshops with dozens of leaders across the health and health care ecosystem to create opportunities to share, learn, and build capacity to advance solutions. A public meeting provided the opportunity to share learnings and begin the next phase of work.

Phase Two took the learnings from our meetings and the community to identify priorities to improve the collection of race and ethnicity data and strategies to address those needs.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Advance
Regulatory Science

Collecting and measuring race and ethnicity data in health care delivery and payment is an important step toward the development of safe and effective medical products and effective health care for all patients — especially people of color.

Engage

More than 500 stakeholders took part in the 11-part RAISE workshop series and the final public meeting.

Inform

RAISE was featured in several articles, webinars, the OMHHE podcast, as well as 'Questions You Didn't Ask' with Niasha Fray. A series of articles on RAISE's efforts will be published on LinkedIn in 2024. The team has drafted two articles for journal publication.

Strategies for Improving Understanding of FDA-Regulated Products

The Foundation tackled the complex issue of health-related mis and dis information at the request of the FDA Commissioner. We reviewed existing literature and engaged directly with Stakeholders across the health care spectrum in a series of listening sessions, roundtable discussions, as well as one-on-one interviews and polling. Our research focused on understanding and addressing consumers' experiences with information related to FDA-regulated products.

We released a report that outlined several strategies and tactics to improve communications at the FDA and empower other health experts and communicators to strengthen their own outreach strategies to combat health misinformation.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

> **[Misinformation] is a challenge that must be addressed head on, in real time, and it can only be effectively responded to through collaboration and teamwork within our own agency, throughout the government, and across the entire public health sector.**
>
> **Robert M. Califf, MD**
> Commissioner of Food and Drugs

Advance
Regulatory Science

Developing strategies to better position the FDA to fulfill its mission statement with respect to "helping the public access the accurate, science-based information they need to use medical products and foods to maintain and improve their health."

Engage

Nearly 800 meeting attendees, 24 expert interviews, 60 Roundtable and Listening Session Participants including consumers, health care professionals, regulated industry representatives, and other experts across multiple disciplines.

Inform

Our report outlined a series of strategies and tactics to improve communications and better combat misinformation.

Evidence Generation

In 2023, the Foundation launched a new project to accelerate our learning about both medical and food products. Recognizing that there are gaps in our understanding of these products, even after their introduction into the market, the Foundation, at the request of the FDA Commissioner, began a two-part project to improve our understanding of the opportunities and obstacles to greater evidence generation.

Clockwise from upper left: Richard L. Schilsky, MD, Reagan-Udall Foundation for the FDA Board Chair; Joanne Waldstreicher, MS, Independent Board Director and Consultant; Robert A. Harrington, MD, Weill Cornell Medicine; Russell Rothman, MD, MPP, Vanderbilt University Medical Center; Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA; Adrian Hernandez, MD, MHS, Duke University School of Medicine

As part of the Medical Products Evidence Generation workstream, an Expert Panel organized a series of roundtable meetings and listening sessions to develop an Evidence Generation Framework. We organized a public meeting to discuss the Framework. Our expert panel published 30 recommendations for the FDA and other stakeholders to encourage and support evidence generation in the course of routine healthcare delivery.

Similarly, as part of the Food Safety and Nutrition Evidence Generation workstream, the Foundation interviewed over two dozen experts from across the food supply chain to help assess the data available to explore the impact of food safety and nutrition regulations and policies on consumer operations, food reformulation, and ultimately, consumer behavior. While there is considerable data about retail food sales and prepared foods, these data are disparate and often not publicly available, which presents a significant obstacle to comprehensive study and strategic analysis. In 2024, the Foundation will be focusing on implementation and dissemination of the Evidence Generation project results.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Advance
Regulatory Science

Improving data collection that supports regulatory decision-making.

Engage

More than 250 stakeholders attended our public meeting.

Inform

Our meeting and companion report were covered by several news outlets, sparking a continuing dialogue about evidence generation.

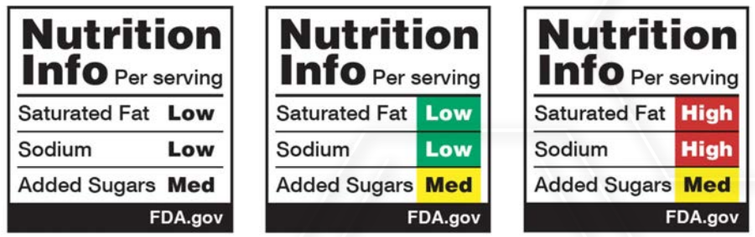
Food and Nutrition

The Foundation's Food and Nutrition work explored the topic of Front-of-Package Nutrition Labeling as part of a dialogue about helping consumers make healthier choices. We provided a public forum for FDA to provide an update on its ongoing consumer research, as well as an opportunity for the newly appointed Deputy Commissioner for Human Foods, Jim Jones, to provide an overview of the agency's work to facilitate improved nutrition. A significant portion of our public meeting included opening the virtual microphone for public comment, as numerous groups and individuals provided input on the design of potential labels and the influence of other nutrition-related work such as other labeling efforts.

Our Nutrition Communications Network continued to grow as consumer, patient advocacy, government, and industry groups disseminated coordinated nutrition messages to those most at risk for nutrition-related chronic disease.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA; James Jones, MS, FDA



The FDA has been conducting consumer research to explore the development of a Front-of-Pack nutrition labeling scheme and meeting with a variety of stakeholders to hear feedback and experiences.

Advance
Regulatory Science

Examining the impact of food safety and nutrition regulations and policies on consumer decision-making.

Engage

Nearly 550 people attended our public meeting on Front-of-Pack Nutrition Labeling.

Inform

Our Nutrition Communications Network shares messaging to build awareness and understanding of FDA's Nutrition Facts label to support healthy food and beverage choices.

Expanded Access Navigator

One of the Foundation's longest-running programs, the Expanded Access Navigator, provides a roadmap for accessing investigational medical products and treatments for seriously ill patients who have exhausted FDA-approved options. The Foundation's web-based Navigator guides patients, caregivers, health care providers through the Expanded Access process.

Expanded Access Navigator

The Expanded Access Navigator provides organized, easy-to-understand information on the Expanded Access request process.

eRequest

eRequest is a web and mobile based site that helps physicians determine whether Expanded Access is appropriate for their patients. It works with the Navigator to provide resources, as well as a single point for uploading relevant documents.

The eRequest app, developed in partnership with FDA, continues to adapt in response to growing health needs, this past year, adding a long COVID component. In 2023, approximately 25% of expanded access requests for drugs were submitted through the app.

This project was supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Engage

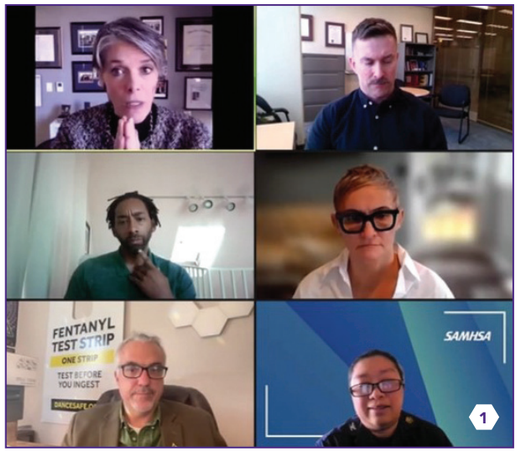
27 companies joined our directory in 2023, 25% of all Expanded Access submissions came in through the eRequest app. More than 16,000 people visited the Expanded Access Navigator in 2023.

Inform

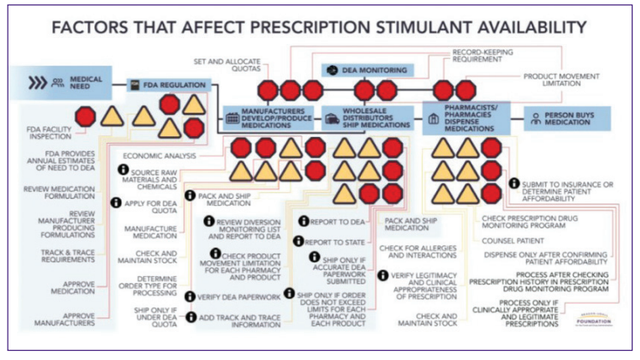
The Navigator provides custom user guides, links to open clinical trials, and detailed information on companies' expanded access policies.

Substance Use Disorder

The Foundation continued to explore strategies addressing the critical gaps in the Substance Use Disorders treatment system. In 2023, we worked with the FDA and stakeholders across the health care ecosystem to examine strategies for primary prevention, harm reduction, evidence-based treatment, and recovery support.



Understanding Fatal Overdoses to Inform Drug Development and Public Interventions to Manage Overdose" was a two-day event that explored the evolving context surrounding fatal overdose and discussed epidemiological trends, drug supply changes, public health interventions to manage overdose, and drug development opportunities. Our goal was to support efforts to develop products and approaches to treat overdose and prevent fatalities. we engaged with federal partners, clinicians, researchers, harm reductionists, and experts with lived experience to convene a two-day public meeting.



Advance
Regulatory Science

Building awareness and consensus on research gaps in the substance use treatment system and how to address them.

Engage

More than 2000 attendees (both virtual and in-person) took part in our convenings.

Inform

Wrote and disseminated three reports on our work to inform the health care community.

Considerations for Buprenorphine Initiation and Maintenance Care" examined real-world experiences and scientific evidence for buprenorphine initiation strategies and medication dosing and management during continued treatment across different care settings. Working with the FDA and the Substance Abuse and Mental Health Services Administration, we put together a two-day virtual public meeting to discuss efforts to develop products and approaches to treat opioid use disorder, participants included people who use drugs, their families and community, harm reduction programs, health professionals from inpatient and outpatient settings, academic researchers, and federal partners.

XYLAZINE is the active ingredient in an FDA-approved veterinary drug which is used as a sedative and analgesic. It is not approved for human use and there are no known benefits. Its use in the illicit drug supply was first documented in the early 2000s, initially in combination with heroin, then combined with other opioids, stimulants, and other substances. Xylazine is used as a cutting agent to enhance drug effects or to add weight to a product to increase its street value.

Mitigating Risks from Human Xylazine Exposure" was a hybrid meeting held in October that explored real-world experiences and scientific evidence on emerging data trends for human xylazine exposure. Stakeholders came together to examine concrete strategies for drug development and clinical research that could directly support the mitigation and reduction of risks associated with human exposure to xylazine.

Stimulant Availability

We also added a new focus: investigating the complex supply chain for prescription stimulants. Working with the FDA's Center for Drug Evaluation and Research, as well as external stakeholders, we compiled information to demonstrate the barriers and challenges patients may face when trying to acquire prescription medications. We detailed the numerous factors that may affect prescription stimulant availability.

These projects were supported in part or in total through a cooperative agreement with the Food and Drug Administration.

PHOTO KEY

1

Clockwise from top left:
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA; Mark Lysyshyn, MD, MPH, Vancouver Coastal Health; Mary Sylla, JD, MPH, National Harm Reduction Coalition; Jennifer Fan, PharmD, JD, SAMSHA, Emanuel Sferios, DanceSafe; Jermaine Jones, PhD, Columbia University

2

Marta Sokolowska, PhD, FDA

3

From left:
Luis Roman Badenas, PsyD, Intercambios; Malik Burnett, MD, MBA, MPH, Maryland Dept. of Health; Susan C. Winckler, RPh, Esq.

Research

IMEDS

One of the Foundation's longest-standing programs, the Innovation in Medical Evidence Development and Surveillance (IMEDS) program leverages the FDA's Sentinel Initiative to support post-market safety of regulated medical products with real-world data.

REAL-WORLD EVIDENCE STEERING COMMITTEE

Many thanks to the following who have been instrumental in discussing strategies, opportunities, and resources to advance the development of RWE.

Ryan Kilpatrick, PhD
AbbVie, Inc.

Peter Marks, MD, PhD
Center for Biologics Evaluation and Research, FDA

Aaron Mendelsohn, PhD, MPH
Harvard Pilgrim Health Care Institute

Vinit Nair, BPharm, MS, RPh
PRACNet®

Christian Nguyen, PharmD, MBA, MS
Eli Lilly

Sara Tartof, PhD, MPH
Southern California Permanente Medical Group

IMEDS, with its Network Partners, engages in all aspects of post market commitments: feasibility assessment, protocol and statistical analysis plan development, specifications and analysis, report preparation, and regulatory response. In 2023, we supported three multi-year post-market required studies.

Increased activity in regulatory science at the FDA (in particular in RWE generation) made for an exciting year for IMEDS as we are able to discuss, implement, and test novel approaches outlined in RWE Guidance documents.

Algorithm Evaluation

The objective of the Algorithm Certainty Tool (ACE-IT) is to be a resource in support of regulatory decision-makers and other stakeholders to appraise to appraise whether a given algorithm is fit-for-use for a specific decision context. The tool was published in Drug Safety and reflects our first use case in Major Adverse Cardiovascular Events (MACE). Our research team has begun work on expanding the tool for the assessment of maternal and birth outcomes during the perinatal period.

QCARD

We collaborated with FDA's Oncology Center of Excellence to develop the Oncology QCARD (Quality Characterization and Assessment of Real Word Data)! The purpose of QCARD is to provide users with a framework to report a set of minimum study design and data elements to assess the fitness of the real-world data (RWD) source(s) proposed in an initial study concept as part of early engagement with scientific reviewers. The goal is to foster early engagement and efficient review of preliminary oncology study proposals involving RWD.

These projects were supported in part or in total through a cooperative agreement with the Food and Drug Administration.

Advance
Regulatory Science
Facilitating evidence generation on regulated product.

Engage
Working with stakeholders on evidence generation in post-market research.

Inform
Providing researchers a framework for future validation studies.

Patient Listening Sessions

FDA's Patient Listening Sessions are interactive, informal discussions with patients, caregivers, and advocates that help provide insight to FDA program leaders and reviewers to inform regulatory decision-making, research, and development. The Foundation partners with the Agency's Patient Affairs Staff to organize these sessions, which allow the FDA to gain invaluable, first-hand knowledge about the impact of living with a disease or other health concern.

ALS and Frontotemporal Degeneration*	1.12.2023
Pouchitis	1.24.2023
Congenital Disorders of Glycosylation (CDG)*	1.30.2023
Juvenile Huntington's Disease*	2.10.2023
C. Difficile Infections*	3.10.2023
Bronchopulmonary Dysplasia	3.20.2023
Canavan Disease*	3.21.2023
Spinal Cord Injury*	4.24.2023
Carcinoid Syndrome	4.27.2023
Sickle Cell Disease*	5.5.2023
Leukoencephalopathy (LBSL)*	5.30.2023
Post-finasteride Syndrome*	6.2.2023
Pelizaeus-Merzbacher Disease*	8.22.2023
Pyruvate Dehydrogenase Complex Deficiency (PDCD)*	9.8.2023
Atypical Hemolytic Uremic Syndrome (aHUS)*	9.21.2023
Spinocerebellar Ataxia Type 3*	9.22.2023
Leber Congenital Amaurosis (LCA)*	10.30.2023
Non-ketotic Hyperglycinemia (NKH)*	12.15.2023

**Patient-requested Listening Session*

Advance
Regulatory Science
Providing insight into various conditions to inform regulatory decision-making.

Engage
More than 750 patients, caregivers, advocates and FDA staff attended patient listening sessions in 2023.

Fellowship in Regulatory Science, Innovation, and Health Equity

This year, the Foundation expanded its fellowship to provide a full year of hands-on learning for a professional school graduate. The Foundation partnered with Howard University, one of the nation's leading research universities, to assist with the design of the Fellowship program and the selection of the 2023–24 Fellow.

The program expansion was made possible through the generosity of sponsors: BeiGene, the Burroughs Welcome Fund, and Roche Diagnostics, who, in addition to funding, also provided additional opportunities for the 2023–24 fellow to engage with regulatory science professionals.

From left: Kendra Getaw, PharmD, Reagan-Udall Foundation for the FDA; Carolyn Hiller, MBA, Reagan-Udall Foundation for the FDA; Kaylan Ware, MPH, Reagan-Udall Foundation for the FDA; Hilary Marston, MD, MPH, FDA

It was an honor and a privilege to serve as the inaugural full-year fellow for the Reagan-Udall Foundation for the FDA. I learned so much in my time here at the Foundation. I appreciated the hands-on experience. I was able to help organize and participate in meetings such as "Mitigating Risks from Human Xylazine Exposure." It allowed me to delve into a growing public health issue and interact with stakeholders across the health care landscape.

I worked on projects disseminated to the public, such as graphics detailing the factors that affect patients searching for prescription stimulants.

This fellowship has been an integral part of my professional development.

Kendra Getaw, PharmD

Advance
Regulatory Science

Supporting the FDA's goal of strengthening health equity in clinical research and across all its activity through strengthening diversity within its workforce, including those engaged in regulatory science.

Engage

Providing an opportunity for professional development through an apprentice-type experience.

Thank You!

As your terms on the Foundation's Board of Directors expire, we and the regulatory science community are grateful for your years of dedication and leadership.

Georges C. Benjamin, MD, MACP
Founding Board Member

Allan Coukell, BScPharm
Board Member

Molly Fogarty
Board Member

2023 Annual Public Meeting

1

2

This year marked the return to an in-person meeting as the Foundation debuted its rooftop conference meeting space. Joined by more than 250 people both in-person and via Zoom, we welcomed Commissioner Califf and other FDA leaders. Attendees learned more about the Foundation's growing portfolio of activities over the past year from the Foundation's new board chair Richard L. Schilsky, MD, FACP, FDCT, FASCO.

An engaging panel discussion, led by Foundation CEO Susan C. Winckler, RPh, Esq., included key agency leaders sharing their perspectives of the FDA's work over the past year. The panel was made up of Chief Scientist Namandjé Bumpus, PhD; Chief Medical Officer Hilary Marston, MD, MPH; Chief Counsel Mark Raza, JD; and Chief of Staff Julie Tierney, JD. They touched on topics such as food safety, the FDA's role in innovation, and how the agency's various divisions work together to ensure the safety of regulated products. Commissioner Califf took questions from attendees and delved into some of the FDA's priorities and how the Foundation supported the agency's work.

3

4

Engage

More than 250 people attended our Annual Public Meeting.

Inform

The Foundation disseminates its annual report at this Annual Public Meeting.

2023 Board of Directors

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EX OFFICIO

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National Institutes of Health

CHIEF EXECUTIVE OFFICER

Susan C. Winckler, RPh, Esq.

PHOTO KEY

1
Foundation Board Chair
Richard L. Schilsky, MD, FACP, FSCT, FASCO

2
Board members
Edward John Allera, JD; Phuong Khanh (PK) Morrow, MD; and Debra L. Ness, MS

3
Robert M. Califf, MD, MACC, Commissioner of Food and Drugs, takes questions from attendees

4
From left:
Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA; Julie Tierney, JD, FDA; Hilary Marston, MD, MPH, FDA; Namandje Bumpus, PhD, FDA; Mark Raza, JD, FDA

Innovations in Regulatory Science Awards

The regulatory science community gathered at the Willard InterContinental Hotel on December 5, 2023, for the ***Innovations in Regulatory Science Awards***. It was an opportunity to recognize the inspiration and dedication of the 2023 honorees for their outstanding contributions to regulatory science.

LEADERSHIP AWARD

Dr. Francis Collins is known for his landmark discoveries in genomic medicine. He is also recognized for his work with the biomedical research community to create principles and guidelines that foster rigor and reproducibility in preclinical research.

INNOVATION AWARD

GenomeTrakr has changed how foodborne illnesses are investigated. Built by the FDA, GenomeTrakr has become a global resource used for sequencing foodborne pathogens, improving the safety of the food supply. It can also sequence non-foodborne pathogens such as the COVID-19 virus, which provides critical information about the virus' evolution and the effectiveness of FDA-regulated vaccines.

ADVOCACY/POLICY AWARD

Congresswoman **Diana DeGette** and former Congressman **Fred Upton** teamed up to create, build support for, and pass the Twenty-First Century Cures Act which provided much-needed funding for improving and modernizing the clinical research process, streamlining the approval processes for drugs and devices, and funded investments in precision medicine. The landmark legislation has paved the way for medical discoveries that translate into safe and effective treatments and cures.

Engage

218 leaders from the federal government, research, non-profits, and industry gathered to recognize achievements in regulatory science.

PHOTO KEY

1
Georges Benjamin, MD, MACP, Reagan-Udall Foundation for the FDA Board Vice Chair

2
Esther Krofah, MS, Reagan-Udall Foundation for the FDA Board member, presents the leadership award to Francis Collins, MD, PhD

3
Steve Musser, PhD, accepting the Innovation award on behalf of CFSAN

4
Rep. Diana DeGette (D-CO) and former Rep. Fred Upton (R-MI) accepting the Advocacy/Policy award

5
From left: Andrew C. von Eschenbach, MD, Samaritan Health Initiatives, Fred Upton, Diana DeGette, Francis Collins, MD, PhD, Steve Musser, PhD, Richard Schilsky, MD, FASCO, Susan C. Winckler, RPH, Esq,

6
From left: Kenneth Quinto, MD, MPH, Eli Lilly and Company, Donna Rivera, PharmD, MSc, FDA, Carla Rodriguez-Watson, PhD, MPH, Reagan-Udall Foundation for the FDA

7
Lynne Zydowsky, PhD, Reagan-Udall Foundation for the FDA Board member

8
Richard Schilsky, MD, Foundation Board Chair and Robert Califf, MD, MACC Commissioner of Food and Drugs

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Awards Chair, Board member,
Reagan-Udall Foundation for the FDA
20th Commissioner, Food and Drug Administration
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Reagan-Udall Foundation for the FDA
Milken Institute

Jennifer McIntyre, PhD
Food Safety Strategies, LLC

Ellen Sigal, PhD
Friends of Cancer Research

George Vradenburg
UsAgainstAlzheimer's

Financials

	2023	2022
REVENUE AND SUPPORT		
FDA Direct Funding*	$1,650,000	$1,250,000
Grants and Contributions	2,724,665	3,544,924
Contracts	3,399,686	3,614,197
Fundraising	353,530	414,550
Miscellaneous and Interest Income	204,342	23,468
Total Revenue and Support	**$8,332,223**	**$8,847,139**
EXPENSES AND CHANGES IN NET ASSETS		
Program Services		
Innovation in Medical Evidence Development and Surveillance	3,837,804	3,786,924
Expanded Access Navigator	172,552	123,537
Evidence Accelerator	6,854	575,477
Food & Nutrition	110,551	55,815
Algorithm Evaluation	96,643	99,667
Other	3,123,850	3,610,640
Total Program Services	**$7,348,254**	**$8,252,060**
Supporting Services		
Management and General	253,700	198,798
Fundraising	301,287	285,708
Total Supporting Services	**$554,987**	**$484,506**
TOTAL EXPENSES	**$7,903,241**	**$8,736,566**
CHANGE IN NET ASSETS	**$428,982**	**$110,573**

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