2021 ANNUAL REPORT

Mission-Driven. Evidence-Based.

REAGAN-UDALL FOUNDATION FOR THE FDA

About Us

The Reagan-Udall Foundation for the Food and Drug Administration is an independent 501(c)(3) organization created by Congress "to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety."

The Foundation embodies FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century and assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the FDA's ability to protect and promote the health of the American public. The Foundation serves as a crucial conduit between FDA and the public, providing a means for FDA to interact directly with stakeholders, including industry and consumers. The Foundation does not participate in regulatory decision-making or offer advice to FDA on policy matters.

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

CEO Message

Nurturing solutions to address public health challenges drove the work of the Reagan-Udall Foundation for the FDA in 2021: enhancing consumer understanding of FDA-regulated products, improving health equity, and advancing regulatory science.

The year brought work on a significant area of regulatory science: the prevention, treatment, and management of substance use disorders. Over the course of 2021, we convened stakeholders from the health, regulatory, industry, caregiver, and advocacy communities, including individuals with lived experience, to identify and address critical gaps across the substance use disorder ecosystem. We look forward to building on these positive first steps, working together with this vibrant, engaged community to find solutions that lead to better outcomes for those with substance use disorders.

Building on our robust COVID-19 work and our post-market drug and biologic safety evaluation efforts through the Innovations in Medical Evidence Development and Surveillance program, we expanded our portfolio to develop research tools, such as algorithm evaluation and the assessment of real-world data. Underpinning much of that work is our commitment to building a greater understanding of how real-world data (RWD) and real-world evidence (RWE) fit into the regulatory process and the recognition of the increasingly important role they play in healthcare decision making.

Our COVID-19 Evidence Accelerator work adapted to reflect the changing priorities of FDA within the pandemic, incorporating vaccines into our ongoing dialogue about therapeutics and diagnostics. Our efforts broadened to a focus on data content (such as race and ethnicity) and data flow and how we can improve existing RWD systems to work better together to share and analyze data.

We were pleased to be able to forge so many new collaborations as our work, described further in this report, expanded over the past year. We are also grateful to our many longstanding partners who continue to propel our efforts to modernize product development, accelerate innovation, and enhance product safety. We are excited to have you with us as the FDA Foundation continues its evolution and advances the FDA's work.

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

> The Reagan-Udall Foundation for the FDA (FDA Foundation) plays an integral role in helping the FDA meet these evolving challenges.

Robert M. Califf, MD
Commissioner of Food and Drugs

FDA Commissioner Message

We are living in a time of extraordinary scientific advancement that requires visionary regulatory response. The U.S. Food and Drug Administration (FDA) remains committed to meeting the challenges of this demanding environment and fulfilling our mission to promote and protect public health now and in the future.

The Reagan-Udall Foundation for the FDA (FDA Foundation) plays an integral role in helping the FDA meet these evolving challenges. We are grateful to have the FDA Foundation partner with us in this invaluable work. Our partnership helps speed innovation to enable safer, more effective medical products and provide the public with accurate, science-based information. We understand the importance of providing the tools and information necessary for people to make the decisions that will impact their health and safety.

We have joined with the FDA Foundation to promote 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. We have been gratified to enhance our ongoing work to create a better understanding of expanded access and to facilitate this pathway that helps patients access investigational therapies that could positively change the course of their disease progression.

We were pleased to collaborate with the FDA Foundation in a completely new sector: the treatment and management of substance use disorders. Over the past year, we've participated in discussions on developing strategies to improve research and ultimately, treatments, as well as gaining insight into the perspectives of those living with substance use disorders.

We've seen the Foundation partner with FDA's Center for Veterinary Medicine to explore antimicrobial use in food-producing animals. We've also seen continued work by the Foundation with the Center for Food Safety and Applied Nutrition, with efforts to create a public-private partnership and plan a series of convenings focused on innovating thinking around nutrition and behavior change.

I look forward to building and expanding our partnership with the FDA Foundation to help create more opportunities to advance innovation and deliver on our promise to protect the nation's public health.

Robert M. Califf, MD
Commissioner of Food and Drugs

Substance Use Disorders

> Fear of stigma when inquiring about options led to anxiety. Hearing from people who have battled addiction was an AMAZING help in finding what treatment options and what level of treatment I was likely to benefit most from.
>
> Patient on the stigma of treatment

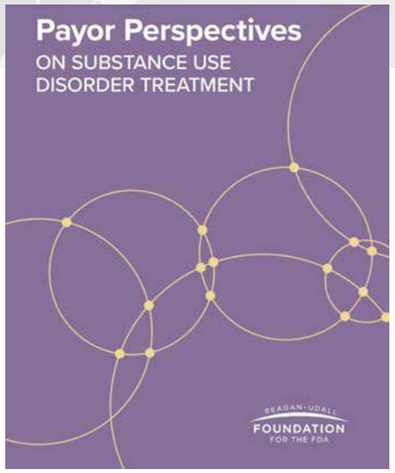
During the global COVID-19 pandemic, overdose deaths in the United States topped 100,000 annually for the first time, driven in part by the increased presence of fentanyl. The FDA Foundation is proud to work alongside the Controlled Substances Program at FDA's Center for Drug Evaluation and Research (CDER) to address this crisis, examining the complexities of substance use disorder (SUD) and exploring innovative approaches to developing solutions. This new and critical work was built upon the FDA Foundation's key mission pillars: research and analysis, engagement, and patient, provider, and consumer education.

I

Research & Analysis

We began with evidence, leveraging the framework from our COVID-19 Evidence Accelerator to explore the data sources needed to identify and recruit those living with stimulant use disorders into research, and the endpoint or study design innovations that could best enable their participation and retention in clinical trials. Partnering with CDER and the National Institute on Drug Abuse, we hosted a public meeting asking researchers and other experts to contribute to a practical research agenda focused on innovation in clinical trial design and candidate endpoints for the evaluation of potential treatments for stimulant use disorders.

I / FDA Foundation Director of Research Carla Rodriguez-Watson, PhD, MPH, discussing patient-centric endpoints with Ivan Montoya, MD, MPH, National Institute on Drug Abuse



Engagement

In March of 2021, the Foundation convened the "Payor Perspectives on Substance Use Disorder Treatment Roundtable" in conjunction with CDER, bringing together the health insurance sector, patient/consumer groups, recovery support organizations, health economists, clinicians, and government officials. The discussion centered around access to SUD treatment, particularly pharmacological treatment, to help inform the development and evaluation of new treatments for SUD, particularly treatments for stimulant use disorder, for which specific medications have not yet been approved by FDA.

We separately engaged stakeholders to better understand community and clinical viewpoints about using drug checking, particularly fentanyl screening, as a harm reduction or clinical strategy. Through roundtable meetings and one-on-one interviews, we convened national and local harm reduction organizations; tribal, state and local government agencies; researchers; and healthcare providers to discuss current perspectives and next steps for technology development, research, and practice. This harm reduction dialogue was conducted in partnership with the Behavioral Health Coordinating Council comprised of several operating divisions within the U.S. Department of Health and Human Services.

Reports on our Payor Perspectives and Harm Reduction work will be released in the spring of 2022.

Patient, Provider, and Consumer Education

To better understand the treatment experiences of individuals living with SUD, the Foundation connected with individuals as well as the treatment community to map their journeys. Looking at two specific paths — the experience of those considering medication for opioid use disorder and the trajectory of treatment for individuals who have gone through treatment for SUD more than once — we plotted where they encountered challenges and where they found meaningful supports. This ethnographic perspective helps identify potential system improvements and engagement opportunities that can inform FDA's outreach.

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

Research

The FDA Foundation expanded its research portfolio in 2021. In addition to our work in post-market safety evaluation, our research program now encompasses the development of research tools, such as algorithm evaluation and oncology Quality Characteristics and Assessment of Real-World Data (QCARD), and convenings to explore how real-world data and evidence can inform regulatory decision making.

IMEDS

We continued to develop public-private partnerships that advance evidence generation on post-market regulated products through the Innovation in Medical Evidence Development and Surveillance (IMEDS) program. IMEDS supports the FDA's Sentinel Initiative by making its data resources available to industry and other researchers to facilitate the analyses of medical product safety evaluations. Besides surveillance activities, the database can be used for population characterization and effectiveness studies.

IMEDS NETWORK PARTNERS

- CVS Health Clinical Trial Services, LLC
- Harvard Pilgrim Health Care Institute
- HealthCore, Inc.
- HealthPartners Institute
- Humana Healthcare Research, Inc.
- Kaiser Permanente Washington Health Research Institute
- Marshfield Clinic Health System/ Marshfield Clinic Research Institute
- Meyers Health Care Institute
- Vanderbilt University Medical Center

Algorithm Evaluation

The Foundation has envisioned a multi-sponsored suite of research studies focusing on the development of the Algorithm Certainty Tool Kit, or ACE IT, to assist users in characterizing the fitness of a given algorithm for a potential use case. Major Adverse Cardiovascular Events, or MACE, was used as an endpoint of interest during the development of the tool. Throughout 2021, our team, with the help of an expert panel, developed and refined the tool with support from a broad group of stakeholders. Ultimately, as we continue our work, we will develop ACE IT as the gold standard for researchers to characterize the suitability of algorithms for use in research, particularly regulatory studies.

OBJECTIVE 1
Algorithm CErtainty Tool Kit (ACE IT)

OBJECTIVE 2
Tool Application & Mapping ICD9 to ICD10

OBJECTIVE 3
Algorithm Development & Validation

Real-World Data

2021 was the year the Foundation's work in real-world data (RWD) and real-world evidence (RWE) advanced significantly, and we began to address methodological approaches across the RWD spectrum. We partnered with the FDA's Oncology Center of Excellence on the Oncology QCARD, developing a forum to characterize the relevance, reliability, and validity of RWD. We look forward to sharing more about this work as it develops in 2022.

RWE STEERING COMMITTEE

Chair

CARL GARNER, PHD
Vice President, Global Regulatory Affairs
Eli Lilly

JACQUELINE CORRIGAN-CURAY, JD, MD
Director, Office of Medical Policy, Center for Drug Evaluation and Research
FDA

SOLOMON IYASU, MD, MPH
Vice President and Head of Pharmacoepidemiology
Merck

PETER MARKS, MD, PHD
Director, Center for Biologics Evaluation and Research
FDA

VINIT NAIR, PHD
Principal Investigator
Humana

SASHA DUBLIN, MD, PHD
Senior Investigator
Kaiser Permanente Washington

BRAY PATRICK-LAKE, MFS
Director of Strategic Partnerships
Evidation

The Foundation, working with the FDA, convened a series of public webinars to discuss the FDA-issued guidances related to RWD and RWE. Highlighting the growing importance of RWD and RWE in health-related decision making.

I / Webinar on Assessing Electronic Health Records (clockwise from top left): Wei Hua, MD, PhD, Center for Drug Evaluation and Research (CDER); Michael Blum, MD, MPH, CDER; Susan C, Winckler, RPh, Esq., FDA Foundation; Natasha Pratt, PhD, CDER; and John Concato, MD, MPH, CDER

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

COVID-19 Evidence Accelerator

In its second year, the COVID-19 Evidence Accelerator addressed new challenges created by the pandemic shifting our pace from a sprint to a marathon. The Evidence Accelerator developed a long-term and sustained strategy to address the complexities of the disease and examine the data sets available to gain a better understanding of various therapeutics, diagnostics, and vaccines.

In March 2020, at the request of the FDA, the Reagan-Udall Foundation for the FDA, in collaboration with Friends of Cancer Research, created the COVID-19 Evidence Accelerator (EA) — a forum for stakeholders across the health care spectrum to share real-world data and to generate ideas on how to deal with COVID-19.

Evidence Accelerator "Lab" Meetings

As the first vaccine was being rolled out in early 2021, the Evidence Accelerator launched a new vaccines workstream to explore the different ways to use real-world data to evaluate vaccine performance. Our coalition of 'accelerators' also continued investigating how the Evidence Accelerator framework for knowledge sharing and advancing opportunities in real-world evidence may help address other critical health needs.

The Diagnostics Evidence Accelerator began the year focusing largely on issues of data interoperability — taking and combining data from different systems to provide a more complete and meaningful analysis. Throughout the year, we also explored various COVID-19 testing strategies and the different environments in which testing took place such as schools, health centers, dialysis centers, and even within professional sports leagues.

As Accelerators began analyzing what was necessary to create an environment for data interoperability to occur, they landed on a minimum set of COVID-specific data elements: 1) device identifier; 2) specimen collected date; 3) test result; 4) test result date. The challenge of data interoperability will continue to be a focus of the Accelerator work in 2022.

THERAPEUTICS EA	Once-Monthly Lab Meeting (3rd Thursdays)	Planning for next steps underway...
DIAGNOSTICS EA	Once-Monthly Lab Meeting (3rd Thursdays)	Data interoperability work underway...
VACCINES EA	Once-Monthly Lab Meeting (3rd Thursdays)	Planning for next steps underway...

PARALLEL ANALYSIS

The use of remdesivir in hospitalized patients with COVID

The incidence of coagulopathy in patients with COVID as compared to patients with the flu

Comparing different types of serology tests and their accuracy/ performance in detecting past COVID infections

Parallel Analysis Workstreams

Parallel Analysis allows groups to analyze their own data, from different types of sources such as electronic health records or insurance claims, using a common protocol. Results are then shared with the Accelerator group and reviewed "in-parallel." This strategy utilized real-world evidence as a tool for rapidly learning about patient characteristics, treatment patterns, and outcomes associated with management strategies for COVID-19.

By the end of the year, the Evidence Accelerator had closed out its three parallel analysis workstreams, which examined priority questions that arose from the earliest days of COVID-19 treatment.

To date, one paper based on the parallel analysis work has been published; four additional articles on this work are currently in review.

COVID-19 Real-World Evidence Primer

The Foundation also led creation of a real-world evidence primer to highlight the use of real-world data and methods as they are relevant to those investigating COVID-19. This online primer will include perspectives from across the research ecosystem. It will be published in collaboration with the International Society for Pharmacoepidemiology and available on the Evidence Accelerator website the second quarter of 2022.

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

Expanded Access

Broadening awareness and use of FDA tools and resources is core to the FDA Foundation's mission. It's also the cornerstone of our work in expanded access, the potential pathway for patients with serious or life-threatening conditions to try an investigational medical product for treatment outside of clinical trials when there are no comparable or satisfactory therapies available.

Through our Expanded Access Navigator and the new Expanded Access eRequest app developed in partnership with FDA, the Foundation works to demystify the pathway and make it more readily accessible to all patients who may benefit.

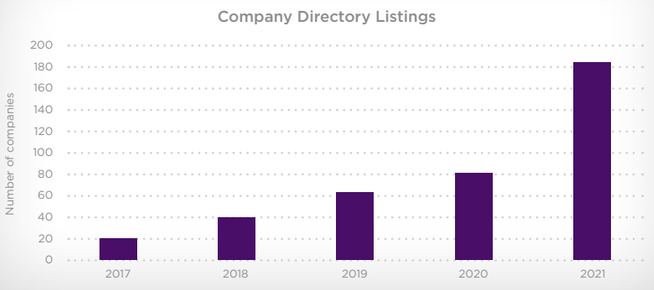
Use of Expanded Access eRequest, which allows prescribers to prepare and securely submit expanded access requests to FDA, grew significantly since its launch the previous year. As more treatment providers used the app, we identified ways to refine the user experience. And, we added new functionality, including the ability for users to upload documentation and reports for already approved emergency expanded access requests.

We also saw growth in the Foundation's Expanded Access Navigator, a robust resource that guides patients, providers, and industry through the process from start to finish. More than 18,000 users accessed Navigator resources in 2021; listings in our company directory rose by more than 20%.

In addition to collaborations with FDA, including the Oncology Center of Excellence's Project Facilitate program, the Foundation focused on educational opportunities to reach healthcare providers, patient groups, and other stakeholders. Among the highlights: presented at the international Operationalize Expanded Access conference and the Transforming Expanded Access to Maximize Support and Study (TEAMSS) Collaborative annual meeting, met with the Cancer Commons Board and authored a guest post for the Curious Dr. George blog, and co-hosted a CME webinar with FDA's Center for Drug Evaluation and Research. The Foundation also strengthened its social media presence to share stakeholder resources, address misconceptions, and improve understanding about Expanded Access.

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

EXPANDED ACCESS NAVIGATOR



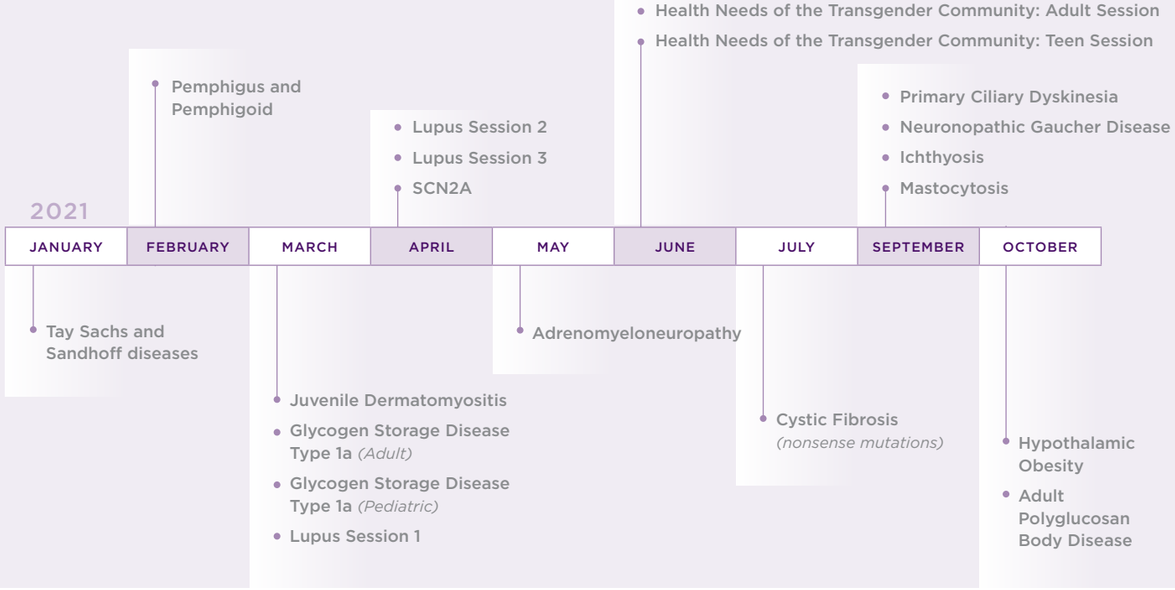
Patient Listening Sessions

Patient Listening Sessions provide an opportunity for the FDA to connect with often under-represented communities.

The FDA Foundation collaborates with the FDA's Office of Patient Affairs to engage with patients through these listening sessions, which allow the FDA to gain a better understanding of the needs and experiences of patients and caregivers. Their voices are integral to the FDA's work by bringing the patient perspective to medical product development and regulatory thinking.

In 2021, the Foundation expanded on its work with the FDA's Office of Patient Affairs to develop an engaging series of conversations and to branch into previously under-explored topics such as the health needs of the transgender community.

THE FDA FOUNDATION SUPPORTED 19 PATIENT LISTENING SESSIONS IN 2021



Nutrition

2021 was a period of expansion for the FDA Foundation's Nutrition program. We marked a year of the Nutrition Communications Network, a group that includes nearly three dozen consumer and patient advocacy organizations as well as government and industry groups widely disseminating coordinated nutrition messages.

The Foundation partnered with the Retail Dietitians Business Alliance (RDBA) to launch *Supporting Healthier Eating in the New Normal: The Ultimate Retail Dietitians Toolkit.* Reflecting changing consumer behaviors around health and eating habits as well as opportunities to closely partner with pharmacies, the Toolkit provides social media templates, fact sheets, interactive quizzes, recipes, virtual tour ideas, and other educational resources. Messages are built largely around the U.S. Food and Drug Administration's new Nutrition Facts label and incorporate the latest science from the *Dietary Guidelines for Americans 2020–2025* (U.S. Department of Agriculture), the U.S. Department of Health and Human Services, and the National Institutes of Health as well as other healthcare and research institutions.

This past year, the Foundation established a public-private partnership to conduct a series of upcoming convenings designed to spark innovative thinking among industry, government, and the consumer and health care sectors about nutrition and behavior change.

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

NUTRITION CONVENINGS PLANNING COMMITTEE

Chair
GEORGES BENJAMIN, MD, MACP
American Public Health Association

Center for Food Safety and Applied Nutrition
Food and Drug Administration

The Kellogg Company

Nestlé USA

Reagan-Udall Foundation for the FDA

2021 Annual Meeting

On May 12, 2021, the Foundation brought together more than 100 stakeholders for our Annual Public Meeting of the Foundation's Board of Directors. The afternoon's virtual discussion focused on how the strength of public-private partnerships helps to advance the Foundation's work and the FDA's mission.

Board members joined with FDA leaders to highlight the impact of cross-cutting collaborations — especially as we addressed unprecedented public health challenges. The meeting featured a series of in-depth conversations providing an overview of the relationship between the FDA and the Foundation, beginning with Foundation Board Chair Ellen V. Sigal, PhD, and Acting FDA Commissioner Janet Woodcock, MD, who recognized the Foundation as "ideally positioned" to support the FDA as they examine how they might become more agile in responding to future health crises.

RADM Denise Hinton on the value of the Foundation in supporting the FDA's mission:

"The work the FDA Foundation has done with the FDA and for the FDA has been profound…

The information given and received from the convener meetings helps to push important information about the evidence-based work that we do… and the information received from stakeholders may help inform our decisions and our guidance."

Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, Center for Drug Evaluation and Research, FDA:

"What the Foundation did is create a critical and powerful tool to use real-world evidence for public health… IMEDS will continue to be such an important part of the real-world evidence ecosystem as we look for more opportunities for the public to engage and support it."

Robin McKinnon, PhD, Senior Advisor on Nutrition Policy, Center for Food Safety and Nutrition on the Foundation's work supporting the FDA's work on food and nutrition:

"Improving nutrition offers one of the greatest opportunities to improve public health… The Foundation… acting as a conduit… to stakeholders and the public to support and extend our work, we see great value in that."

Lori Bickel, JD, Regulatory Counsel, Office of Medical Policy, CDER spoke to the Foundation's work on Expanded Access innovations such as the Navigator and eRequest:

"The Foundation has been instrumental in being a bridge to all of the stakeholders… in getting that continual feedback about what's working, what's not, what can be simplified. It's been a long and fruitful partnership for both of us."

I / FDA Foundation Board Chair Ellen V. Sigal, PhD, with Acting FDA Commissioner Janet Woodcock, MD

II / RADM Denise Hinton speaking in her role as FDA's Chief Scientist

III / Robin McKinnon, PhD, MPA, Senior Advisor for Nutrition Policy, Center for Food Safety and Applied Nutrition

IV / Adrian Hernandez, MD, IMEDS Committee Chair, sat down with Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, Center for Drug Evaluation and Research, FDA, discuss the IMEDS program

V / Lori Bickel, JD, Regulatory Counsel, Office of Medical Policy, CDER, discussing the FDA Foundation's work on Expanded Access

Convenings

An important role the FDA Foundation plays is helping FDA understand the environment in which the products it regulates are used. By bringing stakeholders together — in small roundtable settings or large public meetings — the FDA Foundation creates opportunities for FDA to share information, learn from stakeholders, and explore pathways forward in often complex areas of regulatory science. These convenings are embedded in much of our program work, from the COVID-19 Evidence Accelerator to our Substance Use Disorder portfolio. However, we also convene groups to discuss critical priorities facing FDA in the moment and in the future.

I

II

Generating Evidence for Racial and Ethnic Minorities During Development of Oncologic Therapeutics Spring 2021

The FDA Foundation brought together pharmaceutical companies, contract research organizations, and the FDA Oncology Center of Excellence to discuss industry's ongoing efforts to build a more representative research population. The roundtable explored strategies already in place, definitions of what diversity could look like, and concrete measures to achieving diversity in clinical trials.

Potential Medication Error Risks with Investigational Drug Container Labels Spring 2021

More than 700 attendees came together, representing sponsors, investigators, U.S. and international regulators, and Institutional Review Board members to examine how current practices for labeling investigational new drug containers can increase the potential risk of medication error. Along with reviewing the prevalence and nature of medication errors, panelists shared their perspectives and experiences offering insights that might inform future regulatory action such as exploring opportunities for global harmonization on labeling and reporting medication errors associated with investigational drugs.

Cannabis Derived Products Fall 2021

The FDA Foundation engaged with health care professionals to learn about their understanding and experiences with cannabis derived products (CDP) to help inform FDA's future research and outreach activities. Through a roundtable conversation, the FDA Foundation explored provider perceptions about CDPs, the types of interactions they have with patients about CDPs and the information, education, and regulatory guidance needs that exist.

Emergency Use Authorization (EUA) Fall/Winter 2021

At times, FDA may authorize unapproved medical products or unapproved uses of approved medical products during a public health emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions. But how do patients and consumers, healthcare practitioners, and leaders in the medical community view these products? At FDA's request, the FDA Foundation sought to answer this question through public polling and a series of roundtable discussions also aimed at understanding how these groups responded to the information shared about EUA products and how FDA might refine future communications about EUA. The roundtable discussions provided insight into how EUA products were integrated into practice, the intersection between medical product availability under an EUA and through clinical trials, and how risk/benefit assessments might vary across diagnostic, therapeutic, and vaccine products.

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

I / FDA Foundation CEO Susan Winckler, RPh, Esq., discusses investigational drug container labels with an international panel including Jason Wakelin-Smith, Medicines and Healthcare Products Regulatory Agency (UK) and Alicja Kasina, MSc, BPharm, Health Canada

II / FDA Foundation CEO Susan Winckler, RPh, Esq., moderates a robust discussion

Understanding Consumer Perspectives and Effective Educational Messages

The FDA Foundation collaborated with the FDA's Office of Minority Health and Health Equity (OMHHE) to expand and advance work with stakeholders and partners to address education, outreach, and public awareness activities on the use of and potential risks from skin lightening products containing hydroquinone and mercury.

The Foundation conducted interviews with researchers, dermatologists, consumers, and other diverse groups. We worked with community-based organizations to host multiple listening sessions with diverse consumers who had used or considered using skin lightening products that may contain hydroquinone or mercury. The sessions explored consumer awareness of ingredients, concern about ingredient safety, and information that would be helpful in selecting skin care products. Building on what we learned, we developed, tested, and refined educational messages that could be used by OMHHE in consumer outreach and education.

Innovations in Regulatory Science Awards

The Innovations in Regulatory Science Awards took on a special significance in 2021, as the continued toll of the pandemic led to the field of regulatory science facing closer scrutiny than ever before. The FDA Foundation was honored to recognize those people and institutions who demonstrated the leadership, innovation, and advocacy vital to protecting and promoting the health and safety of the American public.

LEADERSHIP AWARD

The FDA Foundation presented the Leadership Award to **Dr. Peter Marks**, lauding his enduring contributions to regulatory science and public health. As head of the Center for Biologics Evaluation and Research (CBER), Dr. Marks laid the groundwork for the public/private partnership formerly known as Operation Warp Speed. He continues to oversee the FDA's work ensuring the safety and effectiveness of biological products, such as vaccines, allergenic products, blood products, and cellular, tissue, and gene therapies.

INNOVATION AWARD

The COVID-19 Research Database was recognized with the Innovation Award for its outstanding efforts to assist researchers struggling to understand the most effective ways to diagnose and treat COVID-19. The award was accepted by Niall Brennan, founding member of the COVID-19 Research Database Governance Committee. The Database has unlocked 85 billion records covering over 250 million unique individuals for a research community that currently includes hundreds of research teams conducting critical observational research on epidemiology, pharmacoepidemiology, population health, and much more.

POLICY/ADVOCACY AWARD

Since his first days in public service, former Congressperson **Patrick J. Kennedy** has believed that mental health should be a national priority. His dedication and unwavering commitment to advancing the cause of more accessible and high-quality mental health services is why the FDA Foundation named Mr. Kennedy this year's Policy/Advocacy Award recipient. During his time in Congress, he was the lead author of the landmark Mental Health Parity and Addiction Equity Act. As founder of The Kennedy Forum, he unites advocates, policymakers, and business leaders to advance evidence-based practices and policies in mental health and addiction.

The event also featured remarks from Acting FDA Commissioner Janet Woodcock, MD, on how the FDA Foundation could play a role in advancing the FDA's work. The evening was an occasion to honor outgoing board members Sally J. Greenberg, JD; Kay Holcombe, MS; and Garry Neil, MD, who were recognized for their contributions to the Foundation's achievements during their tenure.

A CONVERSATION WITH 2021 AWARDEES

A highlight of the 2021 Awards program was a conversation with this year's awardees about how best to harness innovation to address some of the most pressing challenges in regulatory science. It was a unique opportunity to hear from three of the best minds in the field as they discussed applying the lessons they've learned to improve the entire research ecosystem.

Using Big Data

I think the challenge going forward is how do we address health equity issues, mental health issues, how do we do a better job of combining the administrative data and clinical data and making them available.

Niall Brennan
Founding Member, COVID-19 Research Database Governance Committee

Addressing Health Crises Beyond COVID-19

If we can see the total context of us not having a COVID vaccine and that 'spurs' us toward that challenge, it's long past due that we have the kind of urgency that we brought to COVID, bringing that to the mental health and addiction crisis.

Patrick J. Kennedy
Former U.S. Representative and Founder, The Kennedy Forum

The Value of Collaboration

Big data is very important…but it's the dialogue we've been able to have with sponsors, with patients, with advocacy groups, with pharmaceutical companies and drug developers, early on in the process to avoid unnecessary work.

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

AWARDS SELECTION COMMITTEE

The FDA Foundation thanks our Awards Selection Committee for their commitment to the Innovations in Regulatory Science Awards

GARRY NEIL, MD
Awards Committee Chair
Board Member, Reagan-Udall Foundation for the FDA

AMY ABERNETHY, MD, PHD
President, Clinical Studies Platforms
Verily Life Sciences

JEFF ALLEN, PHD
President & CEO
Friends of Cancer Research

MICHAEL M. LANDA, ESQ.
Former Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

JOHN M. TAYLOR, ESQ.
President and Principal, Compliance and Regulatory Affairs
Greenleaf Health

TED THOMPSON, ESQ.
Senior Vice President, Public Policy
The Michael J. Fox Foundation for Parkinson's Research

ANDREW C. VON ESCHENBACH, MD
20th FDA Commissioner
Board Member, Reagan-Udall Foundation for the FDA

LYNNE ZYDOWSKY, PHD
Board Member, Reagan-Udall Foundation for the FDA

Financials

REVENUE AND SUPPORT	2021	2020
FDA Direct Funding*	$1,250,000	$1,250,000
Grants and Contributions	1,097,120	754,845
Contracts	2,725,836	2,485,707
Fundraising	428,200	407,250
Miscellaneous and Interest Income	2,092	21,782
Total Revenue and Support	**5,503,248**	**4,919,584**

EXPENSES AND CHANGES IN NET ASSETS	2021	2020
Program Services		
Innovation in Medical Evidence Development and Surveillance	3,267,672	2,920,865
Expanded Access Navigator	47,719	82,617
Evidence Accelerator	575,581	643,974
Vaccine Confidence (COVID-19)		209,094
Food & Nutrition	49,312	91,316
Algorithm Evaluation	101,018	
Other	883,834	
Total Program Services	**4,925,136**	**3,947,866**
Supporting Services		
Management and General	189,623	218,032
Fundraising	256,671	338,593
Total Supporting Services	**446,294**	**556,625**
TOTAL EXPENSES	**$5,371,430**	**$4,504,491**

CHANGE IN NET ASSETS	2021	2020
	$131,818	$415,093

*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)).

The FDA Foundation receives additional project funding (noted in previous pages of this report) through the Supporting Patient Access, Real-World Data, and Critical Collaborations cooperative agreement with the U.S. Food and Drug Administration.

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