ANNUAL REPORT 2020

ENGAGEMENT. **INNOVATION.** **EVIDENCE.**

REAGAN-UDALL

FOUNDATION

FOR THE FDA

Letter from the CEO

MOST ANNUAL REPORTS FOR 2020 BEGIN WITH A LONGER, LITERARY EQUIVALENT OF 'OH MY' OR 'WOW'. Our Annual Report is different only in that we will use that shorter version: wow. Like many other organizations, the 2020 faced by the Reagan-Udall Foundation for the FDA did not resemble the 2020 for which we planned. Thankfully, we were in a position to help as the novel coronavirus brought much of the world to a near standstill.

The unprecedented events of 2020 tested resources, inspired innovation, and highlighted the need for reliable real-world evidence. It was an honor for the FDA Foundation to bring together disparate stakeholders to support the FDA in one of its most challenging times, and to facilitate work to find solutions.

As part of our COVID-19 response efforts, we launched the COVID-19 Hub, a resource to provide the most up-to-date science-based information regarding COVID-19, as well as information on investigational treatments. We partnered with FDA's Center for Biologics Evaluation and Research to lead the Vaccine Confidence Project: listening to under-represented communities and frontline workers and developing responsive, credible messages to inform their decision about whether or not to receive a COVID-19 vaccine.

A significant part of our pandemic response was the COVID-19 Evidence Accelerator, created in collaboration with Friends of Cancer Research. This initiative brings together members of the real-world data community to share insights and compare results; to help keep pace with scientific understanding of COVID-19; and the role of FDA-regulated products. The proven Evidence Accelerator framework can serve as a resource for other fields of inquiry.

As you will see in the pages of this report, we executed a portfolio of COVID-related activities while also advancing our other programmatic work to advance regulatory science, building on existing partnerships and forging new ones. From engagement to innovation and evidence, 2020 proved to be a remarkable year — one in which we learned to not only adapt but to excel.

We are so grateful to our many partners who joined us in 2020 for this important and invaluable work in supporting the mission of the FDA. Together, we play a vital role in promoting and protecting the public health.

Susan C. Winckler, RPh, Esq..

CHIEF EXECUTIVE OFFICER
REAGAN-UDALL FOUNDATION FOR THE FDA

Acting FDA Commissioner Message

AT THE U.S. FOOD AND DRUG ADMINISTRATION, our mission is to protect the public health by ensuring the safety and efficacy of the products we regulate. In 2020, that mission took on extraordinary significance as the worldwide COVID-19 pandemic reshaped our lives, causing profound loss and compelling us to adapt how we live, work, and learn.

Months later, the FDA staff continue to work tirelessly to gain greater understanding of COVID-19, and to help to ensure the rapid deployment of diagnostics, therapeutics, and vaccines, in response to this unprecedented public health emergency. I am extremely proud of, and gratified by, the hard work demonstrated by the Agency.

I also appreciate our unique relationship with the Reagan-Udall Foundation for the FDA and for what we have achieved together. The Reagan-Udall Foundation, in collaboration with Friends of Cancer Research, built the COVID-19 Evidence Accelerator, establishing an expansive public-private partnership that combines the efforts of academic, government, and private sector organizations. FDA has been an active participant in the Evidence Accelerator since its inception. Applying data analytics to accelerate the understanding of COVID-19, the Evidence Accelerator is a vital component of our COVID-19 response, helping us to answer critical questions about the natural history of the disease.

Our COVID-19 work also included collaboration with the Reagan-Udall Foundation for the FDA on the Vaccine Confidence Project in which we listened to the perceptions and concerns of front-line workers and traditionally under-represented communities. Our goal was to gain better insight into the information and messages the vaccine hesitant might need to decide about getting a COVID-19 vaccine. The project's findings are being shared broadly to inform federal education initiatives as well as community-based public health outreach.

We are eager to build on this 14-year partnership, exploring new avenues of research and stakeholder engagement. I thank the Reagan-Udall Foundation for the FDA for our continued collaboration, which has proven so integral to our public health mission.

Sincerely,

Janet Woodcock, MD

ACTING COMMISSIONER OF FOOD AND DRUGS

COVID-19 Evidence Accelerator

EVIDENCE ACCELERATOR

In 2020, there was no more pressing issue than the novel coronavirus and the resulting health crisis.

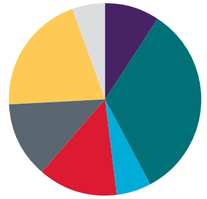
Responding to the novel coronavirus stimulated unprecedented collaboration and cooperation in the health and research communities. For its part, the Reagan-Udall Foundation for the FDA was uniquely positioned to bring together cross-cutting teams to gather insights about the virus and the data on diagnostics, treatment, and looking ahead to 2021, vaccine work. In collaboration with Friends of Cancer Research, we created the COVID-19 Evidence Accelerator — a forum for stakeholders across the health care spectrum to share real-world data to foster a better understanding of the virus, and the impact of FDA-regulated products used in the pandemic response.

The genesis of the Evidence Accelerator was a request from the FDA. The Agency recognized the value of a regular look at real-world data to help process information and generate ideas surrounding how to deal with COVID-19. The first meetings began in the spring of 2020 and grew quickly to participants from more than 230 organizations. Researchers, clinicians, data aggregators, academia, FDA-regulated industry, and government agencies came together to discuss what we were learning about COVID-19, identify where the gaps in our information lay, and explore how to address a growing list of questions.

The initial work of the Evidence Accelerator focused on therapeutics. Little was known about how to treat illness from the virus at the time; there were questions related to the use of dexamethasone, hydroxychloroquine, azithromycin, and other drugs as well as the natural history of the disease itself. The Evidence Accelerator participants used a "parallel analysis" approach where participating groups analyzed their own data, from different types of sources such as electronic health records or insurance claims, using a common protocol. Results were then shared with the Accelerator 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.

COVID-19 EVIDENCE ACCELERATOR PARTICIPANTS

Information/Data System	77
Research Academia	47
Hospitals and Health Systems	31
Nonprofit	30
Pharma	22
Government Agency	14
Other industry	13

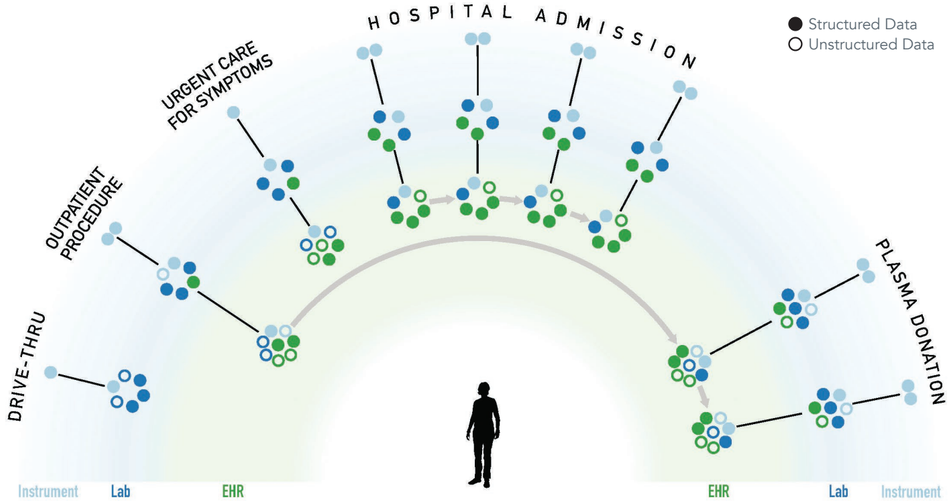


The COVID-19 Evidence Accelerator is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $460,288 of federal funds (65% of the project period from September 2020 to August 2021). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

Only a few weeks into our therapeutics work, the need for a second workstream for diagnostics was identified. In May, the Diagnostics Accelerator began the mission of reviewing real-world data related to test performance, surveillance trends, contemporaneous symptoms and presentation, and other issues. Supported in part by a grant from The Rockefeller Foundation, data organizations jumped into a parallel analysis research project evaluating the performance of certain COVID-19 tests. Our meetings enlisted some non-traditional stakeholders to gain new perspectives: representatives from the National Football League and National Basketball Association presented data on their 'bubbles' to provide insight on testing strategies.

There is significant work ahead for the Evidence Accelerator. Looking to 2021, the Foundation is building out a vaccine workstream as well as providing a gathering place

> "Protocols have evolved empirically over the season, driven by analytics and ongoing expert review of real-world evidence; this has been key to having effective operational protocols in the unprecedented 2020 season."
>
> — ALLEN K. SILLS, MD, FACS
> CHIEF MEDICAL OFFICER OF THE NATIONAL FOOTBALL LEAGUE

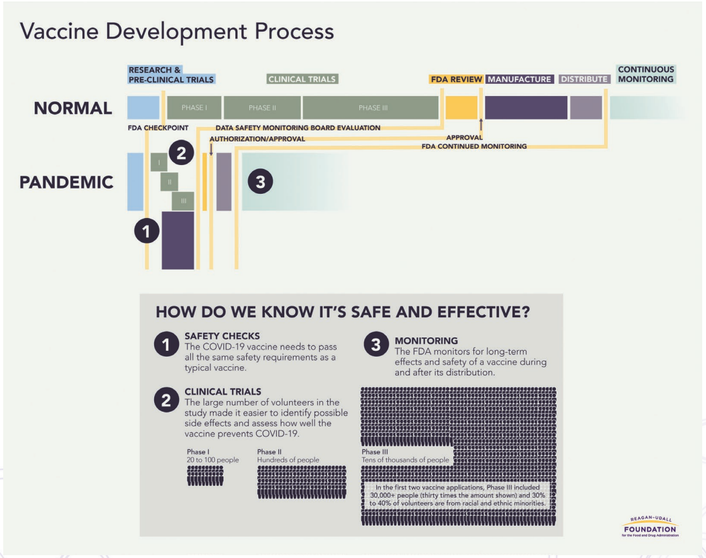


Presented at the 08.20.20 COVID-19 Diagnostics Evidence Accelerator
Original content by R.J. Andrew and Gina Valo, Inquiries: gina.valo@fda.hhs.gov

for those engaged in researching Post-Acute Sequelae of SARS CoV-2 infection or 'long' COVID. We are also exploring how the Evidence Accelerator framework for knowledge sharing and exploring opportunities in real-world evidence may help address other critical health issues such as substance use disorders.

VACCINE CONFIDENCE PROJECT

Another vital piece of the Foundation's COVID-19 work was the Vaccine Confidence Project. The Foundation worked with Hamilton Place Strategies to develop messages and identify credible messengers to the public. Focused specifically on communication about FDA's role in vaccine review, authorization, and approval, the objective of the Vaccine Confidence Project was to provide those who are vaccine-hesitant with the information they need to decide whether or not to receive a COVID-19 vaccine.

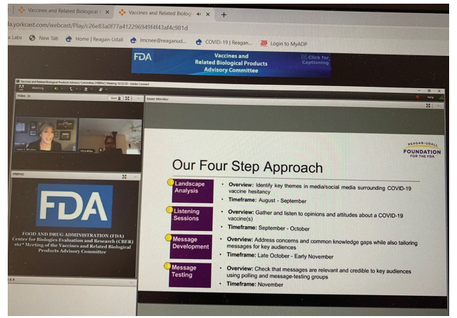


The Vaccine Confidence Project began with listening — convening a series of 14 listening sessions throughout the fall of 2020 to hear from front line workers and traditionally under-represented populations. We shared our sobering work-in-progress with FDA's Vaccines and Related Biological Products Advisory Committee in October 2020, allowing them to hear concerns in the real, often-emotional words of session participants.

Based on what we heard in the listening sessions, the potential messages were then tested extensively through national survey, expert interviews, and focus groups. Our final report, presented in December, outlined several effective messages (See SIDEBAR), and identified the most trusted messengers to build vaccine confidence. These findings are shared to inform outreach campaigns at the federal, state, and local levels as well as one-on-one conversations between healthcare professionals and patients.

COVID-19 HUB

To provide consumers with access to the most up to date information on pandemic developments from FDA and its regulated industries, one of the first steps the FDA Foundation took was creating its COVID-19 Hub. Designed to centralize critical COVID-19 information, the Hub provided twice-daily updates on clinical trials and a directory of companies working on COVID-19 interventions as well as the latest FDA COVID-19 briefings. As the world's, and our own, COVID-19 work progressed, we provided updates on our Vaccine Confidence Project and links to the Evidence Accelerator as well as additional information on diagnostics and testing, medical products and personal protective equipment, and the latest guidelines for researchers, healthcare workers, the food industry, and the public.



Foundation presentation by Susan C. Winckler and Dr. Christine Wilks at the October 2020 FDA Vaccines and Related Biological Products Advisory Committee

The FDA Foundation shared tested messages with community health leaders, practitioners, educators, and influencers to inform federal, state, and local vaccine outreach efforts.

"The FDA is publicly sharing information about COVID-19 vaccines so you can see the evidence for yourself."

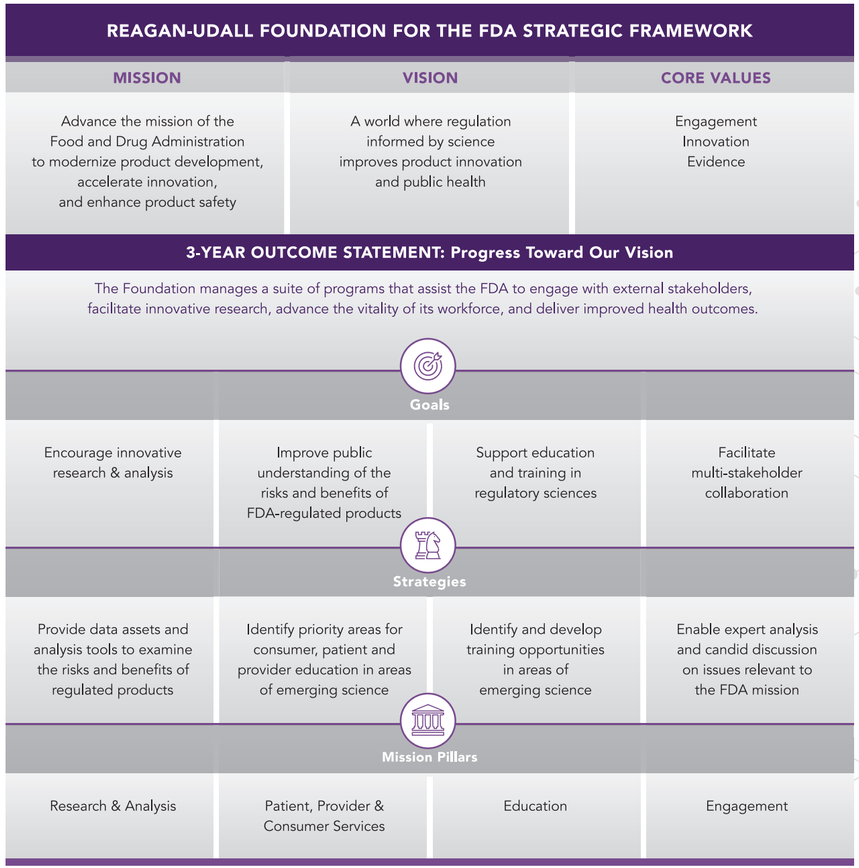
"Only safe and effective COVID-19 vaccines that have been rigorously tested on tens of thousands of volunteers will be approved."

"Scientists and career public health officials, not politicians or their appointees, will decide when a COVID-19 vaccine is safe, effective, and ready for public use."

"By getting a COVID-19 vaccine, you are protecting yourself, your children, parents, grandparents, and other loved ones."

The COVID-19 Vaccine Confidence Project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $150,000 of federal funds (88% of the project) and by $20,000 from non-governmental, non-industry sources (12% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov. This project was completed in 2020.

Strategic Framework



Innovation in Medical Evidence Development and Surveillance (IMEDS)

ADVANCING EVIDENCE GENERATION ON REGULATED PRODUCTS is the hallmark of the FDA Foundation's Innovation in Medical Evidence Development and Surveillance (IMEDS) program. In 2020, IMEDS continued its work utilizing the FDA's Sentinel Initiative, making its data resources available to industry and other researchers to facilitate the analyses of medical product safety evaluations. Besides surveillance activities, the IMEDS database can be used for population characterization and effectiveness studies.

IMEDS 2020 STUDIES

The IMEDS program saw significant growth and development in 2020. IMEDS is continuing its implementation of the "Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents."

IMEDS advanced its work to help design and execute a study to assess the safety of risankizumab among pregnant women with psoriasis. The ongoing research activities, which help fulfill a requirement from the European Medicines Agency are a collaborative effort between the Foundation and other participating IMEDS Network Partners.

IMEDS initiated an effort to assess the risk of adverse cardiac events among African American patients with heart failure who use sacubitril/valsartan.

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 NETWORK PARTNERS

CVS Health
Harvard Pilgrim Health Care
HealthCore, Inc
HealthPartners Institute
Human/Humana Healthcare Research
Kaiser Permanente Washington Health Research Institute
Marshfield Clinic Health System
Meyers Primary Care Institute
Sutter Health
Vanderbilt University Medical Center

IMEDS GOALS

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

Make the analytic tools, methodologies, and expertise of FDA's Sentinel Initiative a national public resource to facilitate studies that will increase our understanding of the real-world safety and effectiveness of pharmacologic therapies.

Help drug manufacturers fulfill regulatory obligations, including post-market requirements and conduct population characterization studies (even for hard-to-reach populations like those with rare diseases), and feasibility assessments.

Initiate cross-cutting research to advance the use of real-world data to efficiently address questions of safety and effectiveness of pharmacologic therapies and 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.

In 2020, IMEDS focused on engagement with investigators and expanding the IMEDS network. The FDA Foundation hosted and moderated a panel on data sharing in the era of COVID-19 at the Drug Information Association Conference in June of 2020. We also took a leadership role in a webinar to explain how those engaged in post-market surveillance might utilize this real-world data to review safety concerns. The project also featured speakers from Harvard Pilgrim Health Care Institute and Saama Technologies. IMEDS began work to capture information about drug exposures, outcomes, and risk factors for joint safety in osteoarthritic patients. This project will include an examination of claims data as well as radiology reports.

The IMEDS program is also exploring multi-sponsored projects and new areas of focus for 2021 and in the years ahead. The initial goal is to develop a tool to evaluate and conduct validation studies of claims-based MACE (major adverse cardiovascular events) algorithms in the context of regulatory surveillance and to promote the adoption of this tool as a standard of practice. Ultimately, the goal is to establish infrastructure and best practices to systematically evaluate existing algorithms and develop and test new algorithms to represent clinical constructs that are consistently used in regulatory studies. We are looking forward to providing updates to this exciting new project in 2021.

Foundation featured in "Active Surveillance: A New Paradigm in Patient Safety" webinar

IMEDS STEERING COMMITTEE MEMBERS

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

Sascha Dublin, MD, PhD
Senior Investigator, Kaiser Permanente Washington Health Research Institute
Physician, Washington Permanente Medical Group, Internal Medicine

Carlos Garner, PhD
Vice President, Global Regulatory Affairs
Eli Lilly & Company

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

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

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

Sally Okun, RN
SallyOkun360 LLC

Bray Patrick-Lake, MFS
Director, Strategic Partnerships
Evidation Health

Marcus Wilson, PharmD
President
HealthCore

Patient Listening Sessions

PATIENTS PROVIDE INVALUABLE PERSPECTIVE IN THE REGULATORY PROCESS. Engaging with patients helps the FDA gain a better understanding of the needs and experiences of patients, caregivers, and patient advocates. These collaborative discussions serve to educate patients about the FDA's work as well as inform FDA staff in their regulatory decision-making, research, and development. In 2020, the FDA Foundation worked closely with the FDA's Office of Patient Affairs to further develop a robust series of conversations. This year, the sessions were adapted to an all-remote format due to COVID-19. We found the remote sessions allowed for wider participation from advocacy groups, patients, and their families who otherwise may not have travelled for an in-person meeting.

FOUNDATION STAFF SUPPORTED
16 PATIENT LISTENING SESSIONS IN 2020

Ocular Melanoma
Hunter Syndrome
Inclusion Body Myositis
Vasolin-Containing Protein Disease
vonHippel
Homocystinurias (HCU)
Pulmonary Alveolar Proteinosis
Progressive Multifocal Leukoenceophalopathy (PML) (Two sessions)
X-Linked Myotubular Myopathy (XLMTM)
Smith-Magenis Syndrome
Clear Cell Sarcoma
Guillain-Barré syndrome
Vascular Ehlers-Danlos
Limb Girdle Muscular Dystrophies
Gorlin Syndrome

Expanded Access

2020 BROUGHT GREAT ADVANCEMENT toward the FDA Foundation's goal of helping patients who have exhausted appropriate approved therapies access potentially lifesaving or life-changing investigational treatments.

Our Expanded Access Navigator is the core of this work. The Navigator makes it easier for patients, prescribers, and companies to move through the expanded access process from identifying potential interventions through ensuring informed consent and submitting requests to both FDA and the product manufacturer. More than 12,000 online visitors used the Expanded Access Navigator in 2020.

Participating in the Expanded Access Navigator's Directory demonstrates company compliance with the requirement to make expanded access policies and contacts publicly available.

2020 ADVANCEMENTS

In September of 2020, the FDA Foundation, with input from experts at FDA, launched Expanded Access eRequest, an app that allows prescribers to submit expanded access requests online. eRequest leverages the strength of our Expanded Access Navigator and adds the ease of online submission and report tracking. With eRequest, prescribers can identify potential investigational therapies; access sponsor information; complete, sign and submit FDA Form 3926; upload supporting documentation; and review additional resources all in one place. The app is compatible with multiple devices, so prescribers can explore expanded access in real time with their patient and then complete and submit the request later.

Our partnership with FDA's Oncology Center of Excellence continued to grow in 2020 following the Expanded Access Roundtable and Project Facilitate collaboration the prior year. As a result of the Roundtable, the Foundation submitted ideas to FDA on clarifying the role and review criteria for Institutional Review Boards (IRB) in single patient expanded access requests. Many of those concepts were evident in FDA's *IRB Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators*. We also worked to educate oncology providers about Project Facilitate's technical assistance through a variety of activities, including a webinar hosted by the Melanoma Research Foundation.

EXPANDED ACCESS NAVIGATOR GOALS

- 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 with a resource to help assure 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

From the inception of the Expanded Access Navigator to our broader work today, the FDA Foundation has grown into a trusted voice and leader on expanded access. Now regularly invited to present at conferences or collaborate on educational outreach, we are committed to broadening awareness, understanding, and use of FDA's expanded access pathways to improve patient care.

The Expanded Access Navigator is an online roadmap to help patients and physicians move through the single patient expanded access process, providing:

- 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 to guide physicians and other prescribers through the request process

The expanded access program, including Expanded Access eRequest, is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $128,712 of federal funds (90% of the project period from September 2020 to August 2021). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

Then Interim Director Amar Bhat speaking at the Expanded Access Summit at the National Press Club (Jan 2020)

Food and Nutrition

IN EARLY 2020, THE FDA FOUNDATION CONVENED A FOCUS GROUP OF STAKEHOLDERS along with FDA leadership from the Center for Food Safety and Applied Nutrition (CFSAN) to identify how the Foundation can best contribute to regulatory science in the food and nutrition sector. What emerged was a two-part approach:

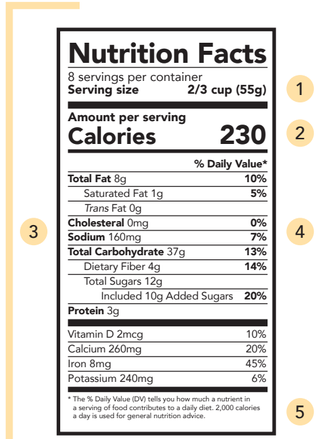
1. Creating a public-private partnership to explore strategies related to food insecurity and nutrition-related chronic disease.
2. Building collaborative opportunities to educate primary shoppers and populations at increased risk for nutrition-related chronic disease about using the new Nutrition Facts label in their daily dietary decisions.

The FDA Foundation regularly met with stakeholders throughout the year, including two additional partnership meetings to share perspectives and discuss evolving consumer needs as the COVID-19 pandemic changed the way people thought about, and accessed, food. These meetings helped the Foundation lay the groundwork for future work and initiate more immediate outreach by establishing the Nutrition Communications Network.

NUTRITION COMMUNICATIONS NETWORK

Focused on amplifying nutrition messages — especially how to use the Nutrition Facts label — more than 20 nonprofit, government, and industry groups joined the FDA Foundation's Nutrition Communications Network. The goal: broadly disseminate coordinated nutrition messages to those most at risk for nutrition-related chronic disease.

In Fall 2020, the first Nutrition Communications Network message guide was distributed providing social media, blog, and website content highlighting the initiative and featuring educational resources, such as FDA's Interactive Nutrition Facts label, fact sheets, and videos on how to use the label, and continuing education webinars for healthcare professionals. Consumer and public health groups, patient advocacy organizations, and industry alliances are active partners in this effort.



1. Serving Size
2. Amount of Calories
3. Nutrients
4. Percent Daily Vaue
5. Footnote

For educational purposes only. This label does not meet the labeling requirements described in 21 CFR 101.9.

2020 Annual Public Meeting

WE CONVENED OUR ANNUAL PUBLIC MEETING OF THE BOARD OF DIRECTORS ON OCTOBER 13, 2020, with nearly 180 stakeholders in virtual attendance. The FDA Foundation's message was focused on how we could best leverage our collaborative knowledge to inform the future of public health.

The 2020 Annual Public Meeting saw the unveiling of the FDA Foundation's new Strategic Framework and Mission Pillars to help guide the work of the organization. It was also an opportunity to introduce the newly appointed CEO, Susan C. Winckler, RPh, Esq., who had joined the organization in May. Winckler moderated a panel discussion among three deputy commissioners for the FDA: Amy Abernethy, MD, PhD; Anand Shah, MD; and Frank Yiannas, MPH. The conversation centered on what lessons, especially pertaining to public-private partnerships, should be advanced and refined in the 'new normal' post-COVID. Dr. Abernethy focused her remarks on the work of the Evidence Accelerator and what that collaborative effort might achieve in the future when focused on health questions other than the coronavirus. Frank Yiannas detailed a blueprint for food safety, and the need for strengthening the partnerships that developed in the past year. Dr. Shah spoke of the innovations spurred by public/private collaboration.

Following the panel, the FDA Foundation Board Chair Dr. Ellen V. Sigal sat down with Commissioner Stephen Hahn who spoke about the FDA's leadership in the federal response to COVID-19. He referenced the massive effort of the FDA's medical products centers supporting the development of safe and effective medical countermeasures, from ensuring that front-line health care workers had the necessary protective equipment, to providing essential regulatory advice, guidance, and technical assistance to advance the development of tests, therapies, and vaccines. Hahn also commented on the work FDA did, in conjunction with partners at the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration, to help employers and employees dealing with food supply chain issues in the earliest days of the pandemic. He also spoke of the non-COVID priorities of the agency, such as implementing the Food Safety and Modernization Act as well as educational campaigns on nutrition labels and genetically engineered foods.

Hahn applauded the work of the Reagan-Udall Foundation and Friends of Cancer Research on the COVID-19 Evidence Accelerator as "a great example of how a large group of stakeholders can come together to advance the science of real-world data and its use."

> I spent 30 years in the private sector, and I know from first-hand experience how much industry can do to keep foods safe. And I know from my time at FDA how much the government can do to keep foods safe. But what's crystal clear to me is that there's so much more we can do together."
>
> DEPUTY COMMISSIONER
> FRANK YIANNAS, MPH

> Not only was the Evidence Accelerator an important precedent about how to solve problems related to COVID-19… but it also teaches us how we are going to do this going forward…"
>
> PRINCIPAL DEPUTY COMMISSIONER
> AMY ABERNETHY, MD, PHD

> The 'whole of America' approach to tackling COVID-19 has really led to the formation of new partnerships and innovative programs that has really enabled us to be responsive to public health needs."
>
> DEPUTY COMMISSIONER
> ANAND SHAH, MD

2020 Innovations in Regulatory Science Awards

IN A YEAR WHERE THE ENTIRE WORLD WAS CHALLENGED TO FIND SOLUTIONS FOR A GLOBAL PANDEMIC, recognizing the innovations of the research and regulatory community took on a profound significance. The Reagan-Udall Foundation is proud to acknowledge the ingenuity, the compassion, and the dedication of the 2020 recipients of the *Innovations in Regulatory Science Awards*. The hallmark of all this year's honorees is their commitment to improving the health and safety of the communities they serve.

Amy Abernethy, MD, PhD, then Principal Deputy Commissioner, U.S. Food and Drug Administration

Leadership Award

The Foundation's Leadership Award was presented to Dr. Amy Abernethy, FDA's principal deputy commissioner of food and drugs since 2018. A noted thought leader and internationally recognized expert in clinical trials, Abernethy brings a passion for real-world evidence to the FDA's plan for technology modernization, a strategy to accelerate the path to better therapeutic and diagnostic options for patients and clinical care providers, as well as more effective tools to enhance and promote public health. She played an integral role in the development of the Evidence Accelerator, a project of the FDA Foundation with Friends of Cancer Research. She helped recruit, inspire, and challenge data specialists and researchers to join this effort to address the challenges of COVID-19.

Jeff Allen, PhD, President and CEO, Friends of Cancer Research

Innovation Award

Friends of Cancer Research is well-known for their invention, creative problem-solving, and commitment to getting new therapies to patients as quickly and safely as possible. *Friends* was recognized for their vision, leadership, and strategy to advance Real-World Evidence. *Friends* recognizes that data, refined into Real-World Evidence, has the power to guide research and inform care. They have established not one, but two Real-World Evidence pilots to create thorough recommendations for researchers to grasp the full potential of using real-world data in clinical research, drug development, and regulatory processes.

Michael J. Fox, Founder, The Michael J. Fox Foundation for Parkinson's Research

Policy/Advocacy Award

In its 20 years, The Michael J. Fox Foundation for Parkinson's Disease has raised over one billion dollars to combat the disease as well as become a strategic leader and trusted partner to researchers, thought leaders, and patients all over the world. With a mission of moving science forward through collaboration, caring, and transparency, the Foundation has helped spur the independent approval of 17 new drugs to treat Parkinson's in the last seven years, and improved the lives of families navigating this disease.

PRESENTING SPONSOR

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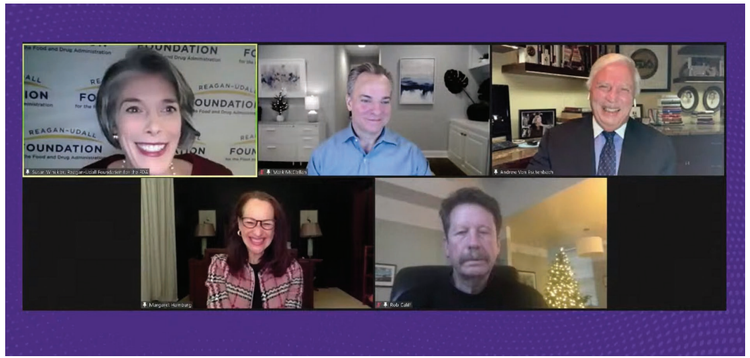

Former Commissioners Robert M. Califf, MD, MACC; Margaret M. Hamburg, MD; Mark B. McClellan, MD, PhD; and Andrew von Eschenbach, MD, discuss "Perspectives on the Enduring Impact of COVID-19" as part of the 2020 Awards program

AWARDS SELECTION COMMITTEE

The Reagan-Udall Foundation for the FDA thanks our Awards Committee members for their commitment to the *Innovations in Regulatory Science Awards*.

Michael Boyle, MD, President and CEO, Cystic Fibrosis Foundation

Arthur L. Caplan, PhD, Drs. William F. and Virginia Connolly Mitty; Professor of Bioethics, Department of Population Health; Director, Division of Medical Ethics, NYU Langone

Theresa M. Mullin, PhD, Associate Director for Strategic Initiatives, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Garry Neil, MD, Board Member, Reagan-Udall Foundation for the FDA

Andrew C. von Eschenbach, MD, Board Member, Reagan-Udall Foundation for the FDA

Joanne Waldstreicher, MD, Chief Medical Officer, Johnson & Johnson

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

2020 Board of Directors

A diverse group of respected leaders from academic research, patient and consumer advocacy, healthcare, and regulated industry comprise the Reagan-Udall Foundation for the FDA's Board of Directors.

Ellen V. Sigal, PhD, *Board Chair*
Chairperson and Founder
Friends of Cancer Research

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Financials

REVENUE AND SUPPORT	2020
FDA Direct Funding*	1,250,000
Grants and Contributions	754,845
Contracts	2,485,707
Fundraising	407,250
Miscellaneous and Interest Income	21,782
Total Revenue and Support	**4,919,584**

EXPENSES AND CHANGES IN NET ASSETS	
Program Services:	
Innovation in Medical Evidence Development and Surveillance	2,920,865
Expanded Access Navigator	82,617
Evidence Accelerator	643,974
Vaccine Confidence (COVID-19)	209,094
Food & Nutrition	91,316
Total Program Services	**3,947,866**
Supporting Services:	
Management and General	218,032
Fundraising	338,593
Total Supporting Services	**556,625**
TOTAL EXPENSES	**4,504,491**
CHANGE IN NET ASSETS	**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))

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The Reagan-Udall Foundation for the FDA fosters expert collaborations that can inform the FDA's work to help 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.

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To learn more about the Reagan-Udall Foundation for the FDA, please visit our website at www.reaganudall.org

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Susan C. Winckler, RPh, Esq., Chief Executive Officer

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