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
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
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.

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 for continued real-world evidence efforts.

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 a grant 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.
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.

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.

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.

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 $120,000 of federal funds (88% of the project) and $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.
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.

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 eritugliflozin 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.
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.

**Patient Listening Sessions**

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.
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.

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.

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 FDAs expanded access pathways to improve patient care.

**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 awareness of physicians and other prescribers to explore expanded access for their patients
- Facilitate and expedite the request process
- Increase awareness of a resource to help ensure 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

**Expanded Access**

Then-interim Director Amar Bhat speaking at the Expanded Access Summit at the National Press Club (Jan 2020)
WE CONVEYED 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. Dr. 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.”

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
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.

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.

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.

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 the communities 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.
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.

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Civica Rx

Financials

REVENUE AND SUPPORT

<table>
<thead>
<tr>
<th>2020</th>
<th>FDA Direct Funding*</th>
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| Grants and Contributions | 744,545 |
| 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 | 2,930,665 |
| Expanded Access Navigator | 82,617 |
| Evidence Accelerator | 643,974 |
| Vaccine Confidence (COVID-19) | 209,094 |
| Food & Nutrition | 93,136 |
| **Total Program Services** | **3,747,866** |

| Supporting Services: |
| Management and General | 218,032 |
| Fundraising | 228,083 |
| **Total Supporting Services** | **456,115** |
| **TOTAL EXPENSES** | **4,504,491** |

CHANGE IN NET ASSETS

| 2020 | 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 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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- Merck & Co., Inc.
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- Kay Holcombe, MS
- PMMA
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