INNOVATIONS IN Regulatory Science AWARDS

DECEMBER 8, 2020

6–7:30 PM (EST)

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

INNOVATIONS IN Regulatory Science AWARDS

Ellen V. Sigal, PhD
Chair, Board of Directors
Reagan-Udall Foundation for the Food and Drug Administration

WELCOME TO OUR 2020 INNOVATIONS IN REGULATORY SCIENCE AWARDS CELEBRATION.

This evening, we recognize more than excellence in regulatory science. We are celebrating the vision, invention, and patient impact exemplified by the achievements of our Leadership, Innovation, and Advocacy/Policy honorees.

2020 has been an interesting year and has presented us with many unexpected challenges — as well as opportunities to work and partner in new ways. The COVID-19 Evidence Accelerator is one example of how the regulatory field is coming together to answer key diagnostic and therapeutic questions as the world responds to the pandemic. We are proud to collaborate with so many of you on this effort and our other pandemic response projects.

Thank you for partnering with us in this memorable year, and thank you for joining us for the *Innovations in Regulatory Science Awards*. We know there are many demands on your time and energy. We hope our event inspires you and re-energizes you as we focus on helping Americans live longer, stronger, and healthier lives.

PROGRAM

Welcome

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

Lynne Zydowsky, PhD
Chief Science Officer, Alexandria Real Estate Equities, Inc./ Alexandria Venture Investments
Presenting Sponsor

Remarks

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

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

Recognition of Special Guests

Richard Schilsky, MD
Vice Chair, Board of Directors, Reagan-Udall Foundation for the FDA

Award Presentations

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

INNOVATION AWARD
Friends of Cancer Research
Accepted by Jeff Allen, PhD, President & CEO

ADVOCACY/POLICY AWARD
The Michael J. Fox Foundation for Parkinson's Research
Accepted by Michael J. Fox, Deborah W. Brooks, Todd Sherer, PhD — Leadership of The Michael J. Fox Foundation for Parkinson's Research

Panel Discussion

"Advancing Innovation in a Pandemic: Former Commissioner Perspectives on the Enduring Impact of COVID-19"

Robert M. Califf, MD, MACC, 22nd Commissioner of Food and Drugs
Margaret A. Hamburg, MD, 21st Commissioner of Food and Drugs
Mark B. McClellan, MD, PhD, 18th Commissioner of Food and Drugs
Andrew C. von Eschenbach, MD, 20th Commissioner of Food and Drugs

BOARD OF DIRECTORS

2020 has been an extraordinarily demanding year for all of us, but especially for the **dedicated staff of the FDA**, who have been challenged, nearly every day, with a new facet of the COVID-19 pandemic. Please know how much we all appreciate the work you do. Thank you for your dedication and tireless focus during this global crisis.

Thank you!

LEADERSHIP AWARD

Recognizing significant contributions, national leadership, and service in regulatory science and public health

Amy P. Abernethy MD, PhD

Principal Deputy Commissioner
Office of the Commissioner
U.S. Food and Drug Administration

Dr. Amy Abernethy oversees FDA's daily operations and high-priority, cross-Center initiatives. While her charge is complex, she follows a simple rule: always innovate with the patient in the forefront.

A leader and pioneer in the use of real-world evidence (RWE), Dr. Abernethy's conviction that patient care should be informed by reliable data is evident throughout her career — and especially during her time at FDA. She works every day to leverage health data to inform regulatory decisions, advance medical innovation, and improve care for patients.

Dr. Abernethy's leadership, commitment, and passion have been especially critical during the COVID-19 global pandemic. She has built important partnerships to speed the use of RWE in our nation's understanding and response to the disease, imploring researchers to "learn what we can as soon as we can." She is instrumental in multiple collaborations, including the COVID-19 Evidence Accelerator, to ensure data integrity while moving quickly to establish the natural history of COVID-19, better understand and apply therapeutic learnings, and expand real-world data efforts into the diagnostics and testing arena.

Prior to joining FDA, Dr. Abernethy, a hematologist/oncologist and palliative medicine physician, served as Chief Medical Officer, Chief Scientific Officer, and Senior Vice President for Oncology at Flatiron Health and in multiple positions at Duke University School of Medicine.

INNOVATION AWARD

Recognizing outstanding, innovative contribution to regulatory science

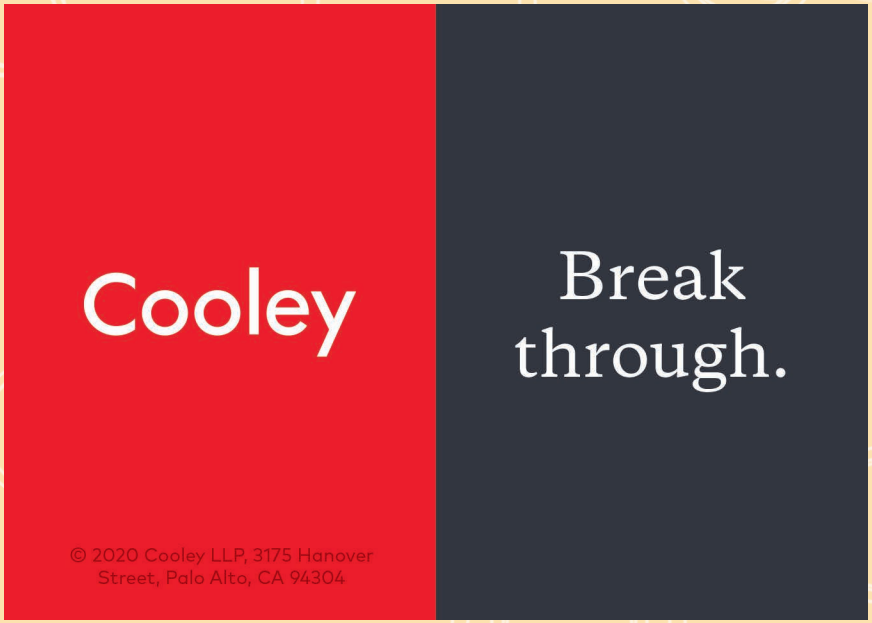
FRIENDS of CANCER RESEARCH

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely.

A leader in the use of real-world evidence (RWE), *Friends* is working to help researchers better grasp the full potential of real-world data. Their Real-World Evidence Pilot Projects 1.0 and 2.0 engage multiple data partners, international populations, and oncology disease settings to create thorough recommendations on the role of real-world data on clinical research, drug development, and regulatory processes.

The projects culminated in the publication of *"Recommendations for Use of Real-World Evidence in Oncology: Lessons Learned from the Friends of Cancer Research Real-World Evidence Framework,"* outlining a replicable process for assembling fit-for-purpose datasets and a common real-world protocol and provides recommendations for developing an RWE framework.

In response to the COVID-19 crisis, *Friends* collaborated with the Reagan-Udall Foundation for the FDA to create the COVID-19 Evidence Accelerator, a unique venue for data organizations, government and academic researchers, and health systems to design quick-turn-around queries and share their results. Real-world data can be a critical tool to help swiftly address the many unknowns of COVID-19, especially for individuals with cancer and other underlying conditions who may be particularly vulnerable during the pandemic.



ADVOCACY/POLICY AWARD

Recognizing significant policy achievements that advance regulatory science and impact public health

THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

The Michael J. Fox Foundation for Parkinson's Research (MJFF) is changing the landscape of Parkinson's research. Working to find a cure and ensure better therapies, MJFF spearheads an aggressively funded research agenda and advances understanding and treatment of the disease.

MJFF leverages expert perspective and global contacts to create an open, collaborative, and replicable research environment that leads to faster results for the six million people living with Parkinson's worldwide. MJFF-funded investigations have resulted in two recent FDA approvals of new Parkinson's therapies and countless more therapeutic programs that have attracted follow-on funding and made it one step closer to the hands of Parkinson's patients and families.

The flagship Parkinson's Progression Markers Initiative has built the most robust dataset and biosample library in the history of Parkinson's research. It is the cornerstone of MJFF's growing understanding of Parkinson's pathology and clinical experience and has heavily influenced emerging clinical trials. In fact, data from the initiative has been downloaded more than 6.5 million times.

MJFF puts patients first and is on a mission to connect with every person with Parkinson's. A powerful patient force on Capitol Hill, MJFF regularly educates members of Congress on issues important to the Parkinson's community and pushes for policies that spur faster knowledge. MJFF defines success simply: scientific solutions that produce tangible improvements in patients' lives.

AWARDS SELECTION COMMITTEE

The Reagan-Udall Foundation for the FDA thanks our Awards Committee 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

COVID-19 EVIDENCE ACCELERATOR

Earlier this year, at FDA's request, the Reagan-Udall Foundation for the FDA established the COVID-19 Evidence Accelerator in collaboration with Friends of Cancer Research. We express our thanks and gratitude to all of the academic, industry, and government groups that have participated in this effort.

We extend special appreciation to the following organizations that have been active participants in one or more of the Parallel Analysis workgroups tackling critical questions of regulatory importance in the worldwide fight against COVID-19. These include institutions which have provided data and/or key advice in the analysis of real-world data regarding COVID-19 treatment and testing.

Aetion, Inc.

Ciox Health

COTA Healthcare

Dascena

Datavant, Inc.

Eli Lilly and Company

Epic Systems

Gilead Sciences, Inc.

Hackensack Meridian Health

Harvard University

Health Catalyst

HealthVerity

Margolis Center for Health Policy – Duke University

Mayo Clinic

The MITRE Corporation

Northwestern University

PCORnet

Regenstrief Institute

Sentinel Initiative (Harvard Pilgrim Health Care Institute, University of Pennsylvania, FDA)

Sutter Health

Syapse, Inc.

Target RWE

TriNetX, Inc.

UnitedHealth Group

United States Department of Veterans Affairs

University of California Health Systems

Yale University

To learn more, please visit EvidenceAccelerator.org.

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SUSAN C. WINCKLER & JOHN GIGLIO

REAGAN-UDALL FOUNDATION FOR THE FDA

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.

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

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

Core Values
- Engagement
- Innovation
- Evidence

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

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