

Thank you for joining



Virtual Attendees: Your cameras and microphones will be off for the duration of the meeting.



Speakers will not address questions regarding any pending regulatory action or discuss specific companies or products.



Attendees: Had the opportunity to submit questions for our speakers during registration.



This meeting is being recorded. Meeting highlights will be available on www.ReaganUdall.org by the end of this week.



Annual Public Meeting of the Board of Directors

May 7, 2024



Richard L. Schilsky, MD
Board Chair
Reagan-Udall Foundation for
the FDA

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FOUNDATION
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Strategies for Improving Public Understanding of FDA-Regulated Products



REAGAN-UDALL
FOUNDATION
for the Food and Drug Administration

October 2023

Strategies for Improving Public Understanding of FDA-Regulated Products

Topline Findings
Efforts to "address" mis- and disinformation can, themselves, be misunderstood and interpreted as tending to silence discussion and are, at best, reactive versus proactive.

This report's overarching finding is that clear, consistent communication, both directly to consumers and via media channels, is critical to the FDA's mission to protect and promote public health.

Consumers won't understand or trust policy—and the scientific evidence it is based on—if it is not well communicated to them or if they never hear about it at all. Strong communications reinforce sound policy and science; insufficient communications undermine it.

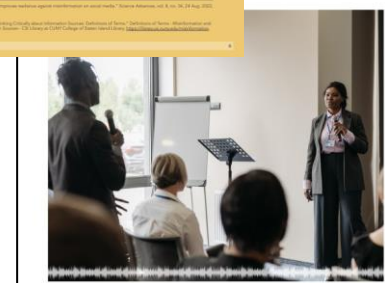
This finding underpins every observation and potential strategy outlined in this report. A strong and continuous communications approach should be viewed as a fundamental aspect of the Agency's work and requires the early and active involvement of a range of FDA staff beyond those with "communications" in their title, including leaders, lawyers, and scientists. Prioritizing communications and being

accountable for communication efforts should permeate the Agency.

In short: sound science, sound policy, and sound communication are each fundamental to the Agency's mission and should be resourced and approached with the same diligence.

A core component of this finding is that an effective way to address misinformation is to "prebunk" it. Prebunking is a strategy by which communicators "proactively build resilience against anticipated exposure to misinformation."¹¹ This includes both preempting anticipated health scares and cultivating consumers' capacity to detect the information manipulation tactics that often drive the spread of "disinformation,"¹² defined as the "deliberate dissemination of false, misleading, or misleading information to discredit a person or organization."¹³

11. B. K. Plante, "Prebunking: A Proactive Strategy to Reduce the Impact of Misinformation," *Journal of Health Communication*, vol. 43, no. 10, pp. 1000-1005, 2018.
12. S. J. Liebowitz, "Misinformation: A Review of the Literature," *Journal of Health Communication*, vol. 43, no. 10, pp. 1006-1015, 2018.
13. S. J. Liebowitz, "Misinformation: A Review of the Literature," *Journal of Health Communication*, vol. 43, no. 10, pp. 1006-1015, 2018.

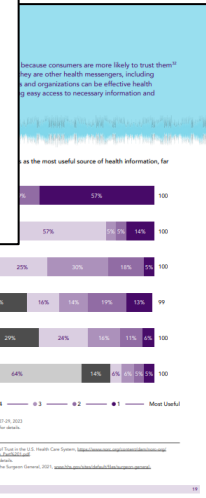


accountability throughout the organization, including communications internal Affairs and center-level law across teams.

FDA, including communications internal Affairs and center-level law across teams.

are knowledge and learnings across related

of all relevant components of the FDA and the public. Communications vehicles underlying source documents for a given or their deeper into the announcement must also.



REGULATIONS, POLICYING, STRATEGIES, AND POTENTIAL TACTICS

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18th Commissioner of the FDA
Duke-Margolis Center for Health Policy
Duke University

Ex Officio

Robert M. Califf, MD, MACC

Food and Drug Administration

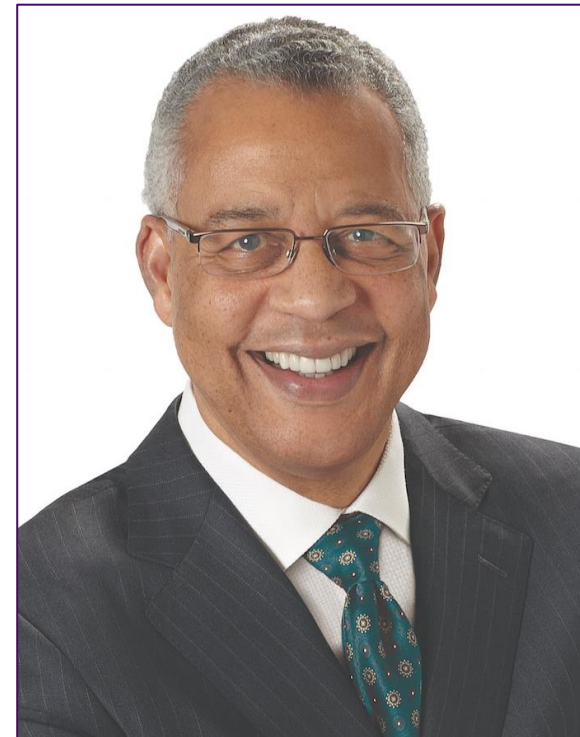
Monica M. Bertagnolli, MD

National Institutes of Health

Welcome to Our New Board Members!



Pietro Antonio Tataranni, MD
PepsiCo



Reed V. Tuckson, MD, FACP
Tuckson Health Connections, LLC

Thank You to Our Board Members Whose Service Concluded in 2023



Georges C. Benjamin, MD, MACP
American Public Health Association



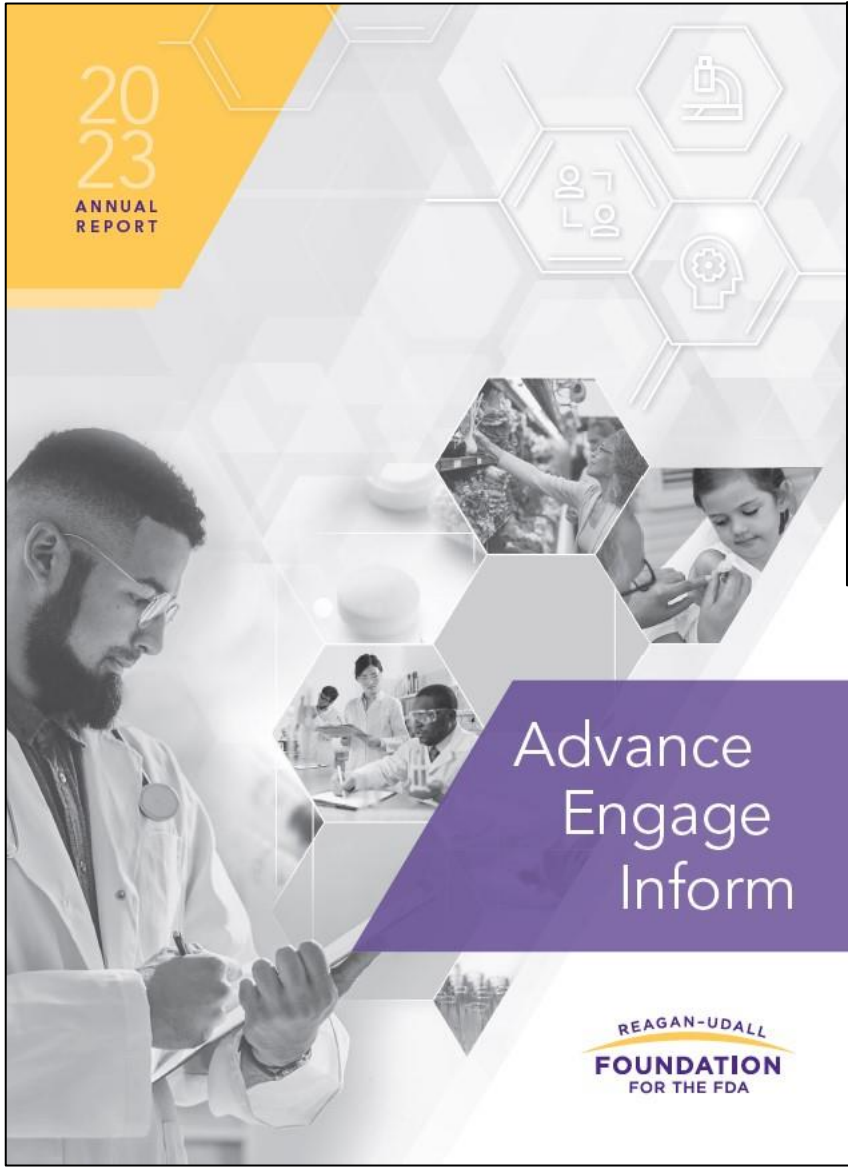
Allan Coukell, BScPharm
Civica Rx



Molly Fogarty
Nestlé

Thank You!

2023 ANNUAL REPORT



Advance Engage Inform

RAISE

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

The project unfolded in two phases:

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

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

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



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

Engage
More than 500 stakeholders took part in the 10-part RAISE workshops and the first public meeting.

Inform
RAISE was featured in several articles, webinars, the OMH&E podcast, as well as "Question Time" Live! with Health Hq. A series of articles on RAISE's efforts will be published on LinkedIn in 2024. The team has drafted two articles for peer-reviewed publication.

Condition	Date
Carexan Disease*	3/21/2023
Spinal Cord Injury**	4/24/2023
Carcinoid Syndrome	4/27/2023
Sickle Cell Disease*	5/5/2023
Leukoencephalopathy (BBLP)*	5/30/2023
Post-herpetic Syndrome**	6/2/2023
Parkinson's Medication Disease*	8/22/2023
Pyruvate Dehydrogenase Complex Deficiency (PDCD)*	9/8/2023
Atypical Hemolytic Uremic Syndrome (aHUS)*	9/21/2023
Sporocystic Acanthamoeba Type 2*	9/22/2023
Labor Congenital Anemias & CAH*	10/30/2023
Non-bacterial Pyomyositis (NBPA)*	12/15/2023

*Work-in-progress (laterally) / **Under review

Advance Regulatory Science
Providing insight into, without conditions to inform regulatory decision-making.

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



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

Regulatory Awards

A community gathered at the Science Awards on December 5, 2023, for an evening of inspiration and dedication to the ongoing contributions to regulatory science.

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

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

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



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

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Panel Discussion

Biologics



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

Drugs



Marta Sokolowska, PhD
Deputy Center Director,
Substance Use and Behavioral
Health, Center for Drug
Evaluation and Research

Food



Jim Jones, MS
Deputy Commissioner for
Human Foods

Medical Devices



Jeffrey Shuren, MD, JD
Director, Center for
Devices and Radiological
Health

Tobacco



Michele Mital
Deputy Director, Center
for Tobacco Products

Veterinary



William Flynn, DVM, MS
Deputy Director, Center
for Veterinary Medicine

Field Force



Douglas Stearn, JD
Deputy Associate
Commissioner,
Regulatory Affairs

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

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Question & Answer

Thank You!

