Annual Public Meeting of the Board of Directors

May 7, 2024

Our meeting will begin shortly.

REAGAN-UDALL FOUNDATION FOR THE FDA

Thank you for joining

REAGAN-UDALL FOUNDATION FOR THE FDA

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

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

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Evidence Generation

As shown in Figure 1, the fragmented health care delivery system in the U.S. impedes our ability to generate new knowledge during care delivery and to learn from the experience of every patient. This report envisions a future where incentives and systems are aligned to enable continuous learning during care delivery for the benefit of current and future patients, as depicted in Figure 2.

Figure 1: Fragmentation of the Health Care Delivery and Clinical Research Systems[11]

The reality is we have is a disaggregated, fragmented system with lack of organization around common, transparent high-quality information

Patients & Families
Clinicians
Payers
Government
Research Orgs

Figure 2: Possible Configuration of Components and Activities to Overcome System Fragmentation and Create a Highly Functional Health Care Delivery System and Clinical Research Enterprise[12]

Given common goals, current technology could support a common information base that could support the primary mission: better outcomes for patients

Enhancing Post-Market Evidence Generation for Medical Products 16

...nce Generation to Support
...ion-Making

...stration (FDA) is an essential agency for protecting
...fety, efficacy, and security of medical products and
...plication of rigorous standards for clinical trial design,
...ndpoints and assurance of study integrity and data
...comprised of outstanding scientists and clinicians, has
...the global leader in managing a regulatory system for
...The system for initial review of marketing applications,
...erstand and navigate, generally works well for delivering
...ucts to the public in a timely fashion.

...in the clinical practice guidelines issued by medical
...the clinical evidence base for many products because
...t disease burdens are often underrepresented in clinical
...t initial marketing applications focus on very narrow
...t FDA initiatives to require diversity plans seek to
...generation of high-quality evidence about medical
...cle is essential to ensure their safe and appropriate use
...the treatment is intended. A system that fosters post-

market evidence generation as part of health care delivery is also important to identify rare or delayed safety signals, to develop information about the relative effectiveness of a product compared to products with similar indications, and to identify new potential uses of products that may broaden their impact on population health. The current system used to generate evidence in support of initial marketing applications is complex, expensive, time-consuming and may not be necessary to deliver the information needed to close evidence gaps in clinical practice or to optimize the use of products already shown to be safe and effective.

Instead, development of a pragmatic evidence generation framework that leverages the U.S. health care system[1] to resolve clinically meaningful evidence gaps for medical

Enhancing Post-Market Evidence Generation for Medical Products

...d Inefficiency of Clinical Trials

...clinical practices across the U.S.
...d with invitations to participate in
...vited to participate.[14] A survey
...with chronic illnesses have never
discussed participating in a clinical trial with a health care provider.[15] In 2020, although over 40% of the U.S. population identified as non-White, only 25% of participants in the clinical trials of the 53 novel drugs approved by the FDA in the same year were non-White.[16,17] External validity of clinical trial results is a long-standing problem that the FDA has now begun to address by requiring that sponsors submit plans for enrolling representative patient populations in clinical trials.

To guide funding of patient-centered comparative clinical effectiveness research (CER) and other initiatives, the Patient-Centered Outcomes Research Institute (PCORI) published five priorities for health (Table 2).[18] In order to achieve these five priorities, significant changes are needed in how post-market clinical research is conducted. Traditional randomized clinical trials, with the complexities identified above, will need to be simplified in their design and conduct to meet these goals. Methods will need to be established to rapidly disseminate new findings to payers and clinicians to secure reimbursement and stimulate use in practice.

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Strategies for Improving Public Understanding of FDA-Regulated Products

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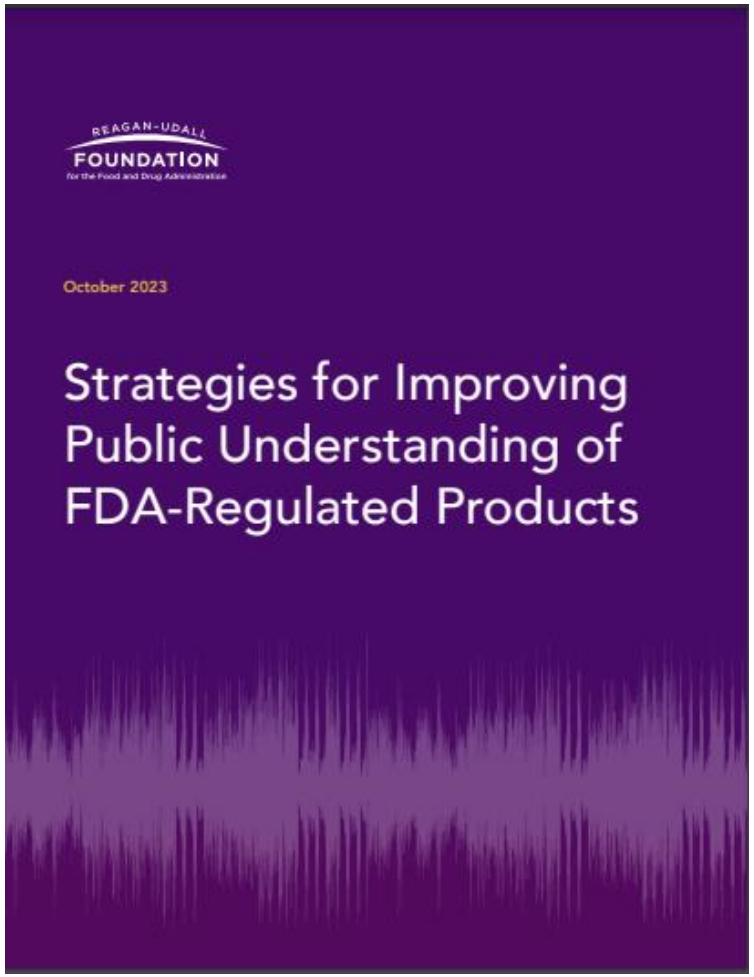

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2024 Board of Directors

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Duke University of Medicine

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National Association of Chain Drug Stores

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Takeda

Richard A. Moscicki, MD
Moscicki Consulting, LLC

Pietro Antonio Tataranni, MD
PepsiCo

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

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20th Commissioner of the FDA
Samaritan Health Initiatives

Senior Advisor to the Board
Mark McClellan, MD, PhD
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!

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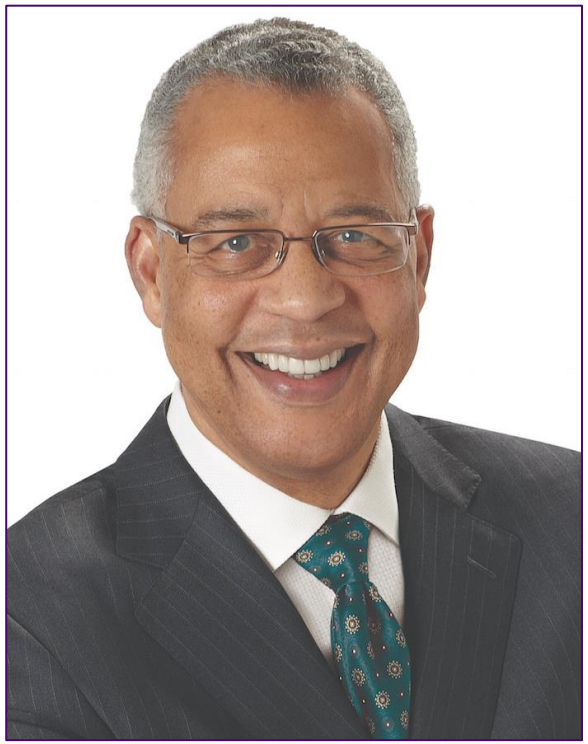
Pietro Antonio Tataranni, MD
PepsiCo



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

Thank You to Our Board Members Whose Service Concluded in 2023

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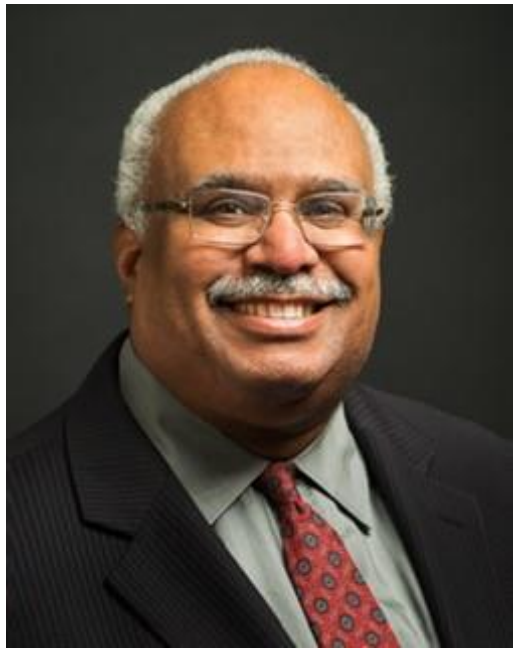

Georges C. Benjamin, MD, MACP
American Public Health Association

Allan Coukell, BScPharm
Civica Rx

Molly Fogarty
Nestlé

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Thank You!

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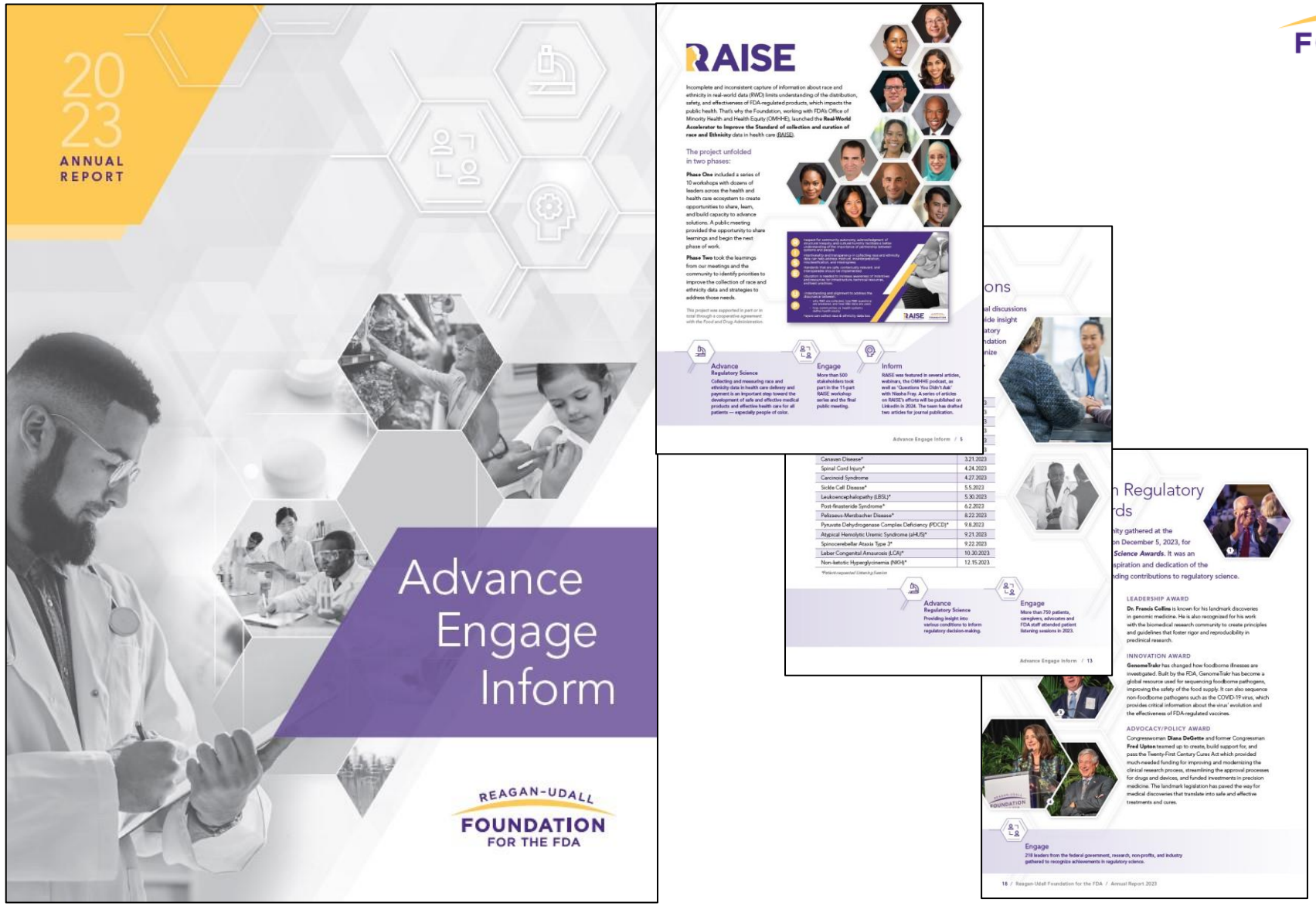

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Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

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Panel Discussion

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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

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Thank You!

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