2024

REAGAN-UDALL FOUNDATION FOR THE FDA

INNOVATIONS IN Regulatory Science AWARDS

DECEMBER 10, 2024

2024 Innovations in Regulatory Science Awards

We are honored to welcome you to the **2024 Innovations in Regulatory Science Awards**. Tonight, we have a special opportunity to celebrate the inspiration and commitment driving groundbreaking progress in public health and regulatory science.

This evening's extraordinary honorees have each made significant contributions to promoting health and safety, and the Reagan-Udall Foundation for the FDA is pleased to acknowledge their work. From helping to define and promote standards for real-world evidence to advocating for funding to support the FDA's vast and growing responsibilities to implementing new initiatives to modernize the regulation of medical devices, our honorees have each helped shape the future of regulatory science. We are proud to celebrate their accomplishments and legacy, as well as their dedication and relentless perseverance that brought their innovations to fruition.

At the Foundation, our goal is to foster collaboration and build connections in support of the FDA's efforts. We envision a future where regulation informed by science improves product innovation and the public's health. Our work is made possible through the leadership of our Board of Directors, the dedication of our staff, and the steadfast support of our partners gathered here tonight, along with the many others who have contributed over the past year. As we applaud the achievements of our honorees, we are energized by their example of the impact we can have on improving the nutrition, health, and well-being of all Americans.

We hope you enjoy this evening's event!

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

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

Biogen is a proud sponsor of the Reagan-Udall Foundation's Innovations in Regulatory Science Awards

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Message from the FDA Commissioner

In a time of remarkable scientific and medical breakthroughs, we are presented with countless opportunities to discover, innovate, and share information in ways that can help protect and promote the public's health. As a public health agency focused on protecting and informing the public, the FDA leverages these advancements to support and benefit the patients and consumers we serve and who depend on the work we do.

Our mission includes protecting the public's health by applying the highest standards of regulatory science to meet today's evolving health challenges. By embracing the most accurate science and data, including recognizing, embracing, and striving to resolve uncertainty, we are better equipped to foster innovation in medical products, food safety and nutrition, tobacco regulation, and beyond—and help the industries responsible for the safety and effectiveness of their products and the well-being of consumers and patients who use them.

This work is complex, deeply fulfilling, and can be quite demanding, on many different levels. The Reagan-Udall Foundation plays a key role in supporting the FDA in meeting these responsibilities. The Foundation has been particularly helpful over the past few years, preparing reports on key activities and initiatives directly pertinent to our work and mission and providing us with advice and guidance that has strengthened the work we do. Like the FDA itself, the Foundation prioritizes the value and application of rigorous science, high quality data and appropriate analyses to solve the public health challenges we face. So, it is appropriate and commendable that the RUF bestows these Innovations in Regulatory Science Awards.

My heartiest congratulations to this year's honorees. Through their steadfast service and dedication, they embody the FDA's commitment to advancing science and transforming it into meaningful approaches that protect our nation's health. I am grateful for their work, as well as for the opportunity to work with such dedicated individuals. It is an honor to join the Reagan-Udall Foundation for the FDA and celebrate their exceptional contributions and accomplishments.

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

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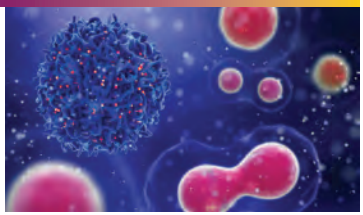
Redefining Possibilities.



Jazz Pharmaceuticals is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing potentially life-changing medicines for people with serious diseases — often with limited or no therapeutic options.

Jazz Pharmaceuticals

2024 INNOVATIONS IN REGULATORY SCIENCE Awards Program

WELCOME

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

FDA REMARKS

Robert M. Califf, MD, MACC
Commissioner, Food and Drugs
U.S. Food and Drug Administration

DINNER SERVED

AWARDS PRESENTATIONS

INNOVATION HONOREE

Real World Evidence Collaborative
Accepted by Rachele Hendricks-Sturrup, DHSc, MSc, MA
Research Director, Real World Evidence
Duke-Margolis Institute for Health Policy

ADVOCACY/POLICY HONOREE

Steven A. Grossman, JD
Co-Founder and Executive Director, Alliance for a Stronger FDA

LEADERSHIP HONOREE

Jeff Shuren, MD, JD
Center Director Emeritus (Retired), U.S. Food and Drug Administration

FINAL REMARKS

Susan C. Winckler, RPh, Esq
CEO, Reagan-Udall Foundation for the FDA

Innovation Honoree

Recognizing outstanding contributions to regulatory science

Real World Evidence Collaborative

Since 2018, the Real World Evidence (RWE) Collaborative at the Duke-Margolis Institute for Health Policy has convened stakeholders representing medical product developers, data companies, payers, researchers, providers, and patient networks, as well as experts on regulatory affairs, law, health and data science, and policy. Members hold shared goals to advance RWE policy among international agencies, health technology assessment bodies, and regulators.

The Collaborative's groundbreaking work has paved the way for advancing regulatory science. By fostering partnership among industry leaders, policymakers, and researchers, the Collaborative has revolutionized the use of real-world evidence in medical product decision-making. Their efforts promote global standards and innovative practices, driving progress in healthcare policy and improving patient outcomes worldwide. In 2023, the Collaborative launched the International Harmonization of RWE Standards Dashboard to address a critical need for global alignment on Real-World Data and RWE standards. This groundbreaking tool provides up-to-date summaries of international regulatory guidance, including key documents like the 2023 ICH Reflection Paper. The Dashboard simplifies access to essential regulatory definitions, data quality standards, and relevant literature, promoting harmonization across global health authorities.

The Dashboard has already gained international recognition, including a presentation at the ISPE 36th International Conference on Pharmacoepidemiology & Therapeutic Risk Management in August 2020. This innovative resource will continue to evolve, providing real-time updates to regulators, practitioners, and the public as RWE regulatory developments unfold.

Advocacy/Policy Honoree

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

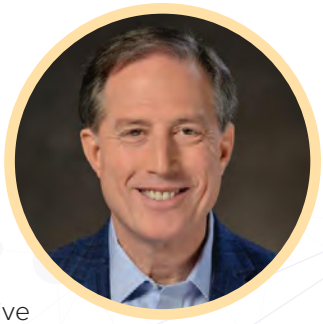
Steven A. Grossman, JD, is a highly respected policy and regulatory consultant with a distinguished career in public health and FDA advocacy.

In response to chronic underfunding of the FDA, Mr. Grossman co-founded the Alliance for a Stronger FDA, a multi-stakeholder coalition that advocates for increased FDA appropriations and educates policymakers and the public about the agency's vital mission. Since its founding in 2006, the Alliance has helped grow the FDA's appropriated budget from $1.6 billion to $3.5 billion and deepened public understanding of the FDA's expanding responsibilities and budget needs. For the Alliance, Mr. Grossman has written more than 500 columns analyzing FDA's budget and programs.

The initial impetus for the Alliance came out of Mr. Grossman's strong ties with the patient and research advocacy communities. Mr. Grossman's advocacy is rooted in public service, having spent six years as counsel to the Senate Health, Education, Labor, and Pensions Committee and four years as a Deputy Assistant Secretary for Health at the Department of Health and Human Services. In the Senate, he helped advance the Orphan Drug Act and the Hatch-Waxman Act, groundbreaking laws that have had a lasting impact on medical innovation and the affordability of pharmaceuticals. In addition to his role at the Alliance, Mr. Grossman is President of HPS Group, LLC, a consulting firm, and has served on the board of the National Organization for Rare Disorders. In the early 1990's, he authored one of the early white papers on expanding the role of pharmacists to include administering vaccines.

Mr. Grossman's tireless dedication to public health, patient advocacy, and FDA funding has transformed the landscape of FDA policy and regulation.

Leadership Honoree



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

Jeff Shuren, MD, JD, has led transformative efforts to ensure that patients have access to safe, high-quality devices, and to position the U.S. as a global leader in medical device innovation.

Dr. Shuren's 15-year tenure at the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) made a profound impact on medical device regulation and innovation. Under his leadership, annual authorizations of innovative medical devices increased five-fold, with more than 50% of new devices now being launched in the U.S. either first or concurrently with other major markets.

Key initiatives launched under Dr. Shuren's leadership included the Breakthrough Devices Program, CDRH's Patient Engagement Program, and the Digital Health Center of Excellence. Additionally, he led the creation of the National Evaluation System for Health Technology to enhance medical device evaluation.

Dr. Shuren co-founded the International Medical Device Regulators Forum to promote global collaboration on regulatory practices and policies. He played a key role in founding the Medical Device Innovation Consortium and led negotiations on the Medical Device User Fee program, ensuring resources for the FDA's medical device reviews.

Before becoming CDRH Director, he held various policy and planning positions within the FDA. Dr. Shuren also served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions Committee in 2000.

With a holistic, patient-centered approach, Dr. Shuren has left an indelible mark on the FDA and medical device regulation.

2024 Awards Selection Committee

We extend our profound thanks to the 2024 Awards Selection Committee for their guidance and contribution to this year's *Innovations in Regulatory Science Awards*.

Andrew C. von Eschenbach, MD, Awards Chair
Board Member, Reagan-Udall Foundation for the FDA
20th Commissioner, U.S. Food and Drug Administration
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Managing Director
Manatt Health

Steven Musser, PhD
Deputy Center Director for Scientific Operations
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Our Profound Thanks

William N. (Bill) Hait, MD, PhD
Board member

As you conclude your service to the Foundation Board, the staff and leadership express our deep appreciation for your contributions to the Foundation and the field of regulatory science. Your commitment to fostering engagement and growing the Foundation in support of the FDA's mission will leave an enduring legacy.

William N. Hait, MD, PhD
Board member

A Warm Welcome

The Foundation extends a warm welcome to the new Directors joining our Board in 2024.

Sumbul Desai, MD
Apple

Pietro Antonio Tataranni, MD
PepsiCo

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

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**As of December 2, 2024*

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Susan C. Winckler, RPh, Esq.

REAGAN-UDALL FOUNDATION FOR THE FDA

About Us

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."

Said more simply, the Foundation helps FDA 'do more' to protect and promote the public's health. The Foundation is *not* involved in direct regulatory activity nor decision making; rather, our projects support the FDA in active oversight of, and engagement with, regulated industry and interaction with all affected by the Agency's work.

2024 Project Snapshot

The Foundation is a trusted partner for FDA, consumers, product innovators, and the Agency's broad stakeholder community to advance regulatory science, develop and disseminate reliable information, and facilitate engagement. In 2024, we gathered:

- The rare disease community to discuss biomarkers, registries, and emerging technologies to improve the health outcomes of individuals with rare diseases
- The controlled substances community to learn more about the distribution, use, and promotion of these products
- The food community to discuss emerging regulatory requirements and the impact of nutrition policy on food formulation and consumption
- Consumers to explore effective communication strategies about the safe use of cosmetic products
- The real-world data and evidence community to improve the usefulness and analysis of real- world data across sectors regulated by FDA

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