

2025 | ANNUAL REPORT



Advancing the mission
of the FDA to modernize
product development,
accelerate innovation, and
enhance product safety

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.”

The Foundation embodies the 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 the FDA and the public, providing a means for the FDA to interact directly with stakeholders, including industry and consumers. The Foundation does not participate in regulatory decision-making.

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Foundation Leadership Message

Established through a bipartisan act of Congress in 2007, the Reagan-Udall Foundation for the Food and Drug Administration has advanced the FDA’s mission across seven administrations. This essential role was underscored in 2025, a dynamic year of transition and heightened engagement and service to the FDA and its ecosystem.

The Foundation’s independence positioned us well to bridge between the FDA and the public, informing the Agency’s decision-making through candid dialogue. We marshaled insight that bolstered the Agency’s deep scientific and regulatory expertise with comprehensive real-world evidence from an array of sources. Through public meetings, roundtables, and patient listening sessions, we elevated perspectives on topics that matter deeply to consumers, researchers, regulators, and regulated industry.

Food was at the forefront of our work, because increasing access to safe, nutritious food could dramatically move the needle on chronic disease. Our efforts supported the development of a Roadmap to Produce Safety and initiatives on infant formula, food labeling and rating systems, and traceability of contaminated foods.

Our controlled substances projects focused on ensuring that medications to treat pain and substance use disorders are available and safely prescribed, and on protecting consumers from the risks of counterfeit drugs and accidental exposures to opioids. We also gathered experts to probe pragmatic ways to improve oncology multi-regional clinical trials and to address unmet needs in women’s health drug development. And we provided a forum to exchange diverse views on prescription fluoride products.

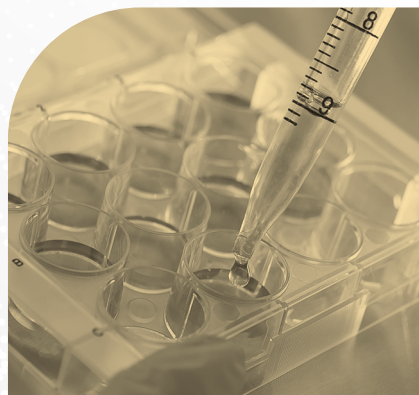
Through our thriving research portfolio, we continued to evaluate the post-market safety of approved medical products. The longstanding Expanded Access Navigator put investigative treatments for compassionate use within reach of more doctors and patients, offering hope to those with life-threatening illnesses.

Our board and staff worked diligently with the FDA last year to drive innovation that protects and promotes the health of the American people. We extend our gratitude to them and especially to our outgoing chair, Richard Schilsky, who concluded his distinguished tenure with an impactful year. We look forward to making continued progress through new and ongoing collaborations.

Sincerely,

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

Adrian F. Hernandez, MD, MHS
Board Chair
Reagan-Udall Foundation for the FDA



“ The Foundation provides a platform for sharing evidence, analysis, and perspectives that inform the FDA’s decision-making, revealing knowledge gaps and potential solutions. ”

Acting Commissioner
Kyle A. Diamantas

FDA Commissioner Message

The FDA’s mission to protect the public health by regulating medicines, food, and other products Americans use daily depends on our ability to accelerate innovation and address emerging threats. Our agency must constantly modernize.

We are grateful for our continued partnership in this effort with the Reagan-Udall Foundation for the FDA. In 2025, the Foundation collaborated in the pursuit of some of the agency’s signature priorities to ensure consumer safety and regulatory flexibility. To combat the root causes of chronic disease and improve the health of children, we worked to make it easier for consumers to understand the nutritional value of their options at the grocery store. To reduce food-borne illness and other health risks, we propelled changes to improve traceability across the supply chain. To protect access to safe, effective medications, we supported post-market research and strategies to prevent shortages, address illegal online sales, and ensure the quality of compounded drugs. To advance how patients and their healthcare providers appropriately access investigational new drugs, we streamlined the Expanded Access Navigator and eRequest app. To speed the development of therapeutics, we listened to the rare disease community and explored strategies to enhance innovation.

The Foundation provides a platform for sharing evidence, analysis, and perspectives that inform the FDA’s decision-making, revealing knowledge gaps and potential solutions. By meaningfully engaging with consumers and stakeholders from across the research, manufacturing, and regulatory sectors, we are better positioned to meet our shared challenges.

In the coming year, the Foundation’s support will continue to be vital as the FDA pursues practical regulatory reform to bring Americans quality food and lifesaving treatments.

Sincerely,

Kyle A. Diamantas, JD

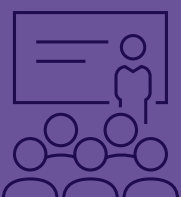
Acting Commissioner of Food and Drugs
Food and Drug Administration



4 journal articles published

2025 At a Glance

7 public meetings convened



8

FDA patient listening sessions coordinated



15

workgroup and expert panel meetings held



4,000+ public comments collected



5,000+ participants registered for public meetings



6,000+ consumers, patients, and providers polled



14 reports issued



27

roundtables moderated



31

stakeholder listening sessions conducted



555,000+ web and social media connections reached



67,000,000+ social media posts analyzed



JAN

FEB

MAR

APR

MAY

JUN

JUL

AUG

SEP

OCT

NOV

DEC

JAN-MAR

Animal Health & Veterinary Industries Roundtable Series & Expert Panel Series

Demand Forecasting for Controlled Substances Roundtable

JAN-MAY

Fresh Produce Safety Collaboration Work Groups

Stakeholder Listening Session

Online Access to Controlled Substances Roundtable

Scientific Advancements in Gene Therapies Article in *Biomedicine*

APR-MAY

Advancing FDA Mechanisms to Address Cross-Sectoral Health Threats Roundtable Series

FDA Patient Listening Session

Produce Safety Stakeholder Dialogue Meeting

Stakeholder Listening Sessions (6)

Supporting FDA's Updated "Healthy" Claim Roundtable Series

FDA Patient Listening Sessions (2)

FSMA Food Traceability Rule Roundtable

Primary Mitochondrial Diseases Public Workshop

Stakeholder Listening Sessions (5)

Clinical Practice Guideline Development Roundtable

Emulations of Oncology Trials Using Real-World Data Article in *American Journal of Epidemiology*

Stakeholder Listening Session

Annual Public Meeting of Board of Directors

FDA Patient Listening Sessions (2)

FSMA Food Traceability Rule Public Webinar

Improving Cross-Sector Health Issue Response Efforts Meeting

Stakeholder Listening Sessions (3)

Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population Public Meeting

Demand Forecasting for Controlled Substances Public Meeting

Developing & Refining the Pregnancy Algorithm CErtaInty Tool (ACE-IT) for Validating Pregnancy Outcomes Article in *American Society for Clinical Pharmacology & Therapeutics*

FDA Patient Listening Sessions (2)

Online Access to Controlled Substances Roundtable

Improving Oncology Multi-Regional Clinical Trials Roundtable

Infant Formula Roundtable Series

Online Controlled Substances Summit

Stakeholder Listening Sessions (6)

Barriers & Opportunities to Improve Alcohol Use Disorder Treatment Expert Discussions

Managing Quality & Risk: Virtual Compounding Quality Discussion

Stakeholder Listening Sessions (6)

Advancing Person-Centered Product Development: Understanding the Health Needs of Women Roundtable

FDA Patient Listening Session

Innovations in Regulatory Science & Policy Awards

Nutrition Incentives Roundtable

RAISE: Elevating Person-Centered Data for Healthy Communities Article in *American Journal of Managed Care*

Food and Nutrition Regulatory Science Medication and Device Use Listening Session

Food and Nutrition

Diet-related diseases including obesity, diabetes, heart disease, and certain cancers are leading causes of death and disability in the United States, and millions of Americans get sick each year after eating contaminated food. Ensuring access to safe, nutritious food is a public health imperative.



Advancing Regulatory Science

Advanced food safety and nutrition policy and implementation



Disseminating Information

Published 4 reports on opportunities to protect and empower consumers



Facilitating Engagement

Gathered insights from more than 2,000 consumer, nutrition, and food chain supply experts

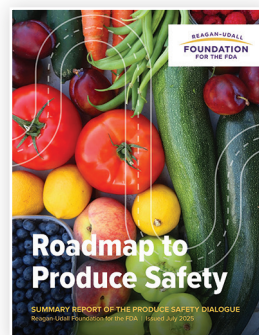
Roadmap to Produce Safety

The Foundation engaged nearly 200 participants to develop the Roadmap to Produce Safety. This ambitious report envisions transformative change to secure the availability of safe fresh fruits and vegetables.

The Roadmap, developed at the FDA's request, represents perspectives from agricultural communities, industry, academia, consumer groups, and government. Through a robust, months-long dialogue, eight working groups conceptualized strategic priorities for a sustainably funded stakeholder collaboration led by the private sector.

This new path recognizes that when foodborne illness strikes, its effects are felt broadly by the public, industry, government, and the health care system. That's why solutions will require collective investment and shared responsibility across the produce supply chain, in contrast to the current fragmented system.

The Roadmap is a pivotal first step toward strengthening consumers' access to wholesome foods they can trust.



PRODUCE SAFETY STRATEGIC PRIORITIES

- Develop and promote a strategy to increase public investment in produce safety
- Create a process for developing science-based, risk-reducing best practices
- Expand technical assistance, resources, and grower incentives to support industry implementation of best practices

The projects in the Food and Nutrition portfolio were supported through a cooperative agreement with the Food and Drug Administration unless otherwise noted.



“The marketing language used on infant formula labels can create a false sense of security for parents, leading them to believe that certain products are inherently better without understanding the lack of evidence behind those claims.”

Roundtable participant

Infant Formula Roundtable Series

Protecting the safety and availability of infant formula is a top priority for the FDA, as evidenced most recently by its launch of Operation Stork Speed with the U.S. Department of Health and Human Services. The initiative aims to enhance formula safety through expanded research and testing. To help inform the FDA's work, the Foundation convened four roundtables with those who are at the forefront of formula issues: families, health care providers, public health experts, state officials, advocates, manufacturers, and researchers.

Participants supported a comprehensive review of formula nutrients that reflects modern science, real-world exposure risks, and functional health outcomes such as neurodevelopment and gut health. Discussions reflected concerns about heavy metals and other contaminants and the proliferation of misleading marketing claims.

To strengthen transparency and consumer confidence, stakeholders envisioned a public database of approved formulas, and resources for pediatricians and other clinicians who are trusted messengers for families. They also stressed the importance of regulatory clarity, effective communication, and cross-sector collaboration.

Our report details strengths, gaps, and opportunities to ensure a high bar of safety, quality, and resilience for these vital products.

OPPORTUNITIES TO ENHANCE FORMULA SAFETY, QUALITY, NUTRITION, AND RESILIENCY

- Prioritize accessible and usable product data and information tailored to relevant audiences
- Ensure that nutrient requirements reflect modern science and real-world exposure risks
- Improve clarity in claims and labeling
- Build trust through transparent communication and outreach strategies
- Present data through simple, visual, accessible tools
- Encourage and strengthen collaboration among stakeholders



Supporting the Use and Implementation of FDA's Updated "Healthy" Claim Roundtable Series

The Foundation convened a series of five roundtables to shed light on opportunities and challenges surrounding the FDA's new evidence-based criteria for labeling food as "healthy." The update reflects the 2020–25 Dietary Guidelines for Americans and exemplifies the Agency's focus on empowering consumers to reduce their risk of chronic diseases related to diet.

The conversations — featuring representatives from retail, manufacturing, trade associations, academia, health care, and consumer/public health groups — sparked ideas to motivate manufacturers to reformulate products to be healthier and to help consumers identify qualifying foods. Participants stressed the importance of consumer education, along with messaging about value, convenience, and taste.

Public-private collaboration will be critical to address challenges, including regulatory clarity, relabeling costs and complexities for manufacturers, and legal concerns for retailers. The "healthy" rule went into effect in April 2025 with a compliance date of February 2028.

UPDATED CRITERIA FOR THE "HEALTHY" CLAIM REQUIRE THAT FOOD PRODUCTS

- Contain a specified amount from food groups or subgroups (fruits, vegetables, whole grains, dairy, and proteins) recommended by the 2020–25 Dietary Guidelines for Americans
- Adhere to limits on saturated fats, sodium, and added sugars designated in the Guidelines



Nutrition Incentives Roundtable

Many grocery stores and third-party apps use nutrition and food rating systems to help consumers make healthier choices. The Foundation convened a dialogue among food retailers, food manufacturers, researchers, and consumers exploring interest in voluntary private sector opportunities to align these systems.

Participants agreed that shoppers would benefit from consistent standards. The criteria should be transparent: based on science, established by an independent expert panel, and in conformance with labeling rules. Alignment could foster innovation and efficiency for manufacturers and competition for retailers.

Roundtable participants concluded that collaboration and common principles could continue to guide future efforts, with participation from consumers, product developers, food and nutrition scientists, third-party scoring system owners, technology and data infrastructure experts, and public health professionals.

This project was supported by Ahold Delhaize USA and H-E-B.

Nutrition Communications Network

The Foundation's Nutrition Communications Network continued to share science-based nutrition messages with dietitians, advocates, manufacturers, and retailers. By incorporating our turnkey content into their communications efforts, Network members easily disseminated practical tips to help consumers improve their health through better nutrition.

Industry Roundtable Series: FSMA Food Traceability Rule

The Food Safety Modernization Act Food Traceability Rule aims to reduce foodborne illness and death through enhanced recordkeeping across the supply chain, allowing for faster identification and removal of contaminated foods. In 2025, the Foundation continued to probe the complexities of implementing the Rule with industry and regulators, culminating in a broadly disseminated report.

A roundtable and public webinar focused on technical challenges, recent pilot projects, and alignment with the FDA's outbreak investigation procedures. The most significant hurdles stem from fragmented systems and standards for collecting and sharing traceability lot code source data. Success will require ongoing FDA support, collaborative investment, and standardized data protocols.

Emphasizing "progress over perfection," stakeholders called for additional pilot programs. The FDA has extended compliance requirements to July 2028 and will use the time to work with stakeholders, address challenges, and provide further assistance and resources.



OPPORTUNITIES TO SUPPORT IMPLEMENTATION OF THE FOOD TRACEABILITY RULE

For FDA

- Support comprehensive cross-sector pilots to test and refine real-world solutions at scale
- Provide assistance to address industry challenges, such as traceability lot code source documentation
- Develop training resources tailored to different supply chain segments, such as small suppliers, retailers, and international partners

For Industry Stakeholders

- Adopt and promote data standards and reduce fragmentation
- Invest in digital infrastructure and scalable tools, especially in warehousing and distribution centers
- Engage in joint traceability efforts, pooling resources to pilot tools, share learnings, and avoid duplicative costs
- Maintain compliance momentum, embedding traceability tasks into regular operations

“Our customer base is diverse, with varying capabilities, and there are notable differences in how information is processed and shared.”

Roundtable participant



CLOCKWISE FROM UPPER LEFT: Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA; Charles Leftwich, MBA, Sysco Corporation; Takashi Nakamura, PhD, MBA, Del Monte Fresh Produce Company; Michael Lookup, Wegmans Food Markets

Rare Diseases

Most rare diseases lack approved treatments because critical research challenges limit progress. For the 1 in 10 Americans who are affected, help is urgently needed.



Advancing Regulatory Science

Worked with the rare disease community and the FDA to inform therapeutic development and review processes



Disseminating Information

Published 1 journal article on strategies to enhance clinical trial innovation



Facilitating Engagement

Connected with more than 1,600 patients, advocates, and scientific experts through meetings and listening sessions

Primary Mitochondrial Diseases: A Rare Disease Virtual Workshop

Primary mitochondrial diseases (PMDs) are rare, progressive genetic disorders that cause variable symptoms in multiple organs, complicating the search for effective treatments. In collaboration with the FDA, the Foundation convened a public workshop on the urgent need to optimize therapeutic development for PMDs.

The event brought patients, families, and advocates together with healthcare professionals, researchers, regulators, and industry representatives from across the PMD community. Speakers explored best practices and lessons learned in designing and interpreting clinical trials to accelerate drug development, including strategies to improve enrollment, select patient-focused outcome measures, manage variability, and support innovation.

This project was supported through a cooperative agreement with the Food and Drug Administration.

Real-World Evidence Consortium for Sickle Cell Disease

The Foundation continued its collaboration with the American Society of Hematology Research Collaborative (ASH RC) on the Real-World Evidence Consortium for Sickle Cell Disease (SCD). The initiative aims to develop a forum and platform for research to improve outcomes for SCD, which affects 100,000 Americans.

With guidance from multi-disciplinary steering and innovation committees, we prioritized SCD clinical concepts, selected and defined SCD-related pain crisis, and began operationalizing the definition in the context of electronic health record data. We also began protocol development for the validation study and data quality assessment of the ASH RC DataHub.

This project was supported by the American Society of Hematology.

EXPANDED ACCESS NAVIGATOR

Expanded access is a potential pathway for a patient with a serious or immediately life-threatening condition to access an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternatives are available. The process requires approval from both the FDA and the product developer.

The online Expanded Access Navigator guides patients, caregivers, and health care providers through the process — and tailored resources and directories help all parties, including product developers, share and find the information they need. Using the Expanded Access eRequest app, physicians can directly submit a new online request to the FDA and stay up to date on other submissions such as treatment plans and progress reports.

The program continued to grow in 2025, doubling visits to the Navigator and increasing the number of product developers listing their resources by 22 percent.

This project was supported through a cooperative agreement with the Food and Drug Administration.

“I refer to the Navigator regularly — it’s my ‘go to’ resource when supporting a patient with a rare disease.”

Practicing physician who uses the Expanded Access Navigator

Expanded Access eRequest App

Part of the Expanded Access Navigator



navigator.reaganudall.org

Prepare, sign, and submit your Expanded Access request to FDA

Step-by-step process

Integrated sponsor information

Receipt Confirmation

Follow up reminders for easy tracking and reporting



Patient Listening Sessions

In 2025, the Foundation collaborated with the FDA to organize eight patient listening sessions on rare diseases and other conditions. These small, informal engagements connect patient communities directly with the FDA to share perspectives and needs that inform decision-making.

APOE e4 Alzheimer’s Disease

Chronic Granulomatous Disease

Familial Alzheimer’s Disease

Juvenile Onset Forms of GM1 and GM2 (Tay-Sachs and Sandhoff) Gangliosidoses

Leukoencephalopathy with Calcifications and Cysts

MAPT Frontotemporal Dementia

MECP2 Duplication Syndrome

Wolfram Syndrome

Real-World Data and Evidence

The United States leads the world in the development of therapeutic innovations that have transformed the care of people with cancer, chronic diseases, genetic diseases, and other disorders. However, work remains to bring safe and effective treatments to those who need them, and to explore the safety and effectiveness of medical products in the real world.



Advancing Regulatory Science

Conducted post-market research and developed recommendations to advance innovation



Disseminating Information

Published 4 reports and 4 journal articles to communicate findings and perspectives



Facilitating Engagement

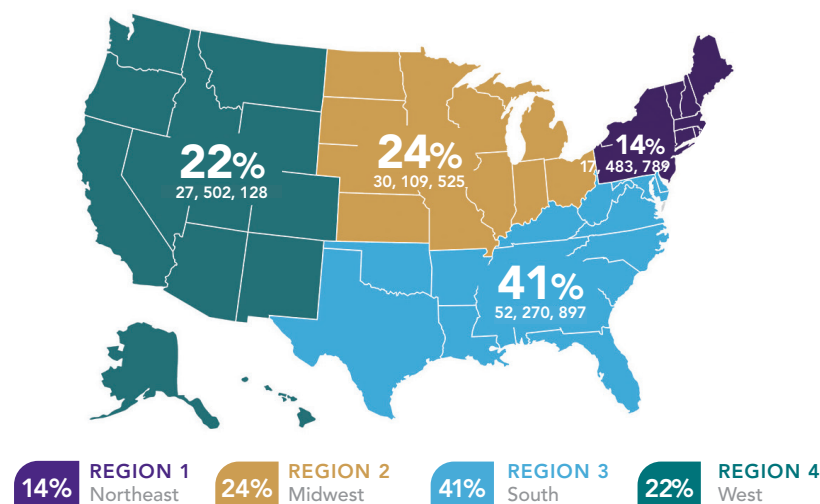
Connected with more than 2,000 people through scientific meetings and roundtables

Innovation in Medical Evidence and Development Surveillance (IMEDS)

The Foundation's IMEDs program is a national resource for generating real-world evidence on the post-market safety of medical products. Our approach allows us to conduct large, rigorous studies efficiently using FDA Sentinel tools and streamlined, privacy-protected data. Scientists in the IMEDS Network are essential collaborators from protocol development through implementation.

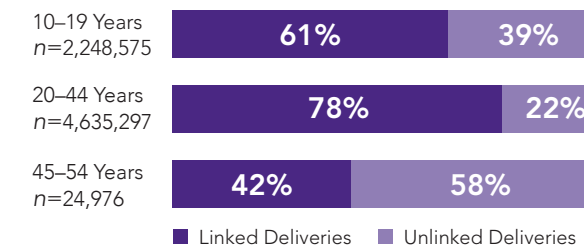
In 2025, we completed post-market research on ertugliflozin in patients with type 2 diabetes (Merck) and reported the results to the FDA and the European Medicines Agency. The study was accepted for publication in the journal *Diabetic Medicine*. We also continued the monitoring phase of studies examining risankizumab in pregnant women with psoriasis and with inflammatory bowel disease (AbbVie).

Patient Distribution of IMEDS Network



Our post-market medication safety studies in pregnant women rely on the Sentinel algorithm to identify pregnancies resulting in a live birth. This involves linking infant to mother using data from insurance claims and/or birth certificates. Of the nearly 5 million deliveries in the IMEDS network, more than three-quarters are linked to the mother (see breakdown by mother's age at right).

Linked and Unlinked Deliveries in IMEDS Network by Mother's Age, 2000–2024 (N=4,908,848)



IMEDS studies in 2025 were conducted for AbbVie and Merck to meet their post-market requirements to the Food and Drug Administration and/or the European Medicines Agency.

Improving Oncology Multi-Regional Clinical Trials

Cancer is on the rise worldwide, but large clinical trials — the cornerstone of treatment innovation — are strained by high costs, long timelines, and unnecessary burden for participants, researchers, and sponsors.

A roundtable discussion identified recommendations for modernizing the clinical trial enterprise in the United States through regulatory and operational improvements. The Foundation invited representatives from trial sites, research organizations, biopharmaceutical companies, and cancer-focused nonprofits. Together, they surfaced potential ways to optimize clinical research by making it more effective, efficient, and sustainable.

This project was supported by BeOne Medicines, Jazz Pharmaceuticals, Lilly, and Merck.

Advancing Person-Centered Product Development: Understanding the Health Needs of Women

The health needs of women and men are not the same. Some diseases present differently by sex, and women are more likely than men to have an autoimmune disorder or to die from a heart attack. Women also experience shifting health concerns throughout the lifespan.

The Foundation, in collaboration with the Milken Institute's Women's Health Network, held a roundtable to explore unmet needs in drug development for conditions that affect women exclusively, disproportionately, or differently. Advocates, clinicians, drug developers, and regulators identified potential solutions to drug development roadblocks in three areas: expanding opportunities for research collaboration, modernizing study trial design while ensuring that women's experiences inform research priorities, and enhancing benefit-risk assessment tailored to women's health. These ideas could help foster the design of safe, innovative treatments for women.

This project was supported by Daré Bioscience, Organon, and ZS.

RECOMMENDATIONS TO IMPROVE CLINICAL TRIALS

- Unlock the potential of network approaches
- Improve enrollment and study start-up timelines by advancing more patient-centric, rather than trial-centric, approaches
- Explore common budget and contract processes for U.S. trial sites
- Ensure utilization and deployment of technology yields benefits
- Align training needs and minimize duplicative activities
- Develop scientific principles for representativeness targets and adapt for disease-specific application
- Manage varying and evolving standards of care by articulating regulator/researcher understanding for specific cancers



Science of Immunity

The Science of Immunity is a free, interactive curriculum that helps middle schoolers learn about the immune system and build critical thinking skills in a whole new way. The Foundation worked with teachers, RTI International, the Center for Medicine in the Public Interest, and Dr. Raven the Science Maven to develop this fun approach to nurturing the scientists of tomorrow.

In 2025, we completed a series of focus groups with science teachers that informed improvements to the curriculum's content and interface. Follow-up surveys and outreach affirmed the curriculum's value as a plug-and-play resource aligned with teaching standards.

This project was supported by the Gordon and Betty Moore Foundation and the Burroughs Wellcome Fund.

Managing Quality and Risk: Virtual Compounding Quality Discussion

In support of the FDA's mission to enhance product safety, the Foundation collaborated with the Agency to convene a dialogue on compounded drugs.

Representatives from 503B compounding outsourcing facilities and supply chain partners discussed strategies for managing quality and risk. The gathering was part of FDA's Quality Discussion Series, which aims to build a community dedicated to compounding quality and best practices.

This project was supported through a cooperative agreement with the Food and Drug Administration.

FDA RISK COMMUNICATION

Recent years have brought major shifts in how people obtain and absorb health information.

The Foundation worked with communications, consumer, and regulatory experts to develop core principles to guide health communicators, including government agencies, in crafting and delivering messages about risk on topics from food safety to medical devices. This work is especially relevant as trust in public health authorities increasingly gives way to personal and social media sources.

This project was supported through a cooperative agreement with the Food and Drug Administration.

Animal Health and Cross-Sectoral Issues

Animal and human health are essential and intertwined. Responses to opportunities and risks call for multilevel public-private approaches that cross veterinary medicine, agriculture, and public health.

Transforming Animal Health in the U.S. for the 21st Century

The FDA's Center for Veterinary Medicine is seeking ways to extend recent biomedical innovations to animal health, a \$600 billion sector that is overdue for regulatory reform.

The Foundation convened representatives from academia, regulated industry, and professional associations to analyze the animal health ecosystem and suggest opportunities for modernization. The expert panel formulated dozens of recommendations for the FDA, other federal partners, and broader stakeholders. The potential actions chart a path toward a more robust, agile regulatory framework.

The panel pointed to the 21st Century Cures Act, which transformed human medicine, as a model. The stakes extend beyond animal welfare to encompass food security, U.S. global competitiveness, and public health.

Addressing Cross-Sectoral Health Issues: A Collaborative Approach

Complex threats at the intersection of human and animal health require a coordinated response, but multiple barriers can stand in the way, from poor communication to siloed data systems.

At the FDA's request, the Foundation spoke with outbreak experts to identify challenges and potential solutions across local, state, and federal public health, agriculture, and regulatory systems. As a case study, we included a discussion on the response to the 2024 spread of highly pathogenic avian influenza from animals to humans.

In a series of roundtable discussions, actionable opportunities emerged to bolster integration and preparedness in advance of the next health issue. Effective crisis response will require groundwork by sectors and jurisdictions to build a culture of trust, transparency, and collaboration.

These projects were supported through a cooperative agreement with the Food and Drug Administration.



Advancing Regulatory Science

Identified holistic approaches to support coordination and reform



Disseminating Information

Published 2 reports to share potential solutions and recommendations



Facilitating Engagement

Gathered insights from more than 180 experts through interviews and roundtables



FROM LEFT: Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA; Sangeeta Vaswani Chatterjee, PharmD, FDA; Marta Sokolowska, PhD, FDA

Controlled Substances

More than 27 million Americans report illicit drug use or prescription drug misuse. Interventions are needed to effectively treat substance use disorders, prevent accidental exposures, and stop illegal sales.

2025 Online Controlled Substances Summit

Almost 1 in 4 Americans who purchase controlled substances online have received harmful, counterfeit, or substandard products. The sixth annual Online Controlled Substances Summit reviewed approaches for addressing this evolving threat, which disproportionately affects youth.

Speakers from technology, government, academia, international partners, and families shared cross-sector, real-world, and research-based strategies. Discussions centered on collaborative interventions to disrupt illegal sales and increase public awareness and understanding.

The issue's human toll was poignantly illustrated by the stories of young people who died after taking products purchased through the dark web and social media.

CALL TO ACTION FOR ADDRESSING ILLEGAL ONLINE SALES OF CONTROLLED SUBSTANCES

- Expand education and health literacy, particularly among younger populations
- Disseminate reliable resources for prevention
- Leverage forums where digital platforms can collaborate
- Grow the network of committed digital partners and share practices
- Explore new models of stakeholder collaboration and information sharing
- Accelerate and strengthen global partnerships to disrupt international supply chains

The projects in the Controlled Substances portfolio were supported through a cooperative agreement with the Food and Drug Administration.

Opioid Disposal

The Foundation collaborated with the FDA to examine safe disposal methods for unused and expired opioids, which are vital for reducing risk in households where the medications are present.

Our landscape analysis focused on the potential impact of mail-back envelope distribution as part of the FDA's Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS). It included a review of relevant studies alongside interviews with pharmacists, clinical researchers, and representatives from professional associations.

The project highlighted the need to increase awareness of the OA REMS and address barriers to incorporating mail-back programs into pharmacy and consumer practice.

KEY TAKEAWAYS ON OPIOID DISPOSAL

- Pharmacists, health systems, and patients want options for disposal of unused opioids; one size does not fit all
- Mail-back envelopes provide an additional disposal method
- Pharmacists want to understand how their current processes align with the OA REMS; new systems involve time, education, and expense
- Disposal by mail raises concerns for some patients

Pediatric Unintentional Exposure to Medications for Opioid Use Disorder

Medications to treat opioid use disorder, such as methadone and buprenorphine, can be lifesaving. But when young children are accidentally exposed, even in small amounts, the results can be deadly.

The Foundation worked with the FDA to develop research-informed educational message frameworks for reducing the risks without affecting patient access or contributing to stigma. Through a literature scan, discussions with experts, and interviews and polling of people with lived experience, we identified gaps in the information patients receive on how to store their medications and respond in an emergency. Organizations can tailor our message frameworks for use with specific audiences.

COSMETIC LABELING

The Foundation continued to research consumer perspectives on cosmetics in 2025, a category that includes makeup along with other regulated products such as deodorant, shaving cream, skin care, and shampoo. The project gathered insight into how cosmetic labeling drives consumer choices, from product claims to ingredients to potential adverse effects.

Our research with the FDA identified potential action areas to improve cosmetic adverse event reporting: support technology-enabled tools to help consumers understand ingredients and risks, normalize and simplify reporting, and raise awareness of the FDA's role in regulating cosmetics.

This project was supported through a cooperative agreement with the Food and Drug Administration.



Advancing Regulatory Science

Explored emerging science to inform improvements in research, clinical practice, and safety



Disseminating Information

Published 4 reports and 5 research summaries to share insights and evidence



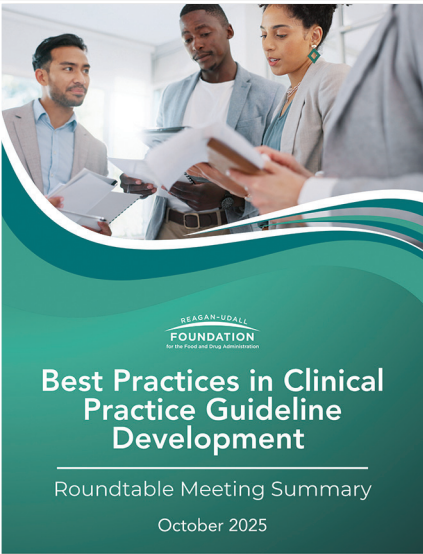
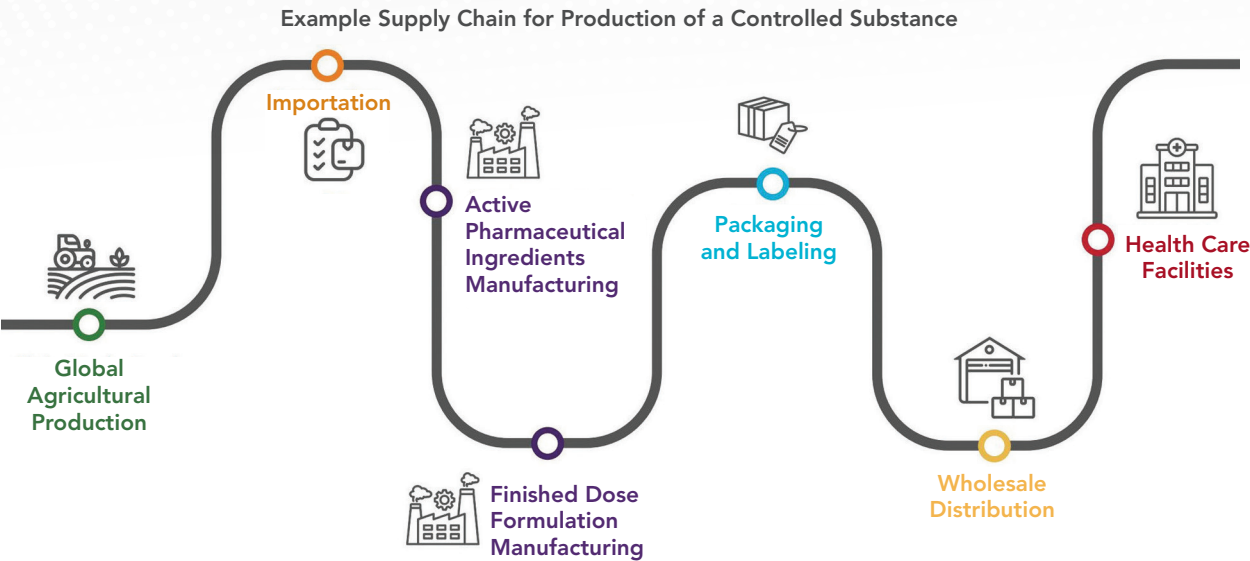
Facilitating Engagement

Learned from nearly 8,000 research, practice, and lived experience experts about unmet treatment needs, safety concerns, and demand forecasting

Demand Forecasting for Controlled Substances

To predict demand for controlled substances, the Drug Enforcement Administration primarily uses historical sales data, augmented by analysis from the FDA and upcoming customer orders submitted by manufacturers. It's a complex process that informs quotas and limits for medications like opioids and stimulants, with broad implications when forecasts are inaccurate or inflexible. Underestimates trigger shortages that can drive patients to illicit sources, while overestimates result in overproduction that risks diversion and misuse.

On behalf of the FDA, the Foundation set out to increase understanding of the issue by reviewing demand forecasting methods, conducting interviews and a roundtable discussion with industry and academic experts, and convening a public meeting. The project highlighted advancements that may improve forecasting by using machine learning, considering external factors such as natural disasters, incorporating buffers, and refining estimates frequently.



Best Practices In Clinical Practice Guideline Development

A roundtable of experts came together to share lessons for developing clinical practice guidelines that involve controlled substances — an essential prescribing tool for effective pain management and substance use treatment in the context of the ongoing overdose crisis.

The event brought together teams that recently developed such guidelines with FDA support, along with Agency and Foundation staff and federal partners. Breakout groups focused on five topics: evidence limitations, stakeholder engagement, communication, implementation, and evaluation.

To bridge evidence gaps, participants emphasized the importance of structured literature reviews and consensus methodologies coupled with clinical expertise and transparency. They advocated for living guidelines, greater standardization, and ongoing investment to efficiently develop and sustain effective guidelines.

Understanding Treatment Needs and Research Priorities for Nicotine, Cannabis, and Alcohol Use Disorders

At the FDA’s request, the Foundation examined treatment and research needs for nicotine, cannabis, and alcohol use disorders, which affect millions of Americans. Each of the three projects entailed a landscape analysis and qualitative research to gain perspectives from consumers and health care providers.

Among the findings: stress and anxiety drive the use of both nicotine and cannabis. In the case of alcohol use, consumers prioritize reduction over complete abstinence, and they are motivated by the chance to make meaningful improvements in their lives. Both providers and consumers want more and better treatment options, including medication and behavioral therapies and other nondrug interventions that incorporate technology.



Ketamine Compounding

Amid growing interest in the therapeutic use of ketamine for conditions such as depression and chronic pain, the Foundation conducted a series of interviews to shed light on the current landscape of ketamine compounding.

We spoke with pharmacy compounders, outsourcing facilities, active pharmaceutical ingredient wholesalers, state regulators, and professional associations. Discussions centered on pharmacy trends, data, regulation, and opportunities to ensure patient protections.

Participants cautioned that limited availability of data, increases in recreational use, and rogue online sales undermine legitimate clinical use of the drug. They also welcomed increased dialogue and collaboration with regulators.

IMPROVING PATIENT AND PROVIDER ENGAGEMENT ABOUT MEDICATION INFORMATION

This mixed-methods research project, a joint effort by the Foundation and the FDA, explored how patients understand and use written information about their medications. Through listening sessions and focus groups with patients and providers, along with a national consumer poll, we learned that patients particularly struggle with drug labeling about dosing, interactions, and side effects.

The findings support potential enhancements as the FDA works to advance patient engagement. Package inserts with clear language and accessible formatting could boost patient comprehension, leading to better outcomes and reduced costs. Communication with clinicians could also be improved using digital tools.

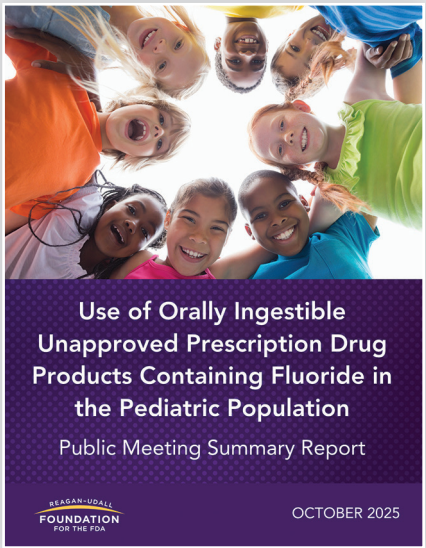
This project was supported through a cooperative agreement with the Food and Drug Administration.

Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population

The Foundation partnered with the FDA to convene a public meeting on the use, benefits, and evidence gaps surrounding prescription fluoride products. Although they are not FDA approved, these tablets and drops have been used to prevent tooth decay in children since the 1940s.

With participation from clinicians, researchers, parents, and advocates, the forum illustrated the importance of gathering multiple perspectives to inform Agency decision-making. Some scientific presenters questioned the safety and efficacy of systemic fluoride products and called for studies to identify safe exposure thresholds, particularly prenatally and in early childhood. Others described the preventive benefits of ingestible fluoride for children in rural and low-income communities who lack fluoridated water or routine dental care, as demonstrated by decades of clinical experience and epidemiological data. Parents spoke about the positive impact of the products on their children’s dental health.

The public comments — 20 shared during the meeting and more than 4,000 submitted in writing — reflected intense interest, as well as broader differences over public health, institutional credibility, and regulatory standards. The way forward will require reconciliation of the reliance on ingestible fluoride as an established, essential health measure with the demand for clinical trials to resolve uncertainties and bolster trust.



Jennifer Webster-Cyriaque, DDS, PhD, National Institutes of Health



Jacqueline Corrigan-Curay, JD, MD, FDA

Fellowship in Regulatory Science and Innovation

The Foundation was pleased to welcome Okunade (Oak) Olateru-Olagbegi, PharmD, as our 2025–26 Regulatory Science Fellow, selected in partnership with Howard University.

The fellowship program expands the regulatory science workforce pipeline while offering professional school graduates meaningful experience. Fellows work alongside Foundation and FDA staff on research, communication, engagement, and operations.

This project was supported by BeOne Medicines, Burroughs Wellcome Fund, and PhRMA.



“My fellowship year has been instrumental in my professional growth. The breadth of experiences accelerated my development and prepared me for what’s next. The research opportunities, especially in real-world evidence and post-market studies, were particularly pivotal. The entire Foundation team was supportive and consistently invested in my growth throughout, making it a challenging, insightful, and distinctive year.”

Okunade (Oak) Olateru-Olagbegi, PharmD, 2025–26 Fellow

2025 Innovations in Regulatory Science and Policy Awards

The Foundation's annual Awards recognize visionary contributions to regulatory science and policy. More than 270 attendees joined us in Washington, DC, on December 9 to celebrate these remarkable achievements in service to public health.



LEADERSHIP AWARD Produce Safety Alliance

Accepted by **Elizabeth A. Bihn**, PhD, Director, and Donna Clements, MS, Coordinator and Northeast Regional Extension Associate, Produce Safety Alliance

The Produce Safety Alliance helps growers, regulators, and industry implement the FDA Food Safety Modernization Act's Produce Safety Rule. Its transformative education and training programs have empowered more than 100,000 growers in 50 states and 30 countries to protect consumers.



INNOVATION AWARD Critical Path Institute (C-Path)

Accepted by **Klaus Romero**, MD, MS, FCP, Critical Path Institute Chief Executive Officer

Through innovative data-sharing consortia and pioneering methodologies, C-Path accelerates the development and regulatory review of medical products. Its groundbreaking work has advanced patient access to safe and effective therapies for conditions such as Alzheimer's disease, tuberculosis, Duchenne muscular dystrophy, and kidney disease.



ADVOCACY/POLICY AWARD

Loren A. Eng, MBA, MA, President, Spinal Muscular Atrophy Foundation

Loren Eng, a fiercely dedicated patient advocate, has redefined how rare disease research is conducted through strategic collaborations with regulators, researchers, and industry. Her tireless advocacy has led to vital treatment options for spinal muscular atrophy while benefiting the broader rare disease community.

FROM LEFT:
Loren A. Eng, MBA, MA; Klaus Romero, MD, MS, FCP; Kristen Swingle, MS; Jennifer Kendra; Elizabeth A. Bihn, PhD; Donna Clements, MS



“The FDA's work changed the course of my daughter's life... The dedication of everyone in this room allowed me to stop worrying about her mortality. You replaced fear with hope.”

Loren A. Eng, Spinal Muscular Atrophy Foundation

AWARDS DINNER TRANSFORMATION SPONSORS

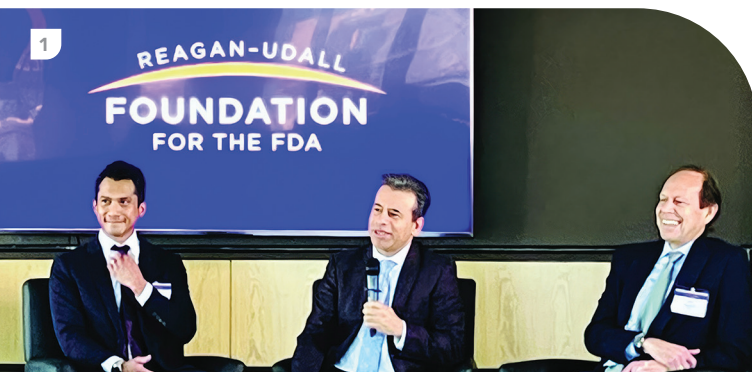


2025 Annual Public Meeting

The Foundation convened the annual public meeting of its Board of Directors on July 17. This forum provides an opportunity for the board and FDA leaders to reflect on their joint progress in regulatory science.

Board Chair Richard L. Schilsky kicked off the meeting and introduced Commissioner Martin A. Makary, who shared highlights from his first 100 days at FDA and discussed the Agency's focus on chronic disease and regulatory reform. Joining Dr. Makary were FDA's Deputy Commissioner for Strategic Initiatives and Special Counsel Lowell Zeta, and Chief of Staff Jim Traficant.

Dr. Schilsky and Foundation CEO Susan C. Winckler provided an update on the Foundation's governance and projects, particularly on expanded access, food safety and nutrition, post-market studies, and controlled substances. Rounding out the meeting, some of the Foundation's board members participated in a panel discussion.



1. **FROM LEFT:** Lowell Zeta, JD; Commissioner Martin A. Makary, MD, MPH; Jim Traficant, FDA
2. Richard L. Schilsky, MD, FASCO, Reagan-Udall Foundation for the FDA
3. **FROM LEFT:** Richard L. Schilsky; Board Members Andrew C. von Eschenbach, MD, Pietro Antonio Tataranni, MD, Debra L. Ness, MS, Edward John Allera, JD; Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA

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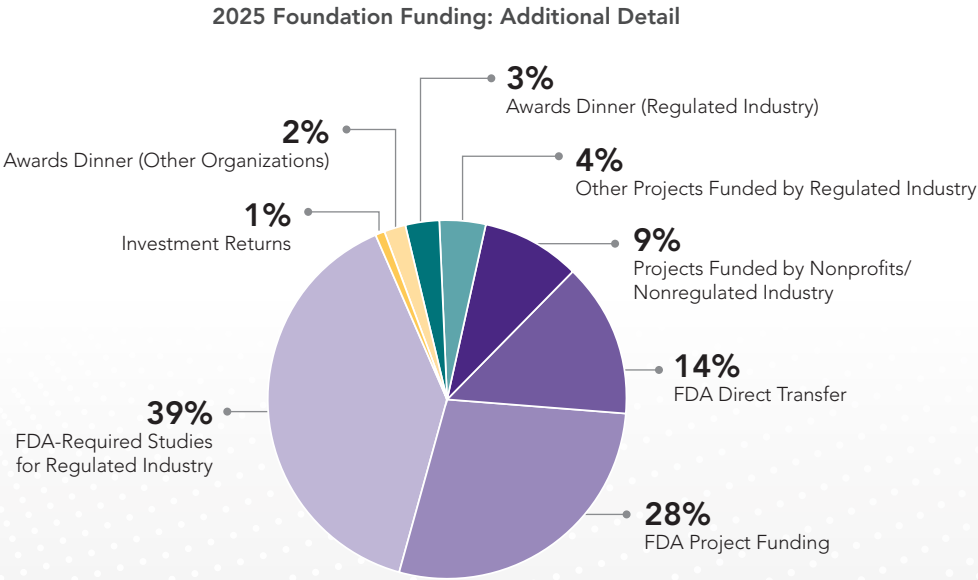
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Engagement Manager

Susan C. Winckler, RPh, Esq.
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Financials

	2025	2024
REVENUE AND SUPPORT		
FDA Direct Funding*	1,250,000	1,650,000
Government Grants**	2,505,316	2,047,045
Other Grants and Contributions	291,668	690,143
Contracts	4,269,352	3,407,304
Fundraising	395,025	414,236
Miscellaneous and Interest Income	128,036	179,276
TOTAL REVENUE AND SUPPORT	\$8,839,397	\$8,388,004
EXPENSES		
Program Services	8,548,188	7,489,729
Supporting Services		
Management and General	259,441	254,642
Fundraising	264,217	281,631
Total Supporting Services	523,658	536,273
TOTAL EXPENSES	\$9,071,846	\$8,026,002
CHANGE IN NET ASSETS	-\$232,449	\$362,002



*The Reagan-Udall Foundation for the FDA's operations are partially supported by direct funding from the U.S. Food and Drug Administration (21 USC Chapter 9, Subchapter VII, Sec. 379dd(n)).

**Government grants include support from the U.S. Food and Drug Administration. The work products are those of the grantee 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.

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The Foundation has a Four-Star rating from Charity Navigator, the nation's largest independent evaluator of philanthropic organizations. This top designation is awarded to highly effective, trustworthy nonprofits that meet or exceed standards across key performance areas, including financial health and governance.



Thank You!



Visionary oncologist, researcher, and leader **Dr. Richard L. Schilsky** helped shape the Foundation and strengthen the FDA's mission for more than a decade. As a dedicated Board member since 2013 and Board Chair since 2023, he championed collaboration, evidence-based innovation, and integrity in clinical research to improve patients' lives. The Foundation and the broader regulatory science community are deeply grateful for Dr. Schilsky's service.



“Dr. Schilsky's steady voice reminded us of who we serve, what our aims are, and what we're pursuing in terms of excellence.”

Dr. Adrian F. Hernandez
Foundation Board Vice Chair



- 1,4. Richard L. Schilsky, MD, FASCO, Foundation Board Chair
2. **FROM LEFT:** Dr. Schilsky; Adrian F. Hernandez, MD, MHS, Foundation Board Vice Chair
3. **FROM LEFT:** Susan C. Winckler, RPh, Esq., Foundation CEO; Dr. Schilsky

STRATEGIC FRAMEWORK

Helping the FDA do more to protect and promote the public's health

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.

3-YEAR OUTCOME

Progress Toward Our Vision: The Foundation manages a suite of programs that assist the FDA to engage with external stakeholders and that facilitate evidence generation, improve public understanding of the FDA, and deliver improved health information to the public.

VALUES

- Engagement
- Innovation
- Evidence
- Patient and Consumer Centered

PILLARS

Advancing
Regulatory Science

Supporting Development and
Dissemination of Reliable Information

Facilitating Engagement
and Information Exchange

GOALS

Encourage innovation
in regulatory science
and career
development

Improve public
understanding of the
FDA and the risks
and benefits of FDA-
regulated products

Support inclusion
of all affected
populations
in research

Facilitate multi-
stakeholder collaboration
to accelerate evidence
generation and
dissemination

STRATEGIES

Provide data assets,
evaluation tools, and
career development
opportunities to help
the FDA assess the
risks and benefits of
regulated products

Identify priority
areas for consumer,
patient, and
provider education
in areas of emerging
science

Improve provider,
patient, and
consumer access to
regulated products
throughout product
life cycles

Enable expert analysis,
candid discussion,
and actionable
recommendations on
issues relevant to the
FDA mission

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