Annual Public Meeting of the Board of Directors

July 17, 2025

Our meeting will begin shortly.

REAGAN-UDALL FOUNDATION FOR THE FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

Richard L. Schilsky, MD

Board Chair
Reagan-Udall Foundation for the FDA

FDA Leadership Panel

REAGAN-UDALL FOUNDATION FOR THE FDA

Martin Makary, MD, MPH
Commissioner of Food and Drugs

Jim Traficant
Chief of Staff

Lowell Zeta, JD
Deputy Commissioner for Strategic Initiatives and Special Counsel

REAGAN-UDALL

FOUNDATION

FOR THE FDA

Foundation Highlights

REAGAN-UDALL FOUNDATION FOR THE FDA

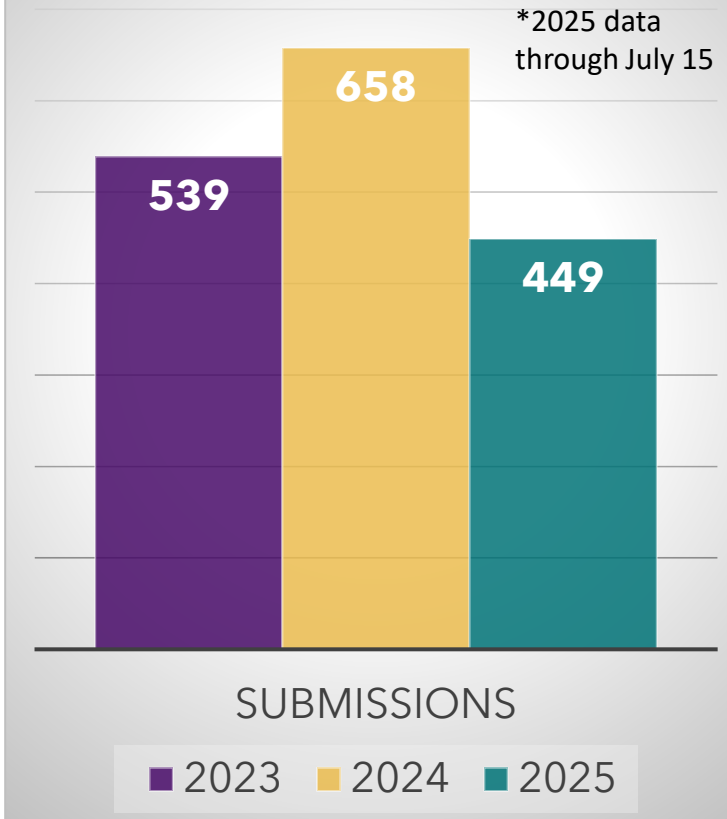
Schilsky

Susan C. Winckler, RPh, Esq
Chief Executive Officer

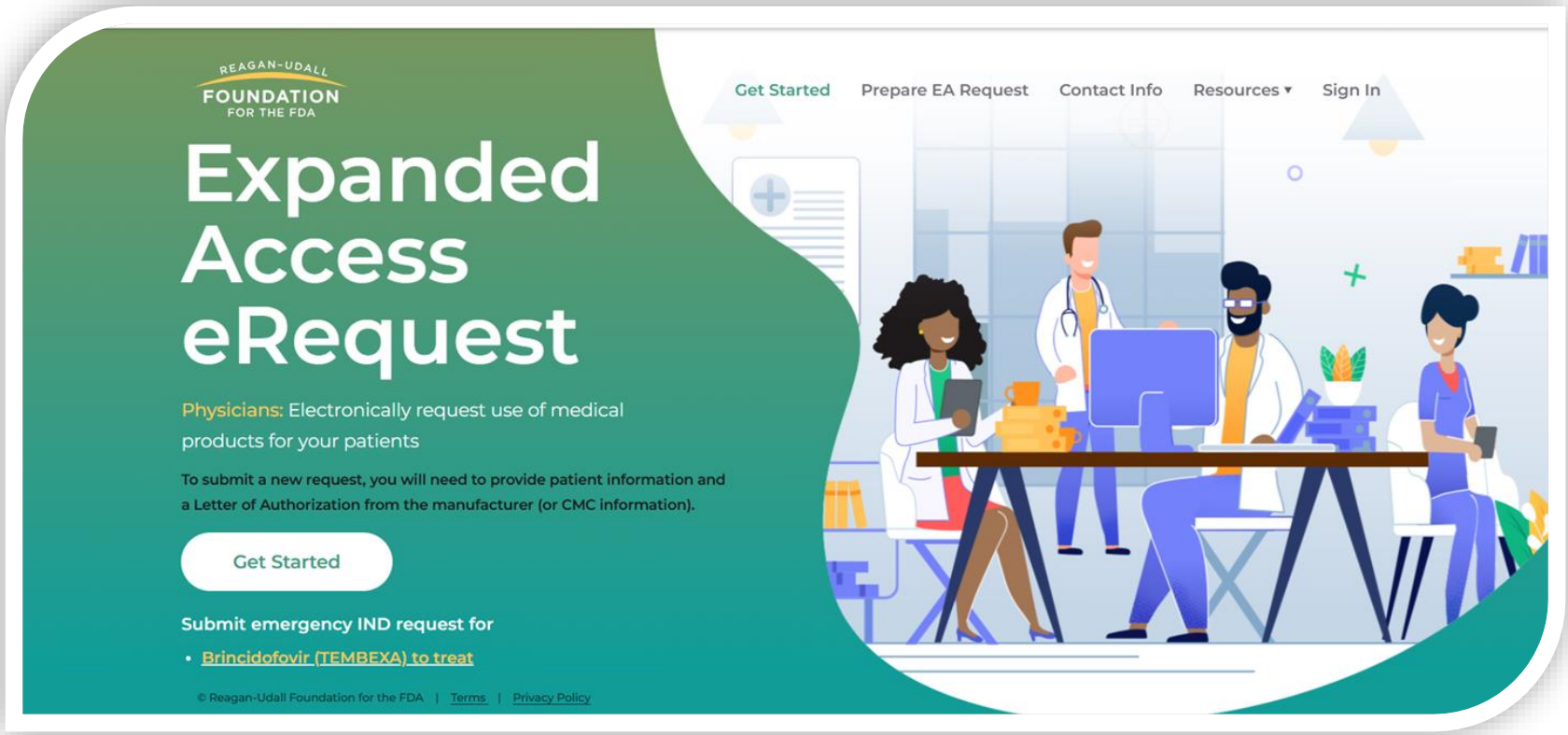
Expanded Access Navigator

REAGAN-UDALL FOUNDATION FOR THE FDA

eRequest Submissions Drugs & Biologics



Nearly half of all non-emergency expanded access requests were submitted through the eRequest App last year



Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

Top-Line Learnings Summary

September 2024

REAGAN-UDALL FOUNDATION FOR THE FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

Real-world Data to Assess Long-term Impact of FDA Food Related Regulations and Polici

A SNAPSHOT

Fourth Quarter 2024

Nutrition Communications Network

REAGAN-UDALL FOUNDATION FOR THE FDA

Science-Based Nutrition Messages for the Holiday Season

Late fall and early winter bring lots of focus on food with holiday celebrations and the end-of-year rush. Use the science-based nutrition messages in this guide to help fuel your social media outreach, web content, and other constituent communication during this busy season. Inside you'll find ready-to-post monthly messages with health-conscious tips, infographics, shareable resources, and a sample blog post that can be used to engage your members or followers. We encourage you to use the #NutritionFactsLabel hashtag along with the messages.

IN THIS GUIDE

- Social Media Messages
- Infographics
- Shareable Resources
- Blog Post

Produce Safety Stakeholder Dialogue

Required Post Market Studies through IMEDS

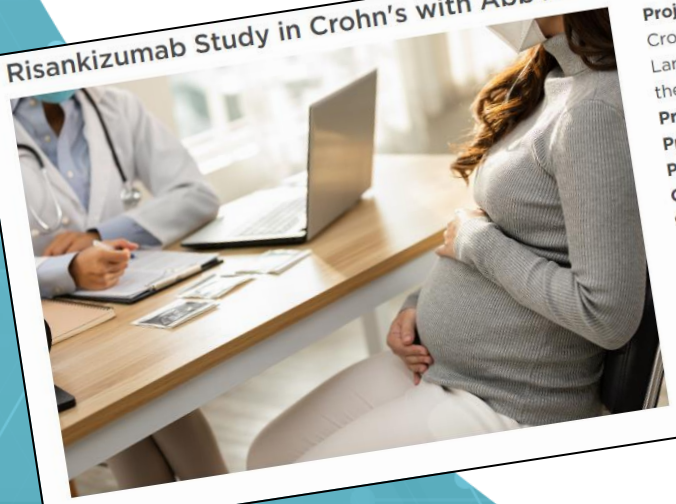
REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Ertugliflozin Study with Merck

Project Title: Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents (AHA)
Project Sponsor: Merck
Project Status: Current
Product: Ertugliflozin
Conditions: Diabetic ketoacidosis, Type 2 diabetes mellitus
Summary: The Reagan-Udall Foundation for the FDA (FDA Foundation PI: Carla Rodriguez-Watson) was recently awarded a contract to leverage data from the Innovation in Medical Evidence Development and Surveillance (IMEDS) Network to continue implementation of a study titled: "Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents (AHA)" (EU PAS Register number: EUPAS31378). This work is being conducted to fulfill a requirement from the European Medicines Agency (EMA). The research activities are a collaborative effort between the Merck research team, the IMEDS Operations Center at FDA Foundation, the IMEDS Analytic Center at the Harvard Pilgrim Health Care Institute, and participating IMEDS Network Partners.

- Click to view the European Union electronic Register of Post-Authorisation Studies (EU PAS) register number (EUPAS31718)

Risankizumab Study in Crohn's with AbbVie



Project Title: Pregnancy Exposures and Outcomes in Women with Crohn's Disease Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States
Project Sponsor: AbbVie
Project Status: Current
Product: Risankizumab
Conditions: Crohn's Disease
Summary: To help fulfill a requirement from the European Medicines Agency (EMA), IMEDS was contracted to help design and execute a study to assess the safety of Risankizumab among women with Crohn's Disease during pregnancy. The risk of pre-specified pregnancy and outcomes will be estimated in pregnant women with Crohn's Disease and are exposed to Risankizumab, as well as in those exposed to comparator biologics (anti-tumor necrosis factor (TNF), integrin receptor antagonist biologics or their biosimilars [comparator biologic-exposed group]).

Risankizumab Study in Psoriasis with AbbVie

Project Title: Pregnancy Exposures and Outcomes in Women with Psoriasis Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States
Project Sponsor: AbbVie
Project Status: Current
Product: Risankizumab
Conditions: Psoriasis, Pregnancy
Summary: To help fulfill a requirement from the European Medicines Agency (EMA), IMEDS was contracted to help design and execute a study to assess the safety of Risankizumab among pregnant women with psoriasis. The risk of pregnancy, birth and infant outcomes will be estimated in pregnant women exposed to Risankizumab, as well as in those exposed to comparator biologics including anti-tumor necrosis factor (TNF), interleukin (IL)-17 biologics or their biosimilars (comparator biologic-exposed group).


REAGAN-UDALL
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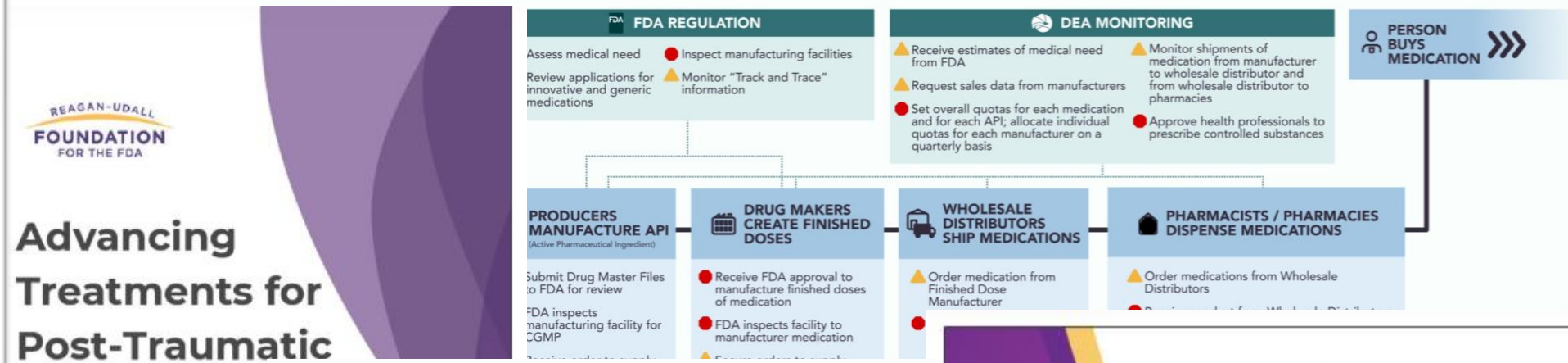
for the Food and Drug Administration
Online Controlled Substances Summit
PUBLIC VIRTUAL MEETING
Meeting Summary
November 2024


FACTORS THAT AFFECT PRESCRIPTION STIMULANT AVAILABILITY
FDA REGULATION
Assess medical need
Review applications for innovative and generic medications
Inspect manufacturing facilities
Monitor "Track and Trace" information
DEA MONITORING
Receive estimates of medical need from FDA
Request sales data from manufacturers
Set overall quotas for each medication and for each API; allocate individual quotas for each manufacturer on a quarterly basis
Monitor shipments of medication from manufacturer to wholesale distributor and from wholesale distributor to pharmacies
Approve health professionals to prescribe controlled substances
PERSON BUYS MEDICATION
PRODUCERS MANUFACTURE API
(Active Pharmaceutical Ingredient)
Submit Drug Master Files to FDA for review
FDA inspects manufacturing facility for CGMP
DRUG MAKERS CREATE FINISHED DOSES
Receive FDA approval to manufacture finished doses of medication
FDA inspects facility to manufacturer medication
WHOLESALE DISTRIBUTORS SHIP MEDICATIONS
Order medication from Finished Dose Manufacturer
PHARMACISTS / PHARMACIES DISPENSE MEDICATIONS
Order medications from Wholesale Distributors

REAGAN-UDALL
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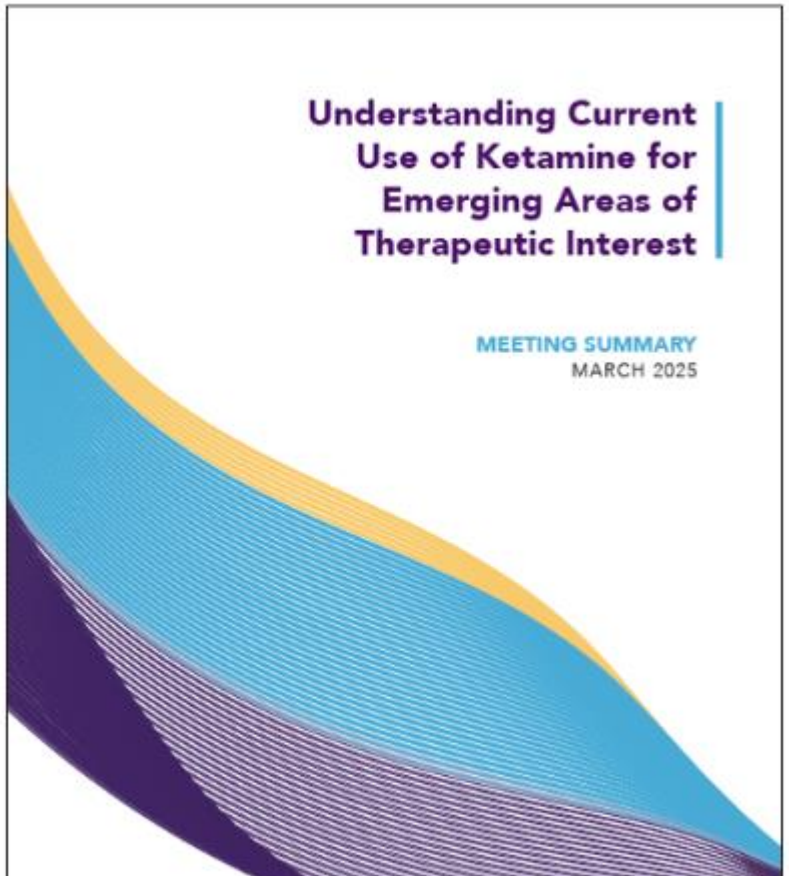
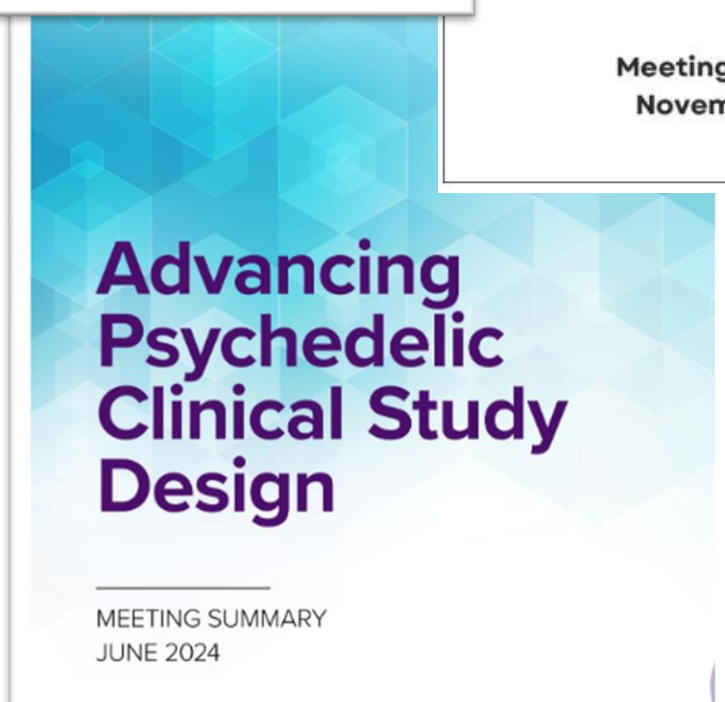
FOR THE FDA
Advancing Treatments for Post-Traumatic Stress Disor
Public Hybrid Meeti
Meeting Sum
November


Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest
MEETING SUMMARY
MARCH 2025


REAGAN-UDALL
FOUNDATION
for the Food and Drug Administration
Advancing Digital Mental Health Innovation:
COMMUNITY PERSPECTIVES SUMMARY REPORT


Advancing Psychedelic Clinical Study Design
MEETING SUMMARY
JUNE 2024

2024 Annual Report

REAGAN-UDALL FOUNDATION FOR THE FDA

2024 ANNUAL REPORT

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

REAGAN-UDALL FOUNDATION FOR THE FDA

FROM LEFT: Cecelia Calhoun, MD, MPHS, MBA, Yale University School of Medicine; Julie Makani, MD, PhD, Muhimbili University of Health and Allied Sciences, Tanzania High Commission to the UK; Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA; Peter Marks, MD, PhD, FDA; Kwasi Nyarko, PhD, World Health Organization Regional Office for Africa; Jimi Olaghere, gene therapy recipient; Hildegard Büning, PhD, Hannover Medical School; Jeremy Farrar, MD, PhD, World Health Organization (virtual)

Gene Therapies

Global Opportunities in Gene Therapies

The FDA has approved pioneering gene therapies to treat diseases such as sickle cell, thalassemia, hemophilia, and Duchenne's muscular dystrophy, and more therapies are in the pipeline. How can global regulators help bring these lifesaving discoveries to patients worldwide?

In September 2024, the Foundation gathered international experts to explore opportunities for regulatory convergence in emerging markets. During the public workshop, advocates, clinicians, regulators, academic researchers, and industry representatives highlighted concerns such as cost and ethics, as well as critical themes for international collaboration.

- Bidirectional learning
- Patient-centered approaches
- Investment in local capacity and regional infrastructure
- Long-term follow-up
- Strategies to reduce costs

Ultimately, a holistic approach is needed to make current and next generation gene therapies affordable, accessible, and sustainable in regions with limited resources.

This project was hosted in collaboration with the Bill and Melinda Gates Foundation.

> We need to find more options and give patients more time, another day to fight … I would love for this to be the last generation of sickle cell as we know it.
>
> Jimi Olaghere, gene therapy recipient

Health Data

Improving Access to Publicly Available FDA Information

From weather alerts to the latest headlines, Americans expect instant access to news and vital updates. They want that same speed and accuracy when it comes to health and medical information. The FDA's trove of critical health data holds great potential for enhancing public understanding and health care innovation. However, accessing and using the data can be tough for both consumers and professionals.

Issued in July 2024, this comprehensive Foundation report examines how audiences engage with FDA data and identifies challenges and opportunities for making information more transparent and accessible. Our investigation relied on various methods, including a landscape analysis, a review of FDA data sources, a consumer survey, and stakeholder interviews and roundtables. Patients and consumers want easy access to accurate, understandable information. For professional researchers, health care professionals, and intermediary partners, the priority is datasets that are searchable, complete, and easy to integrate into digital tools, such as websites and apps. In addition to presenting the research findings, the report extensively catalogs FDA datasets and includes metadata to improve usability.

Enhancing the transparency and usability of FDA data in innovative ways will expand the benefits of the information, empowering consumers and propelling health research and interventions.

This project was supported by Arnold Ventures and Lyda Hill Philanthropies.

> People usually already have their prescription form or their pharmacy bottle when they go to Google. There's a reasonable chance they end up on the FDA's website.
>
> Website publisher

Information that Users Seek Online

Patients and Consumers	Health Care Professionals	Professional Researchers	Intermediary Partners
• Health condition or disease • Treatment options • Side effects	• Prescription and over-the-counter drug information, including dosing, treatment duration, and potential side effects	• Pharmacovigilance and other product-specific data • Data for improving treatment and patient care at the individual level • Data for policy considerations • Commercial: real-world data for label expansion and market surveillance	• Data for B2C and B2B digital products • Health care-focused information • Structured data in the form of APIs • Support from the data providers (FDA)

Fundraising and Financial Support

REAGAN-UDALL FOUNDATION FOR THE FDA

Strong Governance

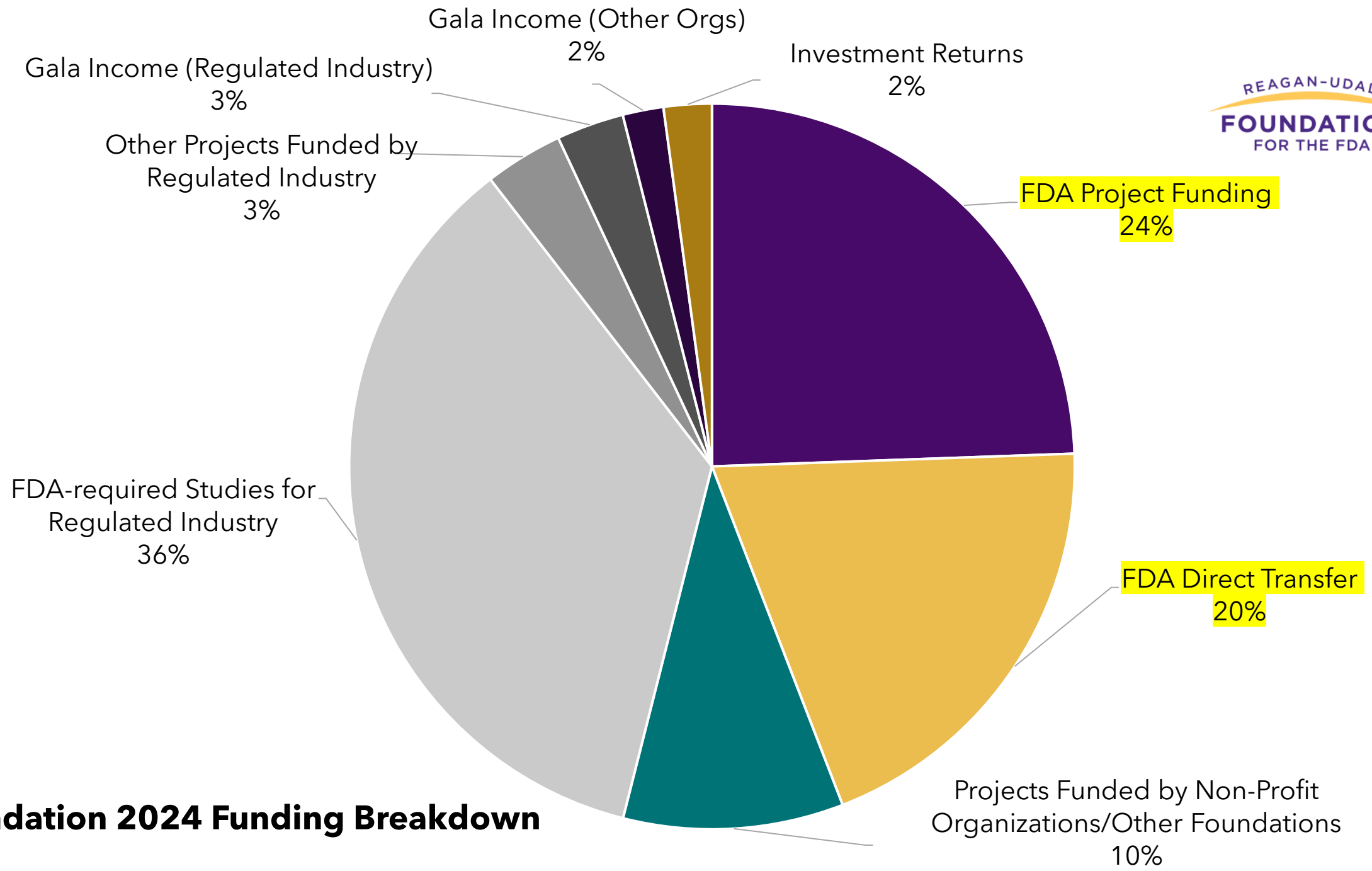
- Intentional, defined-in-statute Board structure requiring seats for consumers, health professionals, academia, and regulated industry
- Financial supporters may provide input, but the Foundation controls all projects
- Industry-supported projects require multiple sponsors
  - Exception: FDA-required studies in IMEDS

Consistent Oversight

- Board is aware of all funding and approves all donations > $250
- Mandatory Federal funding supports independence from private *and* public sector

Transparent Practices

- All funding sources and the use of all funds are reported in the Annual Report (available at reaganudall.org)
- Each project discloses funding sources



Foundation 2024 Funding Breakdown

2024 Reach

REAGAN-UDALL FOUNDATION FOR THE FDA

14 Reports

13 Public Meetings

38 Listening Sessions & Roundtables

2025 Board of Directors

REAGAN-UDALL FOUNDATION FOR THE FDA

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Adrian F. Hernandez, MD, MHS
Duke University School of Medicine

Secretary and Chair, Development Committee
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Zydowsky Consultants, LLC

Treasurer
Debra L. Ness, MS
Strategic Advisor on Consumer and Health Policy Issues

Edward John Allera, JD
Buchanan Ingersoll & Rooney PC

Christie Boutte, PharmD, RPh
National Association of Chain Drug Stores

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Apple

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University of Pennsylvania

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Veracyte

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Meharry Medical College

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Milken Institute

Phuong Khanh (PK) Morrow, MD
Takeda Oncology

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Moscicki Consulting, LLC

Pietro Antonio Tataranni, MD
PepsiCo

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

Andrew C. von Eschenbach, MD
20th Commissioner of the FDA
Samaritan Health Initiatives

Senior Advisor to the Board
Mark McClellan, MD, PhD
18th Commissioner of the FDA
Margolis Institute for Health Policy
Duke University

Ex Officio
Martin A. Makary, MD, MPH
Food and Drug Administration

Jay Bhattacharya, MD, PhD
National Institutes of Health

Panel Discussion with Foundation Board Members

REAGAN-UDALL FOUNDATION FOR THE FDA

Edward John Allera, JD

Debra L. Ness, MS
Treasurer

Pietro Antonio Tataranni, MD

Andrew C. von Eschenbach, MD

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Thank You!

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Annual Public Meeting of the Board of Directors

July 17, 2025

REAGAN-UDALL FOUNDATION FOR THE FDA