



2026

Annual Public Meeting of the Board of Directors

July 21, 2026 | 2:30pm ET

Hybrid Public Meeting

FOR VIRTUAL PARTICIPANTS



Your microphone will be muted
for the duration of the meeting.



Please submit any questions
using the **Zoom Q&A**.

The meeting will begin shortly



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WELCOME & CALL TO ORDER

Adrian F. Hernandez, MD, MHS

Chair, Board of Directors

Reagan-Udall Foundation for the FDA

Agenda



01 Welcome & Call to Order

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

02 Year in Review

Adrian F. Hernandez, MD, MHS · Susan C. Winckler, RPh, Esq. · Reagan-Udall Foundation for the FDA

03 The Year Ahead: Strategic & Scientific Priorities with FDA Leadership

Steven Kozlowski, MD · Lowell M. Zeta, JD · FDA

04 Exploring the Foundation's Impact

A discussion with members of the Board of Directors

05 Remarks from the Acting Commissioner

Kyle Diamantas, JD · FDA

06 Closing Remarks & Adjourn

Susan C. Winckler, RPh, Esq.

ABOUT THE FOUNDATION

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance the mission of the U.S. Food and Drug Administration

As a neutral convener, the Foundation brings together the FDA, patient groups, academia, industry, and government to modernize product development, accelerate innovation, and enhance the safety of the products people rely on every day

Demand Forecasting for Controlled Substances



✓ Partnership with CDER

Reviewed the forecasting techniques and data sources used to estimate medical, scientific, and reserve stock needs for Schedule I and II substances

✓ Hybrid public meeting – August 2025

Convened speakers from government agencies, the private sector, and academic research to explore the complex factors behind demand estimates

✓ Informing improvement

Findings help inform improvements in predicting demand for controlled substances, supporting FDA's annual estimates used in DEA quota-setting

Understanding Current Use of Ketamine



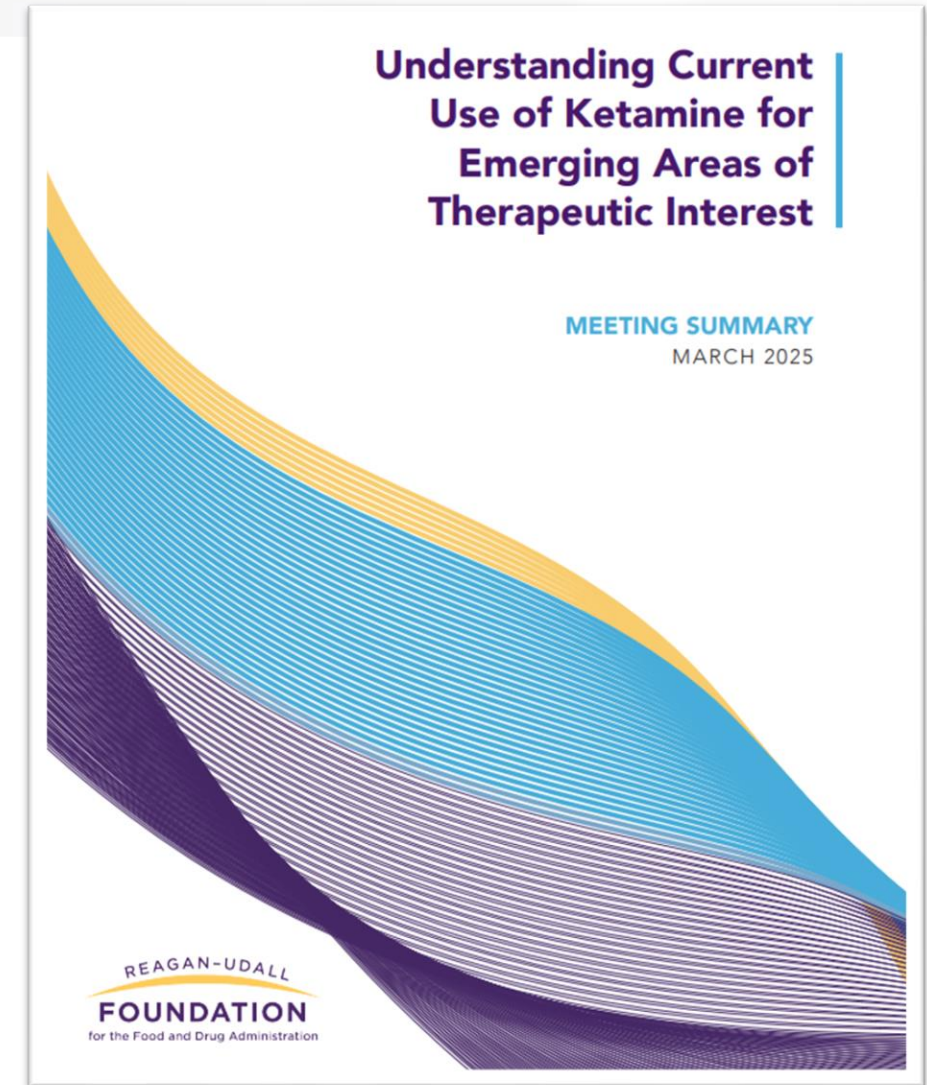
Emerging Areas of Therapeutic Interest

The Foundation convened stakeholders to examine ketamine pharmacology, emerging therapeutic uses, safety considerations, and growing online promotion and access

Pharmacology

Safety

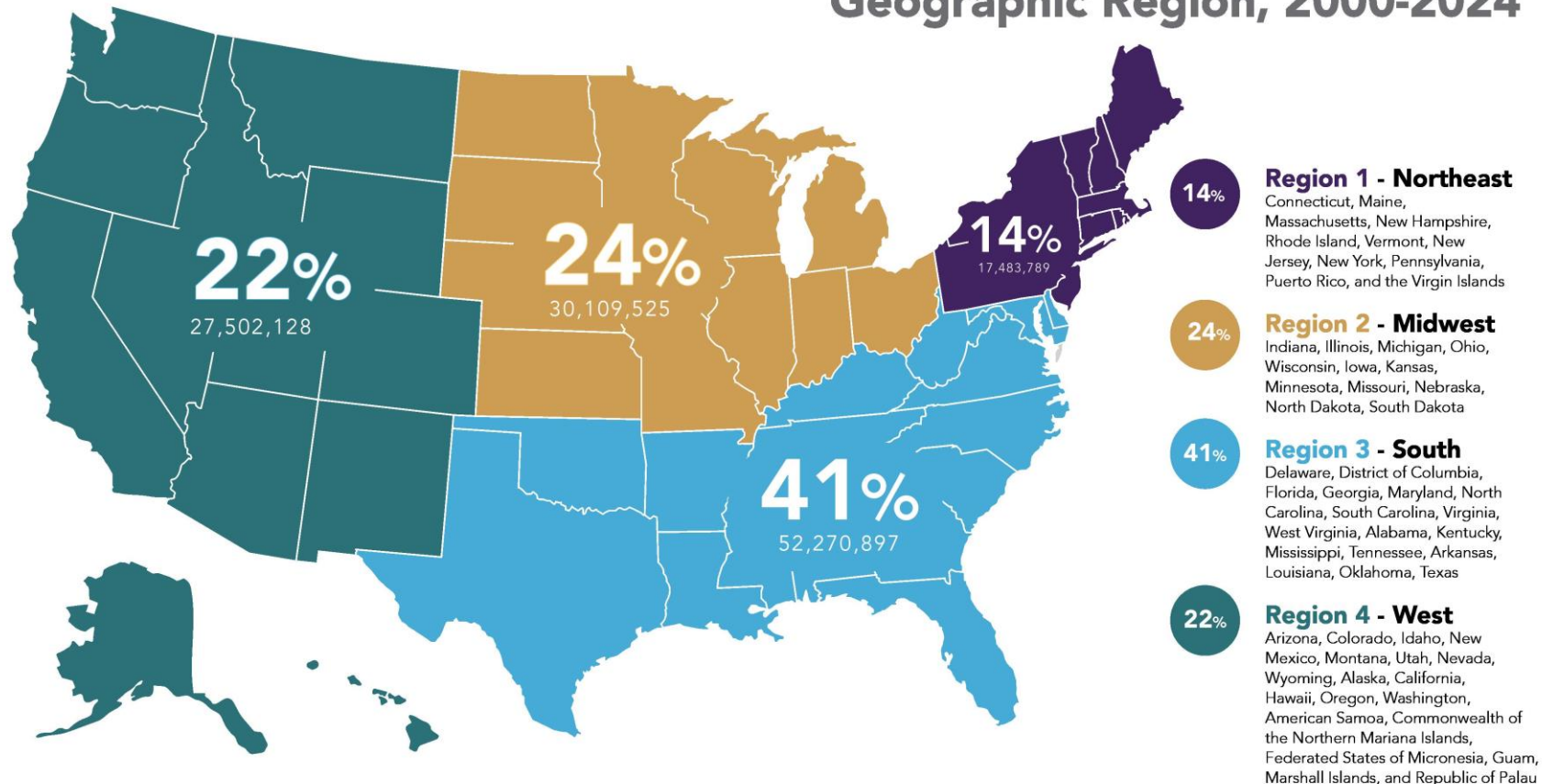
Online access



IMEDS Network by Geographic Region



Patient Distribution of IMEDS Network by Geographic Region, 2000-2024

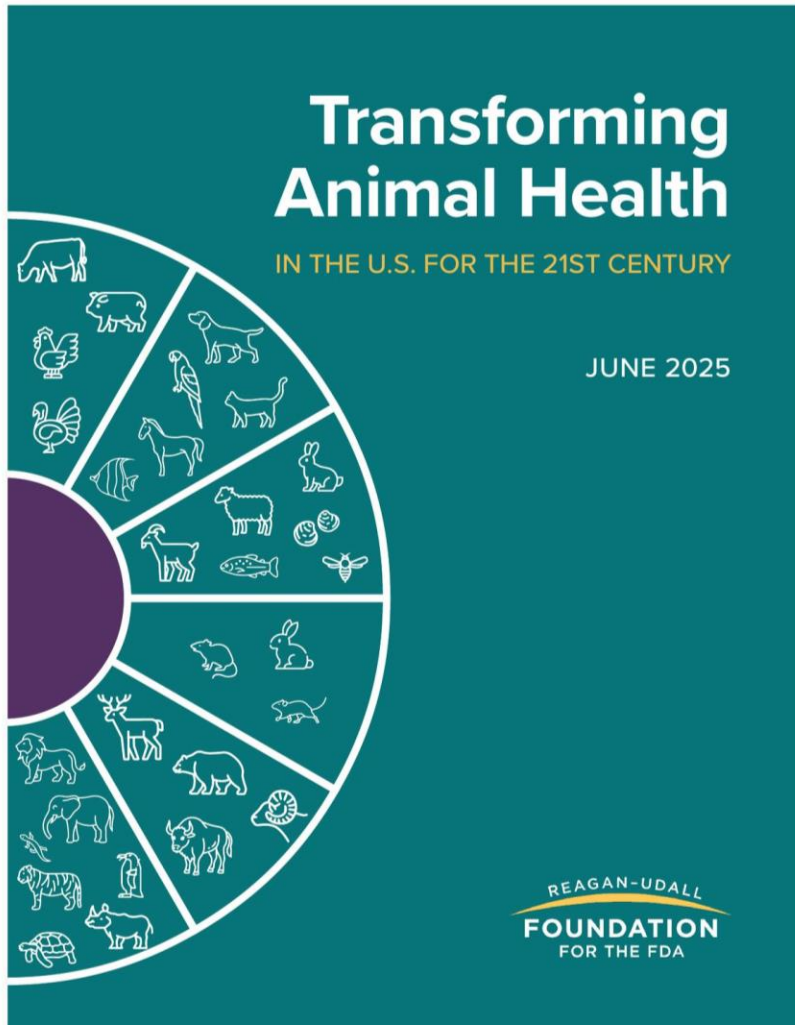


Innovation in Medical Evidence and Development Surveillance

A real-world data program supporting FDA-required post-market safety studies of approved medical products

2000-2024

Transforming Animal Health



Animal and human health are closely intertwined

The report put forward 38 recommendations to help regulators and stakeholders chart a more robust and agile regulatory framework for veterinary medicine, agriculture, and public health

38 recommendations

Addressing Cross-Sectoral Health Issues



Addressing Cross-Sectoral Health Issues: A Collaborative Approach Proposed Solutions

October 2025



Preparedness before the next animal-to-human health crisis

This work brought local, state, and federal public health, agriculture, and regulatory systems together to identify actionable opportunities for integration and readiness

Public health

Agriculture

Regulatory systems

Board of Directors



The Foundation is governed by a multi-sector Board that includes expertise from various sectors: academia, patient and consumer advocacy, FDA-regulated industry, & health care

OFFICERS

Adrian F. Hernandez, MD, MHS

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Phil Febbo, MD

Vice Chair

Lynne Zydowsky, PhD

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Margolis Institute for Health Policy, Duke University

EX OFFICIO • NON-VOTING

Kyle Diamantas, JD

Food and Drug Administration
Acting Commissioner of Food and Drugs

Jay Bhattacharya, MD, PhD

National Institutes of Health
Director

2025 ANNUAL REPORT

Read the Full Story of 2025



In the room?

Printed copies were provided as you arrived



Joining virtually?

Access the report through the link in the chat



Anytime

Find every annual report at reaganudall.org
under About > Annual Reports



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

YEAR IN REVIEW

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

Statement of Activities

Fiscal years ended December 31 · 2025 and 2024



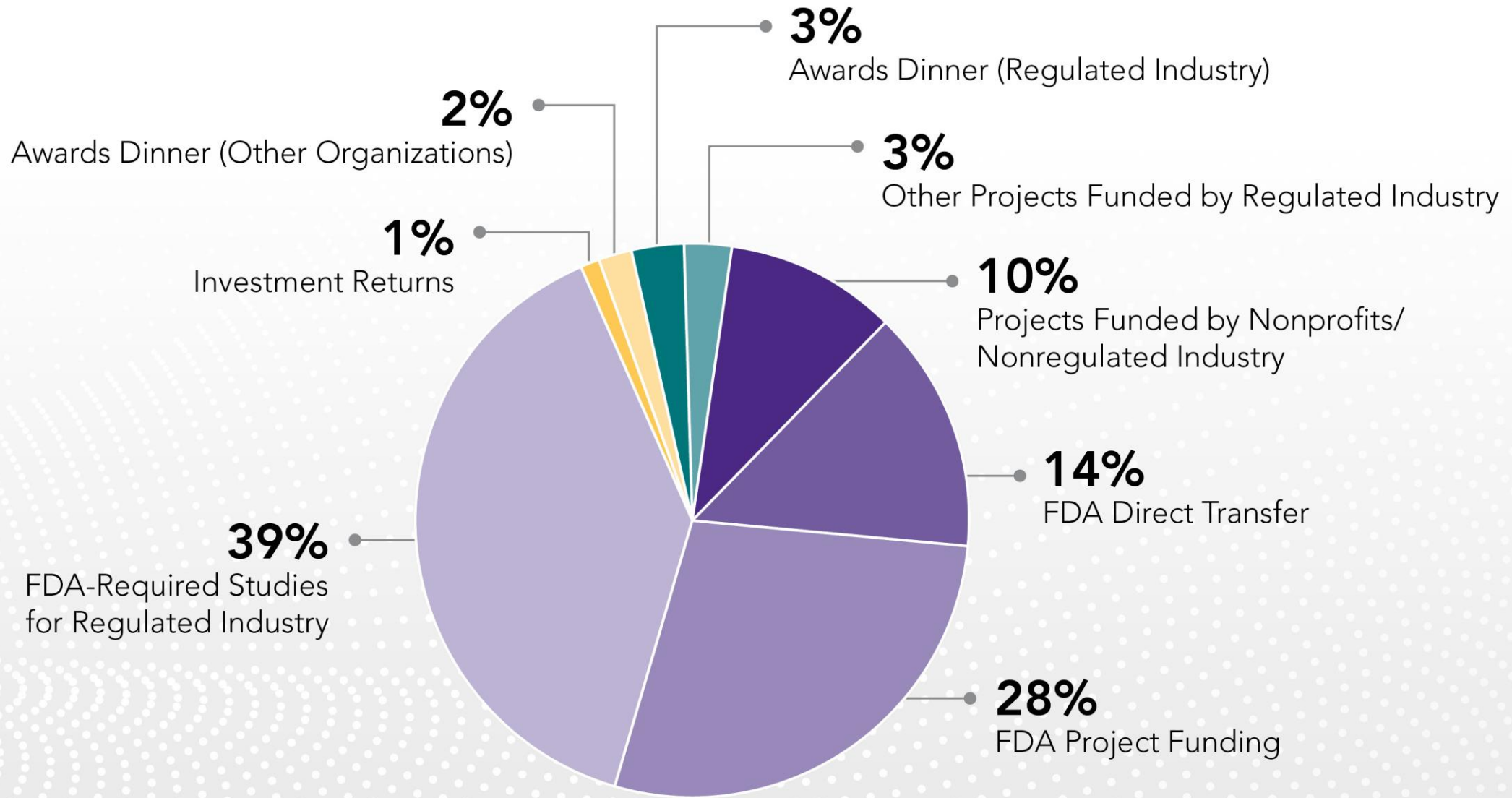
	2025	2024
REVENUE AND SUPPORT		
FDA Direct Funding*	1,250,000	1,650,000
Government Grants**	2,505,316	2,047,045
Other Grants and Contributions	291,668	690,143
Contracts	4,269,352	3,407,304
Fundraising	395,025	414,236
Miscellaneous and Interest Income	128,036	179,276
Total Revenue and Support	\$8,839,397	\$8,388,004

	2025	2024
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](https://www.fda.gov).

2025 Foundation Funding



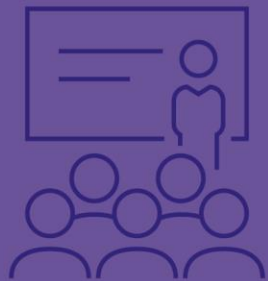


4 journal
articles
published

2025 At a Glance

7

public
meetings
convened



8

FDA patient
listening
sessions coordinated



15

workgroup
and expert panel
meetings held



14

reports
issued



27

roundtables
moderated



31

stakeholder
listening sessions
conducted



4,000+

public
comments
collected



5,000+

participants
registered
for public
meetings

6,000+

consumers, patients,
and providers polled



555,000+

web and social media
connections reached



67,000,000+

social media
posts analyzed



5 Years
74 Projects
38 Reports

Substance Use
Disorder and
Controlled
Substances

Nutrition &
Food Safety

Other

Animal Health

The Year Ahead: Strategic & Scientific Priorities



Steven Kozlowski, MD

Chief Scientist - Office of the Chief Scientist
FDA



Lowell Zeta, JD

Acting Chief of Staff, Deputy Commissioner for
Strategic Initiatives, and Special Counsel in the
Office of the Chief Counsel
FDA

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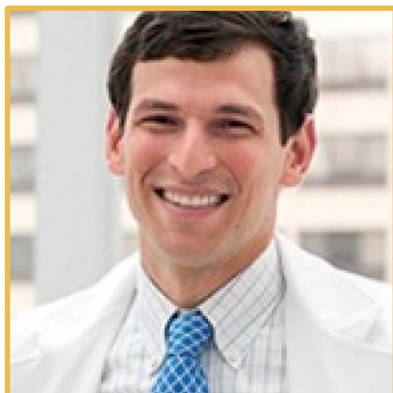
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FOR THE FDA

Exploring the Foundation's Impact



**Adrian F. Hernandez,
MD, MHS**

Board Chair



**David C. Fajgenbaum,
MD, MBA**

Board Director



**Phuong Khanh Morrow,
MD**

Board Director



**Pietro Antonio Tataranni,
MD**

Board Director



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Enhancing Early-Stage Drug Development

IN THE UNITED STATES

Recommendations Report | June 2026

Women's Health Convening



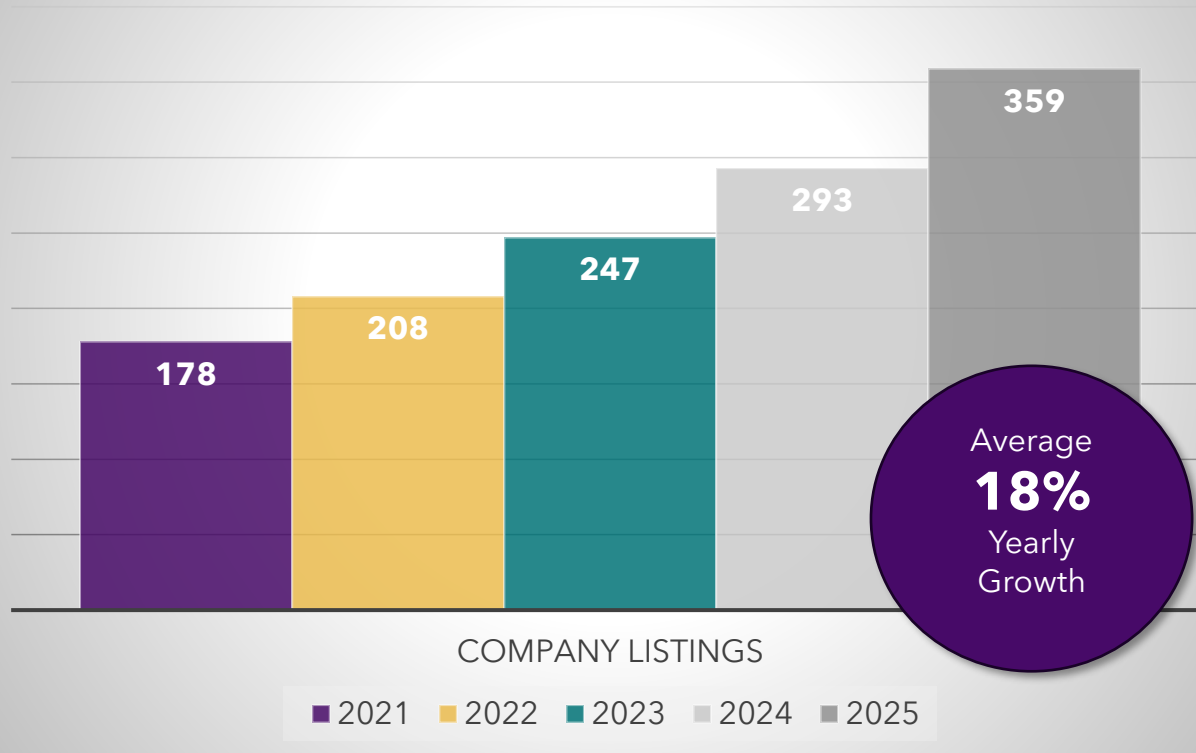
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Expanded Access Navigator

Company Directory



2025 eRequest App

- Submissions: 503
- New Users: 309

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FEATURED REMARKS

Kyle Diamantas, JD

Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration



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Thank you!

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of the Board of Directors

