Marking 10 Years

PAST, PRESENT, & FUTURE PERSPECTIVES IN FDA LAW

Thursday, May 14, 2026

Opening Remarks

Mark Gardner, Founder & Managing Partner

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Mark founded Gardner Law, specializing in FDA regulatory, compliance, privacy, commercial, and litigation matters.

Leveraging extensive in-house and private practice experience since 1999, including roles with leading healthcare companies, Mark helps clients manage complex FDA issues, regulatory strategy, due diligence, sales and marketing compliance, transparency reporting, and internal audits and investigations.

He also founded Chrysalis Incubator, where he works with inventors and early-stage teams to bring medical technologies from idea to market.

Mark interacts with FDA, CMS, OCR, DOJ, and OIG officials and teaches at University of Minnesota Law School, Mitchell Hamline School of Law, and the University of Minnesota Carlson School of Management.

Agenda

1:00 – 1:05	Opening Remarks *Mark Gardner*
1:05 – 1:40	When Issues Escalate: A Discussion on Litigation & Government Scrutiny *David Graham, Vivian Egbu, & Amanda Johnston*
1:40 – 2:15	From the Past to the Present: Leveraging FDA Experience to Shape Future Strategy *Nathan Downing, Rebecca Zadaka, Brynn Stanley, & Darya Lucas*
2:15 – 2:50	A Decade of Compliance: How Expectations Have Evolved and What Comes Next *Amanda Johnston, Lisa Damhof, & Jake Leys*
2:50 – 3:00	Refreshment Break
3:00 – 3:35	**Critical Trends in Privacy, AI, and Cybersecurity Enforcement** *Paul Rothermel & Josh Arkulary*
3:35 – 4:15	**FDA Leadership Perspectives for the Next Decade: A GC Panel Discussion** *Mark Gardner, Scott Smith, Anne Miller, Bryan Phillips, & Neil Ayotte*

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Housekeeping

- **Continuing Legal Education credits**: This course has been approved for 3 CLE credits by the Minnesota Board of Continuing Legal Education
- Please request a CLE certificate to self report in other states from office@gardner.law.
- **RAPS Course Credit**: This course has been approved for 3 RAC recertification credits.

RAPS RECERTIFICATION APPROVED PROVIDER
Regulatory Affairs Certification (RAC)

This meeting will be recorded and its materials disseminated.

When Issues Escalate

A DISCUSSION ON LITIGATION & GOVERNMENT STRATEGY

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Agenda

- Team Introductions
- Brief Overview
  - How the Government Shows Up
  - What Drives Escalation
  - How Cases Actually Unfold
- Panel Discussion
- Questions

The Evolution of Government Enforcement

FDA + State authority (Federal vs. State powers)

Core enforcement tools

Administrative: inspections, warning letters
Civil: injunctions, penalties, consent decrees
Criminal: prosecution, exclusion/debarment

Multi-agency coordination

What Drives Escalation

Risk to patients / public health

Failure to respond or remediate

Repeat issues / pattern of conduct

Lack of cooperation or credibility

Fraud / false statements

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The Lifecycle of a Government Investigation

Trigger:

- Inspection
- Complaint
- Whistleblower

Investigation tools:

- CID / EUO / interviews
- Cross-agency coordination

Resolution paths:

- Administrative action
- Civil (FCA / injunction)
- Criminal

Questions?

From the Past to the Present:

LEVERAGING FDA EXPERIENCE TO SHAPE FUTURE STRATEGY

Panelist Information

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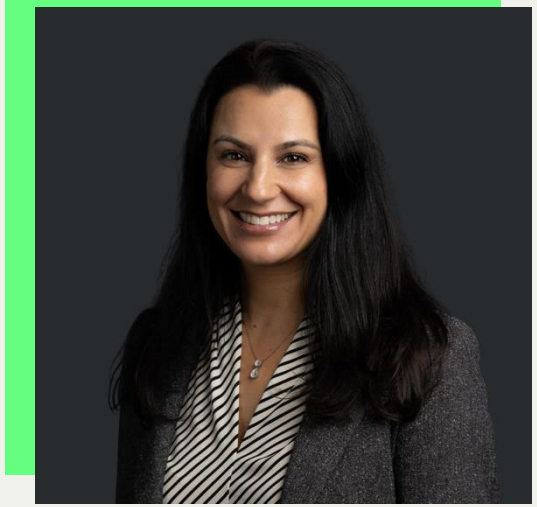

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Agenda

- Team Introductions
- FDA Update
- Panel Conversation
- Questions

FDA: A Year in Review

- Leadership Updates
- Enforcement Focus Areas
- FDA Programs to Spur Innovation
- Looking Ahead

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Regulatory Team Panel

- Lessons from the past
- Focus on the future
- Advising clients across a broad spectrum of regulatory issues

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Questions?

A Decade of Compliance:

HOW EXPECTATIONS HAVE EVOLVED, AND WHAT COMES NEXT

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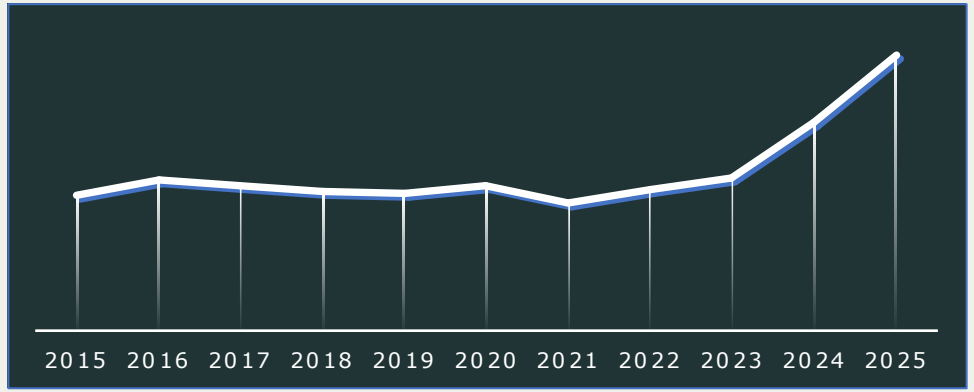
Agenda

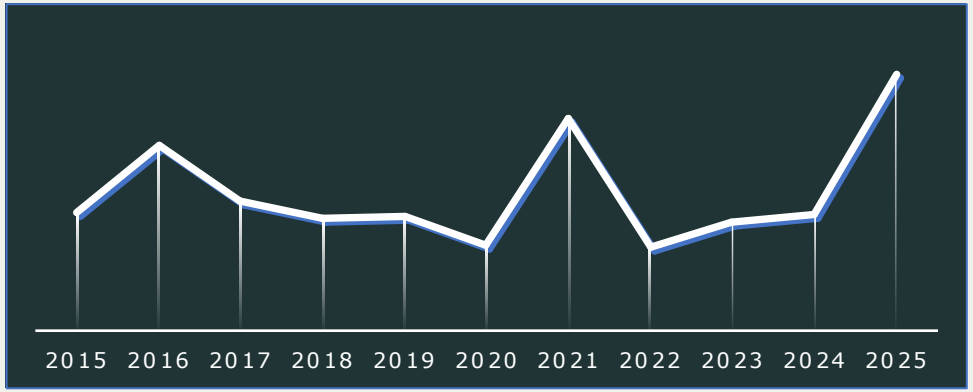
- Introductions
- FCA Recovery Trends
- Focused Risk Conversations:
  - Pricing & Discounts
  - Speaker Programs
  - Reimbursement Support
- Questions

DOJ FY2025 FCA Stats

FCA Trends: Then vs. Now

Fiscal Year	New Qui Tam Matters	New Non-Qui Tam Matters	Total Qui Tam Recoveries	Declined Qui Tam Recoveries	Relator Awards	Total FCA Recoveries
2015	639	129	$2,422,330,458	$516,875,695	$484,552,709	$3,160,772,945
2016	710	184	$3,037,685,292	$108,298,069	$555,205,423	$4,967,491,353
2017	682	176	$3,157,962,787	$602,682,052	$547,436,234	$3,456,477,586
2018	650	133	$2,210,126,638	$210,796,053	$365,857,449	$2,994,123,091
2019	641	150	$2,218,144,158	$305,554,613	$365,756,728	$3,076,174,290
2020	679	261	$1,760,847,877	$193,883,475	$337,248,044	$2,305,572,819
2021	598	212	$1,693,421,136	$482,504,272	$264,114,843	$5,710,339,956
2022	660	305	$2,006,630,594	$1,199,211,531	$500,221,987	$2,256,967,793
2023	712	506	$2,528,717,807	$499,637,944	$486,254,025	$2,898,003,215
2024	980	425	$2,629,721,006	$311,728,929	$479,204,866	$3,133,818,400
2025	1,297	401	$5,340,006,336	$2,288,271,506	$330,358,218	$6,888,096,266





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The Evolution of Pricing and Discount Risk

Enforcement Trends

- AKS violations serve as predicates for FCA liability
- AKS enforcement focus has sharpened around how pricing incentives are structured—not whether discounts exist

Advisory Opinion 25-11 (Dec. 2025)

- Reflects more flexibility and openness to a range of discount models
- Risk Signals:
  - Discounts tied to services/non-product benefits rather than pure price reductions
  - Bundled discounts across products reimbursed under different federal programs/methodologies
  - Failure to ensure customer can accurately report discount amount
- Government is showing more flexibility

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The Changing Landscape of Speaker Programs

HHS-OIG 2020 Special Fraud Alert: Speaker Programs

- **Suspect Characteristics:** Alcohol available (or free), venue purpose, repeated topic, Attendees w/out legitimate need, sales/marketing influence, and more!

Enforcement Trends

- **Gilead Sciences (April '25) $202M**
  - **What Happened:** Speaker programs allegedly used honoraria, meals, travel, and luxury venues to engage high-prescribing HCPs, with minimal incremental educational value.
  - **Lesson:** Venue choice, repeat attendance, and prescriber targeting are treated as evidence of intent
- **Pfizer/Biohaven (January '25) $59.7M**
  - **What Happened:** High-end meals and paid speaker programs were allegedly used to induce prescribing, including repeat, low-value programs during the COVID era
  - **Lesson:** Repeat attendance and low educational value quickly convert "education" into inducement risk.

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Reimbursement Support Compliance:
Then, Now, and What's Next

Reimbursement Support

- Benefits verification • Prior auth • Appeals • Coding/billing guidance

Enforcement Landscape

- Limited direct enforcement on reimbursement support programs
- Risk inferred from adjacent cases, OIG guidance, and Advisory Opinions

What Drives Risk

- Free services as value • Influence over outcomes • Provider burden relief • Steering

Risk Mitigation

- Program design, controls, and clear boundaries between support and influence

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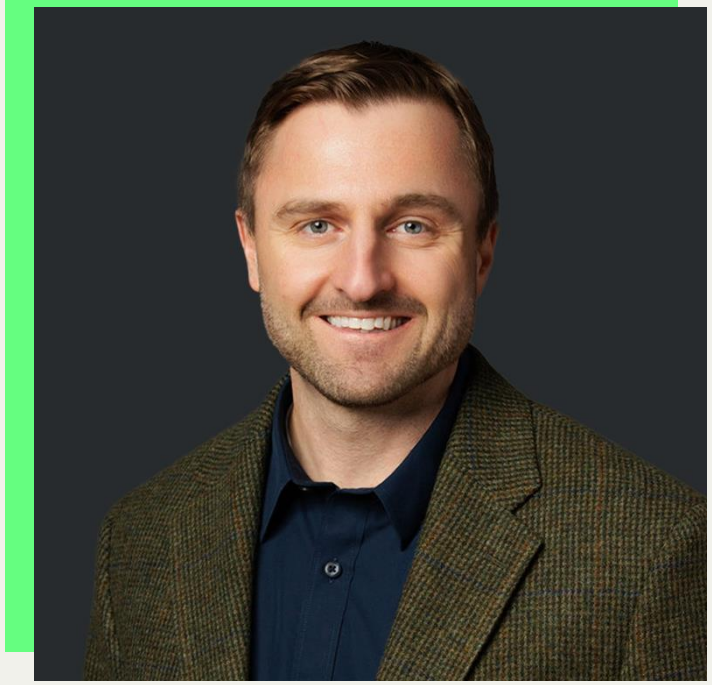
Questions?

We are taking a brief break. The program will resume at 3:00 p.m. CDT

Critical Trends

IN PRIVACY, AI, AND CYBERSECURITY ENFORCEMENT

Presenter Information



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U.S. Privacy Law 2016 vs. 2026

2016

- Health Insurance Portability and Accountability Act
- State medical records laws
- Children’s Online Privacy Protection Act
- Section 5, FTC Act and Health Breach Notification Rule
- Telephone Consumer Protection Act

2026

- California Consumer Privacy Act, California Privacy Rights Act, and new regulations
- 20 states with comprehensive privacy laws
- Consumer health data laws (Washington, Connecticut, Nevada)
- California Invasion of Privacy Act; wiretapping laws
- AI governance laws

Shifting Enforcement Landscape

2016

- Cybersecurity failures and breaches
- Inaccurate privacy policies
- HIPAA
- TCPA litigation

2026

- “Know your data”
- Artificial intelligence
- Business models (data brokers, ad tech)
- Secondary data use/sharing
- Online tracking technologies

Online Tracking Technology

- Cookies: Can involve website visit tracking and third-party data sharing.
- Session replay: Records interactions with website or app, can include all movement/scrolling, inputs, and clicks.
- Fingerprinting: Collects data points from device, browsers, etc. to create a unique digital signature for that device. Can bypass private browsing modes to track users that reject cookies.
- Tracking pixels/web beacons: Embedded in webpage or email. Collect user activity on webpage.
- SDKs (Software developer kits): Used in mobile apps and can involve data sharing with SDK provider.
- Mobile device ID/advertising ID: Some apps collect this ID and link to app usage.

Privacy Claims and Enforcement

GoodRx: Privacy Policy = Promise

Key allegations from FTC complaint

- Shared consumer health data with ad/analytics parties including Meta/Google/Criteo via online tracking mechanisms
- Privacy policy promises didn't match sharing
- HIPAA seal implied compliance with stringent HIPAA rules
- Lacked governing policies and procedures for handling health information
- Accepted standard terms from third party partners and vendors, including adtech companies, without evaluating how they were using and sharing consumer health information

GoodRx: Privacy Policy = Promise

Enforcement Theory

- FTC framed "breach" to include unauthorized disclosure (not just hacking) to argue violation of Health Breach Notification Rule (HBNR)
- Deceptive statements (privacy promises) used as core narrative for violation of Section 5 of FTC Act
- FTC first enforcement action under the HBNR

GoodRx: Privacy Policy = Promise

- **Results:** Proposed order includes $1.5M civil penalty and restrictions on sharing health data for advertising

- **Implications for FDA-regulated industry:**
  - Be wary of accepting standard terms from third-party partners and vendors
  - Consider non-monetary impact of violations – ban on using consumer information for advertising, mandatory privacy program and oversight, consumer notification, among other consequences
  - Privacy policy promises must match actual data practices

Other similar FTC cases

- BetterHelp
  - July 14, 2023:

FTC Gives Final Approval to Order Banning BetterHelp from Sharing Sensitive Health Data for Advertising, Requiring It to Pay $7.8 Million

FTC alleges online counseling service shared consumers' sensitive data with third parties after promising to keep it private

- Monument
  - April 11, 2024

Alcohol Addiction Treatment Firm will be Banned from Disclosing Health Data for Advertising to Settle FTC Charges that It Shared Data Without Consent

FTC says Monument shared consumers' health data with third-party advertising platforms without consent

April 11, 2024

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Sephora: CCPA Enforcement Begins (2022)

- First major CCPA enforcement case (Aug. 2022). Allegations included:
  - **Failure to Disclose Data Sale:** Sephora failed to disclose that it was "selling" personal information through the use of third-party trackers (cookies, pixels) on its website and app
  - **Missing opt-out link:** Lack of conspicuous "Do Not Sell My Personal Information" link, and not recognizing user-enabled **Global Privacy Control (GPC)** signal

  Result:
  - **$1.2 million penalty and 2-year monitoring: Company must** assess and report on its compliance with opt-out processing

Healthline:
Enforcement and Health Information (2025)

Key allegations:

- Shared data with third parties for targeted advertising purposes despite opt-out requests
- **Used misleading cookie banners** that claimed to disable tracking cookies
- **Shared** article titles read by users with ad tech that inferred sensitive health conditions (e.g., HIV, cancer, MS)
- Failure to ensure contracts with ad tech partners contained mandatory privacy terms

Results:

- $1.55 million settlement
- **Injunction** prohibits Healthline from sharing further health data with third parties for advertising purposes

healthline

Disney: Opt-Outs Apply to Infinity and Beyond

- Settlement in February 2026 for Disney's alleged failure to honor consumer opt-out requests from sale/sharing across all platforms and services
- The California AG found that a user would potentially have to opt-out across as many as 10 different services and other devices to effectively opt-out of sale/sharing
- Key takeaway:
  - Opt-out request made by consumer should be applied across all services/platforms associated with their account, not only on the specific service where the opt-out request is submitted
  - FDA-regulated industry – with the various services consumers might interact with (websites, mobile apps, etc.) it's important that consumers are able to opt-out from sale/sharing without separately making requests through each service and device

“Pixel” Litigation

What’s Driving It

- Plaintiffs repurposing California Invasion of Privacy Act (CIPA) and other ”wiretapping” or computer fraud laws for web tracking claims
- Targets include Meta Pixel, analytics, session replay, chat functions
- Courts divided

Mitigation

- Inventory website and mobile app tracking tools; know what data is collected and when and who is receiving it
- Explicit consent via opt-in vs. implied consent with opt-out

What Comes Next?

What’s Next?

- Artificial intelligence and automated decision-making technology
- Privacy risk assessments
- Shifting cybersecurity requirements

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Questions?

FDA Leadership Perspectives for the Next Decade

An Industry Panel Discussion

Moderator Information

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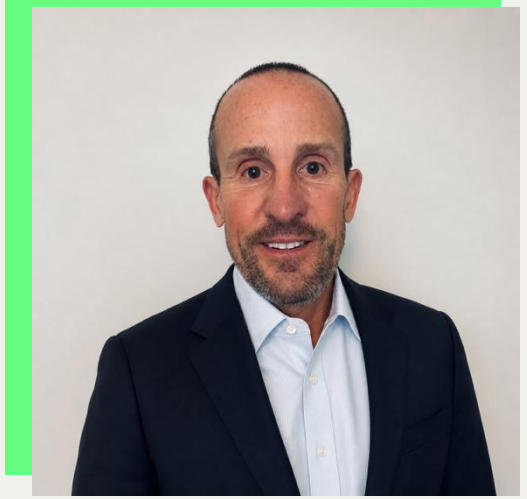

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Questions?

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