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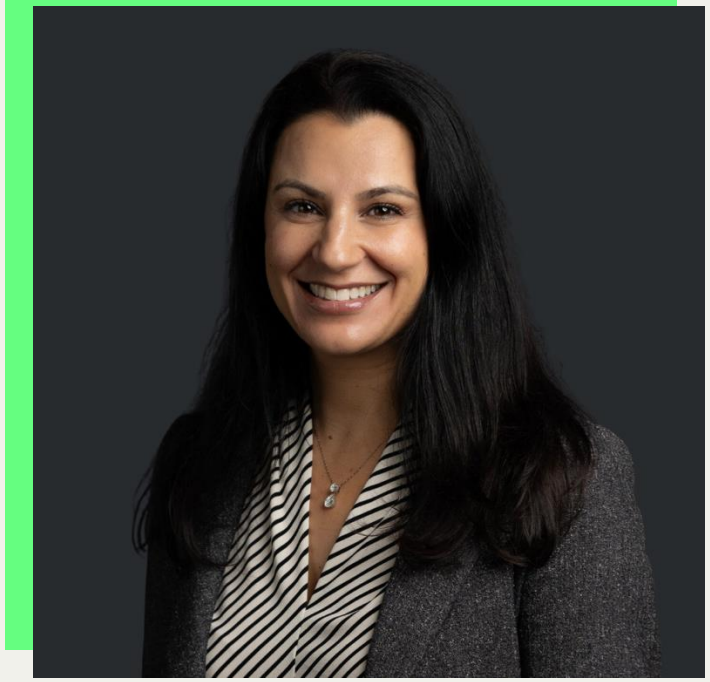
Saison-al Session

A LEGAL UPDATE FOR FDA-REGULATED INDUSTRY

From the Team at Gardner Law

Thursday, May 22

Emcee Introduction



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- Represents medical device and pharmaceutical clients in FDA-related matters
- Advises clients across all stages of product lifecycle, including:
  - Product Development
  - Commercialization
  - Post-market surveillance
- Expertise in:
  - Regulatory Strategy
  - Product Submissions
  - Advertising and Promotion
  - Clinical Research

Agenda

12:00 – 12:30	*What's Brewing in Compliance? Hot Topics and Enforcement Trends* Amanda Johnston & Katy Herman
12:30 – 1:00	*Tapping into FDA: Regulatory Hot Topics* Nathan Downing, Rebecca Zadaka, & Brynn Stanley
1:00 – 1:30	*Pour Decisions: Lessons from Health Care Fraud & Liability Cases* David Graham
1:30 – 1:45	*Refreshment break*
1:45 – 2:15	*Hot or Cold? A Privacy Enforcement Update* Paul Rothermel
2:15 – 3:00	*Panel Discussion* Mark Gardner, with Jonelle Burnham (CVRx), Bryan Phillips (Inspire Medical), Wendy Cusick (CoNextions Medical)

Program Introduction

- This program is being recorded, and the recording will be available post-event.
- Slides are available during the presentation via the handout window on the control panel.
- Remote participants: Please submit questions via the question function on the control panel.
- CLE credits: 2.75 credits are pending approval by the Minnesota Board of Continuing Legal Education. The CLE approval code will be sent out in a program follow-up email. Please request a CLE certificate to self-report in other states from office@gardner.law.
- RAPS Recertification Credits: This course has been approved for 2.5 RAC credits

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What’s Brewing in Compliance?
Hot Topics and Enforcement Trends

Amanda Johnston & Katy Herman

Thursday, May 22

Presenter Information

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Topics to Cover

- Key Enforcement Statutes
- FY 2024 Enforcement Trends
- DOJ Priorities for FY 2025
- Emerging Themes
- Case Spotlights
- Q&A + Open Discussion

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Key Enforcement Statutes

False Claims Act (FCA) – 31 U.S.C. §§ 3729–3733

- Prohibits knowingly submitting false or fraudulent claims to the government
- Includes civil penalties, treble damages, and whistleblower (qui tam) provisions
- Common theories: off-label promotion, medically unnecessary services, improper billing

Anti-Kickback Statute (AKS) – 42 U.S.C. § 1320a-7b(b)

- Criminal statute prohibiting offering, paying, soliciting, or receiving remuneration to induce referrals for items/services reimbursed by federal healthcare programs
- Violations render claims false under the FCA
- Applies to payments to physicians, marketers, co-pay foundations, and more

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Why These Matter

- The False Claims Act & the Anti-Kickback Statute are used together
- They are central to DOJ's focus on sales practices, marketing strategies, and financial arrangements with HCPs

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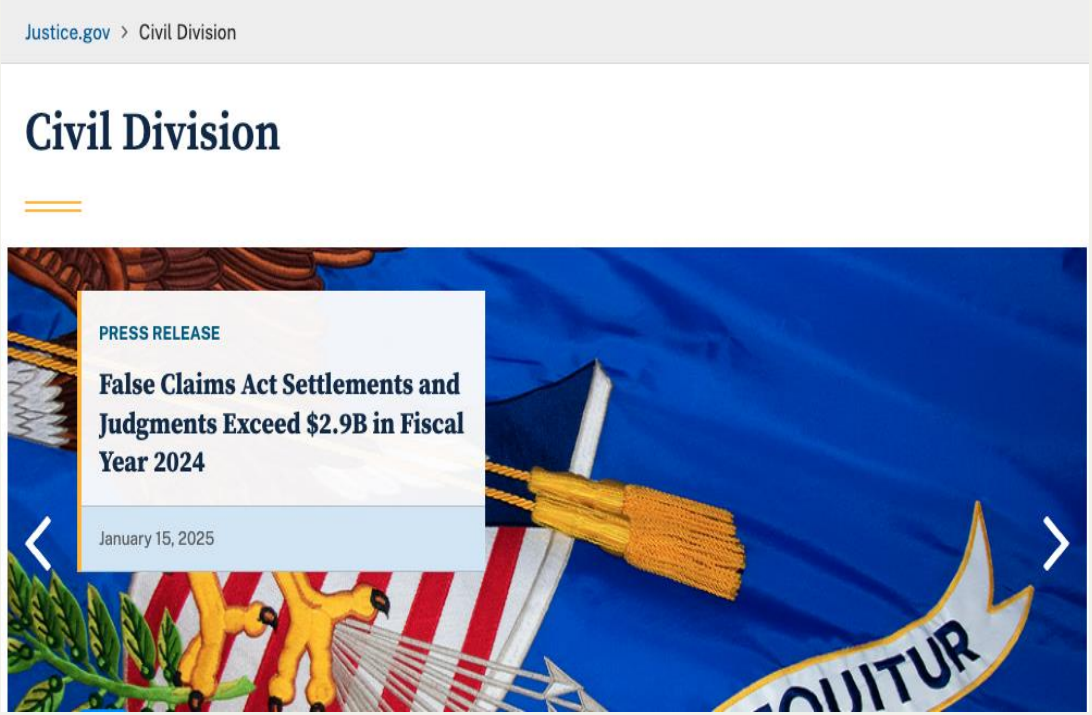
False Claims Act Enforcement FY 2024

- Total Settlements & Judgments: $2.9 billion
- Number of Qui Tam Lawsuits: 979 (highest in history)
- Total Settlements & Judgments Since 1986: $78 billion
- Total Cases Resolved: 558 (2nd highest after 2023's record of 566)



https://www.justice.gov/archives/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024

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What DOJ Is Saying

"We will aggressively enforce the FCA…"
– DOJ, Feb. 20, 2025 speech

DOJ reaffirmed its commitment to FCA enforcement, aligning with the new administration's priorities:

- Government efficiency
- Waste and fraud prevention
- Accountability across healthcare and life sciences

Emerging Questions:

- Will DOJ scrutinize DEI-linked funding or programs under FCA?
- Will we see DEI-related qui tam suits?

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Key Themes & Practical Risks

- FCA enforcement is bipartisan and accelerating
- Whistleblower activity is at an all-time high
- Commission-based rep models are under scrutiny
- Use of speaker programs, foundations, and coverage support tools continues to draw DOJ focus
- FDA labeling and safety missteps can result in FCA exposure
- Financial arrangements with HCPs still in focus
- Medicare Advantage, telehealth, and genetic testing are emerging hot zones

Recent Cases

Kickbacks & Foundations

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FCA Settlement: Teva Pays $425M for Co-Pay Kickback Scheme

Largest Settlement to Date Involving Charitable Foundations

- **Overview**
  - Teva paid $425 million to resolve allegations it used co-pay foundations to funnel kickbacks for its MS drug, Copaxone
  - From 2006–2017, Teva coordinated with third parties to steer donations to Copaxone patients
  - Meanwhile, Teva increased Copaxone's price by thousands of dollars
  - Alleged violation of Anti-Kickback Statute and False Claims Act
- **Key Takeaways**
  - DOJ targeting use of charitable foundations to mask kickbacks
  - Medicare co-pays are meant to act as cost control, not be bypassed by pharma
  - Co-pay assistance tied directly to prescription volume = AKS risk

 **Oct 2024**  **DOJ-Led** 

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Pfizer Pays $60M for Biohaven Kickback Allegations

- **Overview**
  - Pfizer (via Biohaven) agreed to pay $59.7 million to resolve claims that Biohaven paid kickbacks to induce prescriptions of Nurtec ODT
  - Payments included honoraria, high-end meals, and repeat speaker programs
- **Allegations**
  - Speaker payments used to influence prescribing behavior
  - Attendees included spouses, friends, and repeat HCPs with no educational need
  - Conduct ended when Pfizer acquired Biohaven and shut down the programs
- **Takeaway**
  - Reinforces DOJ scrutiny of speaker programs
  - Reminder: intent matters—educational value must be genuine

📅 **Jan 2025** 👤 **Qui Tam Case** 💰

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DOJ Targets Speaker Programs: *U.S. v. Gilead Sciences* (S.D.N.Y. 2025)

Allegations:

- Gilead paid $23M+ in kickbacks (honoraria, meals, travel) to physicians through 17,000+ "HIV Speaker Programs" from 2011–2017
- Programs were held at lavish venues (e.g., James Beard House), often with repeat attendees and little educational value
- Some HCPs received $300K+ in honoraria and prescribed millions in HIV drugs reimbursed by Medicare, Medicaid, TRICARE & ADAP
- Gilead's compliance monitoring failed to detect or prevent abuse, despite internal warnings

Legal Theories:

- AKS violation = FCA liability under 42 U.S.C. § 1320a-7b(g)
- Counts: (1) Causing false claims; (2) Causing false records; (3) Unjust enrichment
- Seeks treble damages + civil penalties

Key Takeaways:

- DOJ continues targeting speaker programs as kickback vehicles
- Lavish settings + poor controls = high-risk profile
- Reinforces need for robust monitoring and FMV documentation for HCP engagements

 **Apr 2025**  **Qui Tam Case**  **$202M**

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AKS & Commission-Based Reps: Legal Landscape

Fifth & Seventh Circuits Reject Per Se AKS Violations for Commission-Based Pay

Legal Update:

- *Mallory* (2021, 4th Cir.) held that volume-based pay to 1099 agents violates AKS
- *Sorensen* (2025, 7th Cir.) & *Marchetti* (2024, 5th Cir.): Volume-based pay to independent sales agents not automatically illegal under AKS
- Focus: Did agents unduly influence provider decisions?

Compliance Takeaways:

- 1099 commissions = risky, but not banned
- Key risk factors: Direct contact with prescribers, acting on behalf of HCPs, separately reimbursable items
- Consider de-risking via policy limits or restructuring

Off-Label & Safety Risks

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Diopsys to Pay Up to $14.25M for Improper Vision Test Claims

- **Overview**
  - Allegations: Diopsys caused submission of false Medicare/Medicaid claims for uncleared ERG testing using its NOVA device
  - NOVA was cleared for VEP testing, but used for electroretinography without FDA clearance
  - Diopsys allegedly modified the device without FDA re-submission
- **Settlement Terms**
  - $1.2M guaranteed, up to $14.25M total based on financial condition
  - Whistleblower (Dr. Jain) to receive at least $207K
- **Takeaway**
  - Use of devices outside FDA-cleared indications can lead to FCA liability
  - Emphasizes compliance risk when promoting unapproved uses to providers

 **Mar 2025**  **Qui Tam Case**  **Up to $14.25M**

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Assertio Pays $3.6M for Improper Fentanyl Marketing

- **Overview**
  - Assertio (formerly Depomed) paid $3.6 million to settle claims it caused false Medicare/TRICARE claims for Lazanda, a fentanyl nasal spray
  - Allegedly marketed for non-approved uses in patients without breakthrough cancer pain
- **Key Allegations**
  - Targeted high-volume prescribers, some flagged for diversion or indicted
  - Used speaker programs and advisory boards to boost prescribing
  - "Signature Support Program" allegedly helped secure insurance approvals improperly
- **Takeaway**
  - Reinforces risk of off-label marketing (especially for opioids)
  - Heightened scrutiny where patient safety and public health are implicated

 **May 2025**  **Qui Tam Case**  **$3.6M**

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FCA Settlement: Prometheus Pays $550K for Unsafe Device Reuse

- **Overview**
  - Prometheus Group and its owner paid $550,000 to settle allegations they caused providers to bill Medicare for reused single-use devices
  - Devices included rectal sensors and catheters used in pelvic floor therapy
  - Prometheus allegedly encouraged reuse with gloves/condoms to cut costs
  - Devices were labeled as single-use/single-user only per FDA clearance
- **Takeaway**
  - Reusing devices against FDA labeling can lead to FCA liability
  - DOJ continues to target device safety violations linked to billing fraud

March 2025 DOJ-Led $550K

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Emerging FCA Risks

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Genetic Testing & Telehealth Under Scrutiny: *U.S. v. Genexe et al.* (E.D. Pa. 2025)

Overview:

- Genexe, Immerge, and two execs paid $6M to settle FCA claims over kickback-tainted genetic tests (CGx & PGx)
- Tests were medically unnecessary and billed to Medicare at up to $6,000/test
- Genetic Testing Kickback Scheme – $6M Settlement

Allegations:

- Untrained marketers collected DNA samples at senior centers & malls
- Telemedicine providers "rubber-stamped" test orders for payment
- Labs kicked back funds to Genexe, Immerge & sales reps

Takeaway:

- Reinforces DOJ focus on genetic testing fraud and telehealth abuse
- Compliance risk for labs and marketers using commission-based models


Mar 2025


Qui Tam Case


$6M

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Medicare Advantage in Focus: *U.S. v. eHealth et al.*

Allegations:

- Aetna, Humana & Anthem paid disguised kickbacks to brokers (eHealth, GoHealth, SelectQuote)
- Brokers steered seniors to higher-paying MA plans while claiming to be "unbiased"; Kickbacks masked as "marketing" or "co-op" fees
- Aetna & Humana allegedly discouraged enrollment of beneficiaries with disabilities

Key FCA/AKS Issues:

- Kickback-tainted claims = FCA violations (42 U.S.C. § 1320a-7b(g))
- False certifications in MA contracts
- CMS discrimination rules used as FCA hook

Why It Matters:

- DOJ intensifying focus on Medicare Advantage
- Case bridges AKS, FCA, and civil rights enforcement
- Internal emails showed awareness of noncompliance
  - "This payment model is not even a little compliant…"
  - "CMS will never figure that one out… Luckily the govt are generally morons."

 **May 2025**  **Qui Tam Case**  **Litigation Ongoing**

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Compliance Takeaways

- Review commission structures and speaker programs
- Monitor charitable support and foundation interactions
- Ensure HCP engagement is FMV and properly documented
- Avoid device use outside FDA-cleared indications
- Address device safety issues

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Questions

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Tapping into FDA

Regulatory Hot Topics

Nathan Downing, Rebecca Zadaka, & Brynn Stanley

Thursday, May 22

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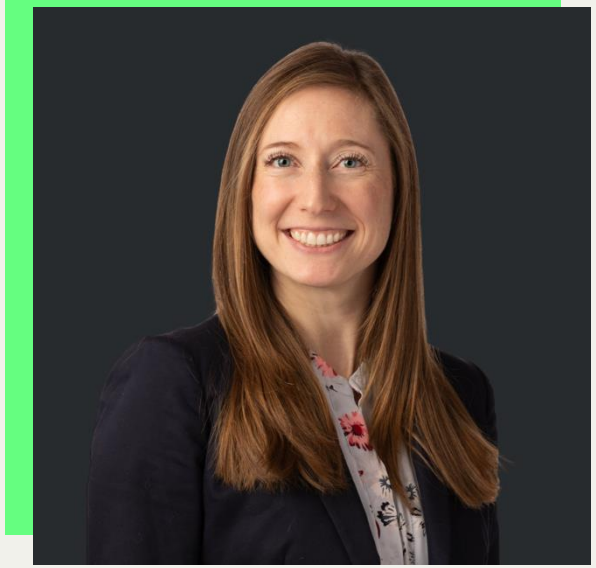

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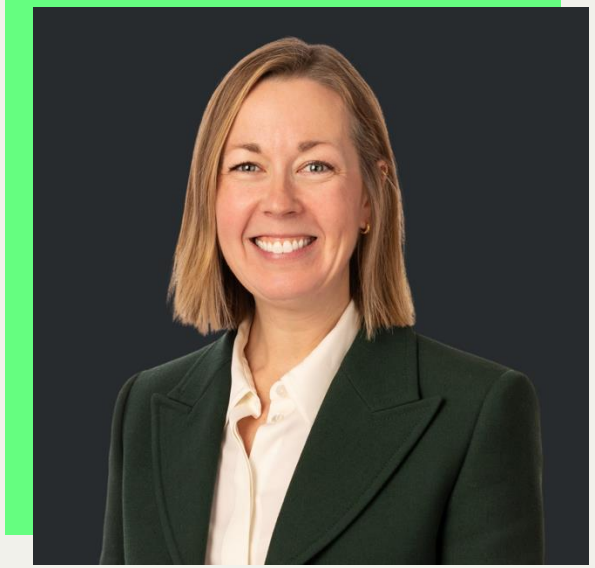

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A Changing FDA

Staffing changes

Policy updates

Enforcement pursuits

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How to Approach a Changing FDA

OVERALL APPROACH TO REGULATORY STRATEGY

MAINTAINING AUDIT READINESS

PROMOTIONAL MATERIAL

ADAPTING TO FDA

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Proposed changes to GRAS and food ingredient regulation

- Currently, if a food ingredient is added to food, it's a food additive, unless it is "Generally Recognized as Safe" or GRAS—how does this system work?
  - What is being proposed to change with food regulation and GRAS?
- Are there benefits to the current system?
- What would be a reason to change the way that food ingredients are determined to be “GRAS”?
- What happens if the GRAS pathway is eliminated?

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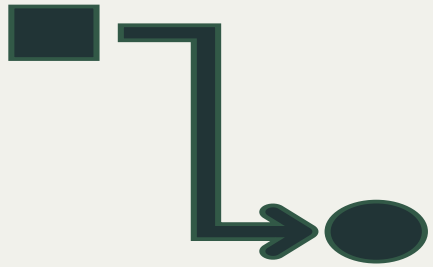
FDA Inspections

The FDA is intensifying unannounced foreign inspection efforts, despite recent staffing reductions.

Manufacturers are advised to improve global readiness by strengthening their compliance through mock inspections, updating training protocols and review of documentation and Quality Management Systems.

What operational changes can manufacturers implement now to reduce risk during FDA's expanded foreign inspections?



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Ad promo updates

- Despite all the recent changes at FDA, there have still been three untitled letters in 2025. **What has FDA enforcement looked like recently relating to warning or untitled letters?**
- Targeting an HCP speaker deck is rare for FDA—usually FDA is most concerned with the consumer-facing material, **so what happened?**
- 2024 saw many untitled letters sent to companies relating to ads on social media. **Are there any added risks of placing promotional material on social media as opposed to other channels?**

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Deregulation

HHS and the FDA issued a Request for Information (RFI) seeking public input on which regulations could be modified or eliminated to lower healthcare costs and reduce administrative burdens.

Under the directive, HHS must eliminate ten regulations for every new one, reduce overall regulatory costs below zero in FY 2025, broaden oversight to include informal policies, and publish annual reports to enhance transparency.

What are the potential impacts this may have on manufacturers?

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DTC Advertising

- RFK has suggested banning DTC pharmaceutical ads from tv, which has sparked debate. **What are the main reasons for supporting this ban?**
- **What are some challenges that could come up from banning these ads?**
- Alternative measures could be less expansive, such as stricter regulations surrounding things like price disclosures or limiting ads for drugs until its safety profile is better understood—**what might some of these alternative measures look like?**

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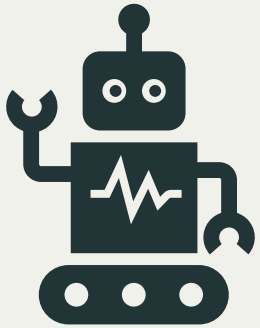
AI-Assisted Scientific Review Pilot

Earlier this month, the FDA announced completion of its first pilot using AI to assist in scientific review

The agency plans an aggressive expansion of AI use across all FDA centers by June 30, 2025

How might this change the review process?



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Questions

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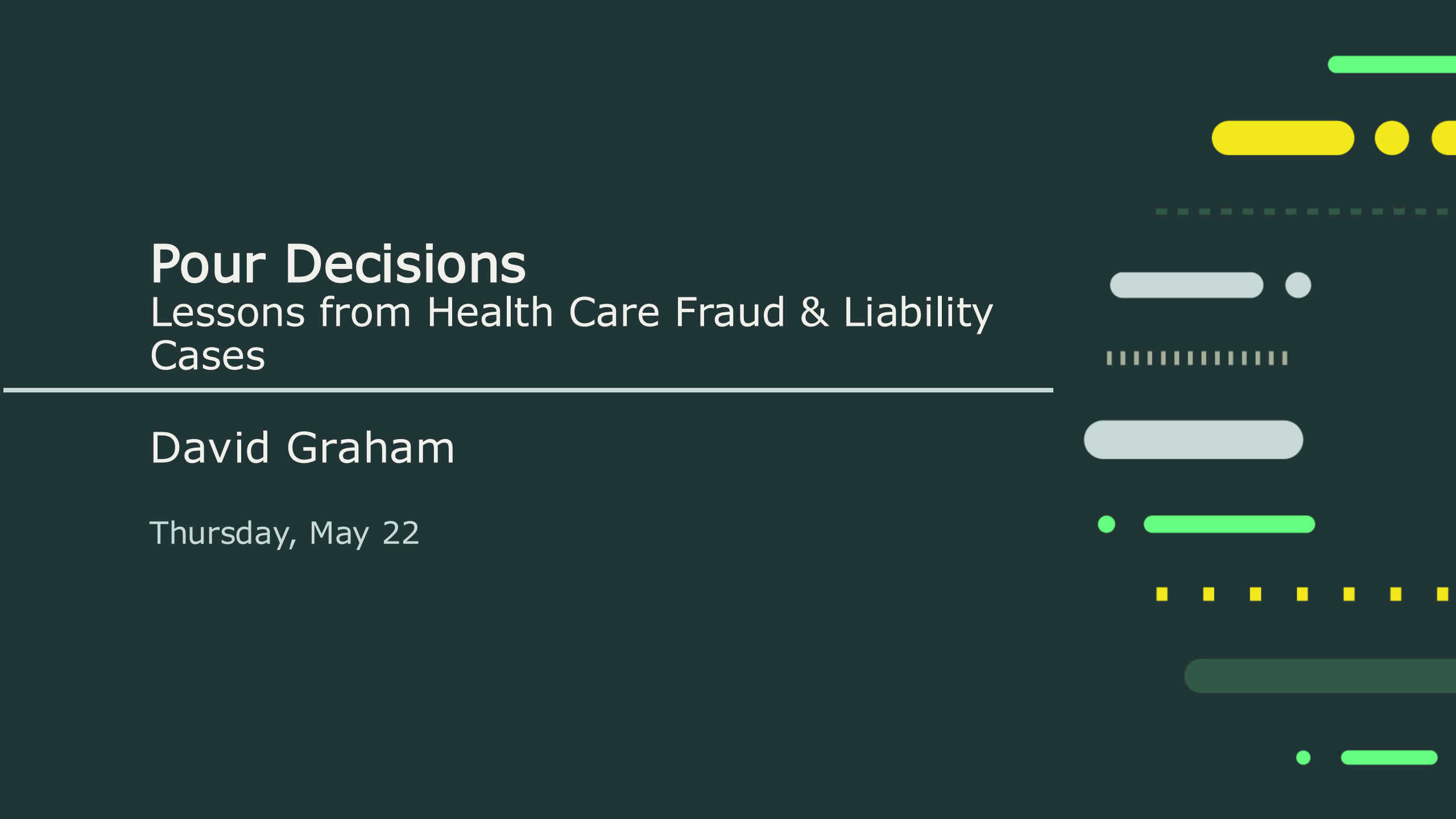
Pour Decisions

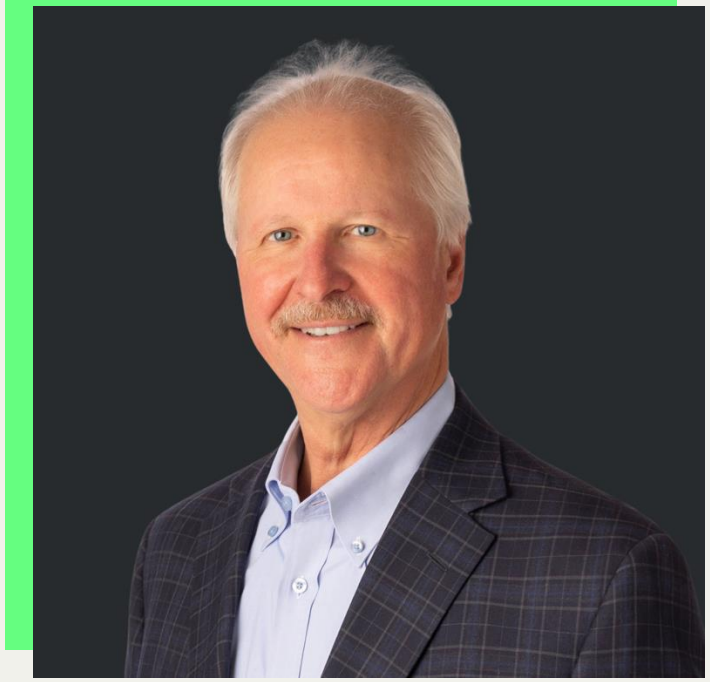
Lessons from Health Care Fraud & Liability Cases

David Graham

Thursday, May 22



Presenter Introduction



David Graham
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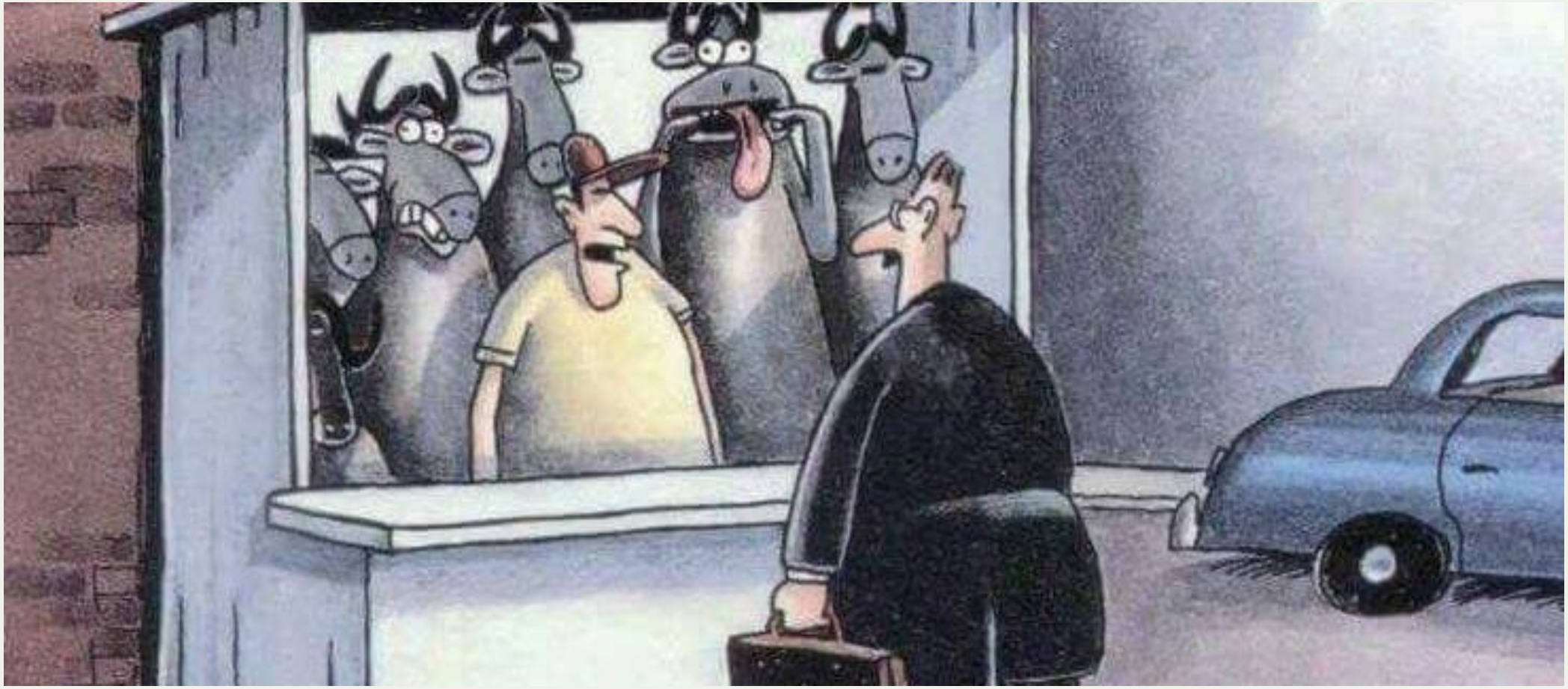
- Seasoned litigator with a track record in high-profile cases involving:
  - Food
  - Medical Devices
  - Pharmaceuticals
- Substantial expertise in:
  - Defending against product liability claims
  - Navigating regulatory challenges involving FDA & USDA regulations
- Renowned strategic thinker and negotiator

Well, I’ve got good gnus, and I’ve got bad gnus



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Agenda

Product Liability and Class Action Trends

- No injury and Consumer Protection Actions
- Change in Expert Evidentiary Rules – Rule 702
- Third Party Funding
- Race-Based Efficacy Issues / Preemption Changes
- PFAs Litigation
- Learned Intermediary Doctrine

Health Care Fraud Trends

- False Claims Act
- Anti-Kickback
- Other fraud related claims

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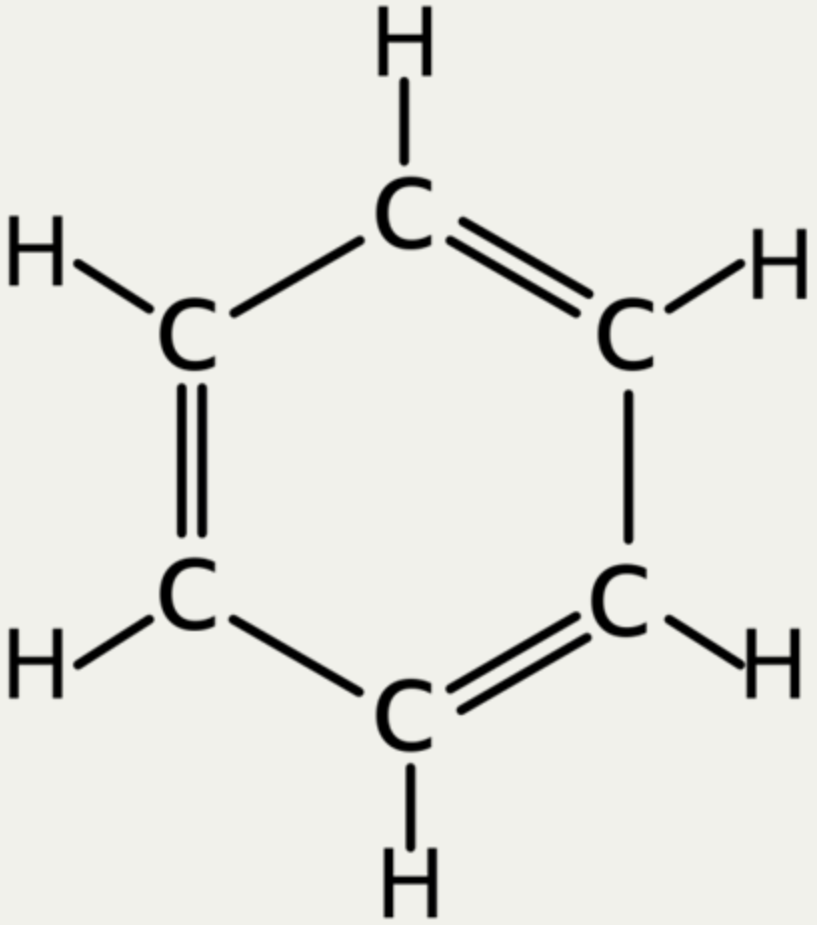
No Injury Consumer Protection Cases

Huertas v Bayer
No. 23-2178 (3d Cir. 2024)

- Alleging non-prescription product contained a contaminant
- No injury allegation or "danger to health"
- No product defect—compared a possible carcinogen to asbestos



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Preemption-Some Good News

Hickey v. Hospira
102 F.4th 748 (5th Cir. 2024)

- In *Hickey* the Fifth Circuit became the first appellate court to recognize extensive federal preemption for medical devices coming to market under 21 U.S.C. §355(b)(2) – the FDA's successor to so-called "paper NDAs."
- Lack of newly acquired information
- Such evidence must not only be "new" but also must "reveal risks of a different type or greater severity or frequency" than material already in the FDA's possession
- Plaintiffs offered only "cumulative" information with no significant change in the degree of risk."
- Adverse events of the sort plaintiffs alleged proved nothing by themselves because the denominator (number of patients treated) was so large.

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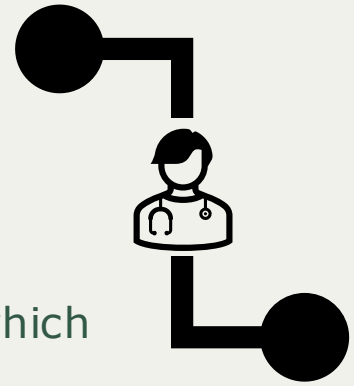
Learned Intermediary Doctrine

Himes v. Somatics, LLC

No. 21-55517 (9th Cir. 2024)



- **Can plaintiffs disregard medical advice?**
- *Himes* is the first California Supreme Court decision applying the learned intermediary rule to medical devices.
- *Himes* rejected plaintiffs' argument that the rule was some sort of defense on which defendants should bear the burden of proof.
- Plaintiffs' argument that the rule ceases to apply where a plaintiff alleges that a manufacturer failed to provide an adequate warning is gone. That would also have abolished the rule, since plaintiffs ***always*** claim warnings are inadequate; that being an essential element of a warning-based claim.
- *Himes*' objective prudent patient standard for causation at least means that plaintiffs cannot prove causation with their own subjective and "self-serving" testimony that they would have declined their doctors' recommended treatment had they only known whatever additional information is at issue in any given case.

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Fed. R. Evid. 702

In re Onglyza & Kombiglyze Products Liability Litigation
No. 93 F.4th 339 (6th Cir. 2024)

- Disqualification of expert testimony
- Plaintiffs' expert ignored contrary studies
- Other studies on which plaintiffs relied did not relate to the claimed injury
- *O&K* expressly cited to the 2023 Rule 702 amendments requiring affirmative proof of a "reliably applied" methodology

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First Amendment to the Rescue

Cal. Chamber of Comm. v. Bonta, 19-cv-02019, Order Granting Summary Judgment (E.D. Cal., May 5, 2025)

- Proposition 65 Acrylamide warning requirement
- Studies about cancer not conclusive
- Government cannot compel untrue or controversial speech
- Larger impact on labeling generally

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Third Party Funding-Bad News

- People investing in plaintiffs' litigation
- Hedge funds and other financiers
- Plaintiff only repays the funder if they win
- Significant funding goes to the funder if they win

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Questions

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Refreshment Break

Thank you for attending Saison-al Session. The programming will continue at 1:45 pm CDT.

Hot or Cold?

A Privacy Enforcement Update

Paul Rothermel

Thursday, May 22

Presenter Introduction

Paul Rothermel
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- Focuses on privacy, cybersecurity, and general health care compliance
- Interprets and applies laws, regulations, and standards including HIPAA, GDPR, CCPA, and other state and federal privacy laws
- Advises clients on:
  - Data privacy and cybersecurity issues
  - Technology matters impacting drug and device manufacturers
  - Innovative health care technologies
  - Clinical research and third-party risk management
  - Contracting and cybersecurity strategy
- Assists in assessing and implementing privacy and data protection programs
- Contracted privacy and data protection officer for various clients

Federal Enforcement

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Warby Parker Breach Notification

WARBY PARKER

HHS Office for Civil Rights Imposes a $1,500,000 Civil Money Penalty Against Warby Parker in HIPAA Cybersecurity Hacking Investigation

- Feb. 20, 2025
- Civil money penalty announced after breach report submitted to HHS
- Manufacturer/retailer of eyewear experienced "credential stuffing" attacks affecting nearly 200,000 individuals
- Cited: Lack of security risk assessment for ePHI, inadequate security measures, and failure to implement information system activity review procedures

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Health Fitness Corporation

HealthFitness

- Dec 20, 2024
- Settlement for $227,816 and corrective action plan
- Business associate providing wellness plans for clients across U.S.
- Misconfigured Internet accessible server containing ePHI – exposed to web crawlers
- Cited:
  - Failure to conduct accurate and thorough risk assessment for ePHI until Jan. 19, 2024

Solara Medical Supplies

HHS Office for Civil Rights Settles HIPAA Phishing Cybersecurity Investigation with Solara Medical Supplies, LLC for $3,000,000

SOLARA℠
MEDICAL SUPPLIES

- Jan 14, 2025
- Diabetes medical supplier, distributor (CGM, insulin pumps, etc.)
- ePHI exposed in phishing incident impacting 114,007 individuals
- Breach notification letters were misdirected resulting in additional breach
- Resolution agreement resulted in monitoring for 2 years and $3m settlement
- Cited failure to conduct security risk analysis for ePHI, inadequate security measures, and failure to timely notify individuals/HHS/media

United States v. Cerebral, Inc.

Cerebral

- FTC order restricting use and disclosure of sensitive data plus $7m penalty

> "As the Commission's complaint lays out, Cerebral violated its customers' privacy by revealing their most sensitive mental health conditions across the Internet and in the mail," said FTC Chair Lina M. Khan. "To address this betrayal, the Commission is ordering a first-of-its-kind prohibition that bans Cerebral from using any health information for most advertising purposes."

- FTC complaint alleged privacy violations through use of tracking tools on company websites and apps that shared sensitive customer information with Snapchat, LinkedIn, and TikTok (plus cancelation policy issues)
- Sensitive information included names, medical/Rx history, demographics, pharmacy and health insurance information, among other health info on nearly 3.2 million consumers

United States v. Monument

MONUMENT HEALTH

- Federal Trade Commission: Sharing health information with ad tech is still sharing, even if it is hashed by ad tech companies, per complaint filed in April 2024
- Monument is an alcohol addiction treatment company that allegedly shared sensitive health data with advertising tech companies without consent.
- ”Monument used [health] information to target ads for its services to both current users who subscribe to the lowest cost memberships and to target new consumers [...].”
- Stipulated order in June 2024: $2.5m with significant oversight from FTC

In the Matter of BetterHelp, Inc

- Federal Trade Commission (FTC) Act, 15 U.S.C. § 45 prohibits "unfair and deceptive acts or practices", which FTC relies on for data privacy and security enforcement actions

- 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

In the Matter of BetterHelp, Inc

- FTC alleged in its complaint that the company, which offers online mental health services:

  > [r]epeatedly promised to keep [health information] private and use it only for non-advertising purposes such as to facilitate consumers' therapy [and] continually broke these privacy promises, monetizing consumers' health information to target them and others with advertisements for the Service. For example, from 2018 to 2020, Respondent used these consumers' email addresses and the fact that they had previously been in therapy to instruct Facebook to identify similar consumers and target them with advertisements for the Service.

State Enforcement

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Tilting Point Media LLC

June 18, 2024:

Attorney General Bonta, L.A. City Attorney Feldstein Soto, Announce $500,000 Settlement with Tilting Point Media for Illegally Collecting and Sharing Children's Data

Press Release / *Attorney General Bonta, L.A. City Attorney Feldstein Soto, A...*

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Tilting Point Media LLC

- The People of the State of California v. Tilting Point Media LLC (2024)
- Complaint alleged, among other things, the mobile game developer:

  > Collected, disclosed, sold, or shared personal information from consumers who self-identified as under 13 years of age without obtaining parental consent, and collected, disclosed, sold, or shared personal information from consumers who self-identified as at least 13 and less than 16 years of age without obtaining the consumer's affirmative consent.

- Also alleged misconfigured software caused the app to not properly seek affirmative opt-in to personal information sharing from 13 to 16-year-old children or parental consent from those under 13.

DoorDash

- $375,000 settlement including injunctive requirements announced Feb. 21, 2024
- Complaint alleged DoorDash violated CCPA and CalOPPA through participation in a “marketing cooperative”
- Companies involved in the cooperative would share customer personal information in exchange for opportunity to advertise to each others’ customers
- Injunction requirements include:
    - Comply with CCPA and CalOPPA
    - Review contracts with marketing and analytics vendors and use of technology to evaluate if it is selling or sharing consumer personal information
    - Provide annual reports to the Attorney General

Washington My Health My Data Act

- Provides private right of action for MHMD violations via Washington Consumer Protection Act
- Violation of MHMDA presumes 3 of 5 WCPA elements are met – injury and causation must still be proven
- Complaint filed Feb. 10 against Amazon alleges violation of MHMDA on basis that Amazon SDK (software development kit) embedded in thousands of mobile apps collects location data, which plaintiff argues incorporates consumer health data, without consent

Other Enforcement

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GDPR – Meta

- Meta Platforms Ireland (Dec. 17 and Sep. 27, 2024)
- Irish DPC issued €251m and €91m fines
  - Privacy breach impacting 29m worldwide users/3m EU or EEA
  - Insufficient protection of passwords (stored unencrypted on internal system), DPC considered this a reportable breach
- Cited failure to implement adequate data protection controls during design and ensuring processing limitations

GDPR – LinkedIn

- LinkedIn (Oct. 24, 2024)
  - Irish DPC issued €310m fine
  - Insufficient legal basis for processing (behavioral analysis and targeted advertising)
  - Cited lack of insufficient consent, no legitimate interest as DPC considered individual's rights and freedoms outweighed company's interests, insufficient privacy notice

GDPR – Medtech

- Argon Medical Devices (March 8, 2023)
  - Norwegian DPA issued €220,000 fine
  - Failure to notify DPA of data breach involving personal data of all EU employees within 72 hours
- Medical Laboratory (August 19, 2022)
  - Belgian DPA issued €20,000 fine
  - Cited failure to conduct data protection impact assessment and noted lack of encryption for personal data, as well as failure to post privacy statement to website
- MedHelp AB (June 7, 2021)
  - Swedish DPA issued fine of €1.2m
  - Telephone hotline offering health-related advice and consultation through subcontractors
  - Data breach occurred via subcontractor through misconfigured network-attached storage device.
  - Cited lack of appropriate security by MedHelp, as well as failure to provide adequate privacy notice, along with unlawful outsourcing to a third-party

Key Considerations

- Implement privacy and security programs
- Perform data protection impact assessments:
  - Identify a valid legal basis for processing and disclose clearly to the individual in privacy notices
  - Design systems to comply with privacy limitations and security requirements
  - Ensure appropriate security (e.g., don’t store user passwords in plain text)
- Implement and comply with incident response plans
- Properly vet and implement effective agreements with third-party service providers

Questions

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Panel Discussion

Mark Gardner, with Jonelle Burnham, Bryan Phillips, and Wendy Cusick

Thursday, May 22

Presenter Introduction

Mark Gardner
Managing Partner
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- Founder of Gardner Law, specializing in FDA regulatory, compliance, and privacy matters
- Brings real-world in-house and private practice experience, including secondments with global healthcare companies
- Uses deep industry knowledge (dating back to 1999) to align business goals with regulatory requirements
- Guides clients through complex FDA issues, sales and marketing reviews, and commercial transactions
- Designs compliant engagement strategies with healthcare providers and oversees transparency reporting
- Regularly interacts with FDA, CMS, OCR, DOJ, and OIG, including during audits and investigations
- Teaches at Mitchell Hamline School of Law, University of Minnesota Law School, and Carlson School of Management

Panelist Information

Jonelle Burnham

VP, General Counsel, and Compliance Officer

CVRx

Bryan Phillips

Sr VP, General Counsel, & Chief Compliance Officer

Inspire Medical

Wendy Cusick

General Counsel and Chief Compliance Officer

CoNextions Medical

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Questions

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Cheers to all our panelists, attendees, and to Surly Brewing Company! 🍻

Mark Gardner

Amanda Johnston

Nate Downing

Paul Rothermel

David Graham

Rebecca Zadaka

Brynn Stanley

Katy Herman

Bryan Phillips

Jonelle Burnham

Wendy Cusick

Darya Lucas

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Thank you for attending our program!

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