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Ski-LE

An FDA & Compliance Legal-Regulatory Update

Gardner Law

Friday, April 11, 2025

Program Introduction

- **CLE credits**: This course has been approved for 4 CLE credits by the Minnesota Board of Continuing Legal Education and the Utah Supreme Court Board of Continuing Education. A 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 Course Credit**: This course has been approved for 4 RAC recertification credits.


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✓ Ski-LE: An In-Person FDA and Compliance Legal-Regulatory — 4 RAC RECERTIFICATION CREDITS

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Agenda

7:00 – 8:00 AM	**Opening Remarks: The State of the U.S. Healthcare Space from a Legal Perspective** Speaker: Mark Gardner, Founder & Managing Partner, Gardner Law
8:00 – 9:00 AM	**Hot FDA Topics: What is FDA Focusing On Right Now, and How Can the Industry Adjust?** Speaker: Nathan Downing, Managing Attorney, Gardner Law
9:00 – 10:00 AM	**Interactive Session: Recent Fraud and Abuse Cases and Compliance Hot Topics Update, and How Can the Industry Adjust?** Speaker: Mark Gardner
10:00 – 11:00 AM	**Tales from the Trenches: A Focus on FDA Fraud, Abuse, and Marketing Compliance** Speaker: *Mike Pisetsky, Chief Business & Legal Affairs Office, SI-BONE, Inc.*

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Opening Remarks: The State of the U.S. Healthcare Space from a Legal Perspective

Mark Gardner

Friday, April 11, 2025

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Presenter Introduction

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

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

Mark Gardner

Founder, Managing Partner
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Phone: 612.382.7584

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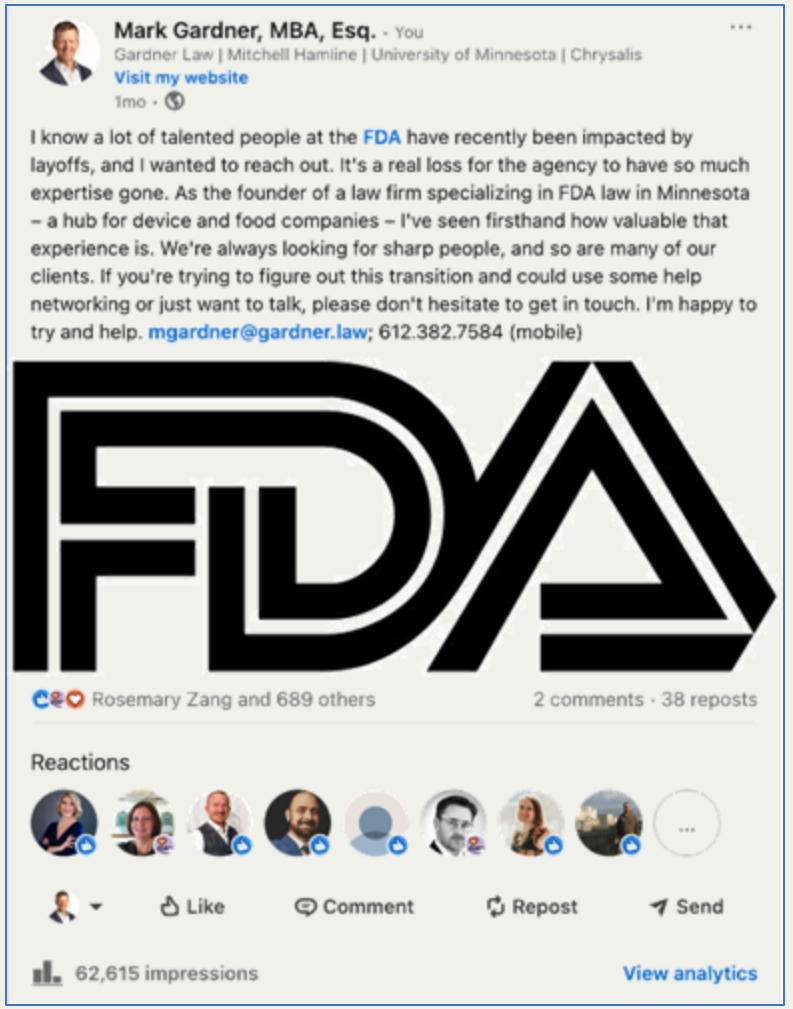
CHANGE
AHEAD

U.S. Department of Health and Human Services (HHS)

- New Secretary, Robert F. Kennedy, Jr.
- Notoriously cutting staff from FDA, NIH, CMS, etc.
- HHS announced last week terminating 10,000 full-time employees, including 3,500 FDA workers
- Federal workers about their future job status
- I've had the privilege of speaking to many impacted employees



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HHS lays off more employees, shutters offices

HHS has started sending layoff notices that could affect up to 10,000 employees in addition to those who have already left. The workforce reduction and reorganization plan includes consolidating certain agencies and creating the Administration for a Healthy America. Positions in human resources, procurement, finance and IT are targeted for layoffs. At the CMS, the Office of Equal Opportunity and Civil Rights and five divisions in the Office of Acquisition and Grants Management have been eliminated, and employees at the NIH, FDA and CDC have been fired, placed on leave or offered transfers.**Full Story:** The Associated Press (4/1), STAT (4/1)

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NIH Sued By Researchers Over 'Ideological Purge' On Grants

By Bonnie Eslinger

The American Public Health Association and others sued the federal government in Massachusetts federal court on Wednesday over the cancellations of billions of dollars worth of National Institutes of Health research grants on such issues as gender identity, diversity, vaccine hesitancy and climate change, claiming the "ideological purge" is illegal.

 Complaint attached | Read full article » | Save to favorites »

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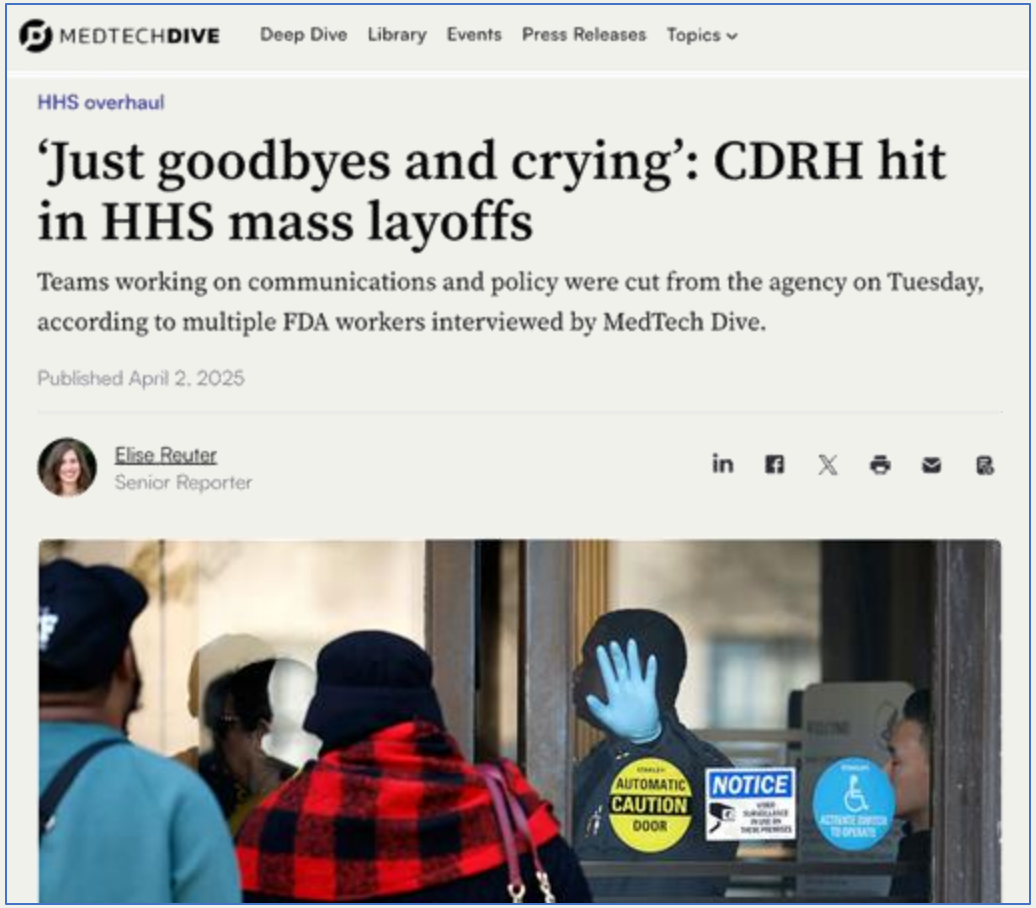
Changes at FDA

- Many employees fired and then rehired
- Many of those rehired are on leave
- Push back on Center for Devices and Radiological Health (CDRH) layoffs
- How is industry impacted?
- What comes next?



MEDTECHDIVE Deep Dive Library Events Press Releases Topics

HHS overhaul

‘Just goodbyes and crying’: CDRH hit in HHS mass layoffs

Teams working on communications and policy were cut from the agency on Tuesday, according to multiple FDA workers interviewed by MedTech Dive.

Published April 2, 2025

Elise Reuter
Senior Reporter

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LEGISLATION & REGULATION

Head of FDA's vaccine center resigns

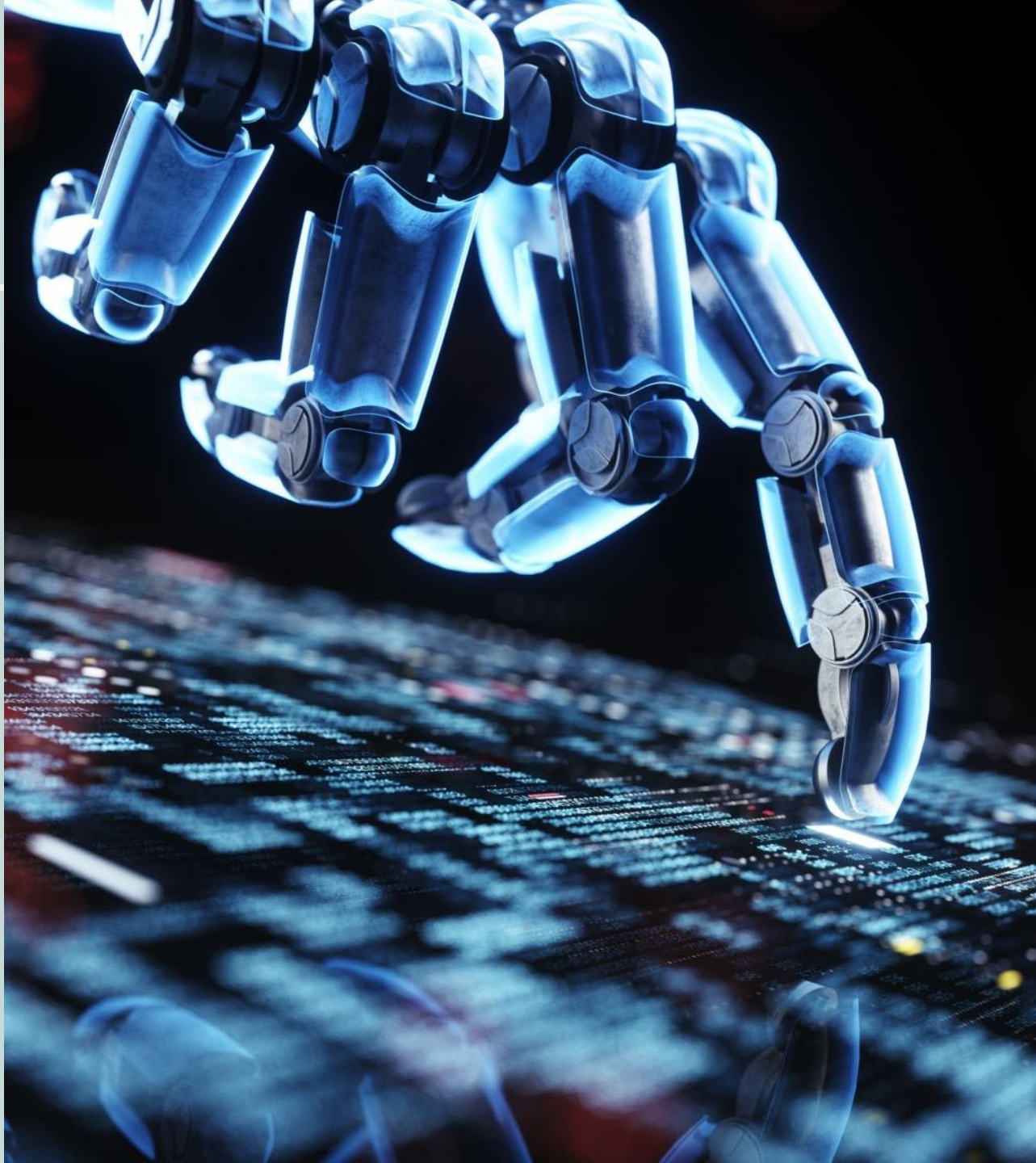
Peter Marks, head of the FDA's Center for Biologics Evaluation and Research, has resigned effective April 5 after being given the choice to step down or be fired. Marks, who played a significant role in developing COVID-19 vaccines, cited a lack of "truth and transparency" in his resignation letter, referring to HHS Secretary Robert F. Kennedy Jr.**Full Story:**

CNN (3/28)

What is *artificial intelligence* and *machine learning*?

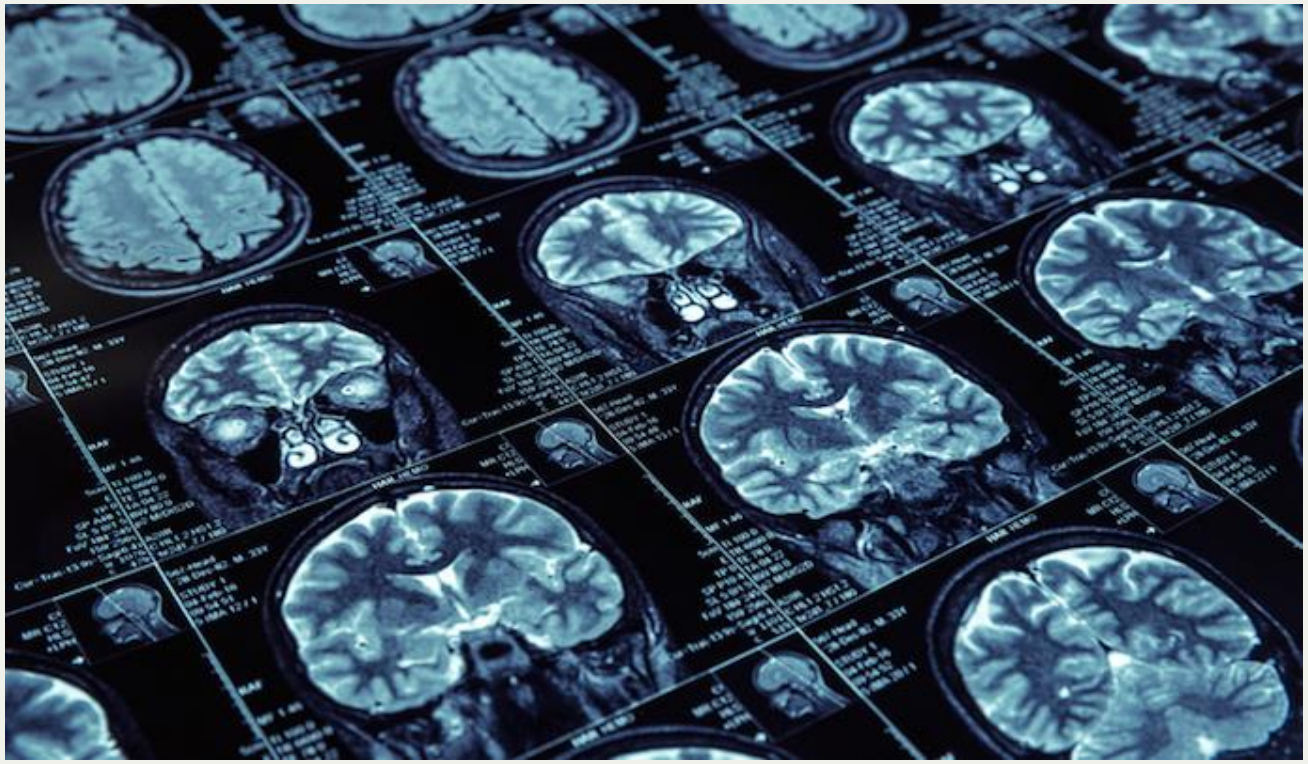
- Artificial Intelligence (AI) has been broadly defined as the science and engineering of making intelligent machines, notably intelligent computer programs.
  - AI can use techniques such as models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning.

- Machine Learning (ML) is an AI technique that can be used to design and train software algorithms to learn from and act upon data.
  - Software developers can use ML to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data.



Segments Where AI/ML Used in Devices (1000+ cleared/approved)

- 87%, Radiology
- 7%, Cardiovascular
- 1%
  - Neurology
  - Hematology
  - GI
  - Urology
  - Ophthalmic
  - Clinical chemistry
  - ENT
  - Dermatology
  - And more!



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Does AI Outperform Providers?

Doctors Wrestle With A.I. in Patient Care, Citing Lax Oversight

The F.D.A. has approved many new programs that use artificial intelligence, but doctors are skeptical that the tools really improve care or are backed by solid research.

Share full article

"The image went to Greensboro Radiology, a Radiology Partners practice, where it set off an alert in a stroke-triage A.I. program. A radiologist didn't have to sift through cases ahead of Dr. Fagan's or click through more than 1,000 image slices; the one spotting the brain clot popped up immediately."

--Jewett, Christina. "Doctors Wrestle With A.I. in Patient Care, Citing Lax Oversight". NYT. Oct. 30, 2023.

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Other Side of Argument

"University of Michigan researchers examined a widely used A.I. tool in an electronic health-record system meant to predict which patients would develop sepsis. They found that the program fired off alerts on one in five patients — though only 12 percent went on to develop sepsis."

--Jewett, Christina. "Doctors Wrestle With A.I. in Patient Care, Citing Lax Oversight". NYT. Oct. 30, 2023.

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Home / Health Lab / Popular sepsis prediction tool less accurate than claimed

Popular sepsis prediction tool less accurate than claimed

The algorithm is currently implemented at hundreds of U.S. hospitals.

June 21, 2021 11:41 AM

Author | Kelly Malcom >

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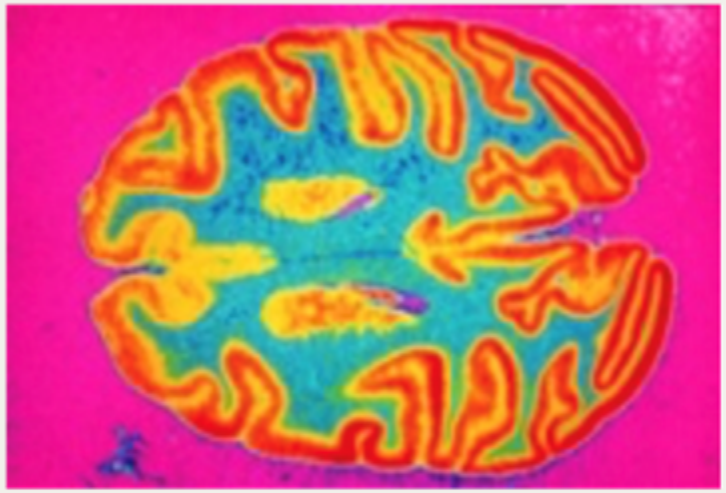
SCIENCE & HEALTH

Brain implant helps woman speak 18 years after stroke



(Ted Horowitz Photography/Getty Images)

A brain-computer interface helped a woman who had been unable to speak for 18 years due to stroke-related quadriplegia to regain their ability to communicate by translating thoughts into spoken words in real time, according to a study in the journal Nature Neuroscience. The implant converted the intention to speak into fluent sentences.**Full Story:** The Associated Press (3/31), Nature (3/31)

OMB Issues Guidance On Agency Use, Purchasing Of AI

By Madeline Lyskawa · Listen to article

Law360 (April 7, 2025, 8:06 PM EDT) -- The Office of Management and Budget issued a pair of memorandums last week that replaced the Biden administration's safeguards on the federal acquisition of artificial intelligence with a policy aimed at accelerating federal agencies' use and procurement of artificial intelligence.

OMB Director Russell T. Vought said Thursday in **memorandum M-25-21** that federal agencies "must adopt a forward-leading and pro-innovation approach" that takes advantage of artificial intelligence to "help shape the future of government operations." The memorandum is titled "Accelerating Federal Use of AI through Innovation, Governance, and Public Trust."

Consistent with these goals, Vought said agencies must slash barriers to innovation and produce the best value for taxpayers. They must also empower AI leaders to accelerate the responsible adoption of AI and ensure that their use of AI works for the American people by implementing minimum risk management practices for so-called "high-impact AI" that could have significant effects when deployed, Vought said.

The memorandum came in response to President Donald Trump's Jan. 23 **Executive Order 14179**, titled "Removing Barriers to American Leadership in Artificial Intelligence." The order upended former President Joe Biden's lengthy **executive order** from October 2023 aimed at setting standards for safe, secure and trustworthy AI systems.

Improved walking ability found with semaglutide

Research presented at an American College of Cardiology meeting highlighted the benefits of semaglutide for patients with type 2 diabetes and associated cardiovascular conditions. The STRIDE trial found that injectable semaglutide improved walking ability in patients with peripheral artery disease and type 2 diabetes.**Full Story:** MedPage Today (free registration)

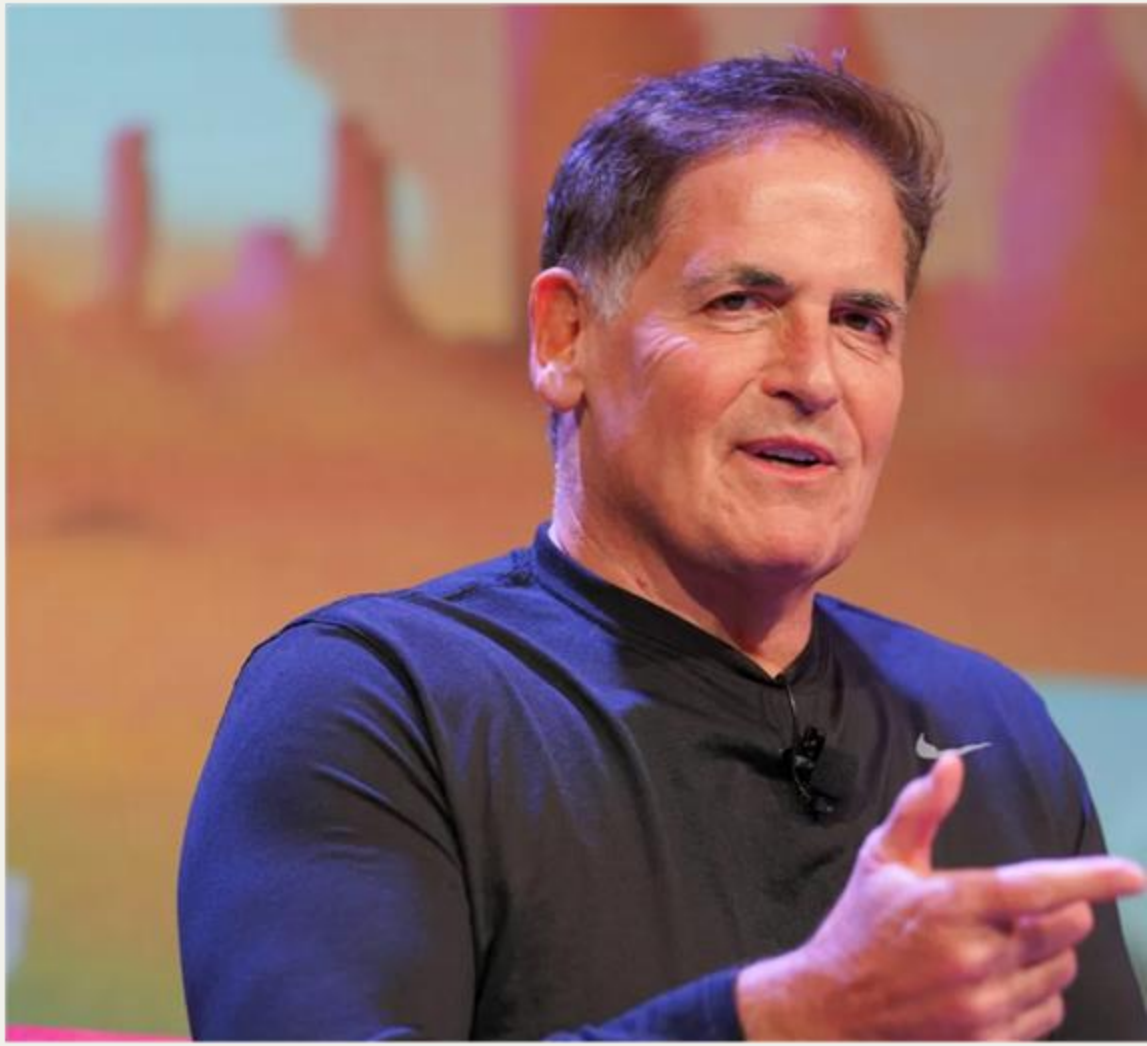
(3/29)

HEALTH · PHARMACEUTICAL INDUSTRY

Mark Cuban warns Trump's tariffs mean his Cost Plus Drugs 'won't have a choice' but to raise prices for consumers

BY ANI FREEDMAN

April 1, 2025 at 1:54 PM MDT



Cuban warns that his company's affordable drug prices could go up with higher tariffs imposed

JULIA BEVERLY/WIREIMAGE

FACT SHEETS

Fact Sheet: President Donald J. Trump Announces Actions to Make Healthcare Prices Transparent

The White House | February 25, 2025

EMPOWERING PATIENTS THROUGH RADICAL PRICE TRANSPARENCY: Today, President Donald J. Trump signed an Executive Order to empower patients with clear, accurate, and actionable healthcare pricing information.

- The order directs the Departments of the Treasury, Labor, and Health and Human Services to rapidly implement and enforce the Trump healthcare price transparency regulations, which were slow walked by the prior administration.
  - The departments will ensure hospitals and insurers disclose actual prices, not estimates, and take action to make prices comparable across hospitals and insurers, including prescription drug prices.

HEALTH | HEALTHCARE

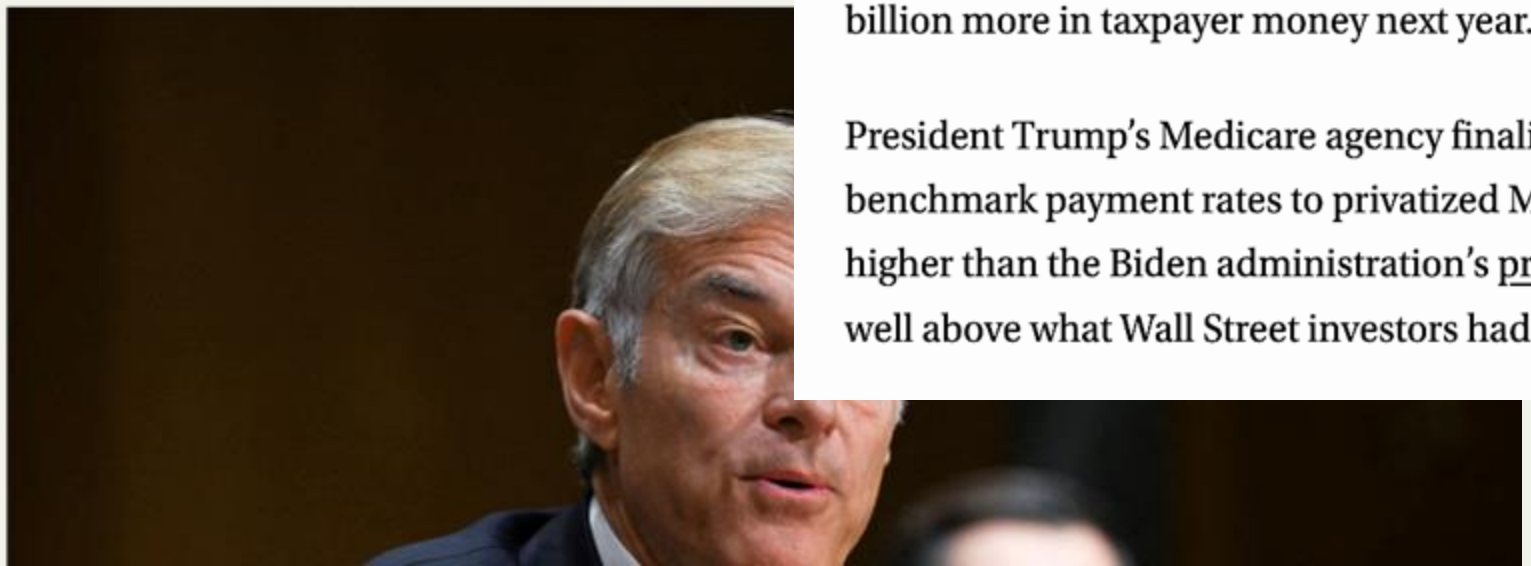
Private Medicare Plans to Get Big Payment Boost From Trump Administration

Medicare Advantage plans will get a 5.06% rate increase, well above the 2.23% bump that the Biden administration proposed

By Anna Wilde Mathews Follow

April 7, 2025 4:15 pm ET

Share Resize



By Bob Herman April 7, 2025

Business of Health Care Reporter

Health insurers that sell Medicare Advantage plans are going to get about $30 billion more in taxpayer money next year.

President Trump's Medicare agency finalized a rule Monday that would raise benchmark payment rates to privatized Medicare plans by 5.1% for 2026. That was higher than the Biden administration's proposed payment increase of 2.2% — and well above what Wall Street investors had expected.

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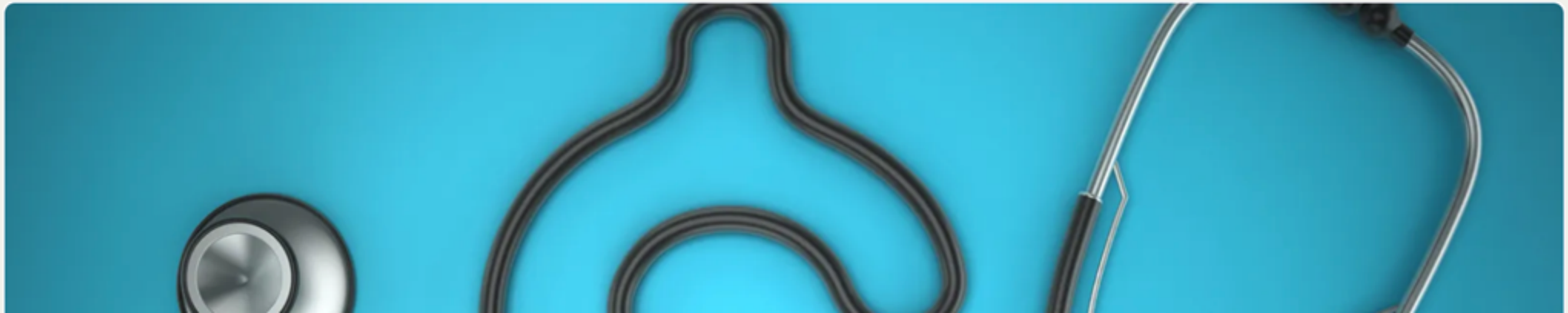
CMS to crack down on Medicare Advantage audits, poised to claw back billions of dollars from insurers

Published Jan. 31, 2023

Samantha Liss
Senior Reporter



Questions

Mark Gardner
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Hot FDA Topics: What is FDA Focusing On Right Now, and How Can the Industry Adjust?

Nathan Downing

Friday, April 11, 2025

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Presenter Introduction

Nathan focuses his practice on FDA-regulated clients. His industry experience allows him to provide actionable legal advice on a variety of health law matters.

Nathan regularly advises FDA-regulated clients on regulatory and compliance matters. He advises clients on their advertising and promotion programs, represents clients in front of the FDA on a variety of matters, and assesses industry initiatives for compliance concerns. Nathan's extensive regulatory experience allows him to advise clients regarding a variety of medical products, including pharmaceuticals, medical devices, medical foods, and nutritional supplements.

Nathan Downing

Managing Attorney
ndowning@gardner.law
Phone: 651.353.6283

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Agenda

- *Latest on FDA*
- *Finding Predictability in the Face of Uncertainty*
  - *Medical Product Conception*
  - *Pre-clinical*
  - *Clinical*
  - *Submission*
  - *Post-market*
  - *Advertising*
  - *Procedural Tools*

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FDA Updates—The Obvious

'Your RIF notice is not cancelled.' Inside a chaotic week of massive layoffs at HHS

'Decapitated': More top vaccine regulators out at FDA, threatening new approvals

Following Dr. Peter Marks' ouster, other top officials have left or have been pushed out of the FDA division that approves certain drugs, gene therapies and vaccines.

Following layoffs, the future of FDA's user fee programs is in extreme jeopardy

HEALTHWATCH

FDA planning for fewer food and drug inspections due to layoffs, officials say

Trump layoffs begin to erode FDA drug review system

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FDA Updates—What We are Hearing

- FDA
- Clients
- Industry Associations

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FDA Updates—Enforcement Focus

- Direct to Consumer Advertising
- Cybersecurity
- Enforcement Discretion?
- Food

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Medical Product Conception

- Funding
- Research
- FDA interaction
- Choosing first market

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Pre-clinical Testing and Development

- Guidance Documents
- Issue areas

  Cybersecurity
  Biocompatibility

- Pre-submissions

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Clinical Studies

- IDE/NDA
- Guidance documents
- Expert assessment

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Clinical Studies—Risk Mitigation

- Study time
- Resource usage
- Post-study confidence

Submission

- Tell your story
- Articulate communications
- Partner with FDA
- Face issues head-on
- Consider timing
- Inspections

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Submission Outcomes

- Delay in review
- User fee issues?
- Appeal options

Post-Market

- Change Control
- Ongoing regulatory compliance
- Predetermined Change Control Plan

PCCP Guidance

- On December 4, 2024, U.S. Food and Drug Administration (FDA) issued its guidance, “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions”
- The Guidance built on the April 3, 2023, draft guidance and further clarified the types of modifications that should be included in the Predetermined Change Control Plan.
- Guidance provides a framework for industry to reduce a lot of post-market submission work

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Benefits to Industry of PCCP Guidance

- Better predictability for launch timing regarding new versions of an approved or cleared device
- Cost savings associated with less regulatory submissions
- Allows for patients to realize benefits of aggregated data sooner

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Advertising and Promotion

- Best practices
- DTC focus
- Competitive concerns

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Advertising and Promotion Overview

- Requirements for promotional claims:
  - Accurate, truthful and not misleading
  - Fair balance of risk and benefit information
  - Consistent with FDA-approved product labeling
  - Supported with substantial evidence
- "Claims" are statements made about the product related to safety, effectiveness, economics, etc.
- Made by company employees or **agents**
- Applies to brochures, ads, websites, presentations, pitch decks, PR materials, practice templates, booth panels, mailers, white papers, supplements, training materials, etc.

2024’s Untitled Letters

- Novartis Pharmaceuticals Corporation for KISQALI (ribociclib) tablets
  - TV ad—misbranded Kisqali due to false or misleading representations of efficacy
- Kaleo, Inc. for AUVI-Q (epinephrine injection, USP)
  - Social media post by Brittany Mahomes (wife of football player)—misbrands Auvi-Q due to statements of benefits with no risk information
- Mirati Therapeutics, Inc. for KRAZATI (adagrasib) tablets
  - Efficacy page on the website—misbrands Krazati due to false or misleading claims or representations about benefits
- AbbVie, Inc. for UBRELVY (ubrogepant) tablets
  - TV ad with Serena Williams (celebrity athlete)—misbrands Ubrelvy due to false or misleading representations and suggestions of efficacy
- Merz Pharmaceuticals GmbH for XEOMIN (incobotulinumtoxinA) for injection
  - Social Media post by Nate Berkus (influencer)—misbrands Xeomin by false or misleading representations and suggestions about the risks and efficacy of Xeomin

2024's Untitled Letters

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- Merz Pharmaceuticals GmbH for XEOMIN (incobotulinumtoxinA) for injection
  - Social Media post by Nate Berkus (influencer)—misbrands Xeomin by false or misleading representations and suggestions about the risks and efficacy of Xeomin

Untitled Letter 1
Kaleo, Inc. for AUVI-Q

RE: **NDA 201739**
AUVI-Q® (epinephrine injection, USP), for intramuscular or subcutaneous use
MA 1021

Dear Sydney Claud:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a social media post (post) for AUVI-Q® (epinephrine injection, USP), for intramuscular or subcutaneous use (Auvi-Q) submitted by kaleo, Inc. (Kaleo) under cover of Form FDA 2253. The Form FDA 2253 submitted by Kaleo states that "piece CM-US-AQ-3329 will be hosted within piece CM-US-AQ-3336" as a post.[1] The post was made by Brittany Mahomes on her personal Instagram account in "[p]aid partnership with **auvi-q**" (emphasis original).[2] This post is false or misleading in that it presents information about the benefits of Auvi-Q but fails to include any risk information about the drug. Thus, the post misbrands Auvi-Q within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). *See* 21 CFR 202.1(e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Auvi-Q, a drug used to treat patients, including infants and children, with life-threatening allergic reactions who are at increased risk of adverse outcomes, including death.

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Background

Below are the indication and summary of the most serious and most common risks associated with the use of Auvi-Q.[3] According to the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI) (in pertinent part):

> AUVI-Q® is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects . . . and biting insects . . . allergen immunotherapy, foods, drugs, diagnostic testing substances . . . and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.
>
> AUVI-Q is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions . . .
>
> AUVI-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.

The PI for Auvi-Q includes warnings and precautions regarding emergency treatment, injection-related complications, serious infections at the injection site, allergic reactions associated with sulfite, and disease interactions. Common adverse reactions to systemically administered epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and respiratory difficulties.

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[1] CM-US-AQ-3329 was submitted as the video portion of the post and CM-US-AQ-3336 was submitted as the text portion of the post.
[2] Posted on Brittany Mahomes' verified Instagram page (https://www.instagram.com/reel/C2fa3XzLxvB/). Last accessed July 16, 2024.
[3] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional communication(s) cited in this letter.

False or Misleading Risk Presentation

Prescription drug advertisements and labeling (promotional communications) misbrand a drug if they are false or misleading with respect to risk. The determination of whether a promotional communication is misleading includes, among other things, not only representations made or suggested in the promotional communication, but also the extent to which the promotional communication fails to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the promotional communication.

The post is misleading because it presents efficacy claims for Auvi-Q but fails to communicate any risk information. For example, the post includes the following claims:

- "So, I have an infant and a toddler both who have severe food allergies . . . . Based on my experience, I can tell you that a severe reaction may not look how you think it should look. So, after the diagnosis, a big part of the plan was going to my pediatrician, and he did prescribe me Auvi-Q. Auvi-Q is the only epinephrine autoinjector out there for infants and toddlers." (AVO, video portion of post)
- "AUVI-q® (epinephrine injection, USP) is for life-threatening allergic emergencies." (SUPER, video portion of post)
- "[S]haring my experience with [my child's] severe allergic reaction to peanuts . . . . partnering with @auvi_q to help spread awareness about severe food allergies in young children and how to best respond . . . . AUVI-q 0.1 mg is for infants and toddlers 16.5-33 lbs." (text portion of post)

The post, however, entirely omits all risk information. We acknowledge that the post includes the statement, "For Important Safety Information, visit @auviq_ISI[.]"[4] However, this does not mitigate the misleading impression created by the omission of risk information.

[4] The FDA Form 2253 submitted with the post states, "a link to the indication and important safety information is provided [within the post]."

Untitled Letter 2
AbbVie, Inc. for UBRELVY

RE: **NDA 211765**
UBRELVY (ubrogepant) tablets, for oral use
MA 934

Dear Dr. Hill:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television advertisement (TV ad), titled "Serena TV :30" (US-UBR-230259) for UBRELVY (ubrogepant) tablets, for oral use (Ubrelvy) submitted by AbbVie, Inc., under cover of Form FDA 2253.[1] The TV ad makes false or misleading representations and suggestions about the efficacy of Ubrelvy. Thus, the TV ad misbrands Ubrelvy within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act) and makes its distribution violative. 21 U.S.C. 352(n); 321(n); 331(a). 21 CFR 202.1(e)(5). These violations are concerning from a public health perspective because the TV ad, featuring Serena Williams, misleadingly suggests that Ubrelvy will provide a greater treatment benefit to patients suffering from migraine headache than has been demonstrated. Migraine headache is one of the most common debilitating neurologic conditions in the US, with millions of Americans (one out of six Americans) experiencing a migraine within any 3-month period.[2] Healthcare providers, patients, and caregivers should not be misled regarding the benefits that can be expected from acute migraine headache treatments. Moreover, the use of a celebrity athlete in this TV ad amplifies the misleading representations and suggestions made and increases the potential for audiences to find the misleading promotional communication more believable due to the perceived credibility of the source.[3]

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Background

Below are the indication and summary of the most serious and most common risks associated with the use of Ubrelvy.[4] According to the INDICATIONS AND USAGE section of the FDA-approved prescribing information (PI):

> Ubrelvy is indicated for the acute treatment of migraine with or without aura in adults.
>
> Limitations of Use
> Ubrelvy is not indicated for the preventive treatment of migraine.

Ubrelvy is contraindicated with concomitant use of strong CYP3A4 inhibitors and in patients with a history of serious hypersensitivity to ubrogepant or any component of Ubrelvy. The PI contains a warning and precaution regarding hypersensitivity reactions. The most common adverse reactions are nausea and somnolence.

False or Misleading Benefit Presentation

Prescription drug advertisements and labeling (promotional communications) misbrand a drug if they are false or misleading with respect to benefits. The determination of whether a promotional communication is misleading includes, among other things, not only representations made or suggested in the promotional communication, but also the extent to which the promotional communication fails to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the promotional communication.

The TV ad includes the following claims and presentations (in pertinent part, emphasis original):

Frames one to four:

- Serena Williams is in a talk show dressing room when she closes her eyes and puts her hand to her head, appearing to experience migraine pain. With her hand to her head, she takes a deep breath and starts walking. Serena Williams looks down a hallway with glaring lights. She holds her hand and recoils from the light, appearing to shield her eyes.

- Seren Williams Voiceover (VO): "When migraine strikes, you're faced with a choice. Ride it out with the tradeoffs of treating? Or push through the pain and symptoms?"

1

00:00-00:01
Open in the afternoon to Serena in a talk show dressing room in casual clothing. She's looking through outfits on a rack when she suddenly starts to feel the symptoms of migraine.

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- Frames five to seven:
    - The Ubrelvy logo appears in the backstage hallway and a soft blue path appears down the hallway. Serena Williams begins walking down the blue path with her face relaxed and arms at her sides, no longer touching her head or shielding her eyes from light. She then holds up a single 100 mg dose packet of Ubrelvy.
    - Serena Williams VO: “With Ubrelvy, there’s another option. One dose works fast to eliminate migraine pain.”
    - SUPER: “**UBRELVY® QUICKLY ELIMINATES MIGRAINE PAIN**”

5

00:07-00:09
As it gets closer to the nighttime show, a UBRELVY logo drops down in front of her and begins to move down the hall, lighting the path in front of her. We see Serena following the blue path to her dressing room.

6

00:10-00:12
Cut to a view of Serena walking down the path from a front angle. We see that the hallway behind her is lit, the pathway has illuminated it.

SERENA VO: ONE DOSE WORKS FAST TO ELIMINATE MIGRAINE PAIN

- Frames 8 to 14:
    - Serena Williams is sitting in her dressing room in front of a lighted stage mirror talking with another person. She is now seen laughing and smiling. Then the blue path appears as she excitedly walks on the blue path through the stage curtains and waves to an audience. Serena Williams continues walking on the blue path onto a brightly lit talk show stage, smiling and waving to the studio audience as they applaud.
    - Serena Williams VO: "Migraine pain relief starts with U. Ask about Ubrelvy."

These claims and presentations misleadingly suggest that Ubrelvy provides greater benefits to patients with acute migraine headache than has been demonstrated. Serena Williams is

presented in frames one through four preparing to appear on a talk show while experiencing pain and photophobia from a migraine headache. Immediately after this presentation, a blue lit path with the Ubrelvy logo appears in frame five. In frame six, Serena Williams is shown walking down the blue lit path, appearing relaxed and no longer holding her head or shielding her eyes from the lights that continue to shine overhead. The presentation in frame six is in conjunction with Serena Williams's VO claim that, "One dose works fast to eliminate migraine pain" and the accompanying prominent graphic "UBRELVY QUICKLY ELIMINATES MIGRAINE PAIN." This compelling before-and-after presentation in conjunction with claims such as, "One dose works fast to eliminate migraine pain" and "UBRELVY QUICKLY ELIMINATES MIGRAINE PAIN" (emphasis added) misleadingly suggests that Ubrelvy eliminates migraine pain and symptoms more quickly than was demonstrated in the clinical trials. According to the CLINICAL STUDIES section of the

demonstrated in the clinical trials. According to the CLINICAL STUDIES section of the Ubrelvy PI, the efficacy of Ubrelvy for the acute treatment of migraine was established in two clinical trials based on two endpoints: 1) effect on pain freedom at two hours post-dose (defined as a reduction of moderate or severe headache pain to no pain) and 2) effect on most bothersome symptom (MBS) (i.e., photophobia, phonophobia, nausea) freedom at two hours post-dose (defined as the absence of the self-identified MBS), compared to placebo. In Study 1, 19.2%, 21.2%, and 11.8% of patients achieved pain freedom at 2 hours in the Ubrelvy 50 mg, Ubrelvy 100 mg, and placebo groups, respectively (7.4%-9.4% difference from placebo); 38.6%, 37.7%, and 27.8% of patients achieved freedom from MBS in the Ubrelvy 50 mg, Ubrelvy 100 mg, and placebo groups, respectively (9.9%-10.8% difference from placebo). In Study 2, 21.8% and 14.3% of patients achieved pain freedom at 2 hours in the Ubrelvy 50 mg and placebo groups, respectively (7.5% difference from placebo); and 38.9% and 27.4% of patients achieved freedom from MBS in the Ubrelvy 50 mg and placebo groups, respectively (11.5% difference from placebo). We acknowledge that the claim, "Some people had pain freedom within 2 hours" appears in a small SUPER on frame six. However, the SUPER is not sufficient to mitigate this misleading suggestion that Ubrelvy can eliminate migraine pain and symptoms more quickly than has been demonstrated.[6]

In addition, the claim in frame six of the TV ad that "One dose works fast to eliminate migraine pain," (emphasis added) misleadingly suggests that all patients who take Ubrelvy can expect their migraine pain to be eliminated after a single dose of Ubrelvy, when this has not been demonstrated. As described above, according to the CLINICAL STUDIES section of the Ubrelvy PI, approximately 19% to 22% of patients achieved pain freedom at two hours after receiving one dose of Ubrelvy. Conversely, approximately 78% to 81% of patients did not achieve pain freedom after receiving one dose of Ubrelvy. In addition, according to the DOSAGE AND ADMINISTRATION section of the PI, in pertinent part, "If needed, a second dose [of Ubrelvy] may be taken at least 2 hours after the initial dose" (emphasis added). We acknowledge that the claim, "Some people had pain freedom within 2 hours" appears in a small SUPER on frame six. However, this does not mitigate the misleading suggestion that "one dose eliminate[s] migraine pain." Therefore, the claim that "one dose eliminate[s] migraine pain" is misleading.

[6] We note that the storyboard submitted with the TV ad on FDA Form 2253 states in frame one, "Open in the afternoon to Serena in a talk show dressing room . . . ." and in frame eight, "In the evening, Serena does a final check in the mirror . . . ."; however, the audience viewing the TV ad is not privy to this information and the TV ad in the public domain does not portray the passing of time in a manner that is consistent with the description in the storyboard.

Administrative Tools and Appeals

- Ombudsman
- Least burdensome approach
- 21 CFR 10.75
- Industry support
- Litigation

Case Study

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Conclusion

- Acknowledge risk
- Regulatory plans to mitigate risk where possible
- Partner with FDA
- Partner with industry members

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Questions

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Thank you!

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Interactive Session: Recent Fraud and Abuse Cases and Compliance Hot Topics Update

Mark Gardner

Friday, April 11, 2025

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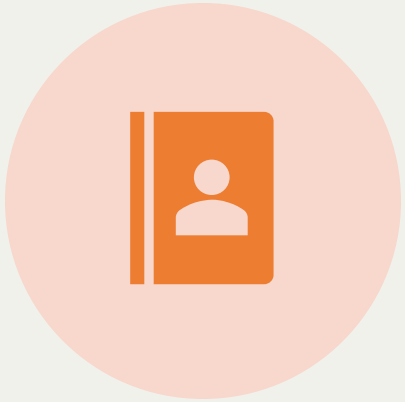
Discussion Outline

RECENT INTERESTING CASES, SETTLEMENTS, AND DEVELOPMENTS



NEW ITEMS ON THE OIG WORK PLAN

2025 PREDICTIONS: HOT TOPICS AND ENFORCEMENT

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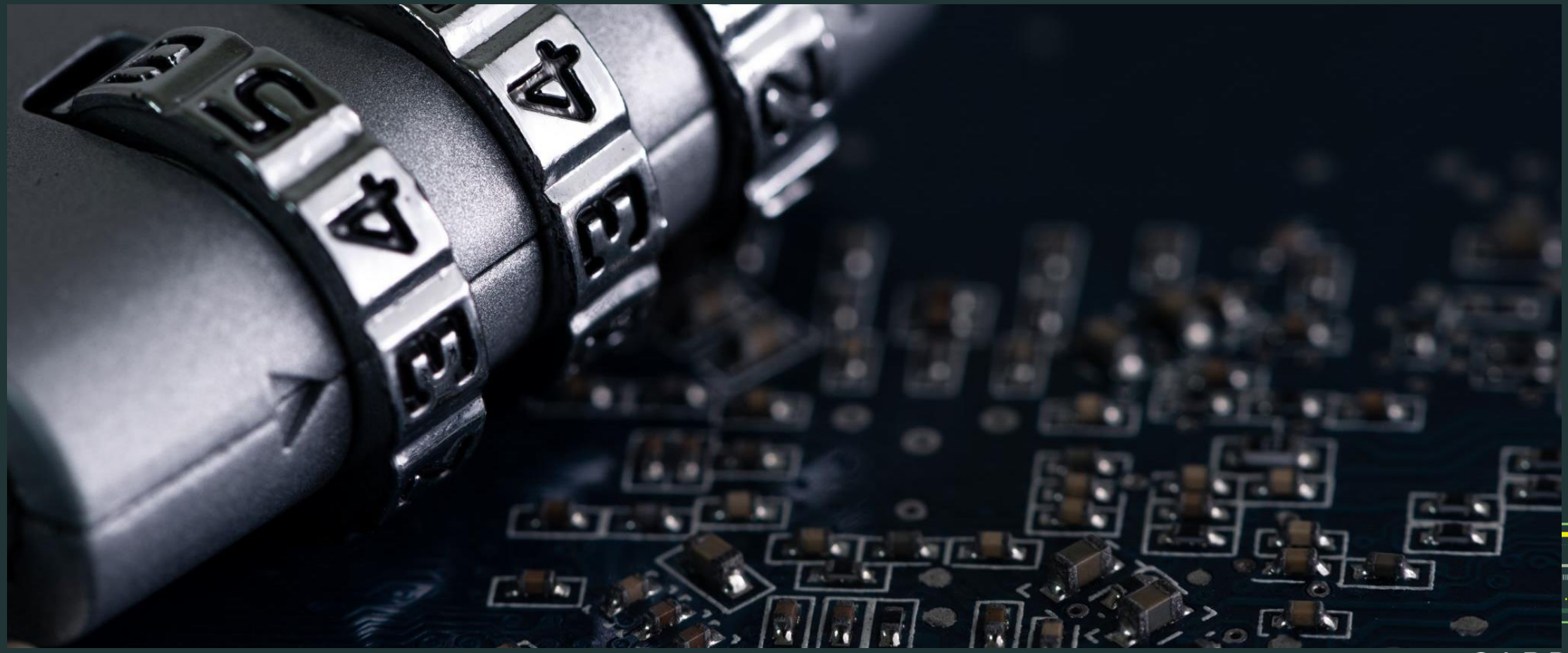
Looking Back:
Notable 2024 Fraud and Abuse Cases



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Teva Pharmaceuticals

About: Manufacturer of expensive multiple sclerosis drug Copaxone

Settlement: Agreed to pay $450 million civil settlement to resolve two allegations

Allegations:

i. Teva used charities that help cover Medicare patients' out-of-pocket drug costs as a means to pay kickbacks to boost sales of its drugs ($425M settlement)

ii. Conspired with other drug companies to fix prices for generic drugs ($25M settlement); entered into DPA

    1. This follows a criminal case settlement in 2023 where Teva paid $225M and divested one of their drugs

Innovasis

Settlement: $12M paid by the company and two senior executives

Allegation:

i. Whistleblower (a former regional sales director, set to receive $2.2M from the settlement) alleged Innovasis paid kickbacks to physicians

ii. Provided improper payments such as consulting fees, intellectual property acquisition (without proper valuation), licensing fees, performance shares, lavish trips, and benefits to orthopedic surgeons and neurosurgeons

iii. Payments were made to doctors, but services were never performed and intellectual property never provided

About: Innovasis manufactures spinal devices

Endo Health Solutions

About: Opioid manufacturer no longer in operation following a bankruptcy proceeding

Settlement:

i. $1.086 billion in criminal fines and $450 million in criminal forfeiture—the second-largest set of criminal financial penalties ever levied against a pharmaceutical company
ii. A portion of the amount will be paid to government opioid abatement programs
iii. Endo affiliates that have emerged from bankruptcy are prohibited from marketing opioids and must publish documents relating to their role in the opioid crisis

Allegation:

i. Violating the Federal Food, Drug and Cosmetic Act in connection with its distribution of the opioid medication Opana ER with INTAC
ii. Endo admitted that sales reps marketed Opana ER to prescribers by touting the drug's abuse deterrence, tamper resistance, and/or
crush resistance, despite a lack of clinical data supporting those claims.
iii. Endo admitted the labeling failed to meet legal standards

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Ra Medical Systems Inc.

About: California medical device company that developed a medical laser marketed for atherectomies to treat peripheral artery disease (PAD) [FDA had not approved the laser for this purpose]

Settlement:

i. The company agreed to a settlement back in 2020, but it was held under seal as the DOJ pursued cases against the doctors accused of accepting kickbacks

ii. Ra Medical Systems, Inc. originally agreed to pay $30M, but the due date was delayed due to the company's inability to pay. To date Ra Medical Systems has paid about $7.5M

iii. Two physicians have agreed to pay another $700,000.

Allegation:

i. The government argued that payments from Ra Medical Systems to the physicians were kickbacks. The payments, according to the government, included cash and fake consulting contracts.

ii. The government alleged that despite knowing the laser had serious issues—such as overheating and needing frequent adjustments, which led to a recall in 2019—Ra Medical continued to market it for use in atherectomies on PAD patients.

Sentynl Therapeutics

About: California pharmaceutical company that marketed and sold the prescription opioids Abstral and Levorphanol, medications to manage breakthrough pain in cancer patients

Settlement: $750,000 to settle accusations

Allegation:

i. The company paid indirect kickbacks through the girlfriend of a doctor who prescribed large amounts of the company's opioids

ii. Hired the girlfriend of a large prescriber as sales representative

iii. The settlement agreement notes that Sentynl denies the allegations and they claim that they fired the girlfriend before the government investigation.

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Cybersecurity and FCA Liability

- Centene Corporation and its subsidiary HNFS agreed to pay $11.2M to resolve claims that HNFS falsely certified compliance with cybersecurity requirements in a contract with the U.S. Department of Defense (DoD) to administer the Defense Health Agency's (DHA) TRICARE health benefits program for servicemembers and their families.
- Most federal contracts now include cybersecurity obligations.
- In 2021, the DOJ launched a Civil Cyber-Fraud initiative, which has used the FCA to prosecute government vendors who knowingly: (1) provide deficient cybersecurity products or services; (2) misrepresent their cybersecurity practices or protocols; or (3) fail to monitor and report cybersecurity incidents or breaches.
- Companies are typically targeted by DOJ after data breaches.
- In his recent remarks, Granston noted the final Cybersecurity Maturity Model Certification (CMMC) rule issued by the DoD in October 2024 and its implications for FCA investigations and whistleblower complaints.

New York Health Data Privacy Act

- Still pending Governor Hochschul's signature
- Applies to entities that control the processing of RHI of NY residents, individuals located in NY, and entities located in NY that control the processing of RHI.
- RHI = any information that is reasonably linkable to an individual, or a device, and is collected or processed in connection with the physical or mental health of an individual
- Could include any data that might directly or indirectly relate to an individual's health status, bodily functions, or mental well-being
- Excludes information governed by HIPAA or collected as part of a clinical trial governed by the Federal Policy for the Collection of Human Data ("Common Rule")
- Stringent Consent Requirements with 24-hour waiting period
- Enforcement by AG (no private right of action)

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Magellan Execs Plead Guilty

- The former CEO, COO, and Director of Quality Assurance and Regulatory Affairs for Magellan Diagnostics pleaded guilty charges of misbranding and making false statements for concealing a device malfunction.
- The executives learned in 2013 (during the FDA clearance process) that a malfunction in their devices could cause inaccurate results (specifically, false low lead test results). They not engage in further testing in order to preserve "plausible deniability," and waited until after company was acquired in 2016 to notify FDA.
- They also provided false and misleading statements to customers and FDA about when and how it discovered the malfunction.
- As a result of their conduct, tens of thousands of children and other patients received "inaccurately low lead test results"
- The charges of introduction of misbranded medical devices provide for a sentence of up to three years in prison, up to one year of supervised release and a fine of up to $250,000. The charge of making false statements provides for a sentence of up to five years in prison, up to three years of supervised release and a fine of up $250,000 or twice the gross gain from the offense, whichever is greater.

Clinical Trials Fraud

- Two owners of A&R Research Group, a Florida clinical research facility, pleaded guilty to conspiracy to commit wire fraud, and a physician pleaded guilty to making false statements to the FDA, in connection with two clinical trials testing asthma drugs.
- One owner served its clinical research director and study coordinator and the other as its regulatory and contract affairs manager. The physician acted as a clinical trial investigator.
- The owners admitted to making fraudulent representations to the trial sponsor regarding subject eligibility, and falsifying and fabricating material documents and data, including case histories, spirometry readings, and echocardiogram data.
- The physician admitted that, during an FDA inspection, he knowingly and falsely told the FDA investigator that he had been present at every subject visit during the two asthma clinical trials.
- A similar case involving another Florida-based clinic (AMB Research Center) resulted in a jury conviction of the owners in 2023.

Schroeder v. Medtronic – Bundled Discounts

- District court ruled that Medtronic complied with the regulatory safe harbor for bundled discounts even though the amount of the discount was not apparent on the invoice and the documentation did not apportion the discount among bundled products.
- Medtronic provided no-charge atherectomy devices with large orders of drug-coated balloons. Its invoice listed the number of balloons purchased and the total charge for those balloons. It also provided an attachment to the invoice listing the number and value of plaque removal devices being provided at no charge. The documentation did not apportion the discount across the products.
- Taken together, the invoice and attachment indicated all of the products included the bundle and the total price for the bundle. The invoice also included a legend referencing the customer's obligation to accurately report discounts to state and federal payers.
- The court concluded Medtronic's documentation was sufficient to qualify for the safe harbor.
- The court also determined that the statutory exception from AKS is distinct from the regulatory safe harbor. This is consistent with another district court decision (U.S. v. Shaw, D. Mass 2000) but inconsistent with guidance given by HHS-OIG, i.e., that the Safe Harbors are co-extensive with the statutory exception (64 Fed. Reg. at 63527-28).

Transparency Reminders

March 31	**U.S.** Open Payments reports due to CMS via Open Payments Portal. **Romania** HCP sponsorship reports due to ANMDMR. **Columbia** semiannual transfer of value reports due to Minsalud.
April 1	**Vermont** compliance officer form, registration fee, and transparency reports are due to the Vermont AG's office (required only if manufacturer has expenditures to report).
May 31	**Belgian** Transparency reports due using BeTransparent.be platform.
June 1	**Nevada** Compliance Form due by e-mail to the State Board of Pharmacy (or postmarked by June 1 if mailed). Forms may not be submitted before May 1.
June 3 – 20	South Korea reports due to KOPS (SK expenditure management system).
July 1	**Massachusetts** report and renewal registration due to the Massachusetts Department of Public Health. *Note, inform the department via e-mail if you have no data to report.*
July 15	**Philippines** semiannual report of financial relationships using FDA Online Disclosure Report System.
September 1	**French** Sunshine ("**Loi** Bertrand") reports due via Transparence Sante site.
September 30	**Columbia** semiannual transfer of value reports due to Minsalud.

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International Update

- ITALIAN SUNSHINE ACT (Sanità Trasparente)
- Reporting platform is currently under pilot test. Companies should anticipate data collection starting in July - Dec 2025 and first submissions in 2026.
- Updates and technical specifications are available at https://sanitatrasparente.com/ (Note, this is an industry-sponsored site unaffiliated with the Italian government or MDMA)
- NEW ANTIBRIBERY ALLIANCE
- Task force announced by the UK's Serious Fraud Office (SFO), France's Parquet National Financier (PNF) and the Office of the Attorney General of Switzerland (OAG) to strengthen collaboration on international bribery and corruption cases.
- Announcement comes in wake of White House EO pausing FCPA enforcement.

What to Expect in 2025: Predictions?

Predictions for hot topics and enforcement in 2025

- General uncertainty but might see:
  - **Caution by DOJ as cracks appear in longstanding, prosecutor-friendly standards**
    - Changes in intervention patterns, particularly in FCA cases premised on an underlying AKS violation
    - "Low hanging fruit" cases (*i.e.*, factual falsity cases)
  - **Focus on Medicare Advantage**
    - Expect new theories of falsity
  - **Cybersecurity/privacy matters**
    - Implied Certification Theory

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Predictions for hot topics and enforcement in 2025 (cont.)

- DOJ continues to focus on the healthcare industry
- Whistleblower suits continue to rise -- DOJ Pilot & Whistleblower Programs incentivize reporting
- AKS/FCA is the predominant area of enforcement
- Patient safety and potential for harm drive enforcement
- Billing accuracy is critical, with a focus on medical necessity and proper coding practices/guidance

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Future State

LESS FDA HELP?

FDA REVIEW TIME STAYS THE SAME OR NOT?

CASE ORIGINATION?

WHISTLEBLOWERS INCREASE IF RECESSION OCCURS

PRACTICE BUILDING

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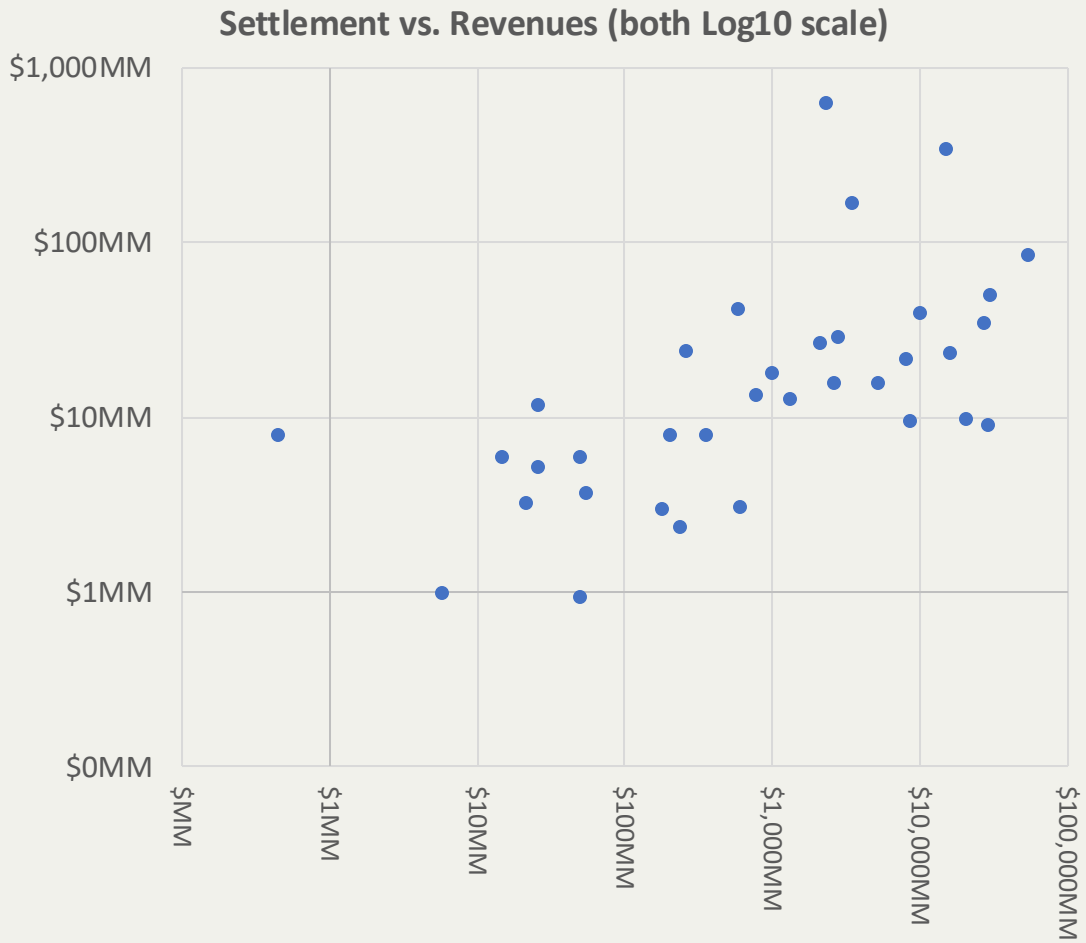
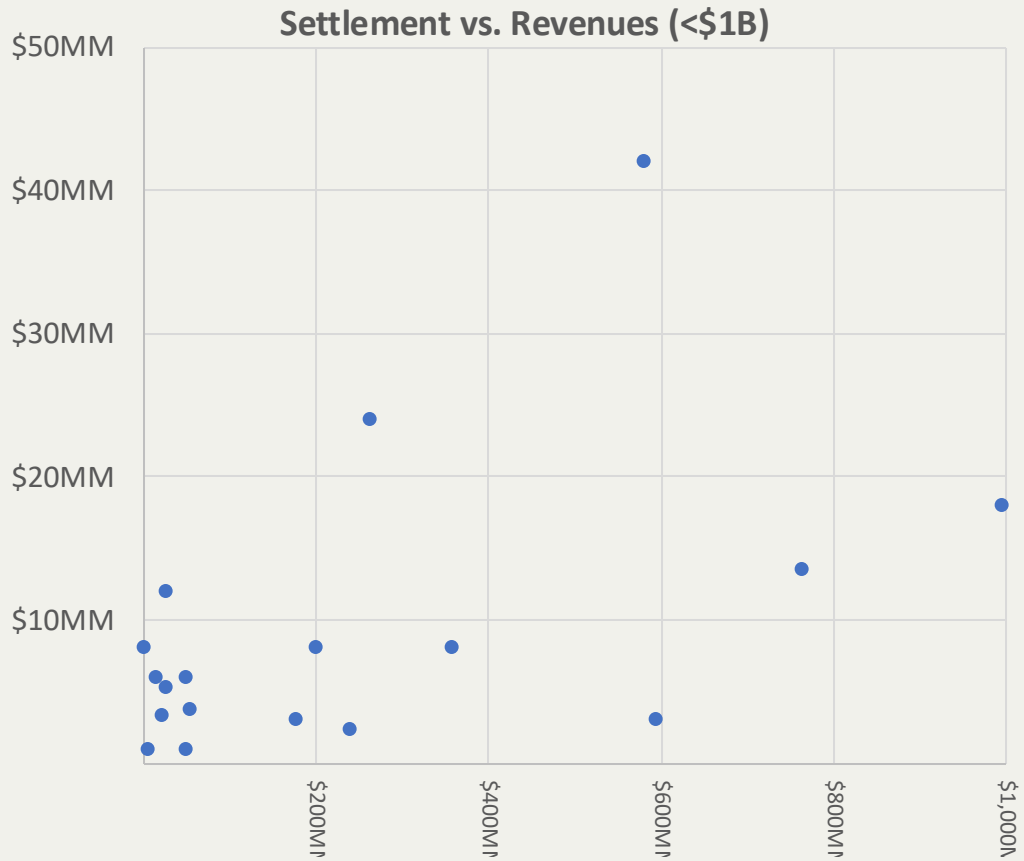
Settlement Value vs. Company Revenues





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Select AKS Settlements – Meals, Practice-Building

Increasingly severe / egregious conduct

Company	Year	Description of alleged misconduct	Settlement Value	Prior Year's Revenue
Abiomed	2018	Abiomed allegedly paid for HCP meals (1) with excessive alcohol; (2) at expensive restaurants, including for spouses; (3) in which the cost per-attendee well exceeded Abiomed's own $150 per person guideline; and (4) in which their employees misrepresented the number of attendees.	$3.1MM	$594MM
Phillips Respironics	2022	Philips Respironics resolved FCA allegations that it paid kickbacks to DME suppliers, in the form of illegal inducements to the DME suppliers. Respironics allegedly gave the DME suppliers physician prescribing data free of charge that could assist their marketing efforts to physicians.	$24.0MM	$263MM
Cardiovascular Systems	2016	CSI allegedly violated the AKS by providing marketing and other practice development services to physicians using its devices, including distributing materials to referring physicians; coordinating meetings with referring physicians; and developing and implementing business expansion plans for utilizing physicians.	$8.0MM	$200MM
Endogastric Solutions	2014	The company allegedly provided illegal kickbacks to physicians and encouraged inappropriate billing practices to promote its EsophyX device. The government also alleged that EGS paid illegal remuneration to certain physicians for participating in patient seminars and provided co-marketing agreements to induce use of EsophyX.	$5.3MM	$26.0MM
Merit Medical Systems	2020	Under the guise of its Local Advertising Program, MMSI allegedly provided remuneration to HCP's in the form of millions of dollars in free advertising assistance, practice development, practice support, and purported unrestricted "educational" grants to induce the healthcare providers to purchase and use MMSI products.	$18.0MM	$1.0B
Medtronic	2015	Medtronic allegedly induced physicians to use its pacemakers and defibrillators by: 1) paying implanting physicians to speak at events intended to increase the flow of referral business; 2) developing marketing/business development plans for physicians at no cost; and 3) providing tickets to sporting events.	$9.9MM	$20.3B
Biotronik	2022	Biotronik is alleged to have abused a new employee training program by paying physicians for excessive and/or unnecessary trainings and to have paid for physicians' holiday parties, winery tours, lavish meals and international travel in return for brief appearances at conferences.	$13.0MM	$1.3B
Innovasis	2024	Innovasis allegedly paid kickbacks to surgeons in form of consulting fees, IP acquisition and licensing fees, registry payments, performances shares in company, travel to ski resort, lavish dinners, holiday parties for surgeons and their staff and family members.	$12.0MM	$26.1MM

Questions

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Tales from the Trenches: A Focus on FDA Fraud, Abuse, and Marketing Compliance

Mike Pisetsky

Friday, April 11, 2025

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Presenter Introduction

Michael A. Pisetsky was named Chief Business & Legal Affairs Officer at SI-BONE in April 2023, overseeing supply chain, customer service, Legal, Quality Assurance, Program Management, IT, and administrative functions. As chief advisor on legal, strategic, transactional, and operational matters, he serves on the Executive Management Team. Previously General Counsel and Chief Compliance Officer, he played a key role in SI-BONE's IPO and financing rounds.

Michael practiced law at Cooley LLP, holds a B.A. from Harvard College, and a J.D. and M.B.A. from Duke University.

Mike Pisetsky

Chief Business and Legal Affairs Officer
mpisetsky@si-bone.com
Phone: 669.206.2501

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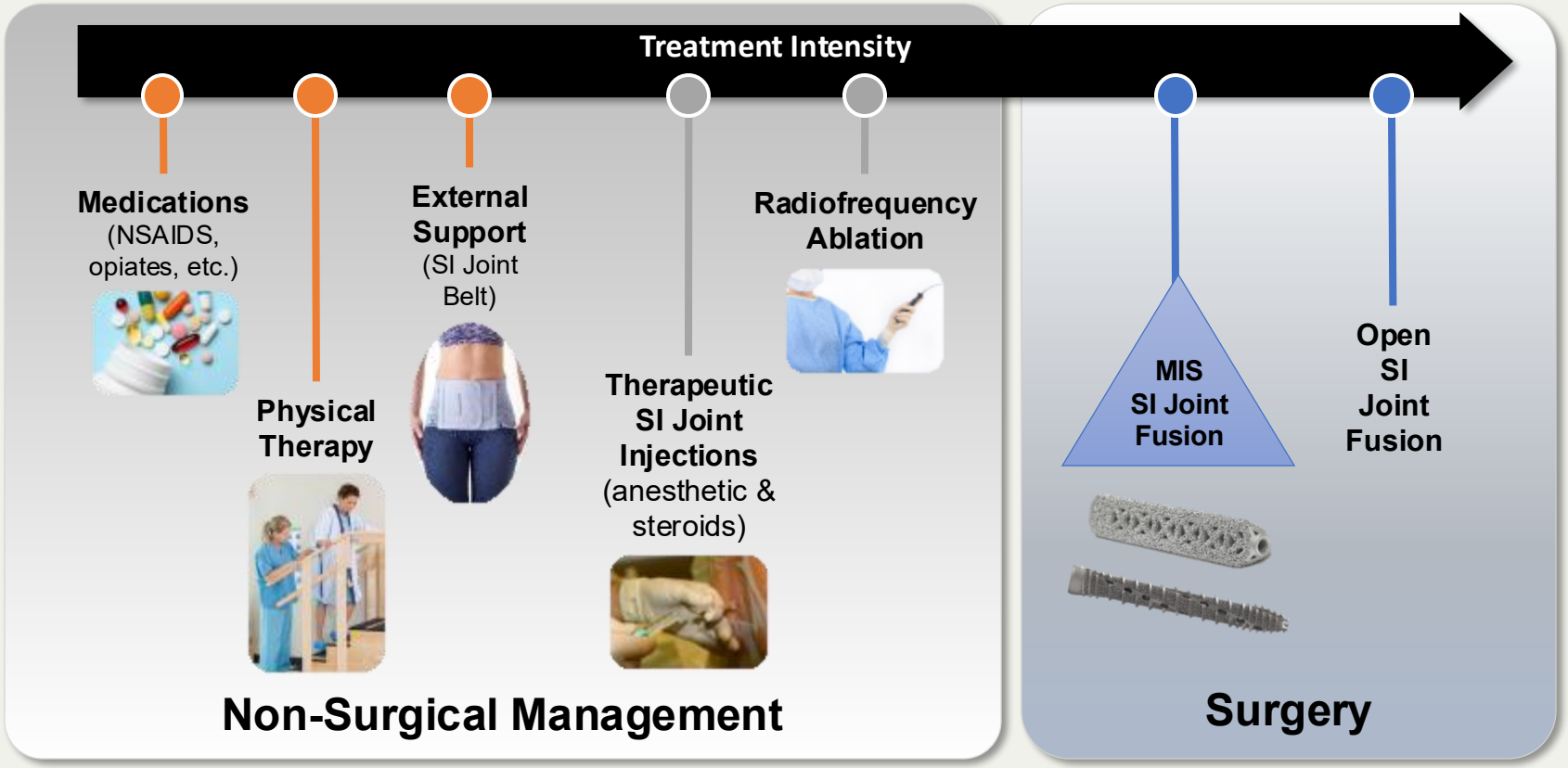
Intro to SI-BONE and SI fusion

- Founded in 2008 as a pre-acquisition spinout of INBONE
- INBONE acquired by Wright Medical, licensed fusion rod to SIBN
- First company commercializing MIS SI joint fusion product
- Aggressively grew the market from 2009 to 2013
- Re-established reimbursement for the procedure: 2013 – 2021
- Went public October 2018; 3 follow-on rounds (2020-2023)
- Diversified the business 2021-present in trauma, TL fusion
- ~$195 million 2025 revenue; ~$115 million in net cash

Foundation: SI joint fusion (SIJF)



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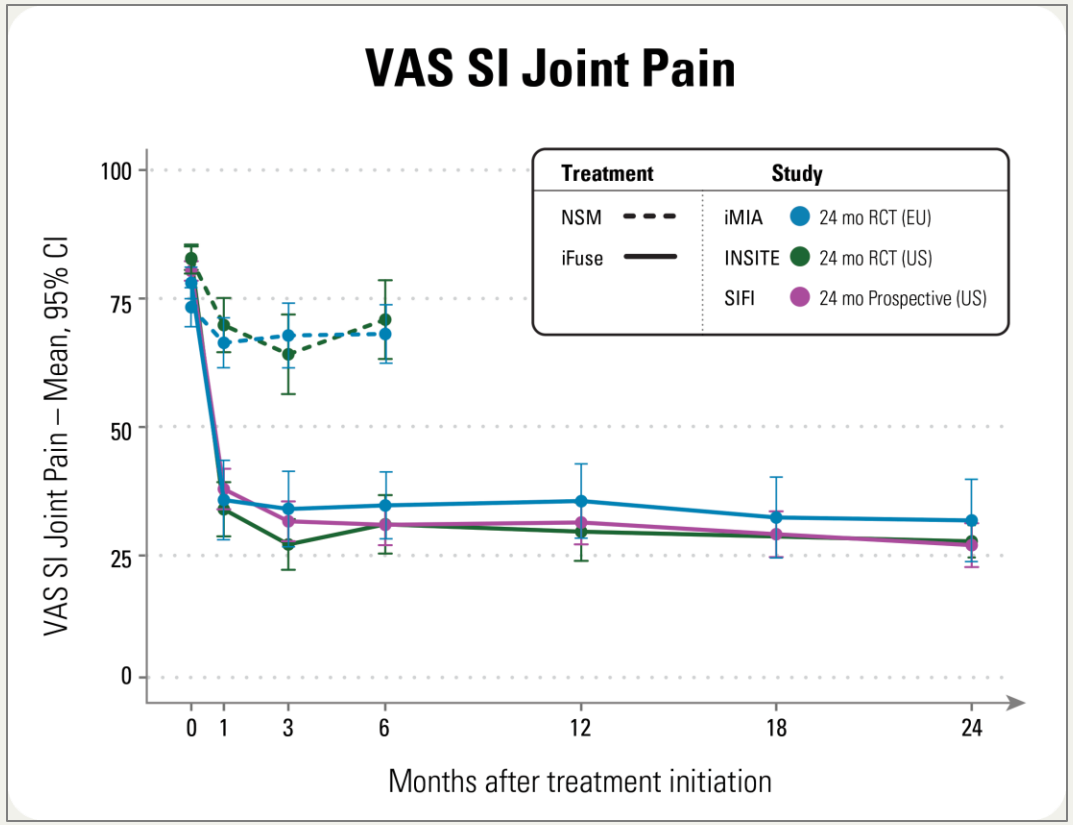
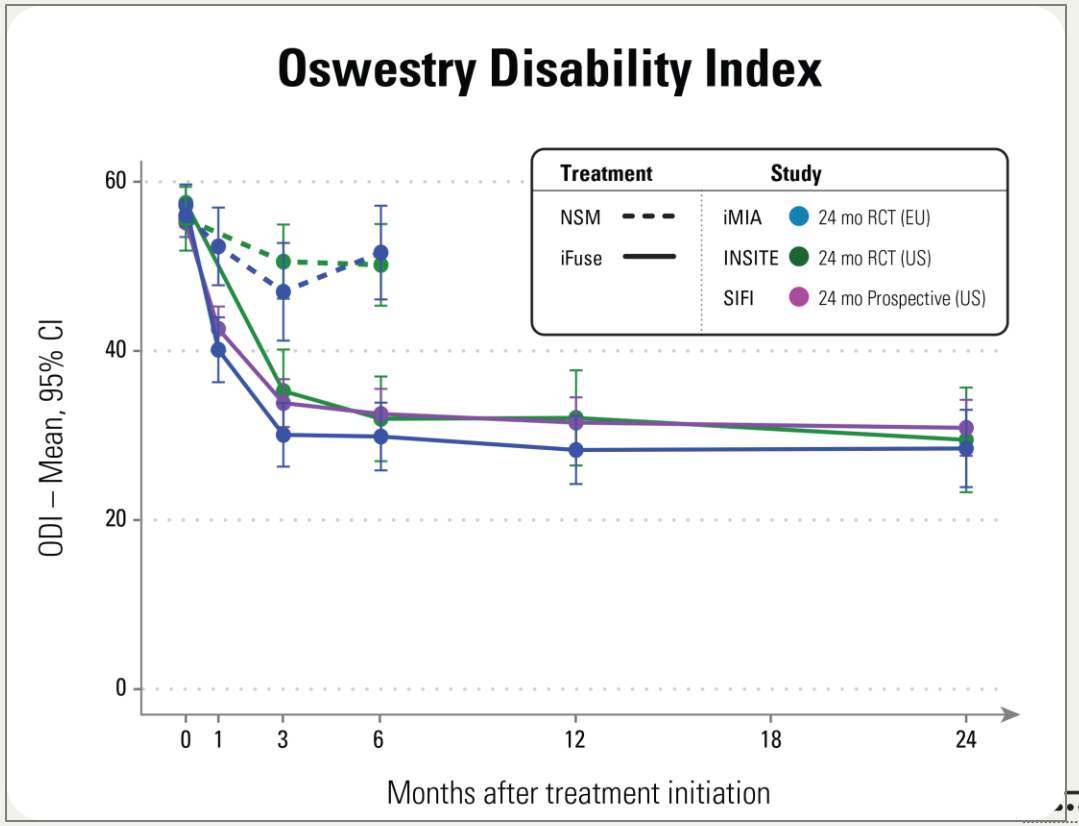
SIJF: 24 mo. clinical results, x3





Graphs using data from:

Dengler – *J Bone Joint Surg Am* 2019 (iMIA 2yr)
Polly – *Int J Spine Surg* 2016 (INSITE 2yr)
Duhon – *Int J Spine Surg* 2016 (SIFI 2yr)

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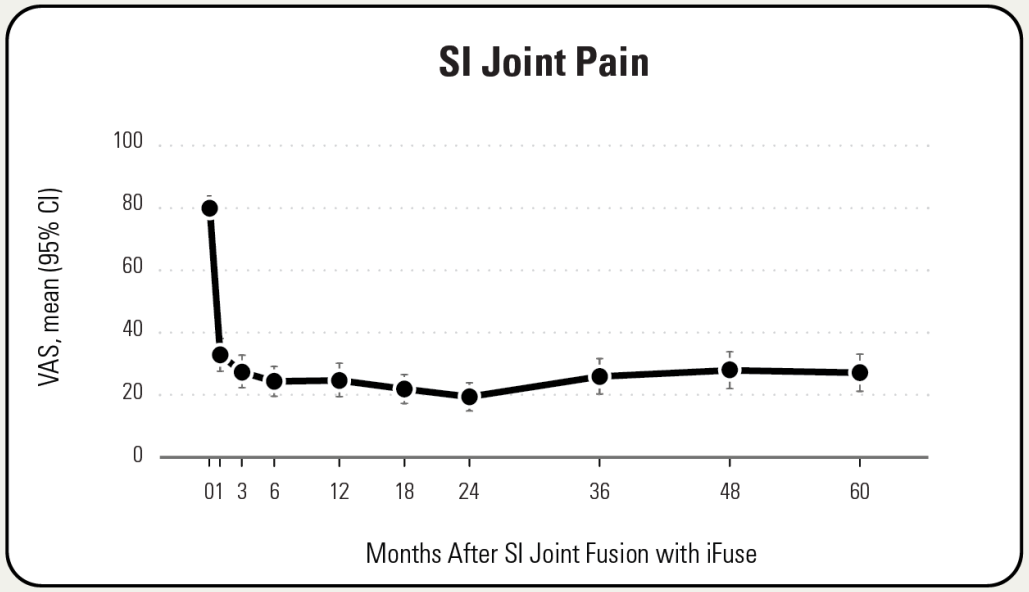
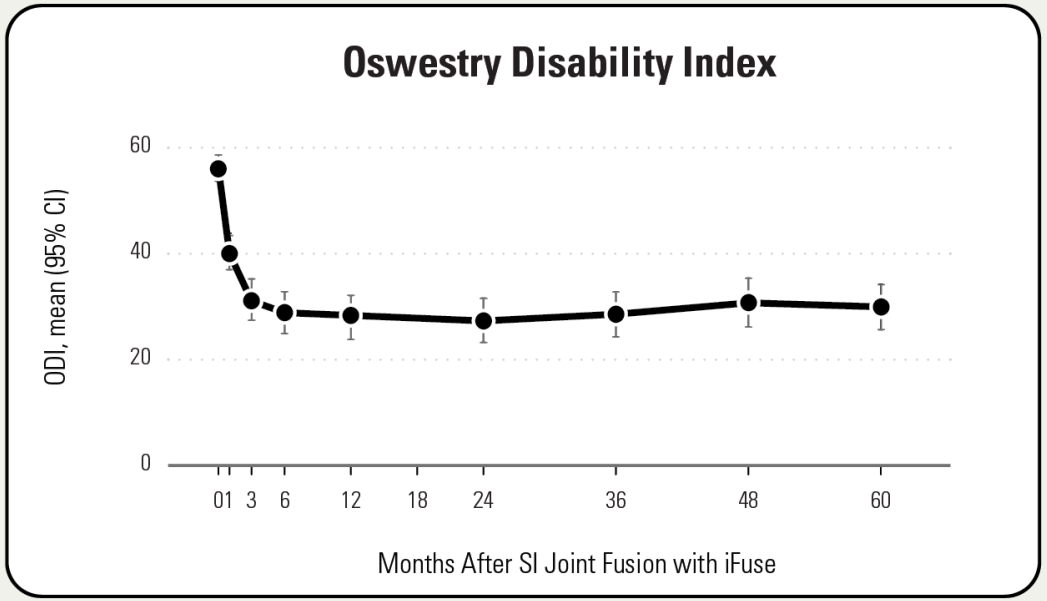
SIJF: Outcomes are durable





	Clinically Meaningful Improvement
VAS	20 points

Source: Childs – *Spine 2005;30:1331.*

	Clinically Meaningful Improvement
ODI	15 points

Source: Copay – *Spine J* 2008

Whang – Med Devices Evid Res 2019 (LOIS 5yr)

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Evolution of our technology and indications

- "intended for *fracture fixation of large bones and large bone fragments* of the pelvis for conditions including *sacroiliac joint disruptions and degenerative sacroiliitis*." –K080398 (11/2008)
- "intended for *sacroiliac joint fusion* for conditions including sacroiliac joint disruptions and degenerative sacroiliitis" -K110838 (03/2011)
- "intended for sacroiliac joint fusion for conditions including *sacroiliac joint dysfunction* that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis" –K141049 (07/2014)
- "… This includes conditions whose symptoms began during pregnancy or int eh peripartum period and have persisted postpartum for more than 6 months." –K150875 (07/2015)
- "… Clinical studies have demonstrated that treatment with the iFuse Implant System *improved pain, patient function, and quality of life* at 12 months post-implantation." –K151718 (10/2015)

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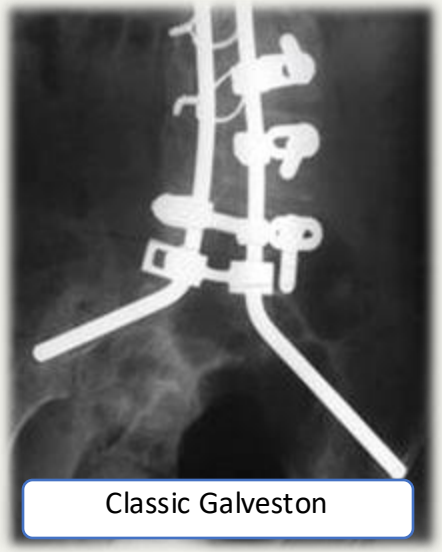
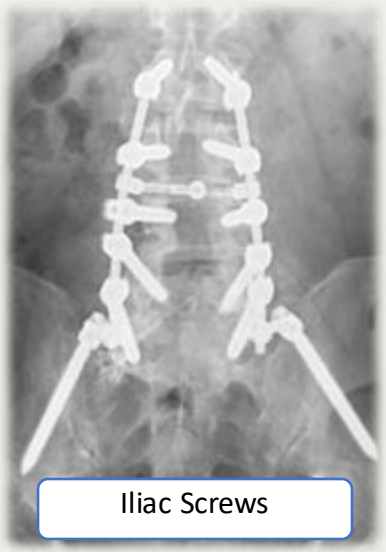
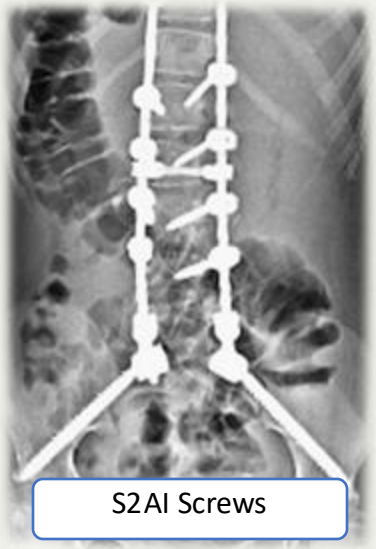
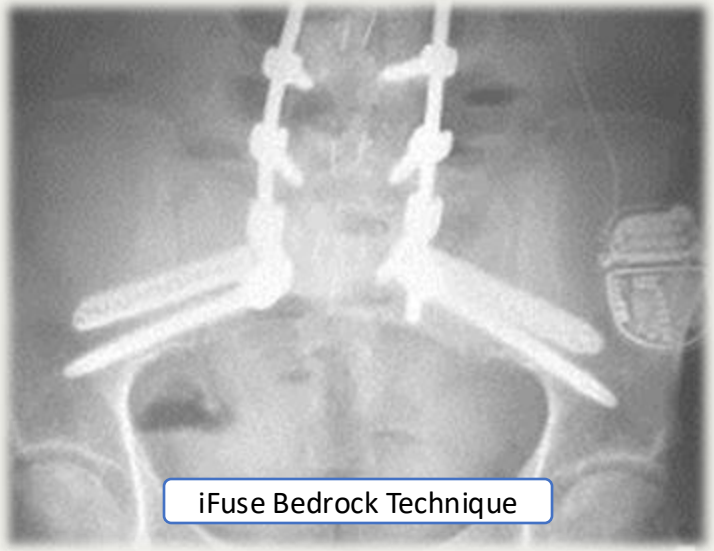
Evolution of our indications (cont'd)

- "The iFuse Implant System is also intended for sacroiliac fusion to *augment immobilization and stabilization* of the sacroiliac joint in skeletally mature patients undergoing *sacropelvic fixation* as part of a *lumbar or thoracolumbar fusion*." –K190230 (04/2019)


Classic Galveston


Iliac Screws


S2AI Screws


iFuse Bedrock Technique

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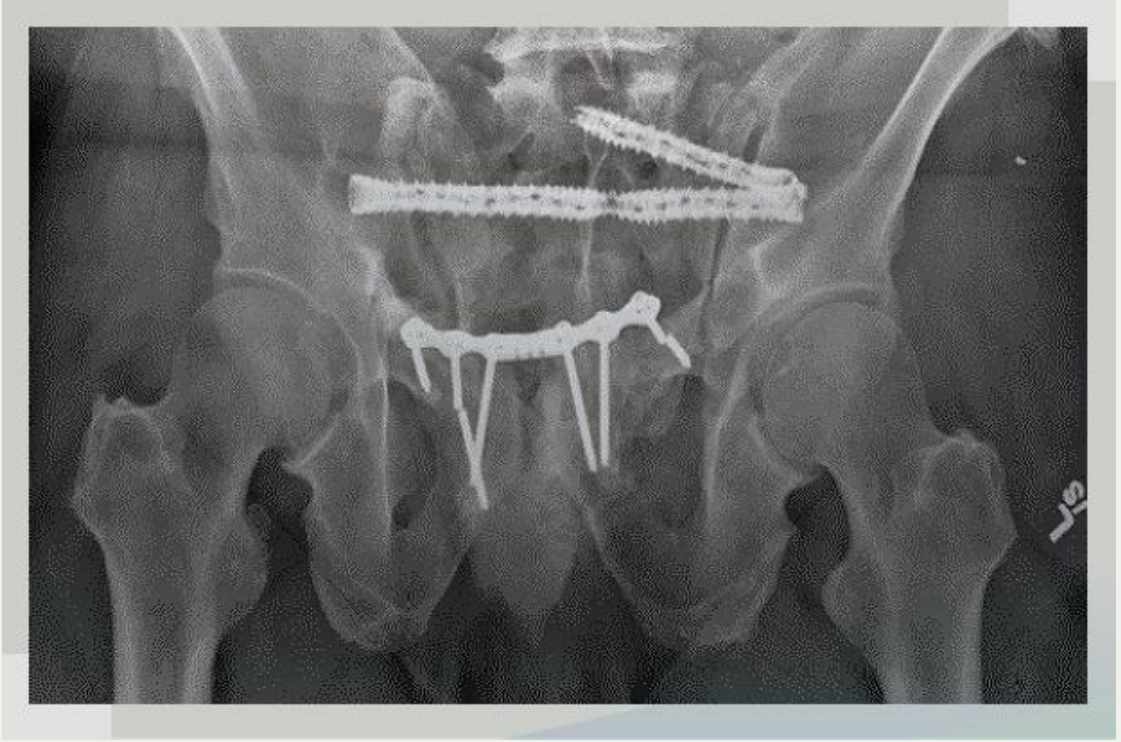
Evolution of our indications (cont’d)

- “intended for sacroiliac fusion for the following conditions: … Acute, non-acute, and non-traumatic *fractures involving the sacroiliac joint*.” K193524 (03/2020)



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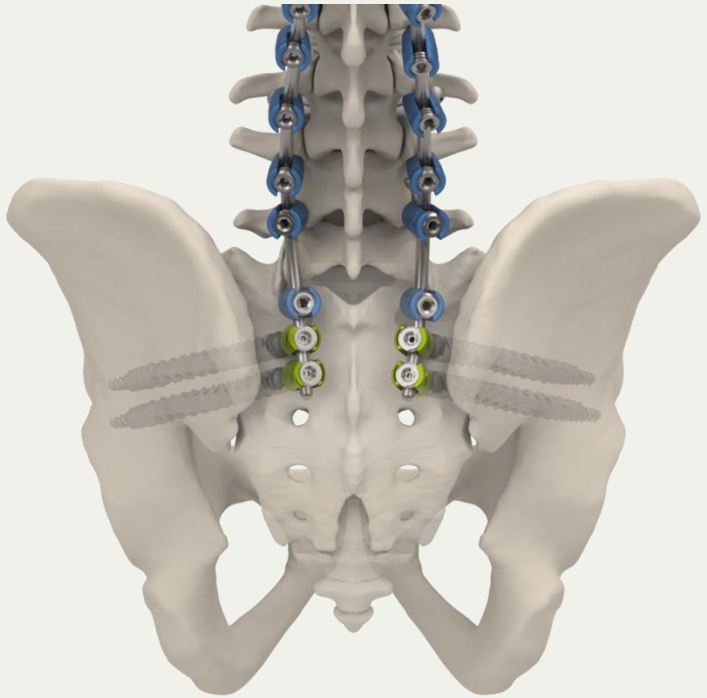
Evolution of our indications (cont'd)

- "When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumboscral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine…" –K222774 (Granite, 12/2022)



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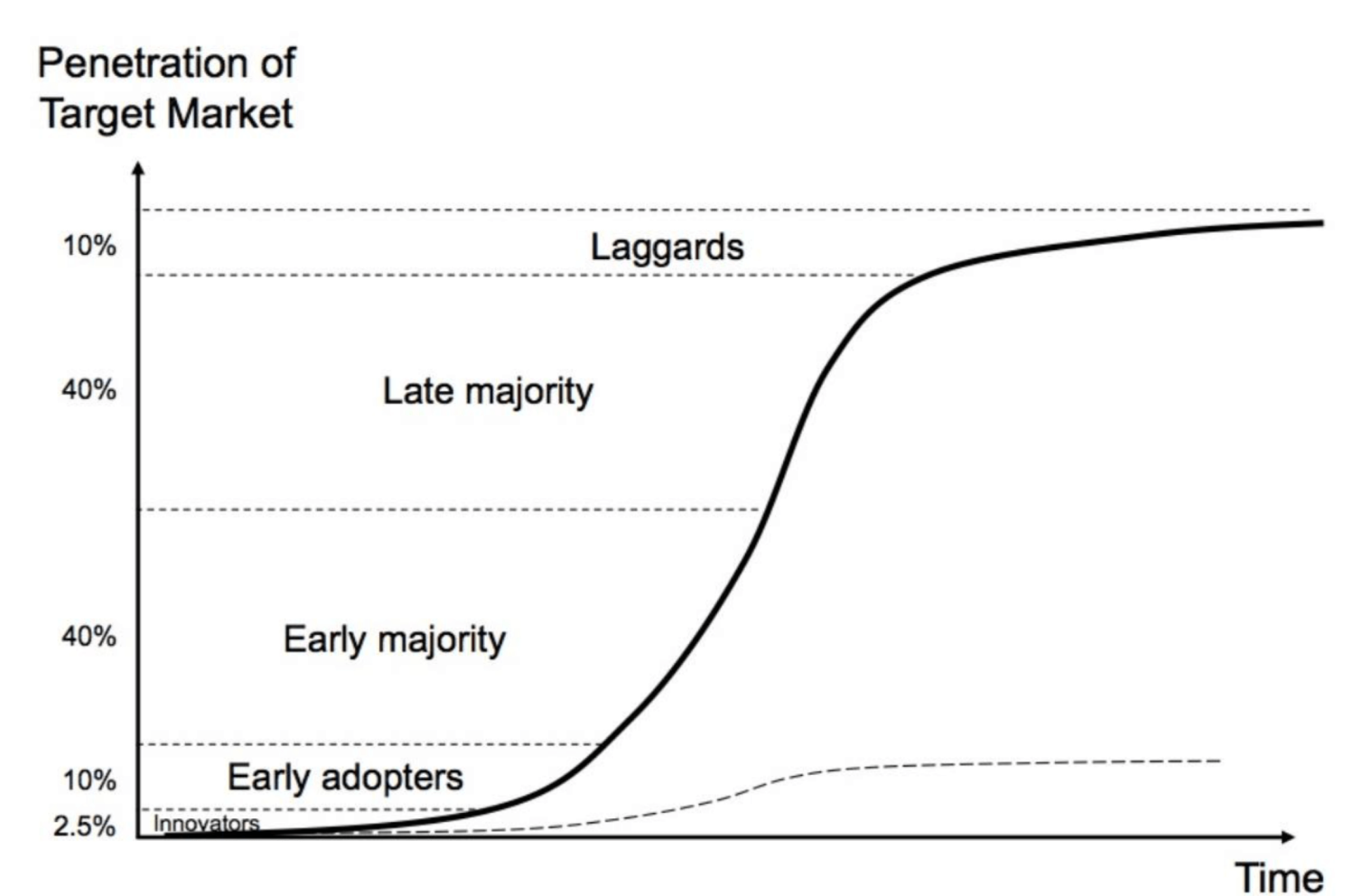
Evolution of our indications (cont’d)

- “The iFuse TORQ TNT Implant System is indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.” –K241504 (TNT, 04/2024

Technology Diffusion - SIJF



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1. **Innovators**: Beware off-label promotion; learn from off-label use

- MIS SI joint fusion developed as result of an off-label use
- Sell for off-label use only based on physician request
- Carefully follow FDA guidance re off-label dissemination
- The First Amendment argument is a "nice theory" – not practical
- Surveil and track off-label use of your product w/o encouraging
- Good data re new uses of products may lead to new labelling
- SIBN's market segments are the result of working with FDA to update labelling to reflect contemporary practice
  - Gained labeling for SIJ fusion for dysfunction and pain reduction claims
  - Created fusion for pelvic fixation labeling based on new physician uses
  - Leveraged this framework for pelvic fixation/SIJ fusion product: Granite

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2. Early Adopters: Considerations re M.D. investors

- SI-BONE literally had the M.D. investors of 2 MedTech start-ups
- Physicians are natural investors in MedTech start-ups
- Pre-IPO option granting to M.D. advisors is a great incentive…
  - But tricky to manage!
  - How do you value and report stock options? Clarity re CMS reporting?
- Be ready for the "POD"/Stark Law fight with customer accounts
  - Open Payments is your best friend!
- Pressure for "Friends & Family" IPO directed shares

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3. Early Majority: The AKS and market-building

- Physician consulting can be done, with the right tracking tools
  - Needs assessment, physician hourly rates; track hours and utilization, but not for ROI!
- Know the difference between Grants vs. Sponsorships, and have a committee
- Carefully govern field-based promotion
  - Develop meal limits and a culture around good meals hygiene
  - 2021 AdvaMed Co-Marketing guidance: clear rules of the road!
  - But, beware M.D. "practice-building"
- Build a culture of compliance
  - "Everything" is illegal under the AKS: intent based statute
  - Need clear guidance for employees – remediation/escalation
- Understand the AKS safe harbors
  - Online Physician Finder tools
  - Reimbursement using value-based care – more than just hype?

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4. Early Majority: Carefully navigate CPT changes

- SI-BONE started with one code: 27280 – "SI joint fusion"
- We migrated our products to a second, newer code: 27279
  - T-code dropped 7/1/13. Cat 1 code effective 1/1/2015 – record time!
  - Then the Reimbursement Wars began – armistice achieved late 2021.
- Beware the compliance pitfalls when a product is placed in a lower value or unreimbursed CPT code
  - Always guide to the proper code for your technology
- Know how to anticipate the changing landscape
  - Tempting to "slide in" to existing CPT coding – but long-term may not work
- Do the studies needed to gain coverage and proper payment
  - Generally, need Level 1 evidence for new Cat 1 code
  - Need two good RCT's to get commercial reimbursement for new code

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5. Late Majority: Understand how to respond to new providers in your code

- 2018: new providers started using 27279 for new procedures
  - "Dorsal allograft"
  - We responded with letters to companies: competitive claims promotion
  - We achieved little success with this strategy
- Enter 3rd CPT Code: X034T announced 2022, effective 1/1/2023
- The T-code did slow down adoption of dorsal allograft

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6. Late Majority: Carefully manage shifts in provider specialty mix

- Rise of interventional pain concurrent with the rise of allograft
- Companies frequently want to limit market to a specialty group
  - Cultivate outcomes with particular specialty groups
- Hard for MedTech to govern the practice of its own medicine
  - FDA cannot regulate practice of medicine
  - Traditional jurisdiction of the states, but states loath to govern
- Picking and choosing docs: beware restraint of trade claims
  - "Residency-trained surgeons" was a convenient objective criteria to use…
  - … but hard to defend / define in the long-term
- Consider FDA labelling to ensure users are properly trained
  - DRG stimulation: industry-led training as a requirement for users

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Questions

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Thank you!

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