Ski-LE

The Mountain Summit for FDA Regulatory & Compliance Leaders

Gardner Law

Friday, April 10, 2026

Program Introduction

- **CLE credits**: This course has been approved for 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.

RAPS RECERTIFICATION APPROVED PROVIDER

Regulatory Affairs Certification (RAC)

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Agenda

7:30 – 8:00 AM	**Opening Remarks: The State of the U.S. Healthcare Space** *Mark Gardner, Founder & Managing Partner, Gardner Law* *Kelvyn Cullimore, President & CEO, Bio Utah* *Mike Pisetsky, Chief Business & Legal Affairs Officer, SI-BONE, Inc.*
8:00 – 9:00 AM	**Hot FDA Topics: What is FDA Focusing On Right Now, and How Can Industry Adjust?** *Mark Gardner, Founder & Managing Partner, Gardner Law*
9:00 – 10:00 AM	**Interactive Session: Recent Fraud and Abuse Cases and Compliance Hot Topics Update** *Nathan Downing, Managing Attorney, Garder Law*
10:00 – 11:00 AM	**Tales from the Trenches: A Focus on FDA Fraud, Abuse, and Marketing Compliance** *Mike Pisetsky, Chief Business & Legal Affairs Office, SI-BONE, Inc.*

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Opening Remarks: The State of the U.S. Healthcare Space

Friday, April 10, 2026

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Presenter Introduction

Mark Gardner, MBA, Esq.

Founder, Managing Partner
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Phone: 612.382.7584

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

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

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

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

Presenter Introduction

Michael A. Pisetsky was named Chief Business & Legal Affairs Officer at SI-BONE in April 2023, overseeing Legal, Compliance, People & Culture and Business Development. 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 Legal Officer
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Presenter Introduction

Nathan Downing

Managing Attorney
ndowning@gardner.law
Phone: 651.353.6283

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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.

Presenter Introduction

Kelvyn H. Cullimore, Jr.

President & CEO
Kelvyn@bioutah.org
Phone: 801.580.4523

BIOUTAH

Kelvyn H. Cullimore Jr. is President and CEO of BioUtah, where he leads the state's trade association supporting Utah's medtech, biotech, pharma, and broader life sciences ecosystem.

He brings decades of executive leadership experience, including 25 years as President and CEO of Dynatronics Corporation, a publicly traded medical device company founded by his family. His background spans business growth, manufacturing, commercialization, and industry advocacy.

Kelvyn has also served for more than a decade on the board of the Medical Device Manufacturers Association and for more than a decade as mayor of Cottonwood Heights, Utah, including as the city's first mayor.

In addition to his work at BioUtah, he serves on boards and advisory groups focused on innovation, trade, and science education, including World Trade Center Utah and the University of Utah's Center for Medical Innovation

The State of the U.S. Healthcare Space

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

Nathan Downing

Friday, April 10, 2026

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Objectives

- FDA Updates
- Opportunities to Adjust
- Open Discussion Throughout

Latest at FDA

Leadership

Priorities

Head Count

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Medical Device Definition
21 USC § 321(h)(1)

"The term *device* … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,

(C) or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man… and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

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Device Law History

- The Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 is passed by Congress
  - Codified 21USC Sec.321 et seq.
  - The FD&C Act gave FDA the power to regulate medical devices for the first time
  - No premarket approval requirement
  - Prohibited acts of adulteration and misbranding
  - Authorized factory inspections
  - Added the remedy of court injunctions to the previous penalties of seizures and prosecutions
- The 1976 Device Amendments come next…

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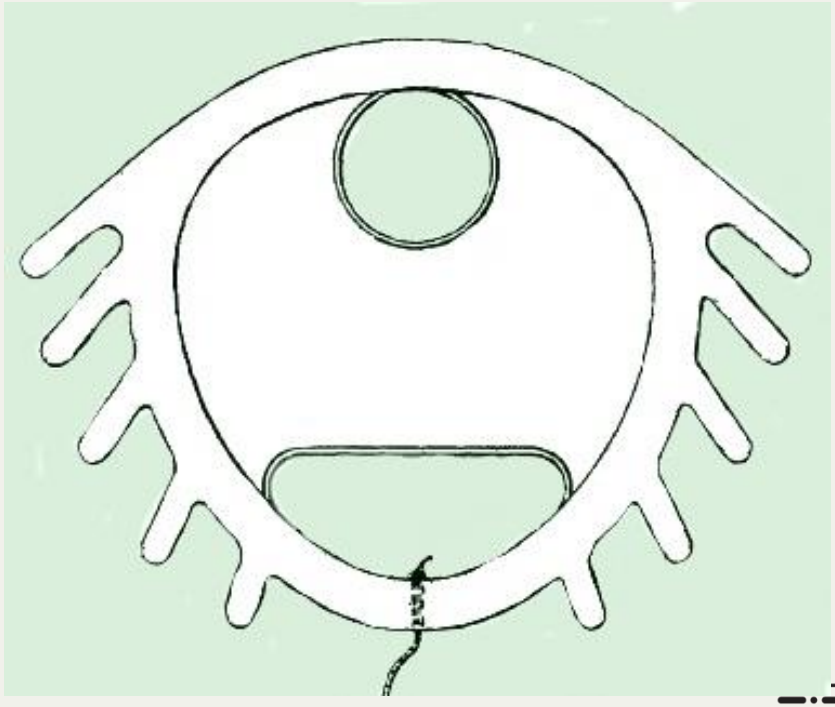
1976 Medical Device Amendments

- The Dalkon case had a huge part to do with the passage of the 1976 Amendments
- Congress also recognized:
  - More and more devices on the market
  - Complexity increasing with space age
  - Dalkon and thalidomide disaster
  - It was time to regulate medical devices further
- Introduced
  - Premarket approval system for medical devices
  - Good manufacturing practices (GMP)
  - Registration and Listing
  - Reporting by manufacturers of serious injuries, deaths, and certain types of malfunctions



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FDA and the Future-Artificial Intelligence

- Artificial intelligence is exploding
- FDA follows a regulatory structure that was not made for AI
- FDA is trying to keep up with innovation while protecting public health
- Recent FDA action speaks to their commitment

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Artificial Intelligence / 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.

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Why is AI/ML Important in Healthcare?

- AI and ML are used to derive new insights from the enormous amount of data generated during the delivery of healthcare.
- AI/ML can learn from real-world use and experience and can improve its own performance.
- Manufacturers are using AI/ML to innovate their products to assist healthcare providers and improve patient care.

“

AI is perhaps the most transformational technology of our time, and healthcare is perhaps AI's most pressing application.

-Satya Nadella, Microsoft CEO

”

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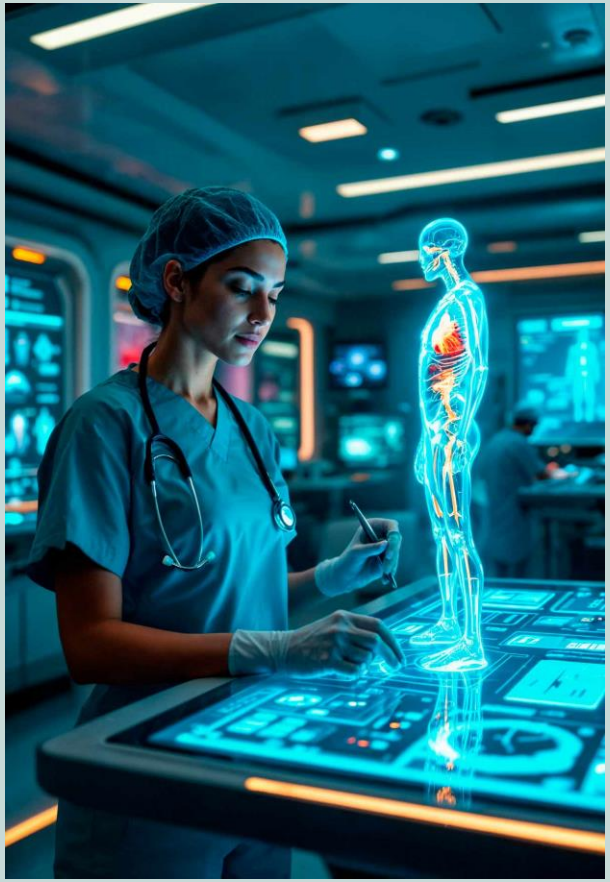
AI/ML in Healthcare



- Predict post-surgical outcomes
- Remote Surgery
- Assist in diagnosing
- Help manage the almost overwhelming amount of data generated in the healthcare space
- Additional applications are a constant in this space

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FDA Regulation of Medical Devices

- The evolving nature of medical devices that employ new technologies differentiate them in a meaningful way from traditional medical devices that are innovated in discrete generations, e.g., a single model or version of a device is improved upon and released as a new model or version.
- Traditionally, FDA reviews medical devices through an appropriate premarket pathway:
  - premarket clearance (510(k)),
  - De Novo classification, or
  - premarket approval.

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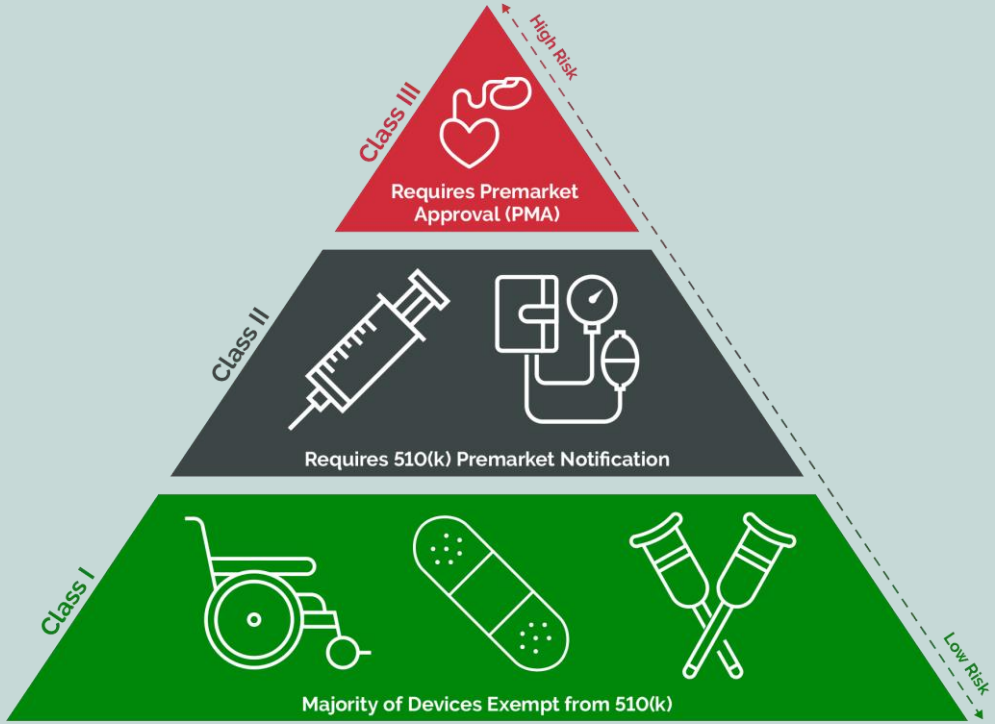
510(k)

Before marketing a device that has a legally marketed predicate device and that is not exempt from premarket notification (most class I and class II devices), each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

- **Class I:** A low to moderate risk device requiring general controls.
- **Class II:** a moderate risk device requiring general and special controls.
- **Class III**: Devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.



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De Novo Classification

- A De Novo classification request is a marketing pathway utilized to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. *See* section 513(f)(2) of the FD&C Act.
- Devices that are classified into class I or class II through a De Novo classification request may be marketed and used as predicates for future premarket notification (510(k)) submissions, when applicable.

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Premarket Approval

- Premarket approval (PMA) is the process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. *See* section 515 of the FD&C Act.
  - Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

- PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

Medical Device "Exceptions"

- Premarket approval (PMA) is the process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. *See* section 515 of the FD&C Act.
  - Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
- PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

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Lab Developed Test

- Laboratory developed tests, or LDTs are in vitro diagnostic products (IVDs) that are intended for clinical use and are designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.

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Software as a Medical Device

- In the digital health context, we see robust innovation in AI/ML in the context of clinical decision support software (CDS).
- FDA has long regulated software that meets the definition of a device (section 201(h) of the FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions.
- CDS is described as a variety of tools, e.g.: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information.

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21st Century Cures Act-Clinical Decision Support

- In 2016, Congress narrowed the scope of software potentially subject to FDA regulation by enacting Section 3060 of the 21st Century Cures Act, which amended Section 520(o) of the FDCA to exclude certain medical software functions, including certain CDS software, from the definition of a device.
- Pursuant to Section 520(o)(1)(E) of the FDCA, CDS software is excluded from the definition of a device if it meets all four of the following criteria:
  1. Is **not** intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system (Criterion 1);

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21st Century Cures Act Cont.

2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (Criterion 2);
3. is intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition (Criterion 3); **and**
4. is intended for the purpose of enabling an HCP to independently review the basis for the software's recommendations so HCPs do not primarily rely on the recommendations when making a clinical diagnosis or treatment decision regarding an individual patient (Criterion 4).

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Clinical Decision Support 2026 Updates

- Provide single recommendation if only one clinically relevant
- Proposed summary of radiologist’s clinical findings
- Remains HCP-Focused
- Discretion remains the key

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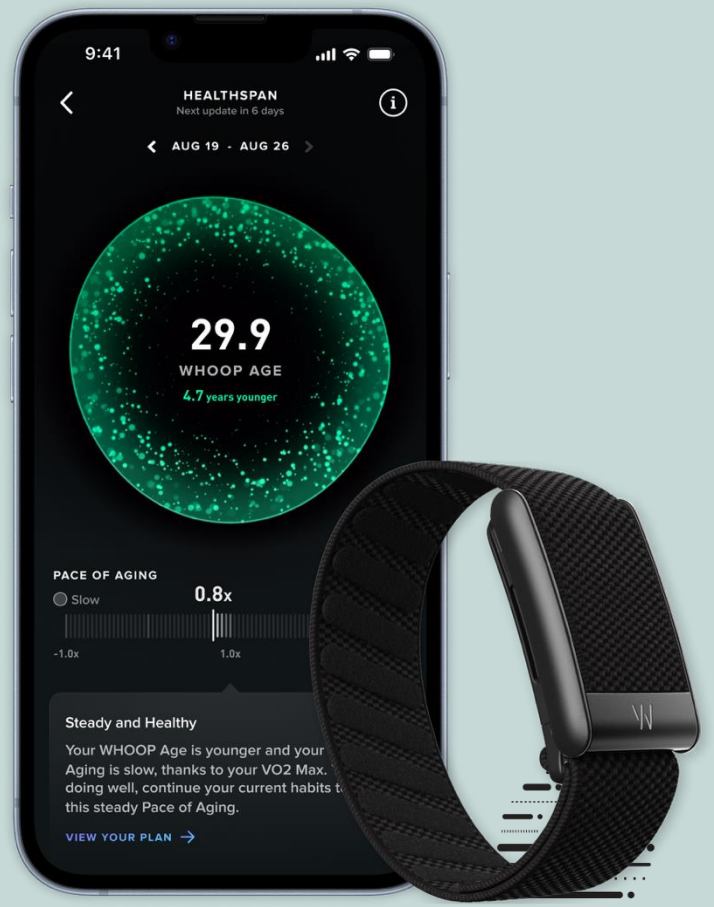
General Wellness Products-Previous

- A **general wellness product**, for the purposes of this guidance, has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.
- If the product's intended uses are not limited to the above general wellness intended uses, this guidance does not apply.



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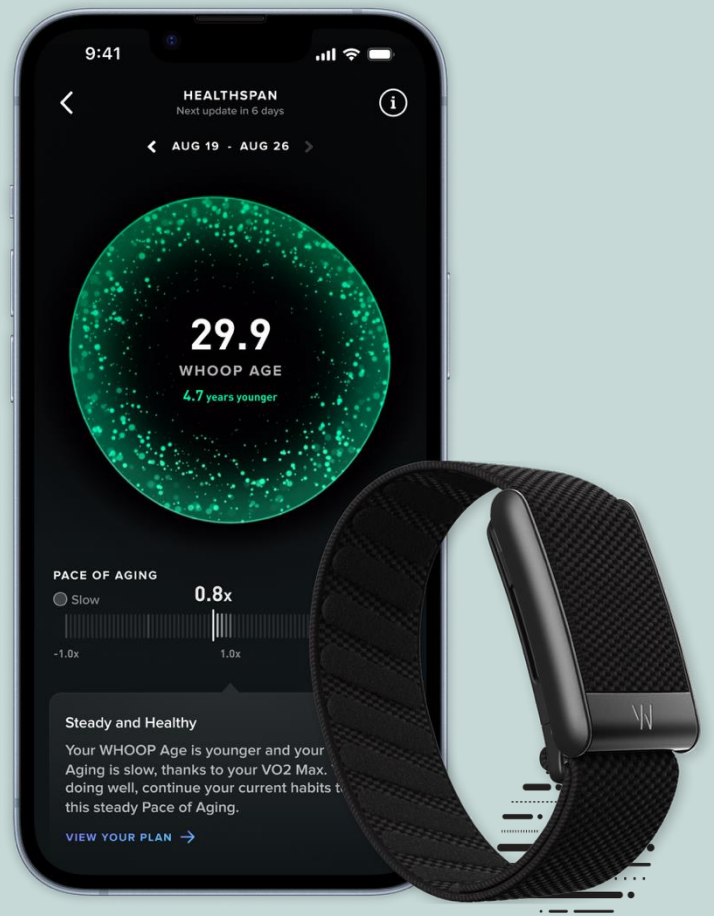
General Wellness Devices-2026 Update

- Still defined as general wellness use and low risk of safety to users and others
- Measurement, like heart rate, blood pressure, now allowed
- Key is interpretation, is it diagnosing, alerting, etc.?
- Claims will be key to assessing intended use



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Other Options for Efficiency

- Breakthrough Device Designation
- TEMPO Pilot Program
- National Priority Voucher Pilot Program
- Faster Clarifications to Meeting Minutes Pilot
- MDUFA VI

Breakthrough Device Designation

- Provides early FDA contact
- Timing and efficiency considerations
- Low success rate

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TEMPO Pilot Program

- Digital Health Pilot Program in partnership with CMS for speed to market
- Industry must request FDA to exercise enforcement discretion on requirements (underway)
- For devices that do not pose a serious risk
- Post-market data requirements
- CMS reimbursement under CMMI ACCESS Model

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National Priority Voucher Pilot Program

- Can limit NDA review times to 1-2 months
- Enhanced communications and rolling review
- Must treat specific diseases of concern
- Process is not entirely clear

Faster Clarifications to Meeting Minutes Pilot

- Pre-submissions are a great tool, but any unanswered questions lead to more pre-submissions
- Pilot program allows for a quick clarification in a single discipline
- Should be utilized as much as possible

MDUFA VI

- MDUFA authorization offers an opportunity to negotiate
- De novo and pre-submission updates expected
- Process also addresses CDRH head count

FDA Communication Strategy

Pre-submission Options

Informational pre-submission
Option to start dialogue early
FDA will be in “listening mode”

Pre-submission to clarify issues

IDE
Pre-market submissions

Other opportunities

Requests for designation
513(g)
Administrative Questions
Ongoing discussing during submission review

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FDA Communication Considerations for Medical Device Classifications

SHOULD YOU RISK ASKING A QUESTION

KNOW WHAT YOU KNOW … AND WHAT YOU DON’T

DO NOT FEAR FDA

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Remaining Issues

- Even with partnership major issues may remain
- Companies need to balance FDA relationship with protecting themselves
- Companies need to understand role each option plays and possible outcomes

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Appeal Options

- Informal appeal/management review
- Ombudsman
- Least Burdensome Flag
- 21 CFR 10.75
- High-level communications
- Article III Courts

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In Closing

MEDICAL PRODUCT REGULATION AND DEVELOPMENT IS COMPLEX AND RESOURCE INTENSIVE

FDA UPDATES ARE FOCUSED ON SPEED TO MARKET FOR DIGITAL HEALTH PRODUCTS

KNOW WHEN TO PARTNER WITH FDA AND WHEN TO CHALLENGE

TAKE ADVANTAGE OF CURRENT CLIMATE

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Questions

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Thank you!

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Interactive Session: Recent Fraud & Abuse Cases & FDA Hot Topics

Mark Gardner

Friday, April 10, 2026

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AKS & FCA Enforcement: Key Cases and Trends

- Copay assistance cases (Regeneron, Gilead, Teva) driving major enforcement
- Speaker programs and consulting arrangements remain high risk
- Pricing and rebate practices under heavy scrutiny (Mallinckrodt)
- Medtech enforcement active (Medtronic, Olympus)
- Whistleblowers fueling record FCA cases
- Bottom line: enforcement expanding across pricing, marketing, and patient support

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DOJ–HHS Expand FCA Enforcement

- New (fall 2025) FCA Working Group → coordinated enforcement push
- Focus areas: pricing, discounts, kickbacks, data reporting
- AKS violations can trigger FCA liability
- Targeting complex contracting and value-based arrangements
- Data analytics driving enforcement
- Bottom line: pricing and contracting strategies under heightened scrutiny

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FCA Enforcement Hits Record Levels

- DOJ recovered $6.8B in 2025 → record year
- Healthcare drove the majority of enforcement
- FCA risk expanding beyond billing → now enterprise-wide
- Whistleblowers at all-time high
- Focus on real-world compliance, not just policies
- Bottom line: how you operate and document drives FCA risk

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OIG Advisory Opinion 25-11: Key Compliance Insights for Manufacturers

- OIG allows flexible discount and rebate structures
- Safe harbor remains anchor:
  - Clear, upfront terms
  - Proper disclosure and reporting (directive from seller to buyer)
  - Accurate net price reflected to payors
- Outside safe harbor = fact-specific AKS risk
- Key risk: discounts that function as inducements
- Bottom line: flexibility exists, but only with transparency and structure

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FDA Escalates DTC Advertising Enforcement

- FDA issued ~100 cease-and-desist letters targeting DTC ads in Sept. 2025
- Signals return to aggressive promotional enforcement
- Focus on risk disclosure and “fair balance”
- Potential rollback of “adequate provision” pathway
- Digital, social, and broadcast ads all in scope
- Bottom line: DTC advertising standards are tightening fast

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OPDP Signals Tighter Scrutiny on Drug Promotion

- FDA OPDP issuing early 2026 Untitled Letters → enforcement signal
- Focus on "net impression," not just literal claims
- Key issues: overstated efficacy, weak clinical support, poor risk disclosure
- DTC advertising (especially TV) under heavy scrutiny
- Disclaimers are not enough to fix misleading messaging
- Bottom line: tighter expectations on claims, visuals, and risk balance

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THE WALL STREET JOURNAL.

ss U.S. Politics Economy Tech Markets & Finance Opinion Free Expression Arts Li

NEW MONEY

Whoop Raises $575 Million at $10.1 Billion Valuation Despite FDA Rift

LeBron James, other athletes join financing for wearable devices company

By Brian Gormley

WSJ PRO March 31, 2026 7:00 am ET

Share Resize Listen (2 min)

Whoop Warning Letter

- "*I do think the guidance brings meaningful clarity to the wearable space and makes clear that Whoop can provide blood pressure readings without violating the law, provided it is done appropriately*."

  -Yours Truly

- FDA's guidance adds clarity and is a positive development for consumers and the growing wearables industry.

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Whoop is highlighted in the FDA "General Wellness: Policy for Low Risk Devices", p. 9...

- Illustrative Example 7: A wrist-worn wearable product intended to assess activity and recovery that outputs multiple biomarkers, among which are hours slept, sleep quality, pulse rate, and blood pressure. Sleep is measured via an accelerometer, while pulse rate and blood pressure are measured via a photoplethysmogram.
  - The claim relates to general wellness and does not refer to a specific disease or medical condition, and thus is a general wellness claim. In addition, the technology for monitoring these biomarkers does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product, provided the product has validated values for blood pressure.
  - Note: However, if the claims made about any of the product's functionality implied the product's use in a medical or clinical context, the product would not be a low risk general wellness product.

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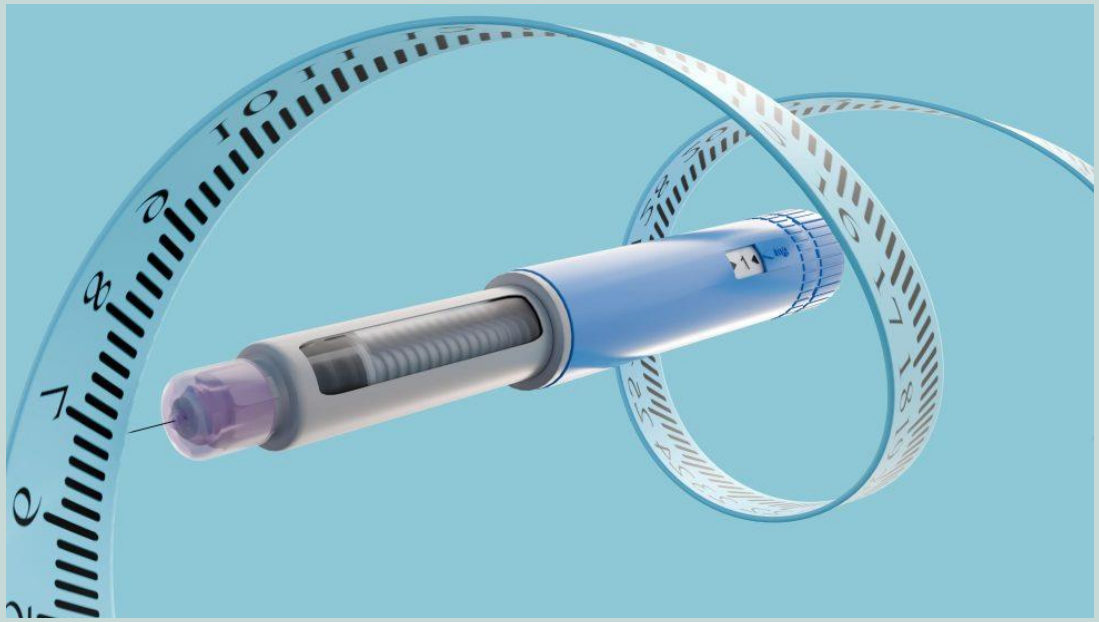
FDA Cracks Down on Compounded GLP-1 Marketing

- FDA sent 30 warning letters on compounded GLP-1 marketing → enforcement is ramping up
- Compounding cannot be used to mass market or bypass FDA approval
- Main issue: misleading claims (FDA-approved, same as branded drugs, safe/effective)
- Telehealth and digital platforms are a key target
- Must tie compounding to patient-specific need
- Bottom line: marketing around compounded GLP-1s is high risk and under active scrutiny



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Regulatory Heat Rising: FTC Expands Healthcare Enforcement

- FTC created a Healthcare Task Force → expect more enforcement
- Same conduct can now be reviewed by FTC, DOJ, and HHS
- Focus areas: marketing claims, commercial models, and partnerships
- FDA compliance alone is not enough
- Increased scrutiny on deals, competition, and data use
- Bottom line: broader risk, more coordinated oversight

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State Privacy Laws Keep Expanding

- 3 new state privacy laws (KY, IN, RI) → now ~20 total
- Patchwork is growing → multi-state compliance getting harder
- Applies based on data volume + revenue thresholds
- Core requirements: disclosures, opt-outs, consent, contracts, risk assessments
- Enforcement is active and increasing
- Bottom line: privacy compliance is now a nationwide issue, not state-by-state

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CIPA Claims Target Website Tracking

- Surge in demand letters over website tracking (cookies, pixels, etc.)
- Claims: tracking = illegal "wiretapping" without consent
- Applies even if company is not in California
- Big risk: tracking before user consent
- Serial plaintiffs driving settlements and lawsuits
- Bottom line: broken consent tools = real litigation risk

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Court Rejects Privilege for AI Use

- Federal court rejected privilege for AI-generated work
- AI is not a lawyer → no attorney-client relationship
- Use of public tools = third-party disclosure risk
- Independent AI use (no counsel direction) is key
- Bottom line: do not assume privilege when using AI
- *United States v. Heppner*, No. 25-cr-00503 (S.D.N.Y. Feb. 2026)

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Questions

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

Mike Pisetsky

Friday, April 10, 2026

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Marking Ten Years

Past, Present, and Future Perspectives In FDA Law

IN-PERSON AND LIVESTREAMED

Thursday, May 14, 2026 | 1:00 – 4:15 P.M. CDT

JX Venue | 123 2nd St. N | Stillwater, MN 55082

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CELEBRATING 10 YEARS

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1:00 – 1:40 PM	**When Issues Escalate: A Discussion on Litigation & Government Strategy** *David Graham & Amanda Johnston*
1:40 – 2:15 PM	**From the Past to the Present: Leveraging FDA Experience to Shape Future Strategy** *Nathan Downing, Rebecca Zadaka, Brynn Stanley, & Darya Lucas*
2:15 – 2:50 PM	**A Decade of Compliance: How Expectations Have Evolved, and What Comes Next** *Amanda Johnston, Lisa Damhof & Jacob Leys*
2:50 – 3:00 PM	**Refreshment Break**
3:00 – 3:35 PM	**A Privacy Discussion on U.S. Enforcement & Compliance Hotspots** *Paul Rothermel & Josh Arkulary*
3:35 – 4:15 PM	**FDA Leadership Perspectives for the Next Decade: An Industry Panel Discussion** *Mark Gardner*

Reception to Follow

We invite all attendees to join us immediately following the programming for drinks and snacks at a networking reception.