Medical Device Recalls Unpacked

FDA Compliance and Litigation Insights

Wednesday, February 5, 2025

About Us

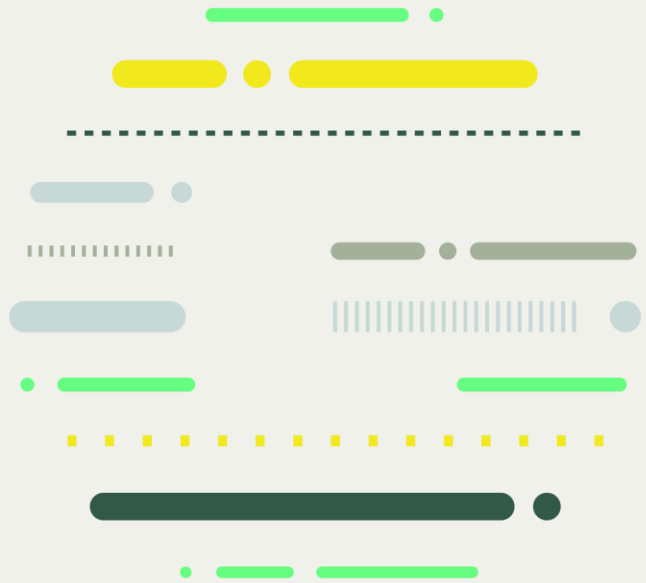
Gardner Law provides expert counsel to FDA-regulated companies on regulatory, compliance, privacy, and litigation matters.

Our industry and government experience enables us to deliver actionable advice, empowering clients to make informed decisions.

We prioritize responsiveness, ensuring timely support. Our attorneys possess deep regulatory knowledge gained through experience at leading organizations.

Legal Practice Areas:

- Regulatory
- Compliance
- Privacy
- Litigation



Presenter Introductions

Amanda Johnston
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Amanda Johnston is a distinguished FDA attorney with expertise in counseling medical device and pharmaceutical companies on FDA law, regulatory strategy, and healthcare compliance matters.

- Medicare Compliance at UnitedHealth Group
- Regulatory at Medtronic Neuromodulation
- Led North America Compliance at Coloplast
- MSBA Food Drug and Device Law Council
- Adjunct professor of Drug and Device Law at Mitchell Hamline
- 2023, 2024 Rising Star, Super Lawyers
- 2023 Women in Business Honoree, Minneapolis-St. Paul Business Journal

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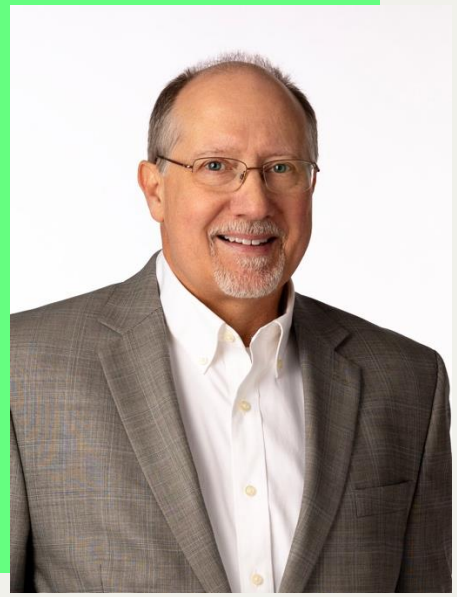

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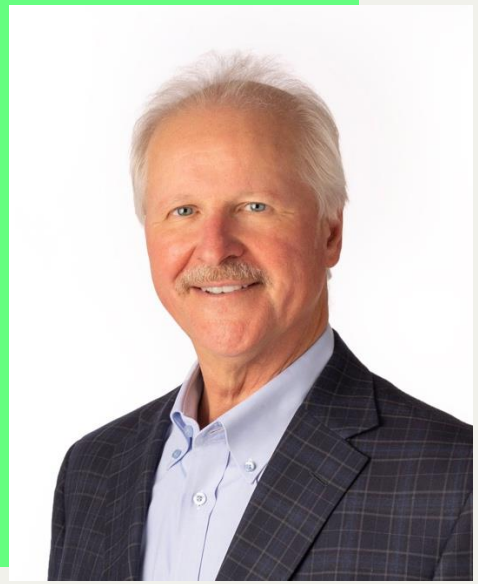
Tim Philips is a quality assurance and regulatory affairs professional with over 30 years of experience in commodities regulated by the U.S. Food & Drug Administration (FDA). He is an expert and instructor in FDA law / regulation, quality systems, inspections, evidence development, enforcement actions, and product recalls with an emphasis on post-market compliance of medical devices.

Presenter Introductions



David Graham is a seasoned litigator with a proven track record of success in high-stakes cases involving food, medical devices, and pharmaceuticals. He has extensive experience defending companies against product liability claims, class actions, and government investigations, including those involving the False Claims Act and Anti-Kickback Statute.

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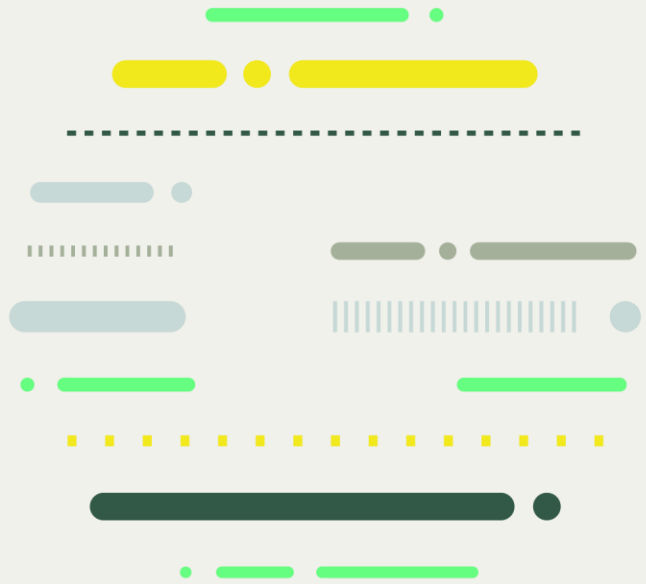
Agenda

- Recall Basics
- FDA Regulations
- FDA’s Recall Process
- Tips & Best Practices
- Litigation Issues with Recalls



What is a Recall?

- A manufacturer's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
  - Removal: the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.
  - Correction: repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

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Voluntary Recalls
21 CFR 7

- **Definition:** A recall is a voluntary action by manufacturers or distributors to remove or correct products that violate FDA laws, posing risks such as injury, gross deception, or defects.
- **Process**: 21 CFR 7 provides procedures for effective recalls and outlines FDA's role in monitoring and assessing recall efforts.
- **FDA Involvement:** Most recalls are voluntary, but the FDA may request a recall in urgent situations involving significant risks.
- **Exclusions:** Recalls do not include market withdrawals (minor violations or no violations) or stock recovery (e.g., normal stock rotation).
- It’s rare, but FDA has authority to force a recall (21 CFR 810).

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Corrections and Removals
21 CFR 806

- Manufacturers are required to report any correction or removal of a medical device(s) to FDA if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Act caused by the device which may present a risk to health.

  Risk to Health:

  (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

  (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

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Health Hazard Evaluation: The Recall Decision-Making Process

- **Purpose:** FDA evaluates the health hazard of a recalled product considering multiple factors, including:
  - **Injuries/Disease:** Whether harm has already occurred from product use.
  - **Contributing Conditions:** Existing factors that could worsen risks.
  - **Population Impact:** Risks to vulnerable groups (e.g., children, pets, surgical patients).
  - **Seriousness of Hazard:** Severity of potential health effects.
  - **Likelihood of Occurrence:** Probability of the hazard happening.
  - **Consequences:** Short and long-term impacts of the hazard.
- **Outcome:** FDA assigns a recall classification (Class I, II, III) based on the relative degree of health hazard.

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Recall Classifications

- Class I – reasonable probability of serious adverse health consequences or death
- Class II – temporary or medically reversible health consequences or remote probability of above
- Class III – not likely to cause adverse health consequences

Example Recall Timeline

- Identification of an issue (Day 0)
- Conduct HHE (Days 0-3)
- Decide to do a recall (Day 5)
- Develop recall strategy and prepare notification (Day 6-7)
- Report to FDA (Day 7-10)
  - If the recall involves a risk to health, a report must be submitted to FDA within 10 working days from the time your company initiates the correction or removal (FDA has interpreted that 10-day "clock" to start when you decide internally to conduct the recall.)
  - After contacting the FDA, the Recall Coordinator will request more information about the device, your recall strategy, the HHA/HHE, etc., so be ready to provide that information in a timely manner.
- Initiate recall (Day 7-10)
- Post-recall work (Days 10-?)
  - Effectiveness checks
  - Recall status reports
  - Complete all recall activities
  - Request termination

Summary of FDA's Recall Process

- Becomes aware of recall
- Reviews and comments on recall notification and strategy
- Recall coordinator (in OII) prepares information for review by CDRH
  - Includes a classification recommendation
- Formalizes recall by reviewing the information, assessing the health hazard, and classifying the recall
- Firm is notified of the classification

Summary of FDA's Process, contd.

- Publishes recall information on the FDA website and in the Enforcement Report
  - Press Release for most Class I recalls and some Class II
- Provides recall information to other federal and government agencies
- Monitors and audits the recall to ensure effectiveness
  - Can include "audit checks" conducted by FDA investigators
- Terminates the recall and provides written notification to the recalling firm

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Tips & Best Practices

- Develop internal policies and procedures for conducting recalls as part of your quality system.
  - See Gardner Law News – Conducting a Recall
- Customers (and FDA) need to be well-informed of the recall and possible risks as well as your instructions or corrections
- Be prepared when you bring the issue to the FDA
  - Examples of NOT being prepared
    - Meet with officials at the local FDA office, drop the problem on the conference room table and say, “What do you (FDA) think we should do?”
    - Expecting FDA to help you detect and assess

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Tips & Best Practices

- Don’t try to downplay/minimize the problem in:
  - Description to FDA
  - Notification to customers
- Don’t try to hide a recall in a “Technical Bulletin” or “Product Information Brief” or similar communication.
  - Technical Bulletins, Service Instructions, etc. are not adequate substitutes for recall notifications
- Amount, quality, and timeliness of information provided to FDA affects their decision on whether to conduct a follow-up inspection.

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FDA Resources

- Recalls, Corrections and Removals (Devices)
- Reporting: FDA Electronic Submission Software (eSubmitter) or by e-mail to a Recall Coordinator
- FDA's Model Recall Letter (and Response Form) for Devices
- Model Effectiveness Check Letter

Litigation Issues with Recalls

David P. Graham

Wednesday, February 5, 2025

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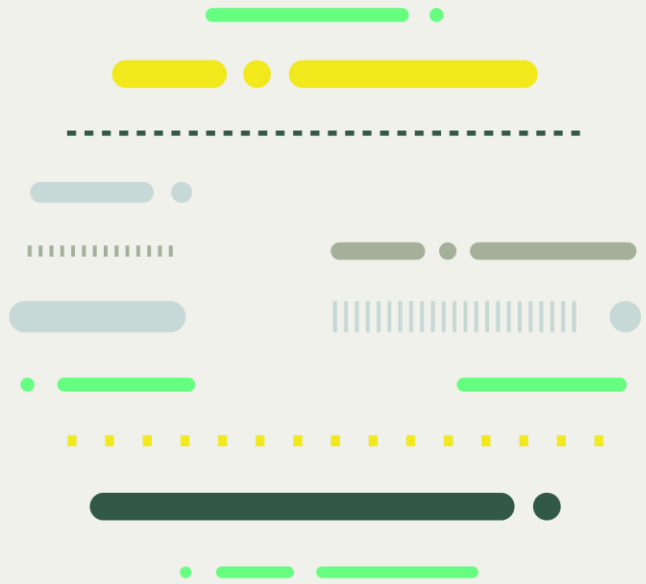
Agenda

- Types of Recall Lawsuits
- Contract disputes to recover costs
- Product Liability Claims
- Shareholder Investor Suits



What Recalls Set in Motion

- Company and government reporting about recall
- Potential product liability claims
  - Lawyer advertisements
  - Patients reach out to lawyers
- Shareholders/investors asks questions about what happened
- Competitors seek advantages
- Internal Analysis of the recall and how to move forward

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Inherent Conflict

- Transparency with FDA and Market Place v. Litigation prevention

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Preparing in Advance

- Develop Recall Team
- Deciding to recall
- Execution
- Communication Plan with:
  - FDA
  - Marketplace
  - Investors
  - Vendors and other business partners
  - Public relations firm (if needed)

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Recall Analysis

- Root Cause Analysis
  - What and who caused the problem?
  - Did something happen in the supply chain which caused the defect?
  - Who pays and how much?
    - Damages analysis
    - Contract analysis
    - Legal analysis
    - Insurance policies and available coverage

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Post Recall Team

- May be the same as the original recall team
- In-house experts
- Legal counsel
- Executive decision maker

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Questions?

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