# Ripped from the Headlines:

## *Life Sciences Regulation in 2025*

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November 12, 2025

# New Leadership and Direction at HHS and FDA

- Installing new leadership at public health agencies was an early priority for the 2nd Trump administration
  - Robert F. Kennedy Jr. was confirmed as the Secretary of Health and Human Services on February 13, 2025, and sworn into office on the same day.
  - Martin Makary was confirmed as the FDA Commissioner on March 25, 2025, and sworn into office on April 1st.
- Both Kennedy and Makary are known disruptors in the healthcare space and have begun implementing substantial changes quickly.





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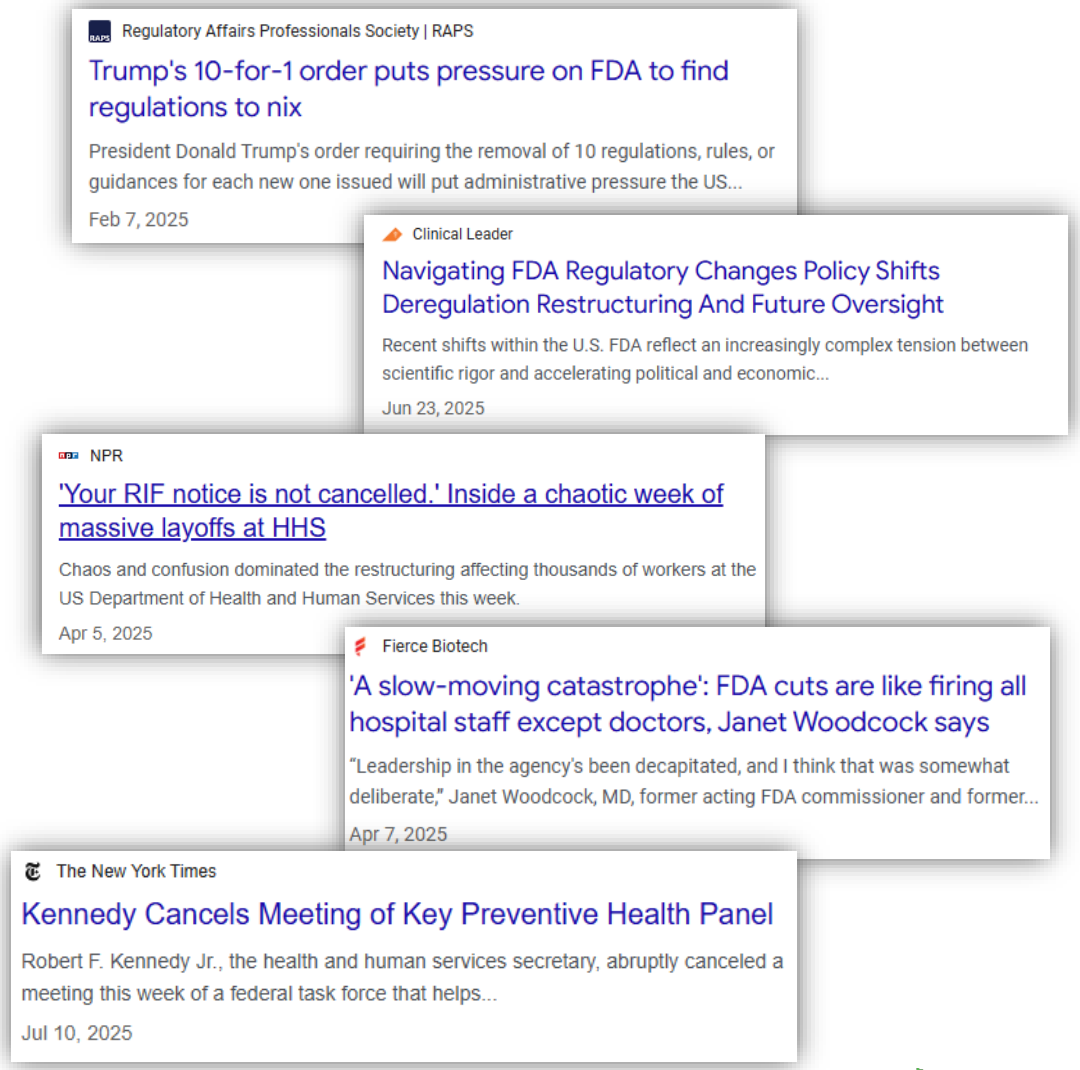
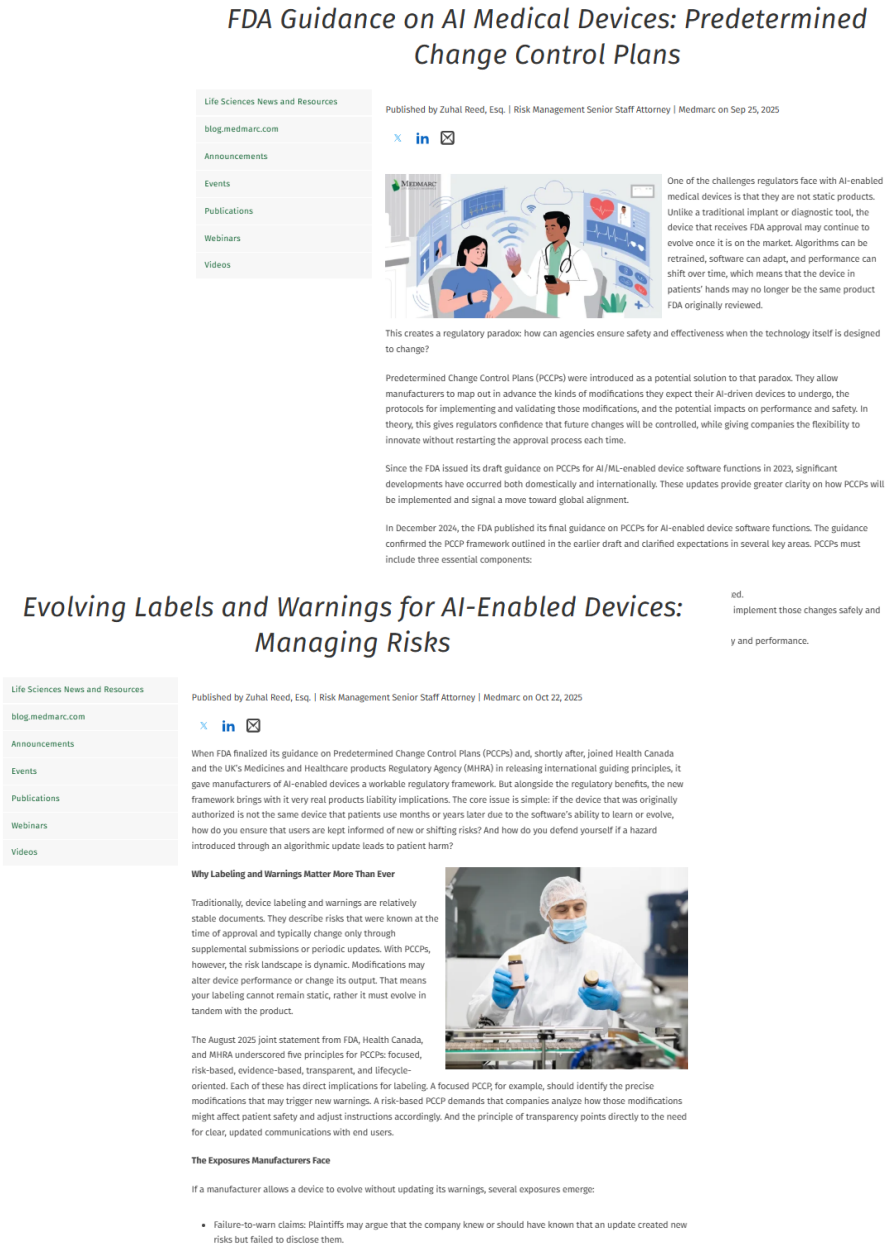
# New Leadership and Direction at HHS and FDA

- Aggressive push toward deregulation
  - Biosimilar policy overhaul
  - Proposed changes to cell and gene therapy reviews with goal of faster approvals
- Operational upheaval
  - RIF of 20% of FDA staff
  - Leadership changes in all three major centers
- Cultural and scientific shifts
  - Moves away from evidence-based medicine
  - "Radical transparency" in safety reporting
  - Interruption of task force intended to prevent public health issues



# FDA Guidance on AI-Enabled Devices

- FDA released its final guidance on Predetermined Change Control Plans, or PCCPs, at the end of 2024.
- A PCCP is a pre-approved plan that a manufacturer submits with their marketing application for an AI-enabled device.
- The plan includes three major parts:
  - Anticipated modifications: what changes you expect to make to the algorithm or model;
  - The modification protocol: how you'll test, validate, and control those changes; and
  - The impact assessment: how you'll ensure any update doesn't undermine safety or effectiveness.



*FDA Guidance on AI Medical Devices: Predetermined Change Control Plans*

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Published by Zuhal Reed, Esq. | Risk Management Senior Staff Attorney | Medmarc on Sep 25, 2025

One of the challenges regulators face with AI-enabled medical devices is that they are not static products. Unlike a traditional implant or diagnostic tool, the device that receives FDA approval may continue to evolve once it is on the market. Algorithms can be retrained, software can adapt, and performance can shift over time, which means that the device in patients' hands may no longer be the same product FDA originally reviewed.

This creates a regulatory paradox: how can agencies ensure safety and effectiveness when the technology itself is designed to change?

Predetermined Change Control Plans (PCCPs) were introduced as a potential solution to that paradox. They allow manufacturers to map out in advance the kinds of modifications they expect their AI-driven devices to undergo, the protocols for implementing and validating those modifications, and the potential impacts on performance and safety. In theory, this gives regulators confidence that future changes will be controlled, while giving companies the flexibility to innovate without restarting the approval process each time.

Since the FDA issued its draft guidance on PCCPs for AI/ML-enabled device software functions in 2023, significant developments have occurred both domestically and internationally. These updates provide greater clarity on how PCCPs will be implemented and signal a move toward global alignment.

In December 2024, the FDA published its final guidance on PCCPs for AI-enabled device software functions. The guidance confirmed the PCCP framework outlined in the earlier draft and clarified expectations in several key areas. PCCPs must include three essential components:

*Evolving Labels and Warnings for AI-Enabled Devices: Managing Risks*

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Published by Zuhal Reed, Esq. | Risk Management Senior Staff Attorney | Medmarc on Oct 22, 2025

When FDA finalized its guidance on Predetermined Change Control Plans (PCCPs) and, shortly after, joined Health Canada and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in releasing international guiding principles, it gave manufacturers of AI-enabled devices a workable regulatory framework. But alongside the regulatory benefits, the new framework brings with it very real products liability implications. The core issue is simple: if the device that was originally authorized is not the same device that patients use months or years later due to the software's ability to learn or evolve, how do you ensure that users are kept informed of new or shifting risks? And how do you defend yourself if a hazard introduced through an algorithmic update leads to patient harm?

**Why Labeling and Warnings Matter More Than Ever**

Traditionally, device labeling and warnings are relatively stable documents. They describe risks that were known at the time of approval and typically change only through supplemental submissions or periodic updates. With PCCPs, however, the risk landscape is dynamic. Modifications may alter device performance or change its output. That means your labeling cannot remain static, rather it must evolve in tandem with the product.

The August 2025 joint statement from FDA, Health Canada, and MHRA underscored five principles for PCCPs: focused, risk-based, evidence-based, transparent, and lifecycle-oriented. Each of these has direct implications for labeling. A focused PCCP, for example, should identify the precise modifications that may trigger new warnings. A risk-based PCCP demands that companies analyze how those modifications might affect patient safety and adjust instructions accordingly. And the principle of transparency points directly to the need for clear, updated communications with end users.

**The Exposures Manufacturers Face**

If a manufacturer allows a device to evolve without updating its warnings, several exposures emerge:

- Failure-to-warn claims: Plaintiffs may argue that the company knew or should have known that an update created new risks but failed to disclose them.

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# FDA Guidance on AI-Enabled Devices

- If there's ever an investigation, an enforcement action, or a products-liability claim, your PCCP, your validation data, and your change-control records are what demonstrate that you stayed inside your approved boundaries.
- AI introduces a "dynamic performance risk."
- The FDA's lifecycle guidance emphasizes that as devices evolve, labeling and warnings need to evolve too.
- What can you do as a manufacturer?
  - Build the PCCP right into your quality management system.
  - Develop a clear post-market monitoring plan.
  - And if you rely on outside vendors, make sure your contracts give you access to the documentation you need to support your PCCP commitments.

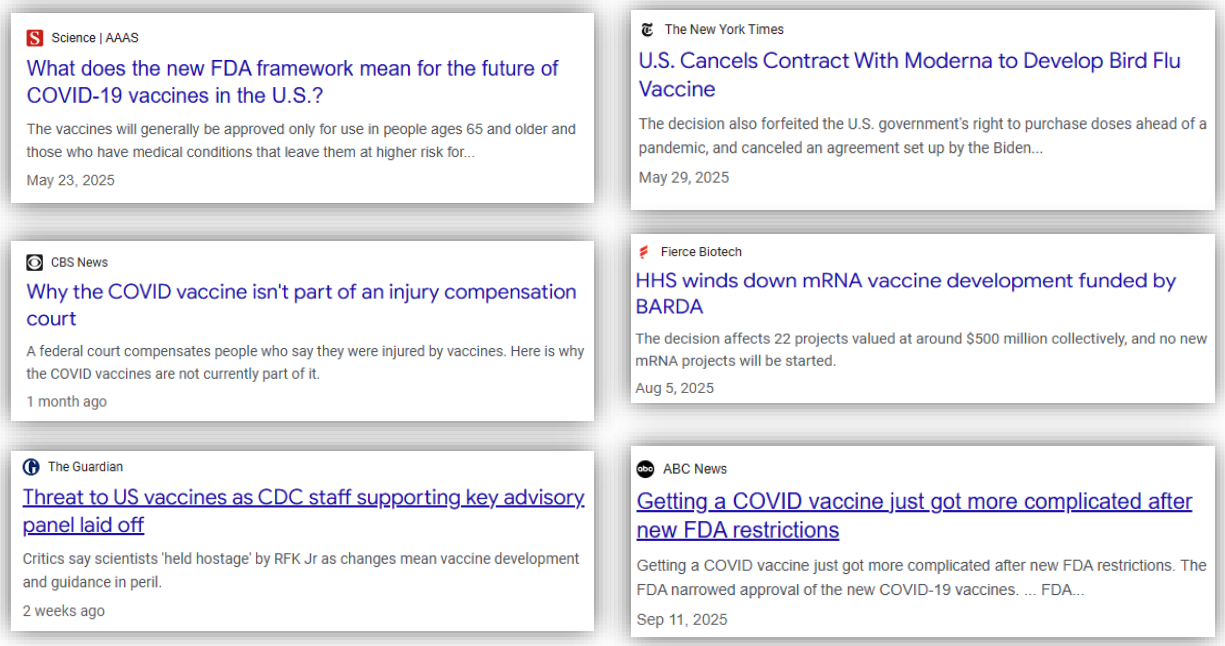
# FDA Guidance on AI-Enabled Devices

- For brokers and underwriters, ask:
  - Does the company maintain verifiable version control?
  - Can they show they followed their PCCP protocol for each fielded update?
  - And if something goes wrong, do they have a defined process for field corrections or recalls?

- Key documents to review:
  - December 2024: FDA finalized the PCCP guidance.
  - January 2025: FDA issued the draft guidance on AI device lifecycle management, expanding expectations around data governance, validation, and monitoring.
  - Mid-2025: FDA, Health Canada, and the UK's MHRA released joint guiding principles, signaling international alignment on these frameworks.

# Dismantling the Vaccine Infrastructure

- Implemented Changes
  - Covid-19 Vaccines
    - Ended federal recommendations for Covid-19 vaccination during pregnancy
    - Updated FDA policy for Covid vaccine testing and approval
    - Covid has not been added to the VICP compensable vaccine injury table
  - Flu Vaccine R&D
    - Canceled contracts with Moderna for late-stage mRNA vaccine development, including bird flu and multiple types of pandemic influenza
    - Canceled contracts to purchase vaccine doses
  - ACIP Overhaul
    - All 17 ACIP members were removed from their positions and replaced with new appointees
      - Significant changes in backgrounds and experience
      - Short window between termination and appointment indicates that the usual conflict of interest investigations likely were not conducted



# Dismantling the Vaccine Infrastructure

- Potential Changes on the Horizon
  - MAHA Commission
    - Tasked with evaluating links between childhood diseases including autism and various environmental exposures, including:
      - Childhood vaccines
        - Panel proposed to study/amend the childhood vaccine schedule
        - Potential impact on Vaccines for Children Program, Medicare/Medicaid coverage, insurance reimbursement
      - Ultra-processed foods and food allergies
      - Psychiatric medications
      - PFAS and microplastics
  - Vaccine Injury Liability
    - LIABLE Act reintroduced in the House and seeks to circumvent the PREP Act and return liability for Covid vaccine injuries to the manufacturers with retroactive application
    - HHS Secretary Kennedy has a history of supporting products liability for manufacturers of vaccines
      - Voiced support for ending Covid vaccine liability shields
      - Gardasil litigation

# FDA's Vacated Rule on Lab-Developed Tests

- Timeline:
  - For decades, FDA had exercised what it called "enforcement discretion" over most LDTs. Oversight was largely left for CMS under the CLIA program.
  - On May 6, 2024, the FDA issued a Final Rule that essentially amended the definition of an in vitro diagnostic device to explicitly include cases where the manufacturer is a laboratory.
  - The FDA argued that modern LDTs are no longer "simple in-house tests." They often use complex instrumentation, software, and are marketed nationwide.
  - A coalition led by the American Clinical Laboratory Association sued the FDA, arguing that the agency had exceeded its statutory authority.

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FDA rescinds LDT final rule

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When FDA declined to appeal the ruling, the rule was officially nullified. With that, FDA's effort to bring LDTs under formal oversight has been...

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Federal Court Vacates FDA's Final Rule on Laboratory-Developed Tests

Key takeaways. A federal court has vacated the Food and Drug Administration's (FDA) attempt to regulate laboratory-developed test (LDT)...

Apr 17, 2025






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# FDA's Vacated Rule on Lab-Developed Tests

- Timeline:
  - March 2025, the U.S. District Court for the Eastern District of Texas agreed and vacated the rule in full.
  - Following that decision, FDA did not appeal within the 60-day window.
  - By September 2025, the agency formally rescinded the rule, restoring the regulatory text to what it was before the 2024 final rule.
  - The long-standing policy of CLIA oversight and FDA enforcement discretion has been restored.

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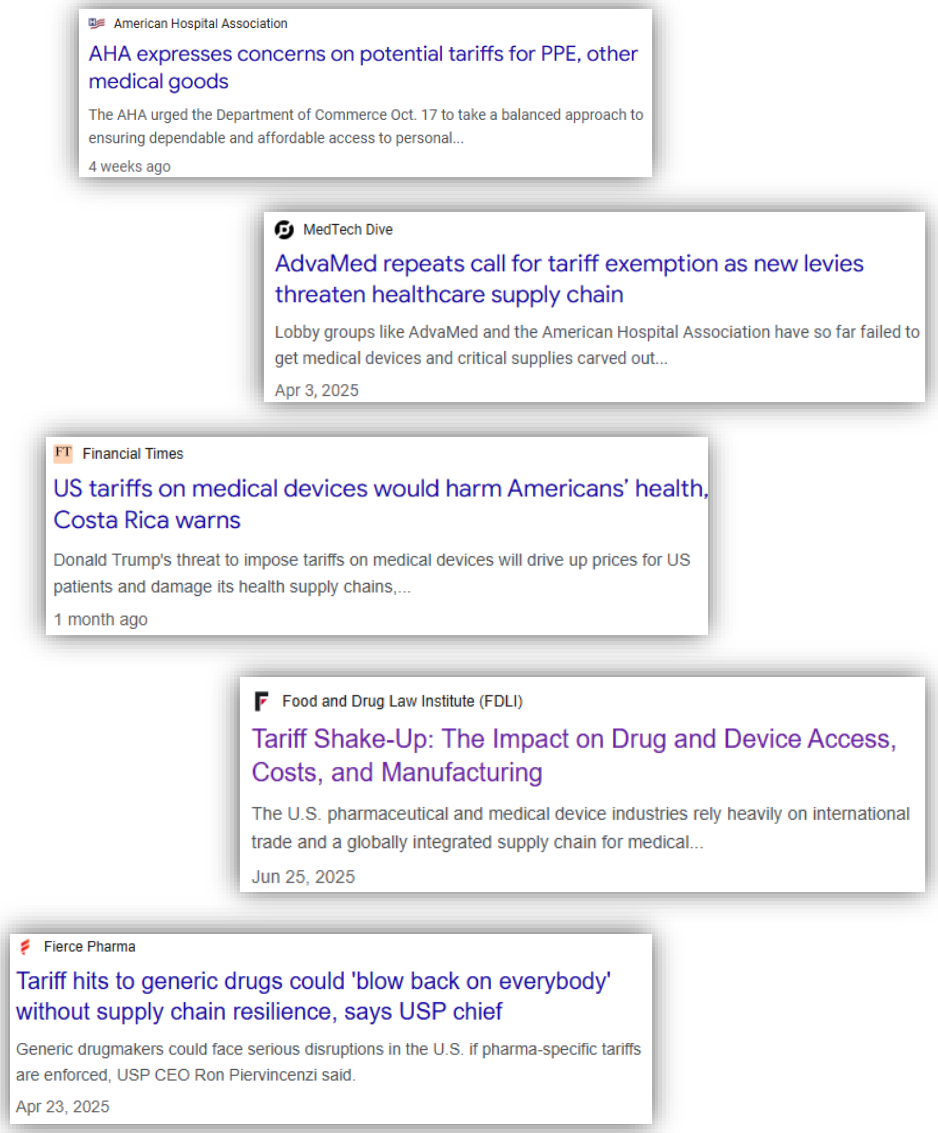
# FDA's Vacated Rule on Lab-Developed Tests

- What does this mean for diagnostic laboratories?
  - The immediate threat of FDA device regulation is off the table. You remain primarily under CLIA oversight.
- What does this mean for biotech and pharma partners?
  - Right now, your LDT partners aren't subject to FDA premarket review, but that could change again. You should review contracts to ensure you have change-in-law clauses, audit rights, and a plan if regulatory oversight shifts mid-project.
- Expect more contractual and insurance scrutiny around diagnostic testing arrangements. Insurers and brokers should be asking labs:
  - What's your plan if FDA oversight returns?
  - How would you handle a shift in regulatory classification?

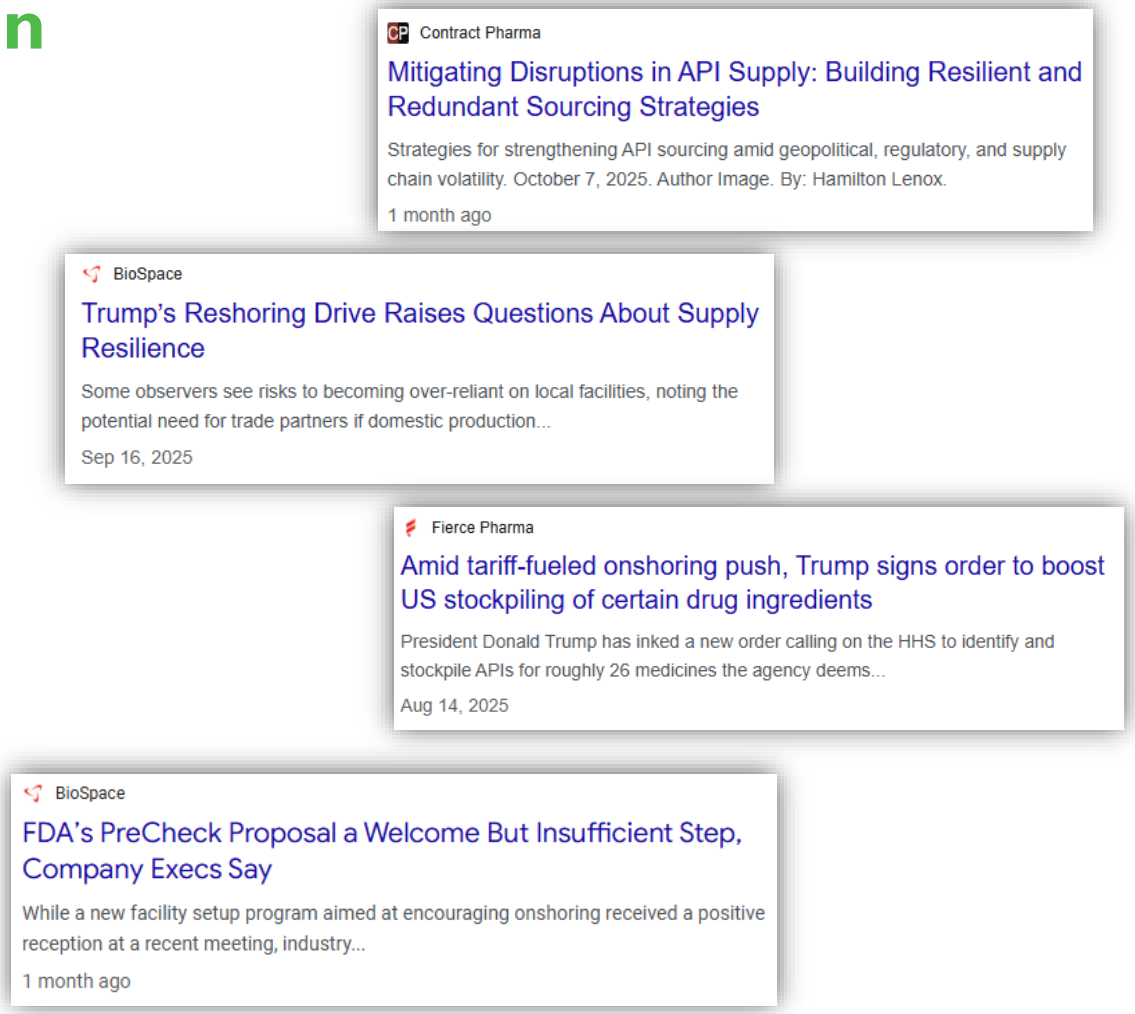
# Tariffs and Supply Chain Localization

- The implementation of tariffs in 2025 has drastically impacted the cost to produce drugs and devices:
  - Tariffs on devices and device components increased to 10-54%, and with punitive rates imposed on Chinese goods, exceeding 100% in some cases.
    - Even US-made devices were impacted as more than half of device components are imported.
  - Pharma tariffs increased to 20-25% on APIs and intermediates from China and India.
  - Lab equipment and packaging were hit with 15% tariffs.



# Tariffs and Supply Chain Localization

- Supply chain bottlenecks
  - Companies forced to reconfigure supplier networks
    - Contract renegotiations
    - Delays and shortages
- Massive cost driver for manufacturers
  - Delays in production = delayed sales
  - Revalidation of products with new materials
  - Generic drugs particularly hard hit
    - Some manufacturers driven from the market



# Tariffs and Supply Chain Localization

- Government push for onshoring and investment in US manufacturing
  - If possible, it is a long-term solution.
    - Drug and device manufacturing plants are highly regulated and take time and oversight to build.
      - Massive financial investment
    - Staffing – can the US labor market compete?
  - In the meantime, the industry is facing a substantial pinch.
    - Increased tariff costs
    - Volatility in working with new supply chain
    - Thinner margins, smaller profits hurt the ability to invest in onshoring

Alliance for American Manufacturing

**What Will It Take to Onshore More Pharmaceutical Production?**

Experts argued that proper incentives and trusted commitments will be needed to build out the US pharmaceutical supply chain.

Jun 20, 2025

Purdue University

**Purdue invests in One Health, from making medicines to advancing chemistry, along America's Hard Tech Corridor**

WEST LAFAYETTE, Ind. — Purdue University has announced a series of new degrees, a synergistic faculty recruitment initiative in the advanced...

May 6, 2025

Chemical & Engineering News

**The unfulfilled dream of drug reshoring**

The government is making the case for US production, but the private sector isn't buying in.

Sep 28, 2024

PharmaVoice

**Trump's tariffs could put more pressure on the U.S. to produce generic drugs. Are we ready?**

The push to bring generic drug production back home has failed to reach a critical mass.

Dec 6, 2024





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# FDA's Final Rule on QMSR: What Changed and Why it Matters

- Effective February 2, 2026, the QMSR will replace the long-standing QSR (21 CFR Part 820).
- It will incorporate ISO 13485:2016 by reference for global alignment.
- Expanded inspection scope: internal audits, supplier audits, and management reviews now reviewable.
- Greater focus on risk-based processes, traceability, and supplier control.
- FDA retiring QSIT: new inspection and compliance program is coming.

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UPDATES: On September 10, 2024, the FDA updated Important Information: Final Rule to Amend the Mammography Quality Standards Act (MQSA),...

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# FDA's Final Rule on QMSR: How to Prepare

- Conduct a gap assessment.
- Update SOPs and quality manual.
- Strengthen supplier quality agreements.
- Train teams.
- Expect expanded FDA access to internal and supplier audit records.
- Watch for increased enforcement as FDA tests new inspection model.
- Consider change-in-law clauses.

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