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# Changing Policies and Attitudes: Impacts on Medical Product Litigation

January 28, 2026



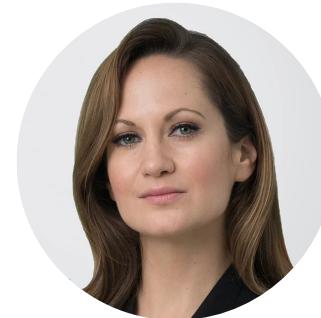
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# Overview

## **I. Introduction**

## **II. Changing Policies**

- A. Changes in FDA/HHS Policies and Practices**
- B. Changes in CMS Policies and Practices**
- C. Changes in DOJ /OIG Enforcement Policies and Practices**

## **III. Product Liability Litigation Impact**

## **IV. Impact on False Claims Act Litigation and DOJ Enforcement**

## **V. Changing Attitudes**

- A. Administrative Procedures Act: Chevron to West Virginia to Loper Bright**
- B. Attitudinal Shifts for Juries about Agencies, Corporations, and Science**

## **VI. Interplay Between These Changes**

## **VII. Questions**

# Administrative Changes: FDA/HHS

## Changes in FDA/HHS Policies and Practices in the Last Year

### Enforcement

- Increased issuance of Warning and Untitled Letters
- Increased inspections, with increased scrutiny of drug and device manufacturers
- Increased foreign manufacturers oversight

### Practices

- Issuances of CRL letters
- Use of AI system - ELSA

### Predictions

- Continued push for domestic manufacturing
- Governing via press release/statements

# Administrative Changes: CMS

## Changes in CMS Policies and Practices in the Last Year

### Enforcement

- Explosive uptick in HHS OIG and DOJ investigations in wound care/cell tissue product space (kickback/FCA focus)
- HHS OIG investigations into erroneous Average Sales Price (ASP) reporting
- CMS imposes civil monetary penalties on participating manufacturers based on the Discount Program Agreement

### Practices

- CMS Innovation Center's rollout of various care delivery and payment models in support of "Make America Healthy Again"
- "Curbing unnecessary spending" by introducing prior authorizations for certain services
- Relying on machine learning/AI for past services review and retrospective claims denials
- Evaluating cost containment of Medicare Part B drugs and biosimilars
- Scrutiny of MCO spending on errant services

### Predictions

- More Medicare and Medicaid program integrity audits resulting in payment claw backs
- Increased automation in payment disputes resulting in errant government payment determinations and technical challenges
- Heightened scrutiny of new entrants in market supporting technology-enabled care
- Changes or modifications to ASP reporting methodology

# Enforcement Changes

## Changes in DOJ/OIG Policies and Practices in the Last Year

### Civil Enforcement / False Claims Act

- Department of Justice / Health and Human Services False Claims Act working group
- *Department of Justice Civil Division Enforcement & Affirmative Litigation Branch*

### Criminal Enforcement

- Criminal Division first priority: Waste, fraud, and abuse, including health care fraud and federal program and procurement fraud that harm the public fisc
- Corporate Whistleblower Awards Pilot Program includes federal healthcare benefit programs
- Expansion of Health Care Fraud Strike Force

### Administrative Enforcement

- Enhanced / bespoke Corporate Integrity Agreement (CIA) requirements imposed as part of HHS OIG exclusion proceedings
- Revocation / Preclusion of Medicare billing privileges related to fraudulent, wasteful or abusive practices

# Change Impacts

## Impacts on Product Liability Litigation

- **Spurring Litigation**
  - Publicity, funding, and advertising
  - New and renewed targets
  - Chaos
- **Preemption**
  - Post hoc changes on product or class
  - Enforcement impacts
  - Undercutting agency credibility
- **Expert Evidence Challenges**
  - Unofficial and unofficial statements/positions
- **Trials**
  - Evidence
  - Attitudes



# Change Impacts

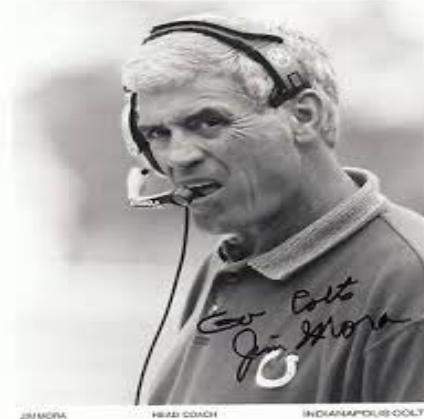
## Enforcement Impacts

- Healthcare False Claims Act cases, trials, and recoveries remain high and trend upwards
  - \$6.8 Billion in recoveries in 2025, highest in a single year in the history of the False Claims Act; over \$5.7 billion related to matters that involved the health care industry
  - Relator-led, litigation funded
- Moving beyond cost: increased product attribute litigation and enforcement
  - Focus on representations made to FDA
  - Curb uses outside FDA approval
  - Representations regard product failure rates
  - Active criminal prosecutions related to adulterated and misbranded devices
- Focus on and leverage technology affirmatively and defensively
  - Cybersecurity / data privacy
  - Increased expectation of data analytics / artificial intelligence during compliance process
- Reduced or strained resources place a premium on cooperation and voluntary disclosure

# Changing Attitudes: Agencies

## Deference? Supreme Court Decisions on the Administrative Procedures Act

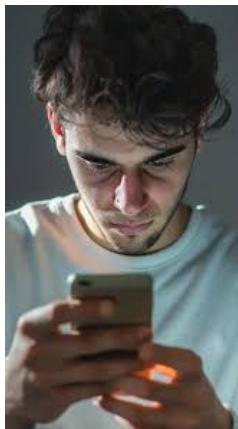
- *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)
  - *Chevron Deference* was the rule for 40 years
  - Court deference to agency interpretation of statute spilled over to non-APA cases
- *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024)
  - Overruled *Chevron*
  - Courts, not agencies, resolve ambiguities in laws that the agencies
- Helps medical product companies challenging FDA or other agency actions
  - Hurts when 1) challenges are made by others, or 2) litigation involves company compliance with FDA requirements



# Changing Attitudes: Judges and Juries

## Public Attitudinal Shifts

- Confidence in public health agencies and corporations have waned
- Confidence in science has also declined
  - Established scientific and public health positions?
- Litigation positions of life sciences and healthcare companies often rely on agency positions and mainstream scientific propositions
- Judges are not immune to these shifts and pressures.
  - Case Study: Second Circuit appeal pending on order knocking out the Acetaminophen ASD-ADHD MDL based on lack of general causation
    - Argued two months after administration statements supporting a link . . .



# Policies and Attitudes Intersect

## Interplay Between The Various Recent Changes

- Bottom Line for Now
  - Regulatory Environment
  - Enforcement Environment
  - Private Litigation Environment
- What is Coming Next?
  - FDA
  - CMS
  - Product Liability
  - DOJ

# Questions?



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