

Changing Policies and Attitudes: Impacts on Medical Product Litigation

January 28, 2026

Presenters



Eric L. Alexander

Washington, D.C.
eric.alexander@hklaw.com



Megan Mocho

Tysons
megan.mocho@hklaw.com



Juliet M. McBride

Houston
juliet.mcbride@hklaw.com



Sara M. Klock

Washington, D.C.
sara.klock@hklaw.com

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

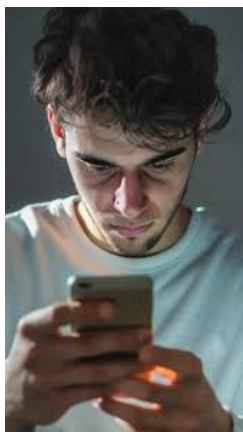
- *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)
 - *Chevron Deference* was the rule for 40 years
 - Court deference to agency interpretation of statute spilled over to non-APA cases
- *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024)
 - Overruled *Chevron*
 - 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 relay 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?

Holland & Knight



A low-angle, upward-looking perspective of a modern skyscraper with a glass facade. The building's structure is composed of a grid of dark metal frames holding large glass panels. The sky is a clear, vibrant blue with a few wispy white clouds. The text "Holland & Knight" is centered in a white, serif font.

Holland & Knight