GENERAL COUNSEL ROUNDTABLE

Exploring the Top 5 Federal Court Cases that Health Care and Life Sciences GCs Should Watch in 2026

ALL PERSONS HAVING BUSINESS…ARE ADMONISHED TO DRAW NEAR AND GIVE THEIR ATTENTION:

Federal Court Cases Healthcare & Life Sciences GCs/CLOs Are, And Should Be, Watching

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As Captain Kirk said:

> "The greatest danger facing us is ourselves, and irrational fear of the unknown. There's no such thing as 'the unknown' — only things temporarily hidden, temporarily not understood.“ Star Trek TOS, "*The Corbomite Maneuver*" (S1, E10, 1966)

Our Goal Today Uncover The Temporarily Hidden and Understand The Temporarily Misunderstood

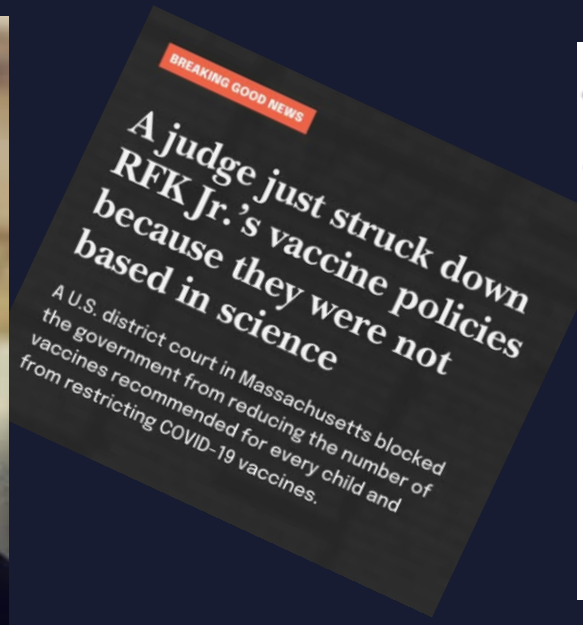
Agenda

1. Introduction of Panel
   i. Kathleen Boozang
   ii. David Opderbeck
   iii. Jim Flynn
2. Example of Following A Case: Past, Present, & Future Of *AAP et al. v. Kennedy et al.*
3. Past Tense: Already Decided Cases Having Ongoing Impacts
   i. ***Loper Bright Enterprises v. Raimondo* (2024)**
   ii. ***Wisconsin Bell v. United States ex rel. Heath (2025)***
   iii. ***Chiles v. Salazar (2026)***
4. The Present Tense: The Technology is Here Before The Law Has Caught Up
   i. ***Estate of Lokken v. UnitedHealth Group* (D. Minn.)**
   ii. ***In re Meta Pixel Healthcare Litigation* (N.D. Cal.)**
5. **The Future Tense: Known Unknowns & Unknown Unknowns**

A Past, Present, & Future Tense View Of Import Litigation

AAP et al. v. Kennedy et al. (D. Mass.) — EBG as Counsel for Plaintiffs

Counsel: Epstein Becker Green | APA & FACA | Vaccine Policy, ACIP, & Childhood Immunization Schedule



The Past Tense:

Already Decided Cases Whose Impact Is Just Beginning

Loper Bright Enterprises v. Raimondo (2024)

U.S. Supreme Court | 144 S.Ct. 2244 | Continuing Major Impact

WHAT IT'S ABOUT

Overruled the 40-year Chevron doctrine, eliminating judicial deference to federal agencies' interpretations of ambiguous statutes. Courts now exercise independent judgment on what Congress intended — regardless of agency expertise.

THE SIGNIFICANCE

Post-Loper, every CMS rule, FDA guidance, and HRSA interpretation once insulated by Chevron deference is now a litigation target. Impact is already materializing in 340B and drug pricing litigation.

One particular example we envision relates to GLP-1 / IRA DRUG PRICING, as semaglutide negotiation — and Part B drugs — raise new theories such as the challenge to Botox's Part B inclusion, and other GLP-1 bundling disputes, open new litigation fronts. Post-Loper, courts will independently interpret "maximum fair price" and drug grouping — giving pharma new arguments prior rounds could not make.

WHY GCs SHOULD CARE

- Every agency rule in healthcare is now subject to independent judicial scrutiny
- Audit CMS, FDA, and HRSA rules that your organization relies on for compliance
- 340B program and drug pricing rules face particular vulnerability
- Monitor agency guidance: what was previously settled law may now be litigated
- Consider challenging longstanding agency interpretations that negatively impact your organization

Wisconsin Bell v. United States ex rel. Heath (2025)

U.S. Supreme Court | 604 U.S. ___ (2025) | False Claims Act Expansion

WHAT IT'S ABOUT

The Court held that a whistleblower can bring an FCA lawsuit over reimbursements from a private, industry-funded program where the government provides any portion of the money — expanding what constitutes a "claim" under the False Claims Act.

KEY CONSIDERATIONS

FCA healthcare recoveries neared or exceeded $6 billion in FY2025 — the highest annual total in history.

Key questions will go beyond definition of "claim," and see how other aspects of FCA will play out in cases involving private, industry-funded program

WHY GCs SHOULD CARE

- Companies receiving even minimal government funding in a mixed program face FCA exposure
- Audit funding structures: Medicare Advantage, CMMI models, research grants, hybrid programs
- Review qui tam exposure: whistleblowers now have a broader avenue for FCA claims
- Engage FCA counsel to map every government-sourced funding stream and assess litigation risk

Chiles v. Salazar, 607 U.S. ___ (2026)

U.S. Supreme Court | Decided March 31, 2026 | 8–1 | First Amendment | Professional Speech & Clinical Standard of Care

WHAT IT'S ABOUT

Colorado's 2019 Minor Conversion Therapy Law (MCTL) banned licensed mental health professionals from engaging in talk therapy intended to change a minor's sexual orientation or gender identity. Kaley Chiles, a Christian counselor, challenged the law as viewpoint discrimination violating the First Amendment. Colorado argued it was regulating professional conduct, not speech.

THE HOLDING (Gorsuch, J., for 8 Justices)

Laws regulating the **content or viewpoint** of a licensed therapist's speech must survive **strict scrutiny**, not rational basis. A state may not simply label clinical speech as "conduct" to avoid First Amendment review. The decision effectively invalidates Colorado's law and the 23 similar state laws on similar grounds.

"The First Amendment stands as a shield against any effort to enforce orthodoxy in thought or speech in this country." — Justice Gorsuch, majority

"I fear the people of this country will get burned… What's next? In the worst-case scenario, our medical system unravels." — Justice Jackson, sole dissent

WHY GCs SHOULD CARE: THE DOUBLE-EDGED SWORD

- **The same First Amendment shield that protects conversion therapy practitioners can be raised against federal funding cutoffs for institutions providing gender-affirming care.**
  - Justice Kagan's concurrence explicitly acknowledged a "mirror image" law banning therapy affirming gender identity would be equally unconstitutional.
  - **CMS is already moving:** Proposed rules would cut off Medicare and Medicaid funding for any hospital providing gender-affirming care to minors. **Chiles gives those hospitals a First Amendment argument.** *Also see* ***Oregon v. Kennedy***
- **Standard-of-care regulation is now in play:** If the government cannot restrict a therapist's speech to enforce a clinical consensus, it may not be able to enforce the opposite consensus either. Jackson's dissent warned this logic "opens a dangerous can of worms" for all medical regulation.
- **Post-Loper amplifier:** Courts no longer defer to HHS on what constitutes the "standard of care" for reimbursement purposes. Chiles compounds this: neither may they accept a government speech restriction as merely incidental to a permissible clinical regulation.
- **Audit now:** Any organization providing, restricting, or planning to restrict clinical speech-based care should assess its exposure under Chiles. Informed consent, prior authorization scripts, clinical protocols, and credentialing standards that restrict what clinicians may say are all potentially implicated.

The Present Tense:

Cases Winding Through the Courts That Demand Your Attention

Estate of Lokken v. UnitedHealth Group (D. Minn.)

No. 0:23-cv-03514 | Active — In Discovery (Sept. 2025) | AI & Coverage Decisions

WHAT IT'S ABOUT

A proposed class action alleging UnitedHealthcare used an AI algorithm ("nH Predict") to automatically deny Medicare Advantage claims for post-acute care. The court found that use of AI in lieu of clinical review could breach contractual promises to members that coverage decisions would be made by "clinical staff and physicians."

THE DEFINING QUESTION

Does using AI for coverage decisions create independent liability to patients — separate from whether the underlying denial was clinically correct?

ANCILLARY QUESTIONS

If AI coverage decisions are ratified by human reviewer, is contract breached?

Must human being review coverage decision on reimbursing pathology determinations made using AI?

WHY GCs SHOULD CARE

- Review what your contracts actually promise about who makes clinical decisions
- Audit whether AI tools are accurately described in member-facing materials
- Assess whether human clinical oversight is substantive or cosmetic
- Applies to all plans using algorithmic tools in prior auth or utilization management

In re Meta Pixel Healthcare Litigation (N.D. Cal.)

Civil Action No. 3:22-cv-03580 | HIPAA, FTC & Class Action | 664+ Hospital Systems Implicated

WHAT IT'S ABOUT

A consolidated class action alleging Meta Platforms received protected health information from hospital websites through Meta Pixel — a JavaScript snippet transmitting patient portal logins, appointment scheduling, and medical condition searches to Facebook's ad infrastructure — without HIPAA-compliant BAAs or patient authorization.

OCR GUIDANCE (2022, updated 2024)

Using pixel tracking tools on hospital websites violates HIPAA unless a BAA exists with the vendor or patients have provided valid authorization.

WHY GCs SHOULD CARE

- 1 in 3 healthcare websites still use Meta Pixel or equivalent — audit yours now
- Meta is not a HIPAA business associate — no BAA can be established
- Triple exposure: OCR enforcement, FTC action, and private class action simultaneously
- Review all third-party tracking tools across patient-facing digital properties

The Future Tense:

Known Unknowns & Unknown Unknowns — Cases Not Yet Filed That Could Keep You Up at Night …Or Surprise Us In the Morning

Practical Takeaways for Health Care & Life Sciences GCs

POST-LOPER BRIGHT

- Audit all agency rules your organization relies on for regulatory compliance
- Identify interpretations vulnerable to legal challenge
- Consider affirmative litigation where agency overreach has harmed your organization

FCA EXPOSURE

- Map all government-sourced funding streams — even indirect or partial
- Brief leadership on qui tam risk given record FCA recoveries

AI & COVERAGE DECISIONS

- Review all member contracts — what do they promise about who decides?
- Ensure AI tools are accurately described in member-facing materials
- Document that human clinical oversight is substantive, not cosmetic

DIGITAL PRIVACY

- Audit all tracking tools on patient-facing websites immediately
- Simultaneous OCR, FTC, and class action exposure is real

LOOKING AHEAD

- Anticipate litigation intersecting AI, data privacy, and new regulatory interpretations
- Proactively advise leadership on emerging risk areas before cases are filed
- Build cross-functional legal-operations-compliance teams for rapid response
- The GC who anticipates is far better positioned than the one who only reacts

Two Cases We Could See Being Filed The Near Future

Where the law, technology, and policy collide — and what GCs should be watching now

AI DIAGNOSTIC LIABILITY

Who is liable when an AI-assisted diagnosis is wrong?

As FDA-cleared AI diagnostic tools proliferate in radiology, pathology, and cardiology, the first malpractice/products liability cases naming the AI vendor, the hospital, and the treating physician jointly are overdue. Post-Loper, FDA clearance may no longer provide the liability shield manufacturers assumed.

MEDICAID WORK REQUIREMENT CHALLENGES

OBBBA work requirements take effect Jan. 1, 2027

State AGs and beneficiary groups will challenge federal Medicaid work requirements under the APA and the Medicaid Act's purpose clause. Hospitals and health systems serving disenrolled patients face uncompensated care surges — and potential standing to sue. Prior Arkansas litigations (*Gresham v. Azar* [and its companion cases]) foreshadow the claims.

...And Two More

Where the law, technology, and policy collide — and what GCs should be watching now

HHS RESTRUCTURING / GRANT CLAWBACK

$11B+ in rescinded grants; 2027 budget proposes $15.8B more in cuts

Research institutions, health systems, and state health departments whose congressionally appropriated grants were unilaterally rescinded will bring Impoundment Control Act, APA, and constitutional spending clause challenges. The AAP $12M restoration ruling is a preview of the damages theory.

STATE AI LAW vs. FEDERAL PREEMPTION

DOJ AI Litigation Task Force vs. CO, TX, CA healthcare AI mandates

The Trump December 2025 Executive Order, and more recently issued National AI Legislative Framework, directing DOJ to challenge "onerous" state AI laws will collide with 43 states' 240+ pending AI bills — including healthcare-specific prior auth disclosure, AI downcoding prohibitions, and clinical AI oversight mandates. A commerce clause/preemption test case is imminent.

Those Six Case Are The Known Unknowns, But What Are The Unknown Unknowns?

How Do We :

- Define Them & Their Characteristics?
- Plan For Them?
- Contain Them?

As we started with Captain Kirk, we can end with something else he said:

“They used to say if man could fly, he'd have wings — but he did fly. He discovered he had to. ....Doctor McCoy is right in pointing out the enormous danger potential in any contact with life and intelligence as fantastically advanced as this. But I must point out that the possibilities — the potential for knowledge and advancement — is equally great. Risk! Risk is our business. That's what this starship is all about. That's why we're aboard her.“ Star Trek TOS, "Return to Tomorrow" (S2, E20, 1968)

We Accept Our Greatest Fears and Manage the Risks Around Them.

EPSTEIN
BECKER
GREEN

Concluding Remarks/Wrap Up

Sources/Materials

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- LOPER BRIGHT ENTERPRISES ET AL. v. RAIMONDO, SECRETARY OF COMMERCE, ET AL. , 144 S.Ct. 2244 (2024)
- Wanerman, Robert, *Supreme Court Alters the Administrative State: Loper and Relentless Decision Shifts Authority from Administrative Agencies and Creates Uncertainty* (EBGLAW July 25, 2024)
- The *Loper and Jarksey* Era: Agency Power to Award Civil Penalties in SEC and FINRA Under Increased Scrutiny, Commercial Litigation Update (EBG, December 9, 2024)
- Wisconsin Bell v. United States ex rel. Heath, 604 U.S. ___ (2025)
- O'Neill Institute Health Care Litigation Tracker
  - Estate of Gene B. Lokken et al. v. UnitedHealth Group, Inc. et al. Tracking
  - State of Oregon et al. v. Kennedy et al. Tracking
- GovInfo In re Meta Pixel Healthcare Litigation (N.D. Cal., Civ. Action No. 22-3580)

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- APA, APA concerned about far-reaching consequences from Supreme Court decision regarding therapy as 'free speech,' March 31, 2026
- Chemerinsky, Erwin, Conversion therapy and professional speech (April 9, 2026)
- Cestonaro C, Delicati A, Marcante B, Caenazzo L, Tozzo P. Defining medical liability when artificial intelligence is applied on diagnostic algorithms: a systematic review. Front Med (Lausanne). 2023 Nov 27;10:1305756. doi: 10.3389/fmed.2023.1305756. PMID: 38089864; PMCID: PMC10711067.
- Cham, Daniel, Navigating Shared Liability in AI-Assisted Clinical Care: A Comprehensive Guide for Healthcare Professionals, *Medium* September 13, 2025
- Krabacher, G., Flynn, J, WHOSE IS THE IMAGE AND SUBSCRIPTION?: COMPARING THE TRUMP ADMINISTRATION'S & CATHOLIC CHURCH'S VISIONS FOR EVOLVING ARTIFICIAL INTELLIGENCE, 7 Notre Dame Journal On Emerging Technologies 1 (2026)
- Center on Budget and Policy Priorities, Medicaid Briefs: Who is Harmed by Work Requirements? (March 10, 2020)

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- Center for Health Law and Policy Innovation, Federal Grant Terminations Whiplash: What Can Litigation do to Protect Organizations? (February 20, 2026)
- Exec. Order No. 14365, 90 Fed. Reg. 58499 (Dec. 11, 2025)
- National AI Legislative Framework (March 20, 2026)
- Press Release, White House, National AI Legislative Framework (March 20, 2026)

AAP et al. v. Kennedy et al. (D. Mass.) — EBG as Counsel for Plaintiffs

Counsel: Epstein Becker Green | APA & FACA | Vaccine Policy, ACIP, & Childhood Immunization Schedule

THE PAST

- **July 2025:** AAP and six medical societies file suit challenging Kennedy's removal of all 17 ACIP members and appointment of vaccine skeptics
- **Dec. 17, 2025:** Oral argument on government's motion to dismiss; EBG argues plaintiffs have standing and the case must proceed
- **Jan. 2026:** Court denies motion to dismiss — case proceeds; HHS separately slashes childhood schedule from 17 to 11 vaccines without ACIP input

THE PRESENT

- **Mar. 16, 2026:** Judge Murphy grants Section 705 stay — blocks Kennedy's 13 ACIP appointments, nullifies all post-June 2025 ACIP votes, and stays the revised childhood vaccine schedule
- Court also orders restoration of $12M in AAP grant funding cut by HHS in alleged retaliation

IN THE NEWS

"Federal Judge Puts Brakes on RFK Jr's Vaccine Agenda"
AJMC, March 2026

"Federal Judge Blocks Kennedy's Changes to Childhood Vaccine Policy"
CIDRAP, March 2026

"Overhaul of Childhood Vaccine Guidance Blocked by Federal Judge"
Pharmacy Times, March 2026

"US Judge Blocks Efforts to Reshape Childhood Vaccine Policy"
Reuters, March 16, 2026

"U.S. District Court Issues Preliminary Injunction Against RFK, HHS for Its Vaccine Schedule Changes"
Above the Law / Techdirt, March 2026

THE FUTURE

- Government appeal anticipated; 1st Circuit to watch
- Apr. 13, 2026 hearing: Can HHS cure FACA defects by revising ACIP charter?
- Full trial on merits pending; vaccine schedule coverage obligations unresolved

LESSONS FOR GCs

- APA & FACA are potent tools against agency overreach — even in high-profile political disputes
- Retaliation for legal advocacy is itself actionable: $12M grant restoration order
- Post-Loper, procedural requirements — not just outcomes — are litigable