

Life Sciences Newsletter

UPDATES AND NEWS FROM THE BAKERHOSTETTLER LIFE SCIENCES TEAM

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CONGRESSIONAL OVERSIGHT RISK: WHAT SHOULD BE DONE NOW

By [Kevin Edgar](#)

With the 2026 midterm elections approaching on Nov. 3, life sciences companies should prepare for more than potential policy shifts. A change in congressional control and leadership come January 2027 will quickly reshape oversight priorities and increase the likelihood of investigations, information requests, briefings, oversight hearings and public scrutiny across the healthcare and life sciences sector. However, clients should not expect calm before the storm. Members of Congress are not waiting until after the midterm elections or for the 120th Congress to convene to start their investigations.

Unlike traditional regulatory or Department of Justice reviews, congressional inquiries often move quickly, unfold publicly and create reputational, operational and legal risks before any formal finding of wrongdoing. Congressional committees and individual members of Congress are increasingly leveraging their oversight authority to seek information that may be public or proprietary, and seemingly friendly inquiries can transform instantly into adversarial, full-blown congressional investigations.

Why Life Sciences Companies Are Likely Targets

The industry sits at the intersection of healthcare, innovation, patient access, government spending and public policy, making it a recurring focus of congressional oversight. Potential areas of scrutiny include drug pricing and reimbursement, pharmacy benefit manager relationships, clinical trials and patient safety, marketing practices, Food and Drug Administration (FDA) interactions, supply chain resilience, foreign manufacturing, artificial intelligence (AI) and digital health technologies, federal

healthcare funds, data privacy, cybersecurity, public company disclosures, private equity, private credit or venture capital-backed financing, customer complaints, and transactions affecting market competition.

For biotechnology, pharmaceutical, medical device, diagnostic, digital health and healthcare services companies, congressional attention can arise suddenly – particularly following a high-profile event, adverse patient outcome, cybersecurity incident, pricing controversy, supply chain disruption, whistleblower claim, consumer watchdog report or complaint, or media report. Many members of Congress also use constituent feedback as the basis for their inquiries into the private sector.

Congressional Investigations Are Different from Regulatory Inquiries

Congressional investigations differ from regulatory inquiries in important ways. House and Senate committees may operate under compressed timelines, request extensive document production, seek executive interviews or testimony, and use public communications strategies that generate media attention. Congress will typically demand a response within two to three weeks of an inquiry letter. That timeline is unrealistic and can be extended, but if companies don't know that or don't know to reach out to counsel upon receiving an inquiry letter, problems can compound quickly.

A routine information request can become more formal if responses are delayed or incomplete or if a company appears uncooperative. In some cases, congressional inquiries may proceed in parallel with reviews by regulators, state attorneys general or private litigants.

Preparing Before a Letter Arrives

The best time to prepare for congressional scrutiny is before an inquiry arrives. Life sciences organizations should implement the following:

Routine federal government interaction. Inventory meetings, interactions and requests for assistance with the administration (White House officials), Cabinet departments and independent agencies.

Rapid response framework. Identify in advance who will coordinate congressional responses from among legal, compliance, government affairs, communications, regulatory and executive leadership. Outside counsel should be the buffer between the company and Congress. Trade associations might choose to respond to a broad-based congressional life sciences

industry inquiry, but Congress will expect individual companies to respond directly to a letter. Congress will not take kindly to a response from a trade association in lieu of a direct response from the company.

Document preservation procedures. Review retention and preservation practices so potentially responsive materials can be identified and collected quickly.

Executive preparation. Prepare senior executives, board members, chief medical officers and scientific leaders who may be asked to participate in briefings, interviews or hearings.

Consistent messaging and coordination. Align internal communications, public statements, investor disclosures, congressional responses and cross-functional teams to reduce legal and reputational risk.

Emerging Areas to Watch

Several issues are likely to remain in focus because they affect patients, healthcare spending and economic competitiveness. These include AI in healthcare, drug pricing and patient access, pharmaceutical supply chain security, data privacy and cybersecurity, requests for exemptions or no-action relief from agencies, disclosures in filings, ownership structures, and transactions that raise questions about market power or consolidation.

The Bottom Line

For life sciences companies, the 2026 midterm elections may bring more than legislative uncertainty. A change in congressional leadership could lead to a meaningful increase in oversight activity directed toward life sciences organizations. These companies will want to limit the inquiry's life and ensure a carefully crafted response so the committee or member can move their attention to bigger targets.

Whether the issue involves drug pricing, AI, data privacy, supply chain resilience, patient access or a company-specific incident, congressional committees have broad authority to demand information, conduct interviews and hold public hearings. The rules that govern regulatory inquiries and enforcement actions by federal regulators do not apply to Congress.

Organizations that establish response protocols, identify key stakeholders, prepare senior leaders and engage experienced counsel before an inquiry arrives will be better positioned to navigate heightened scrutiny.

As congressional oversight activity accelerates, preparation may prove just as important as the response. Congress will demand information from the Trump administration, and when that information does not arrive, they will turn to the private sector for answers.



FDA UPDATES

FDA Advisory Committee Reviews Peptides for Compounding

In July, the FDA's Pharmacy Compounding Advisory Committee convened to review seven peptides for potential inclusion on the 503A bulk substances list. After two days of presentations and discussion, the committee recommended adding six of the seven peptides to the list, which would permit licensed compounding pharmacies to prepare them pursuant to a valid prescription. Although the committee's votes are nonbinding, the FDA will now review the full record, which includes those recommendations along with public comments and the scientific data presented. A second review of additional peptides is expected in early 2027.

Revised Draft Guidance on Substantial Evidence of Effectiveness

In June, the FDA issued a significantly updated draft guidance regarding the type and amount of evidence sponsors need in order to demonstrate that a drug or biologic is effective. This foundational document affects how companies design clinical trials and support New Drug Applications. Public comments were due Sept. 22.

FDA Updates Labeling for Menopausal Hormone Therapy

Based on its analysis, the FDA has requested drug sponsors of all hormone replacement therapy (HRT) products that contain estrogen or progestogen – in all dose forms – to remove language about the risk of cardiovascular disease, breast cancer and probable dementia from the boxed warning. The FDA requested other safety-related labeling changes as well but has not asked drug sponsors to remove the risks of cardiovascular disease and breast cancer from the labels' Warnings and Precautions section. Nor has the agency requested removal of the boxed warning for endometrial cancer for systemic estrogen-alone products.

These labeling changes are being requested, per the FDA, to provide women and their physicians with updated information on the benefits and risks of these medications, enabling the parties to make informed decisions. The revision process is being handled on a product-by-product basis as companies submit labeling updates for FDA review and approval. There is no one publicly announced universal compliance date that applies to every HRT product.



PATENT UPDATES

Supreme Court Decision Strengthens Position for Generic Drug Manufacturers and Biopharma Defendants

A recent unanimous U.S. Supreme Court decision provides important clarity for pharmaceutical and biotechnology companies navigating patent risk, particularly in the context of generic drug launches. In *Hikma v. Amarin*, the Court held that induced patent infringement claims require allegations that a company took active steps to encourage infringement, which tightens the pleading standard for patent owners. The ruling offers greater certainty for generic manufacturers using FDA-approved “skinny labels” and limits the ability of patentees to rely on implied or indirect allegations of infringement. More broadly, the decision provides life sciences companies with clearer guidance on how courts will evaluate inducement claims involving product labeling, marketing communications and regulatory compliance.

Read more here: <https://www.bakerlaw.com/insights/unanimous-court-resets-inducement-landscape-tightens-pleading-standard/>

IN THE NEWS

BakerHostetler Represents Cardinal Health in Strive Medical Acquisition

BakerHostetler served as legal adviser to Dublin, Ohio-based Cardinal Health in its acquisition of Strive Medical, a urology-focused multispecialty supply provider. The purchase accelerates Cardinal Health’s at-home solutions growth strategy, expanding the company’s ability to provide comprehensive solutions for home medical equipment providers. Strive Medical currently serves more than 20,000 people annually.

BakerHostetler Secures Precedent-Setting OSHA Victory for ExxonMobil

BakerHostetler secured a significant win for ExxonMobil in the U.S. Court of Appeals for the Fifth Circuit, where the court struck down the Occupational Safety and Health Administration’s (OSHA) mental illness recordkeeping rule, creating a new precedent that is immediately applicable to all employers in Louisiana, Mississippi and Texas. The ruling provides important guidance for navigating OSHA recordkeeping obligations in complex workplace safety matters, and employers across the nation should consider how this ruling will affect them.

2026 BIO International Networking Reception in San Diego

BakerHostetler’s Life Sciences Industry team hosted a networking cocktail reception as part of the 2026 BIO International Convention in San Diego. The convention is widely recognized as the premier annual gathering for the biotechnology industry. The reception, held June 23 at Hudson & Nash restaurant, attracted more than 100 registrants, bringing together clients, industry leaders, investors, entrepreneurs, academics and other stakeholders from across the life sciences ecosystem. Send us an email at lifesciencesevents@bakerlaw.com if you’d like to be included in the next event.

BakerHostetler Partner [Lee Rosebush](#) Coauthors Book, ‘The Peptide Revolution: Past, Present, and Future’

The book explains why peptides have become such a major topic in healthcare, wellness and pharmaceutical discussions, along with examining what they are and how they function in the body. Well-known peptide-based therapies such as insulin and GLP-1 medications are highlighted, and the scientific history and potential of peptide treatments are explored.

BakerHostetler Sponsored the First Annual PepMed 2026 Regenerative Health World Congress

BakerHostetler sponsored PepMed 2026 in Washington, D.C., Sept. 17-18. The event brought together physicians, researchers, pharmacists, manufacturers, policymakers, investors and other industry stakeholders to discuss the future of peptide therapies and regenerative health. The conference had more than 400 attendees and featured more than 50 speakers, representing a broad cross-section of scientific, clinical, business and government leadership.

BakerHostetler Exhibited at Life Sciences Future 2026

BakerHostetler Partners [Ron Kern, Ph.D.](#), and [Laura Carlson, Ph.D.](#), connected with attendees at the firm’s exhibitor booth during the Life Sciences Future conference Sept. 30-Oct. 1 in King of Prussia, Pennsylvania. Hosted by Life Sciences PA, this event is the annual meeting of the Pennsylvania life sciences ecosystem.

FREE VIRTUAL CLE WEBINAR SERIES

BakerHostetler is offering a virtual CLE webinar series designed for in-house counsel

this fall. The Six in Six Webinar Series: Around the Law in Six Sessions addresses the need for training for in-house counsel.

The program, presented virtually over six weeks starting in early October, is designed to provide in-house counsel with a foundation in the core legal areas impacting the corporate environment. Six in Six offers a course from each of our practice groups, as follows; click the corresponding session to RSVP via Zoom:



**SIX IN SIX
WEBINAR SERIES**
AROUND THE LAW
IN 6 SESSIONS
BakerHostetler

- **Labor and Employment** | **Oct. 7** – Real World Strategies for AI, Accommodations and Wage & Hour Risk
- **Digital Assets and Data Management** | **Oct. 14** – AI Horror Stories: Lessons from the AI Mishaps, Missteps, and Near-Misses Spooking In-House Teams
- **Intellectual Property** | **Oct. 21** – When Consumers Want the Copy: Brand Protection Strategies in the Age of Dupes
- **Tax** | **Oct. 28** – Tax Controversy and International Tax Update: Litigation Trends, IRS Enforcement, and Transfer Pricing Developments
- **Litigation** | **Nov. 4** – AI in Litigation: Opportunities, Risks and Emerging Challenges
- **Business** | **Nov. 11** – Recent Developments and Market Update in M&A and Capital Markets Transactions

All dates are Wednesdays, and sessions run from **1 – 2 p.m. ET** (Noon – 1 p.m. CT, 11 a.m. – Noon MT, 10 – 11 a.m. PT).



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