Sheppard

2026 Top-of-Mind Issues for

Life Sciences Companies

Every so often, a moment occurs that shifts the tectonic plates of an industry.

In 2010, the Obama Administration largely disrupted the healthcare industry with its landmark legislation, the Affordable Care Act. We are in another such moment, where the Trump Administration is transforming the life sciences industry, not through legislation, but through regulation. Two different methods to achieve the same result: enact significant change. The way in which the Food and Drug Administration (FDA) is regulating life sciences products and enforcing the Food, Drug and Cosmetic Act is altering the foundation of the industry. We would be remiss not to recognize the significance of the moment.

We're seeing real shifts at the FDA—not just in terms of new faces at the top, but also in the direction and speed of regulatory priorities. These changes reach far beyond the Agency's walls, influencing everything from the speed of product approvals to the intensity of enforcement actions.

The two drivers of this change are the Make America Great Again (MAGA) and the Make America Healthy Again (MAHA) movements. MAGA is pushing a deregulation agenda while MAHA is reevaluating everything from the safety and efficacy standards to over-the-counter use. These two movements are making marks across the entire industry, as policies increasingly collide in areas like tariffs, drug pricing negotiations and the implications of initiatives such as "TrumpRx."

To be sure, 2026 will be a year of realignment for how life sciences companies get their products approved and consequently operate. The Commissioner's new National Priority Voucher Program is being watched as a bellwether—what's working, what's not and how it might evolve. Also, much talk has been made about reassessing the approval process itself—with the FDA indicating openness to Bayesian statistics or defaulting to a one randomized control trial standard instead of two.

On the enforcement side of the house, we have seen an uptick in FDA activity, with companies facing a heightened risk of untitled and warning letters, as well as cease and desist demands. This enforcement underscores a renewed focus on compliance, signaling that companies must maintain robust internal protocols and be ready to respond quickly to enforcement actions that can have immediate operational—and reputational—impact.

Against this backdrop, innovation powers ahead—especially with the impact of AI for both how the FDA and industry use it. We're watching closely as AI drives new tools and therapies, even as AI raises novel questions about oversight, liability and intellectual property rights. Digital health technologies and telehealth platforms that skyrocketed in popularity during the pandemic remain squarely in regulators' sights, with federal and state authorities updating their approaches to direct-to-consumer advertising and purchasing as well as patient privacy.

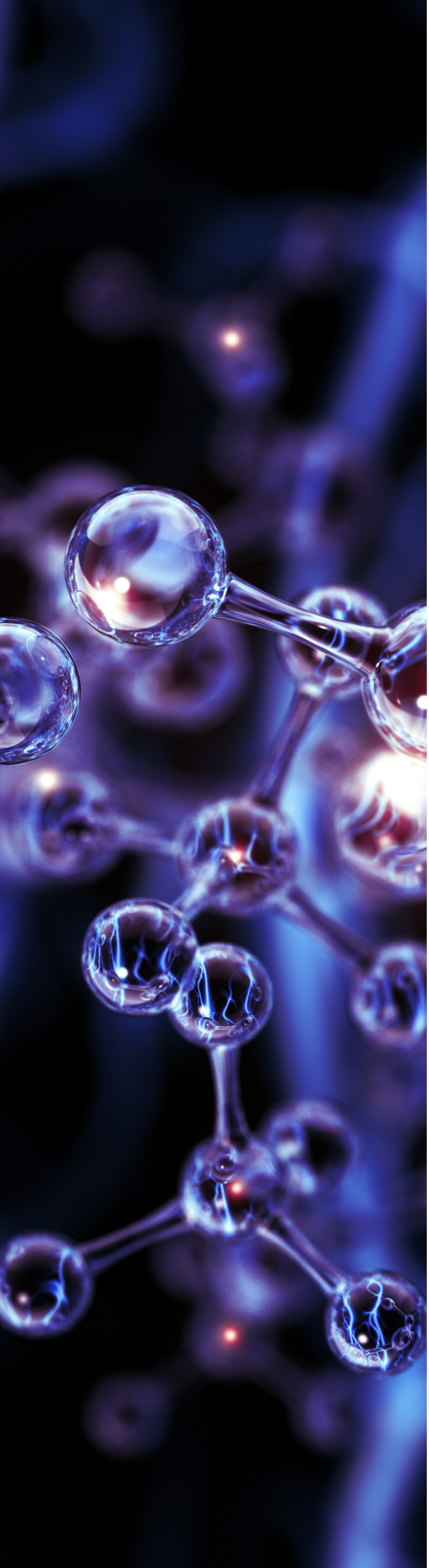
In this year's "Top-of-Mind Issues for Life Sciences Companies" publication, our team unpacks these developments and offers practical insights to help your business anticipate, adapt and thrive. The goal is to equip you with the most up-to-date perspectives and legal strategies, so you can navigate the unique challenges—and seize the emerging opportunities—in the year ahead. As always, we invite you to reach out to us for deeper guidance tailored to your specific goals and concerns as we all prepare for a dynamic year in the life sciences sector.

Co-Chair, Life Sciences Practice
Chair, FDA Practice

Scott Liebman
Co-Chair, Life Sciences Practie
+1.212.634.3030 • New York
sliebman@sheppard.com

Jeffrey Fessler
Co-Chair, Life Sciences Practie
+1.212.634.3067 • New York
jfessler@sheppard.com

Lorna Tanner
Co-Chair, Life Sciences Practie
+1.650.815.2658 • New York
ltanner@sheppard.com



Contents

The Impact of Artificial Intelligence on Patenting Biotechnology Inventions

A Comparative U.S. and European Perspective

By David Fournier, Allison Glasunow & Madison Aufai

Overview of AI and the Biotechnology Innovation Lifecycle

Artificial intelligence (AI) is now embedded across the biotechnology innovation lifecycle—from early discovery and target identification to candidate optimization and experimental prioritization. For life sciences companies, AI is no longer an emerging capability; it is a core R&D asset. As a result, AI is reshaping not only what is invented, but how patent portfolios must be built, governed and defended.

U.S. and European patent systems continue to require that inventions be conceived by humans, even where AI plays a substantial role. Courts and patent offices on both sides of the Atlantic have been unequivocal: AI systems cannot be named as inventors. They are tools, useful tools akin to a piece of technical laboratory equipment, but nothing more when it comes to inventions. The practical issue for companies is therefore not formal compliance, but whether they can clearly demonstrate human conception where AI systems generate or refine technical solutions to posed problems.

Disclosure and claim scope now represent a significant pressure point in addition to delineating inventorship between human and machine. AI expands the design space, which encourages broad claims, while courts and patent offices demand experimental support commensurate with claim scope. Computational predictions alone are rarely sufficient.

Finally, AI intensifies the tension between patent disclosure and data governance. AI models in biotechnology often rely on sensitive clinical, genomic and real-world data subject to HIPAA and GDPR. Patent strategies must therefore balance regulatory compliance, confidentiality and long-term IP value.

Introduction

Artificial intelligence (AI) is changing how biotechnology inventions are discovered, optimized and validated. Machine learning models can mine multi-omic datasets to identify targets, generate candidate biologics or small molecules, predict structure—function relationships and prioritize experiments. These advances promise faster timelines and lower R&D costs, but they also test the fit of patent doctrines built around human conception, conventional disclosure practices and relatively stable innovation workflows.

The friction is especially sharp in biotechnology. Inventions often include complex structure/function relationships, outcomes can be unpredictable, claims frequently seek genus-level scope and large, sensitive datasets are increasingly relied upon. Here we compare how AI pressures four patent law pillars—inventorship, subject matter eligibility, enablement and related disclosure doctrines and data privacy—under U.S. and European (EPC/EPO) frameworks. We conclude with practical drafting and governance strategies for AI-enabled biotech patent portfolios.

AI's Role in Modern Biotechnology R&D

AI influences biotechnology at two levels: a discovery engine and an optimization engine. In discovery, models uncover patterns in biological and clinical data or propose mechanistic hypotheses. In optimization, generative and predictive models iterate through vast design spaces, including protein variants, antibody CDR combinations, RNA sequences, cell engineering strategies and propose candidates predicted to meet functional thresholds. These systems typically generate probabilistic candidates rather than deterministic solutions as outputs.

Human researchers still set objectives, choose datasets, validate outputs experimentally and make go/no-go decisions. But as AI becomes more autonomous in proposing solutions — and as inventions are claimed more broadly based on AI-driven design rules or functional screening — core patent doctrines face renewed stress and require both additional diligence and scrutiny regarding the invention and its origins.

Inventorship: Who Is the Inventor When AI is Involved?

United States

U.S. patent law requires inventors to be natural persons. This requirement was clarified by the Federal Circuit in *Thaler v. Vidal* (2022), which held that an AI system cannot be listed as an inventor under the Patent Act. The court's analysis turned on statutory interpretation and precedent, concluding that an "inventor" must be a human being. Accordingly, AI cannot be an inventor and applicants must identify the human—or humans—who conceived the claimed invention.[1]

For AI-enabled biotechnology inventions, the operational issue is not simply naming a human inventor, but ensuring that each named inventor can credibly be shown to have conceived the claimed features. The USPTO's inventorship guidance for AI-assisted inventions emphasizes that traditional conception standards apply and that AI should be treated as a tool, analogous to laboratory equipment or software.[2,3]

In practice, the most reliable risk-reduction step is documentation. Applicants should maintain contemporaneous records of human contributions in problem framing, selection of training data and constraints, evaluation criteria, interpretation of model outputs and – perhaps most importantly – experimental confirmation. In biotechnology, where claims may target a specific sequence among millions of disclosed candidates, inventorship can become a litigation pressure point if the human contribution narrative is thin.

Europe (EPC/EPO)

European patent law similarly requires that the inventor be a human being. In the DABUS appeals (J 8/20 and related cases), the EPO's Legal Board of Appeal confirmed that an inventor under the EPC must be a natural person, rejecting applications that named an AI system as an inventor. The EPO has summarized this position explicitly: AI cannot be named as an inventor on European patent applications.[4,5]

Although the U.S. and Europe converge on the human-inventor requirement, the practices differ in emphasis. Europe's inventor designation is important for formal requirements and entitlement, but European validity disputes often concentrate more heavily on technical character, sufficiency and plausibility than on inventorship battles. Still, where AI's role is substantial, European applicants should expect questions about who devised the technical teaching, particularly when inventorship affects entitlement (e.g., employee inventors).

Convergence and Divergence

Both systems demand human inventors, but the U.S. has more developed litigation pathways where inventorship can be a direct validity and enforceability attack, whereas in Europe inventorship is less frequently litigated. For global biotech portfolios, the practical takeaway is to build a consistent, credible human contribution narrative aligned to claim scope—and to treat inventorship governance as a portfolio-level discipline every step of the way rather than a filing formalism.

Subject Matter Eligibility: Natural Phenomena, Abstract Ideas and AI-Discovered Biology

United States: § 101 and Biotech/Diagnostics

U.S. subject matter eligibility is governed by 35 U.S.C. § 101 and has been a major constraint on biotechnology claims, especially in diagnostics and natural phenomena. In *Mayo v. Prometheus* (2012), the Supreme Court held that claims directed to correlations between metabolite levels and drug efficacy/toxicity were ineligible as effectively claiming a law of nature.[6] In *Association for Molecular Pathology v. Myriad Genetics* (2013), the Court held that isolated naturally occurring genomic DNA is not patent eligible as a product of nature, though cDNA (as a synthetic construct) may be eligible[7]

AI does not change the doctrinal test, but it increases the frequency of inventions that resemble the excluded categories. AI is particularly effective at extracting correlations from biological data – exactly the kind of insight that can be framed as a natural law under Mayo. Likewise, AI can quickly identify naturally occurring sequences or naturally present relationships among biomarkers. Eligibility prospects are typically strongest when claims emphasize (i) engineered compositions having, for example, modified sequences, non-naturally occurring constructs, (ii) technical steps beyond observation which include sample processing, assay design, thresholding and quality controls and/or (iii) concrete laboratory or manufacturing methods that implement more than the mere application of an identified correlation.

Europe: Technical Character, Art. 52 EPC and Medical-Method Exclusions

Europe approaches patent "eligibility" through the lens of whether the claim recites an invention with technical character. Article 52 EPC allows patents for inventions in all fields of technology but excludes, among other things, discoveries and mathematical methods "as such".[8] This framework often makes it easier to patent technical implementations involving computation, but it remains difficult to obtain claims that amount to a discovery without technical application.

For diagnostic methods and other biotech inventions, the EU has a separate constraint: Article 53(c) EPC excludes diagnostic methods practiced on humans or animals and methods of treatment by surgery or therapy. Under EPO practice, a diagnostic method claim is excluded if it includes all phases of the diagnostic decision-making process and is carried out on the human or animal body.[9] In many cases, this is navigable using various claim styles and strategies such as omitting certain steps, claiming in vitro methods, or using device/reagent/use-type claims. Still, applicants must demonstrate technical character beyond an abstract classification or mathematical model "as such."

Comparative Takeaway

In the U.S., the principal risk is § 101 when AI outputs look like natural correlations or products of nature. In Europe, the focus is on technical character and medical-method exclusions—often navigable through claim form. Because AI increases the volume of correlation-based innovation, careful claim framing is more important in both jurisdictions.

Enablement and Related Disclosure Requirements: When AI Expands Claim Scope

United States: Enablement and Written Description

U.S. patent law requires enablement: the specification must teach how to make and use the full scope of the claimed invention without undue experimentation. In *Amgen v. Sanofi* (2023), the Supreme Court invalidated broad functional genus claims to antibodies, emphasizing that if a patent claims an entire class, it must enable that entire class.[10] This is particularly relevant to AI-driven biotech because AI can propose vast genera, often millions of variants with similar function, tempting applicants to claim overly broadly.

Beyond enablement, U.S. law imposes a separate written description requirement. In *Ariad v. Eli Lilly* (Fed. Cir. en banc 2010), the court reaffirmed that written description is distinct from enablement and requires that the specification reasonably convey possession of the claimed invention.[11] AI outputs can encourage claiming broad functional endpoints supported by limited data, which can be vulnerable under both enablement and written description.

Practically, AI-generated in silico candidates do not automatically justify enabled genus claims. Strong filings increasingly include representative species across the scope, structure–function mapping and experimental validation across diverse examples. Portfolio value is often maximized through tiered claim sets—narrow sequence/species claims, intermediate subgenus/ epitope/consensus claims and carefully supported functional/genus claims.

Europe: Sufficiency of Disclosure (Art. 83 EPC), Support and Plausibility

Europe's primary disclosure requirement is sufficiency of disclosure under Article 83 EPC, which requires the application to disclose the invention clearly and completely enough for it to be carried out by a person skilled in the art.12 The EPO Guidelines further explain that objections must be based on "serious doubts, substantiated by verifiable facts".[13] Although Europe lacks an exact analog to U.S. written description, the EPO uses Article 84 (support/clarity) and Article 83 (sufficiency) to police overbroad claiming.

In biotech, European practice also scrutinizes technical effect and the role of post-filed data. The Enlarged Board of Appeal in G 2/21 addressed when post-published evidence may be relied upon, focusing on whether the effect described is encompassed and embodied by the technical teaching of the application as filed.[14] This matters for AI-driven inventions where computational predictions may outpace wet-lab validation at filing.

In practice, the EPO may accept well-justified predictions, especially where predictability is higher and mechanistic rationale is strong, but the application must disclose a credible technical teaching. For AI-designed candidates (small molecules, peptides, biologics), applicants should include experimental data for representative candidates and explain why the model's predictions are technically meaningful, not merely statistical artifacts.

Comparative Takeaway

AI expands the design space of biotechnology inventions and encourages broader claims. In parallel, the U.S. has become increasingly strict on full-scope enablement (*Amgen*) and written description (*Ariad*), while Europe polices breadth through sufficiency, support and technical effect. Across jurisdictions, AI-enabled discovery campaigns that result in patent applications are strongest when computational generation is paired with robust experimental anchoring — most importantly, performed and analyzed by humans — and tiered claim sets balancing scope and style.

Data Privacy and Confidentiality: The Patent Disclosure–Data Governance Squeeze

Why AI Changes the Privacy Problem

AI use in the biotechnology industry often relies on sensitive data such as genomic sequences, clinical records, imaging and other real-world evidence. Even when raw datasets are not disclosed, enablement and support requirements may require describing data sources, data processing, or model training. This creates a dilemma: provide sufficient disclosure to satisfy patentability while maintaining confidentiality, avoiding privacy violations and preserving trade secret value.

United States: HIPAA and Related Constraints

In the U.S., health data handling is governed by a patchwork of regulations. HIPAA is one of many and places strict limitations on uses and disclosures of protected health information, but it includes de-identification pathways that can enable broader use of data.[15] In practice, companies rely on de-identified data, data use agreements and institutional review processes. Patent applications typically do not include patient-level information and instead describe cohorts, data provenance and processing steps in generality.

European Union: GDPR and Special-Category Data

In the EU, the GDPR applies broadly to personal data processing and provides heightened protections for special categories of personal data, including genetic and health data.[16] GDPR compliance influences data minimization, purpose limitation, cross-border transfers and model governance. As with HIPAA, a practical approach is to focus patent disclosure on technical methods and validated outcomes while maintaining internal governance documentation for compliance and evidentiary needs.

Comparative Takeaway

The U.S. often operationalizes privacy through compliance frameworks and contracts, while the EU relies on comprehensive rights-based regulation. In both systems, patent disclosure should avoid personal data, while internal records preserve the evidentiary trail needed for inventorship and technical effects. Certain AI assets, such as training datasets, model weights, feature engineering pipelines, may be best protected as trade secrets, with patent strategy instead focused on downstream compositions and validated methods of use.

Practical Strategies for AI-Enabled Biotech Patenting (U.S. and Europe)

AI-enabled inventions commonly implicate four recurring requirements: (1) human conception and inventorship; (2) patentable subject matter beyond laws of nature, products of nature, or mathematical methods "as such"; (3) disclosure and support aligned to claim scope; and (4) compliance with data privacy and confidentiality obligations.

First, build an inventorship record early. Document who identified the problem, curated and selected data, set constraints on the AI model or other AI tools, defined success metrics, interpreted outputs, selected candidates for validation, designed validation studies and analyzed validation outcomes. These records support U.S. conception narratives and reduce entitlement friction globally.

Second, draft claims around engineered artifacts and concrete implementations. In the U.S., emphasize steps beyond observation to mitigate *Mayo* risk and focus on non-naturally occurring compositions to mitigate *Myriad* risk. In Europe, ensure technical character and use claim formats that navigate Article 53(c) (e.g., in vitro methods, devices, reagents or purpose-limited product claims).

Third, treat AI as a breadth amplifier that can weaken disclosure if claims and/or disclosure outpace the validation data. Use tiered portfolios including focused sequence claims, intermediate motif/epitope/consensus claims and only as-broad-as-supported functional and genus claims. Pair computational predictions with representative wet-lab validation—particularly important post-*Amgen* in the U.S. for enablement and under European technical-effect expectations. Such validations also further distance from AI being considered an inventor.

Fourth, integrate privacy-by-design. Keep patient-level training data out of patent applications and rely on aggregate descriptions, de-identification frameworks and compliance controls. Preserve internal unpublished technical dossiers that can substantiate model development, validation and invention conception if challenged.

Key Takeaways

- AI is now a patent-strategy issue, not just a science issue. How teams use AI affects validity, enforceability and portfolio value.
- Human inventorship must be defensible and documented early including problem framing, constraints, model oversight and validation decisions.
- Broad claims require deep support. Align experimental evidence with the full scope of what you claim.
- Eligibility risk is predictable and manageable with careful claim framing especially for diagnostics and correlation-driven inventions.
- Not all AI value belongs in patents. Datasets, model weights and pipelines may be better protected as trade secrets.

Pitfalls to Avoid

- Claims that read like raw model output, with thin human contribution or limited validation.
- Overbroad functional genus claims supported by too few representative species or insufficient structure–function mapping.
- Diagnostics framed as correlations rather than technical implementations or actionable methods.
- Over-disclosure of sensitive data (patient-level information) that creates regulatory risk without strengthening the patent.
- Assuming Europe is 'easier'. Sufficiency, support and technical-effect requirements remain rigorous.

Conclusion

AI is not merely a more efficient calculator for biotechnology; it reshapes what gets invented and how. This shift pressures inventorship doctrines built around human conception, eligibility frameworks wary of natural correlations and disclosure rules designed for inventions reproducible from a written specification rather than proprietary data and models.

The U.S. and Europe converge on the necessity of human inventors, but diverge in eligibility emphases and in how they police claim breadth and evidentiary support. For biotech innovators, the near-term solution is not to wait for doctrinal overhaul but to operationalize best practices: careful inventorship documentation, claim drafting that emphasizes engineered and technical applications, robust experimental anchoring for AI-expanded claim scope and privacy-aware disclosure paired with strong internal governance.

When used properly, AI can increase both the pace of innovation and the quality of patent assets—provided patent strategy evolves as quickly as the models do.

Trade Policy Meets Health Policy:

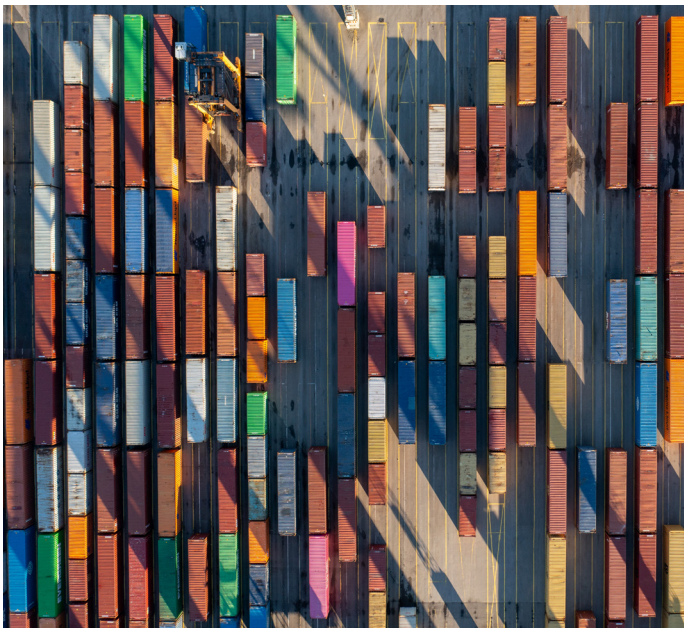
Tariffs, Drug Price Negotiations and the Rise of TrumpRx

By Julian Klein

Since taking office in 2025, the Trump administration has adopted the approach of using trade mechanisms, particularly tariffs, as leverage to influence drug pricing and to strengthen the Medicare drug price negotiation program established by the Inflation Reduction Act ("IRA"). Simultaneously, a new consumer-oriented initiative, TrumpRx, is being touted as a means to lower prescription drug prices and bring direct-to-patient benefits. Here's a look at how these policy threads connect and what they could mean for Americans and the global pharmaceutical industry.

A priority goal of the administration has been moving drug manufacturing to the U.S. and tariff threats have been used strategically to shape the behavior of pharmaceutical companies to meet these policy goals.[17] Moving beyond traditional regulatory action, the administration now leverages trade policy as a bargaining tool. Major drugmakers have entered into multibillion-dollar deals with the administration, agreeing to cut the prices of some drugs in exchange for exemption from tariffs.[18] This transactional model—where tariff benefits hinge on price concessions and investment in U.S. manufacturing—reflects a realignment of federal economic and health priorities, using trade incentives to encourage domestic production and supply chain shifts.

Meanwhile, the Medicare drug price negotiation authority under the IRA continues to move the needle on prescription costs. Last year, the Centers for Medicare & Medicaid Services (CMS) announced new negotiated price reductions for fifteen high-cost drugs, set to save billions for Medicare Part D beginning in 2027.[19] These savings build on the initial phase of IRA negotiations, which targeted a first set of drugs for price reductions in 2026. The IRA's negotiation program, while separate from the administration's tariff-linked strategy, provides critical context for the broader landscape: government-driven price negotiation is already reshaping how both Medicare beneficiaries and pharmaceutical companies navigate the prescription drug market.



TrumpRx marks a prominent shift towards a direct-to-consumer pricing model and seeks to recruit major drugmakers through negotiated deals, leveraging tariff relief as its primary incentive. For instance, several manufacturers of GLP-1 drugs have recently agreed to sell their products through TrumpRx.[20] The program requires participating companies to offer "most-favored-nation" pricing, meaning they must match or beat the lowest prices for these drugs in other comparable wealthy countries. Unlike the IRA, which operates mainly within the insurance system, TrumpRx is designed—at least in theory—to offer lower out-of-pocket costs for individuals without traditional insurance coverage. However, because the vast majority of Americans are insured—and early data indicates that purchasing prescription drugs through traditional insurance plans remains more cost-effective—the overall impact of TrumpRx, which promotes itself as offering "the lowest prescription prices in America," remains uncertain for most Americans.

Looking Ahead to 2026 and Beyond

These parallel policy initiatives—tariff-backed dealmaking, IRA negotiations and TrumpRx—are likely to increase pressure on manufacturers to lower drug costs while also encouraging them to bring manufacturing onshore. This creates a clear tension, as foreign manufacturing has traditionally been the more cost-effective approach. Watch for expanded use of tariffs and exemptions as negotiating tools, additional drugs pulled into both IRA price negotiations and TrumpRx-style arrangements and continued announcements tying U.S. manufacturing investments to price concessions. For manufacturers, the message is clear: continued access to the U.S. market and the ability to avoid tariffs will increasingly depend on lowering drug prices or, more broadly, maintaining favorable relationships with the current administration.

The effects of these programs will not stop at U.S. borders. Due to most-favored-nation pricing and public scrutiny, manufacturers are already facing pressure on prices in Europe—a trend highlighted recently as companies reassess product launches across EU markets.[21] If U.S. policy continues to anchor prices to the lowest levels in peer countries, European health systems may see both downward price pressure and tougher negotiations, as companies seek to offset U.S. concessions. As these policies continue to evolve and manufacturers adapt, we anticipate that 2026 will be a turning point in the global landscape for drug pricing, availability and manufacturing.

FDA and the Administration's Deregulatory Agenda

By Justine Lei

2025 saw the current administration focus heavily on deregulation. At the heart of the initiative is Executive Order 14192 "Unleashing Prosperity through Deregulation" which mandated that for each regulation proposed, at least ten existing rules or guidance documents must be repealed. As a regulatory agency, the U.S. Food and Drug Administration (FDA) was subject to this executive order, leading the agency to issue a Request for Information (RFI) inviting industry stakeholders and the public to identify regulatory requirements for repeal. While FDA leaders framed this effort as a way to reduce administrative overhead and lower health care costs, from an industry perspective, this deregulation has created a ripple effect, influencing FDA's approach to everything from policies to device and drug regulation to inspections.

FDA introduced new frameworks for drug and device approvals and published a regulatory and deregulatory agenda in 2025. One such new framework was the National Priority Vouchers program aiming to reshape the drug review process by fast-tracking approval for drug and biologic products that meet certain criteria. It is unclear how review and approval under this program works and whether staff reviewers are part of the final approval process. This has led industry and agency personnel to express reservations about this program as FDA's final approval certifies that a medication's safety and effectiveness satisfies FDA standards. It is simply too early to tell if the National Priority Vouchers program is able to deliver on all fronts, speed and safety and efficacy and stakeholders seeking to utilize this program should ensure their product satisfies FDA's safety and efficacy requirements under FDA laws, regulations and guidances. Another effort to speed up the FDA product review process includes incorporation of a generative artificial intelligence (AI) review tool in place of FDA scientific reviewers.

The FDA's deregulatory focus is part of a broader federal push for deregulation. The push to eliminate and reform regulations has had real consequences for FDA operations, including staff reductions and high leadership turnover at the FDA. Those wary of the deregulatory agenda have warned that rapid rollbacks of policies, review procedures and approval standards without adequate substitutions for existing processes could potentially expose consumers and the general public to greater risk. Stakeholders should continue to be mindful of the changing regulations and the impact that may have on any existing and future applications or submissions for drug or device approvals with the FDA.

Pharma and Life Sciences Investigations and Prosecutions Update – January 2026

By Joseph Jay & Tom Reklaitis

Following the first year of the second Trump administration, our annual summary of enforcement trends in life sciences considers shifting priorities in enforcement and significant prosecutions and settlements in the past twelve months.

As prognosticated by many, enforcement in healthcare is a significant priority for the administration spurred, in part, by its war on waste, fraud and abuse. Talking heads and blog authors also predicted that the second Trump administration would de-prioritize FCPA enforcement, but few saw the wholesale realignment of the government's approach to enforcement of the 1977 law altogether with its months-long pause or the re-evaluation of, and in some cases, dismissal or closure of pending cases. To be sure, President Trump's administration will leave its mark everywhere government touches – and life sciences and pharma will not be left unchecked.

Enforcement Policies and Priorities

In May 2025, the then-head of the DOJ's Criminal Division, Matthew Galeotti, issued a memorandum outlining enforcement priorities and policies for white collar crime enforcement in the second Trump Administration.[22] He identified ten areas as priorities for investigations and prosecutions with healthcare fraud and federal program fraud, perhaps unsurprisingly, topping the list.[23] Perhaps a surprise to some, the DOJ included "[v]iolations of the Controlled Substances Act and Federal Food, Drug and Cosmetic Act" as another "high-impact area."[24]

Consistent with its stated commitment to prioritizing investigations of healthcare and procurement fraud, the DOJ soon partnered with HHS in July 2025 to reconstitute the DOJ-HHS False Claims Act Working Group.[25] The Working Group identified the following priorities for itself, echoing the administration's priorities in many ways: (i) Medicare Advantage; (ii) drug, device, or biologics pricing; (iii) barriers to patient access to care; (iv) kickbacks related to products paid for by federal healthcare programs; (v) defective medical devices; and (vi) manipulation of electronic health records systems.

While the DOJ's discussion of these priorities in the abstract is in itself telling, its prosecutions and civil enforcement efforts have proven to be confirmation of the administration's intentions.

Criminal Prosecutions

In June, the DOJ announced its 2025 National Health Care Fraud Takedown, resulting in criminal charges against 324 individuals for their alleged role in healthcare fraud involving an eye-watering $14.6 billion in alleged losses.[26] In announcing the takedown, the DOJ singled out certain enforcement actions, including those involving fraudulent wound care and telemedicine fraud.[27]

The administration has also emphasized efforts to combat elder fraud. In November, the DOJ released its annual report on combatting elder abuse, in which it noted that it pursued over 280 enforcement actions involving the alleged theft or attempted theft of over $2 billion from elderly citizens.[28] In one such prosecution, the DOJ criminally charged the owners of certain wound graft companies who they alleged submitted over $1.2 *billion* in false and fraudulent claims to Medicare and other payors for what the DOJ contended were medically unnecessary treatments for elderly patients.[29] The owners pleaded guilty and were sentenced to 15.5 and 14 years in prison, respectively.[30] In another similarly themed prosecution, a federal jury convicted a doctor and employee of healthcare fraud for ordering medically unnecessary lab tests on behalf of elderly patients.[31]

Civil Enforcement

In addition to the prosecutions outlined above, the HHS-OIG continued to rely upon civil remedies to combat fraud perpetrated upon federal programs. In its semi annual report to Congress issued in June, the HHS-OIG announced that it had initiated 395 civil actions during the preceding six-month window.[32] In one of the more notable civil actions, DOJ and Walgreens entered into a $300 million settlement to resolve allegations that the pharmacy filled invalid prescriptions for opioids and other controlled substances.[33] In another, a multi-national life sciences company agreed to a $202 million settlement to resolve allegations that it paid kickbacks (often in the form of speaker programs) to practitioners to induce them to prescribe certain HIV Drugs.[34]

While the allegations underlying these high-dollar settlements varied, as a whole they demonstrate that HHS fully intends to pursue enforcement actions against fraudulent actors, including corporate entities. Industry participants should not subscribe to a notion that somehow enforcement will be down in this administration; if anything, this administration's focus on waste, fraud and abuse will shine a brighter light in pharma.

Corporate Integrity Agreements

While traditional criminal and civil cases continue apace across life sciences, we did see a reduction in 2025 in the number of Corporate Integrity Agreements ("CIAs") entered into by the Department of Health and Human Services Office of Inspector General ("HHS-OIG") to settle False Claims Act investigations against healthcare providers.[35] In 2025, the HHS-OIG entered into a total of 14 CIAs with healthcare providers compared to 25 entered into during 2024.[36]

While this downturn is significant, past precedent suggests it may be an anomaly. During the first Trump administration, CIAs steadily increased, beginning with a low of 8 CIAs in 2017 and concluding with 33 during 2020.[37] Perhaps this is not surprising as the new administration takes time to gain its feet, implement its priorities and march towards their execution. But likewise, there is cause to believe that we may continue to see fewer CIAs. The administration appears uniformly against the broad use of blunt enforcement and remedial measures like CIAs, preferring to employ them more surgically where they deem necessary. The same is true for corporate compliance monitors, a not unsimilar tool, which senior DOJ administration officials have pared back the use of considerably.

Conclusion

In sum, 2025 made clear that the current administration views what it sees as fraud in any space, but perhaps particularly in healthcare and life sciences, as a top enforcement priority. While we may see fewer CIAs or other remedial tools, we expect to see continued heightened use of criminal and civil cases across the industry.

BIOSECURE Act Update

By Arushi Pandya & Julian Klein

The Biosecure Act (the "Act"), was signed into law on December 18, 2025 as part of the National Defense Authorization Act ("NDAA") for Fiscal Year 2026 and is positioned to significantly impact federal engagement with certain biotechnology firms. Under the Act, the Office of Management and Budget ("OMB") has to publish a list of "biotechnology companies of concern," ("BCCs") based on recommendations from the Secretary of Defense, by the end of 2026.

A BCC is defined by a three-part test:

01 companies named on the Department of Defense's annual list of Chinese military companies operating in the U.S.;

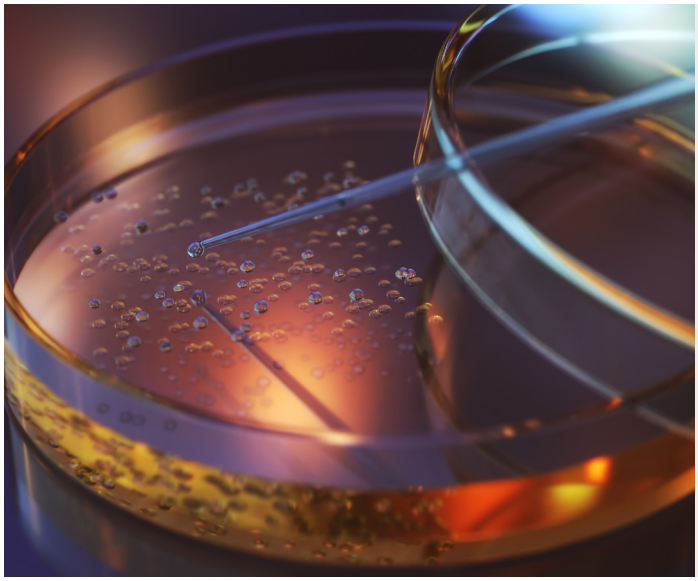
02 entities found to be under the control or acting on behalf of a foreign adversary, involved in biotech activities and posing a national security risk—such as links to foreign military or intelligence services, or improper handling of sensitive data; or

03 any subsidiaries, parents, affiliates, or successors of such companies if they too are subject to foreign adversary control.

For most companies with clear ownership and no foreign government influence, the risk of falling under these restrictions is low, but ongoing diligence and awareness of evolving guidance arising from this legislation is essential.

A key procedural safeguard applies to companies designated under the second prong of the definition. Those entities are entitled to formal notice and a 90-day opportunity to submit information and arguments challenging their proposed designation. The Act's definition of "control" is intentionally broad, encompassing not only direct equity ownership and voting rights, but also contractual, financial, or other arrangements that confer substantial decision-making authority. Importantly, purely passive economic interests, such as royalty rights that do not carry real influence, are generally not expected to constitute control on their own.

For new licensing or royalty arrangements, additional steps can be taken to protect companies from risk, such as including clear contractual language stating that royalty payments do not grant governance, operational, or control rights. Nevertheless, ongoing vigilance is recommended, as additional federal regulation or executive orders targeting biotechnology deals—particularly those involving China—remain possible. It is also important to remember that various implementation stages including guidance, rulemaking and enforcement may take up to three years, providing a transition period for organizations to adapt.



Looking Ahead

The Act seeks to introduce a novel national security framework that will increase scrutiny of biotechnology companies with material foreign ties, particularly those involving China or other designated foreign adversaries. At the same time, the statute provides relatively clear designation pathways, procedural safeguards and a drawn-out timeline. Companies should assess current ownership, governance and data-handling structures, build protective contractual language into new deals and closely monitor guidance, executive orders and other associated regulations in 2026 and beyond, as these developments will ultimately define the Act's true impact.

Mind the Gap: AI Governance When the Rules Are Still Being Written

By Julia Kadish

Two years ago, we examined the emerging legal landscape for artificial intelligence (AI). In case you missed it, we'll cliff note it for you—there was not much formal regulation in place. That remains largely true today. While regulatory progress has been limited—and, at the federal level, there is increasing interest in delaying or rolling back certain requirements—AI adoption has accelerated significantly. More companies are deploying AI solutions and exploring new use cases every day. Legal and compliance teams in life sciences (among other industries) are being faced with a deluge of AI questions. For many, the use of AI at work is quickly evolving from the preliminary instances focused largely on productivity and operational tools. In the absence of clear legal boundaries, organizations must rely on an AI governance program that can efficiently, yet thoughtfully, weigh opportunities against risks, support implementation and provide ongoing oversight and monitoring.

Fortunately, organizations can draw on established compliance models to guide their approach to AI. In recent years, many company privacy programs have looked to adopt a principles-based approach to manage constantly evolving regulations. Rather than aligning to individual laws, companies focused on common themes—such as transparency, user choice, individual rights, vendor oversight and data security—to build scalable compliance frameworks. AI presents a similar challenge, but with a key difference: the primary variable is not changing laws, but rapidly expanding use cases. While guidance does exist—including the NIST AI Risk Management Framework, OECD principles and the EU AI Act—this article focuses on distilling that guidance into a practical, business-ready approach to AI governance. The goal is to translate and condense the existing body of knowledge into a practical approach for evaluating AI that can withstand the legal uncertainty of the current times while still maintaining flexibility for the future.

Establishing and Defining Strategic Priorities

Defining a company's strategy on any particular topic is not exactly an easy task. When it comes to AI, companies that are AI developers (e.g., those that sell a solution for others to deploy AI in their organization) *may* have an AI strategy or set of principles in place. But for many life sciences companies whose core business is not centered around AI (at least not yet), developing a strategy may be more challenging. While we aren't suggesting that AI should be halted until a strategy is formulated, organizations that have taken the time to at least consider its risk appetite when it comes to AI will see efficiencies when it comes to evaluating new AI use cases. In practice, many companies develop this perspective through early experimentation. Regardless of timing, senior leadership involvement in defining where AI will—and will not—be used is critical. Clear direction from leadership enables teams responsible for implementation and risk management to make faster, more consistent decisions aligned with enterprise priorities.

Understanding the Use Case

Establishing a process to understand and evaluate use cases is critical to any effective AI governance program. In practice, this starts with defining a straightforward intake process that captures proposed AI initiatives early and consistently. Practical governance may include focusing on distinguishing low-risk, efficiency-driven applications from higher-risk uses that could influence clinical decision-making, research outcomes, manufacturing quality, or regulatory submissions. For some companies, there may be existing procurement processes to leverage for the intake questions specific to AI. But ensuring that everything gets into that intake "funnel" can also be a challenge. Once the intake process is in place and employees understand how and when to use it, the focus shifts to asking the right questions to gather enough information to assess the use case, understand the underlying risks and evaluate the potential business value of the AI.

Fundamentally, a company must understand what business decision or workflow is going to be changed: R&D, clinical activities, manufacturing, or commercialization? Is the AI supporting human decision-making, or making automated decisions independently? Who will be affected: business partners (doctors, etc.), employees, or patients? What data will be used to train, fine tune, or operate the AI? Will the data include personal data or confidential information? When armed with as many facts as possible about these types of questions (and others), legal and compliance professionals can effectively vet the vendor.

Vetting the AI Vendor

For life sciences companies, vetting AI vendors should start with a clear understanding of how the technology is actually being used and where it might touch regulated or confidential information. Companies should assess the vendor's data sources, training methods and model validation practices, with particular attention to the use of clinical, patient, or real-world data and compliance with applicable privacy, cybersecurity and regulatory requirements. Practically, this means reviewing and asking about the vendor's own governance controls, including documentation. It also includes an understanding of human oversight and change-management processes. This review should also consider how the vendor monitors performance, bias and model drift over time.

Negotiating AI-specific Terms

Contracting plays a critical role in managing risk and ensuring regulatory readiness when deploying AI solutions. Well-drafted AI terms can help clarify data ownership and permitted use, establish transparency and audit rights and allocate responsibility for model performance, compliance and incident response. Given the sensitivity of clinical, patient and research data—and the potential impact of AI on regulated activities—contracts should also address validation, human oversight, change management and regulatory disclosures. Depending on the criticality of the service, companies may also want to consider provisions that address how the models will be updated and how might services be transitioned if needed. With contracts that consider the provisions unique to AI, companies will be armed to implement AI tools with greater confidence and control.

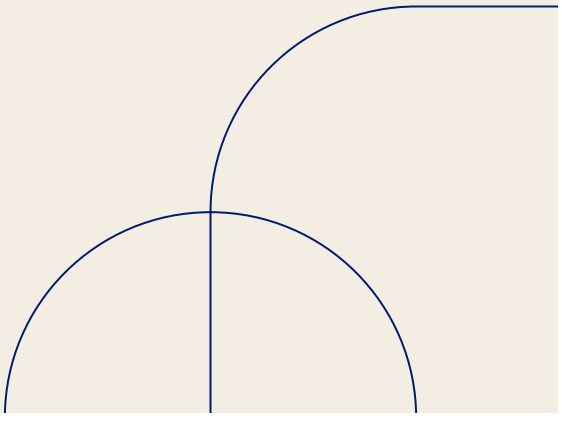
Post Integration Monitoring and Oversight

Effective AI governance does not end with vendor diligence or deployment; it requires ongoing monitoring and oversight once AI tools are in use. Companies should establish clear criteria for when human intervention is required, particularly for high-risk or consequential decisions and define regular checkpoints for human review of AI outputs. Just as important is creating a transparent process for users to escalate concerns, challenge AI-driven outcomes, or report unexpected behavior.

Ongoing oversight should include periodic performance reviews—such as quarterly or biannual assessments—to evaluate accuracy, reliability and potential model drift over time. Finally, organizations should regularly brief executive leadership or the board on the overall AI portfolio, enabling informed, top-level oversight without getting lost in technical detail or compliance complexity.

Summing it Up

Integrating AI often requires some cultural change, new skill sets and cross-functional coordination, all while managing expectations to leadership about cost, scalability and return on investment. As AI adoption accelerates, a governance framework and program will be essential to the building of trust—with employees, patients, regulators and business partners—while still maintaining flexibility in a landscape that continues to shift.



AI Focus

By Arushi Pandya

The FDA has aggressively embraced AI, and in this administration, the use of AI by the agency itself rather than by industry has received the most attention. AI is currently being used by the FDA to support internal operations, review workflows and accelerate clinical protocol reviews and scientific evaluations. Over the summer, the FDA rolled out Elsa, an agency-wide AI tool, to assist in reviews. In December, the FDA announced that agentic AI capabilities were available to agency employees to support complex workflows. The FDA is expected to continue incorporating AI into its activities in its push for efficiency and faster reviews, as well as its enforcement activities. To the extent the FDA is not already using AI to analyze promotional materials, these tools will likely be utilized in 2026 for industry surveillance, conducting investigations and perhaps even training algorithms.

We're Six Months into the Commissioner's New National Priority Voucher Program – How's It Looking?

By Audrey Mercer

In June, the United States Food and Drug Administration ("FDA" or the "Agency") announced a new pilot program—the Commissioner's National Priority Voucher program (the "Program")—which borrows the well-established priority review voucher concept for accelerated product approvals (subject to some notable changes) and aligns it with priorities of the current administration.[38] Although a number of vouchers have already been issued under the Program, recent reports indicate that the Program may not be operating as intended—that is to say, the FDA is still ironing out the kinks.

The Program

The Program's big sell is that it promises a review period of 1-2 months (compared to the standard review times of 12 months or more) for select drug and/or biological products that are "aligned with" one of five (very broad) national health priorities identified by the administration: (i) addressing a health crisis in the U.S.; (ii) delivering more innovative cures for the American people; (iii) addressing unmet public health needs; (iv) increasing domestic drug manufacturing as a national security issue; and (v) drug affordability.[39] However, hidden in the fine print, sponsors must submit chemistry, manufacturing and controls ("CMC") data at least 60 days before submitting the full application, bringing the total time for application review closer to 3-4 months. Even so, it's an ambitious review timeline and is purportedly facilitated by convening experts from multiple offices for a team-based review, rather than the standard review system of a drug application being sent to numerous FDA offices. More specifically, for each application (which can be submitted by the sponsor or facilitated by an FDA staff member), a multidisciplinary team of physicians and scientists will pre-review the submitted information and convene for a 1-day "tumor board style" meeting to jointly review the application and decide whether to grant a voucher.[40] As an adjunct benefit to the accelerated review time, the Program promises enhanced communication throughout the process. All in all the Program aims to "allow companies to submit the lion's share of the drug application before a clinical trial is complete" in order to "reduce inefficiencies.

Comparison to Other Priority Review Voucher Programs

Although the Program borrows the "voucher" framework from the FDA's existing Priority Review Voucher ("PRV") programs, including the Tropical Disease PRV Program, the Rare Pediatric Disease PRV Program and the Material Threat Medical Countermeasure PRV Program (collectively, the "PRV Programs"), there are several key differences. First, FDA's existing PRV Programs were created by statute, while the Program is a regulatory program created by the FDA according to its interpretation of its authority to regulate drugs and biologics under the [41]Food, Drug and Cosmetics Act ("FDCA"). This means that especially in a post-*Chevron* judicial landscape, the Program may be more easily dismantled if challenged as an overstep of authority.[42] Second, a key feature of the FDA's existing PRV program is that they are granted upon approval of a sponsor's different product and are transferable—that is, it is awarded to a company who already has an approved product in the space and can be redeemed for an expedited review on a future product application or can be sold to another company, who may then redeem it for priority review. As such, the sale of these PRV vouchers constitutes a material part of the U.S. life sciences economy, with a PRV selling for a whopping $200 million just this month.[43] The vouchers awarded under the Program, however, are non-transferable (although they do remain valid through changes in company ownership). Finally, the FDA's existing PRVs require sponsors to pay a separate user fee (almost $2 million per voucher for 2026) to redeem the vouchers,[44] while awardees can redeem vouchers under the Program without paying a separate fee. Theoretically, this would allow newcomers and smaller companies with less funding to bring innovative therapeutics to market—supporting the administration's stated goal of increased access to breakthrough medications for Americans.

Current Status and Future Predictions

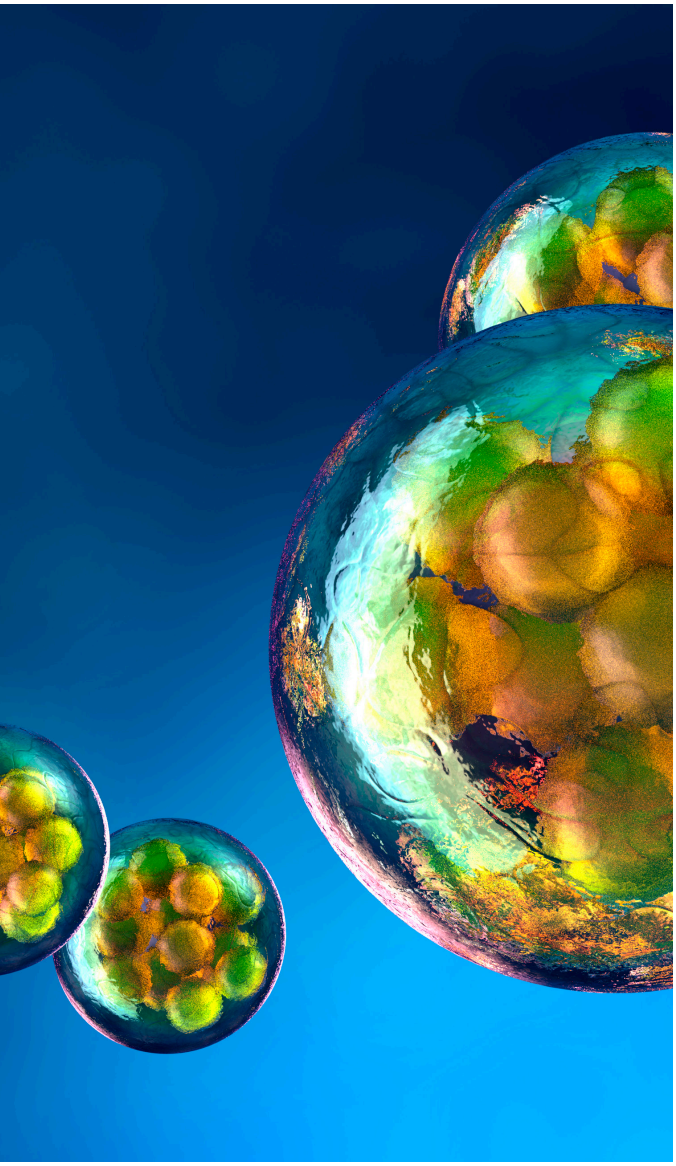
Since the Program's inception in June, the FDA has awarded 18 vouchers, including 16 for products intended to address a range of therapeutic areas, including infertility, diabetes, nicotine addition, deafness, blindness, pancreatic/lung/rectal cancers, porphyria, lung cancer, childhood tuberculosis, sickle cell disease, obesity, high cholesterol; two intended to facilitate domestic manufacturing for anesthesia and antibiotics, respectively; and one "proactively" awarded based on strong Phase 3 data for a therapeutic intended to treat refractory multiple myeloma.[45]

Interestingly, more than half of the vouchers were awarded to companies valued at more than $50 billion and almost all of the vouchers were awarded to already-marketed products seeking new indications that have already been awarded some other type of accelerated review designation (e.g., Breakthrough Therapy, Orphan Drug, etc.), so the Program may not be living up to its altruistic goal of offering newer, smaller companies a chance at accelerated market approval—at least, not yet. Additionally, the FDA recently announced that it is extending the review period for at least two voucher therapies over safety and efficacy concerns, so we wonder whether the Agency will ultimately find that 1-2 months is simply too tight a timeline to sufficiently determine a medication's safety and/or efficacy before releasing it to the public.[46] Finally, we will be interested to see whether the broadly defined criteria for Program eligibility effectively operates as a loophole for the FDA to grant favorable treatment to companies who are "buddies" of the Trump administration generally, as critics have warned. As at least four of the vouchers awarded under the Program are associated with other deals struck between the relevant companies and the Trump administration (e.g., EDM Serono, who was granted a voucher in October, struck a "most favored nation" deal with the White House to reduce the price of three of its infertility medications), this possibility may not be too distant; however, we hope that the Agency would be held accountable for any such abuse of power under the post-*Chevron* judicial regime.

SEC Considers Shift from Quarterly to Semiannual Reporting for U.S. Reporting Companies

Assessing the Benefits and Drawbacks for Public Life Sciences Companies

By Jeffrey Fessler & Nazia Khan



Background

During both his first administration as well as during his current administration, President Trump continues to advocate for the United States Securities and Exchange Commission ("SEC") to end the long-standing requirement for public companies to file quarterly reports, replacing them with semiannual reports similar to other jurisdictions such as the United Kingdom, European Union and Australia. President Trump noted this shift would "save money and allow managers to focus on properly running their companies."[47] At the 2025 Institute for Corporate Counsel held on December 3, 2025, Commissioner Uyeda noted "Other major capital markets have shifted their reporting periods specifically in order to minimize burdens and promote longer term thinking. Even in the United States, foreign private issuers are not required to file quarterly reports, in contrast to the quarterly filing requirement that applies to domestic issuers."[48]

In 2018, the SEC sought input from the public[49] regarding quarterly earnings releases and reporting practices; however, the rulemaking process was stalled. The goal was to identify ways to make periodic reporting more efficient by eliminating duplicative disclosures. The SEC was also interested in understanding how potential changes might impact capital formation, while emphasizing the importance of maintaining strong investor protections.

During a September 19, 2025 interview, SEC Chairman, Paul Atkins, discussed exploring a path forward that would give U.S. public companies the option to move from quarterly reporting to semiannual reporting.

Transitioning to semiannual reporting would mark a major shift in U.S. securities disclosure practices which have been in effect since 1970 and would likely present both advantages and disadvantages for public companies and investors alike.

Potential Benefits of Transitioning to Semiannual Reporting

Long-term Growth and Valuation Creation

As some commentators have noted, frequent reporting may distort executive decision-making, encouraging management to focus on short-term results rather than fostering long-term growth and value creation.[50] Reducing reporting frequency can enable management of public life sciences companies to concentrate on strategic initiatives (i.e. achieving substantive development, regulatory and commercialization milestones) rather than structuring activities to fit a quarterly narrative. With less pressure to provide quarterly clinical development updates alongside earnings releases management can allocate more resources toward research, innovation and clinical advancement—ultimately enhancing long-term value for shareholders. Furthermore, less frequent disclosure may enable life sciences companies to maintain the confidentiality of competitive intelligence and sensitive clinical development updates for longer periods, thereby reducing the risk of early information leaks to competitors.

Mitigation of Short-Term Market Fluctuations

Some believe that quarterly earnings releases can contribute to short-term fluctuations in the market and moving to a semiannual reporting schedule may help curtail such volatility. With reduced pressure to produce quarterly updates, there may be less incentive for management to "manage" results or make decisions based solely on short-term analyst expectations, enhancing transparency and trust.

Reduced Regulatory and Compliance Burden

Preparing quarterly reports demands significant organizational resources. Reducing the number of required filings could ease budget constraints and allow management to focus their efforts elsewhere, which may be especially impactful for smaller public companies. For public life sciences companies, this shift would allow management to devote more time and resources to strategic growth initiatives and core scientific activities such as advancing clinical trials, accelerating research and development initiatives and exploring opportunities such as expanding internal sales and manufacturing capabilities, thereby supporting innovation and growth.

Alignment with Reporting Requirements for Foreign Private Issuers and International Markets

Unlike U.S. domestic companies, foreign private issuers (as defined under the Securities Exchange Act of 1934[51]) are not obligated to file quarterly reports. Additionally, jurisdictions such as the United Kingdom, European Union and Australia require only semiannual and annual financial disclosures. Aligning U.S. domestic company reporting frequency with such international jurisdictions would harmonize compliance obligations for companies listed on multiple exchanges and synchronize disclosure obligations with the obligations imposed on foreign private issuers.

Enhancing the Appeal of Companies Going and Remaining Public

By removing the burdens and costs associated with quarterly reporting, more companies may be inclined to enter and remain in the U.S. public markets. This approach aligns with the SEC's broader objective of "mak[ing] being a public company an attractive proposition for more [companies] by eliminating compliance requirements that yield no meaningful investor protections, minimizing regulatory uncertainty and reducing legal complexities throughout the SEC's rulebook."[52] For example, by streamlining compliance and reducing the frequency of required filings, life sciences companies—especially emerging or pre-revenue entities—face fewer administrative and financial obstacles to becoming or staying public. This will enable them to access larger pools of capital necessary to fund research, development and commercialization initiatives.

Potential Drawbacks of Transitioning to Semiannual Reporting

Reduced Transparency and Access to Information

Mandating less frequent reports could undermine corporate transparency, delay the dissemination of critical information to investors and increase gaps in access to material information. Advocates of quarterly reporting maintain that it enables investors and analysts to monitor company performance more closely and respond quickly to developing market trends. A reduction in the frequency of mandatory reporting could result in diminished analyst coverage, making it more challenging for investors to access the information needed to make well-informed decisions as well as potentially resulting in decreased valuations.

Limited Impact on Market Expectations

A shift in legal requirements may not necessarily relieve public companies from the ongoing pressure to provide quarterly financial updates. Market expectations, analyst and investor relations practices and contractual covenants may drive public companies to maintain quarterly reporting obligations regardless of regulatory changes. Companies should evaluate their specific industries and determine how essential quarterly reporting is to their sector, including monitoring practices of their industry peers. Furthermore, companies should take into account investor expectations regarding the frequency and detail of information disclosed. As one study noted, "[w]hen quarterly reporting was no longer required of U.K. companies in 2014, less than 10% stopped issuing quarterly reports (as of the end of 2015) …"[53] For life sciences companies navigating complex scientific, regulatory and financial landscapes, the predictability and clarity of mandated by quarterly reporting might outweigh the flexibility of voluntary disclosure—especially during periods of heightened market attention, such as late-stage clinical trial readouts or pre-commercialization phases.

Lack of Uniformity in More Frequent Reporting; Market Efficiency Risks

To the extent that companies elect to voluntarily provide quarterly financial and other disclosures to address issues such as market expectations, analyst, investor relations and industry practices and investor expectations, such disclosures would be governed primarily by the antifraud provisions of the U.S. federal securities laws, rather than by the structured standards relating to quarterly reporting as are currently in place. This could result in inconsistent reporting across different industries, exposing companies to greater risk of stockholder litigation. For example, given the significance of clinical milestones to company valuation, inconsistent or non-standard disclosure practices could expose life sciences companies to heightened scrutiny under antifraud provisions, especially if investors allege that material information was omitted or selectively disclosed. Furthermore, investors in life sciences rely heavily on transparent, comparable data for pipeline tracking and assessing research and development progress. Without uniform quarterly reports, there could be greater confusion or speculation regarding clinical timelines, anticipated catalyst events and ongoing regulatory matters, potentially increasing market volatility for the sector. Furthermore, reducing the frequency of standardized financial information could lead to increased reliance on selective or non-GAAP disclosures, making it more challenging to compare companies' financial performance, which in turn could lead to greater uncertainty in the market. For example, life sciences companies often use non-GAAP measures (e.g., research and development spend, cash runway, milestone payments, or non-recurring licensing revenues) to inform the market. In a less standardized reporting landscape, the risk that such metrics are presented inconsistently across peer companies or over time is higher, complicating benchmarking and investor analysis. As such, companies may prefer the clarity offered by the mandated Form 10-Q requirements when making more frequent disclosures.

Extended Duration of Exposure to Material Nonpublic Information

Less frequent reporting could lengthen trading blackout periods. Insiders might possess material nonpublic information for several months before it is made public. This could lead to substantial delays in insiders' ability to trade, as they may have to wait until a semiannual report is filed—unless the company issues an interim filing to cleanse insiders of material nonpublic information. Moreover, longer intervals between disclosures of material nonpublic information could lead companies to exercise greater caution when opening trading windows for share repurchases, insider transactions and establishing Rule 10b5-1 trading plans.

Increased Single-Day Volatility.

Consolidating more information into fewer disclosures may lead to greater price volatility on earnings days, potentially resulting in more pronounced single-day market movements than if information was release more frequently. For life science companies, where pivotal developments (like clinical trial results, regulatory updates, or strategic partnership announcements) can trigger significant market reactions, the bundling of such news into less frequent earnings releases may amplify market movements. As a result, investors and management may need to prepare for potentially more pronounced market swings around reporting dates, which could also impact liquidity, investor confidence and the predictability of trading in a company's stock.

Regulation FD Implications

Longer intervals between periodic reports could increase the risk of inadvertently disclosing material nonpublic information in violation of Regulation FD.

Financial Statement Stateless and Comfort Letter Considerations

A transition to semiannual reporting would likely require revisions to staleness dates for financial statements and comfort letters, to align with the new reporting intervals, including changes to accounting rules.

Key Takeaways

Despite the Trump Administration's push to move away from quarterly reporting to semiannual reporting, quarterly reports may remain a valuable resource. While eliminating quarterly reports may ease compliance burden and costs, encourage management to focus on long-term growth and value creation, curtail short-term volatility, align reporting requirements with other jurisdictions and those for foreign private issuers and enhance the appeal of companies looking to go public and access the U.S. markets, quarterly reports provide regular, valuable insights that help the investing community assess and analyze company performance. Additionally, a shift in legal requirements may not necessarily relieve public companies from the ongoing pressure to provide quarterly financial updates and may instead contribute to a lack of access to uniform information. Furthermore, shifting to semiannual reporting may contribute to reduced transparency, greater uncertainty in the market, extended exposure to material nonpublic information and potentially more pronounced single-day market movements. For public life science companies, quarterly reporting may ensure regular, predictable updates, which are particularly valuable for investors tracking the progress of clinical pipelines, research and development spending and milestone achievements. Additionally, these routine disclosures may enable analysts and investors to effectively compare company performance with industry peers, particularly regarding key metrics such as cash runway and trial progress. Frequent reporting builds greater transparency which may be important for life sciences companies, whose valuations often depend on forward-looking scientific developments, potentially outweighing the benefits of semiannual reporting (allocating more resources toward research, innovation and clinical advancement; and maintaining confidentiality of competitive intelligence and sensitive clinical development updates for longer periods).

Putting aside the potential for long-term cost savings, transitioning to a semiannual reporting schedule may initially require companies to devote significant time and resources to the shift in reporting. Before any potential rule change, companies should carefully consider the trade-off between reduced regulatory burden and the potential downside of diminished timely transparency and its impact on a company's valuation, stock price and investor, analyst and insider sentiment.

Telehealth and Direct-to-Consumer Platforms Remain in the Crosshairs

By Arushi Pandya

Regulatory scrutiny is not new to telehealth platforms, but as direct-to-consumer ("DTC") arrangements, especially involving weight loss drugs and arrangements between industry and the government continue to expand, telehealth platforms are anticipated to remain a ripe area of focus in the upcoming year.

Overview of DTC Arrangements

Under these DTC arrangements, patients click on "talk to a doctor now" buttons on digital banner ads for a drug, or wherever such links are prominently displayed on manufacturers' websites. Patients can then fill out a questionnaire that assesses their eligibility for the drug and subsequently schedule a virtual visit through a third-party provider network. This visit may be virtual or asynchronous. After a patient has received a prescription, the medication can be shipped from an online pharmacy and delivered directly to the patient's home.

While these arrangements were originally adopted by smaller companies, over the past two to three years, major manufacturers have entered this arena as well, especially driven by the demand for GLP-1 medications.

Regulatory Scrutiny and Senate Letters

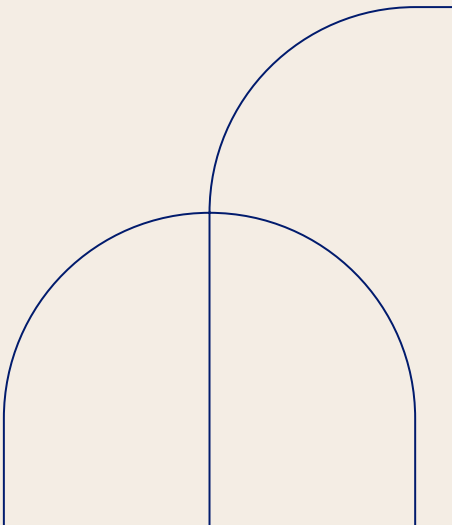
DTC telehealth arrangements can raise concerns of kickbacks and improper prescribing and these arrangements have historically been the subject of Office of Inspector General ("OIG") fraud alerts as well as letters from Congress, including multiple letters from Senator Dick Durbin. In 2025, Senator Durbin and others continued to send letters and in October 2025, specifically sent letters to pharmaceutical manufacturers regarding their affiliated telemedicine platforms.

The letters note the following issues in DTC arrangements: (1) encouraging telehealth prescribers to favor certain medications, regardless of medical necessity or clinical appropriateness, which could lead to inappropriate prescribing practices and increased federal healthcare program spending in violation of the federal Anti-Kickback Statute, (2) increasing the demand for specific medications through DTC advertising, even if such medications may not be medically necessary, thereby inflating costs for federal healthcare programs and (3) failing to provide comprehensive healthcare services to patients that ensure thorough patient evaluations and follow-ups. The letters specifically requested quantitative information on the manufacturers' telehealth platforms relating to (1) the amount of money the manufacturers have spent on DTC advertisements for specific medications in the most recent six-month period for which data is available, (2) the percentage of consumers who, after consulting with a healthcare provider on a manufacturer-affiliated telemedicine platform, receive a prescription for one of the manufacturer's medications and (3) the revenue generated by the manufacturers from telehealth platforms in the most recent 30-day period for which information is available.

The inquiries into these arrangements have also been shaped by the FDA's changing leadership. In Senator Durbin's letter expressing concern over Office of Prescription Drug Promotion (OPDP) leadership, he noted that there appear to be promotions on the telehealth company's website that may be considered advertisements for off-label uses of the drug and may also fail to adhere to the FDA's requirements for providing a "fair balance" of risk information, given the limited safety disclosure that is buried in the text and only accessible via an external link. A telehealth company that has formally partnered with a drug manufacturer to sell the manufacturer's blockbuster medication—citing its trademark and other promotional statements—should be subject to the same misbranding standards as the manufacturer.

What to Watch

The telehealth arrangements inherently create tensions with the administration's and Make America Healthy Again movement's push to increase oversight of DTC prescription advertising laws. This interplay remains a key area to watch, especially as new DTC websites by both the federal government and major industry groups are set to go live this year. Furthermore, based on the FDA's increased enforcement and letter-writing in the past year, we can expect to see continued enforcement in this area.



What to Know About the Enforcement Crackdown on DTC Advertising

By Alex Kitson

As we begin a new year and the second year of the second Trump administration, it's safe to say that 2025 will be a year to remember for direct-to-consumer ("DTC") prescription drug advertising.

For years, regulation and enforcement of DTC advertising remained relatively stable. With only the occasional guidance and a handful of warning and untitled letters each year, excitement in this area remained low. That all changed in September.

Following a Make America Healthy Again Commission report calling for increased oversight, the President issued a memorandum targeting "misleading" DTC prescription drug ads. In the fall of 2025, the FDA quickly followed with a public enforcement crackdown, issuing approximately

40
untitled letters,

80
warning letters and nearly

100
cease-and-desist letters.

Cutting to the chase, what do in-house counsel and promotional review committees really need to know about the FDA's 2025 letters?

TV and Social Media are Priority Targets

Television ads were the star this round, but social media and influencers are poised to be next up.

Risk Omission is Still #1

Omission of risk information is still the quickest way to get a letter. Singing, dancing, celebrities, catchy theme songs (you know the one)—all of these are a one-way ticket to enforcement if they're not balanced with appropriate risk information.

Broader Efficacy Claims are Off-limits

Make sure your claims are narrowly tailored to approved indications, studied populations and trial endpoints. Keep a close eye on quality of life and implied claims!

Third-party Content is Not a Safe Harbor

Reposting, endorsing, or commenting on third-party communications about a product can turn it into a single promotional communication you're responsible for.

Product Name + Use/Benefit = Claim

There are no get-out-of-jail-free cards. Anything with a product name and its use and/or benefits must include balanced safety and indication disclosures, even advocacy content.

Data on File is Not a Free Pass

The FDA can, and will, look at data on file references. Prepare and vet these like any other scientific source.

While more personnel turnover may be the only sure bet at the FDA right now, here's what we're going to be watching out for this year.

Rulemaking?

Despite their broader deregulatory agenda, the administration appears amenable to more rules in this space. A wholesale ban still seems unlikely, but never say never with this administration. Expect any new regulations to trigger an onslaught of First Amendment challenges.

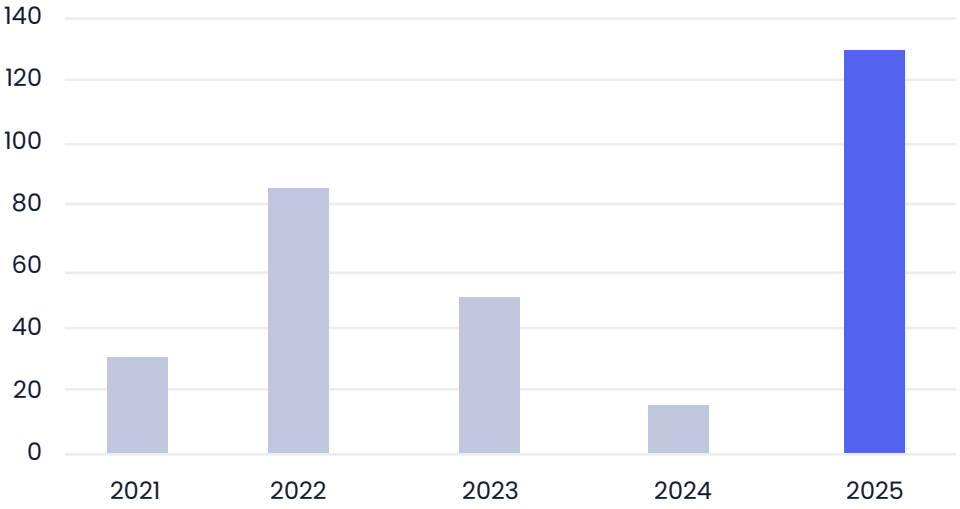
More Letters?

Can the FDA keep up with the volume of warning and untitled letters they're putting out? With the help of AI analyzing promotional content, maybe. Look for letters on social media and influencers to hit mailboxes this year.

Real Enforcement?

Despite the deluge of warning and untitled letters, we haven't yet seen a noticeable change in the drug ads on TV. So the question remains, will the FDA escalate enforcement tactics if manufacturers don't comply or has this all been one large PR stunt?

Number of Warning Letters



This graph depicts the number of warning letters released each year by the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) and Office of Prescription Drug Promotion (OPDP) for certain subjects related to misbranding.

Personnel Changes at the FDA

By Justine Lei

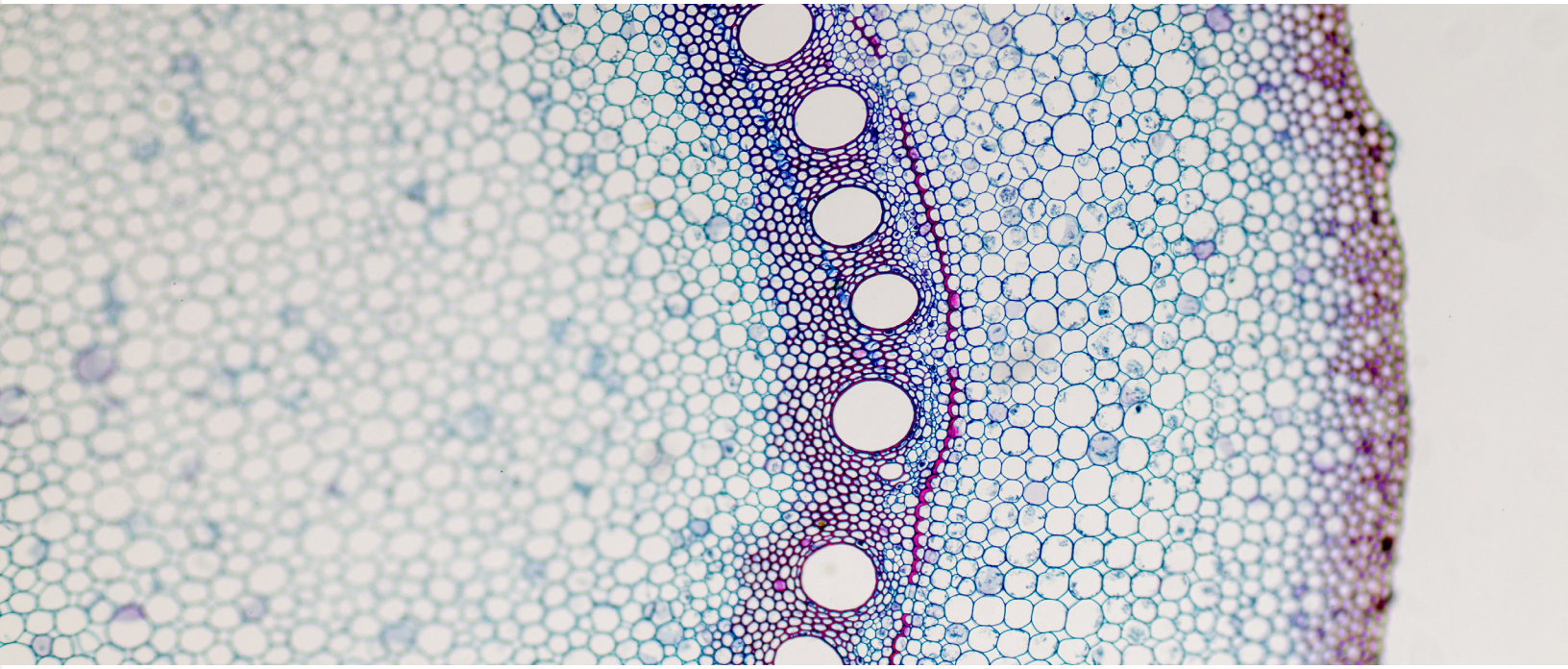
The U.S. Food and Drug Administration (FDA) has experienced significant personnel changes in 2025 across the agency. Starting at the top, Robert F. Kennedy Jr. was confirmed as Secretary of the Department of Health and Human Services (HHS) in February. In March, Dr. Marty Makary was confirmed as FDA commissioner followed by a nearly 20% reduction in the FDA workforce. Approximately 3,500 FDA employees were notified of their termination as a result of sweeping workforce reductions mandated by the HHS under the current administration's broader effort to slim down federal agencies. However, in early 2026 FDA confirmed it received Office of Management and Budget (OMB) approval to hire more than 1100 new employees under the FY26 FDA Hiring Plan. These workforce cuts aimed to target employees working on policy, human resources, information technology, procurement and communications and initially spared core drug, food and device reviewers and inspectors. However, the reality of the situation is that the substantial reduction of FDA staff led to uncertainty and instability within the agency and delays in drug approvals and post-market monitoring and surveillance tasks.

In addition to the mandated personnel reduction, a number of senior leaders within the agency's centers resigned or were replaced in the last year, with the Center for Drug Evaluation and Research (CDER) going through five directors in 2025 and the Center for Biologics Evaluation and Research (CBER) going through three directors. These changes coincide with a number of changes to the agency's desire to conduct thorough reviews and inspections while speeding up the drug approval process. In reality, these changes have led to the FDA falling behind on its responsibilities including missed drug review meetings and delays in drug review timelines.

As the FDA continues to navigate these staffing changes and stabilize in this new year, stakeholders seeking to go through a product review, application, submission or approval process should keep in mind the FDA's limitations and ensure they are prepared for interactions with the FDA to minimize delays.

FDA Regulation of Human Cell and Tissue Products in 2025 and Beyond

By Audrey Mercer



Over the past year, the U.S. Food and Drug Administration ("FDA"), guided by principles of the Make America Healthy Again ("MAHA") movement, has touted its commitment to supporting the development of human cell and tissue products ("HCT/Ps") through premarket pathways, while continuing to hold steady against HCT/P developers who inappropriately evade such pathways. Based on discourse from the FDA in the early days of 2026, we expect the same moving forward. But of course, under this administration, it's always prudent to expect the unexpected.

FDA Regulation of HCT/Ps

As outlined in greater detail in our previous articles on the subject,[54] the FDA regulates HCT/Ps through a tiered, risk-based approach.[55] The default status of HCT/Ps is "drugs" or "biologics" under the Food, Drug and Cosmetics Act ("FDCA"), subject to the full scope of the FDA's drug and biologic regulations, including the HCT/P-specific regulations set forth at Title 21 of the Code of Federal Regulations ("CFR"), Section 1271.[56] These HCT/Ps are known as "351 HCT/Ps" because they are regulated under Section 351 of the PHSA. However, HCT/Ps that meet the four requirements set forth at 21 CFR 1271.10 are exempt from premarket review and approval—and are only required to comply with the FDA's registration/listing requirements and the requirements outlined in the FDA's HCT/P-specific regulations, mostly focused on limiting the transmission of communicable diseases.[57] These HCT/Ps are known as "361 HCT/Ps" because they are regulated solely under Section 361 of the PHSA. Further, an HCT/P is eligible for complete exemption from FDA regulation if it meets one of five regulatory exemptions outlined at 21 CFR 1271.15.

FDA Challenges and Priorities

Interestingly, this three-tiered structure informs the particular regulatory challenges the FDA faces and the associated priorities it has chosen to pursue.

01 HCT/Ps Regulated as Drugs/Biologics (351 HCT/Ps)

With respect to 351 HCT/Ps, the FDA's current focus is on facilitating development and patient access. Over the past year, the FDA has specifically focused on a subset of 351 HCT/Ps known as cell and gene therapies ("CGTs"), which face a host of unique barriers to entry, including: (i) scientific challenges (many CGTs are intended to treat rare diseases, presenting challenges with trial design, funding, participation and execution); (ii) manufacturing challenges (processing of these products is significantly more complex and sensitive than processing of traditional pharmaceuticals); and (iii) safety challenges (not only are CGTs intended for ultra-sensitive populations, meaning that failures in quality control can be life-threatening, but due to their nature, they are capable of harboring communicable diseases). Due to these unique challenges, there are fewer than fifty approved CGTs on the market today, across all disease types[58]—a metric that FDA purports to improve.

Over the past year, in the name of patient access, the FDA has publicized several efforts to support the innovation of CGT products regulated as drugs/biologics. Most recently, the FDA issued a press release describing its willingness to afford certain regulatory flexibilities to CGT developers with respect to chemistry, manufacturing and control ("CMC") requirements in light of certain realities facing CGT development.[59] For example, the FDA will permit "minor manufacturing changes" as development progresses from Phase 1 into pivotal testing without requiring "overly stringent and onerous" comparability data. Although the FDA has implemented these regulatory flexibilities on a case-by-case basis in the past, according to the press release, the FDA plans to implement them on a more consistent basis for CGTs across the board. Additionally, the FDA issued two CGT-specific guidances documents last fall that provide recommendations on how CGT developers can conduct post-market safety and efficacy analysis and clinical trials for small populations.[60] The CMC flexibility policy and CGT-specific guidances represent some of the first concrete actions from the FDA following the CGT Roundtable held by the FDA this summer, during which Commissioner, Martin Makary, emphasized the FDA's intent to accelerate regulatory pathways and increase efficiencies for CGTs, especially those intended to treat rare diseases.[61] The CMC flexibility policy also follows closely behind and seemingly dovetails with, Makary's announcement of the FDA's proposed "plausible mechanism" pathway, which would allow for accelerated approval based on strong biological plausibility for highly personalized, "bespoke" therapies (beyond just CGTs), especially for rare diseases with known genetic causes, where traditional trials aren't feasible, shifting the burden of confirmatory testing for these products to a post-market basis.[62]

U.S. Health & Human Services ("HHS") Secretary, Robert F. Kennedy, Jr., has also been vocal about the need to reduce regulatory barriers to stem cell products, specifically;[63] however, as discussed in the following section, FDA appears to be less willing to afford flexibilities to HCT/Ps that are not regulated as drugs/biologics and which, therefore, do not come to market through pathways involving FDA review.

02 HCT/Ps Subject to Limited or No Enforcement (362 HCT/Ps)

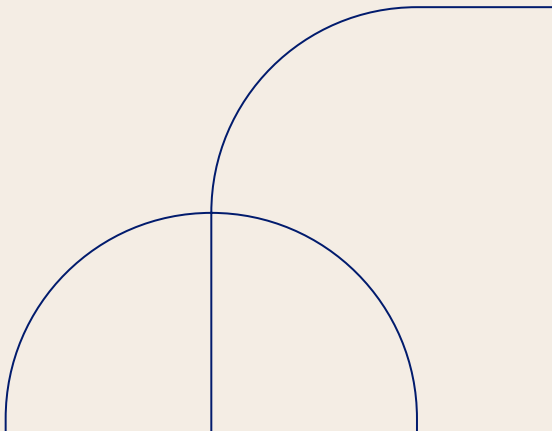
Of course, meeting the criteria under 21 CFR 1271 for limited regulation or exemption from regulation altogether means that a company can bring its product to market for a fraction of the resources it would have had to spend if its HCT/P were regulated as a new drug/biologic. For this reason, the industry has seen an influx of new competitors seeking to bring HCT/Ps—specifically, stem cell products—to market under limited or no regulation, even when they may not qualify under the three-tiered structure. The potential evasion of pre-market approval requirements by some of these competitors presents a serious patient safety risk[64] on top of the already increased safety risk associated with HCT/Ps generally, due to the inherent potential of communicable disease.[65] Accordingly, following its issuance of six (6) guidance documents related to communicable disease safety in HCT/P development early last year,[66] the FDA has been notably less permissive with these products as it has been with 351 HCT/Ps. For example, the FDA issued a whopping fifteen (15) warning letters last year to entities inappropriately marketing unreviewed HCT/Ps under the 21 CFR 1271 exceptions.

What's more, the FDA appears to have the backing of Congress and the courts in its scrutiny of HCT/Ps that fail to comply with 21 CFR 1271. In June, the U.S. House of Representatives passed the Shandra Eisenga Human Cell and Tissue Product Safety Act—named for one of the victims of the 2023 tuberculosis outbreak—which gives HHS authority to levy civil penalties against anyone who violates the good tissue practice and/or communicable disease prevention requirements under the HCT/P-specific regulations.[67] Several months later, in October, the Supreme Court declined to take on *California Stem Cell Treatment Center v. U.S.*,[68] a Ninth Circuit decision that upheld FDA's narrow construction of the "same surgical procedure" exemption under 21 CFR 1271.15(b) and, in doing so, appears to have passively condoned the FDA's narrow construction of the regulatory exemption for HCT/Ps under 21 CFR 1271.15.[69]

However, this increased scrutiny has received pushback from the industry. In November, the law firm, Orrick, Herrington & Sutcliffe, filed a Citizen Petition on behalf of its client, making a ten-point argument as to why stem cell products should be categorically granted the limited regulation afforded products that otherwise qualify under 21 CFR 1271.10, with Baker Hostetler signing onto the petition a month later.[70] PhRMA, one of the industry's heavy-hitting lobbies, has also publicly urged the FDA to reform its HCT/P framework, stating that, "given the challenges with developing cell-based therapies and tissue-based products, we encourage FDA to continue to take a flexible, risk-based approach and seek stakeholder feedback, including through notice and comment, as the Agency considers any revisions to or reinterpretation of its current regulatory approach."

Predictions

In 2026, we will be watching to see whether and to what extent the industry is effective in persuading the FDA to loosen its regulation of HCT/Ps, especially 361 HCT/Ps. However, in the meantime, we expect the FDA to continue supporting the development of 351 HCT/Ps through existing regulatory pathways and potentially new regulatory pathways, such as the proposed plausible mechanism pathway, which could usher in abbreviated trial requirements for bespoke, rare-disease therapies and a greater emphasis on post-approval data. We also expect to see the FDA operationalize the CMC flexibility policy it recently announced for CGTs. However, we also expect to see the FDA maintain a balance between reducing barriers for innovation of 351 HCT/Ps, while continuing to crack down on HCT/P developers who try to evade pre-market approval by inappropriately claiming an exception under 21 CFR 1271.10 and/or 1271.



Contributing Authors

Joseph Jay
Partner • New York & Washtington, DC
+1.202.747.1953
jjay@sheppard.com
Bio

Jeffrey Fessler
Partner • New York
+1.212.634.3067
jfessler@sheppard.com
Bio

David Fournier
Partner • Chicago
+1.312.499.6307
dfournier@sheppard.com
Bio

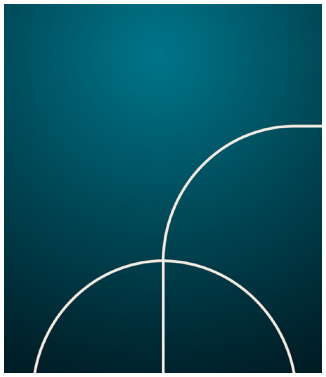
Allison Glasunow
Partner • Chicago
+1.312.499.6309
aglasunow@sheppard.com
Bio

Julia Kadish
Partner • Chicago
+1.312.499.6334
jkadish@sheppard.com
Bio

Scott Liebman
Partner • New York
+1.212.634.3030
sliebman@sheppard.com
Bio

Kourtney Merrill
Partner • Washington, DC
+1.312.499.6318
kmerrill@sheppard.com
Bio

Lorna Tanner
Partner • San Francisco
+1.650.815.2658
ltanner@sheppard.com
Bio

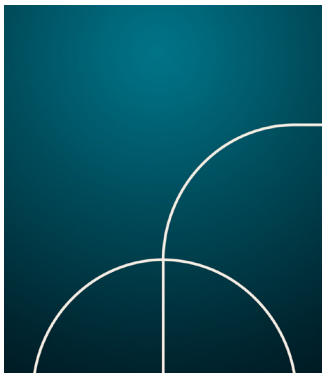


Alex Kitson
Special Counsel • New York
+1.212.653.8173
akitson@sheppard.com
Bio

Nazia Khan
Associate • Washington, DC
+1.202.747.2651
nkhan@sheppard.com
Bio

Julian Klein
Associate • New York
+1.212.896.0686
jklein@sheppard.com
Bio

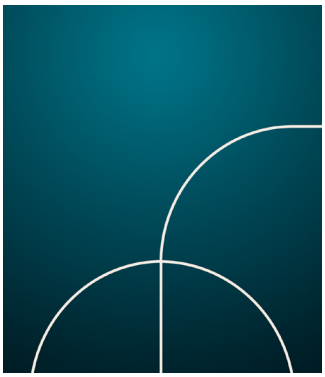
Justine Lei
Associate • New York
+1.212.263.4303
jlei@sheppard.com
Bio



Audrey Mercer
Associate • Dallas
+1.469.391.7454
amercer@sheppard.com
Bio

Arushi Pandya
Associate • Washington, DC
+1.312.499.6349
dpoell@sheppard.com
Bio

Tom Reklaitis
Associate • Washington, DC
+1.202.747.2335
treklaitis@sheppard.com
Bio



Madison Aufai
Patent Agent • Chicago
+1.312.499.0569
maufai@sheppard.com

Endnotes

1 *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022).
2 USPTO, "Inventorship Guidance for AI-Assisted Inventions" (Federal Register notice, Feb. 13, 2024).
3 USPTO, "Revised Inventorship Guidance for AI-Assisted Inventions" (Federal Register notice, Nov. 28, 2025).
4 EPO Legal Board of Appeal, J 8/20 (DABUS) (Dec. 21, 2021).
5 European Patent Office, "AI cannot be named inventor on patent applications" (news release, Jul. 6, 2022).
6 *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).
7 *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
8 European Patent Convention, Article 52 (Patentable inventions) (EPO legal text).
9 EPO Guidelines for Examination (2025), G-II, 4.2.1.3 (Diagnostic methods; G 1/04).
10 *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023).
11 *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 (Fed. Cir. 2010).
12 European Patent Convention, Article 83 (Disclosure of the invention) (EPO legal text).
13 EPO Guidelines for Examination (2025), F-III, 1 (Sufficiency of disclosure).
14 EPO Enlarged Board of Appeal, G 2/21 (Decision dated 23 March 2023; published in OJ 2023).
15 HIPAA Privacy Rule, 45 C.F.R. § 164.502 (Uses and disclosures of protected health information).
16 General Data Protection Regulation (GDPR), Regulation (EU) 2016/679, Article 9 (special categories of personal data).
17 *See* Exec. Order No. 14293, Regulatory Relief To Promote Domestic Production of Critical Medicines, 90 Fed. Reg. 88 (May 8, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/ (directing federal agencies to streamline and eliminate unnecessary regulatory barriers to the construction and expansion of U.S. pharmaceutical and critical medicine production facilities, accelerate review and permitting and strengthen the domestic supply chain for essential medicines).
18 *See, e.g.,* Ben Fidler, *AbbVie pledges $100B to US production in drug pricing deal with Trump*, BioPharma Dive (Jan. 13, 2026), https://www.biopharmadive.com/news/abbvie-drug-price-deal-trump-most-favored-nation/809441/.
19 *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors*, CMS Press Releases (Jan. 17, 2025), https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower.
20 *See* David Mills, *TrumpRx to Lower Cost of GLP-1s, but Experts Say Overall Savings Are Minimal*, Healthline (Nov. 13, 2025), https://www.healthline.com/health-news/trump-rx-lower-costs-glp-1s-prescription-drugs.
21 *See* Michael Erman and Maggie Fick, *Drugmakers brace for Europe pricing fight after Trump's US price-cut deals*, Reuters (Jan. 8, 2026), https://www.reuters.com/legal/litigation/drugmakers-brace-europe-pricing-fight-after-trumps-us-price-cut-deals-2026-01-08/.
22 Department of Justice, Memorandum from the Head of the Criminal Division, *Focus, Fairness and Efficiency in the Fight Against White Collar Crime*, https://www.justice.gov/criminal/media/1400046/dl?inline (May 12, 2025).
23 *See id.*
24 *See id.*
25 Department of Justice, *DOJ-HHS False Claims Act Working Group*, https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group (July 2, 2025).
26 Department of Justice, *National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over $14.6 Billion in Alleged Fraud*, https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-324-defendants-charged-connection-over-146 (June 30, 2025).
27 *See id.*
28 Department of Justice, *Annual Report to Congress on Department of Justice Activities to Combat Elder Fraud and Abuse*, https://www.justice.gov/opa/pr/department-justice-releases-2025-annual-report-congress-efforts-combat-elder-fraud-and-abuse (November 17, 2025).
29 Department of Justice, *Wound Graft Company Owners Sentenced for $1.2 Billion Health Care Fraud and Agree to Pay $309M to Resolve Civil Liability Under the False Claims Act*, https://www.justice.gov/opa/pr/wound-graft-company-owners-sentenced-12b-health-care-fraud-and-agree-pay-309m-resolve-civil (Dec. 12, 2025).
30 *See id.*
31 Department of Justice, *Prison time for healthcare employees in multimillion dollar adult daycare fraud scheme*, https://www.justice.gov/usao-sdtx/pr/prison-time-healthcare-employees-multimillion-dollar-adult-daycare-fraud-scheme (Jan. 13, 2026).
32 Department of Health and Human Services Office of Inspector General, *Semiannual Report to Congress*, https://oig.hhs.gov/documents/sar/10324/Spring_2025_SAR_508.pdf (June 2, 2025).
33 Department of Justice, *Walgreens Agrees to Pay Up to $350M for Illegally Filing Unlawful Opioid Prescriptions and for Submitting False Claims to the Federal Government*, https://www.justice.gov/opa/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and-submitting (Apr. 21, 2025).
34 Department of Justice, *U.S. Attorney Announces $202 Million Settlement With Gilead Sciences For Using Speaker Programs To Pay Kickbacks To Doctors To Induce Them to Prescribe Gilead's Drugs*, https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs (Apr. 29, 2025).

35 U.S. Department of Health and Human Services Office of Inspector General, *Corporate Integrity Agreement Documents* https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp (last visited Jan. 15, 2026).

36 *See id.*

37 *See id.*

38 *See* Press Release, FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests, FDA (June 17, 2025); Commissioner's National Priority Voucher (CNPV) Pilot Program, FDA.

39 Interestingly, this fifth criterium was not part of the initial Program rollout, but, rather, was added several weeks later.

40 This approach is similar to the approach used in other accelerated review program, such as the coronavirus treatment action program ("CTAP").

41 *See* Tropical Disease Priority Review Voucher Program, FDA; Rare Pediatric Disease Designation and Priority Review Voucher Programs, FDA; Draft Guidance: Material Threat Medical Countermeasure Priority Review Vouchers, FDA (Jan. 2018).

42 *See* our previous article for a more fulsome discussion of FDA policy in a post-*Chevron* judicial landscape.

43 *See* JPM26: Jazz's $200M voucher sale shows drumbeat of rising prices isn't stopping, FiercePharma (Jan. 14, 2026).

44 *See* 90 Fed. Reg. 45042.

45 *See* Press Release, FDA Awards First-Ever National Priority Vouchers to Nine Sponsors (Oct. 16, 2025); Press Release, FDA Awards Second Batch of National Priority Vouchers (Nov. 6, 2025); Press Release, FDA Proactively Awards National Priority Voucher Based on Strong Phase 3 Study Results (Dec. 15, 2025); Press Release, FDA Grants Two National Priority Vouchers (Dec. 19, 2025).

46 *See* US FDA Delayed Two Drug Reviews in New Voucher Program after Safety, Efficacy Concerns, Reuters (Jan. 15, 2025).

47 https://www.sec.gov/newsroom/speeches-statements/uyeda-remarks-institute-corporate-counsel-120325

48 *Id.*

49 chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.sec.gov/files/rules/other/2018/33-10588.pdf

50 https://poole.ncsu.edu/thought-leadership/article/do-we-need-mandatory-quarterly-reporting/

51 The SEC is currently considering changes to the definition of foreign private issuers as indicated in its recent June 2025 concept release.

52 https://www.sec.gov/newsroom/speeches-statements/atkins-091725-open-meeting-statement-policy-statement-concerning-mandatory-arbitration-amendments-rule-431

53 https://www.sec.gov/newsroom/speeches-statements/uyeda-remarks-institute-corporate-counsel-120325#_ftn12

54 *See* What To Expect For Stem Cell Regulation Under Trump Admin, Law360 (Mar. 25, 2025); What to Watch: Human Cell and Tissue Product Regulation, Sheppard Mullin FDA Law Update (Oct. 17, 2025).

55 *See* FDA Guidance on Regulatory Considerations for HCT/Ps (July 2020).

56 *See* Public Health and Safety Act ("PHSA"), Section 351.

57 *See* PHSA, Section 361; 21 CFR 1271.10.

58 *See* Approved CGT Products, FDA (current as of Dec. 9, 2025).

59 *See* Press Release, FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation, FDA (Jan 11, 2026); *see also* Flexible Requirements for Cell and Gene Therapies to Advance Innovation, FDA (Jan. 11, 2026).

60 *See* Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products | FDA (Sept. 2025); Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations | FDA (Sept. 2025).

61 *See* CGT Roundtable, FDA (June 5, 2025).

62 *See* FDA's New Plausible Mechanism Pathway, N. Engl. J. Med. (Nov. 12, 2025).

63 *See, e.g.,* X Post, RFK (Oct. 25, 2024).

64 For example, 360 stem cell-related adverse events were reported between 2004 and 2020. *See* Harms Linked to Unapproved Stem Cell Interventions Highlight Need for Greater FDA Enforcement, Pew Charitable Trusts (2021).

65 For example, in 2023 a tuberculosis outbreak was linked to an FDA-approved bone matrix product. *See* Bone Matrix Product: FDA Safety Communication, FDA (Sept. 12, 2023).

66 *See* Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (May 2025); Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (May 2025); Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (Jan. 2025) Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (Jan. 2025); Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (Jan. 2025)l Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | FDA (Jan. 2025).

67 *See* H.R.1082 - Shandra Eisenga Human Cell and Tissue Product Safety Act, 119th Congress (2025-2026).

68 *See* Petition Denied, U.S. v. Cal. Stem Cell Treatment Ctr. Inc., No. 22-56014 (9th Cir. 2024).

69 Until further action is taken, this narrow construction will remain the law of the land, at least in the Ninth and Eleventh Circuits, where it has been applied by the courts.

70 *See* Citizen Petition from Orrick, Herrington & Sutcliffe, LLP, Docket No. FDA-2025-P-6021 (11.12.25).

Sheppard

Brussels • Century City • Chicago • Dallas • Houston • Los Angeles • London • New York • Orange County
San Diego (Del Mar) • San Diego (Downtown) • San Francisco • Seoul • Shanghai • Silicon Valley • Washington, DC

sheppard.com