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2026 Life Sciences Policy Outlook

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VIEWPOINT TOPICS

- Life Sciences & MedTech

After a year defined by aggressive and often unorthodox executive action, the life sciences sector enters 2026 on the defensive. The Trump administration has shown little inclination to de-escalate, and the pressures of a midterm election cycle are likely to intensify scrutiny rather than moderate it. With incumbent Republicans in need of tangible policy wins, drug pricing, supply-chain security, and federal leverage over industry remain central tools.

About This Series

The ML Strategies 2026 Policy Outlook Series explores the policy, political, and regulatory dynamics shaping key sectors in the year ahead. Across six installments, our team analyzes how federal action, election-year pressures, and agency decision-making are converging to influence business strategy, investment decisions, and risk management in an uncertain environment.

Explore the Full 2026 Policy Outlook Series To See Which Federal Priorities are Shaping Key Sectors

Drug Pricing Pressure: White House and HHS Strategies

Congressional action on drug pricing may remain limited, but the White House and Department of Health and Human Services (HHS) are expected to sustain — and expand — their pressure campaign. In mid-2025, the president sent **letters** to 17 drug manufacturers demanding steps to lower prices, prompting a majority of recipients to announce agreements or concessions. That approach is evolving into a more direct strategy, with the administration planning to launch **TrumpRx**, a direct-to-consumer online prescription marketplace, early this year.

The administration is also likely to continue pressing companies to adopt most-favored-nation pricing in 2026, reinforcing a regulatory and political environment in which pricing decisions are increasingly shaped by executive leverage rather than statutory reform.

Trade Policy and Tariff Uncertainty

Regardless of the outcome of the pending Supreme Court case on country-based tariffs, the life sciences sector remains exposed. Ongoing and potential Section 232 investigations into biomedical inputs, medical devices, and branded pharmaceuticals could lead to product-specific tariffs. While many companies are restructuring supply chains and commercial arrangements to mitigate risk, disruptions and cost increases appear likely, particularly for firms with globalized manufacturing and sourcing footprints.

National Security and Biotechnology: Implementing the BIOSECURE Act

The enactment of the BIOSECURE Act as part of the **FY 2026 National Defense Authorization Act** (NDAA) marks a significant shift in how the federal government approaches biotechnology supply chains. The law prohibits federal agencies from contracting with "biotechnology companies of concern" and bars recipients of federal R&D funding from using those funds to engage such companies. Products reliant on equipment or services from designated entities will ultimately be excluded from federal procurement.

While earlier drafts named specific companies, the final law instead ties designation to the Department of Defense's **1260H list** and a forthcoming Office of Management and Budget process. Implementation will be deliberately paced to minimize disruption. OMB has one year from enactment to publish its list — expected by December 2026 — followed by 180 days to issue guidance and up to a year to revise the Federal Acquisition Regulations.

Despite the extended timeline and grandfathering provisions in the law, activity will be constant throughout 2026. Many life sciences companies have already begun decoupling from entities on the 1260H list, anticipating future compliance obligations and procurement risks.

FDA User Fee Reauthorization: PDUFA, MDUFA, GDUFA, and BsUFA

Negotiations between FDA and industry over the next round of user fee programs — PDUFA VIII, MDUFA VI, GDUFA IV, and BsUFA IV — began in 2025 and will continue through 2026, with frameworks expected to reach Congress in early 2027 ahead of the September expiration.

FDA has signaled interest in incentivizing domestic development, including proposals to impose higher fees on non-US-based companies. Commissioner Martin Makary has also emphasized the agency's intent to expand the use of AI in product review, making technological capability and staffing support part of the negotiation calculus. For industry, predictability of process and sufficient FDA staffing remain core concerns.

NIHFunding Policy and the Redistribution of Federal Research Grants

The administration's **Make America Healthy Again agenda** is also reshaping the federal research ecosystem. National Institute of Health (NIH) Director Jay Bhattacharya's **Unified Strategy**, released in August 2025, signals a deliberate move away from concentrated funding at dominant research institutions. The agency is seeking to spread grant awards more broadly, directing resources to less prominent hospitals and universities.

While the immediate impact has been muted in established life sciences hubs, the effects of this redistribution will become more visible in 2026, altering funding dynamics and potentially reshaping

regional research competitiveness.

Bottom Line

In 2026, life sciences policy will be driven less by legislative compromise than by executive pressure, trade enforcement, and national security framing. Companies should plan for continued volatility where pricing, supply chains, and federal funding are increasingly shaped by political strategy as much as by traditional regulatory process.

Authors

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