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R&D SUMMARY OF THEMES

Advancing sustainable R&D in a time of uncertainty

May 2026

From October 2025 through February 2026, Tapestry Networks spoke with life sciences and health sector leaders about the current landscape for biopharmaceutical research and development (R&D). Conversations focused on fostering an environment for sustainable R&D and innovation at a time when the sector is facing significant changes, especially in the US.

This *Summary of Themes* provides a brief overview of the analysis from those conversations, integrated with insights from Tapestry's Fortune 100 board director forums and broader health-sector work.

Tapestry works across corporate governance, financial services, emerging technologies, and healthcare at the board and executive levels. Our networks provide candid listening posts for leaders on cross-cutting issues. In healthcare, we foster candid insights and design and pilot new models, all aimed at sustainable healthcare progress. Learn more at tapestrynetworks.com/focus-area/healthcare/.

This *Summary of Themes*[1] is organized around the following:

Note: This document was finalized immediately prior to Marty Makary's resignation as US Food and Drug Administration (FDA) commissioner. Tapestry made limited updates in May 2026 to reflect that development.

Background

The US regulatory and policy environment for biopharmaceutical R&D is undergoing rapid change. Shifts in federal research and healthcare priorities, organizational and leadership changes at the US Department of Health and Human Services (HHS) and the FDA, and trade and geopolitical dynamics amid increasing commercial pressures are prompting reflections by many leaders on the future of biopharmaceutical R&D.

To better understand how senior leaders are interpreting and responding to these issues, Tapestry Networks spoke confidentially with a variety of stakeholders from October 2025 through February 2026. These leaders consisted of industry executives and board directors, regulatory and policy experts, and advocacy leaders, and conversations were supplemented by insights from Tapestry's Fortune 100 board director forums and broader health-sector work.

This *Summary of Themes* synthesizes takeaways from those discussions across four interrelated topics: decision-making, influence, and leadership in the US on biopharmaceutical research, innovation, and regulation; evolving FDA evidentiary requirements; geopolitics, with a focus on China and geopolitical risk; and stakeholder engagement strategies.

"Crazy things are happening at FDA. There's no stability in the US, and that's where the bulk of sales are.

It's a really big deal—the agency is so unstable. In the past, leaders were in key roles for a while; it didn't really change or move like this. So now is not the time for risk taking."

—Biopharma R&D industry leader

Dynamic developments driving shifts in sentiment

Stakeholder sentiment, as expressed in discussions with Tapestry, has not moved in a linear fashion over the past several months. Instead, it has reflected a series of inflection points tied to political, regulatory, and commercial events. Concerns around federal research funding, FDA organizational stability, commercial pressures, geopolitical exposure, and the influence of key political figures have waxed and waned with each new development.

The following takeaways summarize how stakeholders described these shifts, with the important caveat that they are based on a limited set of conversations, not a comprehensive sector-wide survey:

- **In late 2025, anxiety peaked** around potential federal research cuts and churn within FDA leadership. The resignation of senior figures, shifting leadership at the Center for Drug Evaluation and Research, high-profile complete response letters, and signals of FDA inconsistency contributed to a sense that institutional norms and

processes were under strain. Acute commercial pressure also stemmed from ongoing Most Favored Nation (MFN) negotiations.

- **In early 2026, some of these concerns began to moderate,** though they rarely disappeared entirely. Congressional action in January to block proposed National Institutes of Health (NIH) cuts provided short-term reassurance on US support for life sciences research,[2] even as longer-term questions about the role and scale of federal funding persisted. The FDA continued to act in a timely manner in most cases, particularly in its adherence to Prescription Drug User Fee Act (PDUFA) goal dates. Nevertheless, worries about reviewer turnover and loss of institutional knowledge continued to color industry interactions with the agency.
- **Sentiments on the commercial landscape eased as MFN negotiations settled.** Some stakeholders described MFN agreements as *"window dressing,"* noting that immediate impacts were less severe than initially feared, although open questions about the long-term impact endure. Ongoing geopolitical unease—especially regarding US–China relations—remained embedded, but views on urgency tended to diverge based on company headquarters, pipeline composition, and global footprint.

Overall, many individual industry experiences and perspectives on the innovation landscape have been less uniformly negative than headlines suggest. However, concerns (as further outlined below) do persist.

"Marty himself is the most operational commissioner I've seen. Commissioners are very far removed from what happens in the trenches; this guy is in the trenches."

—Former FDA and current nonprofit leader, prior to Dr. Makary's resignation

Where sentiments stand in early 2026

In general, discussions pointed to a sector recalibrating how it operates amid signals of inconsistency and evolving channels for industry engagement, coupled with cautious optimism by some stakeholders. The sections below synthesize how participant sentiment has settled across four key areas.

US leadership on biopharmaceutical research

In 2025, the Trump administration moved to reshape the NIH through various measures, including proposed cuts to biomedical research, prompting concerns among many leaders in life sciences and research.[3] However, some industry leaders discounted the implications of these moves, with one observing, *"Everyone thought that withdrawal of funding for academia would matter, but it hasn't had a significant impact so far."*

Congress's January 2026 decision to block the proposed NIH cuts

alleviated immediate fears, but some stakeholders viewed the proposed cuts as a signal rather than a singular event. More senior leaders and board directors framed the issue systemically, noting that the NIH's role in de-risking early biology has historically underpinned private capital allocation, and warning that if that function erodes, investment will migrate elsewhere.

Decision-making, influence, and leadership at HHS and FDA

Few topics in discussions generated as much intensity as perceptions of leadership and influence across the White House, HHS, and FDA. Until mid-February 2026, Robert F. Kennedy Jr. and his inner circle were seen as leading decisions on vaccines and shaping public discourse around topics including autism, ADHD, and Make America Healthy Again (MAHA) issues like nutrition. *"For vaccines, it's RFK Jr. calling the shots, 110%,"* remarked a trade association leader. Engagement with Mr. Kennedy's HHS was viewed by some leaders as difficult, given the dominance of staunchly antivaccine voices.

More recently, the White House exercised selective veto power, as first evidenced by the February 2026 Moderna episode, demonstrating that Mr. Kennedy's agenda—especially on vaccines—faces constraints.[4] However, leaders emphasized the overlap and integration between the MAGA and MAHA movements, suggesting that disentangling the two—including on vaccines—may not be easy.[5]

Perceptions of FDA leadership under then-Commissioner Dr. Marty Makary were nuanced. Many described him as engaged, accessible, and operationally involved. Others saw him as constrained by internal politics, competing influences, and external pressure from HHS, the White House, and other stakeholders (which ultimately contributed to his resignation).[6] Notably, some industry leaders in discussions with Tapestry more recently doubled down on positive perceptions of Dr. Makary, underscoring his openness to engaging on complex topics with a variety of stakeholders, including industry. Beyond Dr. Makary, many stakeholders had expressed concern about Vinay Prasad and his policies as Center for Biologics Evaluation and Research (CBER) head prior to his departure.[7]

> *"We did studies at FDA that signaled average medical reviewers take 5.5 years to train before they can operate independently.*
>
> *Without rigorous training and the benefit of senior leaders with institutional knowledge, given that knowledge is now gone, [junior reviewers] may make the wrong decisions."*
>
> —Former FDA leader

Consistency, evidence, and regulatory practice

A clear distinction emerged between regulatory timelines and regulatory consistency. PDUFA goals have largely been met, and the timing of

reviews is not a concern. However, many participants reported inconsistency among individual reviews in interim communications and regulatory advice, along with what some perceived as inexperienced or overly conservative reviewer judgment following staff turnover. Leaders noted that in most cases, such inconsistency was managed and overcome.

Stakeholders also described a persistent gap between FDA rhetoric and implementation in regulatory guidance on emerging issues, particularly around trial design flexibility and surrogate endpoints. Some pointed to uneven application of principles such as the plausible mechanism pathway, especially for smaller biotechs and rare-disease programs.[8]

Even so, some participants noted they were keen to take FDA leadership at face value—especially around its effort to formally reduce the default number of pivotal studies—and maintain a positive outlook. As one leader said, *"FDA has said they want to move to a place where you don't have to do replicate phase 3 studies. If this can happen—and there seems to be willingness from the agency to do so—then we should seize the opportunity. That's the mentality I'm seeing now in my firm."* Such sentiments were not only shared by large pharmaceutical companies but also some small biotech leaders. A key question for the near future will be to what extent FDA priorities from late 2025 and early 2026 might carry forward, considering ongoing turnover of senior leaders such as Dr. Makary.

"We are cutting our legs off on basic science and research, especially from a talent view. We're not signaling to the biomedical community that [the US] will be a great place to work.

Add to that the general uncertainty about the future of jobs and what is a human job versus what is the job of AI, and it's a lot."

—Board director, large pharma and nonprofit CEO

Geopolitics and the China question

Geopolitics emerged not as a peripheral consideration but as a structural force shaping long-term R&D strategy, with China central to those perspectives. Several key points emerged:

- **China is no longer merely a "me-too" developer** but is now a formidable innovator in life sciences, with recent research indicating almost half of Chinese drugs in development target novel mechanisms of action.[9]
- **China's value proposition for preclinical and early clinical development will be challenging to counter,** with implications for the US. As one board director noted, *"It's an issue for patients in the US if they can't get onto a trial because all phase 1 trials have gone to China or Australia."*
- **The question is no longer whether China matters for R&D but how companies—especially US companies—should engage**

amid rising political risk and tensions between the two nations. Large non-US-headquartered companies tended to speak about China with more unambiguous enthusiasm and pragmatism than their US counterparts, with the latter more likely to describe China through a dual lens of opportunity and threat. That said, nearly all stakeholders Tapestry spoke with cautioned that blunt restrictions for US life sciences companies doing business with the Chinese that go beyond current measures (e.g., the recently passed BIOSECURE Act) would ultimately undermine competitiveness.[10]

- **Even if geopolitical risks can be managed,** biopharmaceutical leaders from US and European companies questioned whether they could outcompete the Chinese in the long term, given that Chinese companies may soon emerge as direct multinational competitors.

Some stakeholders contended that the appropriate response is to discuss with policymakers how US firms can continue to *"out-innovate, not block"* vis-à-vis Chinese engagement. Others, pointing to signals of protectionism between Europe and China in the medical-device sector[11] and a general trend toward regionalized corporate organization, urged scenario planning for a world based more on economic blocks anchored by the US and China, with an uncertain role for Europe.

Evolving engagement channels for industry

Against this complex backdrop, the biopharmaceutical sector's engagement with external stakeholders is adapting in ways that reflect both constraint and opportunity.[12] Traditional advocacy through trade and other professional/third-party associations is viewed as less effective; in its place, unilateral, C-suite-level engagement has emerged as a more salient lever, provided those interactions generate positive outcomes and optics, with the latter becoming more important than ever. Some observed that while some stakeholders may feel *"outrage"* at new norms of engagement with the administration, *"these are the new rules of the game, at least for a while."*

Finally, sustainable innovation itself represents a common industry challenge. There is growing recognition that this challenge may be addressable through targeted, issue-specific collaboration rather than broad, precompetitive coalitions. Clinical trial efficiency, early development in the US, and the complexities of multiregional trials were cited as consensus areas where multistakeholder engagement could help advance progress.

Implications and conclusions

Discussion participants consistently framed the current moment as one of uncertainty: institutional turnover, new norms within US health authorities, and growing tension between public rhetoric and regulatory practice. Timelines hold even as staffing is strained; rhetorical openness to innovation coexists with conservative decision-making; and global interdependence in R&D is deepening while political narratives emphasize self-reliance.

In this landscape, biopharmaceutical companies and the partners with whom they work—associations, patient organizations, patient advocates, and even counterparts within regulatory authorities—have an opportunity to:

- advance the implementation of a coherent, long-term strategy for life sciences innovation, in partnership with other stakeholders—shifting from describing the challenges (which have been well characterized by a variety of stakeholders and forums[13,14]) to focusing on actions and outcomes;
- model responsible engagement with regulators and policymakers as new modes of engagement become predominant; and
- invest in resilient R&D strategies that can withstand political cycles and geopolitical shocks, especially with respect to China and its role in R&D.

Despite some uncertainty in the environment, many leaders remain committed to optimism, strategic thinking, and constructive engagement—both individually and collaboratively—in navigating the way forward. As one US nonprofit leader observed, *"We could lose this industry. People don't think we can, but we can. Long-term conversations are important."*

About Tapestry Networks

Tapestry Networks is a trusted convener of board directors, executives, policymakers, and other stakeholders, connecting them with information, insight, and each other. Top experts join our discussions to learn from the leaders we convene and to share their knowledge. Our platforms help educate the market, identify good practices, and develop and launch shared solutions. We call this the power of connected thinking.

Tapestry's healthcare team fosters candid insights, research, operational models, and pilot programs, all aimed at progress in healthcare. In forming agile and disruptive research initiatives, multistakeholder networks, and working groups, our team brings deep sector expertise and problem-solving capabilities to the sector's most pressing issues.

Endnotes

[1] This *Summary of Themes* reflects the use of a modified version of the Chatham House Rule whereby comments are not attributed to individuals or organizations. Quotations in italics are drawn from confidential conversations with discussion participants or from participants in Tapestry's ongoing board forums and health-sector work. Portions of this document may have been prepared with the assistance of artificial intelligence tools; all content has been reviewed and approved by Tapestry Networks.

[2] Jocelyn Kaiser, "Final Funding Bill: NIH Pushes Back against Trump Cuts," *Science*, March 2026.

[3] Richard G. Frank and Sherry Glied, "The Trump Administration's NIH and FDA Cuts Will Negatively Impact Patients," Brookings, May 14, 2025.

[4] Lauren Gardner and Tim Röhn, "FDA's Reversal on Moderna Flu Shot Bid Followed White House Pressure," *Politico*, February 18, 2026.

[5] Daniel Payne and Chelsea Cirruzzo, "White House Says It's 'Done' with Vaccines. MAHA Begs to Differ," *STAT*, March 13, 2026.

[6] Liz Essley Whyte and Josh Dawsey, "Inside Marty Makary's Downfall at the FDA," *Wall Street Journal*, May 12, 2026.

[7] Christina Jewett, "Divisive F.D.A. Vaccine Regulator Is Resigning," *New York Times*, March 6, 2026.

[8] Christina Jewett, "F.D.A. Faces Upset Over Denials of New Drugs," *New York Times*, March 5, 2026.

[9] Lu Chen, Brian Bush, Mike Brochu, and Gian King, "Emerging New Drug Modalities in 2025," Boston Consulting Group, October 9, 2025.

[10] Rob Copeland and Rebecca Robbins, "U.S. Drugmakers Warn White House of Chaos as Trump Weighs Curbs on China," *New York Times*, September 10, 2025.

[11] "China Retaliates Against EU Ban with Import Restrictions on Medical Devices," *Reuters*, July 7, 2025.

[12] Daniel Payne and Lizzy Lawrence, "Pharma Lobbyists Focus on a Surprising New Target: the FDA," *STAT*, February 23, 2026.

[13] Esther Krofah and Sung Hee Choe, *The Future of US Biomedical Research and Innovation: Recommendations for Action* (Washington, DC: Milken Institute, 2025).

[14] National Security Commission on Emerging Biotechnology, *The Future of U.S.-China Biotechnology Competition* (Washington, DC: National Security Commission on Emerging Biotechnology, 2025).