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US Health Agency Restructuring Implications

April 2025

U.S. Federal Health Agency Layoffs Pose Strategic Risk and Disruption to Life Sciences

Executive Summary

Impact of U.S. Federal Health Agency Restructuring on Pharma and Biotech

Recent sweeping layoffs across U.S. health agencies—FDA, CDC, NIH, CMS, and HHS—represent a major disruption to the regulatory and scientific ecosystem that life sciences companies operate. With an estimated 10,000 job cuts, including experienced reviewers, researchers, and policy leaders, companies should prepare for regulatory delays, decreased collaboration opportunities, and increased market access challenges.

Key Impacts by Agency:

- **FDA:** Slower drug and biologic approvals, delayed sponsor meetings, and potential inconsistencies in regulatory guidance.
- **CDC:** Disruptions to disease surveillance, vaccine implementation partnerships, and health equity initiatives.
- **NIH:** Reduced research funding and public-private collaboration, especially affecting early-stage and rare disease innovation.
- **CMS:** Delays in reimbursement policies and coding determinations, impacting patient access and commercial uptake.

Opportunities For U.S Pharma and Biotech Amid Changing Landscape

- Greater industry leadership in setting standards and shaping policy
- Expanded role for private capital and consortia in driving early innovation
- New models for public-private collaboration in areas like decentralized trials and digital health
- Incentive to modernize internal capabilities for regulatory and evidence generation

Recommended Actions to Mitigate Disruptions

- Scenario-plan for launch delays and regulatory bottlenecks
- Strengthen internal regulatory and policy functions
- Expand real-world evidence and HEOR infrastructure
- Increase proactive external engagement with policymakers and stakeholders
- Redesign operating models for resilience and agility

Conclusion

This marks a pivotal shift from government-guided progress to private-sector leadership in life sciences innovation. Companies must act decisively to safeguard development pipelines, adapt commercial strategies, and maintain momentum in delivering patient value amid a more unpredictable U.S. regulatory environment.

Detailed Perspective

Sweeping layoffs across key U.S. health agencies including the FDA, CDC, NIH, CMS, and broader Health and Human Services (HHS) signal a fundamental disruption to the regulatory, research, and public health ecosystem that life sciences companies depend on. With reports of up to 10,000 job cuts, including scientific reviewers, regulatory experts, and public health leaders, the industry must prepare for a less predictable, slower, and more fragmented environment.

These layoffs are part of a broader restructuring that will reduce the HHS workforce by 24%—from approximately 82,000 to 62,000 employees—aiming to save $1.8 billion annually. While the sheer numbers are shocking, it is the loss of decades of institutional knowledge and key groups within agencies that is causing concern among the industry.

Key agency-specific cuts include:

What the CDC Cuts Mean for Life Sciences

The CDC's influence is far-reaching. These cuts may impact:

- **Disease surveillance and data-sharing** that helps manufacturers monitor outbreaks, shape R&D priorities, and develop vaccines and diagnostics.
- **Partnerships in vaccine implementation**, where the CDC traditionally leads on deployment strategies, safety monitoring, and public trust.
- **Health equity efforts,** where CDC-driven insights help companies design more inclusive access and education programs.

In summary: when the CDC is diminished, the ripple effect is real, from real-time epidemiological data to the infrastructure behind mass immunization campaigns. Life sciences organizations may need to lean more heavily on their own data and collaborations to fill in the gaps.

What the NIH Cuts Mean for Life Sciences

The NIH has long been a critical partner in helping life sciences companies push the boundaries of science, especially in the earliest stages of research. The recent staffing cuts may slow down:

- **Grant funding and collaborative studies** that support everything from basic science to early clinical trials.
- **Rare disease networks** that often inform trial design and accelerate understanding of small patient populations.
- **Public-private partnerships**, especially in high-risk or low-commercial-return areas like neuroscience and infectious disease.

For many emerging biotechs, NIH funding and collaboration are essential lifelines until commercialization. With less of that available, companies may need to shoulder more of the early-stage risk and rethink how they validate innovation in the absence of traditional government partners.

What the CMS Cuts Mean for Life Sciences

CMS' decisions impact payers and these impacts ripple directly into access, pricing, and commercial strategy for life sciences organizations. With fewer people in place, we may see:

- **Slower updates to Medicare reimbursement policies**, including those tied to newly approved therapies and diagnostics.
- **Delays in coding and payment determinations,** which can stall physician uptake and patient access.
- **Uncertainty around value-based care initiatives**, especially those requiring alignment across CMS, payers, and providers.

Companies bringing therapies to market particularly in oncology, rare disease, or seniors-first indications may need to build in more time and resources to navigate CMS-related hurdles. In the meantime, field teams and market access functions will need to be ready with more proactive strategies and contingency plans.

Launch Delays and Regulatory Bottlenecks

The FDA's Center for Drug Evaluation and Research (CDER) and Office of New Drugs (OND), already strained prior to these cuts, will now be operating with diminished staff and expertise. This threatens:

- Slower reviews for NDAs, BLAs, and NDAs.
- Delays in sponsor meetings (pre-NDA, advisory committees).
- Decreased capacity to support accelerated pathways like Breakthrough Therapy or Fast Track designations.

The compounded effect of staffing reductions is expected to increase the average drug review cycle time and reduce the FDA's ability to provide timely feedback to sponsors. This may create bottlenecks in submission queues and prolong pre-approval and resubmission processes.

Launch planning becomes more complex as approval timelines stretch and post-marketing requirements risk reprioritization. Companies will also face uncertainty in regulatory expectations, as less experienced reviewers or overburdened divisions may provide inconsistent guidance. Lifecycle

management efforts, new indications, formulations will also face delays, threatening revenue forecasts and limiting market access.

Smaller biotech companies that rely heavily on early FDA engagement and milestone-based funding may be disproportionately impacted, potentially delaying or derailing entire development programs.

The **immediate impact** is a slowdown in innovation velocity and increased risk in the development and commercialization lifecycle. The **longer-term concern** is the erosion of predictability, trust, and the institutional expertise that underpins the U.S. regulatory gold standard.

Risk level	Who is affected	Why it matters
High risk	Small to mid-size biotech companies	• Limited resources and heavy reliance on FDA/ NIH engagement and funding • Delays or shifting expectations could stall programs
High risk	Cell & Gene Therapy Rare Disease companies	• Rely on specialized FDA support and expedited review pathways. • Slower review cycles may jeopardize viability.
High risk	Vaccine manufacturers	• Dependent on CDC infrastructure for surveillance, safety monitoring, and uptake
Mod risk	Large pharma	• Can absorb delays, but launch timelines, FDA interactions, and CMS processes will still be impacted
Mod risk	Large indications (e.g., diabetes, CV)	• Less regulatory uncertainty, but still exposed to general FDA slowdown and reimbursement lag
Mod-low risk	Companies with diversified global operations	• Can pivot to non-U.S. markets or regulatory pathways more easily • Better positioned to adapt

Potential Opportunities Ahead

While these sweeping changes present significant challenges, a modest level of opportunity arises including:

- **Increased Industry Leadership:** With government agencies stepping back, life sciences organizations have an opportunity to take the lead in setting scientific and operational standards, building coalitions, and influencing health policy more directly.
- **Acceleration of Innovation Ecosystems:** Private capital and industry-led consortia may fill some of the gaps left by reduced NIH and FDA involvement. This could lead to more agile, focused, and commercially viable models for early-stage research, real-world evidence, and diagnostics validation.
- **Expansion of Public-Private Partnerships:** As the government recalibrates, there may be new openings for industry to co-create solutions—especially in areas like digital health infrastructure, decentralized trials, and health equity programming.
- **Greater Investment in Regulatory Capabilities:** The disruption may serve as a catalyst for companies to modernize and expand their internal regulatory, policy, and evidence functions, resulting in long-term resilience.

Strategic Considerations for Life Sciences Sector

In this evolving landscape, life sciences companies must move from regulatory dependence to strategic adaptability/transformations to set up for operating in an evolving US market.

- **Scenario-plan for launch delays:** Build flexible product development and launch timelines that incorporate regulatory uncertainty. Consider alternate launch strategies, such as regionally staggered rollouts or international-first models.
- **Invest in internal regulatory capabilities:** Strengthen internal regulatory intelligence and governance processes to reduce over-reliance on FDA guidance.
- **Expand evidence generation infrastructure:** Reinforce product credibility with real-world evidence (RWE), health economics and outcomes research (HEOR), and post-market safety data.
- **Elevate external engagement:** Shape the evolving policy environment by increasing coordination with policymakers, trade groups, advocacy organizations, and scientific societies.
- **Drive strategic transformation:** Align enterprise-level vision and change initiatives to meet the demands of a post-restructure environment.
- **Redesign operating models for resilience:** Ensure the organization is structured to be nimble, collaborative, and future-ready.

Conclusion

This moment represents a shift from agency-guided innovation to private-sector self-reliance. Life sciences leaders must move quickly to de-risk launches, safeguard development investments, and ensure patients continue to benefit from scientific progress despite public sector turbulence. Between round II of the IRA, tariffs proposed on APIs and radical change to the US health framework, life sciences companies appear to be pausing and taking stock of strategic choices and priorities on the horizon before acting too quickly.

Over the long term, the life sciences industry will need to monitor whether these cuts result in lasting regulatory instability, a weakened innovation pipeline, and greater public skepticism of the sciences will continue as challenges that will require continued foresight, agility, and collaboration to overcome.