Magnolia market access

a medical knowledge group company

The U.S. Biopharmaceutical Innovation Ecosystem at Risk:

The 20-Year Threat to U.S. Innovation and Cures

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Changes in research funding, regulatory pathways, and drug pricing policy are reshaping the U.S. biopharmaceutical market in interconnected ways. Although long-term trends previously suggested continued acceleration in drug development, these emerging pressures may slow that momentum. Together, they could reduce future drug innovation and limit the availability of new treatment options, particularly in areas with significant unmet need. Magnolia Market Access (Magnolia) predicts that, rather than surpassing historical growth trends as once anticipated, the number of new drugs reaching the market over the next 2 decades could decline by up to 55%.

Our findings raise concerns that current and proposed policies may constrain industry growth and innovation, with patient advocates cautioning that the effects on treatment availability could be felt for generations.

Executive Summary

Interacting changes in research funding, regulatory capacity, and drug pricing policies threaten to weaken the U.S. biopharmaceutical ecosystem.

- National Institutes of Health (NIH) funding instability is already reducing grant activity and could slow the flow of early discoveries, creating long-term gaps
- Food & Drug Administration (FDA) staffing losses, leadership changes, and reduced expertise may increase uncertainty, increasing manufacturer risk and slowing approvals and translation from science to therapies
- Market disincentives, such as shorter effective commercialization windows under the Inflation Reduction Act (IRA) and potential Most-Favored Nation (MFN)-style pricing and resulting lower returns, discourage high-risk research and limit post-approval studies and additional indications

The core risk is not a single policy, but a compounding, unpredictable environment that deters investment; coordinated action is needed to stabilize research, strengthen predictable regulatory capacity, and preserve incentives for innovation.

Magnolia estimates that combined pressures, such as NIH-funding reductions, IRA price negotiations, and MFN pricing, could significantly reduce the number of novel drugs approved by up to 55% over 20 years. Patient advocates believe these reductions could cause permanent damage to drug innovation and access to innovative treatments.

Introduction

The United States has led in biomedical innovation thanks to an ecosystem that supports scientific risk, long-term investment, and the translation of discoveries into treatments. But drug development is slow, costly, and uncertain, typically taking 10 to15 years, with only a small share of candidates reaching patients. This reality depends on a stable, interconnected system spanning early research, translational science, regulation, and market incentives. Incremental policy shifts are now putting this leadership at risk and should be assessed holistically to identify key risks and opportunities for improvement.

Multiple pressures threaten the U.S. biopharmaceutical system, with cumulative rather than isolated effects. NIH funding instability may reduce the flow of early-stage discoveries; disruptions in translational research weaken the path from lab to therapy; and FDA staffing losses erode expertise, making reviews less predictable and potentially limiting patient access. At the same time, policies that reduce returns on innovation, such as the IRA and potential MFN-based pricing models, are likely to discourage investment in both new and follow-on research.

Magnolia estimates that, taken together in the high-end scenario, these forces could reduce the number of new medicines by up to 55% over the next 2 decades, well beyond the impact of any single policy. Beyond measurable effects, less visible risks are emerging: a more unpredictable environment, loss of scientific and regulatory expertise, shifts in R&D investments to China and other countries, slowing scientific momentum, declining investor interest, and erosion of an innovation ecosystem that takes decades to build and cannot be quickly restored.

This issue extends beyond economic or market dynamics to broader public health implications. Patients rely on the U.S. drug development ecosystem, including translational science, incentives to encourage researchers to take risks, regulatory consistency, and post-approval research. Still, certain groups, such as those with rare diseases, may be more sensitive to changes in innovation incentives, funding, and regulatory pathways. By the time declines in new treatment approvals become apparent, underlying scientific and institutional capabilities may already be difficult to restore.

A New Lens on the U.S. Biopharmaceutical Innovation Ecosystem

The U.S. biopharmaceutical innovation ecosystem has been built over decades to manage risk and deliver new therapies, balancing leading scientific research, predictable regulatory pathways, and market conditions that support reinvestment. This structure has enabled sustained progress despite the long and uncertain nature of drug development (typically 10 to 15 years),[i] with only about 1 in 10 candidates that begin clinical trials reaching approval.[ii] As a result, the U.S. continues to lead global pharmaceutical R&D, supported by its scale, access to capital, and strong scientific foundation.

Additionally, in areas like orphan and rare diseases, where R&D challenges include small patient populations, heterogeneous disease presentation, lack of outcomes data, and delayed and underdiagnosis, the U.S. has combined legislated orphan-specific incentives, such as 7 years of manufacturing exclusivity, tax credits, and grants, with NIH-supported rare-disease science and translational programs, and an FDA framework tailored to the challenges of small-population trials, to promote the development of these products.

In recent years, changes in research funding, regulatory processes, and pricing policy have threatened to reshape this current ecosystem. And while many discuss these policies in isolation, they are all interconnected across the development cycle and collectively influence innovation and patient access.

To better understand the combined effects of these dynamics on the future health of the U.S. biopharma landscape, Magnolia has taken a comprehensive approach, evaluating how changes in NIH funding, FDA staffing and review processes, and pricing and reimbursement interact. This evaluation, along with perspectives from patient advocacy organizations focused on patient access to care and biopharma investors willing to invest in U.S. innovation, was used to model how these combined factors may shape the pharmaceutical landscape over the next 2 decades.[iii]

The Combined Impact Is More Than What We See

Advancing the U.S. biopharmaceutical ecosystem is a collective effort that involves multiple public and private stakeholders. For example, NIH research funding, FDA staffing and review processes, and pricing and reimbursement each shape different stages of the innovation lifecycle, from early discovery to patient access, but their combined effects are synergistic. Changes in one area influence decisions in others, and when pressures occur simultaneously, they reinforce each other. Understanding these interactions is essential for assessing how the ecosystem is evolving and why the impact on future therapies may be greater than that of evaluating each policy in isolation.

> *"… [T]he chaos is real. I think the diversion of time and attention is real. It's time that's being taken away from people being able to bring great medicines to market … [I]n the meantime, you've got folks like China sitting there laughing … quietly, saying 'These guys literally can't get out of their own way.'"*
>
> —Biopharma Investor

The NIH Effect—Destabilizing Scientific Foundations

NIH research and research funding seeds the early innovation pipeline, supporting basic and translational research that enables academic institutions, startups, and biopharma companies to translate discoveries into new therapies. This foundation is essential to the development lifecycle and is increasingly under strain.

By late May 2025, approximately 2100 NIH grants totaling $9.5 billion had been terminated, with nearly 30% of those tied to clinical studies. Although a federal judge ordered some funding reinstated, the broader impact remained significant: 5844 NIH grants and 1996 NSF grants were ultimately canceled or suspended, including more than 800 grants in infectious disease research.[iv]

> *"Rare disease patients really have looked to the NIH as a core organization that has really been helping to drive forward research in rare [diseases] and it's been tremendously impactful."*
>
> —Charlene Son Rigby, Global Genes

At the same time, NIH-funding mechanisms have contracted. Notices of Funding Opportunities declined from 756 in 2024 to 120 in 2025 and just 14 in 2026, while total grants issued fell by 24%.[v,vi] Competition has intensified, with only 13% of applications funded.[vii] Budget uncertainty has added

further instability, including a proposed $19 billion (40.6%) cut for FY2026,[viii] followed by renewed proposals for reductions in FY2027 despite Congress ultimately increasing funding to $47.2 billion.[ix,x]

Market Disincentives—Shortening the Horizon for Innovation

Concurrently, pricing and reimbursement policies play a central role in shaping investment decisions by determining the expected return on innovation. The implementation of the IRA is compressing this window for recouping R&D investments, influencing where, when, and whether companies invest in new medicines in the United States.

> *"… [T]hat lagging effect can impact… fundamental research for years down the road. So I think that's the biggest concern. It's the on-off again. People conducting the science, even for people wanting to go into research, who were thinking of going into research. It's a deterrent for them. There's an instability."*
>
> —Kim Czubaruk, CancerCare

The IRA effectively reduces the commercial window to 9 years for small molecules and 13 years for biologics. Early evidence suggests measurable impacts: an April 2025 interrupted time series analysis found an immediate decline of more than 11 industry-sponsored trials following passage, with an additional drop of one trial per month thereafter. Post-approval trial activity declined by 38.4%,[xi] and small-molecule trial starts fell from 96.7 to 81.7 per month (15.6% decline).[xii] While longer-term industry projections have estimated up to an 8% reduction in industry revenue and a 12.3% decline in R&D investment, which would translate into 79 fewer treatments over the next two decades, the ultimate effects could be much more detrimental.[xiii]

> *"The consensus is [the IRA is] terrible. And we all hope it gets repealed, or at least modified … because not only is it an existential threat to investment in small molecule medicines, it represents that the federal governments or the powers that pass this fundamentally do not understand drug-making."*
>
> —Health Affairs Scholar[xiv]

These changes also affect follow-on innovation. More than half of the drugs approved between 2000 and 2023 later received supplemental indications (47% of biologics, 52% of small molecules), often requiring substantial additional investment.[xv] This means that on average, every novel drug approval leads to an estimated 1.6 additional follow-on indications beyond the initial approved indication. This lifecycle pipeline continuously addresses persistent unmet need, frequently bringing new treatment options to patient populations facing long-term therapeutic stagnation, rare diseases, or high disease severity.[xvi] Post-approval oncology trials declined by 40% after the IRA's passage, suggesting reduced incentives to pursue these expansions.[xvii] As expected returns decline, companies may shift away from higher-risk programs, smaller patient populations, and complex diseases, narrowing the scope of innovation over time.

Pricing policies may also influence where and when therapies are launched. Among more than 500 cancer drugs introduced between 1990 and 2022, 45% launched first in the United States, with launches elsewhere lagging by over 18 months on average.[xviii] Separate analysis found that delayed access to just 2 cancer drugs in Europe may have resulted in more than 30,000 lost life-years.[xix]

Additional policies, such as MFN-style pricing, could further reduce returns and increase uncertainty. While MFN pricing discussions are currently focused on products already on the market, the long-term effects could be even more detrimental if they were expanded to new drugs entering the market. If U.S. pricing is tied to lower international benchmarks, companies may stop or delay launches, reduce investment in supplemental indications, or deprioritize certain therapies. Over time, these dynamics may narrow innovation, slow access, and reduce the number of new and expanded treatment options, particularly in areas of high unmet need. First quarter 2026 earnings disclosures from biopharma companies show R&D discipline and portfolio reprioritization across the sector, including R&D job losses and reductions in R&D funding.[xx,xxi]

FDA Capacity and Predictability—Friction in Translation

A strong FDA provides regulatory clarity, scientific continuity, and predictable review processes that are critical for long-term investment in drug development. When staffing constraints, inconsistent guidance, or evolving standards weaken this role, uncertainty increases across the development lifecycle, raising risk and reducing the number of programs that advance, particularly more complex ones.

Recent trends point to growing capacity constraints. FDA staffing has declined by approximately 25%,[xxii] with more than 3500 positions eliminated by May 2025, alongside additional resignations and retirements among experienced reviewers and leadership.[xxiii] These losses and confusion about whether they are permanent or temporary reduce confidence in seeking employment or in staying at the FDA and erode the institutional knowledge that supports efficient and consistent reviews. Operational impacts are also evident, including more than 170 cuts to the workforce supporting inspections,[xxiv] an area already widely viewed as understaffed,[xxv] and a decline in guidance issuance to levels seen during the first Trump administration.[xxvi]

> *"We'll lose really competent people who are going to review this drug and make the drug approval process efficient and effective and safe ... So, I think the impact is real … not only near term, but it's also medium and longer term. … [S]ome damage is already irreversibly done."*
>
> —Biopharma Investor

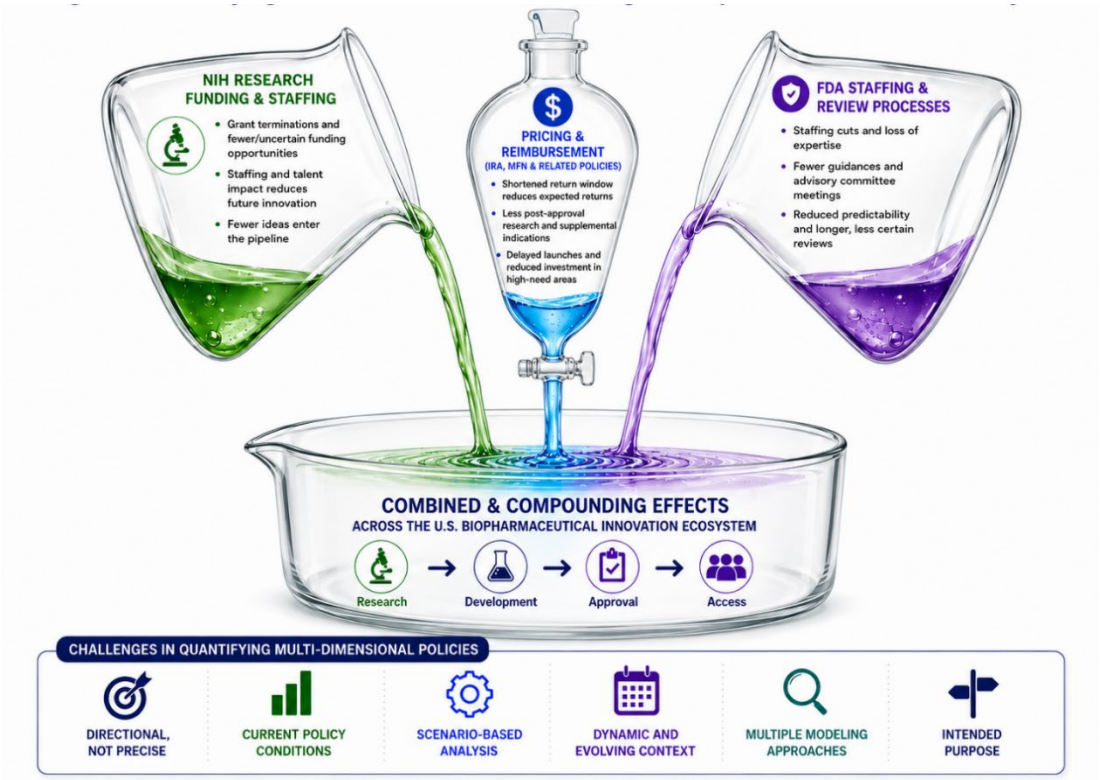
Regulatory activity has also shifted. Advisory Committee meetings declined from 25 in 2023 to 14 in 2024 and just 7 in 2025,[xxvii] while 71% of 2025 meetings resulted in recommendations against approval, the highest rate in more than 20 years.[xxviii] Patient engagement has also decreased, with patient-focused meetings falling to 18 in 2025 from roughly 26 to 34 annually between 2021 and 2024.[xxix] Additionally, changes in FDA leadership introduce further uncertainty, including whether the FDA will continue to prioritize drug approval reform or pivot to other areas under new leadership.

Taken together, these trends indicate a more constrained and less predictable regulatory environment. As clarity declines, developers face greater uncertainty in trial design and approval pathways, investors apply more conservative assumptions, and fewer programs move forward. Over time, reduced regulatory predictability can slow development, increase investment risk, and delay patient access to new therapies.

Quantifying the Compounding Effect of Policy Pressures on the Future Biopharmaceutical Industry

Magnolia assessed how changes in research funding, regulatory capacity, and pricing policy could interact to shape future innovation, estimating their combined impact on future drug development and treatment availability (Figure 1). This approach integrates evidence from published literature, industry data, and stakeholder interviews. Also, it incorporates assumptions about the responsiveness of R&D investment to changes in expected returns, the influence of NIH funding on early-stage research, and downstream effects on pipeline progression.

Figure 1: Quantifying Interconnections Between Drug Development and Market Stability



While these results should be viewed as directional estimates rather than precise forecasts, they offer a dynamic assessment of potential impact under current policy conditions. For example, the Inflation Reduction Act (IRA) has already been projected to reduce industry revenue by approximately 8%; our model estimates the incremental effects beyond those already attributable to the IRA.

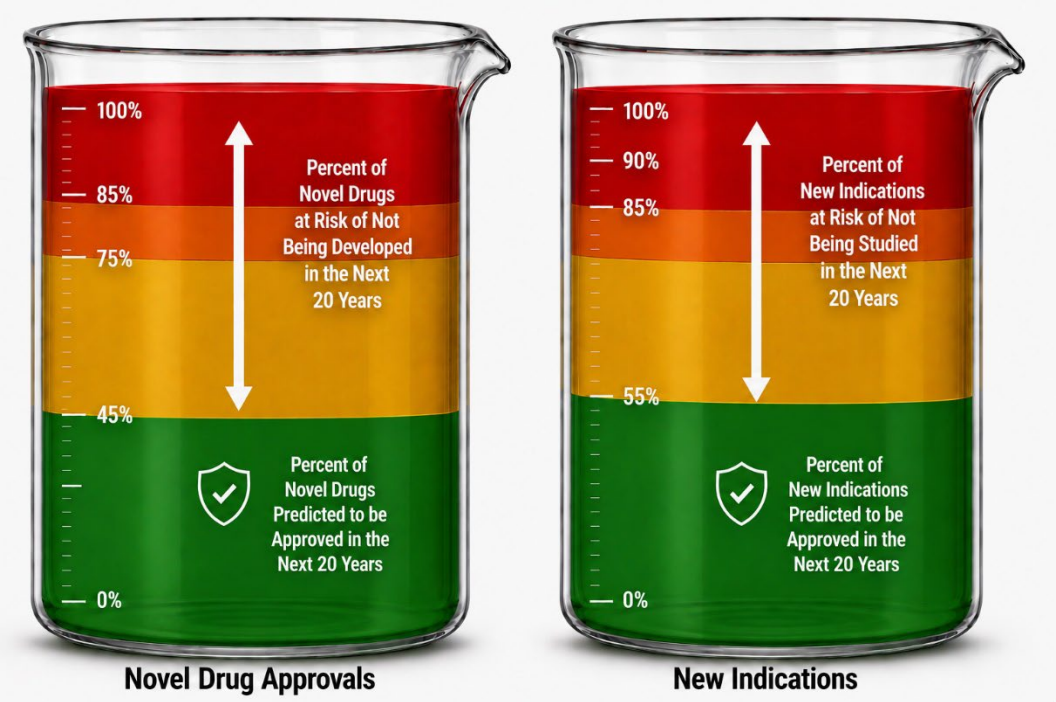
Given the highly dynamic and evolving nature of the market, precisely modeling these effects remains inherently challenging. Many factors, including uncertain revenue effects and related changes in R&D funding and approval rates, shape the impact on future innovation. Our approach incorporates as many relevant factors as possible within the current evidence base. However, many of these policy and market changes are recent, and available data—particularly on long-term impacts in a rapidly evolving

environment—remain limited. We also recognize that there are multiple accepted modeling approaches, each with its own strengths and limitations, and we evaluated and incorporated these considerations into our methodology. For example, the long-term effects of the Inflation Reduction Act (IRA) remain widely debated across public and industry analyses, reflecting a range of plausible future outcomes. Accordingly, the model is intended to provide directional insight into potential trends and impacts rather than definitive forecasts.

When combining the available estimates for these factors, Magnolia developed two predictions (Figure 2): first, how many drugs may never reach the market as a result of policy changes, and second, what percent of indications could be affected as a result of novel drugs not coming to market, or manufacturers not seeking label expansions for existing treatments? Our model predicts that:

- Of the approximately 1,200 novel drugs that otherwise are expected to launch over the next 20 years, reductions in approvals could reach 55% (high-end estimate)[xxx].
- This could affect up to 45% of drug indications, due to drugs not receiving initial approval and manufacturers not seeking label expansions for existing drugs.

Figure 2: Projected Percent of Novel Drugs and New Indications at Future Risk in the U.S. in the Next 20 Years



While the reduction in treatment availability will affect all Americans, these losses could disproportionately affect small-molecule drug development, oncology, high-risk programs (e.g., Alzheimer's disease), and conditions prevalent in elderly populations. They are also expected to disproportionately affect areas of high unmet need, including rare diseases with limited existing therapies. Taken together, these dynamics suggest that cumulative policy changes may reduce both initial and follow-on innovation, ultimately reshaping the trajectory of drug development and limiting future treatment options for patients.[xxxi]

Conclusions and Policy Recommendations

The U.S. health care system has long been a global leader in drug innovation, supported by strong scientific research, investment incentives, robust clinical trial infrastructure, efficient regulatory processes, and rapid adoption of new therapies. Recent and proposed changes—including shifts in NIH funding, reduced regulatory capacity, evolving evidentiary requirements, fewer Advisory Committee engagements, and more limited regulatory guidance—may increase uncertainty around development pathways and investment decisions. Collectively, these factors could reduce predictability within the innovation ecosystem and influence the pace and direction of future biopharmaceutical innovation in the United States.

> *"Commercial entities will try not to be stopped if there are barriers put in the way and that's one reason that you start to see investments in research being shifted to other parts of the globe. ... [I]t will reach a point where there are drugs that are being developed elsewhere in the world that are no longer available to U.S. patients as an option [for] part of their care."*
>
> —Jeff Allen, Friends of Cancer Research

Magnolia's modeling and evidence synthesis indicate that policy changes across the innovation lifecycle can meaningfully reduce future drug development, with cumulative effects that may challenge the U.S. position as a global leader in biopharmaceutical innovation. Because drug development operates on long-time horizons, often spanning decades, policy decisions must be evaluated for both their immediate and long-term implications across the full ecosystem.

These findings highlight several considerations for maintaining a stable and productive innovation environment:

- ***Sustained and reliable research funding:*** Stable public investment, particularly through NIH, supports early discovery, research infrastructure, and the pipeline of future therapies
- ***Predictable and efficient regulatory processes:*** Clear guidance, consistent evidentiary standards, and sufficient agency interaction and capacity reduce uncertainty and support investment in complex and high-risk programs
- ***Incentives aligned with meaningful innovation:*** Policies that ensure a predictable and adequate return on investment can sustain both initial development and follow-on research, particularly in areas of unmet need
- ***Support for talent and ecosystem collaboration:*** Continued investment in scientific talent, entrepreneurship, and cross-sector partnerships are critical to maintaining a dynamic and competitive innovation system

Taken together, these considerations underscore the importance of coordinated policy approaches that recognize the interdependence of the biopharmaceutical ecosystem and its role in shaping future treatment availability.

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Appendix: Methodological Notes

For this analysis, Magnolia leveraged models previously created by industry stakeholders and further expanded them into a macroeconomic framework, incorporating a targeted literature review and insights from payer stakeholders to inform model development. These published frameworks and data points were adapted to examine the effects of NIH-funding reductions and revenue-driven market disincentives (e.g., IRA/MFN-related pricing pressures) to develop a 20-year outlook.[xxxii,xxxiii]

For translational erosion, the model follows a decade-based structure consistent with prior research, resulting in stepwise increases in effects over time.[xxxiv] This framework was also applied to market disincentives using elasticity-based adjustments to reflect projected revenue changes.[xxxv] No smoothing function was applied due to a lack of empirical evidence supporting an alternative distribution of effects over time.

Post-initial indication outcomes were assessed beginning in the first year following policy implementation (2027), rather than retroactively. The denominator for estimated losses assumes continued growth in drug development over the next 20 years, reflecting recent trends of higher development activity than in prior decades.[xxxvi,xxxvii,xxxviii] All values and percentages have been updated to reflect rounding to the nearest 5% or to the nearest multiple of 5.

While this approach provides a directional, scenario-based estimate of cumulative effects, further refinement could improve precision as additional data become available.

Limitations

Quantitative modeling was feasible for NIH and market dynamics; however, data limitations precluded robust estimation of FDA-related variables. These factors are addressed qualitatively, though they may further compound other policy pressures and contribute to additional impacts not captured in the model. In addition, while this analysis reflects MFN implementation as modeled—specifically, international reference pricing applied to marketed drugs—alternative approaches, including MFN application at launch, would likely exert similar downward pressure due to increased uncertainty and reduced expectations for future revenues. As a result, outcomes related to MFN codification are expected to fall within the range of estimates presented, particularly in the latter half of the projection period (2041–2046). Finally, while the model captures post-initial-approval losses from the baseline period (2027) onward, it does not account for foregone post-approval opportunities before the baseline period, which may lead to an underestimation of lost indications and downstream treatment opportunities.

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