FROM DISCOVERY TO DELIVERY:

A National Competitiveness Strategy for American Biotechnology

Written Testimony Submitted to the U.S. Senate Finance Subcommittee on Health Care

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August 4th, 2026

EXECUTIVE SUMMARY

America remains the world's leader in biomedical discovery. Our universities, academic medical centers, biotechnology companies, pharmaceutical industry, nonprofit research organizations, entrepreneurs, investors, and federal research agencies together comprise the world's most powerful biomedical innovation enterprise.

Yet the United States faces a growing paradox: too few of our discoveries become new medicines, companies, domestic manufacturing, and economic growth. America does not have an innovation deficit; it has a translation deficit.

Over the past two decades, the biopharmaceutical innovation model has changed. Universities, biotechnology startups, nonprofit translational institutes, entrepreneurs, and investors now generate a growing share of early therapeutic innovation. Meanwhile pharmaceutical companies increasingly access that innovation through partnership, licensing, and acquisition before applying their unmatched capabilities in clinical development, regulatory science, manufacturing, and commercialization. This shift has widened the “Valley of Death”, the gap between discovery and commercial development, where promising science is often too advanced for academic funding, too early for industry investment, and too risky for private capital. The result is a diminished return on federal research investment, longer periods of waiting for patients, lost domestic manufacturing, and weakened competitiveness.

At the same time, China has adopted a coordinated national strategy that integrates research, artificial intelligence, clinical development, advanced manufacturing, workforce development, financing, and commercialization. Congress has begun to respond to the security dimension of this challenge. The BIOSECURE Act, enacted in December 2025, restricts federal engagement with Chinese biotechnology firms of concern.[1] That is necessary but insufficient. Restricting a competitor’s access does not, by itself, build America’s own capacity to translate discovery into commercial and clinical reality.

[1]BIOSECURE Act, enacted as Section 851 of the National Defense Authorization Act for Fiscal Year 2026, signed into law December 18, 2025; restricts federal agency contracting with designated Chinese biotechnology companies of concern.

To close that gap, I propose a National Translational Biotechnology Initiative (NTBI): a public-private competitiveness framework, not a new federal agency, and not a substitute for NIH or NSF, that aligns federal investment with state initiatives, regional ecosystems, industry, philanthropy, and private capital around six priorities:

1. Build America's cutting-edge translational infrastructure across the continuum of therapeutic innovation, human disease models, regulatory science, and advanced biomanufacturing.

2. Establish a complimentary national network of Regional Biotechnology Translation Hubs.

3. Develop the multi-disciplinary biotechnology workforce through experiential education and cross-sector partnerships.

4. Strengthen and expand domestic biomanufacturing and supply-chain resilience.

5. Align federal tax and financing incentives to keep taxpayer-funded discoveries developed domestically.

6. Measure success through outcomes that include therapies advanced, companies formed, capital leveraged, and costs avoided.

Maintaining American leadership in biotechnology is not inevitable. It is a policy choice, and one this Committee is uniquely positioned to make.

PART I. WHY BIOTECHNOLOGY IS A SENATE FINANCE ISSUE

Biotechnology has become one of the defining strategic industries of this century. It is not only a scientific enterprise, but a driver of economic growth, advanced manufacturing, and national security.

For the Finance Committee, this is fundamentally a question of fiscal stewardship. The federal government invests roughly $47-48 billion annually in biomedical research through the National Institutes of Health,[2] while Medicare and Medicaid together spend more than $2.1 trillion each year treating the chronic disease, cancer, neurodegenerative disorders, and infectious disease this research aims to prevent or cure.[3] These are not two separate line items. They are two sides of the same equation. Research that succeeds in producing better therapies reduces future federal health spending, extends working lives, and expands the tax base. Research that fails to translate into medicines leaves that spending curve unchanged while forfeiting the return on the taxpayer's initial investment.

Too often, promising American discoveries fail to become medicines. When that happens, patients wait longer, taxpayers receive a diminished return, private capital and manufacturing

[2]Final FY2026 NIH appropriation of approximately $47.2-48.7 billion (base budget, excluding certain transfers), a modest increase over the FY2025 level of approximately $46.8 billion; Senate and House Labor-HHS Appropriations Subcommittee FY26 bill summaries; NIH FY2026 Congressional Justification.
[3]Combined Medicare and Medicaid spending of approximately $2.18 trillion in 2025 (Medicare: ~$1.21 trillion; Medicaid: ~$0.97 trillion), Centers for Medicare & Medicaid Services, National Health Expenditure data and FY2025 CMS Financial Report.

migrate overseas, and strategic supply chains grow more vulnerable. The United States continues to lead the world in biomedical discovery. The open question is whether America will also lead in translating that discovery into medicines, economic growth, and improved health outcomes, which is why this is squarely a Finance Committee question.

PART II. THE VALLEY OF DEATH: HOW THE INNOVATION MODEL HAS CHANGED

Historically, large pharmaceutical companies performed most of the innovation process internally from target discovery through commercialization. Universities focused on basic science; industry translated it. That model has evolved dramatically. During my three decades in pharmaceutical research, I watched this transition firsthand. Early in my career, large companies discovered most new medicines internally. By the time I left industry, partnerships, licensing, and acquisitions had become central to how innovation reached patients.

Today, research universities produce groundbreaking science; biotechnology startups pioneer new therapeutic platforms; venture investors fund early-stage programs; nonprofit translational institutes reduce technical risk; academic medical centers contribute clinical insight. Large pharmaceutical companies remain indispensable but increasingly acquire innovation externally rather than generating it internally. This has created a more entrepreneurial, more distributed innovation ecosystem, however with more transitions between discovery and commercialization. These transitions invariably introduce increasing scientific, technical, financial, and regulatory risk.

Scientific discovery alone rarely produces an investable therapeutic opportunity. Before private investment or pharmaceutical partnership will follow, an innovation must demonstrate reproducible biology, efficacy, safety, intellectual property protection, manufacturability, and regulatory feasibility. This work requires medicinal chemistry, computational biology, human disease models, translational pharmacology, and regulatory science that few single institutions possess end to end. Many promising discoveries stall not for lack of scientific merit, but because this supporting infrastructure is fragmented across organizations with different missions, incentives, and timelines. That fragmentation, not a lack of discovery, is the modern Valley of Death, and it sits precisely where scientific and commercial uncertainty are both greatest, past the reach of academic funding and ahead of private-investor risk tolerance. Public investment at this stage should not replace private capital; its purpose is to discharge enough risk that private capital participates earlier and at greater scale.

This dynamic has a further variable the Committee should weigh. In my experience, private investors have followed a consistent pattern for close to a decade. They wait until a molecule has effectively cleared the Valley of Death, with scientific and commercial risk substantially reduced, before committing capital. That pattern is not cyclical, it reflects a durable shift in risk tolerance, and there is little reason to expect the market will reverse it on its own. If anything, the trend may deepen. Investor appetite today is concentrated in new areas such as artificial intelligence and adjacent technologies, which compete directly with early-stage biotechnology for the same pool

of venture capital. Absent a deliberate public strategy to bridge this gap, the market is unlikely to close it unassisted.

Nonprofit translational research institutes, public-private partnerships, and specialized innovation organizations have emerged over the past two decades to fill exactly this role. These organizations create multidisciplinary teams, execute translational strategies, fund raise, and facilitate unique partnerships that neither universities nor industry typically can do alone. The Indiana Biosciences Research Institute was built for this purpose. Indiana's experience shows that translational success is not the product of any single institution; it is the product of intentional collaboration among universities, pharmaceutical and biotechnology companies, health systems, entrepreneurs, investors, philanthropy, and government. In the twenty-first century, biotechnology competitiveness will be determined less by individual discoveries than by the strength of the systems that translate discovery into patient benefit. That is the purpose of the National Translational Biotechnology Initiative proposed in this testimony.

PART III. GLOBAL COMPETITION: WHY BIOTECHNOLOGY IS A STRATEGIC IMPERATIVE

Other nations now treat biotechnology as a strategic national capability rather than a scientific sector. China has pursued the most comprehensive strategy, investing across the full continuum including research, artificial intelligence, clinical development, advanced manufacturing, workforce development, and commercialization. This is a marked departure from China's past competing mostly on low-cost manufacturing. Chinese biotechnology companies are increasingly generating novel therapeutic candidates that are licensed or partnered with multinational pharmaceutical companies for global development, reflecting an innovation system engineered to shrink the time between discovery and commercial opportunity. China is not simply investing more, it is competing ecosystem against ecosystem.

Congress has already begun to respond to the security half of this challenge. The BIOSECURE Act, enacted as part of the FY2026 National Defense Authorization Act, restricts federal agencies from contracting with biotechnology companies of concern.[4] That step is necessary, but it is defense, not offense. Restricting a competitor's access to the American market does not, on its own, build the domestic translational capacity needed to keep discovery, company formation, and manufacturing here. The National Translational Biotechnology Initiative is the complement BIOSECURE needs: a strategy for building American capacity, not merely restricting a rival's access to it.

Despite China's progress, the United States retains advantages no nation has matched, the world's leading research universities, academic medical centers, a global pharmaceutical and biotechnology industry, the deepest venture capital markets, and the most productive federal research agencies. The challenge is not scientific capability, it is coordination. These strengths too often operate independently rather than as an integrated national system. The United States

[4]BIOSECURE Act, enacted as Section 851 of the National Defense Authorization Act for Fiscal Year 2026, signed into law December 18, 2025; restricts federal agency contracting with designated Chinese biotechnology companies of concern.

should not replicate a centralized industrial model. Our comparative advantage has always been institutional diversity and entrepreneurial culture. The objective is to strengthen the connections among these institutions, not to replace them with new centralized structures. This is imperative at a time when the pace of scientific advances and opportunities are accelerating, and the US needs to capitalize on its inherent strengths. Maintaining America's biotechnology leadership is not guaranteed. It is a policy choice.

PART IV. THE NATIONAL TRANSLATIONAL BIOTECHNOLOGY INITIATIVE

America does not need another basic research program or an isolated commercialization initiative. The institutions responsible for research, translation, manufacturing, commercialization, workforce development, and investment too often operate independently rather than as an integrated enterprise. The NTBI addresses that problem directly: a national coordination and investment framework that aligns existing federal investments (including BARDA, ARPA-H, Manufacturing USA, and the National Institute for Innovation in Manufacturing Biopharmaceuticals) with state initiatives, regional partnerships, industry, philanthropy, and private capital to accelerate translation.

To be clear the NTBI is not a substitute for the National Institutes of Health, the National Science Foundation, or the other federal agencies whose basic research funding remains the foundation of American biomedical science. The NTBI does not compete with these agencies for appropriations, and it does not duplicate their mission. It begins where their funding ends, providing the translational capacity to carry NIH- and NSF-funded discoveries through the Valley of Death and into investable therapeutic opportunities. Put simply, the NTBI supplements the nation's basic research investment, it does not replace it.

Five principles should guide it. Public investment should catalyze private investment, not substitute for it. Regional excellence should drive national competitiveness. Federal policy should strengthen existing regional ecosystems (Boston, San Diego, the Bay Area, Research Triangle Park, Seattle, and emerging hubs like Indiana) rather than centralize innovation in a single location. Collaboration should be treated as a competitive advantage, encouraging universities, institutes, companies, health systems, manufacturers, investors, and government to act as integrated partners. Outcomes, not publications or patents, should drive investment decisions. And resilience, the capacity to respond rapidly to future pandemics, supply-chain disruptions, and biological threats, should be designed into the system from the outset.

Operationally, the NTBI should establish a competitive national network of Regional Biotechnology Translation Hubs, each building on existing regional strengths and collaborating through shared standards, workforce exchanges, and data sharing rather than competing with one another. It should be funded as a competitive public-private partnership where every federal dollar leverages matching commitments from states, industry, philanthropy, and private investors. Hub designation would require demonstrated scientific excellence, commercialization capability, workforce programs, and regional financial commitment. National coordination should run through a small strategic steering committee including federal agencies, universities, industry, investors,

states, and philanthropy. This group sets priorities and metrics while leaving operational control with the Hubs themselves.

The Finance Committee's own authorities are central to this effort. Tax policy can encourage domestic commercialization and manufacturing; public-private financing mechanisms can leverage private investment; Medicare and Medicaid policy can reward value-based innovation. Part V describes how.

PART V. SIX STRATEGIC PRIORITIES

Priority One. Build America's Translational Infrastructure

Objective: Expand the technical and operational capabilities that convert discoveries into investable, clinic-ready therapies including therapeutic innovation, AI-enabled platforms, human disease models, translational pharmacology, regulatory science, and advanced biomanufacturing. These capabilities should be treated as national research infrastructure, as prior generations treated national laboratories and clinical research networks, and funded through shared, broadly accessible facilities within the Regional Hubs.

Outcomes: more discoveries advancing into preclinical and clinical development; increased private co-investment; shorter development timelines.

Priority Two. Establish Regional Biotechnology Translation Hubs

Objective: Create a competitive national network of Hubs that integrate regional scientific, clinical, manufacturing, investment, and workforce capabilities, designated through a competitive process based on scientific excellence, public-private collaboration, and sustained financial commitment, with projects advancing through stage-gated milestone reviews modeled on pharmaceutical portfolio management.

Outcomes: more therapies entering development; increased startup formation; stronger regional economies.

Priority Three. Develop the Biotechnology Workforce of the Future

Objective: Build the multidisciplinary workforce needed to sustain leadership across discovery, development, manufacturing, clinical and commercialization, through internships, apprenticeships, industry rotations, and graduate fellowships anchored in the Regional Hubs.

Outcomes: expanded and more diverse workforce; stronger talent pipeline; improved regional retention.

Priority Four. Strengthen Domestic Biomanufacturing and Supply-Chain Resilience

Objective: Expand America's capacity to develop and manufacture critical medicines, diagnostics, biologics, and enabling technologies domestically, with Hubs working directly with manufacturing partners to seamlessly scale discoveries into commercial production.

Outcomes: increased domestic manufacturing capacity; reduced supply-chain vulnerability; greater pandemic preparedness.

Priority Five. Align Federal Incentives to Accelerate Commercialization

Objective: Use the Committee's own tools to keep taxpayer-funded discoveries developed and commercialized in the United States. Congress has already taken one important step. The One Big Beautiful Bill Act's new Section 174A permanently restored full, immediate expensing of domestic research and experimental costs, reversing the 2022 capitalization requirement that had penalized U.S.-based R&D.[5] That fix should be built on, not left as a one-time gain. I recommend the Committee consider extending comparable treatment to capital investment in domestic biomanufacturing facilities. The Committee should also examine matching-fund and co-investment structures that let federal dollars leverage state, philanthropic, and private capital in the Regional Hubs, and consider how Medicare and Medicaid payment policy can reward therapies that reduce downstream cost of care.

Outcomes: increased domestic development and commercialization; greater private-sector co-investment; higher return on taxpayer-funded research.

Priority Six. Measure Success Through Outcomes

Objective: Modernize how federal agencies evaluate biomedical investment. Publications and patents do not fully capture the public value of federal research spending. Agencies should adopt common metrics that include therapies entering clinical trials, INDs filed, startups formed, private capital leveraged, licensing activity, and Medicare/Medicaid costs avoided.

Outcomes: better accountability; improved resource allocation; a clearer measure of return on taxpayer investment.

CONCLUSION

These six priorities work as a single system: infrastructure enables discovery, Hubs connect institutions, workforce development supplies talent, biomanufacturing builds resilience, aligned incentives leverage private capital, and outcome metrics keep the system accountable. None of this requires a new federal bureaucracy, it requires connecting assets America already has at a moment when a rival nation is doing exactly that at national scale.

Maintaining American leadership in biotechnology is not inevitable. It is a policy choice, and the Finance Committee through its authority over tax policy, Medicare, and Medicaid, has tools no other committee holds to make that choice impactful. I welcome the Committee's questions and would be glad to work with the Committee and its staff as this framework is developed further.

[5]One Big Beautiful Bill Act, signed into law July 4, 2025; new Internal Revenue Code Section 174A permanently restores full, immediate expensing of domestic research and experimental expenditures for tax years beginning after December 31, 2024, reversing the five-year amortization requirement imposed by the 2017 Tax Cuts and Jobs Act. Foreign R&D expenditures remain subject to 15-year capitalization and amortization under Section 174.