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Bureau of Industry and Security Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

California Life Sciences (CLS) offers this submission in response to the request by the Department of Commerce for comments on section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients. This investigation presents a critical opportunity to examine the intricacies of biotechnology supply chains and chart a path forward that strengthens national resilience while keeping the United States at the forefront of scientific innovation. CLS is the state's leading advocacy organization for the life sciences and, on behalf of the over 1,300 organizations CLS represents, we appreciate the opportunity to provide input.

CLS and its members are committed to working with the administration to maintain U.S. leadership in biotechnology and enhance both national and economic security. As outlined in Section I, the biotechnology sector is a vital engine of the American economy—supporting millions of jobs and generating billions in economic output annually. The life sciences sector in California produces more than $275 billion in direct economic output and supports more than 1 million direct and indirect jobs.[1]

Biotechnology is also indispensable to national security. The sector enables rapid responses to pandemics, helps meet urgent healthcare needs, protects the food supply, and defends against bioterrorism threats. However, that leadership is not guaranteed. Without targeted action, the U.S. risks falling behind as geopolitical competitors make aggressive investments in biotechnology and biomanufacturing to challenge U.S. dominance in the global bioeconomy.

However, the biotechnology supply chain is inherently complex and globally integrated, and reshoring is a long-term, capital-intensive effort - often requiring 5 to 10 years (see Section II). As a result, immediate reshoring risks disrupting patient access and delaying critical research and development (R&D). As outlined in Section III, imposing tariffs would undermine—rather than advance—the goal of strengthening U.S. biomanufacturing. Instead of encouraging domestic investment, tariffs would raise production costs, delay expansion efforts, and place disproportionate pressure on small and emerging biotech companies that drive innovation. Operating with limited capital and tight development timelines, these firms cannot absorb additional financial burdens without jeopardizing critical R&D. Tariffs would also increase costs across the

[1] CLS. "Sector Report." (2023).
https://info.califesciences.org/hubfs/California%20Life%20Sciences%20Sector%20Report%202023.pdf

healthcare system, restrict access to essential and future therapies, and weaken U.S. competitiveness in the global bioeconomy.

To secure access to essential medicines, preserve U.S. biotech leadership, and unlock the full economic potential of the sector, CLS urges the administration to pursue a comprehensive manufacturing strategy. As outlined in Section IV, this strategy should include domestic reforms, such as expanding tax incentives, streamlining regulatory and permitting processes, and investing in workforce development, as well as international trade initiatives that strengthen partnerships with trusted allies and promote supply chain resilience. These policies will help scale U.S. biomanufacturing capacity while preserving the globally integrated systems on which innovation depends.

Where genuine vulnerabilities in the supply chain exist, the solution must be collaborative and strategic. The COVID-19 pandemic highlighted the importance of secure, reliable supply chains in the face of geopolitical, environmental, and other disruptions. But meaningful progress requires thoughtful, long-term reform. CLS stands ready to work with the administration to identify and address these vulnerabilities through targeted, effective solutions.

CLS and its members are committed to working closely with the administration to ensure the U.S. remains the global leader in biotechnology—protecting patients, driving economic growth, and advancing national security.

I. Biotechnology is a Strategic Imperative for Economic and National Security

Biotechnology is foundational to America's national security and economic security. Since the turn of this century, the U.S. has developed and expanded its global leadership in biopharmaceutical innovation and production, thanks to robust intellectual property protection, substantial investments in bioscience and pro-innovation healthcare systems. Biotechnology's importance includes ensuring public health, pandemic preparedness, defense against biological threats and safeguarding food systems. Given its far-reaching implications for national security and economic stability, it is essential that any policy affecting the biotech sector is crafted with strategic foresight - ensuring that actions meant to strengthen security do not inadvertently harm patients, disrupt innovation, or compromise America's long-term security and prosperity.

Economic Security

The biotech sector is a critical engine of the American economy - supporting millions of jobs and generating billions in economic output annually. In 2023, the bioscience industry employed nearly 2.3 million people in the U.S. and generated an economic output exceeding $1.68 trillion.[2] The U.S. leads the world in biotech innovation. The country is home to the largest concentration of small biotech firms - more than 80% of U.S. biopharmaceutical companies are considered small or emerging - demonstrating that

[2] **BIO and TEConomy Partners**. *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy, 2023*. Biotechnology Innovation Organization, 2023.
[Available at: https://www.bio.org/value-bioscience-innovation]

innovation is being driven by a vibrant base of entrepreneurial firms.[3] A significant share of new therapies and vaccines are launched first in the U.S., granting American patients' early access to groundbreaking medicines. The nation's global leadership has been reinforced by its strong participation in a rules-based international trading system - one that values innovation, protects intellectual property rights, and enables open trade. Maintaining this framework is essential to sustaining U.S. competitiveness and ensuring continued access to life-saving technologies.

National Security: Biodefense, Crisis Response, and Protecting the Food Supply

Biotechnology is our first line of defense against biological threats - both natural and man-made. Tools such as synthetic biology, rapid diagnostics, and platform technologies have enabled the U.S. to quickly detect pathogens, develop life-saving medical countermeasures, and scale up biomanufacturing during times of crisis. Operation Warp Speed (OWS) was a clear demonstration: thanks to robust biotech infrastructure and the unprecedented public-private partnership, the United States led the world in COVID-19 countermeasure development and deployment, which saved millions of lives and enabled rapid economic recovery.

Equally urgent is the threat of zoonotic disease – roughly 75% of emerging infectious diseases in humans originate from animals.[4] Preventing zoonotic spillover is not only a public health priority, but also a matter of economic and national security. A major outbreak of animal disease could lead to massive animal culling, export bans, food supply chain disruptions, and consumer panic. Animal vaccines can prevent outbreaks before they start. The animal health industry underpins more than $600 billion of economic activity in the United States, supporting critical, and primarily rural-based, sectors such as meat production, meat and dairy processing, veterinary services, and pet services.[5] In addition, the industry contributes over $1.5 billion annually in U.S. tax revenue and invests more than $1 billion domestically each year in research and development.[6] Proactive investment in biotech innovation, especially for animal health products with veterinary applications, is critical to securing the food supply and avoiding these high-cost scenarios.

II. Why a Strategic Approach is Needed: The Complexity of the Biotechnology Supply Chain and Business Model & The Challenge of Reshoring

The U.S. biotechnology sector depends on a highly complex, interdependent global supply chain. Disruptions at any point, whether logistical, regulatory, or geopolitical, can jeopardize patient access to life-saving therapies and undermine the innovation ecosystem that drives the sector. From sourcing raw materials to securing regulatory approvals, each stage relies on a precisely coordinated and validated network. While reshoring portions of this supply chain is possible, it cannot happen overnight. It is a time-intensive and resource-heavy process, complicated by regulatory, logistical, and economic challenges. These realities underscore the need for a long-term, strategic approach to strengthening U.S.

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[3] **BIO and TEConomy Partners**. *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy, 2023*. Biotechnology Innovation Organization, 2023.
[Available at: https://www.bio.org/value-bioscience-innovation]

[4] **Centers for Disease Control and Prevention (CDC).** "One Health: About Zoonotic Diseases." *Centers for Disease Control and Prevention*, 2023.
https://www.cdc.gov/one-health/about/about-zoonotic-diseases.html

[5] Pham, N., & Donovan, M. (2022). *The Economic and Social Contributions of the Animal Health Industry*. ndp | analytics. Retrieved from https://ahi.org/animal-health-industry/

[6] Ibid.

biomanufacturing - one that combines domestic investment with sustained partnerships among trusted international allies.

Reinforcing a Complex and Globally Integrated Biopharmaceutical Supply Chain

The biopharmaceutical supply chain includes far more than the production of finished medicines. It encompasses a vast ecosystem of specialized inputs, components, and equipment. In addition to APIs, companies must source other materials, including precursor chemicals, reagents, enzymes, growth media, and lab equipment. In addition, biopharmaceutical companies rely on a range of highly engineered materials like sterile vials, stoppers, syringes, bioreactor bags, filtration systems, cold chain packaging, and capital equipment like bioreactors and chromatography systems. Reliable access to all of these components is essential for maintaining a resilient and responsive manufacturing base.

Notably, most medicines consumed in the United States are already made in the United States. Nearly two-thirds of U.S. pharmaceutical consumption is manufactured domestically across more than 1,500 facilities nationwide.[7] For inputs and finished products that are imported, the majority come from longstanding allies. In 2023, 90% of U.S. imports of biopharmaceutical products—including finished drugs, APIs, and critical inputs—originated from allied nations, with the EU, UK, and Switzerland alone accounting for 73%.[8] While 28% of the APIs used in the U.S. are produced domestically, additional supply comes from the EU (26%), India (18%), China (13%), and others.[9]

As the U.S. works to strengthen domestic capacity, it must also secure reliable access to the global infrastructure that supports modern biopharmaceutical manufacturing. For certain products such as synthetic DNA, a domestic supplier that offers high quality, cost-competitive products is immediately available. Nonetheless, the supply chain's resilience depends on both expanding U.S. capabilities and maintaining trusted international partnerships.

However, vulnerabilities do exist - particularly where there is overdependence on countries of concern for a limited number of essential medicines and APIs. Addressing these national security risks will require strategic collaboration between government, industry, and allies. Where this investigation identifies specific products tied to overreliance on problematic sources, the U.S. biopharmaceutical industry is committed to partnering with the government to develop targeted, sustainable solutions. A more effective approach lies in the strategic policy recommendations outlined in Section IV, which offer a path forward to expand and modernize domestic biomanufacturing capacity while preserving patient access and global competitiveness.

Tariffs, however, are not a viable solution. Rather than resolving these vulnerabilities, tariffs would increase production costs, disrupt supply chains, and delay research and development—ultimately harming patients.

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[7] **Pharmaceutical Research and Manufacturers of America (PhRMA).** (2022, July 17). *Biopharmaceutical manufacturing companies continue to expand their economic footprint across the United States*. Retrieved from https://phrma.org/blog/biopharmaceutical-manufacturing-companies-continue-to-expand-their-economic-footprint-across-the-united-states

[8] **Ernst & Young. (**2025, April 22). *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry*. Pharmaceutical Research and Manufacturers of America (PhRMA). Retrieved from https://www.ey.com/en_us/insights/life-sciences/why-the-trump-pharma-import-inquiry-is-pivotal

[9] Ibid.

Reshoring Biomanufacturing: Long Timelines and High Capital Requirements

Reshoring biomanufacturing is not as simple as building new facilities - it is a long, capital-intensive, and highly regulated process. Establishing or expanding biomanufacturing capacity requires companies to weigh whether to build a new site, expand an existing one, or contract with a CDMO (Contract Development and Manufacturing Organization). Each option involves years of planning and significant investment. New facilities can cost up to $2 billion and take five to ten years to become fully operational, reflecting the time needed for permitting, regulatory compliance, workforce development, and infrastructure construction. [10] Currently, U.S. domestic capacity for manufacturing finished products - and especially for producing inputs, lab equipment, and components - falls short of what would be needed to reshore effectively in the near term without risking disruptions to patient care and scientific progress.

Small and emerging biotech companies, which drive much of the sector's innovation, typically do not have the capital to build or operate their own manufacturing facilities. These firms rely heavily on CDMOs to advance their products through clinical development and into production. Ensuring a robust domestic CDMO ecosystem is critical, as many of these firms face difficult decisions about allocating scarce capital—either toward advancing their pipeline or investing in manufacturing infrastructure. Without adequate U.S.-based CDMO capacity, promising technologies risk delay, discontinuation, or acquisition by foreign entities, resulting in the loss of both innovation and strategic advantage.

While large companies often build and operate their own sites or enter into long-term CDMO partnerships, even they must navigate a range of complex requirements. Federal, state, and local permitting can take several years.[11] Facilities must comply with Good Manufacturing Practices (GMP), incorporate HEPA-filtered cleanrooms, validated equipment, and tightly controlled production environments. The regulatory approval process includes extensive reviews by agencies such as the Food and Drug Administration (FDA), Environmental Protections Agency (EPA), Occupational Safety and Health Administration (OSHA), and Drug Enforcement Agency (DEA), and site inspections can cause further delays, especially amid a shortage of federal inspectors. Technology transfer to new sites requires pilot runs and process validation that can take more than a year to ensure quality and consistency.

Manufacturing planning also involves developing a secure, reliable supply chain. Companies must source high-quality raw materials, identify backup suppliers for redundancy, and create risk mitigation plans for disruptions such as natural disasters. As clinical trials progress, firms must prepare to scale up production to meet FDA standards for commercial manufacturing - a process that requires both time and technical precision. This scale-up phase also depends on the availability of a skilled workforce and the implementation of robust quality control and testing systems to protect patients and ensure regulatory compliance.

Workforce shortages present a major constraint. The U.S. biomanufacturing sector currently has over 60,000 unfilled positions, including critical roles such as bioprocess engineers and quality assurance

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[10] **Pharmaceutical Research and Manufacturers of America. (n.d.).** *Manufacturing*. PhRMA. https://phrma.org/en/policy-issues/Research-and-Development/Manufacturing#:~:text=Setting%20up%20the%20manufacturing%20capacity,comply%20with%20various%20regulatory%20requirements.

[11] Friedman, Yali. *Building Biotechnology*. Washington, DC: Logos Press, 2014.

specialists. [12] Hiring and training talent takes time, and wages are significantly higher in the U.S. than in lower-cost manufacturing regions. For example, an entry-level bioprocess engineer earns $75,000–$95,000 annually in the U.S., compared to just $15,000–$21,000 in China.[13] While expanding domestic employment is a long-term goal, in the short term, higher labor costs will require greater capital investment—especially challenging for small and mid-sized companies operating in a difficult funding environment.

Other structural costs also limit reshoring. U.S. facilities face higher operational expenses due to stringent environmental regulations, energy costs, and water use. Producing just one kilogram of a protein-based therapeutic, for example, may require up to 30,000 kilograms of water - an input that is considerably more expensive in the U.S. than in countries like China.[14] Environmental permitting alone can take several years, further extending timelines and deterring investment.

Together, these realities illustrate why reshoring biomanufacturing is a long-term challenge that requires a coordinated and strategic approach. Public-private investment, regulatory streamlining, workforce development, and support for domestic CDMO growth will be critical to building the robust, resilient manufacturing base the U.S. needs - without jeopardizing patient access or stalling scientific innovation in the interim.

The Unique Challenges of the Biotech Business Model

Biotech innovation comes with extraordinary risks. Developing a single therapy can cost as much as $2.6 billion and take more than a decade.[15] Despite these investments, nearly 90% of drug candidates fail during the clinical trial stage of development.[16] Much of this work is driven by small, pre-commercial companies that operate with limited funding and face significant uncertainty. These firms are the engine of innovation in the sector, but their success depends on continued access to capital and a stable policy environment that supports early-stage research.

And these companies are operating in an increasingly difficult funding environment, making it harder to attract the investment needed not only for research and development, but also for manufacturing. In the first quarter of 2025, only 55 U.S. biotech startups secured initial funding - the lowest figure in a decade and just 35 received early-stage financing, marking a reversion to pre-pandemic levels.[17] Broader market indicators reflect deep distress: the SPDR S&P Biotech ETF (XBI) is down 20% year-to-date, and 25% of Nasdaq Biotech Index firms now trade below cash levels, signaling severe strain.[18] Merger and acquisition activity has also slowed significantly, reminiscent of the 2008 financial crisis.[19] In this constrained capital

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[12] Labiotech.eu. (2023, August 23). *Addressing the skilled labor shortage in the biopharma industry*. https://www.labiotech.eu/opinion/skilled-labor-shortage-biopharma/

[13] **U.S. Bureau of Labor Statistics (BLS) and Zhaopin Talent Reports.** "Skilled Labor Shortage in Biopharma."

[14] Friedman, Yali. *Building Biotechnology*. Washington, DC: Logos Press, 2014.

[15] **Tufts Center for the Study of Drug Development**. *Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion*. Tufts University, 2016.
[Available at: https://csdd.tufts.edu/news/complete-story/pr-tufts-csdd-study-estimates-average-cost-to-develop-and-win-marketing-approval-for-a-new-drug-is-2-6-billion]

[16] **Biotechnology Innovation Organization (BIO),** Biomedtracker, and Amplion. *Clinical Development Success Rates 2006–2015*. BIO, 2016.
[Available at: https://www.bio.org/clinical-development-success-rates-2006-2015]

[17] Ibid.

[18] "SPDR S&P Biotech ETF (XBI) Stock Price, News, Quote & History." *The Wall Street Journal*, https://www.wsj.com/market-data/quotes/etf/XBI. Accessed 23 Apr. 2025.

[19] **Reuters.** (2025, April 16). Biotech M&A activity slows as deal discussions face delays.

environment, companies are facing increasingly difficult decisions about where to allocate limited resources, whether to sustain R&D, secure manufacturing partnerships, or invest in new production infrastructure, further underscoring the need for supportive policy and investment frameworks.

Certain sectors within biotechnology, particularly those focused on rare diseases, face even greater challenges. Developing therapies for small, often geographically dispersed patient populations is inherently costly and complex. Clinical trials for these conditions are notoriously difficult to enroll and frequently depend on international collaboration. While incentives like the Orphan Drug Act have played a vital role in encouraging innovation - resulting in the approval of over 800 orphan drugs in the U.S. - the underlying economic model remains fragile.[20] This is especially true for the 85% of orphan-designated products in clinical development that originate from small and emerging companies. These firms are especially vulnerable to rising supply chain costs and often have limited flexibility in sourcing the specialized materials required for rare disease R&D.[21] Maintaining a stable and supportive policy environment is therefore essential to sustaining progress in this high-need, high-risk area of innovation.

Vaccine development also presents a high-risk investment because vaccines are developed to target individual specific pathogens. High development costs approaching $1 billion per vaccine, coupled with limited commercial markets and lower pricing contribute to underinvestment. Further, vaccines often require larger, global clinical trials, sophisticated storage, cold chain logistics, and access considerations that compound the challenge.

III. Tariffs Will Weaken U.S. Biotechnology Leadership

Tariffs are often framed as a tool to protect domestic industries and reduce foreign dependency. However, in the context of the biotechnology sector—a field defined by long development timelines, high upfront costs and deep global integration- tariffs would have unintended and far-reaching consequences. Rather than strengthening the U.S. biotech industry, tariffs would increase production costs, disrupt research and clinical development, limit access to medicines, and slow the growth of domestic manufacturing. In practice, tariffs would weaken America's global biotechnology leadership.

Tariffs Mean Less Capital to Bring Manufacturing Back to America

Tariffs on biopharmaceutical imports would significantly increase costs across the entire drug development lifecycle and directly undermine efforts to expand domestic biomanufacturing. The United States currently lacks sufficient biotechnology manufacturing capacity, and as described earlier, building new facilities requires substantial capital and long lead times. Strengthening domestic production will depend not only on expanding company-owned manufacturing sites but also on supporting the growth of CDMOs.

However, tariffs would make it more difficult for companies to invest in U.S. manufacturing by driving up production costs. A 25% tariff on the sector could impose more than $50 billion in additional costs,

[20] **U.S. Food and Drug Administration (FDA)**. *Orphan Drug Act: 800 Orphan Drugs Approved in the U.S.* 2023. [Available at: https://www.fda.gov/industry/biologics-marketplace/orphan-drug-designation]

[21] Thomas, D., & Wessel, C. (2019). *2019 Emerging Therapeutic Company Trend Report*. Biotechnology Innovation Organization. https://go.bio.org/rs/490EHZ999/images/BIO%202019%20Emerging%20Company%20Trend%20Report.pdf

including up to $15 billion specifically for inputs.[22] [23] Instead of accelerating reshoring, these burdens would divert capital away from building new domestic facilities as companies struggle to absorb tariff-related expenses.

Further compounding the challenge, retaliatory tariffs on U.S. biopharmaceutical exports could reduce global revenues and weaken the financial health of U.S.-based companies, further limiting their capacity to invest in domestic production. The result would be a loss of competitiveness and fewer incentives to expand U.S. manufacturing operations. To truly strengthen domestic capacity, a strategic approach is needed—one that combines targeted incentives, public-private partnerships, and international cooperation

Tariffs Threaten Patient Access, Drug Development and Clinical Trials

Tariffs on biopharmaceutical imports would ultimately harm patients by driving up the cost of both critical inputs and finished therapies. These added costs would ripple through the healthcare system - raising overall healthcare spending, increasing the risk of drug shortages, and disrupting the clinical trial pipeline. Tariffs would also slow the pace of research and development by making it more expensive to access the specialized materials needed for innovation. Historically, the U.S. has exempted pharmaceuticals from tariffs to protect public health and uphold ethical commitments to patient care—principles that remain just as urgent today.

Tariffs would also exacerbate supply chain vulnerabilities and delay access to life-saving medicines. As seen during the COVID-19 pandemic, even temporary disruptions can trigger cascading bottlenecks as manufacturers scramble to secure raw materials. Tariffs could replicate this dynamic by inflating demand and straining logistics networks, resulting in empty shelves and delivery delays. Products held at the border due to customs misclassification, documentation issues, or inspections may miss critical delivery windows. For temperature-sensitive items—such as vaccines, insulin, and cell or gene therapies—even brief delays can result in spoiled or unusable shipments. These same risks apply to clinical inputs like reagents and cell cultures shipped on dry ice, which are vital to ongoing research and clinical trial progress.

Beyond access challenges, tariffs would significantly curtail the industry's ability to invest in research and development—delaying the development and delivery of new treatments to patients who need them most. Added costs could force companies to delay or cancel trials and scale back on the development of promising technologies. Early-stage clinical research, particularly Phase I and II trials, would be especially impacted. These studies rely on small-batch, time-sensitive production using highly specialized inputs that are often unavailable domestically at the necessary quality or scale. Because many of these therapies may not advance to market, companies must operate with agility and cost discipline. Tariffs on these components would increase development costs, delay timelines, and make it more difficult for small and mid-sized firms to advance therapies.

Patients with rare diseases or complex conditions would be among the most severely affected. Many therapies, particularly orphan drugs, are produced in single facilities abroad, often in allied nations such as

[22] Lee, S. (2025, April 11). *How tariff regulations reshape global pharmaceutical drug pricing*. Number Analytics. Retrieved from https://www.numberanalytics.com/blog/tariff-regulation-pharma-pricing

[23] **Ernst & Young. (**2025, April 22). *Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry*. Pharmaceutical Research and Manufacturers of America (PhRMA). Retrieved from https://www.ey.com/en_us/insights/life-sciences/why-the-trump-pharma-import-inquiry-is-pivotal

the EU, due to their limited patient populations. Tariffs on these products could jeopardize both affordability and access.

To support early-stage research, the Harmonized Tariff Schedule of the United States (HTSUS) includes provisions such as subheading 9817.85.01, which exempts prototypes used in research, development, and clinical trials from tariffs and Merchandise Processing Fees. These exemptions enable companies to access the materials necessary for R&D without unnecessary cost or delay. In comparison, the European Union provides broad duty-free treatment for clinical trial inputs, offering a more supportive policy environment. Recognizing the need to strengthen U.S. competitiveness, Congress passed the Product Development and Testing Act (PDTA) to expand tariff exemptions and reinforce domestic R&D capacity. Any Section 232 action that undermines these provisions would dismantle a carefully constructed framework designed to drive innovation, support early-stage development, and protect patient access.

Ceding U.S. Biotechnology Leadership

Rather than strengthening the U.S. biotechnology sector, tariffs would weaken it - placing American firms at a global disadvantage at a time when leadership in this field is strategically vital. Reshoring biomanufacturing capacity takes years of sustained investment and planning, yet the cost burdens imposed by tariffs would be immediate. By increasing the price of essential imports—ranging from inputs to finished therapies—tariffs would strain already limited resources, particularly for small and mid-sized companies that drive much of the sector's innovation. The result would be slower R&D progress, reduced competitiveness, and diminished capacity to respond to emerging public health threats.

The consequences extend beyond lost economic opportunity—they carry serious national security implications. As U.S. firms face rising production costs, foreign competitors, particularly those backed by state-led industrial strategies, stand ready to fill the gap. China's "Made in China 2025" initiative explicitly targets global leadership in biopharmaceuticals through massive subsidies, technology acquisition, and long-term strategic investment. If American companies are forced to scale back due to tariff-induced pressures, we risk ceding both market share and technological leadership to geopolitical rivals - undermining U.S. economic security and global influence in one of the most critical industries of the 21st century.

National Security Consequences and Public Health Risks

Tariffs on biotechnology inputs would pose a direct threat to U.S. public health and national security. Rapid and reliable access to vaccines, antibiotics, and medical countermeasures is essential during pandemics, disease outbreaks, or bioterrorism events. Tariff-driven delays or cost increases could hinder emergency response efforts and limit the availability of life-saving therapies when they are needed most. These risks extend to military readiness, as service members—whether deployed abroad or stationed at home—may require immediate access to vaccines for weaponized pathogens or treatments for chemical and radiological exposures.

The implications are equally serious for the agricultural sector. Delays in the availability of animal vaccines could heighten the risk of zoonotic disease transmission, trigger food shortages, and destabilize critical supply chains. Moreover, access to many frontline medicines is already under strain. As of mid-2024, antimicrobial shortages are 42% more likely than shortages in other drug categories, and 37 antibiotics are

currently in limited supply. [24] Vaccines and antibiotics already face fragile economic models due to low pricing and erratic demand. Introducing new cost burdens through tariffs could drive more companies out of these markets altogether—severely weakening U.S. health infrastructure and undermining the nation's ability to respond to future crises.

IV. Policy Recommendations: How to Secure Biotech and National Security

Medium-Term Strategy Rooted in Resilience, Not Retaliation

Securing the U.S. biotechnology sector requires a proactive, partnership-driven strategy. While well-intentioned, tariffs and other retaliatory trade actions could unintentionally harm U.S. patients and companies, many of whom rely on globally integrated supply chains. Instead, a forward-looking strategy must focus on building domestic resilience while deepening cooperation with trusted international partners.

Industry collaboration will be essential to designing solutions that are both economically viable and operationally effective. A formal public-private mechanism, such as a biomanufacturing consortium, could provide the structure needed to align industry expertise with national policy goals and ensure that incentives and programs are targeted for maximum impact. Biopharmaceutical companies are also ready to partner with the U.S. government to identify and address vulnerabilities in the supply chain where they exist.

To succeed, this effort must go beyond supporting drug developers alone. A resilient biotechnology base depends on the full ecosystem, including CDMOs, Contract Research Organizations (CROs), and specialized suppliers of chemicals, lab equipment, and biologics inputs such as APIs. Strengthening U.S. capacity also means reshoring or nearshoring upstream production of critical manufacturing infrastructure, including single-use systems, bioprocessing equipment, and sterile vials.

The policy recommendations below are designed to catalyze private investment, reduce structural barriers, and build long-term competitiveness for the U.S. biomanufacturing sector - securing not just innovation, but also national health and security.

1. Support Domestic Manufacturing and Services Ecosystem

To build a resilient and competitive biotechnology sector, the United States must reinforce its domestic manufacturing base and the interconnected network of service providers that enable innovation and scale. A strong biomanufacturing ecosystem - encompassing everything from contract manufacturers and research partners to suppliers of specialized inputs, such as APIs and their inputs - requires targeted policy support to overcome capital barriers, mitigate market volatility, and build a skilled workforce.

The following policy mechanisms are designed to stimulate investment, expand capacity, and ensure that critical capabilities remain within U.S. borders.

Key policy mechanisms include:

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[24] Goldstein, David. "Why We Have Antibiotic Shortages and Price Hikes, and What One Very Enterprising Doctor Did in Response." *HIV & ID Observations*, 8 Oct. 2024, blogs.jwatch.org/hiv-id-observations/index.php/why-we-have-antibiotic-shortages-and-price-hikes-and-what-one-very-enterprising-doctor-did-in-response/2024/10/08/. Accessed 23 Apr. 2025.

- **Reauthorize Tax Cuts and Jobs Act (TCJA):** The 2017 TCJA spurred manufacturing investment, with capital spending increasing by 4.5% in 2018 and 5.7% in 2019. [25] To maintain this momentum, Congress should extend key TCJA provisions, including the 21% corporate tax rate, repatriation of overseas profits, and accelerated depreciation of capital expenditures. These measures reduce the cost of capital and encourage companies to invest in U.S.-based manufacturing infrastructure.

- **Expand and Modernize Corporate Tax Incentives:** Strengthen the federal R&D Tax Credit by restoring full expensing under Section 174 and expanding eligibility for start-ups and small businesses. Introduce additional incentives to offset the higher costs of domestic manufacturing, including:
    - Patent boxes and enhanced orphan drug tax credits
    - Tax benefits for domestic biomanufacturing income
    - Infrastructure-related tax incentives (e.g., bonus depreciation)
    - Bonus access to Net Operating Losses (NOLs) for U.S. manufacturing investments
    - Lower sales tax rates for manufacturing equipment and inputs.

  All incentives should be retroactive to include companies that have invested in U.S. biomanufacturing over the past decade.

- **Provide Access to Low Interest Loans:** Given the high cost of construction of biomanufacturing facilities, the U.S. government could offer low-interest loans, such as those offered by the U.S. International Development Finance Corporation, to assist companies looking to increase domestic manufacturing. Many foreign nations, such as Spain, offer similar incentives to reduce the massive capital expenditure required to build a manufacturing facility.[26]

- **Market Stabilization Tools:** Long-term pricing agreements and volume guarantees can reduce investment risk and ensure predictable demand for essential inputs and finished products. These tools are especially important in markets with volatile pricing and uncertain purchasing cycles.

2. Reinforcing and Expanding Global Trade Cooperation

Securing the U.S. biopharmaceutical supply chain requires expanding global collaboration. Strengthening partnerships with long-standing trading partners will enable U.S. companies to share manufacturing costs, reduce duplication, secure diversified inputs, and meet both domestic and global demand. These partnerships also ensure protections for U.S. intellectual property, regulatory agreements, and commercial relationships. The March 2025 National Security Commission on Emerging Biotechnology (NSCEB), chaired by Senator Todd Young (R-IN), highlighted the importance of "cross-border collaborations with allies and partners," including trade agreements that expand market access, address regulatory bottlenecks, and stimulate demand for biotechnology products.[27]

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[25] Salamido, G. J. (2025, April 1). *NC's place as No. 1 state for manufacturing under threat if 2017 tax cuts expire*. Carolina Journal. Retrieved from https://www.carolinajournal.com/opinion/if-2017-tax-cuts-expire-ncs-place-as-no-1-state-for-manufacturing-under-threat/

[26] Bloomberg News. (2025, April 2). *How Spain attracted investment from pharma giants AstraZeneca, Novartis, Roche*. Bloomberg. https://www.bloomberg.com/news/articles/2025-04-02/how-spain-attracted-investment-from-pharma-giants-astrazeneca-novartis-roche

[27] National Security Commission on Emerging Biotechnology. (2025, April). *Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity*. Retrieved from https://www.biotech.senate.gov/final-report/chapters/

Key Recommendations:

- **Recognize and strengthen current supply chain relationships**, particularly for APIs and essential manufacturing inputs, many of which are sourced from facilities in Europe and other allied nations.
- **Coordinate with partners to identify vulnerabilities** in the global supply chain and ensure strategic access to critical raw materials and biomanufacturing components.
- **Leverage trade negotiations** to:
    - Eliminate unfair trade practices, including inadequate IP enforcement
    - Expand market access for U.S. manufacturers
    - Secure commitments to transparent and science-based regulatory systems
- **Deepen regulatory and manufacturing cooperation** with key allies by:
    - Aligning quality and safety standards
    - Facilitating joint investment in infrastructure and innovation
    - Developing shared approaches to R&D support and scale-up capacity
- **Negotiate new bilateral and sectoral trade agreements** with trusted partners (e.g., EU, UK, Japan, South Korea, Switzerland, India, Canada) to:
    - Eliminate tariffs on biopharmaceuticals and inputs
    - Strengthen IP protections and enforcement
    - Promote fair and equitable market access
    - Establish good regulatory practices and mutual recognition frameworks
- **Build on existing agreements like the United States-Mexico-Canada Agreement (USMCA)** to reinforce biopharmaceutical trade priorities, particularly IP standards and expedited regulatory pathways.

3. Workforce Development

Investing in the current and future workforce is critical to supporting advanced biomanufacturing operations. A strong domestic biomanufacturing ecosystem requires a diverse set of skills—from manufacturing operations and quality control to biomanufacturing construction and R&D. These roles span a wide range of educational backgrounds, including technical certifications, associate and bachelor's degrees, and terminal degrees such as PhDs.

Education and Training Pathways

- **Enhancing STEM Education:** A stronger emphasis on science and associated trades in the U.S. education system is essential for building long-term capacity. Expanding graduate fellowships and increasing investment in two- and four-year degree programs would help strengthen the pipeline.

- **Community College Programs:** Special attention should be given to two-year programs at community colleges, particularly those focused on manufacturing operations and quality control. Models like Ireland's National Institute for Bioprocessing Research and Training (NIBRT), and its counterpart K-NIBRT in South Korea, demonstrate how targeted training centers can efficiently prepare a skilled workforce. Since its founding in 2011, NIBRT has trained over 50,000 individuals.[28]
- **Retraining the Existing Workforce:** Upskilling workers from adjacent sectors, such as traditional factory and manufacturing roles, into biomanufacturing positions would help quickly meet labor needs and expand talent pools.

Incentives and Support Mechanisms

To support workforce growth and development, several strategies should be considered:

- **Employer incentives:**
    - Tax credits for companies offering tuition coverage or in-house training programs
    - Bonus payroll tax credits for workforce development activities
- **Federal and state investments:**
    - Expanded public grants and public-private partnerships for terminal degrees (M.D./Ph.D.) in critical fields
    - Targeted loan forgiveness programs to attract students into biomanufacturing and life sciences
    - NIH funding for private-sector postdoctoral positions
- **Curriculum development and standardization:**
    - National certification programs focused on core biomanufacturing skills
    - Standardized, multi-sector curricula for non-PhD technical training
    - Promotion of relevant associate and vocational degrees through community colleges

Geographic Workforce Challenges

CDMOs and biopharmaceutical companies often face difficulties recruiting skilled workers to non-traditional biotech hubs. Federal and state governments can play a vital role by offering targeted incentives to attract and retain talent in diverse geographic regions across the country.

4. Expedite Regulatory and Permitting Pathways

Regulatory and permitting reform at the local, state, and federal levels is essential to accelerating domestic biomanufacturing. Biopharmaceutical manufacturers support commonsense reforms that uphold environmental protections and public health while enabling timely facility construction and production

[28] **National Institute for Bioprocessing Research and Training.** (2025, April 11). *NIBRT publishes Annual Report 2024*. Retrieved from https://www.nibrt.ie/nibrt-publish-annual-report-2024/

scale-up. The current regulatory process is often lengthy and costly—one 2022 study estimated that federal regulations alone impose a $350 billion annual burden on manufacturers, with small companies disproportionately affected.[29] To strengthen domestic capacity, governments should streamline inspections, environmental assessments, and permit approvals. Puerto Rico offers a successful model, having implemented a fast-track permitting system that spurred manufacturing growth. By reducing red tape, requiring timely agency decisions, and curbing unnecessary litigation, policymakers can create a more efficient regulatory environment that promotes investment, job creation, and U.S. biomanufacturing leadership.

5. Improve Access to Capital

The ability to fund early research is crucial for fostering innovation in the biotech and pharmaceutical sectors. While the current system already allows for relatively swift movement from university research laboratories to funded startups, we should continue to ensure access to seed funding through grants, angel investors, and venture capital specifically targeting early-stage biotech companies that can help bridge the gap between research and product development. Programs like the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) provide vital initial funding. Bipartisan legislation that passed the House in the 118th Congress would promote capital formation for early-stage innovators. H.R. 2797, the Equal Opportunity for All Investors Act, would expand the accredited investor definition to emphasize the ability to evaluate investment risk and H.R. 2792, the Small Entity Update Act, would reform public float thresholds—reflecting the existing economic realities of small companies and current market definitions. These initiatives are essential to bridge the gap between research and commercial readiness.

6. Develop Regional Manufacturing Hubs

To spread the benefits of biotech investment nationwide, federal and state governments should incentivize the creation of regional biomanufacturing hubs. These centers can anchor ecosystems of innovation, workforce development, and local supply chain resilience. An example of a program that could be leveraged for building additional biotechnology manufacturing capacity is the Tech Hubs Program through the U.S. Economic Development Administration.[30] Six of the thirty-one sites are already designated for biotechnology manufacturing, and the knowledge and best practices learned through the development of these hubs could be used to build out additional infrastructure. To further incentivize investment, the Administration could consider designating specific regions as biomanufacturing zones -similar to the Opportunity Zones framework from President Trump's first term—tailored specifically to the needs of the biotechnology industry.

7. Strategic Technology Leadership

Next-generation technologies like artificial intelligence, automation, and molecular engineering are poised to revolutionize biotechnology innovation. These tools enable faster drug discovery, more efficient manufacturing, real-time data analysis in clinical trials, and the design of novel therapeutics that were previously unimaginable. The nation that leads in deploying these technologies will not only dominate the future of biotech but also shape the trajectory of adjacent strategic sectors—such as defense, agriculture,

[29] **National Association of Manufacturers.** (2023). *The Cost of Federal Regulation to the U.S. Economy, Manufacturing and Small Business*. Retrieved from https://nam.org/wp-content/uploads/2023/11/NAM-3731-Crains-Study-R3-V2-FIN.pdf

[30] **U.S. Economic Development Administration.** (n.d.). *Regional Technology and Innovation Hubs (Tech Hubs)*. Retrieved May 6, 2025, from https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs

energy, and advanced materials. To secure U.S. leadership, the federal government should invest in smart manufacturing infrastructure, create national centers of excellence to accelerate innovation, and cultivate a skilled workforce equipped to apply these technologies. Strong intellectual property protections will also be essential to safeguarding U.S. innovation and maintaining a competitive edge.

To truly safeguard national security, we must recognize biotechnology as a driver of economic growth and innovation and as a cornerstone of American strategic strength. CLS urges the administration to partner with the biotech industry in a deliberate, informed approach—one that continues to accelerate domestic capacity while preserving the global partnerships that have enabled life-saving breakthroughs. With smart policy, public-private collaboration, and sustained investment, we can fortify the biotech supply chain, ensure continued patient access to critical therapies, and maintain U.S. leadership in the life sciences for generations to come.

Thank you for the opportunity to respond to your request for information. CLS welcomes any questions and further discussion on the topics above, and you can contact me at bfisk@califesciences.org.

Sincerely,

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