Biocom California

May 7, 2025

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

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (BIS-2025-0022)

Submitted electronically

Dear Sir/Madam:

Biocom California appreciates the opportunity to offer comments on the national security investigation of imports of pharmaceuticals and pharmaceutical ingredients (XRIN 0694-XC120 Pharmaceuticals 232 Notice)[1].

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates over $414 billion in annual economic output, supports 1.24 million jobs, and produces $128.6 billion in labor and sole proprietor income[2].

Biocom California shares the Department of Commerce's interest in protecting our country's national security and ensuring that our pharmaceutical supply chain remains strong and stable. While we support efforts to incentivize domestic manufacturing, we are concerned that trade policies that would restrict imports of pharmaceutical products and pharmaceutical ingredients would not facilitate re-shoring pharmaceutical manufacturing and could, instead, significantly harm U.S. drug development, increase patient costs, and disrupt essential supply chains, ultimately weakening national security. Indeed, the U.S. maintains a symbiotic relationship with many foreign nations, most of which are trusted U.S. allies and non-adversarial partners, whose supply of pharmaceutical products plays an integral role in maintaining the strength and stability of the U.S. drug supply chain and meeting domestic demand. We appreciate the opportunity to provide comments on the Section 232 investigation.

[1] Federal Register, 90 FR 15951, pp. 15951-15952, April 16, 2025.
[2] Biocom California 2024 Economic Impact Report Databook. https://www.biocom.org/eir/

Maintaining a Robust U.S. Drug Supply Chain

The symbiotic relationship of the United States and allied nations plays a significant role in maintaining a robust domestic drug supply chain. There is an increasing demand for biological products (also known as 'large molecule drugs'), which provide a targeted treatment for multiple life-threatening and chronic diseases and conditions, including rare diseases, cancer, and autoimmune conditions, where patients have few effective treatment options. There are currently FDA approved biologics across the fields of oncology, inflammation and immunology, rheumatology, gastroenterology, diabetes, neurology, and inherited conditions. Contract manufacturers in both the United States and in allied nations such as South Korea, Ireland, and Singapore play an important role to help meet growing demand. In 2024, the global biologics contract manufacturing market was valued at $22.2 billion and is expected to grow to $58 billion by 2035, with significant growth of this manufacturing investment in the United States [3].

Biological product production is a cost intensive and challenging process with long development timelines, a high rate of attrition of pipeline therapies, regulatory and compliance-related issues, and inconsistencies related to final product quality attributes[4]. **Contract manufacturers in the United States and its network of allied nations already have the required resources, technical expertise, FDA-inspected facilities, and capacity to sustain the continuous production of biological products. This network of contract manufacturers is building additional manufacturing capacity in the U.S. and abroad to keep pace with demand, which is projected to grow with continuing investments by pharmaceutical companies and contract manufacturers.**

Additionally, maintaining free trade flows for pharmaceuticals, APIs, and other key pharma manufacturing inputs is essential for sustaining a reliable patient drug supply and enhancing R&D and domestic manufacturing investments. In 2021, the United States imported over $166 billion in pharmaceutical products, many of which were active pharmaceutical ingredients (APIs) used in the manufacturing of pharmaceutical drugs and materials necessary for the treatment of patients[5].

Trade restrictions on imported pharmaceutical products, APIs, raw materials used to develop APIs, and their packaging materials would cause large-scale disruptions in essential drug supply chains. Costs would substantially increase, and it would be more challenging to source materials critical to pharmaceutical manufacturing processes, compromising the ability of U.S. biotechnology companies to reliably supply critical medicines. This would lead to drug shortages, delayed clinical development, and limit patient access to care.

The U.S. Government should enable international cooperation with allied nations to keep pharmaceutical trade open via multilateral frameworks, such as 1) expanded mutual recognition agreements (MRAs) for regulatory approvals to streamline global manufacturing and supply-chain logistics, 2) coordinated international agreements (i.e., zero-for-zero) and trusted trade partner agreements such as the bipartisan, bicameral Medical Supply Chains Resiliency Act,[6] ensuring transparency, predictability, and mutual assistance during global health emergencies, and 3) enhanced cooperation in R&D and manufacturing among allied nations to build robust global health security infrastructure, maintaining open pharmaceutical trade routes and shared preparedness.

[3] https://www.globenewswire.com/news-release/2025/03/18/3044236/28124/en/Biologics-Contract-Manufacturing-Market-Industry-Report-2024-2035-Intense-Competition-Among-Service-Providers-that-Claim-to-be-Focused-on-the-Niche-and-Upcoming-Drug-Classes.html

[4] Ibid.

[5] Pharmaceuticals: Trade Statistics. https://globaledge.msu.edu/industries/pharmaceuticals/tradestats

[6] https://www.tillis.senate.gov/2025/3/tillis-colleagues-introduce-bipartisan-bill-to-strengthen-medical-supply-chains

Domestic Manufacturing Capacity Limitations

The onshoring of pharmaceuticals and APIs is an important undertaking that will require time to improve upon the current infrastructure to support greater domestic manufacturing, enhanced workforce capabilities, substantial capital investments, and shorter operationalization timelines. While there has been an increased interest from pharmaceutical and biotechnology companies to invest in domestic manufacturing, it could take years and cost billions of dollars before U.S. manufacturing facilities are operational at the scale needed [7,8,9]. Additional policy measures could greatly facilitate the onshoring process.

To meet these goals, Biocom California supports proposals that would gradually **enhance domestic manufacturing capabilities, including 1) targeted tax incentives and accelerated depreciation for infrastructure investments in domestic manufacturing, 2) expanded government-funded workforce training and apprenticeship programs to rapidly grow a specialized biomanufacturing workforce, and 3) government investment in strategic stockpiles and incentives to enhance domestic sourcing of essential raw materials.**

Sustained Competitiveness in U.S. Biotechnology Innovation, R&D, and National Defense

Biomedical research plays a major role in fueling innovation in the U.S. by generating life-saving products and economic gains that benefit local communities, individual states, and the entire country. The U.S. stands as the global leader in biomedical R&D investment, with U.S.-based life science companies responsible for nearly twice as much R&D investment as all their European counterparts combined[10]. In 2019, the United States performed 27% or $656 billion of global R&D[11].

Tariffs would threaten the ability of the U.S. to maintain its position as a global leader in biomedical innovation. These restrictive trade measures would directly hinder U.S. biotech companies' R&D efforts and clinical trial operations by significantly increasing operational costs and introducing uncertainty into supply availability. **Increased API and intermediate costs would divert financial resources from innovative research; therefore diminishing the U.S.'s competitive edge and capacity to accelerate the development of next-generation therapies, especially for unmet clinical needs in rare disease.**

Additionally, trade restrictions would risk strengthening competitors and weakening U.S. leadership in biomedical innovation. **Increased manufacturing costs due to tariffs would place the U.S. biotechnology sector at a strategic disadvantage as escalating U.S. production costs would drive international customers to foreign suppliers, such as China.** This unintended consequence would significantly weaken the U.S. biotechnology industry's global market position, reduce export competitiveness, and negatively affect job creation and economic growth domestically.

Furthermore, biotechnology innovation plays a significant role in supporting national defense and trade restrictions would threaten innovation that is critical to defense applications, including treatments for battlefield injuries and rapid-response biological countermeasures. **Leveraging existing initiatives such as the Industrial Base Expansion (IBx) program is preferable to tariffs as IBx can strategically bolster a resilient domestic biotechnology infrastructure and maintain the U.S.'s global leadership position in biopharma**.

[7] https://www.jnj.com/media-center/press-releases/johnson-johnson-increases-u-s-investment-to-more-than-55-billion-over-the-next-four-years
[8] https://investor.lilly.com/news-releases/news-release-details/lilly-plans-more-double-us-manufacturing-investment-2020
[9] https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-new-investment-manufacturing-its-industry
[10] Powaleny, New research: American biopharmaceutical investment in R&D drives transformational innovation 2024
[11] The state of U.S. Science and Engineering 2022 | NSF - National Science Foundation 2022

Addressing Foreign Trade Practices

Predatory trade practices pose challenges such as foreign subsidies, lack of intellectual property protection, and artificial price suppression. **In lieu of imposing tariffs, alternative solutions to combat these practices could include targeted trade negotiations, multilateral diplomatic engagement, strengthened global regulatory coordination, enhanced transparency in supply chains, and targeted policy instruments such as reciprocal market access agreements.** These solutions would address the root causes of unfair trade practices without negatively impacting the domestic life science industry.

Rules of Origin Considerations

Current U.S. Customs rules of origin for pharmaceuticals, uniquely based on API sourcing, is significantly different from other global standards. U.S. biotech companies have strategically developed global supply chains and sophisticated trade compliance programs tailored to existing U.S. Customs origin criteria. Any alterations to these established rules would substantially burden the industry's supply chains, increasing both administrative complexity and compliance-related costs. Furthermore, in scenarios involving tariff retaliation, pharmaceutical products could potentially face multiple tariffs as they transfer through various manufacturing stages across different countries. Such cumulative tariff impacts would drastically elevate manufacturing costs and adversely affect the affordability, availability, and timely patient access to critical medications. **Any changes to origin determination policies, particularly before a robust domestic supply chain for essential medicines and critical APIs can develop, should be carefully considered as to ensure stability and to avoid unintended consequences on patient access to care and industry competitiveness.**

Conclusion

Restrictive trade measures are unlikely to incentivize domestic pharmaceutical manufacturing in a meaningful way and American patients would disproportionately bear the consequences of increased drug prices, reduced availability, and disruptions in timely access to critical medications. Higher operational costs for biotechnology companies would lead to reduced investments in developing innovative therapies, delayed access to clinical trials, and restricted drug availability. All of which would have negative implications to patients' access to healthcare and would compromise patient outcomes and public health. **We urge the U.S. Government to consider the alternative measures discussed above to incentivize domestic manufacturing, strengthen the U.S. pharmaceutical sector, support U.S. biomedical innovation and R&D, and maintain the U.S.'s position as a global health leader.**

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Regulatory Policy Manager, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,

Tim Scott
President and CEO
Biocom California