Biosimilars
FORUM

May 6, 2025

Hon. Howard Lutnick
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

Attn: Eric Longnecker

Re: BIS-2025-0022: Comments of the Biosimilars Forum on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (XRIN 0694-XC120)

Dear Secretary Lutnick:

The Biosimilars Forum (the "Forum") appreciates the opportunity to provide comments on the Department of Commerce's investigation into the national security impact of imports of pharmaceuticals and pharmaceutical ingredients.[1] The Forum represents a diverse group of companies responsible for developing the majority of biosimilar products for the U.S. market.

The Forum is dedicated to creating significant cost savings through biosimilar development and increasing competition in the market for biologic medicines to lower costs for patients and their families.

For the reasons outlined below, imports of biosimilar medicines (and their inputs) do not threaten or impair the national security of the United States, and thus adjustment to imports pursuant to Section 232 are not necessary to protect national security. In addition, import restrictions would undermine other key Administration objectives. President Trump's April 15, 2025 Executive Order on Lowering Drug Prices, specifically calls out the objective of lowering drug prices in the United States, including through increased utilization of biosimilars.[2] In that context, the Forum

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients,* 90 Fed. Reg. 15951 (Apr. 16, 2025).

[2] Executive Order, Lowering Drug Prices by Once Again Putting Americans First (Apr. 15, 2025).

urges the Department to avoid the imposition of tariffs, quotas or other import restrictions on biosimilar products. Such restrictions would be both unnecessary and at odds with the President's objectives of increasing biosimilar use and maintaining low prices for such products.

I. Background

The Biosimilars Forum is a non-profit organization with the mission of educating stakeholders on the value of biosimilars and advancing biosimilars in the United States with the intent of expanding access to biological medicines and improving health care while lowering costs. Our members represent the majority of companies with the most significant U.S. biosimilars development portfolios and experience in the U.S. market.[3] The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive and sustainable biosimilars market, providing more options to patients and physicians.

The Biosimilars Forum's membership spans the entire biosimilar development pipeline, from initial research to regulatory approval to commercialization. Our membership includes nine biosimilar companies that collectively employ thousands of people in the United States as well as around the world. Our members have invested hundreds of millions of dollars in the U.S. over the past decade on research and development, manufacturing, patient outreach and advocacy, and commercialization of biosimilars.

Biological products are medicines that typically are synthesized from living organisms, such as human, animal, or microorganism cells. They are generally produced through biotechnology, often culturing the drug substance in living cells and then purifying that drug substance. The resulting medicines are made up of large, complex molecules. These medicines play a critical role in the treatment of many serious illnesses, including cancer, genetic disorders, and autoimmune conditions.

Biosimilars are biological products that are approved through an abbreviated licensure pathway in section 351(k) of the Public Health Service Act.[4] In order to be approved by FDA, biosimilar products will have demonstrated high similarity to approved biological reference products. Like all biological products, biosimilars must be produced in highly regulated and sophisticated facilities. Production facilities must be sterile, and require advanced equipment, strict product controls and highly trained workers.

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[3] Unless indicated otherwise, the term "biosimilar" includes interchangeable biosimilars.

[4] 42 U.S.C. § 262(k).

Transportation, distribution, and supply chain security of biosimilars and their active ingredients are also all heavily regulated activities with considerable oversight by FDA.[5] The drug supply chain security provisions of the Federal Food, Drug, and Cosmetic Act requires a system of interoperable and electronic identification and tracing of prescription drugs at the package level as they move through the supply chain from the finished dose manufacturer to wholesale drug distributors and other trading partners and, ultimately, to pharmacies. This system is designed to ensure drug supply chain integrity, detect any potential suspect or illegitimate drugs that may enter the supply chain, and enable rapid response to quarantine, investigate, and remove potentially harmful drugs from the supply chain to protect patients.[6]

The Forum and its member companies actively collaborate with FDA as well as other regulators, law enforcement and customs agents to ensure that biosimilars meet the rigorous U.S. standards of safety, efficacy, quality, and are transported safely to provide U.S. patients with access to cost-effective biologic medicines.

II. Tariffs are Likely to Undermine Growth within the Newly Established Biosimilars Industry

Biosimilars bring enhanced competition to the U.S. market, expanding patient access to high-quality treatment options while reducing costs. Since the first biosimilar was approved around ten years ago, these safe and effective medicines have generated substantial savings: biosimilars cost on average 50% to 85% less than the originator products they reference and have the potential to save hundreds of billions of dollars. In fact, if all products with a patent expiring in the next 10 years were to have a biosimilar in the pipeline, the U.S. healthcare system could save an additional $189 billion in addition to savings generated by biosimilars already on the market or expected to enter.[7]

Biosimilar competition is therefore crucial to lowering healthcare costs and maintaining a robust marketplace. In addition, by adding new sources of key biologic medicines to the market, biosimilars help avoid shortages and other risks that can arise with respect to single-source biological products.

Yet as a relatively new segment of the market, biosimilars have faced a number of obstacles to growth, including high costs of production and high regulatory burdens. In particular, the Forum

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[5] See, e.g., Drug Supply Chain Security Act (DSCSA), Pub. L. 113–54 (Nov. 27, 2013).

[6] *Id.* More information on the DSCSA and compliance obligations for companies is available at FDA's website at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/fdas-implementation-drug-supply-chain-security-act-dscsa-requirements.

[7] IQVIA *Assessing the Biosimilar Void in the U.S.* (Feb. 3, 2025), *available at*: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us ("*Biosimilars Void*").

is concerned that there is a biosimilar void looming. A typical biosimilar costs from $100 million to $300 million to develop and takes six to nine years to go from analytical characterization to approval.[8] This is a rigorous scientific research and development process, but its cost and duration leaves the nascent biosimilar market particularly vulnerable to negative impacts from additional costs.

The Forum is deeply concerned that, against this already fragile backdrop, the cost implications of tariffs could endanger the much-needed growth of this still-emerging industry. In order to bring cost-saving medicines to the market, biosimilar producers must ensure efficient and cost-effective supply chains and manufacturing processes. Tariffs will increase costs and undermine supply chains for existing biosimilar medicine and threaten the viability of future biosimilar product development. Tariffs today could not only raise costs and create shortages for existing biosimilar products but undermine development of new biosimilar medicines.

As mentioned, even without tariffs, there are already significant barriers to the expansion of the biosimilar market. The difficult cost structure and onerous timelines for biosimilar development mean that today only about 6 percent of the biologic medicines available on the market have a biosimilar counterpart. Currently, *only 10 percent* of the 118 biologics expected to lose patent protection in the next decade—for which biosimilars could offer enormous cost-savings—have biosimilars in development.[9] Tariffs would increase the cost of research and development, among other costs, exacerbating this biosimilar void and undermining the development pipeline for the next generation of cost-saving biosimilar medicines.

Tariffs on imported biosimilars or API for biosimilars will significantly raise costs, both for biologic medicines made in the United States and for imported products. Those additional costs threaten the continued viability of the biosimilar segment. Producers will be forced to raise prices, resulting in higher costs to patients. And in some situations, they may face fixed reimbursement rates that prevent price increases. In the latter scenario, companies may curtail production or exit the market if they cannot recoup the increased costs from tariffs, resulting in shortages and limited access to important biosimilar medications.

The goal of biosimilar development and access is to provide cost savings to patients in the United States who need these life-saving medicines. Adding tariffs to these lower cost medicines is contrary to the goal of this important industry and would undermine President Trump's fundamental objective of lowering drug prices, as detailed in the Lowering Drug Costs Executive Order.

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[8] McKinsey & Company, *Three imperatives for R&D in biosimilars* (Aug. 19, 202), *available at*: https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars.

[9] *Biosimilars Void*, supra fn 6.

III. Imports of Biosimilars Do Not Threaten or Impair National Security and Should be Exempted from Any Tariffs.

The purpose of a Section 232 investigation is to determine the effects of imports on national security, and specifically to determine whether the goods in question are being imported in ways that "threaten to impair the national security."[10] A key factor that the Department must consider in this analysis is U.S. national defense requirements and whether the domestic industry can meet those needs.

However, biosimilar medicine imports *do not impact defense preparedness or national security.* Biosimilars are by their very nature creating more diversity and resilience in the supply chain for a particular medicine or therapeutic area; there cannot be a biosimilar without a biological reference product. In fact, by creating redundancies in product supply and increasing access options for patients, biosimilars actually provide security to the domestic supply chain for critical medicines and help avoid shortages and other risks that can arise with respect to single-source biological products. Given the potential this new industry has to combat shortages and reduce healthcare costs, and the low potential for biosimilars to face future security threats, policies should be designed to support biosimilars—and hence improving patient access and resilience in the overall armamentarium.

To further support the Department's analysis, the Forum provides the following information in response to questions raised in the Department's request for comments.

i. The current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States

Within the biosimilar segment of the biopharmaceutical market, the demand for biosimilars remains low. Low demand for these lower cost products is the result of market access barriers, such as the rebates and other policies that pharmacy benefit managers use to block U.S. patient access to lower cost biosimilars. Uptake of biosimilars, whether U.S. made or imported, is hindered by such policies and conditions, resulting in overall higher costs for patients and the U.S. health care system. These policies further hinder patient choice and prevent patients from accessing lower cost biosimilar medicines.

[10] 19 U.S.C. § 1862(b)(3)(A).

ii. The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand

At this time, the biosimilar industry's domestic production cannot meet U.S. patient demand. While some biosimilar products are made in the United States, other key medicines on which U.S. patients rely are produced outside of the United States. Establishing a production facility for biologic medicine is a time consuming and costly process. The biosimilar industry cannot maintain our promise to bring lower cost biosimilars to U.S. patients while producing all biosimilar medicine in the United States.

Unilateral tariffs and forced localization would not result in onshoring of biosimilar production. Rather, measures restricting imports would lead to erosion of cost savings for patients and potential drug shortages.

iii. The role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients

Biosimilar imports are highly regulated by FDA and other entities. The limited amount of biosimilar importation into the United States is controlled by U.S.-licensed manufacturers in compliance with FDA requirements. No one country or company dominates the segment. Indeed, given the low demand for biosimilars in the United States and the complexity of manufacturing biosimilars, there are not any dominant countries in the global biosimilars arena.

iv. The concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks

Unlike small molecule medicines, including generics, which can be produced using a number of different active pharmaceutical ingredients sourced from multiple suppliers, biosimilars, like their branded biologic reference products, are synthesized from living cells. Given the unique development parameters of biologic products supply and manufacturing, there is not a significant concentration of U.S. imports of pharmaceutical ingredients for biosimilars.

Further, as described above, biosimilars expand the number of suppliers for biologic medicine, resulting in less market concentration and more competition. Biosimilars are by their very nature creating more diversity and resilience in the supply chain for a particular medicine or therapeutic area. As such, biosimilars provide security to the

domestic supply chain for critical medicines by creating redundancy in product supply and increasing access options for patients.

v. The impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness

Biosimilar competitiveness in the United States is limited by domestic market barriers to patient access, including U.S. policies that constrain patient uptake of biosimilars, not foreign government subsidies or trade practices. The biosimilar industry is small and new to the United States. To improve the competitiveness of the U.S. biosimilar industry and improve patient access, U.S. policy should focus on eliminating existing barriers within the U.S. market. Import restrictions will only limit growth for the biosimilar industry, including domestic producers.

vi. The economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction

Given the complexities, time and cost of development of biosimilars (i.e., 7 to 9 years and $100 to $300 million per biosimilar), and the low margins due to high discounts of biosimilars in the U.S., as well as the complex manufacturing required for biosimilars, our industry has not been subject to unfair trade practices or state-sponsored overproduction. Biosimilars are unique medicines requiring complex development, sophisticated manufacturing facilities, and highly skilled employees while maintaining low cost of the final product.

vii. The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies

Biosimilars are complex, multi-source, low-margin products that face ongoing domestic market barriers, such as those put in place by pharmacy benefit managers. As such, the likelihood of biosimilars being targeted for foreign disruptions is low. In addition, biosimilars are produced in multiple countries and the number of U.S. patients relying on a particular biosimilar product is also generally very limited. Thus, there is no incentive for foreign nations to "weaponize" control over biosimilars, as such actions would have very limited impact.

viii. The feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance

Due to the high cost to manufacture a highly complex, low-margin biosimilar for the U.S. market, coupled with the ongoing market barriers for biosimilars sales in the United States, increasing domestic capacity for developing and manufacturing biosimilars is not feasible at this time.

The Forum supports President Trump's Executive Order on drug pricing which calls for increasing market access to lower cost biosimilars in the U.S. Our shared goal is to keep the costs low for biosimilars, and we have a deep concern that tariffs on biosimilars would have a negative impact on that goal.

Bringing biosimilar development and manufacturing to the U.S. first requires the growth of the biosimilar marketplace in the United States. Together, we need to focus on this priority while we explore opportunities to partner with the Administration to expand domestic capacity based on future increased demand for biosimilars in the US. In fact, the significantly higher production costs are magnified by the lack of end-to-end supply chain capabilities needed in the United States. Without substantial financial and tax incentives and reform of the biopharmaceutical capability infrastructure in the United States, it would be cost prohibitive to replicate biological product manufacturing domestically. We recommend that the high production costs and manufacturing challenges of biosimilars should be assessed separately in analyses of supply chain resilience and potential vulnerabilities.

ix. The impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

Imports of biosimilar medicines do not undermine national security. Indeed, the Forum believes that less restrictive markets facilitate patient access to biosimilars and promote growth in the segment.

Highly complex, low margin biosimilars with low sales and limited uptake in the United States do not a threat due to disruption of U.S. manufacturing or from supply chain weaponization. As mentioned previously, these low margin products coupled with their low market share in the United States are not a high value product that foreign entities would target for disruption. Adding a tariff to a low margin product like a biosimilar will have a negative impact on U.S. patients, U.S. healthcare costs and the U.S. biosimilar industry. It also would not address the most significant barrier

to market access, even for U.S. biosimilar makers -- Pharmacy Benefit Manager policies.

To grow the biosimilars industry and achieve billions of dollars in cost savings, the focus, as President Trump has emphasized, needs to be on building the U.S. biosimilars marketplace and removing barriers to patient access.

x. Any other relevant factors

Biosimilars are subject to a highly complex set of rules designed to ensure the safe, secure, and effective movement of medications from manufacturers to patients around the world. Biosimilar transportation and importation regulations cover multiple areas such as temperature control, packaging, documentation, security, and storage facilities, as well as additional supply chain requirements detailed above. Subjecting a biosimilar to a tariff will only disrupt supply chains, causing potential shortages for U.S. patients as well as increased costs.

With President Trump's stated goal of bringing competition to the prescription market and lowering prescription drug prices, biosimilars provide critical options to reduce healthcare spending. Furthermore, biosimilars provide additional treatment options for patients, especially in therapeutic areas where biologics are critical, thus helping to mitigate potential supply chain vulnerabilities. Biosimilars also increase overall price competitiveness in the market, as the introduction of biosimilars typically results in both a lower price biosimilar option and a decrease in price for the reference biologic. Given these impacts on access and affordability, the Secretary's recommendations should exclude biosimilars from any tariffs or include options for exemptions for biosimilar products.

IV. Any Tariffs Recommendations Should be Narrowly Tailored and Paired with Onshoring Incentives to Avoid Exacerbating Drug Shortages and Patient Access Challenges

The U.S. biopharmaceutical supply chain is complex and global, and the Forum is concerned that unilateral tariffs, without infrastructural support and adjustment periods, can lead to drug shortages and problems with patient access. In particular, potential drug shortages, as a result of unilateral tariffs, are more likely to affect low-margin drugs including biosimilars.

Instead of tariffs, strategic partnerships and diversification of supply sources can enhance resilience. In particular, collaborations with trusted and aligned trading partners can diversify market entry points. That, in turn, would mitigate risks associated with over-reliance on specific suppliers and address vulnerabilities associated with localized single-point productions.

To that end, we recommend that the Secretary consider solutions that would foster strategic collaborations with trusted and aligned trading partners. For instance, if the Secretary recommends imposing tariffs, an exemption for pharmaceutical imports from trusted allies could mitigate some of the resulting supply challenges without significant national security implications.

Similarly, attention should be paid to ensuring that any tariffs affecting biosimilars do not cause short-term supply chain disruptions and shortages resulting in patient access issues. If tariffs are recommended, it will be critical that they be phased in with sufficient lead time and exemptions to allow adjustment and investment. In addition, any tariffs should be offset by robust mechanisms to incentivize and facilitate the onshoring of pharmaceutical manufacturing. A skilled U.S. workforce, for example, will have to be built up to meet increased domestic production needs.

V. Any Tariff Recommendations Should Take Account of the Unique Challenges in Localizing Manufacturing of Biological Products

The manufacturing of biologics and biosimilars presents unique challenges due to their complexity and high costs of manufacturing, requiring tailored strategies to effectively address supply chain vulnerabilities. Biologics and biosimilars differ fundamentally from small-molecule drugs in terms of manufacturing complexity, cost structure, and regulatory pathways, resulting in a need for more capital investment and time for any shifts in the manufacturing footprint. The complex and time-consuming regulatory approval process for biosimilars further complicates market entry and supply chain reliability. These costs are magnified if end-to-end supply chain capabilities were needed in the United States.

In short, without substantial incentives and reform of the capability infrastructure in the U.S., it would be cost prohibitive to replicate biosimilar manufacturing domestically. The higher production costs and manufacturing challenges of biosimilars need to be assessed separately in analyses of supply chain resilience and potential vulnerabilities. To the extent any tariffs are considered for biosimilars, we recommend that the Bureau of Industry and Security conduct a separate vulnerability and capability assessment to examine the impact of unilateral tariffs on potential supply chain disruptions and reduced innovation and growth in the biosimilar industry. The assessment can further discuss financial resources required to increase domestic pharmaceutical production.

VI. The Department Should Consider Additional Policies to Grow the U.S. Biosimilar Industry and Ensure Stable Supply Chains

Any policies implemented need to address the unique challenges posed by biosimilars manufacturing, which require tailored approaches to ensure their availability and affordability. As discussed above, biosimilars should not be subject to any proposed tariffs on pharmaceuticals or pharmaceutical ingredients. To the extent the Department recommends action to improve access and resilience in the biosimilar segment, the Forum suggests that the Secretary consider:

- **Streamlining of Regulatory Compliance to Facilitate Onshoring**: FDA's stringent requirements for safety and efficacy involve extensive documentation, inspections, and testing, which are both time-consuming and costly. Post-approval changes for API manufacturing for the U.S. market can take 3-7 years, with biologics (including biosimilars) on the longer end of the spectrum.
- **Workforce Training and Availability**: The skills gap in the U.S. manufacturing sector is a critical barrier. According to Deloitte and The Manufacturing Institute, this gap could result in 2.1 million unfilled jobs by 2030, including technical skills and expertise in pharmaceutical manufacturing processes.[11] Significant investment in education and vocational programs is required to train a workforce capable of meeting these demands. Long-term collaboration between companies, educational institutions, and government agencies is essential to develop and implement these training programs.
- **Private-Public Partnerships** to incentivize onshoring of biosimilar manufacturing while maintaining their low cost structures.
- **Removal of domestic market access barriers in the United States**, such as those put in place by pharmacy benefit managers, to increase access to low cost biosimilars.

VII. Conclusion

With the Administration's focus on lowering drug prices through biosimilars, adding tariffs to biosimilars is counter to the President's goal. The Biosimilars Forum urges the Department to address the unique challenges posed by biosimilars which require tailored approaches to ensure their availability and affordability.

Given the uniqueness of the biosimilar industry as outlined in our comments, it is clear that biosimilars do not meet the criteria for implementation of a tariff (or other "import adjustments") under the factors relevant to this Section 232 investigation.

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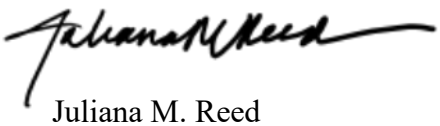
[11] Victor Reyes, Heather Aston, Chad Moutray, *Creating Pathways for Tomorrow's Workforce Today*; Deloitte Insights (May 4, 2021), *available at:* https://www2.deloitte.com/us/en/insights/industry/manufacturing/manufacturing-industry-diversity.html

The Biosimilars Forum requests that biosimilars developed for the U.S. market be exempt from any tariffs that may be considered. The Forum believes this exemption would support President Trump's Executive Order to Lower Drug Prices and allow us to continue to offer low-cost medicines to the patients of the United States.

Respectfully submitted,



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