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May 7, 2025

Under Secretary Jeffrey Kessler
Bureau of Industry and Security
U.S. 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 (Docket No. 250414-0065, XRIN 0694-XC120)

Dear Under Secretary Kessler:

The Massachusetts Biotechnology Council (MassBio) appreciates this opportunity to submit comments in response to the Department of Commerce (the Department) request for information (the RFI) from the Bureau of Industry and Security (BIS) Office of Strategic Industries and Economic Security to inform its investigation of the national security of imports of pharmaceuticals and pharmaceutical ingredients, under Section 232 of the Trade Expansion Act of 1962.[1]

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,800+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

I. Overview

MassBio supports the administration's efforts to support U.S. leadership in biotechnology innovation, including manufacturing, and provides these comments to inform the development of a potential tariff policy with respect to pharmaceuticals and pharmaceutical ingredients.

In summary, we provide the following comments:

- Tariffs on imported pharmaceutical products and imported pharmaceutical ingredients poses a significant threat to the competitiveness of U.S. biotechnology companies, with

[1] 90 Fed. Reg. 15,951 (Apr. 16, 2025).

small, early-stage companies that are essential to sustaining innovation being the least able to deal with such disruption.
- Tariffs will disrupt the successful U.S. biotechnology economy, which delivers lifesaving and life-transforming therapies to American patients.
- In implementing any tariff policy on pharmaceuticals and pharmaceutical ingredients, the Department should consider, and the broader administration should consider what support, and flexibilities can be provided to manufacturers working to onshore production to the United States.

II. Tariff Impact on U.S. Biotechnology Leadership

The United States is widely considered to lead the world in biopharmaceutical innovation, which is an asset not just to our economy but also to our national security. At the same time, however, rivals—particularly China—are gaining ground as biotechnology innovators, especially in recent years.[2]

In order to sustain U.S. leadership in biotechnology, it is important to understand the diverse nature of the biotechnology economy, ranging from small firms researching pre-clinical or investigational drugs—with hundreds of such companies residing in Massachusetts alone—up to much larger manufacturers with which these smaller companies typically partner to commercialize innovative products.

In fact, 80 percent of MassBio's biopharma member companies have fewer than 50 employees, and these companies have no commercial revenue because they do not yet have an FDA-approved product. These small companies rely on services from overseas CMOs and CDMOs for critical R&D expertise and manufacturing capabilities, including raw material sourcing, molecule development and production, cell line development, biomarker testing, and more. Tariffs would cause significant increases in the cost of these companies' inputs for investigative drugs, delaying or potentially making entirely impractical the research they need to advance products to eventual FDA approval and marketing. Such companies do not have the financial resources or organizational expertise to make investments in onshoring production, and any delays created by having to seek new partners for research and manufacturing represent real and harmful delays in the race toward biotechnology innovation.

III. Tariff Impact on U.S. Patients

Because U.S. companies are leaders in biotechnology innovation, adding costs, delays, and disruption to the ability of U.S. companies to develop and manufacture products will have significant effects on the ability of these companies to advance innovative drugs and deliver them to patients.

Delivering new drugs faster to patients means saving lives and delaying the progression of disease for American patients. Key elements of the drug development process—like FDA

[2] *See, e.g.,* https://publications.jrc.ec.europa.eu/repository/handle/JRC137266 ("The US are by far the country with the highest share of biotech patents, the EU is lagging behind (with an increasing gap with the US) , while China seem to have started catching Up with the EU").

commitments to review drug applications on a certain timeframe or accelerate such reviews—are measured in days and weeks because every day a product is delayed means delayed access to patients and heightened financial risk that an innovative product may become an unviable investment. To the extent that pharmaceutical ingredients and manufacturing services are available in the United States today, innovative companies often do prefer them because they can offer reliable and rapid access to the materials and services needed, but such options often simply do not exist in the United States, and continuing to build such capacities—a priority that MassBio supports—will take years. Finally, as noted above, small biotechnology companies are the least well-equipped to address the potential impact of tariffs, while it is widely acknowledged that small companies themselves are responsible for the majority of novel new drugs.[3]

IV. Recommendations

Below are specific recommendations that MassBio encourages the Department to consider in developing any potential policy of tariffs on pharmaceuticals and pharmaceutical ingredients, as well as more general recommendations we encourage the administration to consider as part of its efforts to continue to grow domestic capacity for pharmaceutical research, development, and manufacturing.

Delayed Timeframe: Any tariff policy implemented should account for Building new biomanufacturing facilities is both cost and time-intensive, with construction costs reaching into the billions—with a typical estimate being 5–10 years for a facility to become fully operational, including construction time and time to meet and clear all necessary regulatory requirements/inspections.[4] The Administration recently announced a phased approach to implementing tariffs on automobile imports,[5] recognizing the complexity of those supply chains, and pharmaceutical manufacturing carries even further added complexities, such as the need for a highly specialized workforce and FDA inspections of new manufacturing sites. A meaningful delay in implementation of tariffs will offer an opportunity for companies to begin making further investments in domestic activities, as well as reaching agreements with U.S.-based partners to move as much production to the United States as possible.

Exemption for Low-Volume Products: For many MassBio members, even once their drug has received FDA approval, production of the product remains a very small volume process—in some cases, a drug approved for a rare disease may serve fewer than 100 patients per year, or a cell therapy is manufactured for even fewer patients per year, in a customized product for each patient. In these cases, it is often commercially impractical to have more than one manufacturing site, and a company may have already invested in a manufacturing site abroad years before the Administration had announced plans to prioritize onshoring pharmaceutical manufacturing.

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[3] *See, e.g.,* https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation ("Emerging biopharma companies are responsible for a record 65% of the molecules in the R&D pipeline without a larger company involved").

[4] *See* https://phrma.org/en/policy-issues/Research-and-Development/Manufacturing.

[5] Amendments to Adjusting Imports of Automobiles and Automobile Parts into the United States, available at: https://www.whitehouse.gov/presidential-actions/2025/04/amendments-to-adjusting-imports-of-automobiles-and-automobile-parts-into-the-united-states/.

Therefore, we recommend that the Department consider either an exemption for all very low volume imports of pharmaceuticals (by weight/volume, rather than dollar value), or for very low volume imports of pharmaceuticals that manufacturers were importing into the United States prior to 2025.

Exemptions for Ingredients for Investigative Products: As described above, tariffs will have a particularly deleterious impact on companies that are particularly cost-conscious because they have no approved drug and are reliant on competing for investor capital to support development of their drugs. Although the United States has historically allowed the use of the Harmonized Tariff Schedule code for prototypes to allow the duty-free import of finished investigative drug products,[6] it is not clear how this exemption will figure into potential pharmaceutical tariffs under Section 232 (and the related reciprocal tariff regime that carves out pharmaceutical products). To support U.S. innovation, the Department should continue to permit duty-free importation of investigational drugs and extend this treatment to ingredients that manufacturers use to produce investigational products.

Exclusions Process: In many cases, the manufacturers—especially small-scale innovators that are still in the pre-commercialization stage—do not have the financing or operational flexibility to secure alternative suppliers. We encourage the Department to develop an exclusions process that recognizes that certain ingredients and capabilities are not feasibly available in the United States and therefore tariffs on such products or ingredients will not serve the purposes of the broader tariff policy.

Administration-Wide Support for Biotechnology Innovation: Both financial and regulatory reforms will be crucial to efforts to reduce U.S. reliance on pharmaceutical imports, by supporting onshoring of manufacturing and the development of the necessary capabilities, including workforce, in the United States. Financial incentives such as tax credits, grants, and logistical support could help offset the costs of construction, utilities, and labor for manufacturing plants that are often much higher in the United States than other nations. Regulatory flexibilities could include streamlining FDA inspections for new facilities and accelerating reviews of innovative technologies used in advanced manufacturing, while reforms to permitting processes at other agencies could accelerate the construction and expansion of U.S. manufacturing plants. We also encourage the administration to think creatively about how existing federal mechanisms for financing healthcare and health research could help defray added costs of manufacturing drugs in the United States and how federal educational investments can be used to support the development of a manufacturing and biotechnology workforce.

V. Conclusion

MassBio thanks the Department for your consideration of our comments and remains available to provide further input on how tariffs may affect U.S. biotechnology companies. We are committed to working with the administration on productive policies that will benefit U.S. patients and innovators and preserve and extend U.S. leadership in the biotechnology industry.

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[6] 69 Fed. Reg. 63445.

Please do not hesitate to contact me at (617)-674-5148 or kendalle.oconnell@massbio.org if you have any questions or would like any additional information to consider our comments.

Sincerely,

Kendalle Burlin O'Connell
CEO & President
Massachusetts Biotechnology Council (MassBio)