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Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
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," Federal Register docket number BIS-2025-0022 (XRIN 0694-XC120).

Dear Director Astle:

The U.S. Chamber of Commerce ("the U.S. Chamber") appreciates the opportunity to respond to the U.S. Department of Commerce's request for comments cited above. The Administration has stated its intent to use these comments as part of its "investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items."

The U.S. biopharmaceutical industry is a global manufacturing leader, allowing for timely access to innovative vaccines and medicines essential for Americans. As discussed below, imports of innovative medicines and related inputs are sourced overwhelmingly from U.S. allies and close partners—including the European Union, Japan, India, Switzerland, Canada, South Korea, and the United Kingdom—and should not be considered national security threats. Such imports complement U.S. production, mitigate the risk of domestic supply chain disruptions, and enable Americans to access a wider range of treatments and cures. This enhances rather than threatens U.S. national security.

In addition, the present investigation should consider carefully the impact broad-based tariffs would have on medicine costs. A 25% tariff on all imported medicines and critical inputs would increase costs by approximately $50 billion annually—or 13% of U.S. pharmaceutical industry's yearly domestic sales. Such costs

would be borne by U.S. manufacturers, healthcare providers, pharmacies, taxpayers, and patients.

Given that approximately 30% of pharmaceutical imports are ingredients for products manufactured in U.S. facilities that are subsequently exported or sold to U.S. consumers, tariffs on these inputs would significantly increase U.S. pharmaceutical production costs. Additionally, tariffs on the other 70% of pharmaceutical imports—finished products packaged and sold to consumers through distributors—would be passed along by the wholesalers or retailers paying the tariff, placing additional financial strain on healthcare systems. Hospitals, pharmacies, and the healthcare system writ large would be forced to absorb increased costs, which would undermine the financial viability of rural hospitals, pharmacies, and other parts of the healthcare system and severely impact patient access.

Shortages are perhaps the most serious risk associated with tariffs. Broad-based tariffs on critical pharmaceutical inputs and finished goods, combined with foreign retaliation, would lead to shortages that could pose grave challenges for patients and healthcare providers. Higher input costs combined with shortages related to lost sales could lead to cases where U.S. companies are forced to reduce headcount, capital, and R&D investments. This would stand in direct opposition to the objective of the U.S. government to strengthen domestic production of medicines.

This investigation should focus squarely on clearly articulated national security concerns, with outcomes focused on the legitimate risks relating to critical dependencies and striking a balance between stimulating investment and preserving access to reliable sources of raw materials and other inputs for domestically manufactured products. The objective of increasing U.S. biopharmaceutical manufacturing will be best achieved by allowing continued access for imports from key allies, opening new markets for U.S. biopharmaceutical exports, and implementing targeted investment incentives. The following comments outline the U.S. Chamber's positive agenda to achieve these objectives while also explaining how broad-based tariffs will raise costs, increase the risk of shortages, and undermine the U.S. healthcare system.

Supply Chains for Innovative Pharmaceuticals

Public misconceptions about this sector's supply chains are common, in part due to complexities related to production formulas and categorization. About half of the innovative biopharmaceutical products Americans consume are manufactured domestically, and most of the rest comes from countries that are close allies. The same is true of the active pharmaceutical ingredients (API) used to produce those medicines.

According to a report by the research firm Avalere, 53% of the API used in domestically consumed medicines (branded and generic) is produced domestically, and most of the remainder (36% of the total) is produced in Europe or Singapore. In other words, the API used to manufacture innovative pharmaceutical products consumed in the United States is overwhelmingly sourced domestically or from trusted partners.

The resilience of the U.S. biopharma supply chain derives from its geographic diversity, and this strong public health industrial base provided a firm foundation for the industry's development of vaccines and therapeutics—spurred by the stunning success of Operation Warp Speed—of great efficacy at record speed.

Concern in Congress about dependency on pharmaceuticals and API from China has been pronounced in recent years. However, for branded pharmaceuticals, the volume share of U.S. prescription API from China in 2024 was just 3%, according to a report from the United States Pharmacopeial Convention (USP).

The innovative biopharma sector has also proven resilient. The FDA has approved more than 23,000 drug products for marketing in the United States. But just over 100 were in short supply before the Covid-19 pandemic, according to the FDA. That figure rose only modestly during the pandemic, and as of April 21, 2025, it was down to 89.

Some specific shortages have drawn public attention in recent years, but most of these have arisen from specific and idiosyncratic causes that do not lend themselves to trade-related supply chain solutions—let alone tariffs. The market for antibiotics, for instance, presents special challenges given unusual incentives for a product where overuse undermines efficacy, and industry has been exploring leapfrog technologies in response.

Supply Chains for Generic Pharmaceuticals

For generic pharmaceuticals, which represent 90% of all U.S. prescription volume, the market realities have some differences. Here, concern has focused on allegedly excessive reliance on Chinese API, though the aforementioned USP report indicates China is the source for just 8% of the API in U.S. generic prescription medicines.

For generic medicines and the API used to make them, the challenge is identifying policy fixes that will help and not hurt U.S. industry. The Association for Accessible Medicines (AAM), which represents manufacturers of generic drugs,

issued *A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain*. It argued that long-term, guaranteed price contracts would be required to incentivize domestic production of API for generics in a cost competitive fashion. Establishing a facility to manufacture API for generics domestically is no small task: Billions in investment and years of planning and permitting are required for such a venture, and there do not appear to be major developments on this front.

On a more hopeful note, recent research has been intriguing: According to research from Washington University's Olin Business School in St. Louis, "currently idle U.S. generic drug manufacturing capacity could keep the nation's drug supply chain 'secure, robust and resilient.'" The report indicates that aggregate excess capacity at U.S. generic pharmaceutical manufacturing sites is nearly 50%. If policymakers in the U.S. are serious about diversifying sources of API for generics, tapping this underutilized capacity would be a relatively cost-effective way to ramp up domestic production. Long-term contracts would be required to give industry the assurance needed to take on the higher costs involved relative to offshore locations.

In addition, it is also important for Congress to appropriate adequate funding to support continued grant funding and the efforts of the Administration for Strategic Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA), and other relevant agencies.

Other Issues: Animal Health, Medical Countermeasures, Medical Devices

Animal health biopharmaceuticals, vaccines, and nutrition ingredients are key to preventing zoonotic disease and protecting the food supply. Imports of animal pharmaceuticals, vaccines, and API serve to protect human health. Approximately 75% of emerging infectious diseases in humans originate from animals. Preventing zoonotic spillover is not only a public health priority, but also a matter of national security.

The animal health industry underpins more than $600 billion of economic activity in the United States. 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. 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 and should be addressed through domestic measures as opposed to tariffs or other import restrictions.

In addition, medical countermeasures (MCMs) are pharmaceutical products expressly designed to meet chemical and biological national security challenges. While they are essential to protecting Americans, government agencies are the sole

purchasers of most MCMs. The importance of the U.S. government as a partner and purchaser to companies developing and manufacturing MCMs cannot be overstated. It is critical that the U.S. government maintains its ability to safeguard the public and the warfighter against high-priority threats.

Finally, the administration, consistent with the investigation's announcement, should also exclude restricting the importation of medical devices—including ones that incorporate API—as well as products such as contrast agents that are only used in connection with medical device procedures.

The High Price of Policy Mistakes: Rising Costs, Spreading Shortages

As noted, the application of broad-based tariffs on medicines and inputs would lead to increased costs and shortages, undermining access for American patients, pharmacies, hospitals, and other key players in the broader healthcare system. Specifically, hospitals would in many instances be unable to pass on the higher costs imposed by tariffs, harming the financial viability of rural healthcare systems in particular. Similarly, the impacts to retail pharmacies will ultimately translate to negative impacts on the health outcomes of American citizens as their access to medications is curtailed by the effects of tariffs.

Drug shortages affect roughly 3% of brand-only markets and 4-6% of generic/brand and generic-only markets, according to a report by the AAM. Generic medicines generally face fixed reimbursement rates set between the government and manufacturers. An intensely competitive industry and low reimbursement rates are among reasons why prices—as well as profit margins—have been kept so low for the increasing number of U.S. generics manufacturers.

In this environment, the shock of tariffs risks creating immediate shortages as manufacturers halt the production of medicines that cannot be produced without incurring losses. As one executive recently put it: "You can raise prices [via tariffs], but it doesn't mean you're going to get reimbursed more because of the way our insurance system works." Tariffs could thus have complex and, in some cases, extreme impacts on the availability of medicines.

Similarly, tariffs would compel the innovative pharmaceutical industry to adopt sharp cost-cutting measures. The added costs of tariffs would undermine the ability of U.S. manufacturers to invest in R&D capabilities and tarnish the attractiveness of the United States as a destination for biopharmaceutical manufacturing. Forced cuts to R&D and reductions in capital available for facility and workforce investments would also potentially disrupt clinical trials. In addition, such conditions would likely impact the ability of the industry to move current prescription drugs to over-the-

counter (OTC) status, and it would thus run contrary to the administration's broader public health priorities related to medication accessibility.

A Positive Agenda for Biopharmaceuticals

Rather than broad-based tariffs, the administration should embrace a positive agenda to enhance the competitiveness of U.S. biopharmaceutical manufacturing and make further domestic investments more attractive.

Taxation. In December 2017, Congress passed the landmark Tax Cuts and Jobs Act ("TCJA"), the most comprehensive tax reform legislation since 1986. The TCJA lowered and simplified the federal tax burden on American families and workers, and it substantially modernized the U.S. approach to taxing business income—particularly with respect to cross-border transactions. A key component of those reforms for IP-intensive industries such as biopharmaceuticals was the allowance of a 37.5% deduction to U.S. corporations for properties sold or services rendered outside the United States (so-called "foreign derived intangible income" or "FDII"). Under a 21% corporate income tax rate, this deduction effectively reduces the tax rate on FDII to approximately 13.125%.

By subjecting FDII to a reduced effective rate of U.S. tax through this deduction, Congress sought to encourage U.S. companies to locate and derive income from intangible property and increase valuable economic activity in the United States. Congress also understood that establishing a deduction for FDII would help the United States compete with countries offering preferential tax regimes for income related to certain forms of IP, such as "patent box" regimes (like the one discussed below). The FDII deduction has proven remarkably effective at furthering these aims. Absent congressional intervention, however, the effective tax rate on FDII will automatically increase to more than 16.4% after the end of this year. Congress should therefore prioritize legislation to prevent this scheduled increase and make the FDII deduction a permanent, undiluted feature of the U.S. international tax system.

Beyond extending current policy with respect to FDII, Congress should also consider smart policy enhancements to facilitate additional IP ownership in the United States. In particular, Congress should consider allowing the transfer of existing IP owned by controlled foreign corporations (CFCs) to their U.S. shareholders without giving rise to U.S. taxable income. Adopting such a provision would remove a significant impediment to transferring the ownership of existing foreign-owned IP to the United States—one that is particularly acute in the pharmaceutical industry. To this end, Congress could revisit proposed section 966, "Special rules for transfers of intangible property from controlled foreign corporations to United States shareholders," which was included in the Senate's version of the TCJA but ultimately

omitted from the final legislation. This provision would have applied for certain distributions of IP held by a CFC, allowing taxpayers to repatriate IP without incurring U.S. taxes because the fair market value of the property on the date of the distribution would have been treated as not exceeding the adjusted basis of the property immediately before the distribution.

At the very least, however, Congress must act to preserve the TCJA's pro-growth reforms and avoid adopting any measures that would otherwise dilute them. Congress should likewise reject any measures that would discriminate against U.S. firms or otherwise undermine their competitiveness in global markets.

Intellectual Property. IP protections provide innovative companies with the legal certainty needed to make high-risk, high-capital investments into the next generation of innovative medicines and technologies. The United States has been a long-standing leader in IP protection, ranking atop the U.S. Chamber's International IP Index in all 13 editions of this annual report. America's IP framework offers certain advantages—such as patent linkage—that have successfully created predictability for both innovative and generic manufacturers alike and gives the U.S. IP system unique advantages over other markets, such as the EU, Switzerland, and the UK. The success of America's IP ecosystem has underpinned U.S. global competitiveness and been a pivotal factor in companies' decisions to increase investment at home.

However, our trading partners are not standing still on IP protection. For example, in the UK, the government introduced a new 20% R&D expenditure credit to facilitate greater investment in R&D in the market. This credit is in addition to the UK's patent box framework which provides a 10% corporate tax rate on income generated through patents assets. In Switzerland, the Swiss National Council is considering amendments to the Patent Act that would improve the process for patent opposition proceedings. If the U.S. is looking to reshore the manufacturing of API from these two markets, it will be critical for policymakers to continue upholding strong domestic IP capabilities to retain America's competitive advantage on innovation.

Regulation. Regulatory reforms—such as permit and documentation streamlining—would also stimulate domestic investment and associated production. For example, some of the FDA's documentation and inspection requirements, especially those related to post-approval changes for API manufacturing, are especially time-consuming and costly, with some taking anywhere between three to seven years for approval. Streamlining regulatory compliance processes would facilitate onshoring of critical supply chains without disruption.

Workforce. Workforce incentives should also be considered to provide the appropriate skills and expertise necessary in pharmaceutical manufacturing processes. Overall, such incentives—which should arise from collaboration between the government, private sector, and related institutions—should align with a critical understanding of the time horizon, adjustment periods and manufacturing capabilities needed to achieve certain onshoring—as well as the extent it is possible or necessary. Relocating production of innovative medicines takes significant resources, with new manufacturing facilities totaling up to $2 billion and taking between 5 and 10 years to be established. In addition, the U.S. Chamber encourages the administration to support a merit-based student visa and immigration system that continues to attract high talent STEM individuals from around the world to contribute to our onshore resilient innovation & supply chain ecosystem.

Trade. It is critical that the administration continue to address foreign trade barriers that shut out world-beating U.S. products in foreign markets, many of which are outlined in the U.S. Chamber's recent submissions to the Office of the U.S. Trade Representative on unfair foreign trade practices and the Special 301 Review.

As articulated in the former submission, several U.S. trading partners continue to implement unfair trade practices to artificially suppress American-made innovator drug prices below free-market levels, including through international reference pricing, clawback measures (e.g., in Europe), and mandatory price cuts (e.g., Japan). Moreover, several trading partners deny adequate and effective IP protection to U.S. pharmaceutical innovators, e.g., by limiting the ability to patent inventions or effectively enforce such patents and by failing to provide regulatory data protection. These practices obstruct market access for American companies, manipulate competition, and depress revenues outside the United States, thus placing an unfair burden on the American healthcare system to fund continued research critical to the development of new treatments for chronic diseases while reducing revenues need to invest in manufacturing in the United States.

On the home front, the administration should urge congressional passage of sectoral initiatives such as the bipartisan Medical Supply Chain Resiliency Act, which would direct the U.S. Trade Representative to negotiate trade agreements with trusted allies to eliminate tariffs and other trade barriers that weaken the U.S. medical goods manufacturing base and that of our allies. Such agreements would also support intellectual property protection, regulatory cooperation, collaboration on public and private R&D efforts, and address broader regulatory obstacles that can serve as impediments to greater manufacturing investments with allies. Fostering strategic collaborations with trusted and aligned trading partners is essential for ensuring diversified resilience in related pharmaceutical supply chains.

Above all, pro-growth reforms should be the objective of U.S. trade negotiations with foreign governments, including enforcing existing deals and striking new agreements that would create more opportunities for U.S. exports. Policymakers are encouraged to engage in continuous dialogue with industry on solutions that minimize disruption to investment activities and the broader economy. The U.S. Chamber urges the president to use any leverage gained through negotiations to break down barriers—not build them up—and to expand opportunities for American businesses, while avoiding tariffs that raise the cost of living and undermine U.S. manufacturing.

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The U.S. Chamber appreciates the opportunity to share these comments and looks forward to further discussion to address these important issues.

Sincerely,

John Murphy
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Head of International
U.S. Chamber of Commerce