Business Roundtable

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May 7, 2025

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

RE: Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket XRIN 0694-XC120)

Dear Secretary Lutnick,

Business Roundtable ("the Roundtable" or "BRT") respectfully submits these comments to the Department of Commerce ("Commerce") and Bureau of Industry and Security ("BIS") in response to the request for public comments on the national security investigation of imports of Pharmaceuticals and Pharmaceutical Ingredients under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232").[1] BRT is an association of more than 200 chief executive officers ("CEOs") of America's leading companies, representing every sector of the U.S. economy. BRT CEOs lead U.S.-based companies that support one in four American jobs and almost a quarter of U.S. gross domestic product ("GDP"). BRT appreciates the opportunity to comment as the production or consumption of products that are potentially within the scope of this investigation reaches across the Roundtable membership.

BRT supports Commerce's goal to increase domestic production of and strengthen U.S. competitiveness in the pharmaceutical and pharmaceutical ingredients sectors. However, BRT believes that: (1) the current broad scope of the investigation, encompassing a wide range of pharmaceutical products, ingredients, and upstream materials, could inadvertently undermine U.S. innovation and competitiveness throughout the supply chain; (2) given the breadth and complexity of the investigation, Commerce should prioritize further stakeholder engagement as it refines the scope, consider a process for companies to petition for relief for inputs that cannot be sourced domestically or available in sufficient quantities to meet domestic demand, and provide sufficient phase-in periods for companies to adjust to any remedial measures

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15,951 (April 16, 2025) (Docket No.BIS-2025-0022; XRIN 0694–XC120).

implemented through the investigation; and (3) to effectively incentivize domestic pharmaceutical manufacturing, the Administration should adopt a targeted approach that makes U.S. production more cost-effective and efficient.

I. Broad Scope of the Investigation Threatens Pharmaceutical Innovation and Competitiveness

The current scope of the investigation is overly broad and insufficiently defined. First, the underlying product scope is wide, potentially covering a wide swath of prescription (both innovative and generic drugs) and over-the-counter pharmaceuticals, medical devices, essential health items and other products that are regulated as "drugs" by the Food and Drug Administration. Secondly, the scope is broadened further to include "derivative products" of other enumerated materials and inputs. This ambiguity creates regulatory uncertainty and risks unintended economic disruptions across the broader pharmaceutical value chain. Inputs that have incidental uses in pharmaceutical products but are used commonly in other consumer goods may be captured in the scope of the investigation, and any resulting tariffs would impose costs on those consumer goods. Moreover, the economic burden on upstream products would amplify throughout the value chain, placing disproportionate burdens on downstream retailers.

The broad scope of the investigation could include products and inputs with no clear national security implications. For the purposes of this investigation, Commerce should use targeted criteria to identify which medicines are essential for U.S. national security. For example, during his first term, President Trump's efforts to reshore medical supply chains focused on certain essential medicines that FDA identified as the most needed for patients in U.S. acute care medical facilities or to respond to pandemics, epidemics, and chemical, biological and radiological/nuclear threats.[2] This FDA Essential Medicines list has been identified as part of that action, and could be utilized for narrowing the scope of the investigation. Additionally, Commerce should refrain from applying tariff remedies under this investigation to pharmaceutical inputs from key U.S. trading partners such as Australia, Canada, the European Union, India, Japan, Switzerland and the United Kingdom.

II. Broadly Applied Pharmaceutical Tariffs Could Severely Impact the U.S. Economy and Healthcare System

The pharmaceutical industry plays an essential role in the U.S. economy, public health, and global leadership. In 2021, this industry contributed approximately $355 billion to GDP and

[2] Exec. Order No. 13,944, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States*, 85 Fed. Reg. 49,929 (Aug. 2020).

generated $655 billion in total economic output, while supporting approximately 1.5 million U.S. jobs across the supply chain.[3]

A broad application of tariffs would significantly disrupt the pharmaceutical value chain, which flows hierarchically from key starting materials ("KSMs") to active pharmaceutical ingredients ("APIs") and then to finished drug products. Tariffs imposed at any stage of this chain would have cascading effects that increase costs and delay drug development and market entry of new products.

Broad-based tariffs would increase manufacturing costs and constrain investment in research & development (R&D) by limiting financial resources and raising the perceived risks of drug development. The pharmaceutical industry is highly innovation intensive. In 2021, the industry's R&D intensity was 16.1 percent, significantly higher than the national average of 4.6 percent.[4] In the broader U.S. biopharmaceutical ecosystem, which includes development-stage firms that invest heavily in R&D before commercialization, R&D intensities may reach as high as 34 percent.[5] In 2024, the average cost to develop a new drug was approximately $2.23 billion and it took 10 to 15 years to develop, making the decision to invest in R&D highly sensitive to cost pressures.[6]

Broad-based tariffs also risk causing supply shortages and price increases in some products, impacting access to important medicines, particularly generic drugs. As a result, many pharmacies may have to stop carrying some items as they are no longer available, or because they are unable to absorb price increases, close some locations and disrupt patient care. For example, 90% of prescriptions filled in the United States are for generic drugs, which heavily rely on the imports of certain key APIs and KSMs. Availability of over-the-counter products that rely on imported APIs, such as acetaminophen and ibuprofen, the widely used fever reducers and pain relievers, is also likely to be impacted by broad tariffs.

To the extent tariffs are considered as part of any remedy recommendations in the investigation, they should be construed as narrowly as possible to address national security risks and avoid stacking with tariffs imposed through different regimes. Imposing tariffs across a broad scope of pharmaceuticals and pharmaceutical ingredients would weaken this competitive advantage by raising production costs and disincentivizing companies from investing or operating in the United

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[3] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 23.
[4] National Center for Science and Engineering Statistics, *Business R&D Performance in the United States Tops $600 Billion in 2021* (Sept., 28, 2023) (Official government data from the 2021 Business Enterprise Research and Development ("BERD") Survey).
[5] Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical R&D Investment*, 23 Nature Rev. Drug Discovery 652 (2024).
[6] Deloitte Centre for Health Solutions, *Measuring the Return from Pharmaceutical Innovation: 15th Edition* (Mar. 2025) at 6.

States.[7] At the same time, China and several countries around the world are aggressively offering tax incentives, subsidies, and streamlined regulations to attract pharmaceutical investment.[8] At this critical juncture, the U.S. should reinforce – not jeopardize – its global leadership in the sector. Strategic reforms that improve the cost efficiency of domestic production are better suited to securing long-term competitiveness.

III. Policies to Incentivize Domestic Pharmaceutical Production

The United States is a global leader in pharmaceutical manufacturing, building on its competitive advantages. In 2023, U.S. consumer sales of finished biopharmaceuticals totaled $393 billion, of which 64 percent was produced in the United States and 36 percent was imported, primarily from U.S. allies.[9] While the United States imports APIs and KSMs, it remains a major exporter of high-value, innovation-driven pharmaceuticals.[10] In 2022, U.S.-based pharmaceutical manufacturers exported over $80 billion in products and ranked third-largest globally.[11] U.S. pharmaceutical exports have more than doubled over the last decade, reflecting growing global demand for American innovations.[12] The strength is supported by advanced R&D, robust intellectual property protections, and a favorable innovation ecosystem.[13]

Relocating or expanding manufacturing production in the United States is time-consuming, costly, and complex. Building a new manufacturing facility has high costs and can take 5 to 10 years including the time and costs to comply with regulations. Rather than imposing broad tariffs that would drive up costs, the Administration should adopt targeted, strategic policies designed to enhance the cost-effectiveness and efficiency of domestic pharmaceutical manufacturing. For the full scope of Business Roundtable's recommendations for building domestic manufacturing capacity and supply chain resilience for synthetic APIs, please review our recent report, Resilient, Diverse and Secure: Improving Critical Supply Chains.[14] Potential areas of focus include:

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[7] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 35.
[8] Sujai Shivakumar, Charles Wessner & Julie Heng, *The United States Cannot Afford Disarray as China Strengthens Its Biopharmaceutical Industry*, Ctr. for Strategic & Int'l Stud. (Mar. 18, 2025).
[9] EY, Impacts of potential tariffs on the US pharmaceutical industry (April 2025)
[10] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 16; Niels Graham, *The US Is Relying More on China for Pharmaceuticals — and Vice Versa, Atlantic Council* (Apr. 20, 2023).
[11] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 16.
[12] *Id.*
[13] *Id.*; Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical R&D Investment*, 23 Nature Rev. Drug Discovery 652 (2024).
[14] The recommendations begin on page 19 of the report. Recommendations include appropriately resourcing agencies, expediting application timelines for FDA-approved suppliers and manufacturers of generic essential drugs, and investing in domestic capabilities for pharmaceutical research support.

A. Pro-Growth Tax Code

Business Roundtable applauds the Administration for working with Congress to maintain a competitive tax code that encourages pharmaceutical and healthcare companies to invest, produce, and create jobs in the United States.[15] The corporate tax rate, the income base against which it is applied and the way in which the United States taxes income earned in foreign markets all affect the incentive to invest and create jobs in the United States. A more attractive U.S. tax environment gives both U.S.- and foreign-headquartered companies an incentive to invest more capital — equipment, technology and other facilities — in the United States.

Retain the permanent corporate income tax rate of no more than 21 percent. Reforms in the 2017 Tax Cuts and Jobs Act ("TCJA") resulted in historic wage and job growth and investment in the United States. Prior to the 2017 reforms, the U.S. corporate tax rate was the highest among industrialized countries. The new combined federal and state corporate rate of 25.8 percent puts the United States in the middle of Organization of Economic Co-operation and Development ("OECD") countries — higher than 23 of our 37 OECD competitors, including Belgium, Spain, and the United Kingdom.

Restore the full expensing for R&D investments and for equipment and machinery investments to further incentivize domestic research and manufacturing expansion. The federal government can stimulate private sector investments in R&D through targeted tax provisions that allow companies to expense research expenditures. For nearly 70 years, the U.S. tax code has allowed businesses to fully deduct their R&D expenses in the year in which the spending occurred. However, since 2022, businesses now must amortize these expenses over a period of five years, making R&D more costly to conduct in the United States. As a result of this change, the United States is now one of two developed countries requiring the amortization of R&D expenses.

Maintain and strengthen an approach to the taxation of international earnings that incentivizes owning intellectual property in the United States and keeps the system of minimum taxes on foreign income competitive. Prior to 2017, the U.S. international tax system penalized U.S. companies for returning foreign earnings to the United States with a significant layer of additional tax. Tax reform moved the United States to a more modern international system and included significant base erosion provisions. Scheduled changes to the international tax regime in 2026 will harm the competitiveness of U.S. companies. Business Roundtable welcomes the Administration's work with Congress to ensure a competitive international tax landscape.

[15] Business Roundtable, *Resilient, Diverse and Secure: Improving Critical Supply Chains* (2023) at 11-12.

B. Regulatory Efficiency

Streamline permitting and approval processes, including harmonization of standards and expedited pathways. The Administration could improve construction speed and reduce costs by streamlining permitting processes to shorten decision timelines, including embracing the National Environmental Policy Act ("NEPA") reforms; requiring agencies to issue final decisions on environmental reviews within 90 days of completing an environmental impact statement ("EIS") and providing preliminary feedback within 14 days of submission; digitizing operations by supporting implementation of a centralized digital system for agencies to streamline processes; and differentiating and prioritizing projects by revising project permitting requirements in areas with operations and community engagement.

Reduce regulatory delays to significantly improve the scalability of domestic pharmaceutical production.[16] The standard review of new drug applications, including the approval of the synthetic API supplier, is a process that takes a minimum of 12-15 months, excluding clinical trial years. Despite the FDA streamlining certain processes, receiving approval for a new supplier of an essential generic medicine API still requires around four months. The lengthy process, which can be further delayed, can add cost and make it more difficult for manufacturers to change or add suppliers.

C. Workforce Development

Modernize and expand education and training programs to help build the pipeline of skilled talent required to sustain long-term growth in pharmaceutical manufacturing.[17] The Administration should work with Congress to improve the Workforce Innovation and Opportunity Act to direct resources to training programs that focus on in-demand careers, including those requiring STEM-related skills. Additionally, the Administration should work with Congress to expand Pell Grant eligibility for students pursuing high-quality, short-term education and training programs. BRT encourages the Administration to support a broad range of work-based learning opportunities that allow workers to develop skills and gain experience in real-world settings, including modernizing the U.S. Department of Labor's Registered Apprenticeship system.[18]

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[16] *See id.*

[17] Brandy Bullen, *Tackling the Skilled Labor Shortage in Biopharma Manufacturing*, Labiotech.eu (Sept. 27, 2023).

[18] BRT is encouraged by the recent executive order, "Preparing Americans for High-Paying Skilled Trade Jobs of the Future," directing the Secretaries of Labor, Commerce, and Education to prepare a "Comprehensive Worker Investment and Development Strategy" and a plan to expand participation in Registered Apprenticeships. Coordinating education and training programs across agencies, using workforce investments more efficiently, and improving individual programs like Registered Apprenticeship are critical to helping meet the needs of workers and employers. *See* Exec. Order No. 14,278, 90 Fed. Reg. 17,525 (Apr. 12, 2025).

IV. Transparent and Efficient Process to Evaluate Individual Circumstances Is Needed

In addition to narrowly crafting the scope of the investigation, Commerce should establish a transparent and efficient process by which interested stakeholders can raise specific situations related to their products to Commerce. This process will enable Commerce to prevent any inadvertent yet harmful consequences of the investigation to U.S. industries, workers, and the economy.

The process must be transparent and easily navigable to both enable companies to share information related to the specific situations related to their products and allow Commerce to fully evaluate all necessary information before making any determinations. The transparent process will also assist both Commerce and companies to save time and resources to determine whether certain products are truly affected by the scope of the investigation and require attention by the Administration.

The process must also be efficient to mitigate any inadvertent disruptions to the U.S. pharmaceutical and pharmaceutical ingredient supply chains. Faster processing time means that companies can carry on with their day-to-day operations more swiftly and without the uncertainty of potential enforcement.

Any remedy should include an appropriate phase-in period to allow time for companies to make changes necessary to supply chains to mitigate economic impacts and achieve the appropriate regulatory approvals for not only direct inputs but also products such as packaging materials. Certain U.S.-manufactured packaging materials have regulatory processes that can take 12-18 months.

V. Conclusion

The strength of the U.S. pharmaceutical sector lies in its innovative capacity and global competitiveness, attributes vital to national security and economic prosperity. Broad tariffs threaten these foundational strengths by increasing costs, reducing innovation funding, and eroding competitiveness of U.S. firms.

Accordingly, BRT urges Commerce to narrow the investigation's scope and prioritize policies that foster a more cost-effective, efficient domestic pharmaceutical manufacturing environment. This strategic approach will reinforce America's economic resilience and secure its leadership position in global pharmaceutical innovation. In addition, the accelerated timeline for initiating this investigation might have resulted in certain procedural oversights, including the unintended inclusion of certain products in the exemption list (i.e., Annex II) of the April 2, 2025, Executive Order establishing reciprocal tariffs, which should be reviewed prior to determining the scope of

this Section 232 action.[19] Thus, to enhance policy effectiveness and strengthen stakeholder confidence, the Administration might benefit from establishing a formalized mechanism through which inappropriately categorized products may be quickly reconsidered, and, where warranted, removed from Annex II classification.

BRT looks forward to working with Commerce as it refines the scope of the investigation and encourages additional opportunities for stakeholder engagement, including public hearings and industry forums, to ensure that the practical implications of the investigation are fully understood and any unintended consequences are mitigated. Active engagement with stakeholders, such as industry and allied partners, would be essential in effectively protecting critical supply chains and successfully achieving the Administration's policy objectives.

Finally, BRT appreciates Commerce's work to swiftly negotiate deals with top trading partners that level the playing field for American goods and services and remove harmful tariffs and retaliatory measures and welcomes the opportunity to engage with Commerce on these issues as well.

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Should you have any questions about this submission, please contact Casey Denoyer, Senior Policy Director (cdenoyer@brt.org or 202-496-3260).

[19] Regulating Imports with a Reciprocal Tariff to Rectify Trade Practices that Contribute to Large and Persistent Annual United States Goods Trade Deficits, Exec. Order 14257, 90 Fed. Reg., 15,041 (Apr. 2, 2025).