

1000 Maine Avenue, SW, STE 500 Washington, DC 20024 202.872.1260 brt.org

October 17, 2025

Uploaded to: https://www.regulations.gov

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

RE: Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices (Docket XRIN 0694-XC134)

Dear Secretary Lutnick,

Business Roundtable ("the Roundtable" or "BRT") respectfully submits these comments to the U.S. 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 personal protective equipment ("PPE"), medical consumables, and medical equipment, including devices (collectively "medical goods") under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232"). 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. BRT appreciates the opportunity to comment as the products within the scope of this investigation reach across the manufacturing and retail operations of the Roundtable membership.

BRT supports the Administration's desire to improve the resiliency of the American health care supply chain by incentivizing domestic manufacturing of essential medical goods and supporting medical technology innovation. However, the imposition of Section 232 tariffs runs a serious risk of threatening American health security, undermining innovation and raising health care costs. If tariffs are deemed necessary, Commerce should recommend that any tariff regime be stayed pending the development of a tailored plan, in consultation with industry, that secures supply chains without inadvertently undermining U.S. manufacturing and

-

¹ Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices, 90 Fed. Reg. 46,383 (Sept. 26, 2025) (XRIN 0694-XC134).

innovation. This will ensure that such tariffs neither hinder the ability of the American health care system to continue to provide the highest quality medical equipment and technologies nor contribute to rising costs of health care, which would contradict President Trump's goal to make health care more affordable and accessible. Finally, to effectively accomplish its goals of bolstering domestic manufacturing in important sectors such as healthcare, the Administration should take a strategic approach that also utilizes domestic policy tools to enable U.S. production to be more cost-effective and efficient.

I. Barriers to Access Resulting from this Investigation Would Threaten the Competitiveness of the American Medical Equipment Industry

The Roundtable appreciates the Trump Administration's recognition that medical goods are essential to the U.S. economy. The U.S. medical goods industry, however, is a unique manufacturing success story and global innovation leader.

As an example, the medical technology industry accounts for 70 percent of the U.S. market and nearly three million U.S. jobs, providing American hospitals, outpatient medical facilities and patients with the highest quality medical technologies in the world.² It is a global leader in manufacturing and innovation, representing an estimated \$80 billion in exports in 2024.³ The industry has also experienced significant growth since 2017, leading to job creation in nearly every state.⁴ With research and development included, the industry supports millions of goodpaying jobs across thousands of manufacturing facilities.⁵ Of particular significance in this investigation is the fact that only about 30 percent of the U.S. medical technologies market is imported, and imports overwhelmingly come from trusted allies in Europe and North America.⁶ Imports from China account for only three percent of the total U.S. medical technology sales.⁷

While the American medical goods industry currently leads the world in innovation, providing American hospitals, doctors, patients and consumers the highest quality medical technologies in the world, the imposition of tariffs would undermine this leadership. For example, tariffs would result in the use of resources that could have otherwise been invested in innovation, research and development and manufacturing capacity. Any cuts in research and development would, in turn, jeopardize American competitiveness as a world leader in medical goods and technologies. Cutbacks to research and development have already occurred in 2025 due to the imposition of reciprocal tariffs.

² AdvaMed, The U.S. Medtech Industry: A Pillar of American Manufacturing and Medical Innovation (July 17, 2025).

³ Id.

⁴ Id

⁵ *Id*.

⁶ *Id*.

⁷ Id.

The U.S. medical goods industry also has a demonstrated record of being resilient and proactive. It has responded to public health emergencies and invested in domestic capacity when there is a national need. This was evident during the COVID-19 pandemic when U.S. production of COVID-19 tests and N-95 masks surged. The domestic industry rose to the challenge by making the United States largely self-sufficient for these products. Government policies, in cooperation with industry, should reinforce these strengths, not undermine them by handicapping the industry with tariffs.

Significantly, tariffs could have a direct and negative impact on the health of the American population. Potential Section 232 tariffs on imported medical goods would raise costs for hospitals, surgical centers, physician and nonphysician providers, pharmacies, insurers, and ultimately patients and consumers. Many of the high-use, essential products used by providers each day like masks, gloves or surgical kits are not reimbursed separately by payors. It will be extremely challenging for providers to accommodate an increase in costs for these critical products when additional reimbursement is not available. For consumers of critical apparatus, like a non-robotic prosthetic, pacemaker or hearing aid, tariff-driven cost increases could ultimately make these products less affordable. Additionally, medical devices include consumer health products sold over the counter with no involvement of a healthcare professional. Tariffs on such products would also contribute to increased costs for consumers on widely used, self-administered medical devices such as dental floss and toothbrushes.

Finally, potential Section 232 tariffs would make U.S. manufacturers less competitive vis-à-vis their Chinese competitors. U.S. companies would need to absorb a significant portion of the tariff cost, as passing along cost to hospitals can take up to two years based on negotiated contracts. Meanwhile, their Chinese competitors would have access to subsidies that would offset this additional cost, further undermining U.S. manufacturers and increasing costs of their products in the United States and abroad.

Under these circumstances, BRT believes that Section 232 tariffs on medical goods will not serve U.S. national security interests. The Roundtable urges the Administration to consider alternative courses of action following a thorough and transparent Section 232 investigation.

II. Even if Tariffs Were to Be Imposed, the Administration Should Stay Implementation to Permit an Evaluation of the Affected Supply Chains

If, notwithstanding the risks identified above, Commerce determines to move forward with a new tariff regime on some or all medical goods, the Roundtable urges Commerce to stay implementation to allow for the development of tailored plans with American industry. It is imperative that Commerce understand the potential impacts on supply chains, consumers and patients so that it can design a nuanced and effective tariff regime—one that does not undermine the industry's global leadership and its ability to continue to provide the highest

quality medical goods to American hospitals, doctors, patients and consumers without increasing the cost of American healthcare.

In considering the scope of any potential tariff remedy, BRT urges Commerce to consider prior actions and existing exemptions for products that may be encompassed by the scope of this investigation. First, the Administration has appropriately exempted critical medical devices, such as insulin delivery systems, diagnostic equipment and protective gear from Section 301 tariffs, and should not now subject them to Section 232 tariffs. Second, in the case of medical goods that remain subject to Section 301 tariffs, any potential Section 232 tariff remedy should not stack upon existing tariffs. Third, there should be continued allowance for Chapter 98 provisions, including repairs and humanitarian accommodations. Lastly, preferential treatment of USMCA qualifying goods should remain in order to preserve investments made by U.S. manufacturers.

In considering the timeline for any potential tariff remedy, BRT urges Commerce to consider that medical goods are highly regulated in the United States. For example, the Food and Drug Administration (FDA) has to approve all moves to new manufacturing facilities to ensure the continued safety and effectiveness of medical technology. The required validation of new suppliers, processes and equipment generally takes three years or more, potentially jeopardizing access to critical medical technologies.

Finally, any potential tariff remedy should not establish a tariff inclusion process, which would inject additional cost, complexity, and uncertainty upon American businesses, healthcare providers, patients and consumers.

Given these complications, stayed implementation to allow for the development of tailored plans with American industry will mitigate the risk of unintended harm to America's status as a leader in medical goods manufacturing and ensure that Americans continue to have reliable access to healthcare.

III. Policies to Incentivize Domestic Production

While Business Roundtable acknowledges the growing importance of the PPE, medical consumables, and medical technology sectors, bolstering U.S. manufacturing activity is better addressed through a targeted suite of policies to reduce domestic production costs. Further, maintaining a reliable supply of covered products while domestic capacity scales up will be important as companies and consumers rely upon these products.

⁸ Office of the United States Trade Representative, Notice of Product Exclusion Extensions and Additional Modifications: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 85 Fed. Reg. 85831 (Dec. 29, 2020).

Accelerating manufacturing requires stable economic conditions and consistent policy support over decades. As noted above, 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 more than five years, including the time and costs to comply with regulations, particularly in the medical space. To support the expansion of the domestic manufacturing base, Commerce should work across the Administration and with Congress to initiate strategic policy reforms that will make production more cost effective and efficient. For the full scope of Business Roundtable's recommendations for building domestic manufacturing capacity, please review our recent report, Revitalizing American Manufacturing. Recommendations include:

- <u>Competitive Tax Policy</u>: Maintain a low corporate tax rate with policies that lower the cost of domestic investment, research and development, and manufacturing.
- <u>Permitting and Regulatory Reform</u>: Reduce regulatory hurdles, including by streamlining permitting policies, and support innovation by accelerating product approvals where appropriate.
- <u>Strategic Trade Policy</u>: Promote market access for U.S. exporters and combat unfair trade practices.
- <u>Energy and Infrastructure</u>: Ensure affordable, reliable access to energy and strong public infrastructure.
- <u>Workforce Development</u>: Support the U.S. workforce through skills development, partnerships with education and training providers, and legal immigration.

IV. Conclusion

Business Roundtable appreciates Commerce's recognition that reliable supply chains for medical goods are important to the security and competitiveness of U.S. manufacturing. Nevertheless, the fact that these products have a direct impact on the health of Americans necessitates a judicious approach. Tariffs are ill-suited to safeguarding U.S. interests in this instance. If tariffs are deemed necessary, Commerce should recommend that any tariff regime be stayed pending the development of a tailored plan, in consultation with industry, that secures supply chains without inadvertently threatening American health security, undermining innovation and raising health care costs.

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 avoided.