NATIONAL ASSOCIATION OF Manufacturers

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Mr. Stephen Astle
Director, 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: Docket numbers BIS-2025-0258 and XRIN 0694-XC134: Request for Public Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices

Dear Mr. Astle:

The National Association of Manufacturers is the largest manufacturing association in the United States, representing manufacturers of all sizes, in every industrial sector and in all 50 states. Manufacturing drives American prosperity—the industry employs nearly 13 million people, contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.[1]

The NAM appreciates the opportunity to comment on the Department of Commerce investigation under Section 232 of the Trade Expansion Act, to determine the effects on the national security of imports of personal protective equipment (PPE), medical consumables, and medical equipment, including devices.

The NAM supports the president's goals to increase manufacturing in America and to grow manufacturing jobs. Manufacturers also support policies to increase domestic production capabilities to ensure sufficient supply of essential medical supplies including PPE, medical consumables and medical equipment. Manufacturers stand ready to partner with the Administration to improve U.S. resilience in the medical supply chain. However, tariffs on these goods are likely to have unintended consequences including increased costs for patients and hospitals and supply chain disruptions. Instead, to unlock opportunities to improve resiliency of

[1] National Association of Manufacturers (May 2025), Manufacturing in the United States, https://nam.org/mfgdata/#KeyFacts

the healthcare supply chain and strengthen domestic manufacturing, the Administration should undertake domestic reforms and seize trade policy opportunities to provide an onramp for manufacturers to achieve these shared goals. This could include providing manufacturers duty-free access to key inputs for manufacturing in the U.S. as well as time to develop alternative domestic sources and/or increase domestic production capacity.

PPE, Medical Consumables and Medical Equipment Role in U.S. Economy

Manufacturers in the U.S. of PPE, medical consumables and medical equipment play a large role in the U.S. economy. Manufacturers in this critical sector range from multinational corporations that produce complex diagnostic equipment to small and medium sized manufacturers that specialize in making sterile barrier packaging for syringes. Medical equipment and supplies manufacturers employ nearly 340,000 workers in all 50 states.[2] At an average annual salary of nearly $70,000, workers in the medical equipment and supplies sector earn higher salaries than the national average.[3]

As of 2022, the medical equipment and supplies manufacturing industry was comprised of 16,000 establishments nationwide.[4] While most medical equipment is manufactured in the U.S. for domestic use, U.S. exports of medical technologies have consistently outpaced imports, resulting in a trade surplus of over $1.1 billion in 2017.[5]

Medical Technology Investments Drive Innovation. Tariffs Could Reduce R&D Spend in the U.S.

The healthcare industry spends a significant amount on R&D. In the medical technology space alone, 95% of research and development (R&D) occurs in the U.S., with medical technology manufacturers spending over $29.2 billion on R&D in the most recent fiscal year.[6] [7] According to the International Trade Administration, when compared to several other industries, the medical technology industry invests a higher percentage of yearly revenues into innovation and R&D as the industry researches ways to better diagnose and treat patients in America.[8] While R&D expenditures would not be subject to a tariff, tariffs on medical technology devices, would necessarily increase the cost of research materials and production, which reduces funds available for increased R&D spend in the U.S.

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[2] U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics https://www.bls.gov/oes/2023/may/naics4_339100.htm
[3] Ibid.
[4] Advamed Fact Sheet, https://www.advamed.org/medical-device-industry-facts/
[5] Ibid.
[6] Medical Design and Outsourcing Report (2025) https://www.medicaldesignandoutsourcing.com/rd-alert-research-and-development-spending-medtech-big-100/
[7] Advamed https://www.advamed.org/
[8] SelectUSA- Medical Technology Industry Report, https://www.trade.gov/selectusa-medical-technology-industry

The Strength of U.S. Industry Depends on Stable and Diversified Supply Chain Networks. Tariffs Threaten to Disrupt Trade Flows, Increase Costs and Impact Access to Critical Healthcare Supplies.

The strength of the U.S. medical technologies industry – from the jobs it supports, to the economic output it produces, to the innovation it drives – depends on stable and diversified supply chain networks that tariffs threaten to undermine. In 2024, the U.S. imported approximately $303 billion worth of medical devices, pharmaceuticals, and life science goods.[9] Of that total, approximately $294 billion entered tariff free as the average MFN is less than 1%.[10] Imports of healthcare products were primarily sourced from allies including Ireland (23%), Germany (10%), Mexico (9%), Singapore (8%), and Switzerland (5.5%), with approximately 5% coming from China.[11]

Access to medical products requires a resilient medical supply chain that can weather both foreign and domestic supply disruptions. As such, manufacturers source from an array of suppliers globally, so long as the equipment and/or inputs meet the required specifications. In some cases, these specific equipment purchases are the result of decades-long partnerships with suppliers across the globe who have met required FDA and NIOSH certification processes.

Importantly, some essential inputs for certain health care supplies are not produced in the U.S. For example, a manufacturer of rubber gloves can only source the raw material from Malaysia. U.S. glove manufacturers are seeking other sources of rubber including developing domestic production of Nitrile Butadiene Rubber (NBR), but they need time to develop this capacity as they currently cannot meet domestic demand. Immediate tariffs or other restrictions on these critical supplies would increase production costs, disrupt domestic manufacturing and jobs, and reduce U.S. competitiveness with foreign producers, such as China, affecting market share in both the U.S. and export markets. Secure and consistent availability and access to these key inputs is imperative for manufacturers who rely on these imports to continue producing these products in the U.S.

Strict Adherence to U.S. Certification Requirements

All imported medical devices must adhere to rigorous U.S. requirements to ensure product safety, including the conditions under which the device is manufactured. For example, surgical respirators are required to comply with both FDA 510(k) standards as well as be certified by the National Institute for Occupational Safety and Health (NIOSH) to meet a variety of criteria from durability to permeability to ensure that they are safe and effective. Any changes to sourcing of a device will trigger a new certification and registration process for the new supplier which can take up to 3-4 years to complete, depending on the classification of the device.

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[9] PwC's US Tariff Industry Analysis – Pharmaceutical, Life Science, and Medical Device (2025) https://tinyurl.com/mpkty8c8

[10] WTO Tariff and Trade Data (2024), https://ttd.wto.org/en

[11] U.S. Bureau of Economic Analysis (2024)

Risks of Wide Scope

This Section 232 investigation has a very wide scope ranging from surgical gowns to high-tech ultrasound machines. While the *Federal Register* notice indicates the investigation focuses on supplies and equipment in the healthcare space, there are a number of products that are also regulated by the FDA but have a different end-use and thus could be at risk of falling within scope of the investigation. For example, PPE includes gloves and respirators, items that are ubiquitous across the country both in hospitals as well as on the shop floor. While the investigation notes for purposes of the investigation that PPE only refers to PPE used in healthcare settings, N95 masks are also used for industrial purposes protecting manufacturers on the shop floor. The HTS code for N95 masks, regardless of whether they are for healthcare or general industrial use, is 6307.90.9845. Tariffs on N95 masks with this HTS code could reduce product availability and increase costs for manufacturers as well as healthcare workers.

While medical devices include complex and high-risk devices that are implanted, life-supporting or life sustaining and used in hospital settings, they also include products that consumers purchase over the counter with no involvement of healthcare professionals. The examples cited in the *Federal Register* notice generally identify equipment and devices (finished products) used in a hospital setting in a patient care context or devices being administered by or with the assistance of healthcare professionals (nurses or physicians). Additionally, the examples cited are not simple devices that are purchased by consumers over the counter in brick and mortar or online stores without the intervention of a healthcare professional. However, there are numerous healthcare products (e.g. adult incontinence pads, menstrual tampons, menstrual pads, bandages, and oral care products like toothbrushes and mouthwash) that are regulated by the FDA as medical devices and could fall within scope of the investigation. As such, we would urge the administration to provide clarity on the scope of the investigation to avoid any unintended consequences as well as to avoid the addition of medical devices that are consumer health products sold directly to consumers over the counter in brick-and-mortar and/or online stores through any subsequent expansions of HTS application via an inclusion process.

Avoid Stacking

Many of the goods within scope of the investigation could be subject to multiple tariff actions, including IEEPA and reciprocal tariffs, Section 232 steel and aluminum derivative tariffs, Section 301 tariffs, as well as possible Section 232 tariffs on semiconductors and pharmaceuticals. Should the Administration decide to implement tariffs on PPE, medical consumables and equipment, we urge the administration to not stack the tariffs on top of other tariff measures, as this could lead to unsustainably high costs for manufacturers and hospitals.

Tariffs on Healthcare Supplies Will Impact U.S. Patients, Hospitals and Safety of Healthcare Workers and Manufacturers

The healthcare industry relies heavily on imported PPE, medical consumables and equipment, including devices. Tariffs and other limitations on imports of these goods would increase prices for patients, hospitals, and manufacturers. For example, according to the GlobalData's Medsource Database, tariffs could increase prices of approximately 75% of available U.S.-marketed medical devices that are manufactured abroad.[12]

Prices for Patients and Increased Healthcare Costs: Tariffs on medical supplies would be borne by patients and consumers. Medical supplies that are imported include anesthesia instruments, inputs for sutures, electromedical equipment, medical gloves, and scanning equipment – all commonly used on a daily-basis to treat patients in America. Suppliers of these goods would not be able to absorb the costs of tariffs and would likely pass them along to consumers and hospitals. Tariffs on these imports would expose American patients to increased prices for needed medical care and could result in patients delaying needed tests or procedures. Furthermore, tariffs will likely increase overall health care costs having implications for insurance premiums.

Hospital Costs: Having adequate and up-to-date medical supplies, devices and equipment are necessary for hospitals to deliver high quality care to patients. Medical supplies compromise approximately 10.5% of an average hospital's budget, with supply expenses collectively accounting for $146.9 billion in 2023.[13] Essential supplies include low-margin high-volume essential consumables like syringes, masks and gowns to costly medical equipment and devices like cardiac magnetic resonance imaging (cMRI) machines (average list price of $3.2 million per machine).[14] The cost of the equipment does not include expenses related to maintaining, repairing, and conducting upgrades to the equipment. For example, advanced medical systems—such as CT scanners, robotic surgical systems, and ultrasound machines—are complex, capital-intensive assets, built to spec and require highly specialized maintenance including imported replacement parts that might fall within the scope of this investigation and subject to tariffs. While some of these costs are passed onto the patients, contracts with fixed reimbursement may limit how much cost increases can be passed downstream. Tariffs would raise costs for hospitals, including rural hospitals that are already facing significant challenges, and possibly limit access to these essential medical supplies.

[12] Global Data Report on Medical Devices (2024), https://www.globaldata.com/media/medical-devices/trump-tariffs-directly-impact-prices-majority-us-medical-devices-says-globaldata/
[13] American Hospital Association Fact Sheet, https://www.aha.org/2024-07-01-fact-sheet-impact-tariffs-health-care-equipment
[14] American Hospital Association Report "America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities" (April 2024) https://tinyurl.com/4tb8japw

Supply Chain Disruption/Reduced Availability: Implementing Section 232 tariffs would disrupt well-established supply chains and put unsustainable stress on supply availability. If essential supplies become less readily available, this could jeopardize Americans' access to essential healthcare supplies and devices, impacting patient care and health outcomes, as well as impact the health and safety of healthcare workers who are kept safe by appropriate PPE.

A Comprehensive Manufacturing Strategy Is Necessary to Support More U.S. Medical Supply Production

Manufactures encourage the administration to foster a domestic policy environment that supports and encourages medical supply production here at home. This includes:

- **Regulatory Reform:** Lengthy regulatory and approval processes remain challenges for manufacturers to build or expand their manufacturing capabilities in the U.S. The Administration could consider using the FDA's Pre-Check Program as a model: the Pre-Check Program is designed to accelerate American drug manufacturing by providing earlier, structured feedback and more frequent communication throughout the regulatory process. Like pharmaceuticals, medical devices and equipment are required to undergo a rigorous certification process which can take years to complete. A pre-check program could shorten the time it takes to bring medical supplies, equipment and consumable production capacity online.

- **Create Adequate Domestic Stockpile**: The Administration should ensure that the Strategic National Stockpile is adequately resourced and prepared in cases of public health emergencies, including by leveraging public-private partnerships, while manufacturers ramp up production in the U.S.

- **Increase "Warm-Base" Manufacturing Capacity**: To ensure that manufacturers can surge production including of idle plants in times of need, the Administration should approve additional "warm-base" manufacturing contracts to ensure that domestic manufacturing facilities are maintained at a low, but operational, level of production during non-crisis periods.

- **Adequately Resource FDA and NIOSH to Review and Approve PPE and MedTech Certifications**: Respirators are required to be certified by both the CDC's National Institute for Occupational Safety and Health (NIOSH) as well as the Food and Drug Administration. NIOSH tests respirators to ensure they meet regulatory standards, and FDA ensures that medical devices, including respirators are safe and effective before they are approved for use. Both agencies have seen cuts in their workforce, including NIOSH that saw a 90% reduction in force. The Administration should restore funding to levels that will ensure manufacturers' certification applications are being expeditiously approved. Certification also directly protects workers by preventing unscrupulous actors

from flooding the market with counterfeit PPE. The proliferation of substandard respirators—in particular from China—is a recurrent problem.[15] These faulty devices could expose employees to hazardous substances and ultimately make it more difficult and less safe for manufacturers to make things here in America.[16]

Trade Policy Solutions

Tariffs on PPE, medical consumables, and medical equipment risk serious unintended consequences, including supply disruptions, lowering U.S. producers' competitiveness, escalating costs to patients, and long-term damage to the R&D foundation that drives competitiveness of medical technologies in the U.S.

Trade policy can be better leveraged to secure preferential access to allied markets as well as to establish a level-playing field for U.S. manufacturers. We recommend the Administration:

- **Pursue zero-for-zero tariff deals** with allied trading partners.

- **Negotiate a life sciences sectoral agreement** as proposed for example in the Medical Supply Chain and Resiliency Act which aims to strengthen the U.S. medical supply chain by enhancing trade partnerships, diversifying sources, and improving overall resilience.

- **Focus on rigorous IP enforcement**. There is an increasing number of counterfeit, fraudulent, and misrepresented medical supplies being sold globally. The Administration should continue to pursue intellectual property protections and high IP standards in global markets to protect the greatest source of national security — R&D and innovation by manufacturers in the U.S.

- **Address foreign anticompetitive practices** such as state subsidies, price fixing, forced localization, discrimination against U.S. companies in government procurement, as well as state-ownership of raw materials that provide further economic advantages to foreign companies over U.S. companies.

- **Provide targeted and time-limited relief** for inputs and materials necessary to accelerate manufacturing production through the issuance of general licenses – or a "manufacturing speed pass".

Conclusion

This investigation is complex with a broad scope that could lead to adverse impacts on both patients and hospitals as well as on the ability of manufacturers to produce medical

[15] CBS News report (2021), https://www.cbsnews.com/news/n95-masks-fake-seized/
[16] CDC Report on PPE (2025), https://tinyurl.com/3upjtdrp

technologies to diagnose and treat patients in the U.S. The NAM's recommendations herein offer several alternative paths to achieving national security and economic resiliency and competitiveness in the medical supply sector. The NAM appreciates the opportunity to comment on this investigation and looks forward to engaging BIS in this investigation as well as working with the Administration to bolster a resilient healthcare supply chain and enhance manufacturing of healthcare products in the U.S.

Sincerely,

Andrea Durkin
Vice President, International Policy