U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

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Julia Khersonsky
Deputy Assistant Secretary for Strategic Trade
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 Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices," Federal Register docket number BIS-2025-0258 (XRIN 0694-XC134)

Dear Ms. Khersonsky:

The U.S. Chamber of Commerce ("the Chamber") appreciates the opportunity to respond to the U.S. Department of Commerce's request for comments cited above. The administration has stated it intends to use these comments as part of an investigation to "determine the effects on the national security of imports of personal protective equipment (PPE), medical consumables, and medical equipment including devices."

This investigation covers a broad range of disparate medical supplies and medical devices that are essential to the functioning of the broader U.S. healthcare system. While each segment has different strengths and circumstances, the medical supplies and devices industry plays a critical role in the country's competitiveness, military preparedness and general wellness and, thus, national security.

Since 2017, U.S. production of medical goods has been on the rise, with high-paying jobs in the sector growing roughly three times faster than the U.S. manufacturing sector average. With a presence in every state, the industry is responsible for nearly 3 million U.S. jobs (direct and indirect).

In the global context, U.S. medtech and related imports overwhelmingly come from trusted allies in Europe, North America, and Northeast Asia. Given the complexity and global scale of medtech and related supply chains, no single country possesses the know-how and ability to produce everything. The complete onshoring of all medical supply chain elements is not feasible, much less in a short period of time. U.S. healthcare systems thus depend on certain imports for goods not

domestically available in sufficient quantities, requiring a blend of both domestic and international sourcing capabilities.

For these reasons, the United States should not impose Section 232 tariffs on imports of medical supplies and devices from allies, trade agreement countries, and other trusted partners. Instead of broad-based tariffs, the United States requires a targeted approach—discussed further below—that limits disruption to American patients and hospitals, minimizes harm to U.S. industry, and avoids undermining U.S. national security. The objective of ensuring the continued competitiveness of U.S. medical goods manufacturing will be better served by opening new markets for U.S. exports, allowing continued access for specific imports from trusted partners, advancing resilience-focused legislative proposals, and implementing targeted investment and workforce incentives. The following comments outline the Chamber's positive agenda to achieve these objectives while also explaining how broad-based tariffs would prove counterproductive to the objective of strengthening a highly successful domestic industry.

I. Maintain the Sector's Trade with Trusted Partners

By many measures, the United States is home to the world's leading medtech industry. U.S. exports of medtech and other medical goods have consistently outpaced imports, with the United States exporting approximately $80 billion worth of medtech goods last year alone. The U.S. medical goods sector currently enjoys trade surpluses with the EU, Japan, India, Brazil, and Canada, among others. While most high-added-value medtech manufacturing is completed in the United States, supplementary manufacturing is carried out in other countries, especially in trade agreement partner nations and other trusted partners.

Companies can provide first-person accounts of how the sector benefits from investments across the complementary economies of U.S. allies and partners. Some companies have engaged in a decade-long project to move supply chains out of China to the markets of trusted partners. One manufacturer noted its international facilities were established or acquired principally to access specific technologies not available in the United States. Others have established presences abroad to deepen access to important foreign markets and operate close to important customer bases.

Securing imports of medical goods from trusted sources serves the dual objectives of complementing domestic production needs while enhancing supply chain resilience. Given the complexities of manufacturing processes for these products, supply chains have evolved over decades, with global regulatory and certification requirement considerations that generally make them impossible to be quickly rearranged. As a result, trade restrictions on key allies and other trusted

partners threatens to restrict growth and reduce access to medical supplies and devices, harming quality of care for patients throughout the U.S. healthcare system.

The imposition of broad-based tariffs may also drive global business away from U.S. manufacturers by raising their costs while firms operating elsewhere benefit from lower tariffs and lower costs. As several companies noted, tariffs on reliable trading partners would not incentivize onshoring in most cases; instead, they could create unintended incentives to de-risk by limiting production in the U.S. market. Such policies would introduce new supply chain vulnerabilities and put U.S. jobs at risk.

The implications of the administration's other tariff regimes (i.e., Section 232 steel, aluminum, copper, and derivative tariffs as well as the "reciprocal" tariffs imposed on most countries) are also worth considering. Medical devices often include components already covered or that could soon be hit with tariffs. Additional tariffs on trusted sources in the medical goods supply chain will hurt U.S. manufacturing capabilities by forcing a contraction of domestic manufacturing output and could incentivize additional sourcing from non-market economies. Given the U.S. medtech industry's leadership in exporting products, the administration should also be mindful of potential retaliatory measures imposed in response to any U.S. tariffs. A detioration of this leadership position would only benefit competitors.

More broadly, companies are increasingly pressing the administration to provide tariff relief—including through rebate and offset arrangements—to mitigate the financial burden, lost competitiveness, and other economic harms these taxes impose. Other companies are seeking the addition of specific imported goods to Annex III to the October 6 executive order entitled "Modifying the Scope of the Reciprocal Tariffs and Establishing Procedures for Implementing Trade and Security Agreements," which appears to open the door to tariff elimination through bilateral negotiations. These entreaties attest to the pain tariffs are inflicting, particularly on U.S. domestic manufacturers, farmers, and ranchers. The Chamber in May called on the administration to shield small businesses from tariffs and to end tariffs for products unavailable from domestic sources in sufficient quantities or where tariffs threaten job losses. Amid these calls for tariff relief, the administration must engage with the business community to provide meaningful relief from these burdensome import taxes.

Instead of global tariffs, the administration should keep the focus of this national security investigation on specific threats and on countries formally identified as of concern and focus on addressing non-tariff barriers and other policies that restrict U.S. exports to new and existing markets. Boosting U.S. exports of medical goods will enhance the scale of domestic manufacturing, improve its cost competitiveness, and incentivize the further development of the domestic

manufacturing ecosystem in this cluster. One example of a foreign non-tariff barrier that harms domestic manufacturers may be found in PRC procurement policies that disadvantage the U.S. medical supplies and devices industry through measures designed to favor domestic products and require domestic supply chains. Such requirements force U.S. and other foreign manufacturers to localize production in China to retain market access, even as Chinese hospitals and other entities are pushed toward purchases of domestic products over those imported from the United States.

II. Improve Definitional Ambiguity, Consider Sectoral Differences

The precise scope of the investigation is ambiguous, which makes its prospective impacts difficult to assess. PPE, medical consumables, equipment, and devices represent a broad category of products ranging from syringes and catheterization tubes to simple devices such as hearing aids, which consumers purchase over the counter, to complex life-sustaining devices that are implanted surgically or sophisticated diagnostic equipment that uses advanced AI tools to assist in precision care including cancer treatments. Accordingly, HTSUS subheadings covering medical goods frequently encompass products used for non-medical purposes. In this sense, extra care is needed when identifying potential remedies since imposing tariffs solely on the basis of HTSUS codes could capture products outside the intended scope of this investigation. As outlined in the U.S. International Trade Commission (USITC) data, Mexico and the EU have been the top U.S. sources of imported medical goods (based on coverage of HTS Chapter 90) over the past two years, followed by China, Japan, Costa Rica, Canada, and Singapore. Duty-free coverage provided under the U.S.-Mexico-Canada Agreement and trade relationships with key allies continue to be essential for access to certain inputs.

However, the exceptional breadth of this investigation has made the sectors challenging to evaluate, especially as the FRN outlines areas that are "including but not limited to." The Chamber therefore encourages the administration to narrow its definition of imports included and ensure the coverage is scoped to specific healthcare items; and further urges that the rationale for how imports of a given product threaten to impair the national security be presented with precision. The breadth of this investigation also implies the Department should be prepared to consider and recommend different Section 232 measures—and not simply tariffs—for different segments of the market. Indeed, the circumstances facing single-use face masks or gloves and those facing complex Magnetic Resonance Imaging (MRI) devices or pacemakers are sufficiently distinct that a one-size-fits-all Section 232 approach would not be appropriate.

The following categorical breakdown highlights economic implications to assess in these contexts.

Personal Protective Equipment (PPE)

i. Definitional Considerations

The investigation has defined "PPE" as equipment used in health care settings, including (but not limited to) "surgical masks, N95 respirators, gloves, gowns, and related medical parts and components." More clarity would be especially useful in how healthcare settings are defined in the PPE context. For example, such gear can be worn to protect workers from hazards in various industries tangential to health care.

ii. Demand Considerations

With respect to projected demand and domestic capacity considerations, one key U.S. producer of PPE notes that there is currently strong domestic capacity for PPE production, including idle capacity that could be ramped up to produce more given recent declines in N95 demand. This has been facilitated by new domestic respirator manufacturing lines, which have been especially helpful in bolstering N95 supply over the last five years. The Section 301 duties on respirators and facemasks were increased to 25% in September 2024 and are set to increase again to 50% in January 2026.

Increased warm-based manufacturing investment incentives, including building and retrofitting facilities and platform technologies to enable surge capacity, would ensure domestic respirator manufacturers are able to scale-up in the event of a sudden demand escalation. The Chamber urges the administration to engage closely with industry on the relevant time horizons, resources, and workforce demands associated with stimulating more domestic production. Additionally, the administration could further support an increase in manufacturing capacity by updating and improving the maintenance and operation of the Strategic National Stockpile (SNS).

iii. Counterfeiting Considerations

Unfortunately, the prevalence of counterfeit, fraudulent, and misrepresented respirators featured in online marketplaces has increased, and they often appear alongside reputable U.S. brand respiratory protection products. These products may look almost identical to U.S. brand respirators, filters, or cartridges. Counterfeit, fraudulent, and misrepresented respirators erode the market share of reputable U.S.

manufacturers, and many do not meet the performance requirements set forth by the National Institute for Occupational Safety and Health (NIOSH) required by law for use in U.S. workplaces, including healthcare settings. This puts American workers, healthcare providers, and patients at risk. Additionally, there are many cases of false claims indicating that off-brand filters can be used with reusable respirators.

It is essential that NIOSH move forward with the adoption of fit performance requirements for non-powered, air purifying respiratory protection, as previously posted in the Unified Agenda (RIN: 0920-AA77). This would help ensure that poor-fitting products designed by non-U.S. enterprises could not receive NIOSH approval and could not be sold for occupational use in the United States. Adopting the fit performance requirements can also better use taxpayer dollars by helping to ensure that respirators purchased for preparedness stockpiles will fit a wide variety of heath care providers.

Additionally, consistency and coordination on PPE requirements across agencies and workplaces is essential to maintain the health of patients and health care workers. Particulate respirators, such as NIOSH-approved N95s and reusable respirators, are the correct PPE selection to help protect healthcare workers from inhaling infectious particles—not surgical masks or barrier face coverings.

Medical Consumables

The investigation has defined "medical consumables" as "single-use or short-term-use items used for patient diagnosis, treatment, and prevention of conditions. Medical consumables include but are not limited to medical/surgical instruments (e.g., syringes, needles, infusion (IV) pumps, forceps, scalpels); medical/surgical supplies (e.g., intravenous (IV) bags, catheters, tracheostomy tubes, anesthesia equipment, gauze/bandages, sutures, diagnostic and laboratory reagents); and related medical parts and components." Supply chain and sourcing issues for such items follow below.

i. Demand, Cost Considerations

The present investigation should take into consideration that onshoring certain production currently taking place in trade agreement countries would be much slower and more costly than widely understood. One firm describes how its catheter manufacturing in South Korea draws on local technical expertise and state-of-the-art production assets that cannot be "tariffed" into existence in the domestic market in short order. The company notes that it would likely take 10 years to achieve the same level of productivity and quality for those specific inputs even if they were able to address the shortage of skilled domestic workers.

Other tariffs also pose a challenge. One firm recently backed off plans to move additional medical goods manufacturing to the United States due in part to tariffs on materials that would need to be imported from Southeast Asia. The current Section 232 investigation relating to industrial machinery and robotics may add further to the high costs of domestic manufacturing as capital goods used in the medtech and medical consumables sector are often of a single-source variety, with little prospect for domestic replication. The Chamber reiterates the need for the administration to engage closely with industry on the relevant time horizons, resources, and workforce capabilities associated with stimulating more domestic production, which is outlined in more detail below.

ii. Competition Considerations

U.S. manufacturers of high-volume essential medical products, such as needles and syringes and other essential medical devices, have faced intense competition from low-cost producers in non-market economies. These foreign manufacturers often benefit from government subsidies and below-market access to raw materials, and in some cases they are able to operate without FDA oversight. U.S. manufacturers that compete in these categories are critical to maintaining a resilient, domestic supply base for American healthcare. The Chamber urges the administration to collaborate with industry on targeted, category-specific strategies to address non-market competition. A nuanced approach is essential to preserve domestic capacity while ensuring supply chain stability.

One potential solution is to explore Centers for Medicare & Medicaid Services (CMS) payment adjustments for domestically produced medical components. The "Ensuring Safety through Domestic Security with Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Providers and Suppliers" rulemaking under EO 12866 is one such avenue. By recognizing and incentivizing U.S. manufacturing through reimbursement policy, CMS can help level the playing field and reinforce supply chain resilience without disrupting access or affordability.

Conversely, advanced medtech including diagnostics and medical devices require U.S. Food and Drug Administration (FDA) approval. An accelerated pathway would allow the FDA to prioritize and fast-track the review process for medical technology products that are primarily developed and manufactured in the United States. This would reward companies for investing in U.S.-based research, development, and manufacturing. By expediting timelines, the policy would ensure that American patients are the first to access cutting-edge, safe medical technologies while strengthening U.S. leadership in the global medtech industry.

iii. Workforce Considerations

Workforce incentives should also be considered to provide the appropriate skills and expertise necessary in highly technical medical 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 supply chains takes significant resources, with new manufacturing facilities taking between 5 and 10 years to be established. In addition, the 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 domestic innovation and supply chain ecosystem.

Similarly, broad-based tariffs would likely compel the innovative medtech industry to adopt sharp cost-cutting measures. The added costs of such 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 broader medical manufacturing. Forced cuts to R&D and reductions in capital available for facility and workforce investments would also potentially disrupt clinical trials and other related work across supply chains.

Medical Equipment and Medical Devices

The investigation has defined "medical equipment" as "durable equipment, tools, and machines used in healthcare to support patient care. Examples include but are not limited to: carriages and wheelchairs; crutches; and hospital beds." A medical device is defined as "any instrument, apparatus, or machine used in the diagnosis, monitoring, or treatment of medical conditions. Examples include but are not limited to: pacemakers; insulin pumps; coronary stents; heart valves; hearing aids; robotic and non-robotic prosthetics; blood glucose monitors; orthopedic appliances; electromedical apparatus (e.g., computed tomography scanners, magnetic resonance imaging machines); electrosurgical apparatus; x-ray apparatus/other radiation equipment; respiratory machines (e.g., ventilators, respirators, oxygen apparatus); and MRI machines."

i. Complexity of Sourcing and Supply Chains

The products in this specific segment are some of the most complex in any industry, drawing on advanced technologies, software, and supply chains that often

exceed a thousand parts. Many of the manufacturers of certain implantable and hospital devices compete not only on the basis of price but on differentiated performance. Continued American leadership in this high-value part of the medtech industry requires a sustained ability to also access parts, technologies, and materials that have been developed by capable innovators outside of the United States. Moreover, since production runs in this segment can be dramatically less than in the daily-use medical consumables segment—a large U.S. plant making hospital equipment may produce only a thousand of these high-cost durable machines each year—U.S. industry demand for specialized foreign parts and technologies is often insufficient to warrant the construction of an additional production facility in the United States.

Additionally, many of these inputs cannot currently be produced in the United States. In molecular imaging, for example, there are specific inputs that are unavailable domestically, including lutetium oxide and certain radioactive isotopes. REE magnets are another example of which the administration is aware. This includes heat resistant samarium magnets, which are important because advanced surgical instruments need to go through reprocessing where they are exposed to extremely high temperatures. With these examples in mind, it is critical to both boost coordination with reliable partners and streamline the permitting process for domestic mining and minerals processing projects, which will enhance the resilience of critical mineral supply chains. By expediting approvals and reducing regulatory bottlenecks, domestic production and processing capabilities can be strengthened and reliance on foreign adversaries reduced.

Such sourcing complications coupled with lengthy parts certifications and economies of scale represent key constraints in onshoring medtech supply chains. Per one company, extensive validation and certification processes often means that switching suppliers can take up to 3-4 years. As another company puts it, localizing production of critical components to the United States from allied markets is extremely costly without economies of scale (for which existing affiliate factories have already optimized). This is especially the case when limited suppliers of customized capital equipment are available. Tariffs on such equipment—for which alternatives are at times completely unavailable—add to costs and reduce domestic competitiveness without mitigating risks.

ii. Competition Considerations

For highly sophisticated, durable medical devices, the United States has been both home to many of the leading businesses in the sector—large and small—and a major exporter to global markets. Many of these devices are products and technologies where the United States enjoys an overall trade surplus. Most head-to-

head competition for U.S. producers is with other developed economies, which is unsurprising given the nature of the advanced technologies involved. Like the United States, these countries have made a policy decision for health and humanitarian reasons not to impose trade barriers on medical device products. In most developed economies, tariffs on medical devices are zero or near zero, government procurement tenders are open to fair and transparent competition, and regulatory policies are non-discriminatory. The success of U.S. firms in this global market is an encouraging indication of how U.S. manufacturing of advanced technologies can flourish in open global markets.

However, this market is increasingly being challenged by emerging competition from China, which has identified "high-performance medical devices" as one of the sectors it is promoting under its "Made in China 2025" and successor industrial policies. In this vein, China is making available all the customary tools of Chinese state support to help displace U.S. and other non-Chinese firms from first the Chinese and then the global market for advanced medical devices. China has also closed its government procurement market to imported devices, requiring since 2021 that government hospitals source 178 key categories of medical equipment from domestic Chinese sources only, effectively closing the door to exports of those medical devices from the United States. China further announced plans in 2024 to set required domestic content levels for those devices.

In response to these policies, the European Commission launched its first ever investigation under the EU's "International Procurement Instrument" (IPI) into Chinese government procurement of medical devices. Upon finding multiple Chinese procurement practices that discriminate against foreign medical devices, the EU imposed the maximum retaliatory sanction permitted under the IPI statute. Chinese medical device producers are currently making aggressive efforts to expand their presence in the U.S., engaging in aggressive pricing (despite simultaneously facing high tariffs on most of their devices and parts), and acquiring U.S. businesses and talent. This Section 232 investigation might well review whether emerging Chinese medical device producers now enjoy greater access to the U.S. market than U.S. medical devices that are global leaders enjoy in the Chinese market. The investigation may also assess if the increasing presence of PRC medical equipment in U.S. health infrastructure poses any cybersecurity or information security risks, consistent with U.S. rules administered by the Department of Justice and the Department of Commerce's Bureau of Industry and Security. Seeing the EU roll out more assertive policies countering Chinese anti-competitive practices should serve as an opportunity for both the U.S. and EU to increase cooperation on these shared challenges.

Over-the-Counter Products

The Chamber encourages the administration to limit the scope of the present investigation and outcomes to preserve tariff-free access to over-the-counter consumer health products sold directly to consumers. The Federal Register notice's examples appear to focus on products used in a patient-care or hospital setting. However, Americans rely on a wide variety of other healthcare products used in dental care, personal hygiene, and hair and skin care. Given Americans' widespread cost of living concerns, these mass market consumer goods should be left outside the scope of this investigation and any related trade restrictions.

III. Avoid New Costs, Shortages

As noted above, the application of broad-based tariffs on critical medical supplies, diagnostics, and devices would lead to increased costs and may cause shortages for some products, 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. Policymakers should not regard this as a win, however, as hospitals' tight margins—particularly in rural hospital systems—would instead compel reductions in service and capability. In a worst-case scenario, rising costs that cannot be recouped will result in closures in some communities.

Sweeping tariffs could also increase the cost of medical supplies and devices hospitals need to provide vital services to patients, including repairs or replacement parts necessary for specific procedures or customized equipment. Any additional financial strain could force more rural hospitals to shut down or significantly curtail services, depriving rural residents of critical care and leading to worse health outcomes and even preventable deaths. In this respect, reliably diversified supply chains are quite important.

IV. Ensure Any Section 232 Measures Minimize Disruption to U.S. Patients, Industry

Should any limited Section 232 trade restrictions be recommended for any segments of the medtech market, it is essential to the welfare of U.S. patients and the continued success of this important U.S. manufacturing industry that the measures incorporate the mitigations that have been provided in earlier Section 232 actions, including:

- **USMCA:** The non-application of any Section 232 tariffs to qualifying USMCA products is critical for medtech, since Mexico and Canada are not merely

valued medtech partners but have become increasingly important locations for nearshored production activities that U.S. medtech companies are moving from China and other more distant locations;

- **Duty Drawback:** The availability of duty drawback for any Section 232 tariffs is essential, or U.S. medtech production plants will not be able to sustain their current global exports, which would in turn lead to declines in export-related employment and investment in the United States;
- **Lower Tariffs with Key Allies:** The Chamber strongly supports the addition of medical technologies to the list of sectors that will enjoy a return to the status quo before the imposition of any additional tariffs with trusted partners that have concluded a framework agreement with the United States (e.g., the European Union, Japan, the Republic of Korea, and the United Kingdom). In no circumstances should Section 232 tariff rates with those key allies exceed current "reciprocal" tariff rates with those countries.

V. Enhance Industry's Innovation, Competitiveness

A pro-competitive economic environment with appropriate legal and regulatory certainty and adequate workforce and training programs should play an important part in the administration's efforts to further expand domestic manufacturing in this sector.

In addition to the ways to enhance domestic manufacturing and strengthen supply chains addressed above, the administration should urge congressional passage of sectoral initiatives such as the bipartisan Medical Supply Chain Resiliency Act. This 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 supplies and devices 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.

Additionally, the administration should work with Congress to advance the Mapping America's Pharmaceutical Supply Act (MAPS Act), which would improve the coordination of federal efforts to identify and mitigate health and national security risks through maintaining a list of essential medicines, conducting a risk assessment of essential medicine supply chains, and creating a monitoring system to map essential medicine supply chains using data analytics.

U.S. manufacturers of medical supplies and medtech share the administration's goal of expanding domestic production and enhancing the sector's global competitiveness. To build on the impressive strengths of the United States as a platform for medical goods manufacturing—to serve the domestic market and for export—the administration should also focus on opening new markets and striking enforceable trade deals. To that end, the administration should continue to address foreign trade barriers that shut out world-beating U.S. products in foreign markets, many of which are outlined in the Chamber's recent submission to the Office of the U.S. Trade Representative on unfair foreign trade practices.

The Chamber appreciates the opportunity to submit these comments and looks forward to working with the Department of Commerce to address these important issues.

Sincerely,

John Murphy
Senior Vice President and Head of International
U.S. Chamber of Commerce