



Submitted Electronically via Regulations.gov

October 17, 2025

The Honorable Julia A. Khersonsky
Deputy Assistant Secretary for Strategic Trade
Bureau of Industry and Security
United States Department of Commerce
Herbert C. Hoover Building
1401 Constitution Avenue, NW
Washington, DC 20230

RE: AOPA Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices (BIS-2025-0248)

Dear Secretary Kheronsky:

The American Orthotic and Prosthetic Association (AOPA), respectfully submits the following comments in response to the recently announced section 232 national security investigation referenced above. Since 1917, AOPA has been the largest orthotic and prosthetic trade association, consisting of more than 1,800 patient care facilities and suppliers that together manufacture, distribute, design, fabricate, fit, and provide clinical care for patients using orthoses (orthopedic braces) and prostheses (artificial limbs). Each and every day, AOPA and its members strive for a world where orthotic and prosthetic care transforms lives. AOPA is committed to ensuring that patients who have experienced amputations, those with congenital limb differences, and those who have acquired limb impairments through injuries or chronic diseases have access to quality orthotic and prosthetic care. AOPA's comments will be limited in scope to those that are relevant to the provision of orthotic and prosthetic care and will address each of the twelve topics highlighted in the request for comments specifically as they relate to the provision of clinical orthotic and prosthetic care to patients.

General Comments on the Provision of Orthotic and Prosthetic Care

While AOPA will provide specific comments on each of the relevant questions, it is important and relevant to first understand that the provision of orthotic and prosthetic care is highly customized, patient-centered, healthcare that involves a comprehensive rehabilitation team that includes physicians, certified and/or licensed prosthetists and orthotists, physical and occupational therapists, and other allied health professionals. Orthoses and prostheses are

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more complex than generic medical devices that are handed to consumers for their use. Rather, orthoses and prostheses are often custom fit and fabricated to meet the specific needs of the individual patient based on the medical assessment of the clinical rehabilitation team.

The highly customized nature of orthoses and prostheses distinguish them from other medical equipment discussed in the request for comments. Every prosthesis and custom orthosis delivered in an orthotic and prosthetic clinic is fit to the patient and assembled for final delivery in that U.S.-based patient-care facility. **AOPA recommends that the Bureau of Industry and Security consider removing orthoses and prostheses from inclusion in this investigation due to their custom nature and clearly distinct differences from personal protective equipment (PPE), medical consumables, and medical equipment.**

AOPA offers the following comments directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

The current and projected demand for PPE, medical consumables, and medical equipment, including devices, in the United States

There is a growing demand for prostheses (robotic and non-robotic), primarily driven by increasing rates of limb amputation, which is a growing health concern in the United States, driven primarily by an increase in diabetes and vascular diseases. There are over 5.6 million individuals living with limb loss or congenital limb differences in the United States today, with projections indicating that limb loss prevalence will double to 3.6 million by 2050.

Nearly 100,000 Veterans receive amputation-related care from the VA, with approximately 9,500 new amputations occurring each year, primarily due to complications from vascular diseases and diabetes. The Department of Defense (DoD) supports more than 118,000 people living with limb loss, including active-duty service members and their families.

The extent to which domestic production of PPE, medical consumables, and medical equipment, including devices, can meet domestic demand

According to the Government Accountability Office, from 2016 – 2019 only 30 percent of Medicare Beneficiaries who lost limbs received a prosthesis, and of those who had upper limb amputations, only 4 percent received a prosthesis. While there is already evidence of unmet need, at present, most patient access issues are unrelated to the supply chain or trade dynamics.



Over the past twenty years, foreign-based prosthetic manufacturers have significantly increased their U.S.-based operational footprint, with increases in device manufacturing, device assembly, device refurbishing, and device repair modalities.

While AOPA believes that there is currently significant unmet need in the United States, this is not a result of domestic production or supply chain issues, but instead, the result of challenges with insurance coverage and complicated reimbursement dynamics that restrict patient access.

The role of foreign supply chains, particularly of major exporters, in meeting United States demand for PPE, medical consumables, and medical equipment, including devices

AOPA does not believe that the role of foreign supply chains in the provision of orthotic and prosthetic care domestically should be of concern in this investigation. This question represents another scenario where it is important to highlight and separate the uniquely clinical nature of the provision of prosthetic and orthotic patient care. Delivery of a functional orthosis or prosthesis is merely the final step in a highly personalized, patient-centric provision of medical care. While foreign supply chains contribute certain raw materials and individual components to the completed orthosis or prosthesis, they are of little use or value on their own. They are simply a small part of an established process of care that involves a comprehensive rehabilitation team including physicians, orthotists, prosthetists, and therapists, who collaborate to restore a patient's ability to perform their activities of daily living. It is difficult to quantify and measure the direct impact of foreign supply chains when the associated patient care by United States based providers is almost always provided within the United States.

The unique clinical nature of orthotic and prosthetic care means that even where there is some reliance on foreign supply chains for certain specialized raw materials and components, the volume is so relatively low that there should be no real impact on national security concerns and should be grounds for exclusion from this investigation.

The concentration of U.S. imports of PPE, medical consumables, and medical equipment, including devices, from a small number of suppliers or foreign nations and the associated risks

AOPA believes the risk associated with United States imports of orthotic and prosthetic devices, components, and raw materials is minimal as they represent an insignificant volume compared to the other subjects of this investigation. Custom fabricated orthoses and prostheses are fabricated using source materials from domestic and international suppliers, some of which provide materials that are unique to their design and fabrication. In some cases, a supplier may be the only source of specialized materials or components. While there may be a relatively small number of suppliers of certain specialized materials, the risks to national security are



minimal or non-existent due to the limited volume of production for these specialized components or materials. The limited volume of production distinguishes prosthetic and orthotic devices from PPE, medical consumables, and medical equipment and underscores AOPA's request for consideration that prosthetic and orthotic devices be excluded from this investigation.

The impact of foreign government subsidies and predatory trade practices on the competitiveness of PPE, medical consumables, and medical equipment, including devices, manufacturers, in the United States

AOPA believes that there is little to no risk of subsidies or predatory trade practices by foreign governments related to the importation of orthotic and prosthetic devices, components, or raw materials. This minimal risk, once again, supports the exclusion of orthotic and prosthetic imports from this investigation as their comparative volume to other subjects of the investigation are inconsequential.

The economic impact of artificially suppressed prices of PPE, medical consumables, and medical equipment, including devices, due to foreign unfair trade practices and state-sponsored overproduction

AOPA believes that there is little to no risk of economic impact of artificially suppressed prices for orthotic and prosthetic devices, components, or raw materials due to foreign unfair trade practices and state sponsored overproduction. The custom nature of orthoses and prostheses supports a demand-based need for raw materials and components, and there is no advantage represented by intentional overproduction. This minimal risk continues to support the exclusion of orthotic and prosthetic imports from this investigation as their comparative volume to other subjects of the investigation are inconsequential.

The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over supplies of PPE, medical consumables, and medical equipment (including devices)

AOPA believes that there is little to no risk of foreign nations to weaponize their control over exports of orthotic and prosthetic devices, components, and raw materials. The relative volume of orthotic and prosthetic devices, components, and raw materials that are exported from foreign nations on an annual basis is inconsequential compared to the other products included in this investigation. The custom nature of orthoses and prostheses supports a demand-based need for raw materials and components, and there is no advantage represented by intentional and strategic export restrictions. This minimal risk continues to support the exclusion of



orthotic and prosthetic imports from this investigation as their comparative volume to other subjects of the investigation are inconsequential.

The feasibility of increasing domestic capacity for PPE, medical consumables, and medical equipment, including devices, to reduce import reliance

Unfortunately, AOPA is unable to comment on the ability of its individual manufacturer members to increase domestic production capacity of orthotic and prosthetic devices, components, and raw materials. Several AOPA manufacturer members will be submitting separate comments in response to this notice, and they are better suited to ascertain their individual abilities to increase domestic production capacity. It is important to note, however, that while many AOPA manufacturer members are global companies with locations in many countries, much of the current production of orthotic and prosthetic devices, components, and raw materials is domestic in nature. It is also important to recognize that the need for certain limited source components and raw materials that are used in fabrication of custom orthotic and prosthetic devices create a need for reliance on a small number of manufacturers that may not have a domestic manufacturing presence. While these are limited in scope, restricting access to their importation may prove detrimental to the provision of appropriate orthotic and prosthetic clinical care, care that is foundational for orthotic and prosthetic patients to perform activities of daily living, return to work, and engage independently in their communities.

The impact of current trade policies on domestic production of PPE, medical consumables, and medical equipment, including devices, and whether additional measures, including tariffs or quotas, are necessary to protect national security

Patient access to quality orthotic and prosthetic care is paramount, and AOPA has serious concerns that unnecessary changes to the current market dynamics, including tariffs or quotas could significantly impact the orthotic and prosthetic care ecosystem, leading to delays in care and other access issues.

Insurance reimbursement for the provision of orthotic and prosthetic care in the United States is based on a bundled payment model meaning that the reimbursement is established for the completed orthosis or prosthesis without regard to the acquisition cost of components or raw materials or the level or complexity of associated clinical care necessary to ensure a successful patient outcome. Reimbursement rates are primarily based on the Medicare Healthcare Common Procedural Coding System (HCPCS) fee schedule which is a fixed reimbursement schedule that is updated annually based on changes to the Consumer Price Index for Urban Areas (CPI-U) an inflation-based index published by the US Bureau of Labor and Statistics.

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Outside of the annual, inflation based, adjustment to the Medicare fee schedule, reimbursement rates are essentially fixed in the United States. An important and impactful result of this fixed reimbursement system is that increased cost of goods, whether through trade issues such as tariffs or supply chain issues, must be absorbed within the fixed reimbursement system. These system dynamics most often impact the clinician providing the orthotic and prosthetic care as they are the ones that are tied to the fixed reimbursement. AOPA is concerned that increased provider costs associated with supply chain issues or impacts of tariffs may negatively impact patient care.

Due to the complex nature of orthotic and prosthetic care, fixed reimbursement dynamics, existing shortages in workforce, and regulatory hurdles impacting the innovation pipeline, AOPA emphasizes its recommendation that the Bureau of Industry and Security consider removing orthoses and prostheses from inclusion in this investigation and advises against additional measures that could further exacerbate patient access challenges.

The potential for foreign control or exploitation of supply chains for PPE, medical consumables, and medical equipment, including devices, supply chain

AOPA believes that there is little to no potential risk for foreign control or exploitation of supply chains for orthotic and prosthetic devices, components, and raw materials. The relative volume of orthotic and prosthetic devices, components, and raw materials that are imported from foreign nations on an annual basis is inconsequential compared to the other products included in this investigation and the custom nature of orthoses and prostheses supports a demand-based system. There is no advantage represented by intentional and strategic exploitation of orthotic and prosthetic supply chain restrictions. This minimal risk continues to support the exclusion of orthotic and prosthetic imports from this investigation as their comparative volume to other subjects of the investigation are inconsequential.

The ability of foreign persons to weaponize the capabilities or attributes of foreign-built PPE, medical consumables, and medical equipment, including devices

AOPA believes that the ability of foreign persons to weaponize the capabilities or attributes of foreign-built orthotic and prosthetic devices and components is essentially non-existent. The provision of orthotic and prosthetic care is a clinical process that involves a comprehensive team of rehabilitation professionals including certified and/or licensed orthotists and prosthetists. Orthotic and prosthetic devices and components are often custom fabricated to meet the individual clinical needs of the specific patient. Previous attempts at weaponization of manufactured products (e.g. pagers, cell phones, etc.) have relied on the likelihood of mass distribution of compromised items into high population areas. This model simply does not exist



for orthotic and prosthetic devices and components. All device components will be inspected during the assembly of the custom orthotic or prosthetic device prior to its delivery to a patient; therefore, there is no viable opportunity to create fear and terror through the weaponization of prostheses and orthoses.

In summary, AOPA respectfully requests that the Bureau of Industry and Security consider removing orthoses and prostheses from inclusion in this investigation due to their custom nature and clearly distinct differences from personal protective equipment (PPE), medical consumables, and medical equipment. The relative risk of foreign governments, corporations, and individuals exploiting opportunities to control supply chain vulnerabilities, achieving competitive advantages through manipulation of imports and exports of orthotic and prosthetic materials, or weaponization of orthotic and prosthetic devices is extremely low. Any changes to the market dynamics that could result from this investigation will lead to challenges in providing appropriate clinical care to an already vulnerable segment of the United States population.

AOPA respectfully submits these comments and looks forward to working with the Bureau of Industry and Security in the future.

Sincerely,

A handwritten signature in black ink that reads "Teri Kuffel". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Teri Kuffel, JD
Executive Director

References:

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<https://health.mil/Military-Health-Topics/Centers-of-Excellence/EACE/Clinical-Affairs#:~:text=The%20Department%20of%20Defense%20supports,transdisciplinary%20health%20care%20team%20a%20proach>

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