

October 17, 2025

## SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Howard Lutnick Secretary c/o Bureau of Industry and Security Office of Strategic Industries and Economic Security U.S. Department of Commerce 1401 Constitution Ave. NW Washington, DC 20230

Re: <u>ITEM Coalition Comments in Response to Section 232 National Security</u>
<u>Investigation of Imports of Personal Protective Equipment, Medical Consumables,</u>
and Medical Equipment and Devices (BIS-2025-0258; XRIN 0694-XC134)

Dear Secretary Lutnick:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee, we appreciate the opportunity to comment in response to the Department of Commerce's (hereafter referred to as the "Department") Section 232 investigation into imports of personal protective equipment ("PPE"), medical consumables, medical equipment, and medical devices.

The ITEM Coalition strongly urges the Department to not impose sudden or significant tariffs, quotas, or other trade restrictions on these important medical products and devices which are vital to the health, rehabilitation, and independence of millions of Americans with disabilities, illnesses, and injuries. Such measures would undermine patient access to essential medical technologies, disrupt the stability of supply chains, and impose severe cost burdens on manufacturers and suppliers, having the effect of compromising their ability to maintain high quality manufacturing facilities in the United States.

The ITEM Coalition is a national consumer- and clinician-led coalition comprised of over 100 national organizations advocating for access to and coverage of assistive devices, technologies, and related services for people with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including spinal cord injury, brain injury, stroke, limb loss, multiple sclerosis, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, and other life-altering conditions.

Personal protective equipment ("PPE"), medical consumables, medical equipment, and medical devices are not luxury or discretionary goods—they are essential medical tools that allow people living with disabilities, chronic illnesses, and severe injuries to live independently and safely in their homes and communities. Medically necessary devices such as wheelchairs, orthotic braces, prosthetic limbs, urinary catheters, ventilators, hearing aids, cochlear implants, infusion pumps, and other mobility or communication technologies play critical roles in supporting basic health and functioning of the American people. Manufacturers and suppliers of these medical products and devices are particularly sensitive to price fluctuations, as reimbursement rates for these goods under Medicare, Medicaid, and private insurance are tightly regulated and not adjusted to absorb higher import or manufacturing costs. Even modest increases in costs driven by tariffs could destabilize domestic manufacturing capacity, limit patient choice, and result in lifethreatening access barriers and supply shortages.

The Department's Section 232 inquiry should recognize that the U.S. healthcare and assistive technology sectors are well represented by both U.S. manufacturers and, at the same time, are deeply integrated within complex global supply chains. Medical equipment and device manufacturers and suppliers depend on specialized components—such as microprocessors, sensors, batteries, and precision parts and materials—and materials that are commonly manufactured in both the U.S. and in allied countries that have strong economic and trade ties to the United States.

Imposing tariffs or quotas on these components and materials—or on the finished devices themselves—would not meaningfully strengthen domestic manufacturing; rather, it would constrain innovation and limit access to next-generation devices and technologies, undermining domestic production capacity over the long term. The ITEM Coalition strongly believes that enhancing resilience in the medical equipment and device supply chains should focus on diversification, redundancy, and collaboration.

Section 232 is intended to protect national security interests where import dependence threatens U.S. defense or critical infrastructure. However, in our view, trade in medical equipment and devices strengthens the resilience of the U.S. healthcare system by diversifying sources of supply and tapping innovations from around the world to help individuals in the United States.

The ITEM Coalition's mission is to safeguard access to affordable and appropriate assistive technology and devices for individuals who depend on them for daily living. We respectfully urge the Department of Commerce to reject any tariffs or quotas that would undermine that access and to preserve the existing trade treatment for these devices, including certain exemptions for medical devices and technologies established under the Nairobi Protocol and related case law and administrative rulings. We encourage the Department to prioritize policies that strengthen access to affordable and reliable assistive devices and technologies. This is essential to ensuring that Americans living with disabilities, chronic illnesses, and injuries can continue to live healthy, independent lives.

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Thank you for your consideration of these comments and for your commitment to maintaining a resilient and patient-centered medical supply system. Should you have any questions, please do not hesitate to contact ITEM Coalition co-coordinators Peter Thomas and Michael Barnett at <a href="Peter.Thomas@PowersLaw.com">Peter.Thomas@PowersLaw.com</a> or <a href="Michael.Barnett@PowersLaw.com">Michael.Barnett@PowersLaw.com</a> or call 202-466-6550.

Sincerely,

## **The Undersigned Members of the ITEM Coalition Steering Committee**

ALS Association Amputee Coalition Spina Bifida Association United Spinal Association