NATIONAL HEALTH COUNCIL

October 17, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
United States Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

RE: Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices [XRIN 0694-XC134]

Dear Director Astle:

The National Health Council (the NHC) appreciates the opportunity to provide comments on the Bureau of Industry and Security's (BIS) investigation into the national security implications of imports of personal protective equipment (PPE), medical consumables, and medical equipment including devices.

Created by and for patient organizations over 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, and sustainable health care. Made up of more than 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC strongly urges the Department to refrain from imposing tariffs or quotas on PPE, medical consumables, or medical devices. Measures of this kind would not only raise costs throughout the health care system but also destabilize established and reliable supply chains, thereby placing patients at risk of dangerous interruptions in access to essential and often lifesaving technologies. For individuals living with or providing care to someone with chronic, complex, and rare conditions, even brief disruptions in the availability of appropriate medical equipment can result in irreversible harm. Rather than pursuing overly broad trade interventions that jeopardize patient care, the Department should adopt a patient-centered strategy that strengthens supply chain resilience through targeted investment in domestic manufacturing, supportive incentives for innovation, and enhanced cooperation with trusted international partners.

Impact of Tariffs on Patient Access to Medical Technologies

Medical technologies are essential to the delivery of modern health care. Unlike discretionary consumer products, PPE, consumables, and devices are foundational to nearly every clinical encounter, from routine preventive services to the most advanced specialty treatments. PPE is critical for infection control and surgical sterility, directly protecting both patients and health care workers. Consumables such as syringes, IV bags, catheters, and diagnostic reagents are indispensable to daily clinical operations. Durable equipment—including ventilators, wheelchairs, and imaging technologies—sustains life, restores function, and enables accurate clinical decision-making. Advanced implantable devices such as cardiac stents, pacemakers, prosthetics, and insulin pumps are not chosen for convenience; they are prescribed because they represent the only clinically appropriate option for managing complex and often life-threatening conditions.

In these contexts, substitution is rarely safe or feasible. For example, a patient with an implanted pacemaker or defibrillator relies on tightly configured generator-lead compatibility: substituting a different model or mismatched lead can result in device failure, loss of capture, or the need for reintervention, all of which carry significant clinical risk.[1] Similarly, for individuals who rely on orthopedic prostheses such as hip or knee implants, substitution is not a simple matter of replacing one device with another. Differences in design, material, and fixation method can significantly alter long-term outcomes, with poorly matched substitutions leading to higher rates of implant failure, painful revision surgery, and lasting impairment in mobility and quality of life.[2] A person with type 1 diabetes cannot switch from an insulin pump to an alternative delivery method without jeopardizing their health.[3,4,5] The PPE shortages witnessed during the COVID-19 pandemic demonstrated how even shortfalls in seemingly basic protective equipment can cascade into systemic challenges, compromising patient safety and straining the entire health care delivery system.[6]

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[1] Jalaj Garg and Evgueni Fayn, "Lead-generator incompatibility with complete heart block-Double whammy: Device troubleshooting," *HeartRhythm Case Reports* 6, no. 9 (June 2020): 606, https://doi.org/10.1016/j.hrcr.2020.06.007.

[2] Peter L. Lewis et al., "Impact of Patient and Prosthesis Characteristics on Common Reasons for Total Knee Replacement Revision: A Registry Study of 36,626 Revision Cases from Australia, Sweden, and USA," *Acta Orthopaedica* 93 (July 5, 2022): 625, accessed October 2, 2025, https://actaorthop.org/actao/article/view/3512.

[3] Isabel Steineck et al., "Insulin Pump Therapy, Multiple Daily Injections, and Cardiovascular Mortality in 18 168 People with Type 1 Diabetes: Observational Study," *BMJ* 350, no. 3234 (2015): 3234, doi:10.1136/bmj.h3234.

[4] Tina K. Thethi et al., “Consequences of Delayed Pump Infusion Line Change in Patients with Type 1 Diabetes Mellitus Treated with Continuous Subcutaneous Insulin Infusion,” *Journal of Diabetes and Its Complications* 24, no. 2 (2010): 75, doi:10.1016/j.jdiacomp.2009.03.002.

[5] Lutz Heinemann et al., "Insulin Pump Risks and Benefits: A Clinical Appraisal of Pump Safety Standards, Adverse Event Reporting, and Research Needs: A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group," *Diabetes Care* 38, no. 4 (2015): 718, https://doi.org/10.2337/dc15-0168.

Imposing tariffs on medical technologies would therefore have consequences far beyond trade policy. Such measures would increase acquisition costs for hospitals, clinics, and community providers, many of which already face constrained reimbursement rates and thin operating margins.[7,8] These added costs would inevitably be passed along to patients and caregivers, either through higher bills, reduced availability of services, or delayed procurement of critical equipment.[9] The result would be postponed procedures, deferred diagnostics, and interruptions in chronic disease management.[10] Evidence consistently shows that even brief delays in treatment initiation or continuation—for example, in oncology, autoimmune disease, or rare genetic conditions—are associated with worsened outcomes, disease progression, and, in many cases, preventable mortality.[11]

The ripple effects of tariffs would magnify longstanding affordability challenges across the US health system. Patients already face substantial out-of-pocket burdens, with nearly one in three American families reporting difficulty affording health care.[12] Tariffs that increase the cost of essential medical technologies would intensify these pressures, leading to higher insurance premiums, more restrictive coverage policies, and greater cost-sharing requirements.[13] These systemic cost increases directly translate into higher rates of cost-related nonadherence, a problem already documented as a significant driver of adverse outcomes among individuals with chronic disease.[14] Millions of family caregivers, who play a central role in securing and managing medical devices for their

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[6] Linda Thai, Trini Beleche, and Oluwarantimi Adetunji, "Understanding the Impact and Costs Associated with Medical Device Shortages During the COVID-19 Pandemic on Providers, Health Systems, Patients, and Manufacturers," *Office of the Assistant Secretary for Planning and Evaluation (ASPE)*, January 17, 2025, https://aspe.hhs.gov/reports/impact-device-shortages-during-covid-19.

[7] American Hospital Association, "The Cost of Caring: Challenges Facing America's Hospitals in 2025," April 2025, https://www.aha.org/costsofcaring.

[8] Thai et al., "Understanding the Impact and Costs Associated with Medical Device Shortages."

[9] American Hospital Association, "Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19," May 2020, https://www.aha.org/system/files/media/file/2020/05/aha-covid19-financial-impact-0520-FINAL.pdf.

[10] Ajay K. V. Hanna et al., "Mortality Due to Cancer Treatment Delay: Systematic Review and Meta-Analysis," *BMJ*, November 4, 2020, 1, https://doi.org/10.1136/bmj.m4087.

[11] *Medical Product Supply Chains* (Washington, DC: The National Academies Press, 2022), https://doi.org/10.17226/26420.

[12] American Hospital Association, "Cost of Caring."

[13] Mark McClellan et al., "Health Care Payers COVID-19 Impact Assessment: Lessons Learned and Compelling Needs," Discussion Paper, National Academy of Medicine, May 17, 2021, https://nam.edu/perspectives/health-care-payers-covid-19-impact-assessment-lessons-learned-and-compelling-needs/.

[14] Maria Achterbosch et al., "Clinical and Economic Consequences of Medication Nonadherence: A Review of Systematic Reviews," *Frontiers in Pharmacology* 16 (June 25, 2025): 1570359, doi:10.3389/fphar.2025.1570359.

National Academies of Sciences, Engineering, and Medicine, *Building Resilience into the Nation's* loved ones, would also experience increased financial and logistical strain.[15,16] Introducing trade-induced price shocks would only worsen this dynamic, placing patients at heightened risk of avoidable harm.

The consequences would fall most heavily on those least able to bear them. Rural hospitals, community clinics, and safety-net providers, which often serve as lifelines for the communities they serve, have limited purchasing power and are especially vulnerable to supply chain cost increases.[17] Patients in these settings—disproportionately older adults, low-income families, and those living with multiple chronic conditions—already face significant barriers to timely care.[18] Additional financial and logistical obstacles created by tariffs would widening existing gaps in access and outcomes.[19] Such a result would undermine national policy goals aimed at improving affordability, expanding access, and strengthening the adequacy of the health care system.

Consequences of Tariffs on Medical Technology Development and Patient Care

The strength of the US medical technology sector is a critical asset to patient care. Domestic manufacturers deliver the majority of the devices used in American hospitals and homes and reinvest substantial revenues into research and development that drive continual improvements in safety, effectiveness, and usability.[20] This cycle of innovation results in the steady introduction of new diagnostic tools, therapeutic devices, and implantable technologies that directly improve patient outcomes, reduce complications, and expand treatment options for those living with serious and chronic conditions.[21,22]

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[15] AARP and National Alliance for Caregiving, *Caregiving in the US 2025* (Washington, DC: AARP, July 2025), 5, https://doi.org/10.26419/ppi.00373.003.

[16] M. L. Longacre, M. Frieler, and E. Schneider, "Family Caregivers' Use and Evaluation of Patient Medical Products or Assistive Devices: A Systematic Literature Review," *Ethics, Medicine, and Public Health* 26 (February 2023): 34, https://doi.org/10.1016/j.jemep.2022.100869.

[17] American Hospital Association, "Cost of Caring."

[18] A. Rupasingha and J. Cho, *Federal Assistance and Rural Hospital Closings: The Impact of the USDA Community Facilities Program*, Report No. ERR-344 (U.S. Department of Agriculture, Economic Research Service, 2025), 15, https://doi.org/10.32747/2025.9015812.ers.

[19]

[20] U.S. International Trade Commission, *COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges* (Investigation No. 332-580, USITC Publication 5145, Washington, D.C., December 2020), 10, https://www.usitc.gov/publications/332/pub5145.pdf.

[21] David E. Wamble et al., "The Effect of Medical Technology Innovations on Patient Outcomes, 1990-2015: Results of a Physician Survey," *Journal of Managed Care & Specialty Pharmacy* 25, no. 1 (2019): 67, doi:10.18553/jmcp.2018.18083.

[22] Medicare Payment Advisory Commission, "An overview of the medical device industry," in *Report to the Congress: Medicare and the Health Care Delivery System* (June 2017), 207, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch7.pdf.

Rupasingha and Cho, *Federal Assistance*.

This progress depends on a stable and integrated supply chain. While most medical technologies used in the United States are produced domestically, manufacturers also depend on imported raw materials, components, and subassemblies that cannot be economically or technically sourced entirely within US borders.[23] These imports, frequently drawn from longstanding allies with equivalent quality standards, enable timely production, ensure high levels of reliability, and support continued advancement of device design and function.[24]

Imposing tariffs on these inputs would disrupt this balance. By increasing production costs, tariffs reduce the capital available for reinvestment. In the medical technology sector, this would mean fewer resources to support research and development, slowing the pipeline of new devices and delaying the availability of improved technologies for patient.[25] Hospitals and providers, already operating under constrained reimbursement structures, would face increased acquisition costs for essential equipment, which would in turn reduce their ability to replace outdated technologies, expand service capacity, or adopt innovations that enhance care delivery.[26] For patients, the consequence would be slower access to new devices that could reduce hospital stays, improve long-term disease management, or restore lost function.[27]

The risks extend to global market participation as well. US medical technology exports support significant reinvestment in domestic manufacturing capacity and innovation.[28] Tariffs that increase production costs would erode export competitiveness, trigger retaliatory measures by trading partners, and diminish revenues that otherwise support product development.[29] Reduced reinvestment and slower innovation cycles ultimately mean fewer advancements available to patients, particularly in areas where timely access to improved devices can determine survival, recovery, or independence.[30]

The patient consequences of reduced innovation are substantial. Delays in the development and adoption of improved devices prolong reliance on older technologies that may be less effective, less reliable, or less compatible with patient needs.[31] In

[23] Government Accountability Office, *Medical Devices: FDA Has Taken Steps to Improve Its Premarket Review Process, but Additional Actions Could Further Enhance Consistency* (GAO-23-105534, Washington, D.C., June 2023), 1, https://www.gao.gov/assets/gao-23-105534.pdf.

[24] GAO, *Medical Devices.*

[25] United States International Trade Commission, *Economic Impact of Section 232 and 301 Tariffs on U.S. Industries* (Publication No. 5405, Investigation No. 332-591, Washington, D.C., March 2023), 1, https://www.usitc.gov/publications/332/pub5405.pdf.

[26] MedPAC, “Overview of the medical device industry.”

[27] National Academies, *Building Resilience.*

[28] MedPAC, “Overview of the medical device industry.”

[29] USITC, *Economic Impact of Tariffs.*

[30] Wamble et al., “Effect of Medical Technology Innovations.”

[31] Thai et al., “Impact and Costs Associated with Medical Device Shortages.”

critical disease areas—such as cardiovascular care, oncology, or advanced prosthetics—these delays can translate into increased complications, diminished quality of life, or preventable mortality.[32] In this context, tariffs are not merely economic policy measures; they are decisions that would reverberate across the continuum of care, slowing progress and reducing the options available to patients who cannot afford delay.

National Security and Supply Chain Resilience Considerations

Health security is an essential component of national security. A system in which patients and providers cannot reliably access the technologies needed for prevention, diagnosis, treatment, and long-term management cannot be considered resilient.

Resilience in medical product supply chains requires strong domestic capacity, diversified sourcing, and cooperation with trusted international partners.[33] Redundancy and transparency are necessary features of this system. Strategies that focus solely on restricting imports—particularly through indiscriminate tariffs—undermine these principles and risk destabilizing the supply chains on which patients depend for safe and timely care.[34,35]

The United States cannot feasibly manufacture the full range of the millions of medical technologies in use today.[36,37] Imports from longstanding allies such as Japan, the United Kingdom, and the European Union complement domestic production and help ensure quality, timeliness, and reliability.[38] Disrupting these relationships through tariffs would not significantly reduce reliance on adversarial nations but would jeopardize dependable supply flows and patient access.

The COVID-19 pandemic demonstrated the dangers of fragile supply chains. Shortages of PPE placed patients and providers at risk. Interruptions in the availability of IV bags and diagnostic reagents delayed treatment and impaired clinical decision-making nationwide.[39] Increasing costs or reducing the availability of imports from trusted sources would exacerbate these vulnerabilities rather than resolve them.[40]

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[32] Wamble et al., “Effect of Medical Technology Innovations.”

[33] National Academies, *Building Resilience.*

[34] *Trade, and Supply Chain Challenges*, Publication No. 5145 (Washington, D.C., 2020), https://www.usitc.gov/publications/332/pub5145.pdf.

[36] National Academies, *Building Resilience.*

[37] USITC, *COVID-19 Related Goods.*

[38] United States Government Accountability Office, *Supply Chain Resilience: Agencies Are Taking Steps to Expand Diplomatic Engagement and Coordinate with International Partners*, GAO-23-105534 (Washington, D.C., 2023), https://www.gao.gov/assets/gao-23-105534.pdf.

[39] USITC, *COVID-19 Related Goods.*

[40] National Academies, *Building Resilience.*

National Academies, *Building Resilience.*

[35] United States International Trade Commission, *COVID-19 Related Goods: The U.S. Industry, Market,*
Concerns about potential exploitation of supply chains by adversarial nations must be addressed with precision. Broad tariffs applied without distinction do little to mitigate this risk. More effective strategies include strengthening transparency, investing in strategic reserves of essential products, and coordinating with allies to ensure continuity of supply during periods of disruption. These measures directly enhance resilience while safeguarding patient access to essential medical technologies.

Recommendations

The NHC urges the Department to adopt a patient-centered strategy that strengthens resilience while safeguarding access. Broad tariffs or quotas would raise costs, destabilize dependable supply chains, and put patients at risk. A more effective path focuses on addressing specific vulnerabilities without undermining the stability of the broader health system.

Discrete dependencies on adversarial nations should be identified and addressed with narrowly tailored measures. For example, if a critical component is sourced predominantly from a single high-risk jurisdiction, the remedy should target that specific supply risk rather than apply across-the-board restrictions. Carefully scoped actions can mitigate national security concerns without disrupting the availability of essential technologies that patients and providers rely on every day.

Resilience should be achieved through investment rather than restriction. Expanding domestic capacity requires policies that encourage advanced manufacturing, support research and development, and provide efficient, predictable regulatory pathways. These measures complement the strengths of US manufacturers and help ensure that new capacity comes online in ways that support timely patient access.

Partnerships with trusted allies must also be reinforced. Imports from Japan, the United Kingdom, the European Union, and other longstanding partners provide essential complements to domestic production and help ensure reliability and quality. Collaborative arrangements that preserve these flows are more effective at diversifying supply and reducing concentration risk than attempts to achieve self-sufficiency through punitive tariffs.
Transparency and preparedness are also vital. Greater visibility into supply chains, combined with targeted reserves of critical devices and consumables, can buffer the system against shocks without increasing costs for patients. These reserves should be designed to supplement—not replace—market supply and should be managed with clear protocols for deployment and replenishment.

Policy actions under Section 232 should be guided foremost by their impact on patient access to essential care. If measures are adopted, they should be time-limited, subject to regular review, and accompanied by transparent exemption processes for products with no substitutes or whose interruption would endanger life. Implementation should also involve close coordination between the Department of Commerce and the Department of Health and Human Services—including the Food and Drug Administration and the Centers for Medicare & Medicaid Services—to ensure that trade

decisions reflect clinical realities.

National security is inseparable from health security. Policies intended to strengthen resilience must be judged by their impact on patients. Approaches that emphasize targeted interventions, investment, international cooperation, and transparency will reinforce the ability of Americans to access the technologies essential to their survival and quality of life, while overly broad tariffs will undermine it.

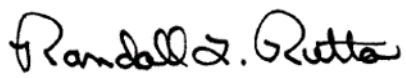
Conclusion

The NHC strongly urges BIS to avoid recommending tariffs or quotas on PPE, medical consumables, or medical devices. Such measures would increase costs, destabilize supply chains, reduce access to essential technologies, and threaten US leadership in medical innovation. Instead, the Department should adopt a strategic approach that combines investment in domestic capacity, cooperation with allies, transparency in supply chains, and narrowly tailored interventions that address specific vulnerabilities.

Patients' lives and health depend on uninterrupted access to medical technologies. Any action resulting from this investigation must place patient needs at the center, ensuring that efforts to enhance national security reinforce, rather than undermine, the ability of Americans to access the technologies essential to their survival and quality of life.

We appreciate the opportunity to provide input on this critical issue and welcome further dialogue. Please contact Kimberly Beer, Senior Vice President of Policy and External Affairs (kbeer@nhcouncil.org), or Shion Chang, Senior Director of Policy and Regulatory Affairs (schang@nhcouncil.org), for additional information.

Sincerely,



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