October 17, 2025

The Honorable Howard W. Lutnick
Secretary
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

RE: Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables and Medical Equipment Including Devices (90 Fed. Reg. 46383, September 26, 2025, XRIN 0694-XC134)

Dear Secretary Lutnick:

The National Foreign Trade Council ("NFTC") appreciates this opportunity to provide input as part of the Department of Commerce's ("the Department") investigation to determine the effects on national security of imports of personal protective equipment (PPE), medical consumables, medical equipment, and devices, under Section 232 of the Trade Expansion Act of 1962, as amended (Docket No. 250924-0160, XRIN 0694-XC134).

The NFTC, organized in 1914, is an association of U.S. business enterprises engaged in all aspects of international trade and investment, including maintaining competitiveness and technological leadership. Our membership covers the full spectrum of industrial, commercial, financial, and service activities, accounting for over $6 trillion in revenue and employing nearly 6 million people in the United States. Whilst NFTC members in the life sciences sector risk being directly affected by any ensuing actions, many member companies across sectors NFTC represents, including technology and manufacturing companies, are also implicated.

Any actions that affect the importation and supply chain for PPE, medical consumables, and medical equipment, including devices, risk profound negative impacts and costs to the innovative U.S. industry, which supports America's healthcare delivery. These costs will add to a U.S. healthcare system that is already burdened and strained. For this reason, it is imperative that extreme caution be exercised, and we urge against the use of any tariffs and that the administration consider non-tariff responses that support industry competitiveness.

Overview:

The U.S. medical technologies industry ("medtech") is a uniquely American manufacturing success story. 70% of the U.S. medtech market is supplied by U.S.-made technologies.[1] The U.S. medtech industry has seen over $340 billion in domestic investment since 2017. These continued manufacturing and production increases have grown U.S. jobs in the sector at three times the U.S. manufacturing average. Owing to the strong domestic manufacturing base, the U.S. medtech industry not only satisfies domestic needs but is also highly export competitive, with over $75 billion in exports annually. Protecting this market access and supporting export success is essential for solidifying the U.S. as the number one choice for future medical technology investments.

Imports of medical equipment, including devices, meet critical U.S. health care needs and do not replace U.S. production capacity. Only 30% of the U.S. medtech market is imported, and the imports are overwhelmingly coming from trusted allies in Europe and North America, reflecting a global network that supports both consistent availability and affordability for American consumers. With over two million medical technologies marketed globally, no single country possesses the know-how and ability to produce everything. Imports complement domestic production and ensure a resilient supply.

The integrity of the supply chain for PPE and medical devices is critical to U.S. health security. Devices such as insulin pumps and blood glucose monitors are integral to daily care for millions of Americans and any disruption to their availability could have severe public health consequences. Today, imports play a crucial role in ensuring that patients and providers have consistent access to these critical devices and supplies.

During the COVID-19 pandemic, in recognition of their essential nature, the first Trump administration exempted critical medical devices, including insulin delivery systems, diagnostic equipment, and PPE, from Section 301 tariffs, and has done the same in past plurilateral initiatives. This highlights the critical importance of the U.S. healthcare system and underscores why this investigation should not result in tariffs but instead consider alternative remedies to support the industry's competitiveness.

There has been a long-standing bipartisan policy in the United States recognizing the critical humanitarian role of medical products in trade policy and excluding them from tariffs. Recognizing this humanitarian imperative, most countries have collectively committed to zero-for-zero tariffs on key life-saving products.

Recognizing these combined factors, the Administration should seek reciprocal, tariff-free trade with key allies, continuing to address non-tariff and unfair market access barriers to key export markets, and consider domestic measures to support U.S. competitiveness.

Scope:

[1] BMI, Fitch Solutions Group Limited; 2024 - https://your.fitch.group/rs/732-CKH-767/images/worldwide-medical-devices-market-factbook-summary.pdf

As noted above, the scope of this investigation, as outlined in the Department's notice, is broad, and covers many different products of varying technological and supply chain complexity, production processes, and trade profiles. A meaningful investigation should be prepared to analyze the four categories outlined in the notice – PPE, medical consumables, medical equipment, and medical devices – as discrete industry segments. Any ensuing recommendations must also reflect these distinctions and be tailored accordingly. We further note that the category the Department calls "medical devices" contains both implantable devices (installed in or on human patients) and capital equipment (installed in hospitals or clinical settings) administered or operated by a healthcare professional, which have distinct product and market characteristics.

While NFTC urges consideration of positive market-based alternatives to tariffs for this investigation, we also want to ensure that the scope of the investigation is contained to the product types specifically listed or inferred in the investigation. For example, items used for routine wellness, personal and oral hygiene, such as wearable consumer devices, dental health (products such as dental floss, picks, or tips, toothbrushes -manual or electronic, dental whitening products, denture adhesives, and tooth whitening products) and personal care products (like electronic hair removers, adult incontinence pads, menstrual tampons, and menstrual pads) are clearly not the types of products referenced in this investigation and should therefore not be in scope. This is an illustrative but non-exhaustive list highlighting the importance of ensuring the investigation is narrowly scoped, while also looking at each of the four categories as discrete segments. We further want to ensure that the scope is not artificially expanded at a future point in time, including, should tariffs or prohibitive measures be considered, that any future actions do not include an inclusion process.

Responses to BIS' questions:

The Federal Register Notice soliciting public comment on this Sec. 232 national security investigation into imports of PPE, medical consumables and medical equipment, including devices, seeks to answer several key questions, including:

(i) the current, projected, and optimal demand for PPE, medical consumables and medical equipment, including devices, and their parts and components in the United States;

(ii) the extent to which domestic production of PPE, medical consumables and medical equipment, including devices, and their parts and components can meet domestic demand;

While the majority of U.S. demand is satisfied domestically, it is simply not possible for the U.S. to meet the entirety of U.S. demand. The reliance and cooperation with trusted allies and import partners for PPE, medical devices and consumables, as well as their inputs, is critically necessary and supports the resilience of the U.S. healthcare industry.

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for PPE, medical consumables and medical equipment, including devices, and their parts and components;

As highlighted above, 70% of all medical technology used in the United States is supplied domestically. Where imports are required, the integration stems from cooperation with trusted allies, including Canada, Costa Rica, Dominican Republic, the European Union, Japan, Korea, Mexico, the United Kingdom, and Southeast Asia. These deep cooperative relationships allow the U.S. to focus on high-value production and R&D while ensuring resilience in the supply chain and cooperation with key export markets for U.S.-made medical technologies.

This supply chain is based on decades of integration and, given the complex nature of regulatory approvals for the industry, cannot be reformulated without millions or billions in costs over several years, which would come at a cost to the U.S. healthcare and insurance system and risk disruptions to patient care.

(iv) the concentration of U.S. imports of PPE, medical consumables and medical equipment, including devices, and their parts and components from a small number of suppliers or foreign nations and the associated risks;

There is no market indication that the United States is critically dependent on a single source of supply for PPE, medical consumables and medical equipment. To avoid such an outcome, U.S. companies must have access to the full range of materials from a wide range of sources to complement robust domestic production.

(v) the impact of foreign government subsidies and predatory trade practices on the competitiveness of the PPE, medical consumables and medical equipment, including devices, and their parts and components, in the United States;

(vi) the economic impact of artificially suppressed prices of PPE, medical consumables and medical equipment, including devices, and their parts and components due to foreign unfair trade practices and state-sponsored overproduction;

(vii) 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, and their parts and components;

(viii) the feasibility of increasing domestic capacity for PPE, medical consumables and medical equipment, including devices, and their parts and components to reduce import reliance;

(ix) the impact of current trade policies on domestic production of PPE, medical consumables and medical equipment, including devices, and their parts and

components, and whether additional measures, including tariffs or quotas, are necessary to protect national security;

Tariffs pose a significant challenge to the U.S. medical device sector's ability to innovate and expand, given its complex supply chains and the higher costs that import duties pose. Tariff costs that industry firms absorb may also reduce our ability to expand R&D and grow jobs and production. These costs will not only affect the ability to innovate, but when combined with the potential tariff impacts of PPE and consumables, there are significant risks to hospitals and the healthcare system overall. These will strain a system already facing cost increases, which risk being borne by end consumers through higher healthcare costs and premiums or higher direct out-of-pocket expenses.

Medical device tariff exemptions were established in the earlier China trade actions, recognizing the critical role medical equipment plays in the safety and well-being of Americans.

Furthermore, medical products have traditionally been excluded from trade actions due to their unique humanitarian role and their importance to ensuring individuals maintain independence and quality of life. This key bipartisan principle is emphasized in the Trade Sanctions Reform and Export Enhancement Act of 2000, which continues to be a critical cornerstone of trade policy.

For these reasons, NFTC encourages alternative approaches to tariffs or quotas to protect any national security concerns. A priority should be for the U.S. to recommit to "zero for zero" tariffs with trading partners, including the European Union, North American partners, Japan, Korea and the United Kingdom. The U.S. should shift its focus to collaborating with allies to mitigate risks to the global trading system. Putting tariffs on these countries risks retaliatory responses, hinders our ability to cooperate with allies, and makes us less competitive.

(x) the impact of the use or lack of use of PPE, medical consumables and medical equipment, including devices, on U.S. manufacturing employment;

(xi) the potential for foreign control or exploitation of the PPE, medical consumables and medical equipment, including devices, supply chain;

(xii) the ability of foreign persons to weaponize the capabilities or attributes of foreign-built PPE, medical consumables and medical equipment, including devices, and their parts or components;

(xiii) the future role of PPE, medical consumables and medical equipment, including devices, in the production of items essential to national security or in activities related to national security; and

(xiv) any other relevant factors.

Conclusion:

Introducing elevated tariffs on imported PPE or medical devices under Section 232 would likely raise costs across the board. Hospitals, surgical centers, physician and non-physician providers, pharmacies, insurers, and ultimately patients absorb those increased costs. For end users who rely on critical apparatus like a non-robotic prosthetic, pacemaker, or hearing aid, tariff-driven price increases could push them out of reach for average Americans. This is especially concerning given that these devices often have limited competition, narrow margins, and high development costs. In the balance between bolstering domestic capability and preserving affordability, policies must err on the side of ensuring continued access, not jeopardizing it with protectionist measures that may backfire on public health.

While the U.S. government and private sector have made significant efforts to boost domestic manufacturing of medical devices, the gap between capacity and demand remains wide. The domestic medical device manufacturing industry is large and innovative, employing hundreds of thousands of workers, driving exports, and supporting research and development as well as infrastructure, but it still cannot fully meet the diverse and specialized demand. Imports are therefore not a vulnerability, but rather an essential complement to domestic production, ensuring that Americans have access to the full range of reliable, high-quality devices needed for daily health and long-term care.

In lieu of tariff changes, the domestic medtech and covered sectors could benefit from policies that provide incentives for additional U.S. R&D and manufacturing expansion, as were recently enacted in the One Big Beautiful Bill Act, ensuring that U.S. national security remains strong alongside a robust local medical device market, and cooperation and open trade with key allies and markets. We should prioritize the competitiveness of the domestic healthcare sector by avoiding the imposition of restrictions on key products and inputs.

About NFTC

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Thank you for your consideration of our comments. We welcome the opportunity to provide additional information and address any questions you may have. Please contact Jeannette Chu, Vice President for National Security Policy (jchu@nftc.org, 703-225-8519) or Brad Wood, Senior Director for Trade and Innovation (bwood@nftc.org or 202-570-1775).

Sincerely,

Jake Colvin
President

cc: Ambassador Jamieson Greer
United States Trade Representative

The Honorable Jeffrey Kessler
Under Secretary of Commerce for Industry and Security