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October 17, 2025

Hon. Jeffrey Kessler
Under Secretary of Commerce for Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue 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 (Docket No. 250924-0160; XRIN 0694-XC134)

The Consumer Technology Association (CTA) appreciates the opportunity to comment on the Department of Commerce's Section 232 investigation into imports of personal protective equipment (PPE), medical consumables, and medical equipment, including devices. CTA represents over 1200 companies in the $537 billion U.S. consumer technology sector, including startups and small businesses that are driving innovation in health technology.

CTA supports the Administration's goals to strengthen national security and industrial resilience, as well as ways to use technology to foster its Make America Healthy Again (MAHA) agenda. However, we urge the Department to exclude consumer medical devices from the scope of this investigation to avoid unintended consequences for devices that are essential to public health, innovation, and economic growth.

Medical Devices as the Backbone of the U.S. Healthcare System
Medical devices play a crucial role in the U.S. healthcare system, serving as the backbone for diagnosis, treatment, and monitoring of various health conditions. From diagnostic imaging equipment to wearable health monitors, these devices are essential for delivering high-quality healthcare. Ensuring the availability and affordability of medical devices is vital for maintaining the efficiency and effectiveness of the healthcare system.

Alignment with the "Make America Healthy Again" (MAHA) Agenda
Consumer medical devices are critical to achieving the Administration's **Make America Healthy Again (MAHA)** agenda. These technologies:

- Expand access to preventive care and remote diagnostics.

- Reduce healthcare costs through decentralized monitoring.
- Empower individuals to manage chronic conditions and wellness.

Tariffs or restrictions on these devices would undermine MAHA's objectives by raising costs, limiting availability, and discouraging innovation in health technology.

Market Evidence and Public Health Impact
CTA's market research underscores the critical role consumer medical devices play in advancing public health and supporting national policy objectives. These devices represent one of the fastest-growing segments in the U.S. technology market:

- **Connected Health Devices**: Over **16 million** connected health monitoring devices — including heart rate, blood pressure, and glucose monitors — shipped in 2024, an **8 percent** increase over 2023.[1]
- **Over-the-Counter (OTC) Hearing Aids**: Shipments exceeded **3 million units** in 2024, marking a **5 percent** year-over-year increase.[2]
- **Digital Health Services**: Subscription-based health platforms and digital therapeutics generated over **$1 billion** in consumer spending in 2024, growing **11 percent** year-over-year.[3]

These technologies are not luxuries – they are essential tools for preventive care, chronic disease management, and remote diagnostics. Consumer medical devices reduce strain on healthcare systems, lower costs for patients, and empower individuals to take control of their health. This aligns directly with the Administration's MAHA agenda by expanding access to care and improving health outcomes.

CTA research also highlights strong adoption among younger consumers and underserved populations. For example, **25% of Millennials and 17% of Gen Z** report that they intend to buy new technology as soon as it is available, and they are leading adopters of connected health devices.[4] Additionally, CTA's study on women's digital health solutions identifies persistent gaps in affordability, trust, and access — shortfalls that consumer medical devices address by offering cost-effective, user-friendly alternatives.[5]

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[1] Consumer Technology Association, *CTA U.S. Consumer Technology: One-Year Industry Forecast, 2020-2025,* 41, (January 2025), https://shop.cta.tech/collections/research/products/cta-u-s-consumer-technology-one-year-industry-forecast-2020-2025-january-2025
[2] *Ibid.*
[3] *Ibid.*
[4] Consumer Technology Association, *Aging in Place: Staying Connected with Technology,* 81, (November 2024), https://shop.cta.tech/products/aging-in-place-staying-connected-with-technology
[5] Consumer Technology Association, *The Future of Women's Digital Health Solutions,* (October 2023), https://shop.cta.tech/products/the-future-of-women-s-digital-health-solutions

Considering the cost sensitive nature of the consumer technology sector, tariffs on medical devices would raise prices on essential health tools used by low- and middle-income households. As a result, tariffs on consumer medical products would reduce access to care and undermine public health.

The Fast-Paced Nature of Innovation in the Consumer Medical Device Sector

The consumer medical device sector is characterized by rapid innovation, technological advancements, and increasing consumer demand for better health solutions. Examples of over-the-counter medical devices sold directly to consumers include blood pressure monitors, glucose meters, digital thermometers, sleep monitors, digital scales, and wearable fitness trackers. Companies in this sector invest heavily in research and development to bring cutting-edge devices to market. Imposing tariffs on these devices would divert scarce resources away from innovation and towards tariff payments, potentially stifling progress and limiting the availability of new and improved medical devices for consumers.

The Integration of Artificial Intelligence in Consumer Medical Devices

Artificial intelligence (AI) is revolutionizing the consumer medical device industry by providing powerful tools for consumers to monitor and improve their health. AI-enabled devices can offer personalized health insights, predictive analytics, and real-time monitoring, empowering individuals to take proactive steps in managing their health. The integration of AI in medical devices not only enhances their functionality but also contributes to better health outcomes for consumers.

Economic Impact on Startups

Startups play a large and vital role in the development of new medical devices in the United States and comprise over 80 percent of CTA's membership. Small medical device companies are typically narrowly focused on creating technologies in specific therapeutic areas, thereby leading to novel advancements in healthcare.[6] Placing tariffs on startups that are driving innovation in health technology would create barriers to market entry and scale, thereby stifling competition, slowing progress toward MAHA goals, and inhibiting patient access.

Diverse Supply Chains and the Impact of Tariffs

The supply chains for individual medical devices vary widely, with components and materials sourced from different regions around the world. Tariffs on medical devices could have significant impacts across the sector, affecting the cost and availability of these devices. Companies may face increased production costs, which could be passed on to consumers, ultimately affecting the affordability and accessibility of medical devices. In some cases, smaller manufacturers may leave the market instead of paying tariffs, leading to product shortages and patient access concerns.

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[6] The Medicare Payment Advisory Commission, *An Overview of the Medical Device Industry*, 210, (June 2017), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch7.pdf

Scope Limitation: Lack of National Security Risks Surrounding Consumer Medical Devices
CTA urges BIS to exclude consumer medical devices from the scope of this investigation because such products do not present the national security risks that Section 232 was intended to address. These devices, including (but not limited to) connected monitors, OTC hearing aids, and wearable health tools, are designed for individual use and the strengthening of public healthcare. As CTA emphasized in its June 2025 comment to HHS on the Health Technology Ecosystem,[7] consumer health technologies are central to expanding preventative care, extending access to healthcare, and reducing overall system costs. Such uses of medical devices are clearly unrelated to national security vulnerabilities, and placing tariffs or other trade restrictions would merely harm public health.

Moreover, applying Section 232 tariffs in this area would create policy inconsistency across agencies, undermining the Administration's own health and innovation priorities. Instead, BIS should focus narrowly on products that present genuine national security risks while explicitly excluding consumer medical devices, which do not present such a threat.

Risks of Overreach and Tariff Stacking
CTA has previously submitted comments on Section 232 investigations into semiconductors, critical minerals, copper, polysilicon, unmanned aircraft systems (UAS), and commercial aircraft. These submissions highlighted the dangers of overlapping tariff regimes and the risk of "tariff stacking."

Consumer medical devices may contain components or materials that are already subject to Section 232 tariffs or potentially subject to future Section 232 tariffs. Additional tariffs on finished medical devices would create a "triple-whammy" effect, compounding costs and compliance burdens for manufacturers and consumers.

Supply Chain Realities and Traceability Challenges
Many consumer medical devices rely on globally sourced components, often through fabless or distributed production models. Tracing the origin of embedded materials, such as polysilicon in chips, is technically infeasible, especially for small and medium-sized enterprises (SMEs). Enforcing tariffs on finished goods would be impractical and disproportionately harm SMEs, which lack the resources to navigate and comply with complex compliance requirements.

The Case for Zero Tariff Treatment for Medical Devices
Zero tariff treatment for medical devices imported from U.S. allies and other aligned trading partners makes sense for the healthcare system, patients, and the U.S. economy. Eliminating tariffs on medical devices would reduce costs for manufacturers and consumers, making these

[7] Consumer Technology Association, *CTA Comments on HHS Health Tech Ecosystem RFI,* (June 16, 2025), https://www.cta.tech/media/udap3db3/cta-cms-health-tech-ecosystem-rfi-fin.pdf

essential products more affordable and accessible. This approach would also support the growth and competitiveness of the U.S. medical device industry, contributing to better health outcomes and economic benefits.

Recommendations for BIS

To avoid unintended harm to consumers and innovators, CTA recommends the following:

- Exclude consumer medical devices, such as those sold over the counter directly to consumers.
- Continue to exempt covered products from any tariffs imposed under the International Emergency Economic Powers Act (IEEPA).
- Ensure that importers can import consumer medical devices duty-free through qualifying exemptions for USMCA-compliant products and products complying with rules of origin under other U.S. free trade agreements.
- Establish exemptions for repair/replacement items.
- Ensure that multiple Section 232 tariffs are not applied cumulatively to the same product.
- Provide simplified compliance frameworks and technical assistance for small firms.
- Allow for duty drawback so that U.S. device manufacturers can export their products abroad without having to pay tariffs on imports of inputs for those devices.
- Provide opportunities for importers to defer duty payments and make payments in installments.

Strategic Alternatives to Tariffs

CTA encourages BIS to pursue non-tariff measures that strengthen and encourage domestic resilience without harming consumers:

- Accelerated permitting for domestic health tech manufacturing.
- R&D investment in alternative materials and device innovation.
- International coordination to diversify sourcing and reduce dependency.

The Importance of International Partnerships and Alliances

International partnerships and working with allies such as the EU, Japan, Canada, Mexico, and South Korea are essential for strengthening the U.S. consumer medical device industry. Collaborative efforts can lead to shared innovations, improved regulatory standards, and enhanced market access. By fostering strong international relationships, the U.S. can ensure a robust and competitive medical device sector.

Addressing Non-Tariff Barriers to Strengthen Competitiveness

Instead of imposing tariffs, the Administration should place a stronger focus on addressing non-tariff barriers in other markets to strengthen the competitiveness of the U.S. consumer medical device industry and encourage domestic manufacturing. By working to eliminate regulatory hurdles, align standards, improve market access, and promote fair trade practices, the U.S. can

enhance the global competitiveness of its medical device sector and ensure that American companies can thrive in international markets.

Legal and Policy Considerations
Section 232 is intended to address direct national security threats – not broad industrial policy. Misuse of the statute could provoke retaliatory trade measures and harm U.S. exporters.
CTA urges BIS to apply Section 232 judiciously and transparently, with clear definitions and commercially practical enforcement mechanisms. Moreover, BIS should for every Section 232 determination of action give industry ample time to prepare and react to alleviate the worst possible burdens on the economy, industry, workers, and consumers.

Conclusion
CTA urges the Bureau of Industry and Security to exclude consumer medical devices from the scope of this investigation. These devices are essential to public health, innovation, and economic growth. Instead of imposing tariffs, the Administration should focus on addressing non-tariff barriers in other markets to strengthen the competitiveness of the U.S. consumer medical device industry.

International partnerships and zero tariff treatment for medical devices imported from U.S. allies are crucial for the healthcare system, patients, and the U.S. economy. By aligning policy with the MAHA agenda and excluding consumer medical devices from this investigation, the Administration can support the growth and competitiveness of the U.S. medical device industry, leading to better health outcomes and economic benefits for all Americans.

CTA looks forward to serving as a resource for BIS as it conducts this investigation. Thank you again for considering our comments.

Sincerely,

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