The Impact of Tariffs on Patient Access to Medical Technology

Importance of Industry

- U.S.-made products account for an estimated two-thirds of the U.S.'s $250 billion medtech market – the other one-third comprises imports mainly from Europe and North America (Mexico and Canada), as well as others such as Costa Rica and Japan.
- International trade and supply chains offer U.S. hospitals and patients the steady, predictable supplies needed to sustain medical needs and support the U.S. medtech manufacturing industry.
- Since the pandemic, our sector has built more resilient, and redundant, supply chains, with over 90 percent of medtech imports from important allies and partners and having sustained a U.S. trade surplus with China in recent years.
- For humanitarian reasons, per the Trade Sanctions Reform and Export Enhancement Act of 2000, all subsequent sanctions legislation, embargoes, and policy disputes with other countries to date have indicated that key humanitarian products, including medical devices, should be excluded from such trade measures.
- **Accordingly, an exemption to tariffs should be provided for all medtech products, given the importance of these life-saving technologies to patients, hospitals, and the overall U.S. health care system.**

Impact of Import Tariffs

- Medtech products are highly complex, some with upwards of one thousand component parts from multiple sources that also require regulatory review and cannot be readily replaced.
- AdvaMed represents a large number of small and emerging business that are drivers of innovation in the U.S. Any increase in the operating costs of these businesses could result in closures, ceding innovation to foreign competitors.
- Changing the country of origin of even components requires time for new FDA approval of the manufacturing site and product quality.
- Tariff volatility could trigger a supply disruption in the medtech market, with spillover impacts to the hospital supply chain, if suppliers began stockpiling in advance of anticipated tariff announcements, particularly in subsectors where suppliers of raw materials of key inputs are limited.
- U.S. manufacturers often cannot mitigate the cost increases for most products in the short term, which impacts patient access.

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  - Most products are sold to hospitals, which are subject to multi-year Medicare and Medicaid payment provisions that also guide private insurance.
  - The Medicare and Medicaid system processes set reimbursement rates in 2-3 year cycles, locking in manufacturers' specific price points and hospital-specific reimbursement. In the short term (minimum 2-3 year), tariffs would result in significant losses for manufacturers.
- In the longer term, tariffs could result in underpayments for hospitals and manufacturers as the system tries to catch up with the impact of increased capital costs.
- As a result, in many cases U.S. manufacturers would bear the full impact to offset tariff costs by reducing employment, cutting R&D on innovation, and disadvantaging the U.S. industry in the face of rising global competition.
- In other cases, the tariff increases would need to be passed on to providers and patients. For example, tariff increases for low-cost, high-use medical devices such as exam gloves, surgical drapes, isolation gowns, and face masks would directly be passed on to providers, increasing the cost of care with no mechanism for additional reimbursement.
- Many medtech subsectors, such as organ preservation solutions and ancillary products, are small markets individually. For products in these sectors, supply chain sensitivity is high, and a single impacted medtech component can cause a market shortage. As competitors are often impacted equally by such raw material availability, supply chain disruptions would force health care systems and customers to face price increases across the board.

Importance of the North American Supply Chain to Serving U.S. Patients

- The Trump Administration’s USMCA Agreement further integrated U.S. medtech manufacturing with Mexico and Canada – strengthening U.S. competitiveness with China. The USMCA provides world class U.S. manufacturers with a nearby, low-cost network of low-tech assembly superior to China’s network. In 2023, Mexico and Canada accounted for roughly 20% of U.S. medtech exports and 25% of imports, respectively.
- U.S. manufacturing benefits from interconnected supply chains in the North American region, and the imposition of tariffs threatens this supply chain.
- Mexico is essential to surgical kitting operations for American hospitals. A 25% increase in costs due to tariffs would lead to a cost increase in each surgical kit. If hospitals are unable to pay the increased cost, surgeries could be canceled or delayed. Over two-thirds of all kits used in U.S. surgeries are manufactured in Mexico.
- There are also examples of medtech products from Canada that are not available from any other source, including the United States. For example, certain radiofrequency guidewires are used in a wide range of non-invasive procedures to cut soft tissues and clear blockages in peripheral vessels, including for vulnerable patient populations and the very young. Proposed tariffs could limit supply and increase pricing, which may lead to a severe impact on the very patients we aim to treat.

Impacts on U.S. Exports

- The highly innovative and competitive U.S. medtech industry, which exported $75 billion in 2023, could be especially vulnerable to disruptions from tariffs.
- Other retaliatory measures such as procurement bans of U.S. products completely eliminate essential U.S. markets in the short term, driving business to other country suppliers such as China. Regaining such lost markets following the removal of tariffs is very difficult medium and long term.

Mitigating Solutions

- Medtech products should be exempt from tariffs because of their importance to patients, hospitals, and the overall U.S. health care system.
- If the Administration proceeds to impose tariffs, we request several mitigating measures.
    - First, the implementation of declared tariffs for medtech should be delayed for at least 3 years, given that manufacturers need regulatory approvals to shift their manufacturing.
    - Second, the Administration should establish a product exclusion process that provides the possibility of tariff relief for manufacturers of critical medical devices over a time-bound period. In particular, we recommend that an express review channel for medical devices be established, given the heightened risks to the U.S. health care system and patients.