October 17, 2025

Secretary Howard Lutnick
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, D.C. 20230

Subject: Advanced Medical Technology Association (AdvaMed) Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, including Devices

Reference: BIS-2025-0258; XRIN 0694-XC134

Dear Secretary Lutnick:

The Advanced Medical Technology Association (AdvaMed) and our over 600 member companies welcome the opportunity to comment on the initiation of the Section 232 investigation to determine the effects on national security of imports of personal protective equipment, medical consumables, and medical equipment, including devices. AdvaMed members, 75 percent of which are small- and medium-sized enterprises, are the medical technology (medtech) companies that invent, develop, manufacture, and distribute products that fill every hospital, health clinic, nursing home, ambulance and doctor's office in America – and increasingly provide more products in home settings.

This submission will respond to the request for public comments on the Section 232 investigation by demonstrating that the U.S. medtech industry is:

- An American success story with a strong and growing industrial base that creates high-paying, skilled jobs for hardworking families across all 50 states;
- The backbone of the U.S. and global health care systems; and
- The global hub and leader for medtech innovation with over $75 billion in annual exports and $340 billion in U.S. investments since 2017, with billions more already pledged in 2025.

In addition, we offer targeted recommendations that will empower the Administration to unlock this sector's full potential and drive the next generation of economic growth and domestic innovation.

Executive Summary

The U.S. medtech industry is an American manufacturing powerhouse, the global leader in medical innovation, and the backbone of the U.S. and global health care industries. As a significant contributor to the U.S. industrial base, our industry supports three million American jobs and nearly 17,000 manufacturing facilities across all 50 states. We are a powerful engine for the U.S. economy, generating approximately $200 billion in production output.[1] Crucially, the medtech manufacturing base is strong and growing, supplying 70 percent[2] of the market by value and attracting over $340 billion in U.S. investment since 2017.[3] We are proud to be a model of this Administration's vision for domestic manufacturing and investment and support the President's America First Trade Policy with a focus on reciprocal trade, leveling the playing field and creating export opportunities for U.S. medtech manufacturers.

The U.S. medtech manufacturing footprint is a strategic asset that drives approximately $75 billion in exports annually, supporting an estimated 160,000 jobs directly.[4] The United States enjoys well-balanced trade, and surpluses, with the majority of its trade partners, especially large economies such as Europe, Japan, and China. Yet, to realistically manufacture and supply the full range of complex and cost-effective products to health care systems — from sutures to pacemakers, neonatal incubators to MRI machines, and strep tests to cancer diagnostics — some imports are required. Most imports come from NATO members, allies and near-shore partners, predominantly in Europe and North America. As proven during and since the global pandemic, our robust trade allows U.S. manufacturers to focus on high-value production and research and development (R&D), 90 percent of which occurs in the United States.

For health care sectors, stringent FDA and global regulations are critical and required for patient safety. As a result, medtech supply chains are inherently less flexible than consumer product sectors; changing a single component supplier can take several years and can cost millions of dollars. Our industry operates in a mostly fixed-reimbursement environment: Medical technologies are purchased by hospitals through multi-year contracts, and adjustment to cost spikes in the short term is difficult. Such outcomes could ultimately disrupt patient care, destabilize hospitals' supply chains, substantially increase costs — particularly for already struggling rural hospitals — and undermine our industry's health care imperative. Moreover, the industry's relatively short and iterative innovation cycles, focusing on enhanced performance for U.S. patients and health care providers, require manufacturers to devote significant resources to these continuous improvements to maintain an edge over foreign competitors.

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[1] Frost & Sullivan, *The Economic Impact of the Medical Technology Industry*, October 2025.
[2] BMI (a Fitch Solutions Company), "United States Medical Devices Report," October 2025.
[3] Ernest & Young, BMI (a Fitch Solutions Company), and member company figures; AdvaMed calculation.
[4] U.S. Census import and export data.

We look forward to working with the Administration to recognize and to reward the unique strength of the U.S. medtech industry and to pursue targeted, America First policies that further bolster our domestic base and export platform. These policies include seeking fair and reciprocal tariff-free trade with our most important allies, aggressively addressing unfair market access barriers in specific countries, and advancing domestic regulatory reforms and procurement incentives to enhance U.S. competitiveness at home and abroad. Appropriately tailored policies can ensure that this critical American industry continues to thrive, innovate, protect, and strengthen the economic and health care systems of our great nation.

General Overview of the U.S. Industry

The U.S. medtech industry represents an American success story, having evolved over the past century into a sophisticated sector that delivers lifesaving medical devices and diagnostics to Americans. Medical technology manufacturing accounted for nearly 500,000 jobs in 2024.[5] Nearly 17,000 medtech manufacturing plants are spread across all 50 states and U.S. territories, with 15,000 of those sites having under 100 employees.[6] The United States has the largest medtech market in the world, valued at $257 billion in 2024.[7] Moreover, the medtech industry underpins the functioning of our health care system. Medtech products are essential in many health care situations and critical to successful patient outcomes that help to lower the cost of health care in the United States.

U.S. Medical Technology Manufacturers Deliver a Diverse Range of Lifesaving Products

The U.S. medtech manufacturing base is as diverse as the over 257,000 medtech products that the FDA regulates[8]. Companies range from the massive, complex manufacturing facilities with thousands of workers that are making millions of units per day, to specialized operations that are hand-stitching the world's most innovative heart valves, to research labs that are developing prototype technologies. As an example, AdvaMed members:

- Provide hospitals with medical devices for every health procedure — from surgical kits to syringes and needles to blood collection vials, bags, and tubing

[5] Frost & Sullivan, *The Economic Impact of the Medical Technology Industry*, October 2025.
[6] Id.
[7] BMI (a Fitch Solutions Company), "United States Medical Devices Report," October 2025.
[8] FDA: 2024 CDRH Safety Report: https://www.fda.gov/media/177865/download?attachment

- Manufacture innovative laboratory instruments, diagnostic tests, and imaging equipment from CT scans and MRIs that detect and identify virtually every form of disease
- Design and produce cardiovascular devices — including heart valves, pumps, cardiac monitors, stents, pacemakers, and defibrillators — that keep hearts pumping
- Create orthopedic and neurosurgical implants and instruments, including artificial joints, that support patient mobility and address brain conditions and traumatic injuries
- Manufacture insulin pumps, kidney dialysis machines, continuous glucose monitors, and other devices that help millions manage diabetes and chronic diseases.

The medtech industry is at the cutting edge of innovations developing AI-enhanced technology already diagnosing health problems earlier, saving lives and money by ensuring early interventions. Just weeks ago, a groundbreaking study of breast cancer patients — the largest of its kind — found a 29 percent increase in breast cancer detection utilizing AI. And that's only the beginning of medtech's ushering in a new dimension of detection and prevention.

Medtech products can be extraordinarily complex — some medical devices require hundreds or even thousands of components. For example, a high-throughput diagnostic analyzer integrates precision robotics, advanced optics, sophisticated electronics, and complex software. Similarly, ventilators require upwards of 1,700 separate component parts and often rely on complex software. Each major product category has its own unique supply chain, sourcing patterns, and processes for component certification to ensure medtech products are safe and effective when they reach the patient. Each component has its own unique set of certified suppliers, component parts, and supply chains.

The U.S. Medtech Industry is the Global Leader in Manufacturing, Exports, and Innovation

AdvaMed members are leading an innovative and growing sector for U.S. manufacturing capacity and employment. As described in detail below, the U.S. medical device industry has been robust and expanding (1) production, (2) investment, (3) exports, (4) employment and (5) innovation. This success has been built on American ingenuity, as well as a network of certified allied suppliers that allow for resilient international partnerships.

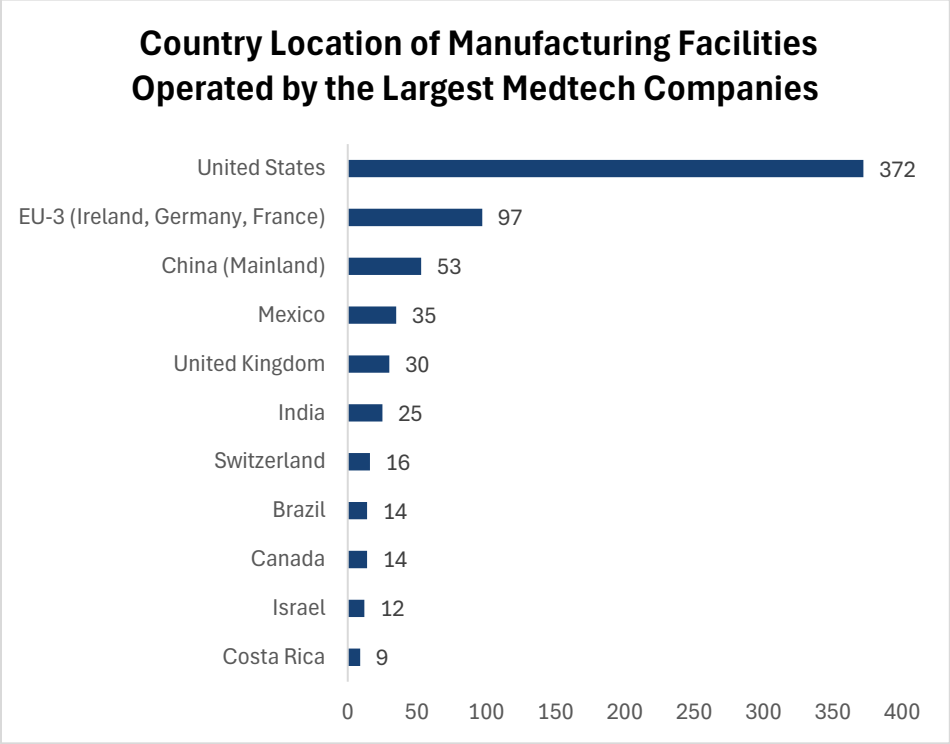
AdvaMed Members Operate On-Shore and Are Expanding U.S. Manufacturing

AdvaMed members are committed to a U.S. manufacturing footprint. In recent years, U.S. manufacturing output of medical technologies has been on an upward trajectory. Between 2016 and 2021, total U.S. medical technology production output grew by 19.5 percent, including the

surge during the global pandemic.[9] Between 2018 and 2023, jobs in U.S. medical technology manufacturing grew three times faster than overall manufacturing employment. In 2022 (the most recent data available by U.S. Census), production output and R&D activity within the United States was just over $188 billion. As we are a growing industry and given historical trends, production output and R&D activity is estimated to have been around $200 billion in 2024. The world's advanced medical technology manufacturing is concentrated in the United States and is underpinned by the U.S.'s 40 percent share of the global medtech market.[10] U.S. production accounts for 70 percent[11] of the market by value, with most of the remainder coming from a certified network of suppliers in predominantly allied or nearby countries.

Advanced Medtech Manufacturing is Concentrated in the United States

Source: BMI's Manufacturing Key Projects Data



Investments in the U.S. Industry Have Exceeded $340 Billion Since 2017

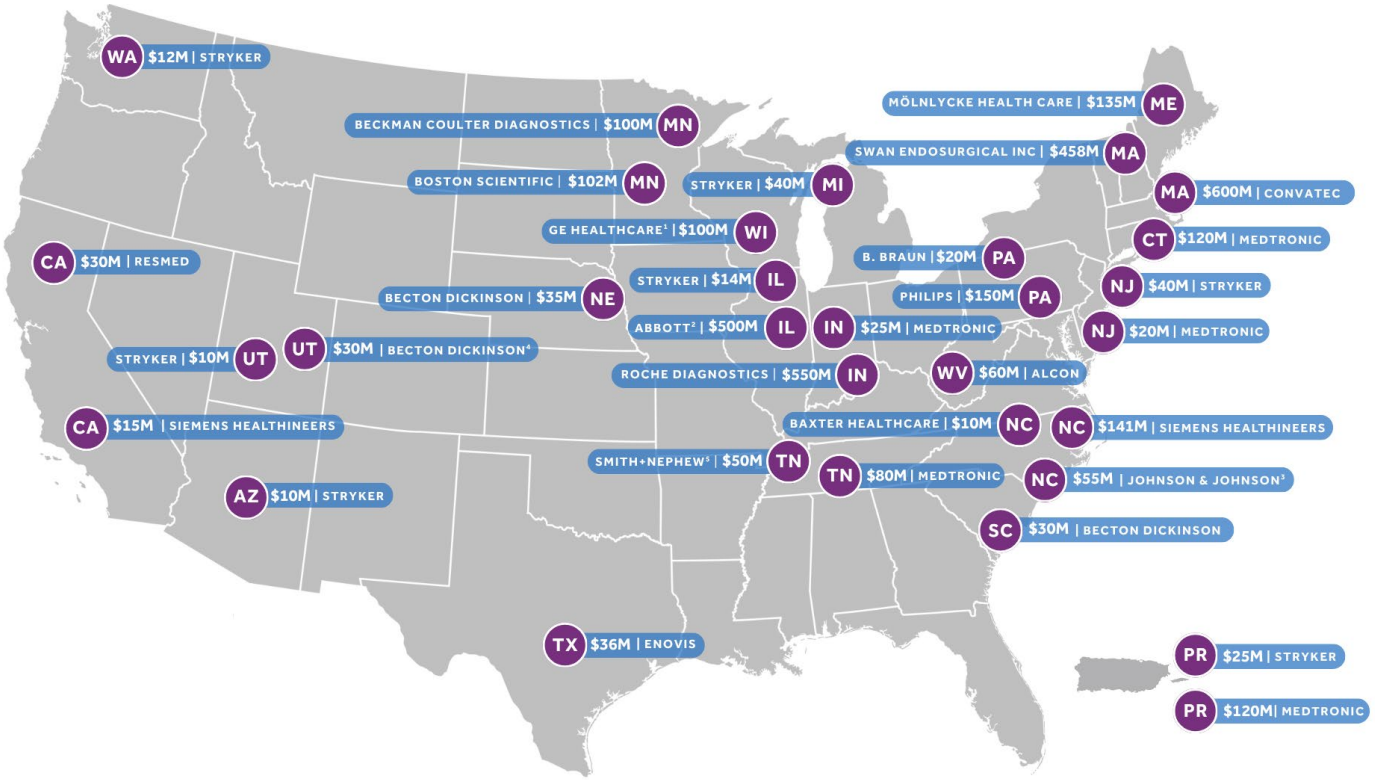
AdvaMed members are investing in the United States. Since 2017, U.S. investments — for new factories ("greenfield investment"), plant expansions ("brownfield" investments), capital

[9] Id.
[10] BMI (a Fitch Solutions Company), "United States Medical Devices Report," October 2025.
[11] Id.

expenditures on new plant equipment and the like — have exceeded $340 billion.[12] Industry investments have generally been weighted toward factory expansions, given the strength of the existing manufacturing base. The U.S. medtech industry, unlike other manufacturing sectors, has maintained and, more importantly, continued investing in a strong U.S. production base over the last several decades.

More than twenty medtech companies have announced expansions within the United States during 2025 alone. We expect that trend to continue. The map below provides a snapshot of just some of the companies that have recently made U.S. investments or have publicly announced plans to expand capacity. (For more detailed information on AdvaMed members' U.S. investments in 2025, please see Annex I).

U.S. Medtech Increases Investment in 2025



1 GE HealthCare is investing an additional $93 million across 14 manufacturing sites in eight states.
2 Abbott announced a $500 million investment to expand manufacturing and R&D operations in its diagnostics transfusion business in Illinois and Texas. The company also has initiated plans to develop a new cardiovascular device manufacturing facility in Georgia to be completed by 2028.
3 Johnson & Johnson's $55 billion over the next four years will include medtech investments.
4 In addition, BD announced plans to invest $2.5 billion in U.S. manufacturing over the next five years.

[12] Ernst & Young, BMI (a Fitch Solutions Company), and member company datapoints; AdvaMed calculation

5 An additional $23 million will be invested in plants in Texas, Maryland, and Massachusetts.

Moreover, investments in the medtech industry have powerful multiplier effects that benefit communities across all 50 states. Revenue, employment, and earnings in the medical technology industry have outsized impacts in their states. On average, in a typical U.S. state:

- Each $1.00 in medtech industry revenue led to an additional $0.84 in total state revenue;
- Each $1.00 in medtech industry payroll led to an additional $0.92 in total state payroll.

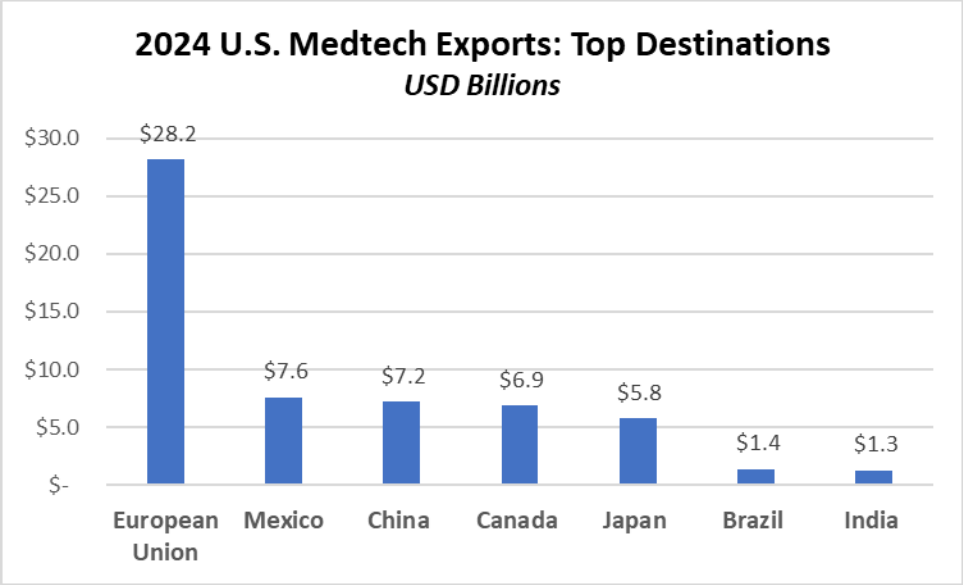
The United States is the World's Leading Exporter of Medical Technologies

U.S. exports of medical technologies surpassed $75 billion in 2024[13], supporting an estimated 160,000 jobs directly within the U.S. medical technology sector. This robust export performance is a testament to the huge industrial base firmly rooted in the United States. Significantly, the strength of our sector's global presence is built on a 30-year foundation of reciprocal binding zero-for-zero tariff commitments with key trading partners that have generated innovation and growth in the U.S. medtech sector.

American companies serve patients in nearly 195 countries. Unique among all major economies, the United States is an export powerhouse across the full spectrum of medical technology: high-tech consumables, implantable devices, imaging equipment and medical supplies, as well as IVD tests. U.S.-made medical technologies are in nearly all hospitals, clinics, doctor's offices, and ambulances around the world.

The United States enjoys trade surpluses with the majority of its trade partners and especially those with large economies. The European Union is our largest export market. U.S. medtech trade with the EU was evenly balanced in 2024, and the United States had a surplus with the bloc in 2023. For 2024, the United States maintained medtech trade surpluses, for example, with China, Japan, Canada, the United Kingdom, Brazil, and India.

[13] U.S. Census data and world import data. The relevant Harmonized Tariff System (HTS) codes for the full breadth of the medical technology sector are spread across numerous HTS chapters. For example, certain key medtech lines, such as in-vitro diagnostic reagents, are often overlooked and others products fall under aggregated lines that scope in medical and non-medical products, and require isolating the medical product portion of the relevant code to the extent possible.

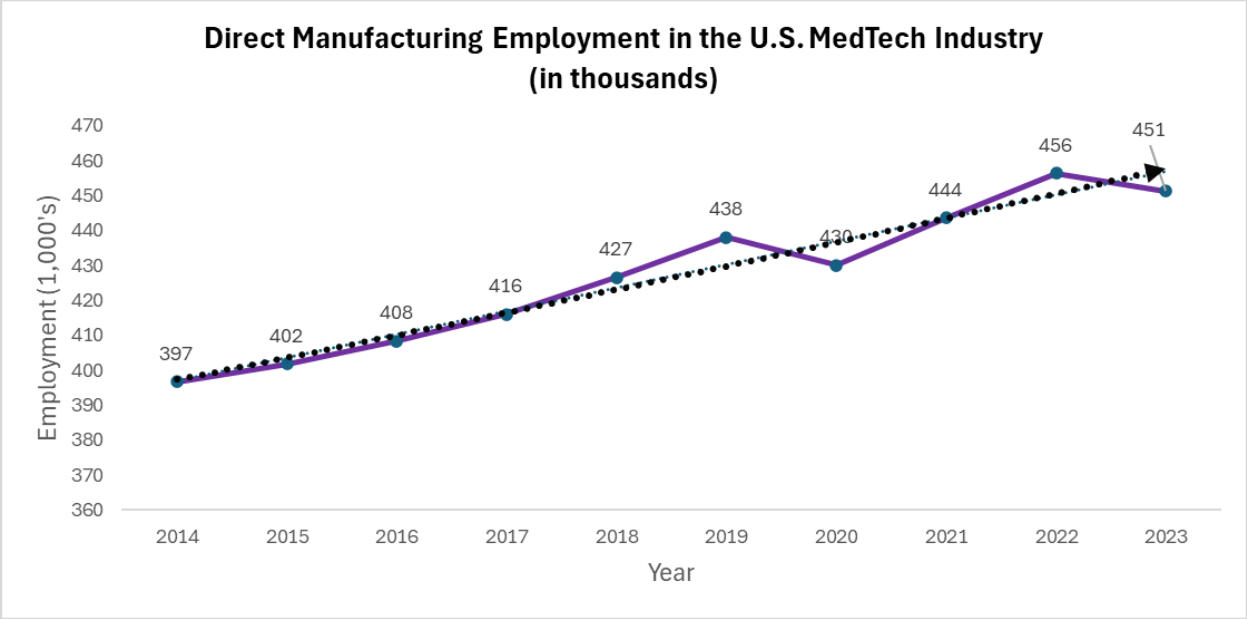


Since the pandemic, U.S. exports overall have witnessed slower growth due to more constrained health care budgets and weaker growth in Europe, the top export market. U.S. exports to China— the world's fastest-growing large medtech market — slightly dipped in 2024 due, in part, to increased market access challenges. Finally, established U.S. brands are facing more price competition from competitors' products in the Global South, especially Brazil, India, and Southeast Asia.

U.S. Medtech Jobs Have Grown Three Times Faster than Overall U.S. Manufacturing Jobs

AdvaMed members are creating good-paying jobs for Americans at about three times the average rate of overall U.S. manufacturing. Between 2018 and 2023, total medical technology employment grew by 5.8 percent, compared to an increase in overall manufacturing employment of 1.7 percent.[14] In 2024, the U.S. medical technology sector accounted for 488,095 jobs, which includes certain R&D-related jobs (Note: The chart below — showing jobs growth since 2014 — is a slight undercount, as it does not capture certain R&D-related jobs).

[14] Frost & Sullivan, *The Economic Impact of the Medical Technology Industry*, December 2024.



Source: U.S. Census data as compiled by Frost & Sullivan

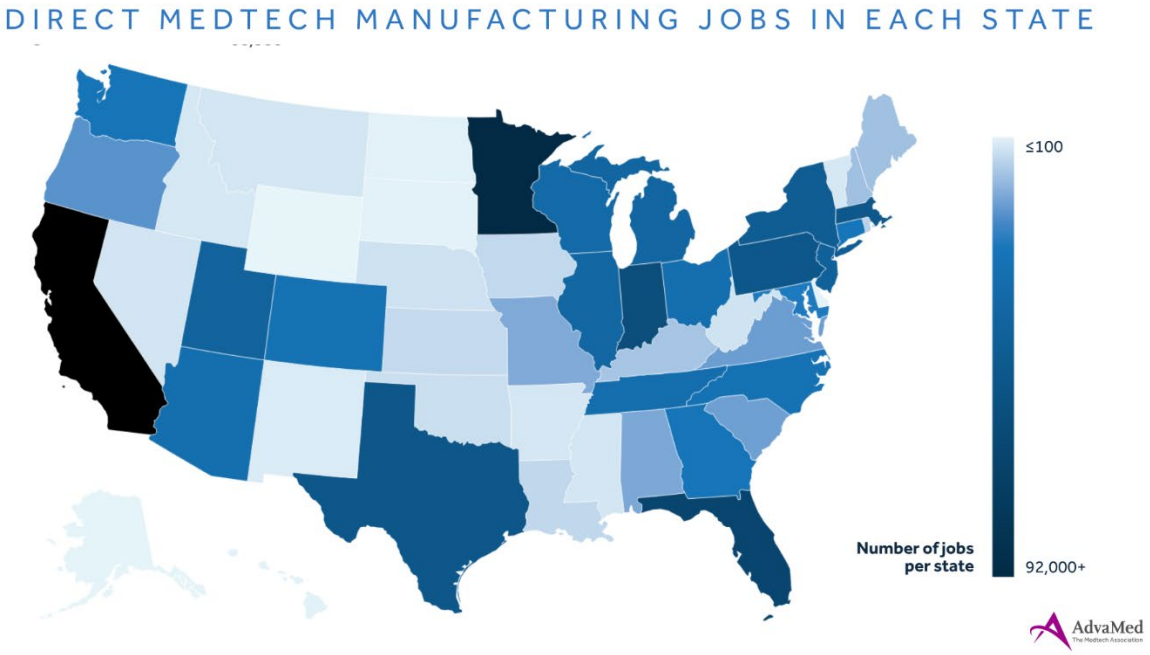
In 2024, employees in U.S. medtech manufacturing were paid $101,142 per year on average, 33 percent higher than the average across all industries, and higher than the 13 percent premium for all manufacturing jobs.[15] Salaries in the *in vitro* diagnostics subsector, for example, were even higher, with average pay exceeding $116,000, representing the highly specialized and skilled nature of this work.

The development, manufacturing, and quality control of sophisticated medical devices and diagnostic tests — including complex molecular assays and immunoassays — require employees with advanced education, technical expertise, and who gain significant responsibility, commanding higher compensation levels than general manufacturing positions. This reliance on a highly skilled, high-value workforce is a defining characteristic of the sector and a key contributor to its innovative capacity. In addition, U.S. medtech companies contribute training health care providers on specialized medical devices and equipment — helping to elevate the skill of U.S. workers and increasing the productivity and safety of clinical staff.

The industry has also established a non-profit organization, MedTechVets, that provides comprehensive training and educational programming to help military veterans transition into careers within this industry.

[15] Frost & Sullivan, *The Economic Impact of the Medical Technology Industry*, October 2025.

In 2024, the U.S. states with the greatest number of medtech jobs were: California, Minnesota, Florida, Indiana, Pennsylvania, and Texas.



Source: U.S. Census data as compiled by Frost & Sullivan

90 Percent of R&D by AdvaMed Member Companies Occurs in the United States

Medtech is a research-intensive sector, with large U.S. medical device companies spending an average of 8-10 percent of revenue on R&D. This commitment to innovation has made the U.S. industry the world leader in R&D spending: total R&D expenditures by U.S. medtech firms were at least $22.6 billion[16] in 2024. This leadership in innovation results from the U.S. industry's focus on patient-centered diagnostics and treatments, which require substantial R&D funding. Recent R&D trends to advance patient care include integrating AI and machine learning to improve diagnostics and surgical precision, as well as advanced robotics for minimally invasive surgeries. 90 percent of AdvaMed members' R&D activity is carried out in the United States.

Despite strong revenues, overall R&D spending growth has leveled off recently due to rising material costs, regulatory challenges, and economic uncertainties. With the tariffs imposed on

[16] Ernst & Young, *Pulse of the MedTech Industry Report 2025*, October 2025.

medtech imports since April 2025, U.S. companies have been shifting resources to manage tariff costs, with R&D spending expected to be the most heavily impacted.

In addition, medtech innovation comes from a network of universities, hospitals, and health care providers. The medtech industry has established centers of excellence to work directly with health care providers across a wide range of medical specialties (see Annex II).

Even with this impressive strength of the U.S. medtech industrial base, job growth, and exports, there is more we can do to work with the Administration to advance its goal of increasing U.S. production. To craft common-sense policies and incentives to do so, it is important to understand the fundamentals of the FDA, global regulatory systems, and U.S. health care reimbursement—all of which govern the medtech sector.

The U.S. Regulatory Framework: Supply Chains to Ensure Patient Safety

The U.S. medical technology industry operates under a stringent regulatory framework overseen by the Food and Drug Administration (FDA) and global regulators to ensure all products are safe and effective for patient use. This comprehensive oversight extends to every stage of the product lifecycle: design, sourcing of individual components and raw materials, manufacturing processes, and sterilization. While these robust regulations are necessary, they also mean manufacturers cannot simply switch suppliers or relocate production in response to market changes.

As a result, medtech supply chains are inherently less flexible than those for consumer products. Modifications to critical components or materials typically trigger lengthy and expensive validation and, in many cases, re-approval processes.

In other words, the ability of medtech companies to react to new tariffs by shifting production is very limited. Manufacturers cannot easily pivot to new suppliers, absent multi-year lead times and multi-million-dollar investments. This environment is particularly challenging for small- and medium-sized enterprises (SMEs), many of whom are driving innovation in our industry. These companies may eventually be less able to absorb such costs and delays and potentially become forced out of business. At a minimum, tariffs that cannot be absorbed would likely lead to supply disruptions and cost increases.

There are important fundamental realities of medical device manufacturing. First, manufacturers must adhere to stringent FDA and global regulators' quality management systems and demonstrate safety and efficacy through documented evidence. This process protects patients and cannot be compromised or accelerated beyond certain limits. Second, any new component or material source requires rigorous verification and validation testing, often spanning multiple

years. This testing scientifically demonstrates biocompatibility, performance equivalence, and reliability under real-world conditions. It cannot be meaningfully shortened without jeopardizing device safety and effectiveness.

Some examples of the difficulties in quickly altering medtech supply chains include the following: (1) One U.S. manufacturer seeking to change suppliers for a raw material used in implantable medical batteries faced a project that cost $10 million and took 3.5 years to complete. Only one company worldwide could produce the material to the required specifications, and validating the new source required years of performance testing across multiple device models. (2) Another example involved a domestic manufacturer changing the supplier for nitinol tubing used in transcatheter aortic valve replacement frames, which took 24 months and cost $5 million per product line. Nitinol, a specialized nickel-titanium alloy, relies on a narrow and complex supply chain. Any sourcing change necessitates new verification testing, and this process cannot be significantly accelerated. These are not isolated cases but reflect thousands of similar scenarios across the industry.

The regulatory rigor extends to sterilization requirements as well. U.S. law requires all medical devices that are intended to be sterilized to undergo validated sterilization processes and achieve a specified sterility assurance level without compromising device performance. Manufacturers must comply with the FDA's Quality System Regulation and periodic facility inspections to ensure sterilization processes remain current with scientific and regulatory expectations. However, sterilization capacity is a major consideration when shifting supply. According to the FDA, approximately 50 percent of all medical devices are sterilized using ethylene oxide (EtO) gas, and the U.S. is at capacity for existing domestic EtO sterilization facilities. While the Trump Administration is addressing regulatory constraints in this space, state and local regulatory activity has disincentivized additional capacity growth. Until domestic sterilization capacity catches up with demand, additional onshoring of sterilization processing will remain constrained.

No single country, including the United States, possesses the full spectrum of resources, specialized manufacturing capabilities, and technical expertise to produce the entire medical device ecosystem domestically at the required scale, quality, and cost-effectiveness to the U.S. health care system. In the short term, major relocations of this multi-tiered supply chain would be technologically infeasible and economically prohibitive, likely resulting in a less efficient, more costly, and ultimately less innovative domestic industry. Access to other markets allows U.S. firms to remain competitive by focusing domestic resources on high-value activities such as R&D, final instrument assembly, software development, and quality control, while leveraging the specialized capabilities of a global network for necessary inputs. This approach ensures that medical technology helps mitigate rising health care costs in an era of tight budgets and the growing needs of an aging population.

Medical Technologies Operate Under Unique Economic Models in the Health Care System

Medtech operates under fundamentally different economic models within the health care system. Unlike other health care industries, the medical device sector is characterized by vastly greater product diversity, ranging from simple bandages to complex robotic surgical systems, each with distinct manufacturing requirements and supply chains. The medtech industry also is dominated by small- and medium-sized enterprises, which tend to have much less flexibility to respond to changes in federal policies and import costs. The relatively short and iterative innovation cycles, focusing on enhanced performance, require manufacturers to devote resources to these continuous improvements — funds increased tariffs would reduce.

Also, the unique structure of the U.S. health care reimbursement systems for medtech differs substantially than payments for other products sold in the United States. Most medtech 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 two- to three-year cycles, in many cases, locking in manufacturers' specific price points and hospital-specific reimbursement. These rates experience a multi-year lag in incorporating new cost pressures such as inflation or additional tariffs. As a result, providers and their suppliers — including medtech manufacturers — may be undercompensated for patient care rendered during shortfall years. In addition, medtech products are typically bundled into broader procedure payments under federal health care programs — such as payments that combine the medical devices and other supplies that are used in orthopedic or pacemaker implants surgery — further limiting manufacturers' pricing flexibility.

In other cases, and especially for high-volume, lower-cost items, the costs would be passed directly to providers, increasing the cost of care with no corresponding increase in reimbursement to the hospitals. Similarly, the prices of medical technologies sold directly to consumers in pharmacies and drug stores are likely to increase if any additional tariffs and costs are imposed.

In the longer term, the unintended consequences of tariffs could result in underpayments for hospitals and manufacturers. As a result, in many cases U.S. manufacturers would bear the impact and be forced to offset tariffs costs by reducing employment, cutting R&D spending on innovation, and disadvantaging U.S. industry in the face of increasingly stiff global competition.

U.S. Medical Technology Helps Mitigate Rising Health Care Costs

Historically, spending on medical technology has been a small share of U.S. health care costs and has maintained low price growth, contributing to stability of its share of overall health care

spending. Using the latest available data (from 2019)[17], spending on medical devices and IVDs was 5.2 percent of U.S. health care expenditures, with an average over the thirty years from 1989 to 2019 of under 6 percent. Over this period, medical device prices have increased at an average annual rate of only 0.4 percent, compared to 2.9 percent for the Medical-Consumer Price Index (CPI) and 1.8 percent for the overall CPI.

Rural Hospitals Already Under Financial Strain Could be Further Impacted

According to the American Hospital Association (AHA), hospital systems are increasingly facing financial difficulties. Nearly half of rural hospitals are delivering care significantly below the cost of providing services, making it financially challenging to remain viable. Many are facing risks of closure due to low patient volumes, high fixed costs, outdated infrastructure, and workforce shortages. With this backdrop, hospital groups are already sounding the alarm about the impact of tariffs on rural hospitals and health centers that are already in a precarious financial position. They have warned that tariffs on medications and essential health care devices could raise hospital expenses by at least 15 percent, compounding existing financial pressures from inflation and inadequate reimbursements and that increased costs from tariffs could force rural hospitals — many of which already operate at a loss — to reduce services or even risk closure, further limiting access to care in underserved regions.

The Strength of the U.S. Medtech Industrial Base is Bolstered by Its Trading Partners in NATO States, Allies and With Near-Shore Partners

As noted above, the U.S. $257 billion medical technology market is on-shore, allied and near-shored. U.S. production provides 70 percent of the market by value. In other words, America produces the majority of its medtech and has a robust "on-shore" industrial base. However, to fully manufacture and supply the diverse range of products and components needed, some imports are required. The medtech sector imports almost entirely from allies and "near shore" reliable partners. As the largest U.S. medtech import partner, the EU, for example, supplies 11 percent of the U.S. market by value. See Annex III, Value of the U.S. Medical Technology Market Supplied by Country Source

European Union and Japan

The U.S. maintains a very balanced trade relationship with the European Union in medical technologies. In 2024, the United States exported approximately $28 billion to the EU, with

[17] Gerald Donohoe. "Estimates of Medical Device Spending in the United States." June 2, 2021. https://www.advamed.org/member-center/resource-library/estimates-of-medical-device-spending-in-the-united-states/

imports at nearly the same levels. This reciprocal and balanced trading relationship is even more remarkable, given that the entire European market for medical technologies ($197 billion)[18] is substantially smaller than the U.S. medtech market (at least $257 billion).

Europe ranks above Mexico and Canada as a supplier of key medical parts and components that support U.S. medtech manufacturing. U.S. medical technology supply chains with the EU are particularly complex and involve high-technology medical devices with high value-add component parts that must be certified and approved by U.S., EU, and global regulators to ensure safety and efficacy. For instance, U.S. companies source:

- Active diagnostic reagent ingredients produced exclusively at a German facility to manufacture cancer tests in Arizona;
- A specialized cobalt-nickel-chromium-molybdenum alloy from Germany and Sweden used in stent production;
- Specialized nitinol frames and catheter components available only from the EU for U.S. stroke device production; and
- Specialty-grade enzymes manufactured by three companies globally, all located in Europe.

This strong transatlantic ecosystem supports robust manufacturing that expands U.S. access to specialized European technologies; reduces the overall cost of products entering the United States, making these diagnostic devices and therapies more accessible for U.S. patients; and enhances U.S. security by diversifying supply chains across trusted sources. In addition to the EU, the UK and Switzerland are also important to the transatlantic medtech ecosystem.

Similarly, the U.S. medtech industry enjoys a positive trade relationship with Japan, a strategic ally and vital supply chain partner. The industry currently maintains a robust $3 billion trade surplus with Japan. U.S. companies supply 40 percent of Japan's medtech market, with $5.8 billion in exports last year. In addition, U.S. medtech companies source critical components and raw materials from Japan, including electronic parts, polymers, specialized metals, and precision instruments necessary for high-tech medical devices. Japan's strong infrastructure, trusted regulatory environment, and commitment to traceability systems make it a critical ally for ensuring the resilience and transparency of supply chains.

Japan is a critical supplier of high-grade precision optics used in endoscopes and imaging systems, specialized electronic components for diagnostic equipment, and medical-grade

[18] MedTech Europe, *Facts & Figures 2025*: *The European Medical Technology Industry in Figures,* September 2025.

ceramics and polymers required for implantable and diagnostic devices. Additionally, Japan is a source of certain rare earth elements that are pivotal to the stability and performance of a broad range of medical technologies. These inputs are difficult to substitute at scale or quality elsewhere.

Mexico and Canada

Mexico and Canada are very important trading partners for U.S. medtech firms and enhance their global medtech competitiveness. U.S. two-way trade with Canada and Mexico reached $32.5 billion in 2024. In 2024, Mexico and Canada accounted for roughly 20 percent of U.S. medtech exports and 22 percent of imports, respectively.

The Trump Administration's United States-Mexico-Canada Agreement (USMCA) strengthened U.S. competitiveness vis-a-vis less reliable suppliers. U.S. manufacturing benefits from interconnected supply chains in the North American region, with long-term investment and production planning. The USMCA-qualifying product rule has been critical to maintaining U.S. companies' competitiveness in the face of tariffs and providing predictable access to critical health care supply chains that are geographically close.

Mexico bolsters U.S. manufacturing with components crossing back and forth for further processing, often numerous times. Mexico also provides a critical network for certain manufacturing nodes superior to distant suppliers that keep U.S. health care costs lower and more stable. In addition, Mexico complements U.S. manufacturing by supplying certain products that are not produced in the United States—continuous glucose monitors and surgical kits are just two examples of how the U.S. health care system and U.S. manufacturing could be impacted by tariffs on medical products.

Canada is one of the top three U.S. export markets for the United States. U.S. medtech exports to Canada are approximately $4.34 billion annually. Moreover, the United States provides over 40 percent of certain critical supplies to Canada's health care system. In addition, Canada, like Mexico, provides certain critical medical components not produced in the United States—medical cannulas (flexible tubes) and certain radiofrequency guidewires offer two examples of items that demonstrate the critical nature of the USMCA qualifying rule for stable and competitive U.S. health care supply chains.

Costa Rica and the Dominican Republic

Costa Rica and the Dominican Republic have also become vital supply chain partners for the U.S. medtech industry, with combined imports of approximately $8 billion in 2024. Near-shored, and much like Mexico, they have developed an important ecosystem of local suppliers that

provide components and sub-assemblies to manufacturers in the United States who export the finished medical technologies globally. These countries also provide U.S. manufacturers with a nearby network of suppliers to augment their domestic production, which is superior to more distant suppliers. Their geographic proximity enables rapid delivery and shorter lead times during public health emergencies, while their end-to-end manufacturing capabilities—from design through sterilization and logistics—ensure continuity of supply. Manufacturing in Costa Rica and the Dominican Republic enable U.S. companies to maintain high-value R&D, engineering, and design operations domestically while remaining globally competitive.

China

Before and after the pandemic, the United States has had a trade surplus with China in medical technology products. For 2023 and 2024, U.S. exports to China averaged approximately $7.5 billion with a U.S. surplus in both years. Most U.S. exports to China are high value-added products spanning Class III implants, complex test reagents, and finished medical parts and components for medical equipment assembly. Currently, approximately 50 percent of China's medtech market is supplied by imports, with the United States being the largest single supplier.[19]

In contrast, China's share of the approximately $257 billion U.S. medtech market is 2.7 percent, and its share of U.S. medtech imports was 8.5 percent in 2024. In addition, the composition of imports from China is diverse and primarily covers FDA Class I and II products with low technology content, such as bandages, wheelchairs, and hospital furniture.

In 2024, U.S. exports to China dropped slightly. An increasingly restrictive market in China for multinationals explains this development at least in part. AdvaMed members have missed business opportunities due to Chinese government requirements for Chinese hospitals to buy from local brands, astonishingly low pricing in government tenders, and regulatory barriers. Ensuring a level playing field in China is critical to U.S. export growth. China's medtech market is the world's second-largest on a per-country basis and will experience double-digit growth well into the 2030s.

The Chinese government has elevated medtech within its industrial policy priorities, beginning with the rollout of "Made in China 2025" a decade ago and, more strikingly, the Dual Circulation self-sufficiency push since 2021. As various studies have indicated, Chinese medtech companies are now marketing low-priced medical technologies that are attractive in the Global South. For instance, Venus Medtech's transcatheter heart valve received regulatory approval in the EU.[20]

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[19] BMI (a Fitch Solutions Company), "China Medical Devices Report," October 2025.
[20] "Venus Medtech's VenusP-Valve TPVR System Approved in Europe," *Cardiac Interventions Today*, (April 11, 2022). Ahttps://citoday.com/news/venus-medtechs-venusp-valve-tpvr-system-approved-in-europe

Still, China has not yet achieved a dominant position in global medical device production and value chains. At present, just one Chinese company ranks in the top 50 medtech companies by global revenue.[21]

Since the imposition of higher tariffs on a select group of products from China, there continues to be greater supply diversification of out of China and to other countries including, for example, single-use, low-cost medical devices and supplies, such as exam gloves and face masks. This subset of medical devices and supplies comparatively has few components and less complicated manufacturing processes than higher-value medical devices. And, as a result, production of such items is generally moving to other countries such as Mexico, Costa Rica, the Dominican Republic, and Malaysia. Such medical devices and supplies are very difficult to produce competitively and supply cost-effectively in the United States, given how medical providers are reimbursed for these products (often as part of procedure rates that are flat and fixed) or over the counter to consumers. As a result, continued access from allied nations will be important for U.S. supply chain resiliency.

Finally, American medical technology companies obtain upstream components and raw materials from China, such as certain critical minerals, that are not currently available in the United States. Critical minerals, including rare-earth elements, are vital across a wide spectrum of medical technologies, including: diagnostic imaging equipment, cancer therapy and treatment, implantable medical devices to treat cardiac conditions, advanced surgical equipment, and various other technologies to support respiration and monitor diabetes. We appreciate the ongoing outreach from the Trump Administration on this concern and would like to continue to work with the Administration to ensure a secure supply of critical inputs for U.S. manufacturing.

Diversification of Supply Chain Helps Meet Surging Demand in Public Health Crises

The complex nature of the supply chain and sources of supply must be considered when determining U.S. policies regarding medtech. The industry's diversified and globally integrated supply chain, particularly its deep and long-standing relationships with trusted U.S. allies and related suppliers, is a strategic asset that enhances resilience, fosters innovation, and ensures U.S. competitiveness. Materials and components routinely cross borders multiple times during manufacturing, with tariffs compounding each crossing—often twice in each direction.

[21] Medical Design and Outsourcing, "Medtech Big 100: The world's largest medical device companies," September 2025. https://www.medicaldesignandoutsourcing.com/2025-medtech-big-100-worlds-largest-medical-device-companies/

The strength of the diversified nature of the medical technology supply chain with trusted trading partners, as described above, has served the United States as well, including during public health crises. This fact can be illustrated by how quickly the industry responded during specific crises.

During the global pandemic, for example, the United States witnessed an unprecedented effort by the diagnostics industry to develop, manufacture, and distribute hundreds of millions of diagnostic tests. The industry rapidly expanded production of the molecular, antigen, serology (antibody), and T-cell tests essential for screening, diagnosing, and managing patients. This surge was critical for supporting public health measures such as contact tracing, treatment decisions, and vaccine development. Supplies of syringes, needles, infusion sets, and plasma collection devices were also rapidly increased to meet U.S. demand, often in partnership with the Trump Administration.

Another example is the hurricane damage to Baxter's North Cove intravenous (IV) facility in Marion, North Carolina, in September 2024, disrupting production at a site that supplies 60 percent of North America's IV solutions and is the largest manufacturer of peritoneal dialysis (PD) solutions in the United States. In addition to providing IVs from existing registered facilities, Baxter partnered with the U.S. HHS and FDA to authorize emergency imports from international facilities while working to restore the damaged plant, with airlifted supplies arriving within weeks to stabilize shortages. By February 2025, the facility returned to pre-hurricane production levels, and supply chains were fully normalized by mid-2025. Through existing alternative supply locations, rapid coordination with federal agencies, strategic international imports, and intensive facility restoration efforts, Baxter successfully stabilized the critical IV and PD solution supply chain and prevented widespread disruptions to patient care across North America.

Another example occurred in early October 2024, just before Hurricane Milton slammed into Florida’s coast. B. Braun worked with the Administration to move 60 truckloads containing 70,000 cases of IV solutions from the company’s manufacturing operations in Daytona Beach to a secure facility north of Florida. Since then, B. Braun has increased production of IV fluids at its Daytona Beach and Irvine, California, facilities by more than 20 percent, helping to secure the supply of critically needed IV fluids across the United States.

Finally, we would note the work of medical device companies that rapidly increased ventilator production during the global pandemic by expanding manufacturing lines, adding shifts, hiring workers, and partnering with non-medical industries to secure critical components. The industry launched the VentConnect platform, which connected manufacturers with suppliers, addressing supply chain shortages. Government agencies expedited approvals and prioritized parts supply, enabling a significant production surge from about 700 ventilators weekly pre-pandemic to an

estimated 5,000 to 7,000 ventilators per week at the peak, showing our industry's ability to meet patient needs, even in the most unpredictable, unforeseen circumstances.

Medtech's Humanitarian Imperative

Our industry has not historically faced tariffs due to its humanitarian mission and support of patients and vulnerable populations. For decades, it has been the consistent, bipartisan policy of the United States to recognize the unique humanitarian nature of medical products in trade policy. The Trade Sanctions Reform and Export Enhancement Act of 2000 is a cornerstone of this principle, establishing a precedent that essential medical goods should be shielded from the impacts of trade disputes. Recognizing the humanitarian nature of medical products, most countries have collectively committed to binding tariff-free trade on these lifesaving products since the 1990s, including the European Union, Canada, Japan, Australia, and the United Kingdom.

Beyond saving and improving lives, we also support vulnerable populations through disease diagnosis and treatment, mobility aids, and much more. Our technologies also empower people with disabilities and chronic conditions to hold jobs, pay taxes, contribute to the economy, and serve in important community roles. Medical technology provides crucial support through physical mobility aids such as wheelchairs, prosthetics, and artificial joints; pacemakers and stents that enable cardiovascular patients to live longer, more productive lives; communication devices such as speech-generating systems and hearing aids; and software like screen readers and voice recognition programs. These technologies help individuals maintain independence and participate fully in daily life by addressing needs related to mobility, communication, sensory impairments, and cognitive function.

This role is increasingly critical as populations age in the United States, Europe, and Japan. Medical technology companies are constantly innovating to help aging populations maintain their health longer so they can stay active and engaged with their communities and, if they choose, the workforce.

Through our robust domestic industrial base, our industry has consistently stepped up in times of crisis, during both peacetime and war, to provide aid and humanitarian support in the United States and around the world. Recent examples globally include the ongoing war in Ukraine and earthquakes in the Middle East, where medical device companies have worked with local organizations, local governments, and U.S. federal aid agencies to donate critical medical supplies and equipment.

RECOMMENDATIONS: Policies to Further Enhance and Support U.S. Production

AdvaMed supports the Administration's America First trade policy with a focus on reciprocal trade and leveling the playing field and creating export opportunities for U.S. medtech manufacturers. We appreciate the opportunity to highlight how a robust U.S. manufacturing presence enables the U.S. medtech industry, across its broad range of segments and products, to both serve the varied needs of American patients and lead the world in medtech manufacturing. AdvaMed and our members stand ready to support the Administration in developing strong, common-sense policies that strengthen our allied supply chains, drive U.S. exports, and continue to provide innovative medical devices to patients in America and around the world. Through reciprocal trade arrangements with trusted countries, attention to unfair trade practices in other countries, and possible changes to the U.S. regulatory system, we can build upon the industry's decades-long legacy as a national asset and secure its role as the engine of American medical innovation for generations to come.

America First Trade Policies to Strengthen the U.S. Medtech Industrial Base

Reciprocal Preferential Trading Relationships with Allies to Bolster U.S. Manufacturing

1. The Importance of Reciprocal Tariff-Free Trade with Europe, Japan, and the UK

Recognizing the significant growth created by 30 years of reciprocal duty-free trading relationships in the medtech industry, establishing a preferred trading bloc with NATO partners and allies will enable the continued growth of U.S. R&D and manufacturing in the medtech sector. This approach would continue to support domestic resilience and enable substantial exports.

Ensuring bilateral and reciprocal tariff-free treatment rates with the EU, UK, and Japan, and other potential reciprocal trade deal partners, will strengthen the American medical technology sector by ensuring the flow of critical products, medical parts and materials, and securing medtech manufacturing competitiveness. In addition, these trading partners maintain robust, high-standard regulatory cooperation with U.S. regulators through mutual recognition agreements and shared commitments to product safety, quality standards, and innovation. Granting tariff-free status to medical technology imports from these allies would provide the much-needed policy stability and predictability that enables companies to make rational, long-term decisions about manufacturing investments, research and development priorities, and supply chain optimization.

This treatment is consistent with the Administration's approach in the EU, Japan, UK, and other reciprocal trade deal partners, for other critical U.S. industry sectors such as aircraft. Like these industries, the medtech industry has (1) a strong U.S. manufacturing and export base in a

complex and highly-regulated technical industry, (2) a decades-long history reciprocal duty-free tariffs with these trading partners, (3) balanced trade or U.S. trade surpluses, and (4) new global challenges from unfair global competition. In addition, our sector has a humanitarian imperative to keep costs stable for the U.S. health care and hospital systems.

2. *Protect North American Supply Chains and Continue USMCA Qualifying Products Rule for Mexico and Canada*

AdvaMed appreciates the Trump Administration's leadership in enacting the USMCA, setting a new benchmark for high-standard trade agreements. The USMCA has secured market and supplier access to bolster U.S. manufacturing and establish more resilient supply chains. Moreover, stronger North American supply chains have reduced dependencies on distant or adversarial suppliers, diversified sources of labor-intensive medical supplies and consumables, and lowered costs to the U.S. health care system. For example, having some operations in Mexico has enabled U.S. manufacturers to remain competitive with manufacturers much further abroad and with supply chains that are riskier and less resilient. Moreover, Canada is one of the top U.S. medtech export markets, and the United States provides over 40 percent of certain critical supplies to the Canada's health care system. The continuation of the USMCA duty-free access for qualifying products is critical to securing resilient and affordable medical technology supply chains in North America. The Section 232 outcomes on autos and auto parts, and more recently on timber, lumber and derivative products, allowed for the USMCA qualifying rule, and this would be critical for the U.S. medtech industry as well.

3. Benefits to U.S. Manufacturing to Expanding the USMCA-type Qualifying Rule to Costa Rica and the Dominican Republic

For the medtech industry, specifically, a USMCA-type of qualifying rule for Costa Rica and the Dominican Republic would further support U.S. medtech manufacturing through additional diversification of supply chains and reduced dependencies on adversarial suppliers and would also decrease costs to the U.S. health care system. This approach would be in line with the Administration's position that certain Western Hemisphere partners provide important alternatives for products and inputs that cannot be realistically made in America.[22] Specifically, this model would further bolster our industry's ability to diversify sources of labor-intensive medical supplies and consumables.

4. Continuation of Duty Drawback

Since many U.S. medtech producers use the United States as an export base from which to serve global customers, it is critical that duty drawback continue to be made available for medtech imports, as it is for reciprocal tariffs and for the recently announced Section 232 tariffs on timber,

[22] U.S. Trade Representative Jamieson Greer, testimony for "The President's 2025 Trade Policy Agenda," Senate Finance Committee (April 8, 2025).

lumber, and derivative products. U.S. jobs rely on a strong export base, which is supported by the duty drawback program. Otherwise, U.S. exports could be jeopardized or made less competitive in international markets.

5. ***Phased-in Implementation of Any Tariffs, Given the Highly Regulated Nature of Medtech***
If any additional tariffs are considered, then a three-year tariff deferral reported in the recent deals in other sectors would be a useful reference for the medtech industry. A phased approach would allow manufacturers time to create new supply sources, secure the necessary regulatory approvals and certifications to shift their manufacturing, and continue to ensure the availability of safe, reliable, and effective devices for American patients and the U.S. health care system.

6. Bilateral Medtech Commitments to Secure Greater Access from Key Global Markets
AdvaMed members urge the Administration to support U.S. medtech manufacturing by pursuing commitments from trading partners to treat American products fairly in the regulatory and government procurement processes.

China: We urge the Administration to support U.S. medtech manufacturing by pursuing purchase commitments by China (as well as by any other trading partners negotiating purchase commitments as part of a bilateral trade deal) to continue to level the playing field for U.S. companies. China's medtech market has registered double-digit growth in recent years, due to a rapidly aging population and a growing middle class. As the Trump Administration seeks to boost U.S. exports, we believe the U.S. medtech industry is uniquely positioned to meet pent-up demand in the world's second largest economy. U.S. exports of medtech to China are stagnating due, in part, to policy challenges restricting market access. The Administration might refer to China's previous purchase commitments of U.S. medtech — commitments that were not met — to bolster its case.

China's market for medtech, in which government-funded hospitals are the primary purchasers, has become increasingly difficult for U.S. companies to access in recent years. We would welcome the opportunity to continue working with U.S. government agencies to secure commitments from China to mitigate these procurement and localization barriers and related discriminatory policies for government procurement including: (1) no further expansion of scope of Volume-Based Procurement (VBP); (2) ensuring sustainable prices by incorporating value-metrics into VBP and limiting cuts to 10 percent; and (3) exemption of medtech from the domestic content requirements under development for government procurement. In addition, China should eliminate country-of-origin requirements in its regulatory approval process.

India*:* The United States maintains a robust trade surplus with India in the medical devices sector in large part due to the country's high dependence on imports and its nascent domestic industry. Specifically, we would welcome the opportunity to continue working with U.S.

government agencies to secure commitments from India to resolve the following medtech challenges in the Indian market during bilateral trade negotiations with the United States: (1) price controls and an opaque pricing policy, which have exacerbated uncertainty in the market; (2) a public procurement order which continues to restrict some U.S. medical device manufacturers' access to India's government procurement market; (3) standards that include provisions for preferences for products meeting Indian standards over global consensus standards; and (4) to date, a ban on the import of refurbished medical equipment.

Pathways for U.S. Regulatory Framework to Bolster U.S. Competitiveness

7. Establish a "MAHA" Pathway to Fast-track Innovation

The establishment of a new "MAHA" (Make America Healthy Again) pathway would allow the FDA to provide priority treatment and expedited review (through the 510(k), PMA, or de novo processes) for medtech products substantially developed and manufactured in the United States. The objectives would be to reduce submission review times related to manufacturing and supplier changes and then appropriately be afforded accelerated coverage and payment (for new technologies without a Medicare benefit category). By significantly reducing regulatory timelines and providing accelerated coverage and payment, this policy would directly reward firms for their U.S. investments in R&D, manufacturing, and new products. It would also ensure that American patients receive first access to the safest and most advanced medical solutions in the world and maintain and grow U.S. leadership in the global medtech industry.

8. Increased Global FDA Inspections to a Level Commensurate with Inspections in the United States

We support the FDA's increased oversight of foreign medtech manufacturers to a level commensurate with the inspection of U.S. facilities. Domestic manufacturers traditionally undergo far greater inspection oversight, creating an uneven playing field. Building on the FDA's risk-based inspection model, the agency should conduct more surveillance inspections of foreign manufacturers to ensure they face the same level of regulatory scrutiny as their U.S. counterparts. This increased oversight is particularly critical for facilities in jurisdictions where on-site investigations have been difficult or where local manufacturers have anomalously low rates of post-market event reporting. Congress should appropriate funds specifically directed to funding foreign facility investigators to increase medtech inspections specifically to reduce the gap between foreign and domestic establishments.

9. Increased Surveillance of Testing Laboratories Outside the United States Producing Fraudulent Data

FDA has identified[23] an increase in submissions with data integrity issues, often associated with certain third-party testing laboratories. FDA highlighted "testing data that are fabricated, duplicated from other device submissions, or otherwise unreliable." FDA also "identified an increase in submissions containing unreliable data generated by third-party test labs." Device applications with data integrity issues are clogging up the review process and potentially could slow down reviews for legitimate device applications. Other regulatory regimes have a concept of "immediate jeopardy," in which, if there are credible indications of fraud or a pattern of unacceptable performance, FDA should be given authority to suspend a lab immediately, with website publication so that companies know right away not to work with that lab, as well as automatic termination from the Accreditation Scheme for Conformity Assessment (ASCA) program[24].

10. Prioritize "America First" Regulatory Approvals: Reliance on U.S. FDA Approvals and Clearances in Key Markets

We would welcome the opportunity to continue to work with the Administration to secure the acceptance of U.S. FDA approvals and clearances in key foreign markets. This "America First" approach would create a powerful incentive for manufacturers to bring their most innovative products to the U.S. market first, ensuring American patients receive access to cutting-edge, life-saving technologies before any other country. By allowing companies that secure U.S. approval to bypass duplicative regulatory reviews abroad, this policy would result in a significant competitive advantage for American innovators, streamline global market access, and reduce costs for manufacturers and patients alike.

The foundation for this policy is already in place. The FDA is the global leader in medtech regulation, known for its scientific rigor and expertise. Regulatory authorities from our key global trading partners, such as the UK and Switzerland, The foundation for this policy is already in place. The FDA is the global leader in medtech regulation, known for its scientific rigor and expertise. Key global trading partners, such as the United Kingdom and Switzerland, have recognized FDA as a trusted regulatory partner and taken steps within their own domestic regulatory schemes to rely on FDA approvals for market entry. We urge the Administration to build on this momentum. A specific focus should be placed on securing a reliance agreement with Mexico, given its critical role in

[23] FDA Notifications on Data Integrity: https://www.fda.gov/medical-devices/industry-medical-devices/notifications-data-integrity-medical-devices#:~:text=The%20FDA%20determined%20that%20Sanitation,testing%20facility%20will%20be%20rejected.

[24] https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/accreditation-scheme-conformity-assessment-asca

the North American supply chain and its status as an affiliate member of the International Medical Device Regulators Forum (IMDRF). Efforts should also expand to emerging markets in Latin America and Southeast Asia to cement the FDA's global leadership and further boost the competitiveness of U.S. medtech exports.

11. Further Workforce Investments to Support Expanded and New U.S. Investments

We also recommend significantly increasing investments in workforce training to support the medical technology sector's innovation and manufacturing capabilities. Building a skilled workforce is essential to sustain the investments in domestic production that have been made during the Trump Administration's first and second terms, secure medical device supply chains, and accelerate the development and delivery of breakthrough health care technologies. By fostering partnerships among government, industry, and educational institutions, the government can ensure a pipeline of talent equipped with the advanced technical and regulatory knowledge critical for medtech innovation. Support from programs like BARDA (the Biomedical Advanced Research and Development Authority), which provide funding, mentorship, and technical guidance for health security innovations, can amplify these efforts.

Investments in workforce training are especially critical for small- and medium-sized medical device enterprises (SMEs), which face unique resource constraints but drive much of the industry's disruptive innovation and job creation. Tailored training for SMEs enables rapid upskilling, enhances regulatory compliance, and boosts their ability to compete and collaborate within the broader ecosystem. These efforts will maintain America's leadership in medical technology, improve patient outcomes, and enhance health care system resilience against future challenges. We would appreciate consideration of the Administration's use of the revenue collected from reciprocal tariffs on medtech since April 2025 to provide zero- or low-interest loans to small and medium-sized medtech companies. These loans would be used for U.S. manufacturing facilities and/or equipment, the training of local employees, and covering the costs related to regulatory approvals.

In closing, AdvaMed and our members welcome the continued opportunity to work with the Department of Commerce to advance the U.S. medtech industry's global leadership and look forward to close collaboration during this matter. We stand ready to assist should you have any questions or need additional information, please contact AdvaMed's Executive Vice President of Global Strategy and Analysis, Ashley Miller (amiller@advamed.org).

Sincerely,

Scott Whitaker
President and CEO
AdvaMed

ANNEX I: Investments by AdvaMed Members During the Second Trump Administration

Medtech is a U.S.-dominated industry, with a tremendous manufacturing and R&D presence in the United States. Thanks to supportive policies, including the medical device tax repeal President Trump pushed for and signed into law in 2019 and tax relief, medtech continues to thrive domestically. Numerous U.S. expansions of medtech operations have been announced this year alone:

Becton Dickinson (BD) is expanding its U.S. manufacturing capacity, in needles, syringes, and IV lines. This expansion includes adding new production lines in Connecticut and Nebraska, as well as investing in its Utah plant for IV line production and blood collection products in South Carolina. In 2025, the company announced plans to invest over $95 million in 2025 and beyond, with additional announcements expected. In May, BD announced its intention to invest $2.5 billion in U.S. manufacturing capacity over the next five years, further strengthening its position as the largest U.S. manufacturer of medical devices and its commitment to ensuring a resilient U.S. health care system. **January 2025, May 2025**

Enovis announced a $36 million U.S. investment over three years to build a new manufacturing facility and expand capacity at existing facilities in Texas to support its growth in orthopedic medical devices. **January 2025**

Medtronic has invested over $100 million to expand its U.S. distribution network, acquiring two new sites in Tennessee and New Jersey, and is proceeding with an investment of over $260 million to expand U.S. manufacturing sites in Indiana, Connecticut, and Puerto Rico. **February, June 2025**

Johnson & Johnson announced a $55 billion U.S. investment over the next four years, including four new advanced manufacturing facilities and expansions of several existing facilities. **March 2025**

Abbott is investing $500 million to expand manufacturing and R&D operations in its diagnostics transfusion business in Illinois and Texas, creating hundreds of American jobs. The investments are on track to go live by the end of the year. The company also has initiated plans to develop a new cardiovascular device manufacturing facility in Georgia to be completed by 2028. **April 2025, June 2025**

Danaher diagnostics company Beckman Coulter Diagnostics is investing $100 million for diagnostic instrument manufacturing expansion in Chaska, Minnesota. This expansion will increase the company's Minnesota workforce by 30 percent, adding jobs in a variety of

manufacturing, R&D, engineering, and managerial positions. The Chaska facility specializes in the production of immunoassay systems and reagents used in clinical diagnostics and laboratory automation. The site supports a wide range of diagnostic applications, including hormone testing, cancer markers, cardiac health, infectious diseases, and chronic conditions such as diabetes, obesity, and cholesterol management and research use support for Alzheimer's biomarker tests. **June 2025**

Boston Scientific is proceeding with its $102 million expansion of its Maple Grove, Minnesota, facility, supporting its device for atrial fibrillation. **April 2025**

Resmed announced a new $30 million high-tech facility in California to focus on research and development for motor technology and the production of silicone mask cushions, critical components of CPAP systems. **April 2025**

Roche Diagnostics announced it plans to invest up to $550 million in manufacturing continuous glucose monitoring (CGM) systems in Indianapolis by 2030. **May 2025**

Siemens Healthineers is investing over $150 million in new projects to expand production, create jobs and better serve customers in the United States, its largest market globally, with investments in North Carolina ($141 million) and California ($15 million). **May 2025**

GE HealthCare is investing $100 million in its Waukesha, Wisconsin, campus and an additional $93 million across 14 manufacturing sites in eight states. Waukesha is a critical hub for GE HealthCare research, development, commercial operations, and high-tech manufacturing in the Badger State, where the company has 7,000 colleagues and full-time contractors generating $8.53 billion per year in total economic impact. The investment in Waukesha will include a new immersive, 30,000 square-foot customer experience center where providers and partners can experience how GE HealthCare technologies are solving real-world challenges and transforming care. Investments in other states such as South Carolina, Arizona, Ohio, Indiana, and Texas will focus on development of new product innovations, capacity expansions, equipment and infrastructure upgrades, and new digital hardware. **July 2025**

Olympus and **Revival Healthcare Capital** announced a new company, **Swan EndoSurgical Inc.**, to invest up to $458 million in gastrointestinal care. The new company's headquarters in Massachusetts bodes well for U.S. jobs. **July 2025**

Philips announced new investments of more than $150 million in U.S. manufacturing and research and development, including the expansion of its Reedsville, Pennsylvania,

manufacturing facility, which produces AI-enabled ultrasound systems for hospitals across the United States. **August 2025**

Baxter Healthcare announced a $10 million cumulative capital investment over the past two years in Raleigh, recently opening a state-of-the-art customer experience and research and development center with approximately 200 full-time employees. **August 2025**

B. Braun announced it will invest $20 million to expand and modernize its manufacturing facility in Lehigh Valley, Pennsylvania, with the creation of at least 200 jobs over three years. The project is supported by $1.5 million in state funding and will enhance IV therapy and compounding operations at the 710,000-square-foot facility. **September 2025**

Mölnlycke Health Care broke ground on a $135 million expansion of its Brunswick Landing facility in Maine. The wound care products facility is expected to increase the company's Maine workforce by about 10 percent. **September 2025**

Alcon celebrated the completion of a $60 million project to expand its manufacturing facility in Huntington, West Virginia, where it has operated since 1989. The site produces intraocular lenses for cataract patients across the globe. **September 2025**

Smith+Nephew is investing $73 million in U.S. manufacturing facilities in 2025 for infrastructure upgrades, automation, and digitization. **September 2025**

Stryker is investing over $150 million in 2025 to expand its U.S. footprint, reinforcing a nearly 85-year legacy of domestic medtech manufacturing to support American patients and global health care systems. This includes increased production capacity and technology upgrades in Cary, Illinois; Kalamazoo, Michigan; Salt Lake City, Utah; Mahwah, New Jersey; Redmond, Washington; Chandler, Arizona; and Puerto Rico. These investments reflect its longstanding, year-over-year commitment to strengthening U.S.-based innovation and advancing health care access worldwide. **October 2025.**

Convatec outlined plans to invest $600 million in research and development in the United States, planning to increase its capacity in Boston by 50 percent. **October 2025**

We expect this positive trend to continue, especially if medtech sees much-needed flexibility with respect to tariffs.

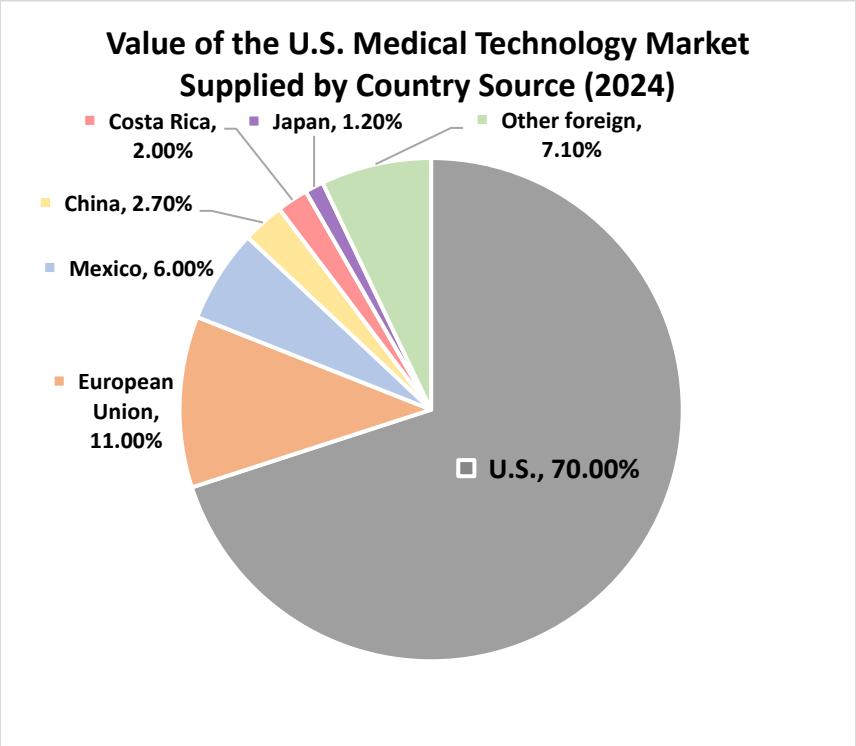
ANNEX II – Centers of Innovation Excellence

Major centers include:

- The Massachusetts Medical Device Development Center,
- The Center for Device Innovation at Texas Medical Center,
- Chicago's mHUB MedTech Innovation Center,
- Caspa Healthcare's Innovation Center and the Midwest Pediatric Device Consortium, both in Ohio,
- The Mayo Clinic's CT Clinical Innovation Center in Minnesota,
- The Consortium for Technology & Innovation in Pediatrics and Children's Hospital, both in California,
- The Mammel Innovation Center in Nebraska, and
- Children's National Hospital of Washington, D.C.

These centers serve as hubs for cutting-edge technology, clinical expertise, and innovative patient solutions. These centers are characterized by their long-term investments, the development and deployment of ground-breaking medical technologies, and track record of advancing public health across a range of medical specialties.

ANNEX III – Value of the U.S. Medical Technology Market Supplied by Country Source



Source: BMI (a Fitch Solutions Company) figures with AdvaMed design