AdvaMed
Advanced Medical Technology Association

April 22, 2024

Juan Millan
Acting General Counsel
Office of the United States Trade Representative
600 17th St., NW
Washington, DC 20508

Re: AdvaMed Comments on Promoting Supply Chain Resilience—Docket Number USTR–2024–0002

Dear Mr. Millan:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide feedback to USTR as it develops policy initiatives that promote supply chain resilience. AdvaMed is the world's leading medical technology association, with over 400 members ranging from the largest to the smallest medical technology innovators and companies. Spread over all 50 states, our industry is responsible for nearly 2 million jobs in the U.S., including both direct and indirect employment at an average annual salary of $88,096—49% higher than the average across all industries and 18% higher than the corresponding premium of all manufacturing jobs. Of the nearly 15,000 medtech facilities nationwide, 94% were small businesses that employed fewer than 100 employees. The U.S. medical technology industry generates approximately $200 billion in annual domestic production output.

The medical technology industry is a manufacturing success story. Our industry is a world leader, with homegrown R&D, domestic manufacturing in communities large and small and worldwide exports of American-made products. U.S. medtech has a robust domestic industrial manufacturing and supply chain footprint. Over two-thirds of all medical technology used in the U.S. is manufactured domestically (69% or $153 billion in domestic sales). The remaining one-third ($61 billion) is imported from the European Union (10.4% or $23 billion), Mexico (5.6% or $12 Billion) and China (3.8% or $8.5 billion). American companies represent about 40 percent of the roughly $500 billion global market for medical devices[1] and provide patients access to the highest quality medical devices and diagnostics in 195 countries.

Medical technology, a complex and heterogeneous industry, ranges from basic consumables such as gloves and catheters to highly sophisticated equipment such as MRI and pacemakers to diagnose, treat and support a wide range of clinical conditions. Medical devices are used in diverse settings by physicians and technicians in hospitals, in nursing homes and at home. These technologies – that save and improve lives - span a range of care areas including critical care/trauma, cardiovascular, cancer, orthopedics, pediatrics, and obstetrics. And while there is no definitive resource providing the exact numbers of medical devices on the market, in 2017 FDA reported that it oversees approximately 175,000 medical devices on the U.S. market, more than 18,000 medical device manufacturers, and more than 25,000 medical device facilities worldwide.

[1] Medical Devices will be used for the remainder of the paper but is generally intended to include medical devices and in vitro diagnostics.

The success of the US medical devices industry is due to a combination of factors including a strong regulatory framework, investments in R&D, a culture of innovation and access to global markets with diverse patient populations. This success has not only translated to huge export opportunities for U.S. companies and benefits to patients around the world, but it has also created a race to the top with the U.S. leading the way on regulatory best practices and setting global standards in core areas such as quality and safety. It has also been an opportunity for the U.S. to take a leadership role on the global stage in advancing policies for smart regulation, good governance, ethics and compliance across the healthcare sector. To continue this virtuous cycle or race to the top, it is critical that the U.S. medical devices industry maintain its competitive edge and continue to lead the world in innovation. With this in mind, we urge USTR to refocus its mission on opening markets, reducing barriers to trade, facilitating investment, and ensuring a level playing field for U.S. medtech companies around the world.

Access to global markets also strengthens the medical device industry's supply chains (for more detail see AdvaMed's supply chain white paper) by providing opportunities to diversify manufacturing locations, enhance upstream suppliers and strengthen regional networks. We welcome the administration's focus on working with partners and allies to support supply chain resilience and urge USTR to move forward with key partners and allies where gaps in our trade relationship still exist. As our partners and allies forge ahead to deepen trade ties, the US should not miss the opportunity to enforce or expand existing trade agreements, initiate long overdue FTA negotiations with stalwart allies and kickstart initiatives with emerging markets that are eager to partner with the U.S. and become more integrated into global supply chains including with robust sector-specific agreements in key areas such a medical technology. As part of this effort, we urge USTR to support the bipartisan Medical Supply Chain Resiliency Act (S. 2115/H.R. 4307) which aims to strengthen medical supply chains with key U.S. allies through trade agreements. This legislation would empower the United States to negotiate Trusted Trade Partner Agreements that would reciprocally eliminate trade barriers and harmonize regulations with U.S. allies and trusted partners that meet high standards.

Comments Relevant to Questions 1 & 2

Our industry requires a highly skilled workforce with backgrounds in biology, chemistry, healthcare, engineering, biomechanics, and digital technologies in addition to well-trained workers that fulfill vital roles on the manufacturing floor and at warehouses. As with most sectors, medtech supply chains have been impacted by dramatic labor shortages and worker retention challenges in the United States that urgently need attention. In addition, workforce issues at various modes of transport (ports, rails, etc.), warehouses, and with key suppliers have exacerbated ongoing global supply chain challenges stemming from the pandemic and continue to this present day as companies work to deliver lifesaving technologies. Downstream, our customers, hospitals, laboratories, clinics, nursing homes and the patients they serve are impacted by the alarming rate of workforce attrition in healthcare emerging from the pandemic. The well-documented lack of skilled and unskilled labor is a key vulnerability that must be addressed in order for companies to expand their footprint or re-orient their manufacturing to the U.S.

In addition to advancing policies that grow our workforce, the U.S. should learn from the investments during the pandemic and develop a more robust strategy for industrial base expansion for medical supplies and equipment. Over the course of the pandemic, the government partnered with industry and made strategic investments in the production of various critical medical supplies and products that were in short supply. Workers were hired, new manufacturing lines were stood up and an ecosystem began to

emerge. These were critical investments that assisted in scaling-up capacity quickly. As the pandemic abated however, demand declined for these products which were not price competitive on a global scale. In the absence of a plan to sustain these investments through stockpiling or long-term contracts, these initiatives were not commercially viable. For example, according to industry estimates cited in the WSJ, about 70% of the 100 or so U.S. mask companies launched during the pandemic have closed.

If the goal is short term production to meet an urgent need, this model works. However, there also needs to be a robust effort in consultation with industry to develop and implement models that sustain manufacturing in the U.S. for the long term. For example, AdvaMed encourages the administration to look at reimbursement incentives for providers to encourage domestically sourced products. On the regulatory side, the FDA should expand pathways to qualify alternatives in the event of a supply chain disruption and address inequities in domestic versus foreign facility inspections. Further, the government should continue to work with industry to develop and enact policies that ensure capacity, including domestic sources, for medical products to ensure future readiness (e.g., warm base manufacturing). And finally, a vital part of this effort, where USTR should lead, includes opening global markets to U.S. manufacturers and ensuring a level playing field so they can weather the ebbs and flows of demand and price fluctuations for critical medical products domestically and around the world.

Comments Relevant to Questions 4, 6 and 7

While nearly every facet of the U.S. economy has been impacted by the events of the last 4 years, from a supply chain management perspective, we have observed that highly regulated sectors, those that must adhere to the highest standards for quality and safety, face the greatest challenges when called upon to be nimble and pivot. Whether the good in question is a ventilator, diagnostic test or contrast media for imaging technologies, a supply chain disruption that warrants change management (i.e., alternative supplier, alternative manufacturing site, alternative transit route, design change, etc.) will ultimately trigger additional regulatory requirements or government interventions to ensure that the "new" product and pathway to the customer is safe.

The entire life cycle of medical devices from early-stage development to post market surveillance is highly regulated to ensure the accuracy, effectiveness, sterility, durability, biocompatibility and safety of every device involved in patient care. For this reason, the supply chains for medical devices and the ecosystem to support their deployment are carefully constructed and refined over time in large part to meet rigorous regulatory requirements in the U.S. and around the world.

In order to ensure patient safety, there are also important regulatory requirements for manufacturing facilities as well as for the products themselves. This requires upfront investments in time and cost to bring new facilities on-line as well as sourcing inputs from new suppliers. For example, for diagnostic testing platforms, it is not uncommon for a duration of 4-6 months from the time an order for such a platform is placed to when it would be installed by the manufacturer on-site at the laboratory.

While agility and the ability to pivot in the face a crisis is the hallmark of a resilient supply chain, disparate and misaligned regulatory frameworks, antiquated paper-based processes, and trade barriers including controls, create delays and hinder response times for medical device manufacturers. While governments may find it challenging to step in and prevent a climate, geopolitical or health related event, they do possess tools and mechanisms to work with partners and across their own government

to mitigate impacts on patients by streamlining regulatory processes, advancing more globally harmonized regulatory frameworks, prioritizing critical industries, investing in supportive infrastructure, and stockpiling products that cannot be sustained by the market during steady state.

In that regard and in recognition of the vital role medical devices play in nearly every aspect of human life, AdvaMed encourages USTR to elevate this sector and urgently work with our partners and allies to develop firm commitments around greater medical device regulatory convergence, adoption of international standards and best practices and a shared commitment to avoiding trade barriers including export controls for healthcare products, their parts and inputs. To achieve this, any new trade initiative or update to existing trade agreements should include sector-specific provisions for medical devices including a Supply Chain Resilience Plan of Action that brings together regulatory, trade and health officials to help speed implementation. Such a resilience plan could build on existing sector-specific provisions such as those included for medical devices in the USMCA as Mexico is a key supplier of medical devices to the United States including in areas such as certain types of PPE.

The Supply Chain Resilience Plan of Action for medical devices would provide a platform for the U.S. and partners to identify and eliminate unnecessary trade barriers; identify critical products for prioritization; promote regulatory cooperation through International Medical Device Regulators Forum (led by U.S. FDA in 2024); utilize the Government Procurement Agreement (GPA), identify trade opportunities to fill health supply chain gaps and diversify upstream suppliers for critical inputs such as semiconductors, resins, critical minerals/gasses and others. Partners would also undertake horizon scanning exercises and work collaboratively to ensure that new regulations (including environmental) were implemented in a manner that avoids disruptions in the timely delivery of healthcare.

Comments on Question 9 on Sourcing

Given the diversity of our industry as described above, and also considering that medical devices can be made up of thousands of components, the supplier networks for medical device companies can be incredibly complex. AdvaMed has spoken at length and produced several studies (here and here) about our industry's reliance on mature semiconductor chips and the impact of shortages on our industry and delivery of healthcare in the U.S. In addition to chips, our industry struggled in recent years to procure sufficient quantities of the raw materials, parts and components used to manufacture, assemble, sterilize, and deliver medical devices and invitro diagnostics. In 2023 our industry identified semiconductors and medical grade packaging among the most needed materials among those facing supply chain constraints, yet our industry also requires sufficient quantities of other raw and semi-finished materials including, but not limited to plastics, polymers, resins, and paper that go into the manufacture of medtech. Also on our watch list of critical inputs and processes are commercial sterilization capacity, helium, and silica-based products, plus critical minerals and metals such as lithium, titanium, cobalt, and steel.

As part of USTR's broader mission of opening markets and ensuring a level playing field for U.S. companies, we welcome USTR's efforts to secure trusted supply chains through strategic arrangements. As part of this process, we urge USTR to examine the upstream needs of vital sectors such as medtech and work with partners and allies to not only ensure adequate supply but also ensure a pathway unencumbered by trade and other regulatory barriers. Such engagements with trusted allies and trading partners will effectively prevent unnecessary barriers to trade and secure free flow of goods and data

which will, in turn, result in more robust supply chains. Critical mineral agreements are a step in the right direction, but we urge USTR to look more broadly across sectors that protect the health and safety of patients in the U.S. and across the globe.

Country/Regional Specific Recommendations

In addition to advancing Trusted Trade Partner Agreements, there are opportunities to evaluate countries whose commercial and trade relationship with the U.S. is at varying levels of maturity, and advance initiatives with those markets to support mutual supply chain resilience and further deepen economic ties.

For example, AdvaMed encourages USTR to launch a bilateral trade initiative with India under the Trade Policy Forum (TPF) specifically focused on medical devices supply chains that would support both countries' medtech supply chain resilience through fostering innovation, facilitating market access, ensuring regulatory alignment, expanding public procurement and greater government-to-government coordination. In addition, Taiwan plays an important role in supplying upstream raw materials and inputs for our sector, including plastics, resins, chemicals, various electronic components, and—of course--semiconductors. Taiwan is also a major source of certain finished medical devices, including surgical masks and blood glucose monitors. As the U.S. looks to strengthen and diversify healthcare supply chains, Taiwan stands out as an important partner worthy of further economic integration.

It is also critical that we advance trade initiatives with stalwart allies such as Japan and the EU, which are major trading partners for the U.S. medtech industry and valuable supply chain partners and continue productive regulatory cooperation and trade facilitation dialogues with regional partners such as Mexico, Costa Rica and Brazil. Additionally, it is important that we encourage emerging trading partners, like Malaysia and Vietnam, to continue to their integration into global medical device supply chains.

Sincerely,

Abby Pratt
Senior Vice President
Global Strategy & Analysis
AdvaMed