AdvaMed & AdvaMedDx Final Paper
International Trade Commission Investigation, No. 332-580
COVID-19 Related Goods: U.S. Industry, Market, Trade & Supply Chain Challenges

Introduction

This paper supplements material previously provided by AdvaMed and AdvaMedDx as part of written and oral testimony – both prior to and during hearings related to the ITC's ongoing investigation. It is intended to respond to several points raised by some participants. We have arranged this material according to key themes and topics, as they were raised during the hearings. In particular, the Commissioners appeared to be most interested in the initial period when demand surged and capacity to meet that demand was stretched, the more recent period following production ramp-ups, and future challenges. For greater clarity, we have used the term "medical technology" (medtech) to refer both to medical devices and *in vitro* diagnostics (IVDs), though U.S. law defines medical devices to include IVDs as well as all other medical devices.

Providing Americans with Medical Technology: Ramp-Up & Initial Challenges

Ramp-up

Our written submission documents how the U.S. medtech industry dramatically expanded output of personal protective equipment (PPE) and ventilators, by multiples of prior years, in a short time frame. This was achieved by adding shifts, repurposing production lines, hiring new workers, retraining existing personnel, qualifying and securing new sources of raw materials, and partnering with non-traditional manufacturers. In response to the Commissioners' questions about the ramp-up for ventilators, invasive ventilator production capacity for U.S. consumption increased over ten-fold from approximately 700 ventilators per week pre-COVID to roughly 10,000 a week by the end of the second quarter.

Our written submission, on page 21, also includes details on the massive mobilization for development and production of IVD tests. This section also explains the related AdvaMed COVID Testing Supply Registry.

Initial Challenges: Data, Demand Surges & Capacity Concerns, and Trade Restrictions

Data

Detailed information about production of specific sectors of the U.S. medtech industry is not readily available. As an association, AdvaMed only collects and maintains information our members want released, and the work involved in any such exercise for such a diverse industry is very extensive. The U.S. Department of Commerce used to publish an annual Industrial Outlook; perhaps that publication could be revived for specific industries.

We have also encountered problems in terms of trade data. The antiquated HTS codes cannot differentiate among the many categories of medtech products. The HTS was developed in the 1980s, before most medtech on the market today was invented. The World Health Organization

reports that there are over 22,000 generic groups of medtech and 2 million types of products. AdvaMed has been working with the Department of Commerce for over a decade on developing a list of HTS codes for medical devices and diagnostics, and periodically revising the list as information changes. This list is, of course, longer than the COVID-related products under ITC investigation but cannot adequately capture the distinct array of medtech products. We will provide our list of medtech products to ITC officials at their request.

When conducting trade analysis, as shown in our written submission, we use the same methodology as described in the ITC's May 2020 Report: "COVID-19 Related Goods: U.S. Imports and Tariffs." That is, we use value data, which is by far the most common way to measure trade flows. We address this point in greater detail below in the China section.

We understand that during the ITC hearings, proposals were considered for frequent and regular reporting by industry on production data. We would be pleased to describe to ITC staff the considerable work and care required to develop AdvaMed's National COVID-19 Diagnostic Supply Registry. We believe similar effort would be needed to collect and report production data for other specific segments of the industry. However, as noted for IVD reporting, the other side of the equation – demand (including data from hospital labs, reference labs, and public health labs) – is also very important to compare output with need.

Demand Surges & Capacity Concerns

As noted above, precise product-specific data are not readily available and, therefore, it is difficult to generalize about the diverse spectrum of technologies needed to address COVID. The ITC identified close to 100 HTS lines of medical technologies – i.e., non-pharmaceutical products needed to treat COVID. We believe others could be included, as we indicated to USTR (please see the "Section 301" material below).

There certainly have been times throughout the pandemic – as demand surged in the U.S. and throughout the world – when certain components or products where in short supply. Much of this shortage was caused by government behavior, as many countries locked down and stopped exports. As we indicated on pages 9-10 of our pre-hearing brief, this situation was exacerbated by the precipitous decline in transport and skyrocketing logistics costs.

The industry was faced with the unprecedented situation of supply obstructions while demand was surging. Our industry has been on the front lines of the coronavirus crisis, working 24/7 to ensure patients and providers have the critical medical technologies they need to diagnose and treat this disease.

There may be instances of individual facilities or areas facing increased demand and potentially limited supply. At present, we do not believe there are any systemic, industry-wide obstacles preventing demand from being met for most COVID products – including ventilators, most PPE, diagnostic tests, or any of the crucial equipment necessary in the fight against COVID. (Please see below our explanations about N-95 respirators).

The Commissioners asked about U.S. regulatory issues. Since the beginning of the pandemic, FDA received approximately 3,000 Emergency Use Authorization (EUA) requests, and over 1,600 pre-EUA requests. Since mid-March, FDA has received over 140 commercial IVD test submissions for COVID-19 EUAs – a critical pathway for the development of new tests – and in record time. During the pandemic, AdvaMed members reported that FDA reviewers worked closely with companies to ensure that the EUA submitters understood FDA requirements for the specific medtech type necessary to support the public health emergency. In many cases FDA published submission templates for the submitter to follow, as they developed the necessary data to receive an authorization from the agency. FDA staff participated regularly in conference calls hosted by AdvaMed to answer our members' questions regarding the EUA process. As a result, industry and the agency worked together to achieve our common goal of timely access to needed medtech to address the public health emergency.

FDA is also required to publish a list of what it deems "Medical Device Shortages" under the CARES Act. However, it is unclear what criteria or information the agency uses to determine which medtech products go on that list – and how medtech products are added and removed from it. Individual company reports do not necessarily mean that an entire medtech sector is experiencing potentially limited supply, nor does it mean there is necessarily a regional or nationwide shortage. A much more thorough analysis is needed, including more accurate reporting on demand requirements.

To the extent that some hospitals report the need for additional supplies of specific medical technology during this public health emergency, it is critical that there be no interference in the global supply chains for medtech so that U.S. companies can continue to tap into their network of suppliers and deliver the technologies that are needed for the U.S. market. We would also note that it is important to think beyond COVID patients. It is our companies' mission to care for all patients and ensure there are sufficient supplies for the general patient population. Our companies also require PPE to ensure their employees are safe and can operate efficiently.

Trade Restrictions

During the initial months of the COVID-19 pandemic, a major source of supply chain disruption came from well-intentioned government intervention. Many countries, including the U.S., restricted the export of PPE and/or controlled allocation of ventilators. Some export restrictions included inputs needed for the production of components or final products. In addition, when governments ordered lockdowns, they initially did not identify completely the full range of "essential" sectors. This lack of planning caused disruptions of critical suppliers and medtech manufacturing facilities, and in the movement of personnel. Such confusion and delays should be avoided in the future. (We discuss China's measures further below.)

The World Trade Organization (WTO), the World Customs Organization (WCO), and private firms provided information on trade disruptions. For example, we have attached to this submission trade restrictions on masks imposed by many countries. WCO's list of trade measures is available here: http://www.wcoomd.org/en/topics/facilitation/activities-and-programmes/natural-disaster/list-of-countries-coronavirus.aspx.

However, within a few months after restrictions were initially imposed, governments began taking action to open-up. By late March, some governments declared that they would not impose export restrictions – as noted in the attached "Joint Ministerial Statement." Shortly thereafter, the G-20 adopted an "extraordinary" declaration:

> *"We commit to continue working together to facilitate international trade and coordinate responses in ways that avoid unnecessary interference with international traffic and trade. Emergency measures aimed at protecting health will be targeted, proportionate, transparent, and temporary. We reiterate our goal to realize a free, fair, non-discriminatory, transparent, predictable and stable trade and investment environment, and to keep our markets open."*

More recently, the WTO issued a report on "How WTO Members Have Used Trade Measures to Expedite Access to COVID-19 Critical Medical Goods and Services." You can read about the report here: https://www.wto.org/english/news_e/news20_e/serv_16sep20_e.htm. In brief, while trade restrictions initially caused disruptions, open trade and the subsequent growth in trade are helping to ease shortages. Going forward, we recommend a coalition of willing governments develop formal and binding commitments (stronger than WTO provisions) to refrain from trade restrictions – an important step to restore trust in trade.

The WTO report states that trade has played a role in improving access to COVID-19 critical medical goods and services since the start of the pandemic. The shortages of medical PPE encountered around the world in the early phase of the pandemic have eased, as production and trade have expanded to meet the unparalleled demand spike. In addition, the note describes a wide range of trade-related measures members have employed, from temporary reductions or deferrals of duties, taxes and charges on COVID-19 critical medical supplies to simplified customs procedures and border clearance. Initial data for 41 countries indicate trade in medical goods grew by 38.7 percent in the first half of 2020. This growth has helped the U.S. overcome some of the capacity challenges that we faced during the initial stages of the pandemic.

Overcoming Challenges – as of September 2020

Strategic National Stockpile

As is now well-known, a fully supplied strategic national stockpile (SNS) would greatly improve the U.S. response to public health emergencies. After 2009, the SNS was not replenished. Going forward, a well-run SNS would be an appropriate first-line of defense to mitigate a demand surge for effective and efficient allocation of supplies. The SNS would add an important dimension for enhancing the resilience of U.S. supply chains.

This objective is likely to require an automatic provision for increased funding levels. The U.S. government should award contracts to willing manufacturers to sell designated quantities at pre-fixed, negotiated prices as production of a particular medtech product begins to exceed demand and their inventories return to more normal levels. This approach will provide manufacturers greater confidence that, as they ramp up to meet the initial demand surge, they will not be stuck with significant quantities of unsold merchandise from redundant production lines. This system

would also fill the SNS when supplies are at more normal levels. The government's goal for each product and the amount of these contracts should be made public to enable manufacturers to plan accordingly. That is, each manufacturer would know how much it should continue to produce, as well as the government's total SNS goal for each product.

Defense Production Act

There have been calls for greater use of the Defense Production Act (DPA). As noted above and in our written testimony, U.S. production capacity ramped up, largely without the need for U.S. government intervention. However, additional capacity limitations had to be overcome, and "hot spots" needed to be identified for supplies to be allocated efficiently. For example, expansion of needed ventilator capacity and allocation of supplies – within the U.S. and outside – were overwhelming challenges. Companies reported that flow down provisions on rated orders, as required through the DPA, supported their allocation efforts.

The DPA also allowed for creation of a Task Force to help support the efforts of the pandemic. While the frequent interactions with HHS and FEMA were helpful, the discussions were confined to rated orders and did not allow for strategic discussions on how to organize around fighting the pandemic with other similarly situated companies and the government, as is envisioned by the DPA. Rated orders created confusion in the supplier market, as many in the industry and government had not experienced them before. In some cases, rated orders diverted supplies away from the medical supply chain to areas where ample supply already existed.

On N95 masks, AdvaMed member companies report that contracts awarded through the DPA helped them to expand domestic production. Similarly, mandates through the DPA allowed them to prioritize orders domestically.

The DPA was also used to restrict U.S. exports of PPE in early April. By mid-April, FEMA recognized that certain exemptions had to be implemented. In brief, FEMA announced that exports of intracompany transfers of covered materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities would be allowed.

The industry and the U.S. government have been collaborating closely on the production and allocation of diagnostic testing. As noted in our written submission (see p. 21) and explained during oral testimony, AdvaMedDx has developed a registry that provides detailed weekly reports on shipments. We are attaching the most recent public version for ITC's reference. In addition, AdvaMedDx members are in regular contact with relevant U.S. government agencies.

However, as discussed during the hearing, AdvaMedDx does not have data on the specific capacities of the labs that run the tests. Information of this nature would help identify potential shortages so that they can be quickly addressed.

VentConnect/MedDevice Network

Separate from the DPA, we noted in our written submission that the National Institutes of Health launched a new initiative, Rapid Acceleration of Diagnostics (RADx). This program is aimed at

expediting COVID testing technologies. RADx is an excellent example of U.S. government-private sector partnership, and is an important complement to the Biomedical Advanced Research and Development Authority, which provides significant support to IVD manufacturers.

Industry has been adopting new ways on its own to overcome supply chain difficulties. For example, on May 2, as part of the medtech industry's multi-front battle to combat the coronavirus pandemic, AdvaMed announced the launch of a new platform, VentConnect, to connect ventilator companies with component suppliers to help quickly scale production and distribution of these vital products. The new platform was developed *pro bono* with the Aerospace Industries Association (AIA), Google, and other industry alliances and partners. Ventilator manufacturers can sign up on the VentConnect site and create secure spreadsheets identifying parts and components that are in short supply. Suppliers wishing to help complete a brief application on their company's capacity and materials. Manufacturers can review supplier applications and decide whether to share their supply list needs. The manufacturer and supplier then separately choose whether to enter an agreement to provide the needed materials.

On Aug. 3, AdvaMed announced expansion of the VentConnect platform to move beyond ventilators to include other complex medical technologies America's patients and caregivers need in the continuing fight against COVID-19 and other future health care emergencies. The renamed platform, MedDeviceNetwork, is designed to connect medical device and diagnostics companies with component suppliers to help quickly boost production and distribution of vital technologies and to reinforce complex supply chain needs. To date, 19 medtech manufacturers and 111 suppliers have signed up for the platform (www.MedDeviceNetwork.org).

"Onshoring"/Buy America

Proposals for U.S. government involvement sometimes include "on-shoring" of manufacturing of medical technology. Reliance on public-private partnerships should be the model for longer-term measures to prepare for future pandemics.

Our members have repeatedly highlighted that during the early stages of the pandemic, the combination of an unprecedented global surge in demand accompanied by the supply constraints highlighted above and during our testimony meant that there were challenges in meeting demand, irrespective of the location of the production capacity. Moving forward as supply chains begin to normalize, there could be opportunities for companies to build greater capacity in the U.S. to create additional redundancies in their global supply chains. Incentives to move companies in this direction should be mindful of how companies will need to pivot and reduce output when demand surges abate. For example, the government should consider mechanisms such as the SNS to absorb excess capacity.

We offer a menu of some incentives, often drawn from congressional or administration proposals, that policy makers should consider to strengthen America's manufacturing base for medical technology. Such incentives should benefit companies that have remained in the U.S. and not just be directed at those for "reshoring." These measures will take time to implement and become effective. They are the right steps to take now.

America should invest in its people. Medtech manufacturing and delivery are very technical and complex operations. The U.S. workforce needs highly trained workers in manufacturing and sophisticated technologies to provide enhanced health care – in normal times to be ready for pandemic emergencies. Tax incentives, such as a "competitiveness" tax credit, should be provided to help medtech companies located in the U.S. to offset the costs of recruiting and training the skilled workforce they need.

America should encourage additional investment in R&D. The medtech industry is already among the most intensive users of R&D to create technologies that usually rely on incremental innovation. New technology development will allow us to respond better to future pandemics. To fuel that innovation, the medtech industry is research intensive. U.S. medtech firms spend over twice the U.S. average on research and development. Medtech companies specializing in the most complex and technologically advanced products devote upwards of 20 percent of revenue to R&D. This share is likely even higher for small- and medium-sized enterprises (SMEs), which account for over 75 percent of U.S. medtech companies. Full tax deductions for R&D expenses should be made permanent and not require amortization. Several other laws should be examined to encourage domestic R&D – such as for foreign-derived intangible income, capitalization of R&D expenses, and investment tax credits. Also, partnerships between industry and universities, focused on R&D of medical solutions, should be funded.

America should invest in facilities and supply chains. Incentives should be granted for renovation of existing facilities, construction of new facilities that relocate back to the U.S., and transforming existing production lines to focus on items included among essential medical technologies. Such incentives should be explored at the federal, state and local levels. Incentives could also include tax breaks for purchasing of new equipment, including to accelerate digitalization for more resilient and agile supply chains.

However, we are not convinced that additional "Buy American" requirements in government procurement would contribute to "on-shoring" of medtech, and could have a negative impact on the U.S. industry. Globally, "localization" hurts U.S. firms. Manufacturers often derive about half of their revenue from their operations outside the U.S. They must be competitive in those countries, as well as in the U.S., which has almost balanced trade with the rest of the world in medical technologies.

Implementing additional "Buy American" requirements could discourage confidence in global supply chains and encourage localization in other countries. Buy American already effectively bans government purchases from China, for example, unless explicitly waived; additional prohibitions would do nothing to limit such purchases. However, withdrawing the U.S. from the WTO Government Procurement Agreement (GPA) and free trade agreements (FTA) with government procurement chapters would likely invite retaliation by some other GPA and FTA members. For example, the U.S. exports about $20 billion worth of medtech to the EU each year. While not all of these sales are directly tied to EU member state governments under the GPA, some portion no doubt was because of the large role governments play in EU health care.

During the ITC hearings, there was mention that the U.S. should not be concerned about "retaliation" due to the withdrawal of the rights of firms outside the U.S. from participating in

our government procurement markets. The rationale was apparently based on the relative size of the U.S government procurement market.

This reasoning is inconsistent with the rights and obligations of participants in trade agreements, in which concessions involving a package of commitments are exchanged. Other WTO members of the GPA and FTAs have negotiated rights to our market and would expect compensation (in trade terms) for loss of these rights, which could involve withdrawal of the right of U.S. firms from participating in their government procurement for medical technologies. The EU, for example, has a proposal to impose reciprocal government procurement access. The requirement for the U.S. to balance concessions was explicitly recognized in implementation of the President's Executive Order (EO) 13944 on Aug. 6, 2020 – "Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States." In particular, the EO requires USTR to negotiate concessions with our trading partners that lose rights as a result of the impact of the loss of the U.S. procurement market for the products to be covered (after FDA determines the list).

The rules of origin should be another concern with new Buy American provisions. EO 13944 and some legislative proposals would appear to require every product input be produced in the U.S. – equivalent to "yarn forward" in the textile industry – i.e., the finished products would need to be crafted entirely from U.S. components. This condition of being "American made" would be difficult, if not impossible, for many medical technologies. If any additional Buy American provisions were adopted, the definition of "produced in the United States" should be consistent with the Federal Acquisition Regulation Part 25.1. Buy American Act-Supplies, and FAR Clause 52.225-1 should be implemented in its totality.

China "Reliance"

The issue of U.S. dependence on imports from China for medtech was raised as a concern during some segments of the ITC hearing. We made the point in our written submission and during the hearing that the U.S. "depends" on China for only about 3.3 percent of our total annual use of medical technology. This calculation relies on U.S. import data (as noted above) and consumption data from an independent source (Fitch Data Solutions). This calculation cannot realistically be done on the basis of volume, given the heterogenous nature of the multitude of medical technology products. We show the U.S. market shares for countries (including the U.S.) at the top of page 3 in our written submission, demonstrating that the U.S. manufactures two-thirds of its medical technology usage.

As noted in our written submission, we attempted to drill down to provide greater specificity on the foreign sources of supplies for medtech. For example, on page 4 of our written submission, the table shows percentages for the foreign country sources of medical technology imports. Likewise, below we show import shares of selected PPE (gloves, gowns) and ventilators from major suppliers. To be clear, these are *not* figures indicating U.S. dependence on those countries for usage. To show the latter, we would need the size of the U.S. market for the products identified – data we do not have. We noted in our written submission that we understand that about 60 percent of ventilators are manufactured outside the U.S. and also demonstrated how

quickly an initial shortage, due to a surge in demand, has turned into a surplus. As we stated in our oral testimony, one indication of such a surplus was that the U.S. government canceled contracts with two ventilator manufacturers.

Selected Imports Related to the COVID-19 Response

Medical Rubber (Latex) Gloves			
Rank	**Country**	**Value**	**% Share**
1	Malaysia	$ 983,844,058	72%
2	**China**	**$ 200,159,326**	**15%**
3	Thailand	$ 124,303,244	9%
4	Indonesia	$ 55,913,716	4%
5	Vietnam	$ 4,356,622	0%
	ROW	$ 3,855,093	0%
HTS: 4015.19.0550			

Ventilators			
Rank	**Country**	**Value**	**% Share**
1	Singapore	$ 919,514,568	34%
2	**China**	**$ 449,696,746**	**17%**
3	Mexico	$ 413,936,879	15%
4	Australia	$ 256,032,376	9%
5	New Zealand	$ 117,454,865	4%
	ROW	$ 541,017,219	20%
HTS: 9019.20.0000			

Plastic Surgical Gowns			
Rank	**Country**	**Value**	**% Share**
1	**China**	**$ 162,761,670**	**44%**
2	Canada	$ 140,591,542	38%
3	Taiwan	$ 13,047,192	4%
4	India	$ 10,702,053	3%
5	Guatemala	$ 8,107,616	2%
	ROW	$ 32,447,724	9%
HTS: 3926.20.9050			

The source of N-95 respirators was discussed in detail during the hearings. We have been attempting to provide the ITC with more detailed information about China's role in N-95 respirator supplies to the U.S. As noted above, N-95 masks have been combined with other imports in the HTS. Until the ITC developed a separate HTS code for N-95 masks in July, there were no separate codes. However, the data for the month of July on U.S. imports from China of over $1.1 billion of these products under the new HTS code does not seem credible or, at least,

not representative of annual trade – and it's perhaps simply a short-term phenomenon – possibly due to a combination of increased prices, project Airbridge purchases, and/or other factors.

In any case, our analysis indicates that the U.S. does not depend on China for a significant share of N-95 supply. Prior to COVID, annual U.S. demand for N-95 respirators was reportedly about 445 million units. At the same time, total production of N-95s in China was on the order of about 200 million units per year (under 600,000 units per day) as recently as Feb. 2. We know that this quantity was insufficient to meet China's own domestic needs during the first quarter of 2020, as COVID struck, and Chinese officials requested assistance from other countries – including U.S. private suppliers. In addition, government entities prevented exports and later required all exports of PPE and ventilators to meet Chinese regulatory requirements (even if the products were only going to be exported). Chinese domestic needs for N-95 masks subsequently eased and U.S. and Chinese government officials were able to resolve the regulatory obstacle.

The data in the chart presented at the ITC hearings by Public Citizen appears to confirm this. China was not shipping many N-95 masks to the U.S. (as total U.S. imports of all "critical" goods (not just N-95 masks) – however Public Citizen defined this term – were only $1 billion, which is less than 20 percent of total U.S. imports of all medical technology). It is also interesting that the Public Citizen chart shows the U.S. and China had a balanced trade relationship in these "critical" products pre-COVID, which is consistent with our bilateral trade in all medical technologies.

After COVID hit, U.S. manufacturers of N-95 respirators ramped up U.S. production by multiples of their previous output to address growing U.S. demand, and are likely to be able to meet U.S. annual demand of 1.5 billion units in the near future and thereafter. In the meantime, U.S. imports from China have substantially increased – although by how much, and how much is useable (see below) is not clear – as Chinese companies dramatically expanded output.

This analysis demonstrates the benefits of international trade. China has been at least partially fulfilling U.S. demand for critical protective equipment. Therefore, in the short-term, our trading relationship with China has been beneficial; in the longer term, the U.S. will not be dependent on China for N-95 masks due to a rapid and considerable ramp-up of domestic production. Of course, the U.S. could reduce any concerns of dependence even further by filling the strategic national stockpile with a sufficient quantity of N-95 masks to meet initial surges.

In addition, concerns about the quality of Chinese N-95 masks are likely to limit their import penetration. According to a recent study be ECRI, about 60-70 percent of Chinese respirators do not meet U.S. health standards. In addition, health care workers complain about the fit.

Public Citizen's chart shows the benefits of trade more broadly. Through the period April-July, U.S. imports of "critical" medical products jumped considerably – again indicating that China was helping meet U.S. demand. The chart also indicates the beginning of what appears to be a reversal, with U.S. imports in July falling below imports of the previous two months.

Public Citizen's chart purports to demonstrate the "concentration" of U.S. imports of test kits (measured by volume), with China having risen from not being a significant supplier in 1999 to

our top source of supply. It is important to note that this chart does not indicate U.S. dependence on China, as it simply shows that as China grew economically, it manufactured and exported more test kits than it did as a developing country. As we explained in our written submission, the U.S. makes up over 40 percent of the global IVD market, with over 300 manufacturing sites. The Public Citizen chart simply indicates that China supplied about 19 percent of U.S. imports – not necessarily a significant share of the U.S. test kits market. Also, it would be helpful if Public Citizen could specify which HTS code(s) it used for this analysis, as we found the following HTS codes could apply (based on the May ITC report): 3002.15.0000; 3821.00.0000; 3822.00.1090; 3822.00.5090; 3822.00.6000; and 9027.80.2500.

More significantly, reporting imports from China of just under 5 million kgs of test kits makes it difficult to compare with the number of test kits in demand. We documented in our written submission the number of molecular test kits shipped in the U.S. by participants in the AdvaMed registry – approximately 170 million as of Sept. 19, and an average of 1.5 million per day for the week ending Sept. 19. The weight of imports of test kits is of little use.

In addition to finished products, there has been concern expressed about inputs. The sources of components for medtech are also widespread, with multiple competitive offerings – mitigating the risk of a shortage by the competitive nature of the market. Medical technology manufacturers also usually make up a relatively small percentage of the global demand for certain components, such as circuit boards and monitors, which means a surge in demand will not overwhelm the supply chain. Likewise, many components of IVD instruments/platforms, IVD tests and test kits are sourced from a multitude of entities across the U.S. and globally.

The issue of whether the U.S. is "overly" reliant on China led to questions about whether U.S. medical technology companies are considering moving out of China. We do not have data to provide a definitive answer. We made the point during the hearings that AdvaMed members tend to locate regionally to supply markets and often manufacture in China for Chinese patients. Of course, trade and political frictions can be factors in future plant locations. We also referred the Commission to a report by McKinsey Global Institute, entitled "Risk, resilience, and rebalancing in global value chains" as a source of the "many considerations" that go into where companies place manufacturing and where they source.

China: Section 301 Tariffs

ITC Commissioners asked about AdvaMed's views on, and experience with, U.S. import tariffs imposed under Section 301 of the Trade Act. This deserves a full explanation.

The U.S. medtech industry is the most innovative and competitive in the world. There are many reasons for this leadership – including our decades of advancement, the high percent of revenue devoted to R&D, efficient supply-chain sourcing, and U.S. government support for leveling the playing field around the world. Another key factor is the industry's consistently strong espousal of open markets – in the U.S. and in other countries. These factors combine to allow U.S. firms to manufacture the best medical technology for patients in the most efficient way, to grow our industry in the U.S., and to hire more American workers.

Rising health care costs around the world are putting pressure on governments to cut costs, including in the U.S. While we have evidence demonstrating that medical technology can help alleviate cost pressures over time, downward pressures on prices continue – including through the use of price controls in some countries – such as maximum sales prices in Chinese provinces. The U.S. industry must be efficient to thrive.

Increasing our supply-chain costs through higher tariffs exacerbates our competitiveness problem – with China, Europe, Japan, and in many other regions. AdvaMed member companies source components and semi-finished products from all over the world, including China, to complete the manufacturing process for medtech here at home for domestic use or export. We cannot accurately calculate the final cost impact of higher tariffs, as the initial tariff hike reverberates and escalates through the various levels of the supply chain. That is, the tariff increase of 25 percent for the imported component could end up being some multiple of that amount as it is used in intermediate products for resale to the next level of processing, and on to final products.

Shifting the source of inputs for finished medical technologies also involves costs. FDA has regulations affecting changes to inputs used in manufacturing medical technology. Depending on the risk classification of the product and the use of the component being changed, FDA may require a supplemental submission to the FDA. If this were to occur, changes in sourcing could lead to delays of several months to possibly a year, as this would require identifying a suitable alternative, notifying FDA, inspecting and validating the specific manufacturing process (e.g., installation, performance, operations), and submitting supplemental registration data. Even if a company believes its product with a new component would not need specific FDA approval, the firm would still be required to use resources to validate that the component from the new source meets specifications, which can also take several months.

The tariff increase acts as a tax on our members – adversely impacting U.S. competitiveness to pioneer the next generation of life-saving diagnostics and therapies. We cannot accurately calculate the relative shares of components versus finished medical technology imported from China. The HTS frequently combines components and finished products, making it difficult to estimate the relative value of each. Our members have identified 90 *non*-medical technology HTS codes for parts and components that are used in their medical technology products. We can review with ITC staff our most recent analysis of the components and semi-finished products on the most recent USTR tariff list that are used to manufacture finished products in the U.S.

In terms of our industry's experience with the Section 301 tariffs, we can provide ITC staff a chronology of our estimate of the value of the products covered and the HTS codes. In brief, since the first imposition of 301 tariffs on July 6, 2018, followed by new tariff actions up until the current time, approximately 40 percent of U.S. medtech imports from China have been subjected to additional (to MFN) tariffs.

In late January 2020 – before the COVID epidemic emerged in the U.S. – AdvaMed wrote a letter to USTR requesting exclusions for a small list of PPE products. In March, USTR granted exclusions for nearly all these products, including: rubber medical gloves (HTS 4015.19.0510), face masks (HTS 6307.90.9889), and surgical gowns (HTS 6210.10.5000). Most of these products were on List 4A from September 2019, with the one-year exclusions having expired on

Sept 1, 2020. On Sept. 2, USTR granted extensions for almost all of these HTS codes (i.e., those pertaining to COVID products), with the new expiration date now pushed back to Dec. 31, 2020.

In response to USTR's March 25 "Request for Comments on Additional Modifications to the 301 Action to Address COVID-19," AdvaMed on April 21 provided a list of more than 80 additional products that our members identified as related to the COVID response and which are subject to 301 tariffs. However, we are disappointed that USTR has not excluded any products in connection with its March 25 request for comments. Some of the same products in our April 21 submission are identified in the ITC's May 4 report on COVID-19 imported products. Several of the products in our April letter are not listed in the ITC's report. These medical technologies include: dialysis machines (9018.90.7520), parts and accessories of respiratory care and anesthesia systems (9018.19.95600), X-ray systems excluding systems for dental or veterinary use (9022.14), and high capacity/throughput immunoassay diagnostic instruments for *in vitro* laboratory use (9027.50.8015). Most of these products are still subject to 25% additional tariffs.

Conclusions

During the COVID-19 pandemic, the medtech industry faced an unprecedented surge in demand for a limited range of products – primarily ventilators, PPE, and diagnostic tests. A well-functioning SNS, coupled with additional information on demand and allocation requirements, could greatly improve U.S. preparation for public health emergencies. Global supply chains must be kept open to secure supplies when demand outstrips domestic capacity, and to ensure sufficient sources of inputs for critical medical technologies. American manufacturing capacity for medtech can be enhanced with a range of appropriate incentives.

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