AdvaMed
Advanced Medical Technology Association

PRINCIPLES FOR PREPAREDNESS:

The Medical Technology Industry's Plan to Respond to an Extraordinary Health Care Crisis

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The Medical Technology Industry's Plan to Respond to an Extraordinary Health Care Crisis

MEDTECH INDUSTRY RAMPS UP

The COVID-19 crisis demonstrated that the industry can respond quickly and effectively to meet the needs of patients and health care providers (please see Annex 1 for detailed examples). Almost overnight, AdvaMed's member companies refocused their operations – expanding production and capacity to develop and manufacture the medical technologies that are critical to our country's fight against this pandemic and arming health workers on the frontlines with the tools they need to save lives:

- Ventilators used to assist patients who are unable to breathe;
- Personal protective equipment (PPE) used by providers on the frontlines;
- Diagnostic tests that are critical to diagnose and track disease; and
- Countless other medical technologies and supplies.

To continue the fight against COVID-19 and to prepare for any future extraordinary health care-related crisis requires a concerted and collaborative effort with government and industry working together based on the following principles:

Storing sufficient supplies in the strategic national stockpile to meet any initial surge in demand from any future health care crisis;

Keeping supply chains resilient so that medical technology companies can efficiently access the components and raw materials they need to ramp up production so the U.S. can continue to supply patients around the world;

Allocating in advance, through careful planning, where and how to get crucial medical supplies to those most in need; and

Investing in America to support a strong domestic medical technology industry that will continue to meet the needs of U.S. patients and health care providers.

IMPLEMENTING PRINCIPLES FOR PREPAREDNESS

The complexity and diversity of the medical technology industry must be understood in order to implement a solid preparedness program.

The World Health Organization counts two million kinds of medical technologies spread over **22,000 device-type categories**.

Innovation is rapid, with new devices replacing current products **about every 18-24 months**.

The industry is global, with American companies providing patients access to the highest quality devices and diagnostics in **nearly all of the UN's 195 countries**.

Our principles are the foundation on which to implement our plan.

STORING SUFFICIENT SUPPLIES

A consensus exists in the Administration, Congress, industry and among other stakeholders that America's strategic national stockpile (SNS) must be substantially increased. The HHS Assistant Secretary for Preparedness and Response (ASPR) leads an interagency process – including FDA, CDC, FEMA, the Biomedical Advanced Research and Development Authority (BARDA) and others – to oversee the operation of the SNS.

The reason for the SNS has been apparent since it was created in 1999 – to address the shortage of supply between the initial surge in demand brought on by a health care-related crisis and the time it takes for production to catch up. When such events are localized – such as a hurricane, major flooding, etc. – or even national but contained (e.g., H1N1) – this period is relatively brief.

The COVID-19 pandemic caused an unprecedented surge in demand for critical medical products. This demand exceeded historical levels by several multiples. It was well beyond any reasonable projection during manufacturers' previous-year planning, even incorporating levels for unforeseen demand spikes, as manufacturers do. The medical device industry responded quickly by instituting policies to protect employees from the virus while ramping up manufacturing to maximize production of critical products (as illustrated in Annex 1).

A major policy issue that needs to be addressed is how the SNS can be improved to respond more quickly, effectively and consistently across the country. Specific medical devices – "Medical Countermeasures (MCMs)" – for the SNS were

identified and purchased, but initial supplies did not prove sufficient, either in quantity, in the range of product categories available, or their locations. BARDA is designed to have supplies reach any location in the U.S. within 12 hours. States also are expected to have stocks of critical medical supplies. However, the sheer scope and global nature of the COVID-19 pandemic simply overwhelmed the system.

The U.S. government should award contracts to willing manufacturers to sell designated quantities at pre-fixed, negotiated prices as production of a particular medical device begins to exceed demand and their inventories return to more normal levels.

In vitro diagnostic tests, and testing supplies and platforms, should be considered for the SNS. If a new pathogen were to emerge, new testing would need to be developed, as has been the case with COVID-19. However, certain rapid, point-of-care diagnostic tests, though they do have a shelf life, could be included in the SNS to ease future emergencies. For example, certain tests that help rule out other infections can be stored – such as rapid flu tests to rule out flu if respiratory symptoms being experienced are from a new pathogen. In addition, testing supplies used in the collection, transport and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets and transport medium/tubes which are generally not specific to a particular test. Consideration should be given also to extraction reagents, used in molecular laboratory testing. Laboratory diagnostic instruments or platforms could also be stockpiled and provided to areas of greatest need in case of emergency.

Congress and the Administration recognize that the operation of the SNS needs to be improved. There are currently over two dozen bills in the House or Senate that include some provisions dealing with the medical technology supply chain. The Administration released a "request for information" seeking advice from the private sector – manufacturers, distributors, trade associations and other organizations – about the structure of the SNS (including a proposed list of products) and ways to improve supply availability. AdvaMed is responding to this request and intends to be actively engaged in this constructive initiative. We are also ready to work with Congress on similar stockpile provisions.

A key issue that must be addressed is financing the stockpile. The SNS is currently funded for five-year periods, with the most recent amount of $1.657 billion for 2022. Both the amount and the funding periods should be carefully examined. Given the relatively (hopefully) infrequent nature of a major health care crisis, such as a pandemic, ten-year funding might be more appropriate. Funding levels should ensure the stockpile is maintained at pre-determined levels, and products are rotated in accordance with industry-recommended shelf-lives and updated to recognize innovative new technologies.

This objective is likely to require an automatic provision for increased funding levels immediately after the emergency has passed in order to rebuild supplies. The U.S. government should award contracts to willing manufacturers to sell designated quantities at pre-fixed, negotiated prices as production of a particular medical device 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. 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.

KEEPING SUPPLY CHAINS RESILIENT

The SNS should be designed to fulfill requirements for critical medical devices during the initial surge in demand, but it cannot continue that role for a lengthy period of time. Production must ramp up, and those supplies have to reach patients in need.

The complexity, resiliency and variety of the medical device and diagnostic supply chains need to be appreciated by policy makers who call for strengthening the supply chains. In addition to stockpiles, the sources of medical technology supplies are domestic manufacturing companies as well as firms in other countries. Both are essential to meeting America's needs.

Two-thirds of all medical technology used in the U.S. is manufactured domestically. The remaining one-third is imported. Our largest source of imported products is the European Union (12.5 percent of overall consumption). Imports from Mexico account for just over five percent of total medical device usage, whereas China accounts for just 3.3 percent. (Please see Annex 2 for more details on the sources of U.S. medical technology.)

The sources of components for medical technology are also widespread, with multiple competitive offerings – mitigating the risk of a shortage by the competitive nature of the market. Medical device 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 most segments of the supply chain. Some models of ventilators, for example, contain upwards of 1,700 parts.

HOW DOES THE N95 MASK VALUE CHAIN WORK?

Design	Test and Gain Approval	Source Inputs	Manufacture	Buy, Allocate, and Distribute
• Need to develop a design that can pass the rigorous testing processes	• Masks must be subjected to testing at the National Personal Protective Technology Laboratory (NPPTL) • Additionally, manufacturing "quality plans" must be submitted	• Outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, third layer of melt-blown polypropylene filter material, layer of spun-bound polypropylene. Outer layer coated with hydrophilic plastic, second inner layer is treated with copper and zinc ions	• Major manufacturers include 3M,Honeywell, Prestige Ameritech, Medicom	• Normally, medical supplies companies have contracts with hospitals and place orders for certain numbers of masks either directly with a (typically overseas) partner factory or an intermediary supplier

Source: Bain & Company

The complexity of the manufacturing process for masks is also instructive. Their production involves several types of inputs and the assembly of different parts in a relatively sophisticated process. The filtering property of masks is a function of a multi-layered structure made of non-woven fabric – most commonly polypropylene, which is "melt-blown" in order to obtain fibers of a small diameter in a random pattern that can trap small particles. The fibers are electrically charged so that particles are attracted while the air passes through ("electret treatment"). N95 respirators have a similar production process, with the filtering enhanced through high-efficiency, melt-blown, electret non-woven material, involving higher-tech machines and increasing production costs. The non-woven fabric has been the main bottleneck in the value chain.

The U.S. is dependent on foreign sources, including China, for certain categories of PPE. For example, China supplies more than half of U.S. imports of surgical masks, protective gowns and protective goggles. The U.S. does not depend on overseas suppliers for N95 masks, as the largest domestic manufacturer has sold 90 percent of its production in the U.S. Malaysia and Thailand account for almost all U.S. surgical gloves, in large part because the resin for these gloves comes from natural rubber trees. However, PPE products, which have a relatively long shelf-life, can easily be stored and alternative sources can be found across the globe.

VARIOUS COMPONENTS ARE NEEDED TO PERFORM EACH TYPE OF COVID-19 DIAGNOSTIC TEST – ISSUES IN ANY OF THESE COMPONENTS COULD LIMIT OVERALL TESTING CAPACITY

Used for	Swabs, blood collection kits, transport media, etc. Used to collect and transport patient samples	Extraction/ processing reagents Used to extract viral RNA from patient sample	Amplification reagents Allow for replication of viral RNA so it can be detected	Biological components Specialized proteins/ molecules used to detect antigens/antibodies	Internal/External controls Materials used to verify the test instrument and reagents are functioning properly	Platforms/Instruments Additional equipment needed (e.g. point-of-care devices, high-throughput machines)
Molecular diagnostics	✓ Swabs and transport media or oral fluid collection	✓	✓		✓	✓
Antigen testing	✓ Swabs and transport media or oral fluid collection			✓	✓	✓
Serology (antibody) testing	✓ Blood and oral fluid collection kits			✓	✓	✓

Platform/instrument not needed for all rapid antigen and serology tests

Diagnostic tests offer a third example – showing that running a test involves not just one product but several, and each element is essential to obtaining a final result. These products include nasal swabs, reagents, controls for testing and platforms/instruments. The supply chains for diagnostics generally rely on specialized suppliers providing the different components to manufacture the final products in a highly complex and closely regulated process. The U.S. is not overly reliant on other countries for these products.

A major source of supply chain disruption has come from governmental interference. Many countries, including the U.S., restricted the export of PPE and/or controlled the allocation of ventilators. Some export restrictions included input for production of masks. For example, Taiwan is a major global supplier of melt-blown fabric, a key ingredient in face mask production. Beginning in mid-March, the Taiwan government began requisitioning melt-blown fabric from the island's factories, resulting in a de-facto export ban and causing global supply chain disruptions. Likewise, India restricted the export of cloth used to manufacture masks.

In addition, when governments ordered lockdowns, they initially did not identify "essential" sectors. This lack of planning caused disruptions of medical device manufacturing facilities and in the movement of personnel. Such disruptions should be avoided in the future.

The World Trade Organization (WTO) could serve as a forum for a plurilateral agreement among willing governments. Such an agreement would open trade further during a global emergency. There would be no additional burdens or requirements imposed on the private sector.

In brief, governments should collaborate to avoid future disruptions by agreeing in advance that they would take specific steps to improve supply chains and reduce costs. Such measures include: (1) prohibiting export restrictions; (2) designating medical device facilities to be "essential" and not threatened with closure; (3) implementing trade facilitation measures to expedite medical supplies through a "fast track" process in customs; (4) immediately suspending all import tariffs on designated medical technologies among the signatory governments; (5) harmonizing specific regulatory procedures – such as the U.S. Emergency Use Authorizations; and (6) providing designated cargo space for medical supplies. The benefits of this agreement could be limited to signatories in a plurilateral undertaking by using the provisions of Article XX of the WTO, which allows for suspension of certain obligations, such as most favored nation status (MFN), to protect health and safety. The penalty for non-compliance in this agreement could be more contractual in nature than the WTO dispute settlement process, perhaps including financial penalties on the governments for failing to keep pre-determined commitments.

In addition, governments should commit to maintaining minimum stockpiles of essential medical technologies to meet immediate demand surges. These stockpiles would provide greater confidence for governments to not impose export

or other restrictions. For lower income countries, willing governments and the private sector could join in a coalition to finance stockpiles for them, including with the WHO.

Instilling greater confidence in supply chains is particularly important now. Government leaders, including in the U.S., are becoming convinced that they cannot rely on overseas sources and are implementing or considering various forms of localization programs – which are neither effective nor efficient to ensure needed supplies. Medical device companies often locate in a region to supply multiple countries in the area. They cannot manufacture in every country. Localization requirements and trade restrictions would inevitably result in some countries receiving some medical supplies some of the time. As a result, global patient access would suffer.

A much more constructive role for the U.S. government would be to focus on opening transportation bottlenecks to ensure medical technology can reach its destination in a timely and cost-effective manner.

Localization also would hurt 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 – with imports and exports each totaling about $55 billion. We have had about the same balance of medtech trade with China, where U.S. imports and exports each total about $6 billion.

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) would likely invite retaliation by some other GPA members. For example, the U.S. exports about $20 billion worth of medical technology to the EU. While not all of these sales were directly to EU Member State governments under the GPA, some portion no doubt was because of the large role governments play in EU health care.

A much more constructive role for the U.S. government would be to focus on opening transportation bottlenecks to ensure medical technology can reach its destination in a timely and cost-effective manner. With passenger traffic ground to a near-halt as a result of the COVID-19 pandemic, the cargo bays of planes have not been as available to move medical supplies, and air transport costs have skyrocketed. Use of military aircraft (such as through Project Airbridge) should be implemented at the start of a pandemic as standard procedure. Recent FAA rules allowing essential cargo in the passenger compartments of planes are appreciated, but broader federal incentives – such as compelling airlines receiving recovery funds to prioritize transport of medical supplies (domestically and internationally) – should be implemented immediately. Such practices should be standard during any health care crisis that limits passenger traffic.

ALLOCATING IN ADVANCE

Potential disruptions in the supply chain described above justify U.S. government planning to allocate essential medical devices in advance. Under normal circumstances, the private sector knows where and how to allocate critical medical technologies. Each company does its own planning. Manufacturers/ distributors know where their supplies are going and the most efficient means of delivering them. Pandemics are extraordinary events, which require government planning for the benefit of the nation.

The Defense Production Act (DPA) grants the President far-reaching powers to purchase supplies, prioritize contracts, direct production, prevent exports, and allocate essential products. When used in collaboration with industry, voluntary arrangements with the U.S. government under the DPA can contribute to efficient allocation, especially by locating critical resources and assigning priorities to "hot spots" and other identified needs as they arise. However, authorities need to recognize that medical device manufacturers operationalized resiliency plans to keep supply chains intact and rapidly built new supply chains to support the new products needed by hospitals and caregivers during such a novel public health threat.

The Administration's proposal for five-year voluntary agreements between FEMA and the private sector would appear to offer the kind of advance planning and public-private collaboration the U.S. needs. According to FEMA's proposed "Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic":

> A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs requiring, pursuant to DPA section 708(c)(1), that an agreement to collectively coordinate, plan and collaborate for the manufacture and distribution of PPE, Pharmaceuticals and other Critical Healthcare Resources is necessary for the national defense. This Agreement will maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, allocation and distribution of Critical Healthcare Resources. The activities included in this Agreement are limited to those necessary to respond to a Pandemic, at the sole determination and direction of FEMA.

AdvaMed, as the industry association, intends to endorse this general approach and seeks to be recognized as a party to the voluntary agreement. This agreement should provide a forum in which to share technical information and advice, identify essential medical technologies, anticipate future needs and allocation practices. We believe a collaborative mechanism allowing government and interested stakeholders to devise in advance the most efficient method of allocating essential medical technologies is far superior to DPA mandates after the health care crisis is underway. The agreement also envisages the participation of manufacturers and distributors. AdvaMed members are in the process of examining the details of this agreement and look forward to in-depth consultations with FEMA. We are ready to examine other possible short-term measures too.

INVESTING IN AMERICA

Reliance on public-private partnerships should be the model for longer-term measures to prepare for future pandemics. The DPA cannot "manufacture" essential medical technologies, as some have proposed, if the capacity does not exist – even with innovative techniques from non-traditional sources. Companies' decisions on where to locate or expand capacity consider a range of factors and are made, in part, to create supply chain resiliency. The right investment incentives can grow U.S. manufacturing and create more good-paying jobs.

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. Medical technology 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 medical device companies located in the U.S. to offset the costs of recruiting and training the skilled workforce they need.

America should invest in R&D. The medical technology industry is already among the most intensive users of R&D to create technologies that usually rely on incremental innovation.

To fuel that innovation, the medical device industry is research intensive. U.S. medical technology firms spend over twice the U.S. average on research and development. Medical device 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. medical technology 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. 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.

CONCLUSION

Let's prepare for the next phase of this pandemic and beyond by planning now. AdvaMed and its member companies are committed to working with Congress and the Administration to ensure the continued supply of essential medical supplies while continuing to look for ways to engage outside industries in the production of essential medical devices and diagnostic tests. As we look to the next phase of the pandemic, where reopening will require vast infrastructure and investment for testing, vaccines (needles/syringes), PPE and hospital infrastructure, we are eager to look at solutions that will support this effort.

Our industry will continue to support our nation's response to the pandemic through increased production of needed products, and coordination with public health authorities and other government agencies. As policymakers evaluate new laws, we encourage them to preserve this vibrant domestic manufacturing sector, and the robust and resilient supply chains that enable this sector to support and protect American frontline healthcare workers. We stand ready to engage with policymakers on steps aimed at accomplishing this important goal.

ANNEX 1

EXAMPLES OF THE MEDICAL DEVICE INDUSTRY RAMPING-UP PRODUCTION

Diagnostic tests

Within weeks, in vitro diagnostic test manufacturers received FDA emergency use authorizations for over 60 commercial tests for COVID-19, just since the first EUA was issued March 12.

Diagnostics manufacturers made and shipped over 32 million molecular diagnostic tests in April and an estimated 39 million-plus molecular tests in May.

Ventilators

By April, AdvaMed members had rapidly scaled manufacturing and increased production by over 300%—going from 700 ventilators per week before COVID-19 to nearly 3,000. By the second quarter of 2020, members were able to manufacture 5,000-7,000 ventilators per week.

AdvaMed has also worked with the private sector to boost the supply of ventilators and critical component parts. Thousands of additional ventilators will be produced by our partners in the automotive and aerospace industries in the coming weeks.

AdvaMed, in partnership with Google and the Aerospace Industries Association, stood up VentConnect – an online portal to connect ventilator companies with component suppliers to help quickly scale production and distribution of these vital devices.

Personal Protective Equipment (PPE)

Our companies built into their business models the potential for "surge capacity." As a result, one AdvaMed member company's worldwide production of N95 masks doubled to 1.1 billion annually, or nearly 100 million per month —almost overnight; this includes 35 million per month in the U.S., with plans to boost production for the domestic market 40% more to 50 million per month for June. By comparison, the company makes only about 14 million masks per month in China and less in Korea.

Another member company developed a process to decontaminate N95 masks up to 10 times using its sterilizers, which were already in many hospitals and other facilities. If fully utilized, that could translate to 750,000 masks per day being decontaminated for re-use across the country, extending the lifespan of these critical supplies. FDA recently issued another EUA to the same company that could provide an additional 30 million masks per day with steam sterilizers that are already in hospitals and other facilities.

Hospital Infrastructure

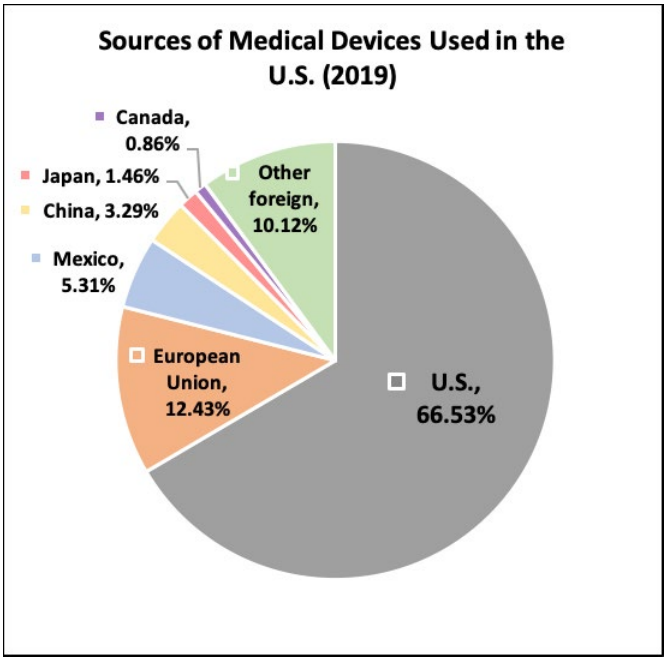
To support the surge of COVID-19 patients, the MedTech industry mobilized to support a necessary expansion of the health care infrastructure. One AdvaMed member company innovated at a very fast pace to go from concept to launch in seven days to bring a new hospital bed to the market by March 27, early in the national response. The company built a new vertically integrated supply chain, acquiring enough steel from suppliers in the United States and Canada to reach from New York City to Dallas and manufactured these beds in the United States. This project demonstrates the agility of this industry to address a critical need and its domestic manufacturing capabilities.

ANNEX 2

KEY DATA POINTS REGARDING AMERICA'S DEPENDENCE ON FOREIGN SOURCES FOR MEDICAL DEVICES AND DIAGNOSTICS

2.1 The U.S. Medical Device Market: Limited Import Penetration

Two-thirds of medical devices consumed in the United States are manufactured domestically; the remaining one-third is imported.



Sources: Annual Survey of Manufacturers (Census), U.S. Customs trade data, Fitch Data Solutions

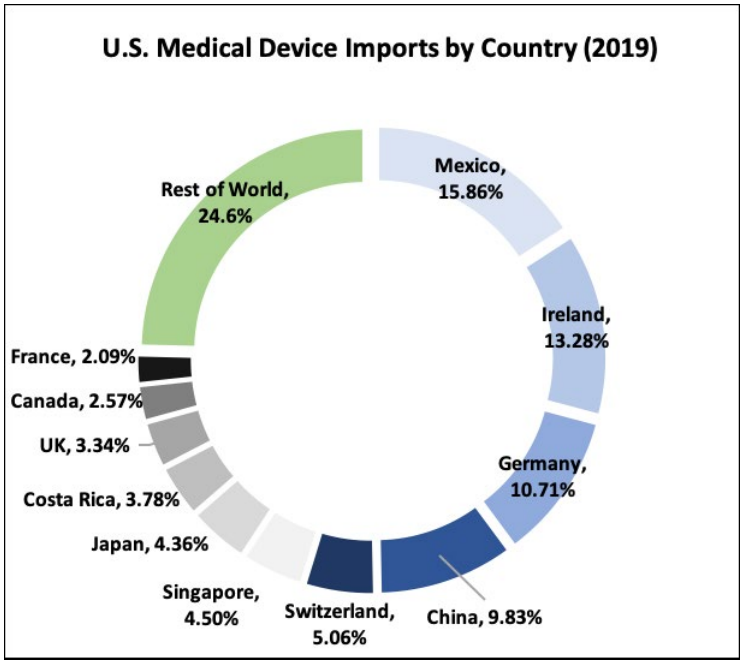
Just 3.3% of the medical devices used within the United States are sourced from China.

Sources of Finished Medical Devices Consumed within the U.S. (2019)		
Country	**Value**	**% share of U.S. market**
U.S.	$ 121,557,752,703	66.53%
European Union	$ 22,712,173,513	12.43%
Mexico	$ 9,699,602,334	5.31%
China	$ 6,009,590,382	3.29%
Japan	$ 2,668,777,897	1.46%
Canada	$ 1,574,671,795	0.86%
Other foreign	$ 18,492,782,195	10.12%

Sources: Annual Survey of Manufacturers (Census), U.S. Customs trade data, Fitch Data Solutions

2.2 U.S. Medical Device Imports: Diverse Suppliers

Imports account for only one-third of the medical devices used within the United States. Mexico is the largest supplier, but only accounts for 16% of imports. China accounts for less than 10% of the imports.



Sources: U.S. Customs trade data, Fitch Data Solutions

Medical device imports from Mexico and China span a broad range of products. Half of the imports from Ireland are artificial joints.

Sources of U.S. Medical Device Imports (2019)			
Country	**Import Value**	**% Share**	**Top Product Categories**
Mexico	$ 9,699,602,334	15.86%	Catheters and syringes; a wide variety of electrical-surgical instruments
Ireland	$ 8,119,458,111	13.28%	Hip and knee implants
Germany	$ 6,550,259,552	10.71%	MRI machines and CT scanners; electrical-surgical instruments
China	$ 6,009,590,382	9.83%	Patient aids such as hearing aids and wheelchairs; otherwise imports are diversified
Switzerland	$ 3,092,468,860	5.06%	Orthopedic implants
Singapore	$ 2,754,623,640	4.50%	Ventilators; diagnostic reagents
Japan	$ 2,668,768,858	4.36%	Physical examination equipment
Costa Rica	$ 2,308,939,194	3.78%	Catheters, drains, and bougies

Source: U.S. Customs trade data

2.3 Selected Imports Related to the COVID-19 Response

Imports account for one-third of the medical devices used within the United States. Mexico is the largest supplier, but only accounts for 16% of imports. China accounts for 10% of the imports.

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			

Source: U.S. International Trade Commission

What about face masks?

A U.S. International Trade Commission report states that the 10-digit HTS code covering face masks (both surgical and N95) is highly aggregated, covering a wide array of miscellaneous paper products. Accordingly, precise import data for face masks is extremely difficult to obtain.

China is estimated to have produced 50% of the world's supply of surgical face masks in 2019. Prior to the pandemic, U.S. output of N95 masks was greater than China's output and that remains the case today.