

DECEMBER 2020

Covid-19 Demand Shock and Preparedness Response

Securing Medical Supply Chains: The Trusted Trade Partner Network

By Meredith Broadbent

Executive Summary

As the U.S. economy restarts and retools after the forced shutdown induced by the Covid-19 pandemic, there is a strong drive in Congress and the executive branch to improve the resilience of medical supply chains. The Covid-19 pandemic caused an unprecedented demand for certain medical goods, including pharmaceuticals, personal protective equipment, and medical devices. Manufacturers in the medical supply sector, the U.S. government, and foreign governments are likely to embrace new policies aimed at readjusting global supply chains to address vulnerabilities that have come to light.

These changing circumstances present a new opportunity for the United States to reinvigorate trade relations with allies, free trade agreement partners, and trusted supplier countries. However, the newfound attention on medical supply chain resiliency has created dangerous momentum for a policy focused on reshoring supply chains. Policymakers should instead opt for an approach that builds resiliency through diversification, trust, and communication.

Just as the pandemic experience revealed vulnerabilities in global supply chains, it also proved that no single country can produce all that it needs to fight Covid-19, let alone cure it. Over the course of the pandemic, international cooperation and global supply chains delivered lifesaving goods and enabled inventive responses to new challenges. The paper describes how a few key supply chains operated during the pandemic. Experience and economic reality suggest that the path to more resilient and secure medical supply chains is through rational diversification, flexibility, and closer cooperation with trusted partners, not protectionism and government directives to make everything at home.

We recommend that Congress enact legislation stating that it is the policy of the United States to offer countries willing to become trusted supply partners through the reciprocal reduction of trade, investment, and regulatory barriers: 1) enhanced commercial ties grounded in a new network of trusted partner countries and 2) a commitment to coordinate and offer reciprocal support to trusted partner countries during emergencies. This would include commitments to avoid new trade restrictions. Trusted supplier partners would keep general medical supply lines open and work together to provide vaccines, therapies, and medical supplies during disruptions caused by a pandemic or another emergency. The United States should also consider public-private cooperative understandings and other initiatives to encourage research and development (R&D) on pharmaceuticals, medical devices, and advanced manufacturing processes among trusted partners.

The structure of the trusted partner network proposed here is designed to be flexible in order to accommodate the new administration's trade priorities, as developed with Congress. Much will depend on the receptivity of candidate countries and their priorities, as developed through their own domestic consultations and political processes. We suggest Congress should authorize the Office of the U.S. Trade Representative (USTR) to negotiate a reciprocal "Trusted Partner Network." As an alternative, Congress could authorize the USTR to set up a unilateral program by designating countries meeting certain criteria as eligible for trusted supplier status. The paper further proposes "criteria" the USTR could take into account to identify eligible trade partners. These criteria include willingness to cooperate on supply chain visibility and traditional trade issues such as regulatory cooperation, market access, intellectual property protection, and trade facilitation. Eligible partners would exemplify "trust and reliability" and commit to reciprocal support and supply chain security in crises.

Current Laws and Regulation

Current policies to identify and address medical supply chain vulnerabilities are unclear and disorganized, with several separate efforts ongoing in law and regulation.

THE AUGUST EXECUTIVE ORDER

On August 6, 2020, amid increased calls for reshoring and locating the production of essential medical products in the United States, President Donald Trump issued an **Executive Order** requiring the federal government to purchase “essential” drugs and other related products solely from U.S. manufacturers rather than from overseas companies, particularly those in China. The Executive Order tasked the Food and Drug Administration (FDA) with compiling a list of which essential medicines, medical countermeasures, and their critical components would be covered within the scope of the Executive Order. The list, which the FDA **published** on October 30, 2020, identifies 96 types of medical countermeasure devices, including diagnostic testing kits, personal protective equipment (PPE), vital-sign monitoring devices, vaccine delivery devices, ventilators, and other devices for managing acute illnesses. In addition, the FDA **identified** 227 drug and biological products as essential medicines that it anticipates “will be needed to respond to future pandemics, epidemics, and chemical, biological and radiological/nuclear threats.”

Currently, pursuant to U.S. commitments under the Government Procurement Agreement (GPA) in the World Trade Organization (WTO) and in free trade agreements (FTAs), these procurements must be made available to GPA and FTA trade agreement partners. Under the Executive Order, the USTR is required to “take all appropriate action” to remove the list of essential medicines and related products from these commitments to allow for free competition for procurements on a non-discriminatory, national treatment basis. The USTR has notified the WTO and the United States’ FTA partners that it intends to renegotiate these commitments, a process that is expected to take at least several months. This move will likely be met with demands for compensation and possibly the withdrawal of equivalent product coverage by other GPA parties and FTA partners who purchase from U.S. suppliers. If negotiations are not successful, the USTR can be expected to take the actions mandated under the Executive Order pursuant the national emergency exception contained in Article III of the GPA.

The Executive Order preserves the general waiver requirements present in current law, including exceptions justified by national interest or non-availability, as well as slightly different exceptions, for items required to respond to a public health emergency. It also authorizes agency officials to waive Buy America procurement requirements if applying them would raise the cost of a procurement by more than 25 percent. This is higher than the previous differential of 6-12 percent. In effect, the United States will treat all procurements of essential medicines, medical countermeasures, and critical inputs from parties to the GPA and U.S. FTAs the same as procurements of such products from non-GPA and non-FTA parties.

INTERNATIONAL TRADE COMMISSION ANALYSIS OF TRADE AND PRODUCTION

At the direction of Congress in December, 2020, the U.S. International Trade Commission (ITC) will complete an investigation of U.S. industrial sectors producing Covid-19–related goods—including manufacturers of raw materials and intermediate and finished medical devices, pharmaceuticals, PPE, and diagnostic products—and describe these sectors’ employment, production, and import and export patterns. The research will identify where shortages were reported during the pandemic and assess what caused supply chains to break down, such as factory shutdowns, reliance on single suppliers for inputs, and logistics tie-ups. The ITC will also consider regulatory requirements that may affect entry and exit from certain markets. In anticipation of possible bottlenecks in the delivery of vaccines, the research may also assess the ability of producers in the U.S. market to manufacture and distribute a vaccine or vaccines once available.

OTHER STATUTES AND LEGISLATION

The Coronavirus Aid, Relief, and Economic Security (**CARES Act**), signed on March 27, 2020, mandates gathering three new types of information to ensure medical supply chain security. First, it requires drug manufacturers to report to the FDA on the volume of drugs and active pharmaceutical ingredients (APIs) they sell. (For now, the FDA has delayed enforcing this requirement.)

Second, it instructs the Department of Health and Human Services (HHS) to form an agreement with the National Academies of Science, Engineering, and Medicine (NASEM) and jointly write a report on the security of the U.S. medical product supply chain. The NASEM report will assess critical drug supply chains, potential security risks associated with reliance on critical drugs and devices sourced outside the United States, supply chain information gaps, and the economic effects of increased domestic manufacturing. The report will also provide recommendations for how to make medical supply chains more resilient and address vulnerabilities of products whose disruption would lead to massive public health risks.

Finally, the CARES Act also grants the FDA the authority to require drug manufacturers to report any large supply chain disruptions for drugs and devices needed in public health emergencies.

In addition, the pending National Defense Authorization Act of 2021 (NDAA)—for which a conference report was released on December 3—would issue related directives to the administration. Section 713 of the **conference report** stipulates that the section of the National Security Strategy regarding the National Technology and Industrial Base (NTIB) shall include guidelines for providing the drugs, biologics, vaccines, and critical supplies required to enable combat readiness and protect the health of the armed forces.

Recent Supply Chain Trends

According to the **McKinsey Global Institute (MGI)**, over the past 20 years, global pharmaceutical value chains have become more far-flung and globally dispersed. Advanced economies such as those of the United States, Germany, Switzerland, and Ireland tend to dominate the production of intermediate ingredients and dosage-ready drugs. Accounting for 30 percent of pharmaceutical exports by value, these products tend to be under patent and command higher prices. Many small-molecule products that are no longer under patent have shifted to lower-cost production locations such as China, India, and Singapore. “While China and India export a relatively small share (3 percent each) of pharmaceutical products by value, they are the world’s key producers of APIs and small-molecule drugs. In some categories, such as antibiotics, sedatives, ibuprofen, and acetaminophen, China is the world’s dominant producer.” Overall, China accounts for 40 percent of global API **production**, but external factors are shifting production in both China and India. Reliable statistics are not publicly available on whether China and India are key producers of API for the U.S. market.

The leading global manufacturer of generic drugs, exports from India account for about 20 percent of global exports by volume. India, however, sources most of the APIs used in pharmaceutical production from China. MGI observes that “when the flow of these ingredients from China was restricted in the early stages of the Covid-19 pandemic, India temporarily placed export controls on dozens of essential drugs, including antibiotics.”

Are Value Chains Shifting?

Global pharmaceutical **value chains** are among the largest (by shares of total exports) that could potentially be relocated. According to MGI, the probability of relocating due to economic factors is small: in recent years, low wages have become less important in determining where companies choose to locate

production, and “only 13 percent of overall goods trade in 2018 involved exports from a low-wage country to a high-wage country.” More relevant in most industries are regulation, intellectual property protection, access to a skilled workforce, infrastructure, tax policy, the ability to tap into a free trade agreement network, and other factors that impact the business and regulatory environment. However, non-economic factors may encourage reshoring as many governments evaluate whether they should pursue policies to boost domestic production of certain medicines and medical equipment for reasons of national security, competitiveness, or self-sufficiency.

MGI observes that trade flows are becoming more regionalized within Asia, Europe, and North America. Some multinational companies, in order to find a balance between cost, speed, coordination, and resilience, are deciding to nearshore production. **MGI estimates** “that 38 to 60 percent of the pharmaceutical value chain could shift geographically in the coming years. However, production of small-molecule drugs would likely need to be highly digitized and automated to be viable in advanced economies; otherwise, the higher cost of doing business might lead to higher drug prices.”

Increased Threat of Disruptions and Movement toward Resiliency

While complex global production networks were developed for efficiency, cost, and proximity to markets, the increased frequency of production disruptions threatens supply chain resiliency. According to MGI, “companies can now **expect** supply chain disruptions lasting a month or longer to occur every 3.7 years, and the most severe events exact huge financial costs.” Pharmaceuticals, as well as medical devices, are among the least exposed to supply chain shocks relative to other industries, although these industries are not immune to shocks. Geographic and capacity bottlenecks present risks, as the industry footprint has become increasingly global in recent decades.

Overall, research indicates that U.S. pharmaceutical companies are focused on improving supply chain resiliency in this disrupted and uncertain environment¹. Industry experts are observing companies conducting more detailed mapping of their tiers of suppliers and improving transparency through more coordination and communication. Companies are building more redundancy into supply networks by diversifying suppliers and storing more inventory—as well as placing more priority on maintaining their ability to reroute inputs and establish flexible production across sites and on developing robust digital systems and analytics to run scenarios based on different contingencies.

Historically, companies developed risk management policies based on shocks stemming from cybersecurity and, more recently, trade disputes. However, anecdotal evidence indicates that many companies are reevaluating their production networks as they seek to improve resiliency to unanticipated shocks. In an MGI survey of supply chain executives conducted in May 2020, “an overwhelming **93 percent** reported that they plan to take steps to make their supply chains more resilient, including building in redundancy across suppliers, nearshoring, reducing the number of unique parts, and regionalizing their supply chains” closer to consumers.

MGI estimates that production of 16–26 percent of global trade, worth between \$2.9 and \$4.6 trillion, might relocate across borders in the medium term. MGI speculates this **trend** could reflect some combination of “reverting to domestic production, nearshoring, and shifting to different offshore locations.”

1. According to MGI’s study on *Risk, resilience, and rebalancing in global value chains*, “Firms are putting new emphasis on supply chain risk management and improved end-to-end transparency through enhanced use of digital technologies aimed at connecting entire value chains with a seamless flow of data.”

A Gartner [survey](#) of supply chain leaders conducted in February and March found that companies, particularly those in the pharmaceutical sector, view improving supply chain resiliency as a priority. It found that 55 percent of respondents expected their company’s supply chains to become “highly resilient”—defined as having relatively transparent supply networks, a willingness to invest in flexibility and resiliency, and the ability to shift sourcing, manufacturing, and distribution within a production network—over the next two to three years. Although only 21 percent of respondents considered their supply chains to be “highly resilient” at the time of the survey, one-quarter of respondents said they have already begun to [regionalize](#) or localize supply chains to dampen disruptions and be closer to demand.

Research from the Organization for Economic Cooperation and Development (OECD), however, [confirms](#) that countries, which reduce interconnectedness via global value chains would experience neither improved resiliency nor efficiency of supply. Simulations run by the OECD find that localization of supply chains reduces GDP and would slow the post-Covid-19 economic recovery. Not to be confused with maintaining global value chains and reorienting them toward trusted partners, the OECD localization model is more in line with attempts at wholesale reshoring and assumes a global rise in tariffs and subsidies, among other restrictions.² No one country can produce all that it needs—whether to respond to a pandemic or in general. Some level of trade is inevitable. Given that, as countries pull back from global supply chains, they will become more vulnerable to shocks—such as a pandemic induced demand shock—due to lack of diversification and the inability to tap into a global network of suppliers and producers.

“More localization also means more reliance on fewer sources of—and often more expensive—inputs. In this regime, when a disruption occurs somewhere in the supply chain, it is harder, and more costly, to find ready substitutes, giving rise to greater risk of insecurity in supply.”

— **“SHOCKS, RISKS AND GLOBAL VALUE CHAINS IN A COVID-19 WORLD,”** BY FRANK VAN TONGEREN, OECD TRADE AND AGRICULTURE DIRECTORATE IMPACT OF TECHNOLOGY ON GLOBAL VALUE CHAINS

Technological progress is affecting global value chains in two main ways: 1) increased automation in manufacturing production and 2) new supply chain management processes that incorporate innovations in digital technology, including the Internet of Things (IoT), big data, and cloud computing.

According to the WTO, anecdotal [evidence](#) suggests that increased automation could result in reshoring labor-intensive manufacturing activities back to high-income countries. Two recent examples illustrate this trend. Adidas, a footwear and sports apparel company, has based [“speed factories”](#) in Ansbach, Germany, and Atlanta, Georgia, which will employ a combination of computerized knitting, 3D printing, and robotic cutting, to produce athletic footwear. A [report](#) by Citigroup and the University of Oxford’s Martin School “found that 70 percent of Citigroup institutional clients surveyed believe that automation will encourage companies to move their manufacturing process closer to home.” China’s economy has

2. As [described](#) by the OECD, “The localised -‘turning inward’- regime reflects a situation where GVCs are shortened, through a global rise in import tariffs to 25%. This is combined with national value-added subsidies equivalent to 1 % of GDP on labour and capital, directed to domestic non-services sectors to mimic rescue subsidies that favour local production. It is also assumed that, in the localised regime, firms are more constrained in switching between different sources of products they use, making international supply chains more rigid.” In addition, the model assumes a reduction of labor supply, a reduction in demand for products from certain sectors, and increased trade costs in part driven by reinforced border controls, new border protocols, and regulatory restrictions on the movement of people.

also seen rapid automation of production, especially as it turns to robotization to address declining wage competitiveness. Foxconn, which produces Apple and Samsung products in China's Jiangsu province, recently **replaced** 60,000 factory workers with industrial robots.

New supply chain technologies and investment in strong digital strategies are transforming supply chain management³. However, it is still unclear whether new digital technologies will reduce the length of supply chains through increased reshoring of manufacturing production—or whether firms will employ technology to support far-flung global supply chains by reducing the costs of tracking and monitoring the components of production, lowering coordination costs across large distances.

Government's Role in Improving Supply Chain Resilience

The OECD maintains that governments can aid in **improving resilience** by “collecting and sharing information on potential concentration and bottlenecks upstream, by developing stress tests for essential supply chains and by creating a conducive regulatory environment which is not a source of additional, policy-related, uncertainty.” However, it cautions that “if governments pursue a supply chain nationalization strategy, the interventions should be transparent, targeted and take fully into account associated costs, trade-offs and risks.” As previously mentioned, the OECD has found that localization undermines both efficiency or resiliency. Additional recommendations from the OECD **include** “the combination of strategic stocks; upstream agreements with companies for rapid conversion of assembly lines during crises and supportive international trade measures.” The WTO likewise warns that conventional reshoring policy tools, such as local content requirements and investment restrictions, often introduce economic distortions that lead to less competitive companies, additional waves of protectionism, and income and welfare loss.

A **working paper** by the National Bureau of Economic Research supports the observation that GDP contractions amid Covid-19 shutdowns would have been worse if global value chains were reshored because government lockdowns also affected the supply of domestic inputs. As we discuss below, there appears to be no evidence that domestic supply chains performed better than international supply chains in terms of security of supply. Our view is that extensive reshoring and nationalization policies would present many costs and added risks. Several case studies support this conclusion.

Case Studies: Global Pharmaceutical Supply Chains, Resiliency, and Vulnerability

U.S.–CANADA COOPERATION AS A FORMULA FOR THE FUTURE

Cooperation between the United States and Canada in response to the Covid-19 outbreak confirms the benefits of maintaining supply chains and other linkages with trusted partners and allies. Canada's membership in the North Atlantic Treaty Organization (NATO) and the North American Aerospace Defense Command (NORAD); its participation in the United States–Mexico–Canada Agreement (USMCA) and longstanding, deep trade relationship with the United States; and its role as an important supplier of many Covid-19–related products sets Canada apart from other U.S. trading partners. Canada's trusted position as a national security and economic partner was reflected in the U.S. Federal Emergency Management Agency's (FEMA) **decision** to exempt Canada from export restrictions on PPE in spring 2020.

3. According to a 2016 PwC survey cited by the World Bank, “a third of the more than 2,000 respondents say their companies have started to digitize their supply chains, and fully 72 percent expect to have done so five years from now.”

The strong U.S.–Canada relationship enhances the ability of both countries to meet challenges Covid-19 in three ways:

1. **Regulatory flexibility and cooperation** between U.S. and Canadian health and safety regulators that accelerate the authorization and use of drugs, disinfectants, and PPE used to fight Covid-19 in both countries.
2. **Improving the North American medical industrial base** through government policies that encourage new investment in domestic PPE and medical supply manufacturing and avoid imposing export restrictions on each other.
3. **Research and development cooperation on new drugs** companies that have a presence in both the United States and Canada.

Each area of cooperation has led to an outcome superior to what either country could have achieved on its own. A history of regulatory cooperation between the United States and Canada **contributed** to Health Canada expediting the review and authorizing the use of U.S. remdesivir (as it was labeled during clinical trials) for the treatment of patients with severe Covid-19 symptoms. Information the FDA exchanged with Health Canada led Canada to adopt measures to improve market access for hand sanitizers and hard-surface disinfectants. In the United States, the National Institute for Occupational Safety and Health **prioritized** applications from Canadian manufacturers for its Respirator Approval Program. Similarly, the history of U.S.–EU regulatory cooperation, in part driven by Mutual Recognition Agreements (MRAs) in the pharmaceutical sector, set the foundation for cooperation during the pandemic on vaccines and therapeutics.

Low trade barriers between the United States and Canada, their mutual exemption from PPE export restrictions, and increased domestic production of Covid-19–related products provided patients and hospitals in both countries with predictable and quality options for where to source critical supplies. While some domestic political interests in both countries pushed for export restrictions, the autarkic approach was ultimately rejected. At the same time, many markets around the world did impose export restrictions, making manufacturing environments and sourcing outside of North America more uncertain. Open supply chains between Canada and the United States prove there is a way to maintain sufficient and predictable access to critical products during emergency-induced demand shocks without pursuing the unachievable goal of reshoring production of all essential medical products.

The United States was able to increase imports of a range of critical medical goods from Canada in 2020. Imports from Canada of both tetracyclines—drugs used to fight Covid-19—and prophylactics affecting the eyes, ears, or respiratory system grew by over 250 percent and 300 percent, respectively, in the first nine months of 2020 compared to the same period in 2019. Imports of disinfectants, subject to a significant demand shock in the spring, grew by over 90 percent. Non-medical grade disposable glove imports grew by 1000 to 4500 percent, depending on the material. Imports of PPE garments skyrocketed. Medical equipment imports also grew significantly: Laboratory sterilizer imports grew by over 200 percent, syringe parts imports grew by over 190 percent, and clinical thermometer imports rose by over 1300 percent.⁴

The United States also supplied Canada with additional medical supplies over the course of the year. U.S. exports of combination antibiotics to Canada rose by over 650 percent in the first nine months of 2020 compared to the

4. HS codes for products by order of appearance: 3004.20.0030, 3004.49.0060, 3808.94.5000, 3926.20.1020, 4015.19.1010, 6210.10.5000, 6210.10.9040, 8419.20.0020, 9018.31.0090, 9025.19.8040.

same period in 2019. Medical-grade glove exports rose by over 200 percent. U.S. exports of patient-monitoring systems to Canada grew by 85 percent, and hospital bed exports were up nearly 200 percent.⁵

Cooperation between the United States and Canada on R&D has the potential to lead to breakthroughs in the fight against Covid-19 and other diseases. Canada is one of the preferred locations for U.S. pharmaceutical and biotechnology companies to conduct clinical trials. U.S. and Canadian biotech companies and universities have taken advantage of government funds to work together on diagnostic tools and vaccines. AbCellera (headquartered in Canada) and Eli Lilly (headquartered in the United States) have developed an **antibody** treatment currently in clinical trials in the United States and which has received **support** from the National Institutes of Health (NIH) through its Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and Operation Warp Speed initiatives.

The United States' and Canada's shared reliance on foreign manufacturers for critical medical supplies is one of the reasons the two countries are expanding the partnership rather than pursuing new policies of autarkic self-sufficiency. Increased domestic capacity in the United States and Canada can serve both markets, which ultimately strengthens the U.S.-Canada medical-industrial base and improves supply chain resiliency. The trust between the two countries, their regulators' longstanding cooperation, and the private sector expertise that operates comfortably across borders make possible lifesaving breakthroughs and innovations that each country could not achieve on its own. The economic and national security foundation of the U.S.-Canada relationship enabled a deeper level of cooperation and partnership in response to the Covid-19 pandemic and offers a formula for the United States to consider using again in the future.

GLOBAL SUPPLY CHAINS IN GILEAD'S PRODUCTION OF VEKLURY (REMDESIVIR)

In the final days of January 2020—within weeks of learning of the Covid-19 threat—Gilead CEO Daniel O'Day **initiated** a task force to investigate the mass production of Veklury (formerly remdesivir). In animal models, remdesivir had previously demonstrated both in vitro and in vivo antiviral activity against multiple emerging viral pathogens, including Ebola, Marburg hemorrhagic fever, and coronaviruses such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). There is **robust evidence** from three clinical trials that Veklury (remdesivir) shortens the time it takes to recover from Covid-19 infection. The drug has been in high demand in many markets to treat hospitalized patients during the pandemic. On October 22, the FDA **granted full regulatory approval for Veklury (remdesivir)**, making it the first FDA-approved treatment for Covid-19 in the United States—and the only one until the Pfizer-BioNTech vaccine was approved on December 11, 2020. Veklury (remdesivir) is also approved or authorized for temporary use to treat patients in about 50 other countries and territories, including Australia, Canada, EU member states, Hong Kong, India, Israel, Japan, Singapore, South Korea, Taiwan, and the United Arab Emirates.

In January 2020, when Gilead leadership decided to ramp up remdesivir supply chains and production, the company held only small supplies of the drug in Switzerland, Canada, and California. Gilead estimated that manufacturing remdesivir at scale would take 9–12 months, given that the drug's production is particularly complex due to its reliance on scarce raw materials, which take time to procure, produce, and ultimately convert to APIs. Furthermore, because the drug is administered intravenously, the pharmaceutical powder must be preserved in specific conditions to ensure its efficacy. It must be dissolved in a solution then packaged in sterile vials for storage and transport. Both steps introduce additional variables to the supply chain process and, therefore, potential disruptions.

5. HS codes for products by order of appearance: 3004.10.5060, 3926.20.1010, 9018.19.5500, 9402.90.0010.

Since January, Gilead has succeeded in reducing the end-to-end manufacturing time of Veklury (remdesivir) to 6–8 months. In February, Gilead’s manufacturing team was able to prepare its La Verne, CA site—which boasts state-of-the-art equipment and automation—to **quickly pivot to remdesivir manufacturing**. In August, Gilead **announced** that it had “expanded its global network of both internal manufacturing sites and external organizations, including partnering with industry peers, to add manufacturing capacity around the world.” It grew its network to include more than **40 companies** in countries in North America, Europe, and Asia. This includes Pfizer, which agreed to team up with Gilead to produce Veklury at the former’s facility in **McPherson, KS**.

To further its global production capabilities, Gilead signed voluntary licensing agreements and completed technology transfers with nine generic pharmaceutical manufacturers in India, Pakistan, and Egypt. These partnerships aimed to globalize the remdesivir supply and bring the generic drug to 127 mostly low-income and lower-middle-income countries. They also provide greater resiliency to Gilead’s production capacity as the pandemic continues to rage unevenly around the world.

In early January, Gilead’s inventory of remdesivir totaled approximately 5,000 treatment courses. Today, as a result of early investments to scale up manufacturing, Gilead’s supply of Veklury **is meeting not just real-time demand** in the United States but also global supply needs. Gilead also **announced** it had signed a joint procurement agreement with the European Commission to ensure access to Veklury in Europe over the next six months, noting that it “is on track to produce more than two million treatment courses by the end of the year and several million in 2021,” if required.

PFIZER’S COVID-19 VACCINE CANDIDATE

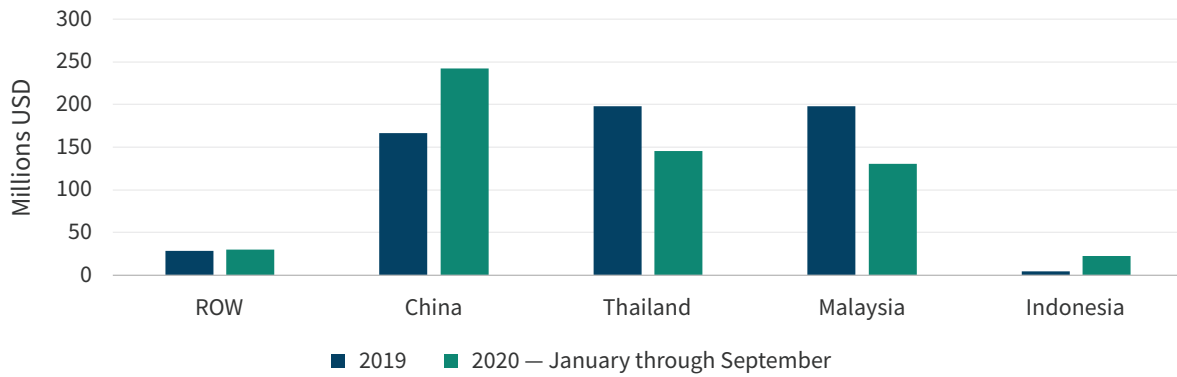
Shortly after the Covid-19 pandemic emerged, Pfizer entered into a partnership with BioNTech, a German biotechnology firm, which succeeded, through transatlantic scientific and commercial collaboration, in developing a successful Covid-19 vaccine candidate. As a global vaccine producer, Pfizer’s ability to leverage multiple sites in the United States to quickly scale, manufacture, and distribute large quantities of a Covid-19 vaccine has been critical. With respect to the United States, Pfizer employed its broad U.S. manufacturing network, including thousands of skilled U.S. workers in multiple states (e.g., Missouri, Massachusetts, and Michigan) and Europe to produce the Covid-19 vaccine candidate for the U.S. market and for patients around the world. In addition, a key aspect of the project has involved putting two parallel supply chains in place—one in the United States and one in **Europe**—to ensure that the company’s efforts could scale and have the appropriate redundancies to reduce risk.

PPE SUPPLY CHAINS

Supply chains for personal protective equipment (PPE) have been unable to keep up with demand over the course of the pandemic, magnifying the public health crisis. As the Strategic National Stockpile’s (SNS) PPE supply was exhausted, states, firms, and hospitals competed against each other in a procurement free-for-all. Counterfeit manufacturers took advantage of the situation and began to peddle ineffective PPE to desperate suitors. PPE export restrictions imposed by governments around the world contributed to shortages. As the pandemic accelerated, the United States quickly realized that it relied on only a few countries for most of its PPE imports; for many PPE products, China is the single largest supplier to the United States. This led to supply chain vulnerabilities that have since drawn the attention of Congress and the Trump administration. It should be kept in mind that the collection of trade statistics for certain medical products will be more granular and reliable in the future due to adjustments made as a result of heightened interest in trade in these goods.

Medical Gloves Imports

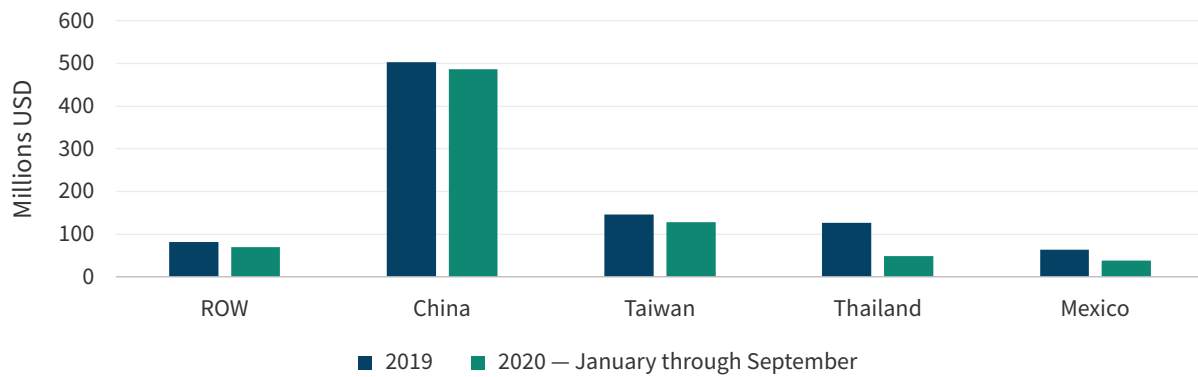
HS Codes: 3926.20.1010, 3926.20.4000, 3926.20.5000, 401511



Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

Medical Goggles Imports

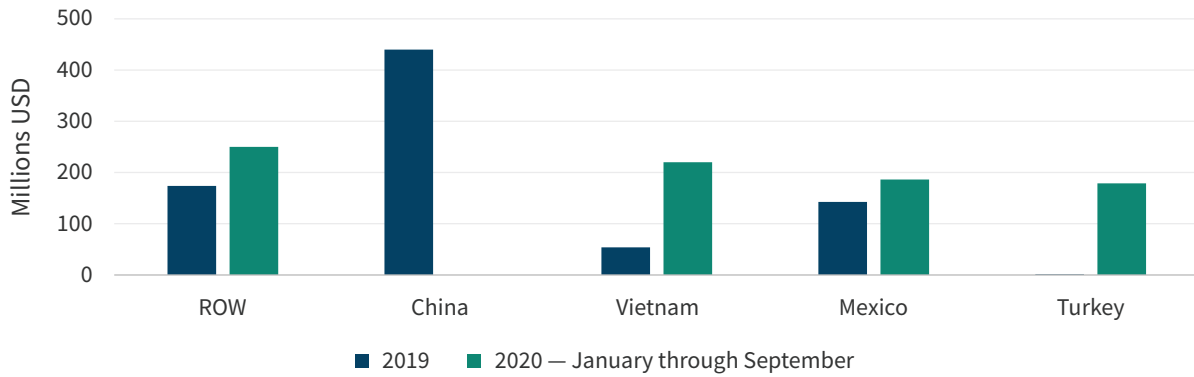
HS Code: 900490



Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

Protective Garments Imports

HS Codes: 3926.20.5000, 621010

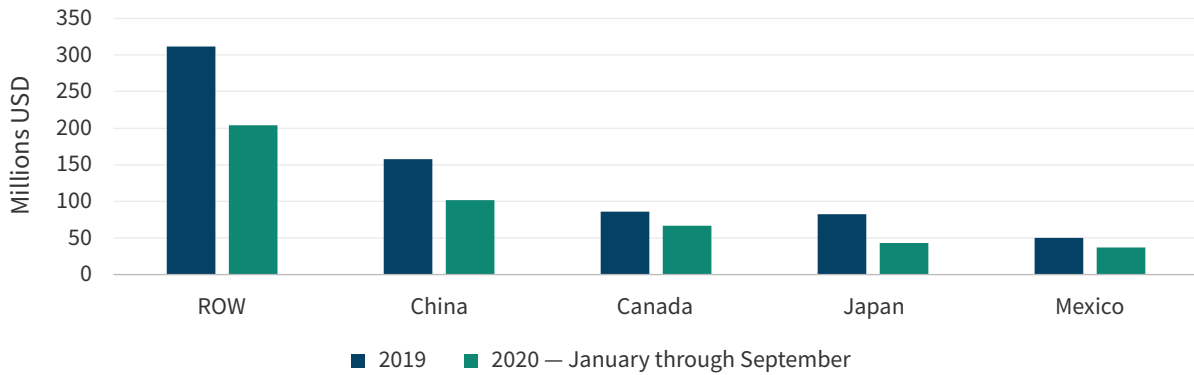


Note: Turkey data unavailable for 2019 and China data unavailable for 2020.

Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

Medical Shoe Covers Imports

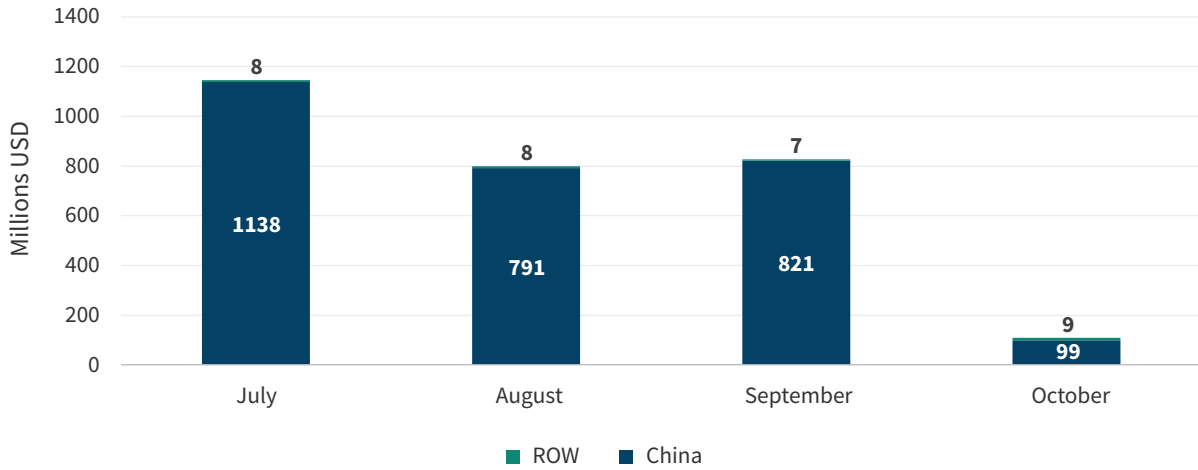
HS Code: 4016.99.6000



Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

U.S. N95 Respirator Imports from China

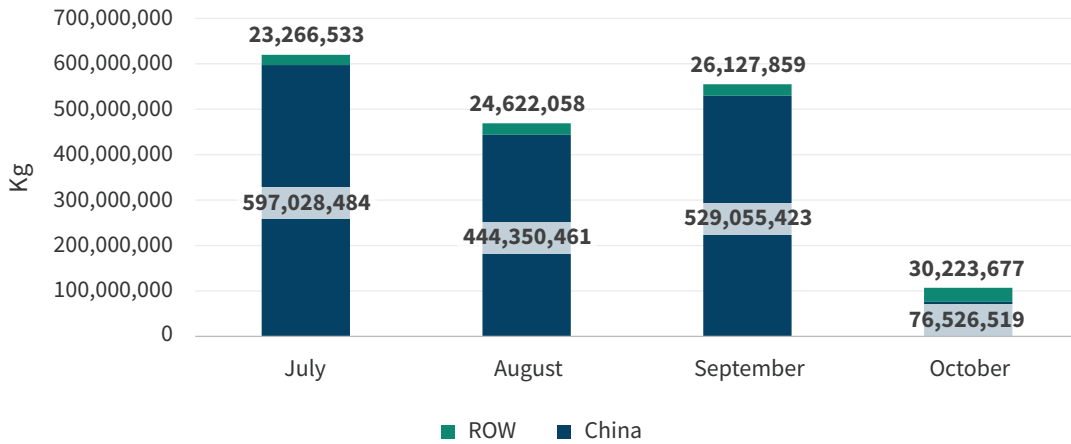
By value, 2020, HS 6307.90.9845



Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

U.S. N95 Respirator Imports from China

By volume, 2020, HS 6307.90.9845



Source: All data generated from U.S. Census Bureau, “USA Trade Online,” Database, <https://usatrade.census.gov/>.

Shortages during the Beginning of the Pandemic

The Association for Professionals in Infection Control and Epidemiology (APIC) conducted a **national survey** of infection prevention experts between March 23 and 25, 2020, and found that “48 percent of U.S. healthcare facilities surveyed were already or almost out of N95 respirators to use in caring for a patient with Covid-19.” Nearly half of the respondents (49.16 percent) said they did not have enough face shields, and nearly one-third (31 percent) of respondents were already or almost out of masks. Despite the shortages, only 12.25 percent of respondents had received federal resources from the SNS.

Shortages of Covid-19 tests strained PPE supply at the outset of the pandemic. Hospitals initially **reported** long wait times for processing the tests, frequently waiting seven days or longer for results. A survey conducted by the **HHS** found that because of this delay, hospitals treated symptomatic patients as presumptive positive cases of Covid-19, which further strained hospital resources. Severe shortages of masks—including N95 masks, surgical masks, and face shields—were most widely reported, followed by gowns and gloves. Hospitals confirmed that significantly above average use of PPE contributed to shortages, which threatened their ability to keep staff safe while treating patients. The administrator of one hospital stated that prior to the Covid-19, the hospital’s medical center used around 200 masks per day but was now using 2,000 per day.

According to the NIH, **in May 2020**, “87 percent of nurses reported having to reuse a single-use disposable mask or N95 respirator, and 27 percent of nurses reported they had been exposed to confirmed Covid-19 patients without wearing appropriate PPE.” Demand for PPE continued to outpace supply: according to **one index**, 80 percent of facilities reported having no supply left of at least one type of PPE in September.

What Caused the Shortage?

A **recent study** in *Preventive Medicine* identifies four major factors that contributed to the PPE shortage: 1) a dysfunctional costing model used by hospitals to budget for PPE, 2) “a very large demand shock triggered by both acute healthcare need and panicked marketplace behavior that depleted domestic PPE inventories, 3) the lack of effective action on the part of the federal government to maintain and distribute domestic inventories, and 4) severe disruptions to the PPE global supply chain.” The Occupational Safety and Health Administration (OSHA) requires that employers provide PPE to healthcare workers at no cost—an expenditure that employers cannot pass on to patients and insurers. Because of the unfunded OSHA mandate, employers lack an incentive to encourage PPE use among employees, replace PPE frequently, or keep a large stock of PPE.

The Worsening Effect of Export Restrictions

Per the **WTO**, by the end of July 2020, almost 90 countries had imposed at least one export restriction in connection to Covid-19. This count is likely an underestimation, as some WTO members, such as China, have not notified the WTO secretariat of all measures taken over the past year. Countries tended to impose export restrictions on both foodstuffs and medical goods, the latter including medical supplies, pharmaceuticals, and PPE. Export restrictions reduce global supply and the availability of goods in countries with limited manufacturing capacity: by artificially reducing export opportunities, they discourage expanding the production capacity necessary to respond to global demand. At the outset of the pandemic, many governments imposed export controls with little notice, creating unpredictability and instability across global supply chains. However, by May, countries not only held off on additional restrictions but began to roll measures back.

With respect to medical supplies, some analysts have argued that actions the Chinese government took in February, including prioritizing domestic distribution and making large state-backed purchases on the international market, fueled global PPE scarcity and prompted additional restrictions around the world. Currently, China is selectively releasing PPE for export, with destinations seemingly chosen according to political calculations. The fact that China was the largest U.S. supplier of N95 respirators, surgical masks, protective garments, medical gloves, medical shoe covers, and medical goggles in 2019 highlights how heavy reliance on China for PPE imports might be a strategic vulnerability during a deadly global pandemic.

The U.S. Response

In early April, the Trump administration invoked the Defense Production Act (DPA) to increase domestic PPE production across medical and non-medical manufacturing companies such as 3M and Ford. Although the Trump administration also implemented export controls on PPEs to prevent further shortages, deficits persist. Dan Cohen, CEO and founder of 3DBio Therapeutics, **explained** that PPE manufacturers are slowing production to avoid the risk of eventually holding surplus inventory.

A recent Government Accountability Office (GAO) **report** found:

“As of 1 September, 2020, the US federal government had provided about 92.4 million N95 respirators, 28.1 million non-surgical gowns, 79.7 million gloves, 228.4 million face masks, as well as other PPE to state, tribal, and territorial entities. As of 10 September 2020, the US federal government had also distributed more than 95 million swabs and 76 million units of test tubes and transport media. However, the US Food and Drug Administration has cited a number of areas of critical shortages, including “examination and surgical gowns, various types of gloves, surgical respirators, ventilator-related products, and various testing supplies and equipment, such as transport culture medium, sterile swabs, and general purpose reagents, among others. Additionally, FEMA told GAO officials that the agency had open requests from state and local governments for more than 139 million nitrile gloves, 11 million surgical gowns, and 6 million N95 respirators, as of 4 August 2020. ‘FEMA also notes that the supply of N95 respirators for medical use is not expected to catch up to demand until January 2021,’ GAO reported.”

3M’s experience of ramping up respirator production in multiple countries for export around the world is instructive. By the end of May, 3M had **supplied** the United States with more than 90 million N95 respirators made in Asia, and by July, this figure had **surpassed** 160 million. In August, 3M Canada began producing N95 respirators at its Ontario plant with support from the Canadian federal government and Ontario provincial government. Ramping up production abroad to serve the United States allowed 3M to continue to use its U.S.-based production to supply Canada and Latin America with respirators. Although the Trump administration requested that 3M stop exporting U.S.-produced respirators to Canada and Latin America in April, 3M **affirmed** in a press release that complying would result in retaliatory export restrictions—which would reduce the number of masks available to the U.S. market and create a humanitarian disaster in Latin America, where 3M is a “critical supplier of respirators.”

Since the United States started collecting trade data on N95 respirators in the summer of 2020, most imports have come from China. The data show a decline in imports from China by over 90 percent between July and October. The steep drop-off in the value of imports from China may be a result of increased production in the United States by companies such as 3M and a drop in N95 respirator prices, itself potentially a result of increased production in the United States and elsewhere. Regardless of the cause, the significant decline in imports from China, even as the Covid-19 case count rose in October, could suggest that the United States has significantly reduced its reliance on China for N95 respirators. This

assessment is that of the **Advanced Medical Technology Association (AdvaMed)**, which represents U.S. medical device companies.⁶

THE ROLE OF GLOBAL SUPPLY CHAINS IN RAMPING UP PRODUCTION OF VENTILATORS

In March 2020, as the United States assessed supply shortages and considered options for ramping up production of essential medical supplies, the ventilator deficit was perhaps one of the biggest concerns. Health officials and politicians were visibly distressed at the prospect of massive shortages of ventilators—devices essential in treating the respiratory issues of Covid-19 patients. **Governor Andrew Cuomo of New York, for instance, said** on March 24 that his state needed at least 30,000 ventilators but had only procured 7,000 so far. The SNS, which accrues medicines and medical devices for public health emergencies, held only 12,700 units in storage. In response, the administration spearheaded an all-out effort to produce as many ventilators as feasibly possible, led by White House adviser Jared Kushner and economic adviser Peter Navarro.

President Trump, on March 27, invoked the DPA and directed General Motors to manufacture ventilators. The DPA was invoked again on April 2 to help supply six companies—General Electric, Hillrom, Medtronic plc, ResMed, Royal Philips, and Vyair Medical—with materials to make ventilators.

At the onset of the Covid-19 pandemic, 60 percent of the global ventilator supply was manufactured outside the United States. Six companies are responsible for around **80 percent of all ventilator production**: Drägerwerk AG (Germany), Royal Philips (Netherlands), Medtronic plc (Ireland), Getinge (Sweden), Hamilton Medical (Switzerland), and Vyair Medical (Mettawa, Illinois). The United States imports ventilators largely from these companies' facilities in Singapore, China, Mexico, Australia, and New Zealand. Ventilators are complicated machines, with some **advanced models containing as many as 1,700 individual parts**. These parts are imported from around the globe; for instance, circuit boards, an essential ventilator component, are overwhelmingly manufactured in Asia.

Nevertheless, spurred by the DPA, domestic manufacturing of ventilators ramped up quickly to meet demand. The federal government contracted with automobile manufacturers General Motors and Ford and with ventilator production companies such as Ventec Life Systems to scale up production. General Motors worked with Ventec to turn the car maker's idle manufacturing facility in Kokomo, Indiana, to a ventilator production site. In its Ypsilanti, Michigan factory, Ford shifted from production of F-150 trucks to ventilators. At present, **nearly 120,000 ventilators sit in the SNS due in large part to the early DPA contracts**. In fact, the government now has a surplus of ventilators, which will lead to the eventual cancellation of multiple ventilator-production contracts.

However, one of the earliest and most severe roadblocks to rapidly scaling production was a shortage of inputs. Multiple companies, including Ford and Vyair, cited global parts shortages as the largest impediment to nonstop production. For instance, Vyair purchases ventilator components from China and Malaysia and is now trying to identify additional suppliers. China restricted large quantities of PPE and medical equipment in mid-April as part of a new regulatory approval system for exports of medical products. These restrictions caused serious shortages, including for circuit boards used in ventilators, which led to delays and a near-shutdown of General Electric's Wisconsin ventilator plant.

6. Document accessible via ITC's Electronic Document Information System (EDIS): AdvaMed and AdvaMedDx, comments on "COVID-19 Related Goods: U.S. Industry, Market, Trade & Supply Chain Challenges," International Trade Commission Investigation, No. 332-580, October 2, 2020.

Government-ordered factory shutdowns, which aimed to stem the spread of Covid-19, inadvertently disrupted the production of critical ventilator inputs even as restrictions on transportation raised logistics costs. As the outbreak worsened in the spring, ventilator manufacturers found themselves competing not only among each other to secure additional components from suppliers but with companies that had not previously manufactured ventilators or other medically relevant life-saving technology. In addition, by not recognizing emergency-use authorizations for ventilators produced by non-traditional manufacturers such as Ford and General Motors, foreign regulators may have missed an opportunity to lessen the burden on global supply chains (emergency-use authorizations apply only to domestic jurisdictions and carry no formal weight with foreign regulators).

General Electric reported that the main problem with its supply chains serving its ventilator production facilities in Wisconsin came from its suppliers adapting to massive surges in demand rather than from export controls or a breakdown of production lines. The company engaged in negotiations with foreign, local, and state governments to make sure factories remained open and supply chain security was ensured. Other companies reported temporary problems with restrictions in Germany and China, among other nations, but the tight relationship between ventilator manufacturers and their suppliers allowed for the eventual, greatly increased production of ventilators. Additionally, Medtronic plc, the Ireland-based manufacturer contracted by HHS to produce 1,056 ventilators, has a strong network of global partners that help create its PB560 ventilator in Bangladesh; India; Ireland; Vietnam; Ontario, Canada; and Wisconsin, United States.

Following the initial panic in March, the projected need for ventilators lessened to some degree as doctors gained greater knowledge regarding effective techniques for treating the respiratory symptoms of Covid-19. Due to less use of ventilator treatment than initially projected in the early days of the pandemic and a slowed trend of positive cases from March through May, production of ventilators was given the time it needed to catch up and actually overshot demand.

Rationale for a Trusted Supply Chain Network

Gilead's experience with ramping up production of Veklury (remdesivir) through its supply chain and global manufacturing network illustrates how the company was able to respond to unanticipated supply chain disruptions and spikes in demand by adjusting sourcing, improving manufacturing processes, shifting production among global facilities, and repurposing and ramping up production facilities in the United States. By supplementing domestic manufacturing with multiple international partnerships, Gilead created a sophisticated network capable of producing large volumes of remdesivir to meet huge domestic demand, as well as the demand in global markets from patients and hospitals struggling with Covid-19. Similarly, Pfizer's success with the Covid-19 vaccine was defined by its ability to mobilize global research, its manufacturing footprint, and its international network, which included an essential scientific and commercial collaborator, BioNTech in Europe.

In contrast, as the SNS for PPE was depleted early on in the pandemic and shortages became apparent, supply chains for certain PPE were strained due to the overwhelming size of demand spikes and insufficient production in the Western Hemisphere. On the other hand, despite delays, global supply lines for ventilators remained intact. Ventilator manufacturers (aided by automobile companies and others) were able to greatly scale up production, retool factories, and ultimately identify new global and domestic suppliers (including SpaceX) for component parts to meet U.S. demand.

The supply chain for any given manufacturer of ventilators, like that of many medical devices, is globalized to the point where it cannot be realistically reshored to a single country. The experience of ventilator manufacturers during the initial wave of the pandemic in the spring suggests that supply chain resiliency would instead be improved by deeper international communication and clearer, more predictable understanding among governments and companies at all stages of the supply chain—not by domestic content requirements and artificial barriers to competition.

A trusted network would not necessarily reduce reliance on certain countries for PPE—doing so may require a set of incentives to attract manufacturing to the United States and other trusted countries. A network of trusted supply chain partners would, however, be able to provide additional certainty during a future public health crisis. For example, partners could agree that ventilator components are an “essential” item that should be exempt from any orders to close facilities for the sake of public health. Similarly, partners could pledge to maintain logistics channels so that critical inputs do not get stalled by travel or export bans but continue to move across borders. Regular communication between regulators and companies would facilitate troubleshooting any disruptions that could arise in rapidly changing regulatory environments during a public health crisis. Trusted supply chain partners could implement procedures to expedite emergency-use authorization for products approved by another trusted partner to lessen the load on global supply chains. Visibility into production capacity and the sharing of non-proprietary information between trusted partners and companies could deconflict the scramble for input materials.

Trusted supply chain networks would set up strong lines of communication among supplying countries and U.S. companies so that navigating a new healthcare crisis would be more manageable and predictable and less prone to debilitating, unforeseen shortages. As countries and companies consider measures to encourage reshoring and nearshoring of PPE production, such a network would provide a platform and a framework for the United States and other participants to proactively engineer resiliency by diversifying trusted suppliers, regularly exchanging information regarding production levels, and coordinate to address vulnerabilities. This partnership and transparency would foster trust and familiar working relationships between national governments and the firms from which they procure PPE.

Recommendations

CSIS research, together with industry and policy experts that participated in attended two roundtables, concluded that a fresh look at supply chain vulnerabilities should be approached not with the goal of mandating the return of all production to the United States but with an appreciation that diversified global supply chains can offer manufacturing and sourcing options for enhancing supply chain security. During the global health crisis, global supply chains have enabled drug manufacturers to ramp up production and maintain supply. Many of these supply chains succeeded in serving patient needs effectively, even while under enormous strain from unprecedented pandemic-related demand spikes.

CSIS recommends that Congress and the new Biden administration work together to draft an updated policy on medical supply chain security centered around diversification among trusted partners. After a comprehensive, White House–led assessment of domestic production and medical supply chain vulnerabilities, Congress should consider legislation directing the president and the USTR to develop a new trade policy initiative to solidify and reinvigorate trade relations with allies and trusted partners. The goal should be to establish a strong, **trusted partner network** of supplier countries that cooperate with the United States to bolster and guarantee a steady supply of essential medical products in the event of a future emergency.

Expanding competitive market opportunities for U.S. exports, “including through the utilization of global value chains,” has been a principal trade negotiating objective of the United States since the **Bipartisan Congressional Trade Priorities and Accountability Act (19 U.S.C. 3802) was approved in June 2015**. This law recognizes that the global competitiveness of U.S. manufacturers is enhanced by investing in supply chains to ensure that production has access to appropriate inputs that are not locally available and that supply chain networks remain flexible and efficient. In the report language, Congress recognized that this goal should be accomplished through additional trade negotiations, including on trade facilitation. According to the House Ways & Means committee **report** on the Trade Priorities and Accountability Act, “A successful example of the utilization of global value chains is the development of a hemispheric textile and apparel industry that resulted from the Dominican Republic-Central America Free Trade Agreement with the United States, which created markets in Central America for U.S. design, research and development, and inputs.”

CSIS research has found that resiliency is best achieved through diversification and frameworks that provide certainty in times of crisis. Across the medical sector, supply chain issues that arose during the early months of the pandemic were caused not by lack of domestic production capacity in most cases but by an uncertain and often chaotic policy environment. Supply chain disruptions were resolved by the private sector working closely with suppliers, the U.S. government, and foreign governments—not by shunning global value chains. In some cases, U.S. government purchasing agreements made private sector investment viable. Policymakers should build a network of trusted supply chain partners to prepare for the next global public health crisis by establishing expected behavior during crises, building a foundation of regulatory cooperation, and creating visibility into global supply chains to mitigate supply chain disruptions.

Elements of the CSIS Proposal

SENIOR WHITE HOUSE OFFICIAL DESIGNATED AS INTERAGENCY COORDINATOR

Because defining and incentivizing more secure global supply chains requires the expertise of several government agencies, the president should designate a senior White House official to be responsible for overall policy coordination. This official should establish an interagency team that includes officials from the National Security Council, the Office of Management and Budget (OMB), the HHS, the USTR, the Department of Commerce, and the Department of Homeland Security to establish an updated policy. The White House official should understand each agency’s strengths and possess the expertise to design and implement a secure medical supply chain policy. For example, OMB follows domestic and international regulatory issues, and the Department of Commerce can track the movement of goods and other logistics. Execution of this policy should include clearly delineated agency responsibilities and deadlines.

THE STRATEGIC NATIONAL STOCKPILE AND OVERALL SUPPLY CHAIN SECURITY

The designated White House official should lead a cross-government review of the list of essential medicines, medical countermeasures, and critical inputs. The official should conduct an interagency assessment of the ability of international supply chains serving the U.S. market to source and manufacture any essential products not currently being produced in the United States in sufficient quantity or quality. This official should oversee the preparation of a gap analysis and vulnerability assessment of current supplies in the SNS so that stocks of essential medicines and medical equipment can be increased and rationalized.

The administration should present Congress with both the list of essential medical products to be maintained in the stockpile and a list of other products that should be monitored for the overall security of supply, including those from designated trusted partners. Assessment and adjustment of the two product lists should be conducted twice a year.

Manufacturers should be contracted to produce specified quantities of products identified for purchase and storage in the SNS. Legislation should task presidential administrations with maintaining and curating the stockpile, including through appropriate rotation of stock, particularly of medical technology, PPE, and diagnostic tests. These provisions will require an increase in funding for the SNS.

CSIS also supports current Trump administration efforts to pursue voluntary agreements between FEMA and the private sector regarding collaboration on advanced contingency planning for future stresses to the supply chain.

While this paper focuses on the trade aspects of supply chains, it should be mentioned that participants in CSIS supply chain roundtables urged the adoption of a cohesive national domestic policy that establishes a welcoming environment in the United States for building new factories, including those with advanced manufacturing capabilities. This would entail an overall review and reduction of regulatory burdens which impact the viability of establishing new and retooling older manufacturing facilities. Extending favorable tax treatment to pharmaceutical and medical equipment manufacturers such as investment tax credits, a reduced tax rate on manufacturing income, accelerated depreciation, innovation tax credits, and intellectual property incentives will improve the attractiveness of reshoring to the United States. Enhanced policies aimed at growing a larger, more highly trained Science, technology, engineering, and mathematics (STEM) workforce in the United States should also be considered.

LEGISLATION ESTABLISHING A NEW TRUSTED SUPPLIER TRADE POLICY

Congress should enact legislation stating that it is the policy of the United States to present countries willing to become a trusted supply partner through the reciprocal reduction of trade, investment, and regulatory barriers with offers of: 1) enhanced commercial ties grounded in a new network of trusted partner countries and 2) a commitment to coordinate and offer reciprocal support to trusted partner countries. This would include access to and sharing of general medical supplies and innovative vaccines and therapies during disruptions caused by a pandemic or other emergency. The United States should also consider public-private cooperative understandings and other initiatives to encourage R&D on new pharmaceuticals, medical devices, and advanced manufacturing among trusted partners. Finally, Congress should authorize the USTR and other appropriate agencies to suspend or remove barriers that increase the costs and reduce availability of needed inputs and medical supplies related to a pandemic.

Membership in the trusted partner network will afford countries the imprimatur of a preferential “trusted supplier” designation and the associated marketing advantages of being recognized as a secure, attractive site for foreign investment with enhanced market opportunities in the United States.

COUNTRIES ELIGIBLE TO BECOME A TRUSTED PARTNER

Based on the criteria described below, the USTR should determine whether allies and current FTA partner countries qualify to be considered for preferential trusted partner status. USTR should also consider any other country that is interested in substantially upgrading its trade and investment relationship with the United States through: 1) a sectoral understanding regarding the regulation of the safety and efficacy of medical products, including with regard to Good Manufacturing Practices set by the FDA 2) improved intellectual property protection, and 3) commitments regarding free data flows.

Legislation should direct the USTR to consider these criteria, which should serve as an overall guide to identify countries eligible for negotiations. The criteria should be considered holistically and not necessarily as hard and fast requirements or prerequisites. In negotiating with eligible countries, the USTR's goal should be a marked improvement in market access, information sharing, rule of law, and cooperation.

1. To enhance **supply chain visibility**, trusted partners should:
 - Cooperate to enhance supply chain transparency that supports the White House–led initiative to assess current production, possible bottlenecks, and potential weak links and vulnerabilities.
 - Share information with the ITC and the FDA on where APIs and other inputs designated essential medical products are sourced.
 - Share information on domestic manufacturing capacity as well as on vaccine development and innovations in therapeutic treatment.
2. To enable a **new plurilateral trade agreement** for the medical sector, foreign governments seeking trusted partner status should:
 - Agree to seek regulatory cooperation on drug and device manufacturing standards, including through MRAs negotiated by the USTR and the FDA.⁷
 - Negotiate lower tariff rates on pharmaceuticals and medical goods.
 - Join the WTO Pharmaceutical Agreement (discussed below) and, alongside the United States, commit to updating and expanding the agreement in terms of product coverage and membership.
 - Fully open their government procurement markets for medical goods from other trusted partner countries or maintain membership in the WTO Government Procurement Agreement. The United States should exempt medical goods Trusted Partners from Buy American requirements.
 - Maintain satisfactory rule of law, for example by ensuring that laws are clear and publicized; laws are enacted, administered, and enforced in a transparent and nondiscriminatory manner; and an independent, neutral, and competent judiciary is available to citizens and businesses.
 - Maintain satisfactory intellectual property protection. This could include strong rights, guarantees, and protections in the following categories: patents, trade secrets, ability to commercialize intellectual property assets, and enforcement of these protections. They should also have a transparent, objective, efficient, independent mechanism to settle disputes regarding enforcement of intellectual property rights and investment (preferably a local remedy).
 - Maintain robust investment guarantees, including—at a minimum—adherence to the national treatment principle and restrictions on expropriation (with adequate compensation if expropriation does occur). This would not necessarily require the adoption of an investor-state dispute settlement regime (ISDS).
 - Fully implement the WTO Trade Facilitation Agreement and put in place mechanisms to ensure compliance with the commitments therein.
3. A trusted partner should exemplify **trust and reliability**, as measured by:
 - Its national security relationship with the United States, such as its participation in a mutual defense treaty with the United States, a historic defense relationship with the United States, and its treatment as either a “friendly country” under the Arms Export Control Act or an “ally and partner” under successive National Defense Authorization Acts. “Friendly countries” generally

7. The FDA can negotiate MRAs, as it has with the European Union. This allows agency investigators to rely on information from foreign investigators, creating efficiencies and freeing investigatory resources for domestic and less-trusted foreign production sites. The MRA process involves evaluating foreign drug regulators, for example, by observing the European Union’s Joint Assessment Process (JAP) of each member state’s inspectorates and sitting in on their investigators’ inspections.

include those to which the United States exports defense material and services. “Allies and partners” generally include countries with formal defense agreements or defense-cooperation relationships with the United States as evidenced by the expenditure of U.S. defense funds.

- Whether the country is a United States’ FTA partner.
4. Trusted partners should commit to **reciprocal support and supply chain security during crisis situations** by:
- Prioritizing **maintaining the flow of goods** during crises. This should include a commitment not to impose import or export restrictions or other measures that would limit the flow of goods during crises. In the event of shortages that could threaten national security, countries should commit to maintaining transparency and imposing the least trade-restrictive measures possible.
 - Pledging to **cooperate and share information** during crises. Cooperation and information sharing should occur not just regarding existing treatments for disease outbreaks, but also regarding the research, development, approval, manufacturing, and distribution of new drugs to respond to epidemics. This cooperation should not require sharing business secrets or other proprietary information. The NIH’s Accelerating Covid-19 Therapeutic Interventions and Vaccines (**ACTIV**) public-private partnership offers a model for future cooperation among trusted supply chain governments and companies.

POSSIBLE STRUCTURES FOR THE TRUSTED PARTNER NETWORK

Reciprocal Negotiations

The structure of the trusted partner network proposed here is designed to be flexible in order to accommodate the new Biden administration’s trade priorities, as developed with Congress and statutory private-sector advisory committees. Much will depend on the receptivity of candidate countries and their priorities, as developed through their own domestic consultations and political processes.

For example, after a review of trusted partner criteria, the USTR might designate Canada, the United Kingdom, or the European Union to be in general compliance with specified criteria and eligible for consideration to be in the network. The USTR would then initiate exploratory discussions with these countries regarding their interest in negotiating a reciprocal agreement aimed at achieving improved medical supply chain security. The USTR should also be amenable to considering interested trading partners who, upon becoming aware of the initiative and the ongoing negotiations, reach out to the United States with the request to be considered a candidate country.

Overall, we expect that a request from the USTR for consultations with trusted supplier candidates would be met with interest and a positive response from many countries, especially those that are in the process of developing similar initiatives individually or jointly with plurilateral groups.

Unilateral Designation of Countries in the Trusted Partner Network

Alternatively, the United States could unilaterally determine that certain countries qualify as trusted partners based on chosen criteria. Using this second approach, which resembles the structure of the Generalized System of Preferences program, the United States could single out trusted partners for regulatory alignment and joint R&D, providing them expanded access to critical medical supplies obtained by the U.S. government in line with the GPA. The advantages and drawbacks of this approach both stem from bypassing bilateral negotiations to establish trusted partner relationships. Like any trade negotiation, a negotiated approach could involve concessions or commitments that would be difficult for the United

States to make; for example, trusted partners may object to the United States withdrawing access to compete for government procurement contracts pursuant to the GPA. A unilateral approach would allow the United States to circumvent this haggling, enabling it to avoid making such concessions and speeding up the process of creating a trusted partner network. On the other hand, a unilateral approach could leave the United States with less leverage and flexibility to negotiate meaningful commitments, including concrete market access improvements, from countries it has targeted as trusted partners but who do not yet meet an adequate number of the designation criteria. Moreover, a U.S. commitment to the norms it asks of trusted partners, as might be required under a negotiated approach, could generate certainty for companies in the United States that are wary of future export controls or domestic production requirements—certainty that may be lacking under a unilateral model.

As mentioned, success in negotiating or designating a trusted supplier network will depend on the international environment and on the domestic political debates occurring in eligible countries. In the wake of the demand spikes caused by the Covid-19 pandemic, many countries are prioritizing building supply chain resilience by lessening dependence on a single supplier and incentivizing more domestic and regional production that would shorten supply chains. Many countries have adopted a spoken or unspoken policy priority of reducing dependence on China. This creates an exceptional opening for competitors of China to attract investment from firms wanting to relocate or diversify sourcing, and several countries have already begun outreach to potential investors in this regard. However, some countries are not seizing the opportunity: Mexico, despite its close geographic relationship to the United States, seems less organized and less willing to create a more hospitable investment climate for foreign companies looking to relocate.

Related Initiatives

Within the post-pandemic international political landscape, there are several related initiatives underway to restructure international medical supply chains that should be considered. These initiatives offer a possible roadmap, foundation, and momentum for the United States to establish a trusted trading partner network for medical supply chains.

THE WORLD TRADE ORGANIZATION PHARMACEUTICAL AGREEMENT

Concluded at the time of the Uruguay Round Trade Agreements, the 1994 Agreement on Trade in Pharmaceutical Products permanently eliminates tariffs on a range of pharmaceutical products and their inputs, permanently binding them at duty-free levels. Participants in the agreement, who have agreed to implement these concessions on a most-favored-nation basis are Canada, the European Union, Japan, Macao (China), Norway, Switzerland, and the United States. These signatories agreed to review the agreement periodically to update and expand the list of items covered. The agreement covers not only all finished pharmaceutical products but also over 7,000 APIs and other chemical components.

A NEW EUROPEAN UNION PHARMACEUTICAL STRATEGY

At the outset of the pandemic, Vera Jourova, the vice president of the European Commission, suggested in public statements that there would be significant changes to the EU pharmaceutical supply chain to address vulnerabilities that came to light during the pandemic. “This crisis has revealed our morbid dependency on China and India in regards to pharmaceuticals [. . .] This is something that makes us vulnerable and we have to make a radical change there.” According to Jourova, the commission will **reassess** these supply chains and try to produce as many supplies as possible within the European Union.

On June 11, the European Commission **released** a concept paper entitled “Trade in Healthcare Products.” The paper expresses concern that “for fear of not being able to secure the relevant supplies, many countries

have resorted to various forms of export restrictions which have led to disruptions of supply chains, transport delays, as well as price spikes for life-saving supplies.” On November 25, 2020, the European Commission published its **Pharmaceutical Strategy for Europe**, which incorporated many comments submitted during a consultation period. The European Union proposes revising the “pharmaceutical legislation to enhance security of supply and address shortages through specific measures including stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages.” Additionally, the commission will establish, “a structured dialogue with and between the actors in the pharmaceuticals manufacturing value chain and public authorities to identify vulnerabilities in the global supply chain of critical medicines, raw pharmaceutical materials, intermediates and active pharmaceutical substances in order to formulate policy options and propose actions to strengthen the continuity and security of supply in the EU.”

The strategy suggests the following aims for both legislative and non-legislative action:

1. Reduce direct dependence on raw materials sourced from non-EU countries.
2. Encourage other countries to harmonize international standards of medicine quality and safety.
3. Help European pharmaceutical companies compete globally on equal footing.

In their comments to the Commission during consultations, several U.S. pharmaceutical companies with production facilities in Europe praised the strategy’s call for greater coordination and cooperation among stakeholders in order to facilitate flexible regulatory frameworks and create more resilient global supply chains. These companies reported that despite large demand spikes in Europe—up to three times higher for certain products—they were able to **meet demand** due to “stable and sophisticated global networks and healthy pre-Covid inventory safety stocks.” In their submissions, companies maintained that a fragmented, localized approach to production could not achieve the shared goal of adequate, resilient supply.

THE OTTAWA GROUP

On June 20, 2020, building on the European concept paper, 13 WTO members acting as the Ottawa Group—consisting of Canada, the European Union, Australia, Brazil, Chile, Japan, Kenya, Mexico, New Zealand, Norway, Singapore, South Korea, and Switzerland—issued a **joint statement on combating Covid-19**. This statement outlines actions WTO member countries can take to support global recovery, including transparency on export restrictions, open trade in agriculture, and advancing negotiations on e-commerce. Pursuing such policies “**supports** the movement of the goods and services people rely on and will ensure stability for our businesses, workers, and people at this uncertain time.”

The Ottawa group proposed a **draft of a “Trade and Health” initiative** at the December 16, 2020, WTO General Council meeting. The proposal includes rules to mitigate the impact of future export restrictions, proposes cooperation on customs and trade facilitation, asks members to attempt to temporarily reduce or eliminate tariffs on goods essential to fighting Covid-19, and improve transparency regarding trade measures taken in response to the pandemic including by working with the WTO Secretariat. Under the proposal, WTO members would also review the effectiveness of the proposal at the 12th WTO Ministerial Conference and consider “adopting possible commitments regarding trade in essential medical goods.”

NEW ZEALAND–SINGAPORE MEDICAL SUPPLY CHAIN PARTNERSHIP

On April 15, 2020, New Zealand and Singapore **announced** a new trade partnership focused on “essential goods needed to respond to the Covid-19 pandemic.” This initiative is an open plurilateral trade agreement,

meaning that any WTO member may participate. Since its launch, ten additional countries have **acceded**: Australia, Brunei, Canada, Chile, China, Laos, Myanmar, Nauru, the United Arab Emirates, and Uruguay. Parties to the agreement **pledged** to maintain open supply chains and to remove trade-restrictive measures on medical supplies and other “essential” goods, including PPE, hygiene supplies, and food and beverage products. For these goods, parties to the agreement pledge to remove tariffs and non-tariff barriers and to refrain from use of export restrictions.

ASIA-PACIFIC ECONOMIC COOPERATION GROUP (APEC)

The 21 countries of the Asia-Pacific Economic Cooperation (APEC) group have made several joint statements responding to trade disruptions caused by Covid-19. In July 2020 APEC trade ministers **committed** to ensuring that any trade measures imposed in response to the pandemic were in accordance with WTO obligations and promised to coordinate on “unnecessary” trade barriers in essential goods. This builds on a previous statement from May 2020, when they **pledged** to facilitate the flow of essential goods and services during the pandemic, committed to keeping trading lanes open, and agreed to bolster APEC’s digital trade agenda. On November 20, 2020, APEC Economic leaders agreed to elevate regional cooperation in the health sector as their top priority.

INDIA—A SPECIAL CASE

India presents an interesting case with respect to whether it should be considered for a trusted partner relationship. Growing strategic synergy has yielded important progress in U.S.-India defense ties. However, India still looks at trade as distinct from foreign policy, and recent protectionist actions have caused renewed friction in U.S.-India commercial ties. However, India desires more integration into global supply chains, and the noticeable narrowing of India’s trade deficit during the Covid-19 period could afford some space to revisit recent trade policies. The largest provider of generic drugs globally, India has a strong competitive advantage in the production of pharmaceuticals and medical products and currently serves as a significant, long-standing supplier to the U.S. market. The Indian pharmaceutical sector is **ranked** tenth globally based on value and third based on volume, and the sector is expected to grow to \$100 billion by 2025. India also has the fourth-largest medical devices market in Asia after Japan, China, and South Korea, a sector that India has the **estimated potential** to grow to \$50 billion by 2025.

On the defense side, as military confrontations on the border between China and India increase, the U.S.-India strategic partnership continues to strengthen. On October 27, 2020, the two governments signed several agreements at the U.S.-India 2+2 Ministerial Dialogue, including the Basic Exchange and Cooperation Agreement (BECA), which will support interoperability between the U.S. and Indian militaries and allow for the sharing of intelligence and analysis, including geospatial intelligence data. At the dialogue, U.S. Secretary of State Mike Pompeo and his Indian counterpart, Subrahmanyam Jaishankar, committed to **efforts** to enhance supply chain resilience and to “seek alternatives to the current paradigm, which had come under severe strain during the pandemic and exposed vulnerabilities.” The two governments resolved to cooperate in developing vaccines, treatments, diagnostics, ventilators, and other essential medical equipment. In the declaration, the United States expressed “strong appreciation for India’s export of Personal Protective Equipment (PPE), essential medicines, and therapeutics to the United States during these challenging times.”

Nisha D. Biswal, former assistant secretary of state for South and Central Asian affairs, has **said**, “It’s not a surprise that the Indians are looking for like-minded strategic and security partners, given concerns around a destabilizing environment in the Indo-Pacific.”⁸ Observers note that India’s border dispute

8. Nisha Biswal is the current president of the U.S.-India Business Council and senior vice president for South Asia at the U.S. Chamber of Commerce.

with China in the Himalayas is pushing it into a regional partnership with the United States, Japan, and Australia—known as the Quadrilateral Security Dialogue, or “Quad.”

At the same time, U.S. exporters and foreign investors in India face some of the most difficult market access barriers in the world. The USTR regularly designates India as a Priority Foreign Country, indicating strong U.S. concerns regarding weak intellectual property protections and enforcement. India has recently promulgated several data localization requirements that are serving as significant barriers to digital trade with the United States. It is actively considering additional data flow barriers as part of a new **electronic commerce policy** that might also include expanded grounds for forced transfer of intellectual property and proprietary source code and preferential treatment for domestic digital products. If passed, the pending **Personal Data Protection Bill** could potentially cover data of non-Indian citizens, making cross-border data flows even more difficult.

India also imposes numerous discriminatory policies in the area of government procurement. As the USTR **notes**, “India lacks an overarching government procurement policy and, as a result, its government procurement practices and procedures vary among the states, between the states and the central government, and among different ministries within the central government. Multiple procurement rules, guidelines, and procedures issued by multiple bodies have resulted in problems with transparency, accountability, competition, and efficiency in public procurement.” For defense contracts that meet a minimum value, India also requires companies to invest at least 30 percent of the acquisition cost in Indian-produced parts or services. In addition, although the Ministry of Defense offers strategic partnerships in some acquisition programs, its mandatory technology transfer requirements make them less attractive to U.S. companies. The federal government’s “Make in India” initiative is similarly “aimed at facilitating local manufacturing and boosting domestic demand for locally manufactured products.” Even before Covid-19, a local content requirement was extended to the procurement of medical devices.⁹

Given global concerns about over-reliance on China as a single source for supply of medical products, India is strategically placed to grow its economy significantly through increased levels of new foreign investment, particularly from U.S.-based multinational corporations. U.S. companies manufacture many medical devices in China, and the Indian pharmaceutical industry is **highly dependent** on China for raw materials and APIs. As such, the United States and India “are **eager** to mitigate their manufacturing risks by diversifying their supply chains.”

It remains to be seen whether a paradigm shift away from India’s traditional closed-market policies is possible, notwithstanding bilateral convergence in the area of national security. If India has an interest in joining a U.S. trusted supplier network, we expect the United States would require significant improvements in market access for U.S. manufacturers and service suppliers. For its part, the United States could be expected to offer expanded access to advanced medical technologies, devices, and new medicines and agree to conduct more R&D activity in India. In any case, competing successfully with countries such as Vietnam and Malaysia over investment leaving China will require improvements to India’s regulatory and investment climate—a dynamic that could make India more open to negotiations for membership in the trusted supplier network.

Conclusion

9. Despite these concerns, the United States in October approved a follow-on program to support India’s C-130 fleet and recently delivered a P-8 maritime surveillance aircraft to India – the ninth since 2009 - and will deliver three more in 2021. In addition, Raytheon and Lockheed Martin’s Javelin Joint Venture inked an agreement with Indian company Bharat Dynamics in February to discuss co-production of the Javelin anti-tank missile system in India.

The strong commitment in Congress and the executive branch to improve the resilience and security of medical supply chains is echoed in many countries around the world, as demonstrated by the international initiatives described above to enhance medical supply chain security through new agreements and understandings. The new global economic environment, in which certain vulnerabilities and deficiencies in global medical supply chains have become evident, holds both lessons and opportunities for the United States. One lesson is that go-it-alone policies focused entirely on reshoring production are likely to be suboptimal.

Responses to emerging health crises do not happen in a vacuum but rather have an important international dimension that usually enhances options for responding quickly and efficiently on the local level and in global markets. During the pandemic, sophisticated and diversified global supply chains, combined with experience, ingenuity, and an impressive “get it done” attitude, enabled manufacturers to continue to meet patient needs in the face of unanticipated demand. Many manufacturers had built redundancies into their global supply chains, enabling them to adapt successfully to unanticipated disruptions and spikes in demand by adjusting sourcing or shifting production to a different facility. U.S. pharmaceutical and medical-device manufacturers struck expansive domestic and international partnerships and engaged in high levels of intra-industry collaboration to solve the challenges they faced. The policy challenge for the U.S. government will be how to capitalize on those partnerships and fit them into a structure that will put the country in a stronger position to weather the remainder of the current crisis—as well as the inevitable next one.

The case of neighboring Canada, which successfully partnered with the United States to confront the challenges of the pandemic, serves as a possible inspiration for a new policy for securing medical supply chains. Congress and the Biden administration should consider reinvigorating trade relations with certain allies and free trade agreement partners who meet agreed-upon criteria as the basis for a new trade policy strategy that builds on lessons learned from the pandemic. ■

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