Securing Medical Supply Chains with Trusted Trade Partners

*Western Hemisphere Case Studies*

By Meredith Broadbent

**Introduction**

There is bipartisan consensus on Capitol Hill and in the Biden administration regarding excessive dependence on Chinese manufacturing and production. An extension of this is that diversification of supply chains for certain medical products will make U.S. citizens more secure in fighting future infectious diseases. While there is conflicting evidence on the extent to which companies are in fact relocating supply chains, a 2020 *survey* of 260 global supply chain leaders indicates 33 percent had moved sourcing and manufacturing activities out of China or plan to move within the next three years. One in four respondents said they had either localized or regionalized supply chains. As companies consider relocating operations from China, there is a rare, historic opportunity to attract new capital to the Western Hemisphere.

The highly disrupted international economic environment, reeling from supply and demand dislocations unleashed by the pandemic, U.S.-China trade conflicts, and war in Eastern Europe, is prompting certain countries in the Western Hemisphere to seize the occasion to aggressively market themselves as attractive hosts for foreign direct investment looking to move closer to the U.S. market. If regional governments hone in on improving investment and regulatory environments in the healthcare sector and work otherwise to pare local structural costs of production, they stand to gain enormously in enhancing their ability to face the next pandemic.

It is an opportune time for the United States to shape some of the larger forces of global economic disruption, including the movement of investment and production capital. In addition to challenges of medical supply chain security, improved sustainability through lower transportation costs and human rights objectives should weigh in favor of adopting new policies to encourage medical supply production to move closer to the U.S. market. Increased production in the Western Hemisphere would also enhance the ability of U.S. businesses and workers to increase exports by partnering on inputs, parts and production, and expertise.
In an era where China aims to be the global leader in delivering healthcare products, including using vaccines as political leverage throughout the Western Hemisphere, it is time to forge enhanced trade links and diversified supply chains with friends and allies to promote health security, stronger economic and diplomatic engagement, commitments to exchange of data on production, and best practices in fighting disease. Joint research and capacity-building activities, as well as prioritized vaccine access, will be key to tackling the post-pandemic world head on.

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In December 2020, CSIS proposed a policy for a Trusted Supplier Network of chosen countries with which the United States would develop enhanced medical supply chain relationships. This report concluded that a goal of autarky and a government mandate that all manufacturing of pandemic-related medical products occur in the United States would only result in higher prices and more shortages. This new research is aimed at a further refinement of this proposal.

Current Policy Proposals in the United States

Following the 2020 CSIS report, pursuant to Executive Order 14017, the White House released a report in June 2021 entitled Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth. The pharmaceutical industry was one of the sectors examined as part of this study. The study identifies three critical features for a robust pharmaceutical supply chain, namely:

(1) the ability to manufacture high-quality products for the U.S. market; (2) diversification of the drug supply chain, such as relying on a geographically diverse set of manufacturers; and (3) redundancy of the supply chain, such as the existence of multiple manufacturers for each product and its precursors.

In particular, the study notes that the United States must work with “like-minded regulatory” partners for the development of secure and resilient supply chains. Similar themes were reiterated in the list of key deliverables for the 2021 North American Leaders’ Summit held on November 18, 2021, which included “reiterating our pledge to shore up our medical supply chains by exploring ways we can make the components of vaccines and other public health supplies here in North America” and “supporting the Global Health Security Agenda, including improving capacity and leadership to prevent, detect, and respond to infectious disease threats.”

Later, on February 24, 2022, the White House released a statement saying:

The Biden-Harris Administration will partner with North American trading partners to prepare for future crises and mitigate resulting supply chain disruptions. Through the U.S.-Mexico High-Level Economic Dialogue, the United States and Mexico will establish a joint list of critical sectors involved in cross-border supply chains and create procedures to maintain continuity of supply chains in the event of times of crisis. The Competitiveness Committee of the U.S.-Mexico-Canada Agreement will also work to define essential industries and effective approaches for supply chains, including through
information-sharing activities, providing advice and recommendations, identifying priority projects and policies, and designating a contact point for these efforts. And, as agreed to at the North American Leaders Summit in November, the United States, Mexico, and Canada will hold a trilateral supply chain coordination meeting by Summer 2022 to explore trilateral opportunities on supply chains based on results from the bilateral supply chain working groups.

As referenced in President Biden's February 7, 2022, capstone report evaluating U.S. supply chain strategies, “the United States cannot make, mine, or manufacture everything ourselves. We must cooperate with our allies and partners to foster and promote collective supply chain resilience.” Tasked by Congress to analyze post-pandemic supply chain vulnerabilities, the National Academies of Sciences, Engineering, and Medicine recently released policy recommendations that reject mandates to reshore medical supply chains as a policy to build resilience. Instead, among its recommendations is that the United States negotiate a plurilateral treaty with trade partners that would prohibit export bans.

In addition to the U.S.-Mexico High Level Economic Dialogue and the North American Leaders Summit, the administration is using a host of other dialogues to engage with partners in Europe and Asia on supply chain resilience for the health sector. Treasury Secretary Janet Yellen has said, “Favoring the friend-shoring of supply chains to a large number of trusted countries, so we can continue to securely extend market access, will lower the risks to our economy as well as to our trusted trade partners.”

While the White House statements are laudable in principle, over a year into the administration, three years after the start of the pandemic and more than 12 months following the president’s first executive order, few concrete measures have been taken with trading partners to ensure that U.S. medical supply chains for priority medical products will be more resilient and diversified in the future. The Biden administration’s evolutionary approach to trade and strategic economic policy indicates a desire to build more resilient supply chains, but a simultaneous focus on domestic production could inadvertently increase costs and reduce supply chain security in the long run.

The administration and Office of the U.S. Trade Representative (USTR) should prioritize taking active measures with trade partners to enhance supply chain resilience in key products (in the face of the many critical sectors the interagency process is considering). This paper expresses the view that the administration should, at a minimum, make a start by offering at least one or two trusted trading partners in the Western Hemisphere the opportunity to negotiate a secure medical supply chain agreement aimed at ensuring more reliable supplies of key medical products in the future. This pilot effort should be driven by the National Security Council and National Economic Council through the U.S. interagency process. In close consultation with the executive branch, leaders in Congress should take responsibility for ensuring that a new policy supporting this objective is put in place as soon as possible.

**The Medical Supply Industry in Latin America**

With the pandemic, the medical supply sector is experiencing dramatic growth in trade. According to the World Trade Organization (WTO) Secretariat, in the first half of 2020, trade in medical goods grew by 12.4 percent compared to the same period in 2020 and comprised 6.1 percent of total world trade. Trade in

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1. In addition to countries in the Western Hemisphere, the Biden administration is engaging with allies in the European Union and the Quad (the United States, Australia, India, and Japan) regarding ways to enhance supply chain resilience. During the Quad leaders meeting summit, the United States engaged partners with the aim of improving the security of global supply chains for vaccine production. The Biden administration has also used multilateral frameworks such as the G20 to call for cooperation on supply chain issues.
items critical for administering vaccines, such as rubber gloves, syringes, and needles, grew by 34.8 percent. Among these critical items, rubber gloves were geographically concentrated in Asia, which hosted four of the top five suppliers of the product, highlighting dependence on this region for many essential items.

Historically, Latin America has had a significant pharmaceutical industry in countries such as Brazil, Colombia, and Mexico. Within Latin America and Caribbean countries, the main sources of imports of Covid-19 products to the United States are Mexico, Costa Rica, Brazil, and the Dominican Republic, which account for 98 percent of the region’s exports in this sector to the United States. With respect to Covid-19-related medicines, Mexico and Brazil are the main suppliers to the United States. Mexico and Brazil are also the main suppliers of pharmaceutical products and antibiotics that may or may not be related to Covid-19. In terms of vaccine production, Mexico and Argentina have entered into a partnership for the production and distribution of the AstraZeneca vaccine, while Eurofarma Laboratories of Brazil has formed a successful alliance with Pfizer and BioNTech.

Total China trade with Latin America has increased dramatically from $18 billion in 2002 to almost $318 billion in 2020. China’s import purchases from the region, aimed at securing access to raw materials and food, consist primarily of natural resources, including ores, soybeans, meat, and copper. On the other hand, China’s exports to the region are dominated by valued-added manufactured products such as electrical equipment, machinery, and motor vehicles and parts. As the United States and allies rethink trusted supply relationships, there will be added mutual benefit in encouraging U.S. firms to partner with counterparts in Brazil, Canada, Colombia, and Mexico to increase reciprocal trade in value-added products, including in pharmaceuticals, medical devices, and personal protective equipment (PPE). Because production facilities and workers in the Americas spend a higher percentage of their income purchasing U.S. exports than factories and workers in Asia, shifting supply chains from China to the four countries identified here can be expected to increase levels of U.S. exports and contribute to diversification and dependability of supply.

As the pandemic hopefully wanes, there is intense interest among politicians and citizens in Latin America in growing the distribution of vaccines, therapeutics, and diagnostics in the region, as well as a strong desire to support development of future indigenous production of these and other medical products. As a result, there is an opportunity to impact the contours of the region’s medical supply industry as well as the region’s regulatory environment in ways that will increase supply chain security for both the United States and its allies and close trading partners in the region.

Decisions to build more resilient medical supply chains in the Western Hemisphere are highly specific to each firm but can be heavily influenced by certain elements of the investment and manufacturing environment offered by a host government. Profiles of the four countries considered here—Mexico, Brazil, Canada, and Colombia—highlight an array of strengths that make them attractive for increased U.S. engagement and, at the same time, reveal that significant reforms will be necessary if the Western Hemisphere is to improve its ability to attract investment that supports health security. Since so much is unknown about potential reforms that will actually be put in place post-pandemic, this paper does not rank one country over another but discusses each in light of their strengths and weaknesses.
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If companies knew which key products have been identified by governments as essential for health supply chain security, and where there is overdependence on one or two countries in Asia, investment decisions to diversify some production to Latin America would be easier. As the Biden administration builds out a plan to ensure the security and diversification of medical supply chains, it should recognize the tremendous opportunities for these four countries to add to the diversity of supply. Concrete progress in this regard will require a full-court press by the administration, which includes employing (1) the leverage of U.S. technical expertise and the size of the U.S. market; (2) U.S. trade tools; and (3) a sustained diplomatic initiative to incentivize the necessary reforms in countries that have the potential to become trusted trade partners.

Nearshoring Opportunities in the Americas

What is the state of the business environment in Latin America and the Caribbean that historically has caused producers of medical supply products to hesitate and err on the side of locating their production facilities (even for goods consumed closer to home) in Asia? Factors such as the primacy of rule of law, including an efficient, objective, and transparent legal system; stability of government policy; educated workforce requirements; availability of raw materials and other inputs; tax incentives; and the location and size of final markets all affect decisions surrounding investment and the configuration of supply chains. Research focused on other sectors of production (e.g., apparel manufacturing) point to differences in transportation costs, efficient port facilities, customs procedures, and cost of electricity as differentiators weighing in favor of opting to produce in China and Asia rather than countries in Latin America.

Long-standing policy issues, including high levels of trade protection and stifling, unpredictable regulatory regimes, have restrained many countries in Latin America from achieving their potential. Covid-19 has made the outlook for fighting future biosecurity threats in the Americas worse. In addition to the physical toll of the disease, many micro, small, and medium enterprises were forced to close as a result of negative demand and financial shocks, pushing millions of people into unemployment and severe poverty. Across economies in the region, larger firms facing shortages of inputs and workers were idled for long periods as well.

Overcoming the toll of the pandemic in the region and preparing for a future pandemic will require broad cooperation in the production and distribution of vaccines, diagnostics, therapeutics, medical devices, and PPE, as well as significant advancements in overall biosecurity capabilities. Amid the global battle to neutralize Covid-19, CSIS sees an opportunity to reset economic trends in the medical products industry and to build new local healthcare capabilities and resilient lines of supply with trusted allies in Latin America. Also, nearshoring is not going to occur without investment, meaning it is vital create an attractive investment climate in Latin American partner countries.

2. The FDA has worked, in consultation with other federal partners, to develop a list of drug and biological product essential medicines and medical countermeasures. Device medical countermeasures are also included on the list. See: https://www.fda.gov/media/143406/download. So far, the administration has not indicated where overreliance on one foreign supplier is of concern.
The protection of intellectual property (IP) rights in the United States and Europe was key to the rapid development of vaccines capable of most effectively neutralizing the disease, upon which the whole world is now depending. Following the pandemic, crafting frameworks of improved IP protection and enlightened regulation will be key to two goals: (1) preserving the incentives needed to innovate vaccines, diagnostics, and therapeutics capable of vanquishing the next pandemic; and (2) spurring the economic development and employment necessary to rebuild livelihoods for populations suffering widespread dislocation and disruption caused by the current disease. Overall, taking a more affirmative approach to the region, as a way to improve the security and dependability of medical supply chains and offset growing Chinese influence, will require new policies to support foreign investment, particularly in countries that seek to improve their capacity to respond more effectively to future pandemics.

**Identifying Trusted Trade Partner Networks**

In line with the U.S. security goal of moving some targeted manufacturing for supply chains from Asia closer to home and engaging with regional allies, CSIS highlighted four strong candidates—Mexico, Canada, Colombia, and Brazil. CSIS discussed with interviewees why their government policies and economic environment make them appropriate candidates for USTR negotiators and FDA officials to offer to work out a trusted trade partner economic relationship. Acknowledging the differences in regulatory structures in each of these countries provide a better understanding of the underlying conditions that make certain markets more attractive for investing in secure medical supply chains, as well as what it would take to develop a more detailed “friend-shoring” strategy.

First and foremost in the criteria for choosing trusted trade partners is the existence of a mature trade relationship with the United States. All interviewees agreed that this is best defined by a free trade agreement (FTA) or, at a minimum, the more limited Agreement on Trade and Economic Cooperation (ATEC), as seen in Brazil’s case. To succeed in the post-Covid environment, the World Bank urges middle income countries to commit to the overall goal of “global value chain liberalization.” The bank emphasizes the importance of “streamlining nontariff, behind-the-border measures to reduce the costs of trade,” such as through mutual recognition of testing and conformity assessment for product standards for PPE.

In the medical device sector, trusted trade partners should increase reliance on international standards and adhere to the obligations of the WTO Technical Barriers to Trade Agreement. The United States-Mexico-Canada Agreement (USMCA) and the U.S.-Brazil ATEC include strong chapters on good regulatory practices, anti-corruption, and trade facilitation, which stand as important updates to the U.S.-Colombia FTA negotiated in 2006. Willingness to engage in new formalized government-to-government and government-to-industry avenues of information sharing regarding stockpiles of essential products, production capacities, and new manufacturing facilities under consideration should be a big consideration when choosing a trusted trading partner.

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Another key criterion for choosing trusted trade partners is the primacy of rule of law. According to the World Justice Project, which maintains data on rule of law around the world, Canada performs highest among the case studies. Canada ranked 12th in the world in 2016 and had improved to 9th by 2020. Each of the other
case study countries experienced some degree of backsliding. In 2016, Colombia ranked 71st but fell to 77th in 2020. Brazil ranked 52nd in 2016 but fell to 67th in 2020. Mexico performed the worst among case studies, ranking 88th in 2016 and sliding to 104th in 2020, ranking just above Mali. The United States, meanwhile, fell from 18th to 21st during the same period. Except for Canada, these countries have significant work to do in this area if they are to become attractive candidates for trusted partnerships.

Table 1: Case Study Country Assessments

<table>
<thead>
<tr>
<th>Country</th>
<th>OECD member?</th>
<th>FTA with the United States?</th>
<th>Satisfactory rule of law?</th>
<th>Satisfactory IP protections?</th>
<th>Susceptible to sudden political changes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mexico</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>Colombia</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>Brazil</td>
<td>Accession pending</td>
<td>No</td>
<td>No</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Source: Author’s research and analysis based on multiple sources.

Other elements of being a reliable supply chain partner include:

1. An improving local economic and legal environment with higher levels of IP protection;
2. Respect for WTO obligations, including rules governing technology transfer, which is a particular drawback in China;
3. A genuine interest in fostering collaboration with the United States, combined with a willingness to embrace new models for public-private cooperation and partnerships on research and development (R&D) and clinical trials;
4. An “all-of-government” approach to expanding regulatory capacities in the healthcare sector aimed at adopting international norms;
5. Full implementation of the WTO Trade Facilitation Agreement and support for other initiatives aimed at aiding the flow of critical goods, such as the potential Trade and Health Initiative; and
6. A true desire to adopt new policies to foster increased production of medical devices, pharmaceutical goods, and PPE in the Western Hemisphere through reforms to the overall business environment.

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3. The WTO’s Trade Facilitation Agreement (TFA) entered into force in 2017 and is designed to reduce bureaucratic red tape that can restrain trade. The TFA streamlines the release and clearance of goods, harmonizes processes and standards for trade, and assists with implementing provisions by providing technical assistance to developing countries.
SUGGESTED CRITERIA FOR COUNTRIES ELIGIBLE FOR A TRUSTED TRADE PARTNER RELATIONSHIP WITH THE UNITED STATES*

To be considered a trusted partner, foreign governments should meet the following criteria:

▪ Agree to seek regulatory alignment/cooperation on manufacturing standards and drug and device approvals, including through mutual recognition agreements (MRAs) negotiated by USTR and FDA[^1]

▪ Negotiate lower tariff rates on pharmaceuticals and medical goods

▪ Join the WTO Pharmaceutical Agreement 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 trusted partner countries and/or maintain membership in the WTO Government Procurement Agreement

▪ Maintain satisfactory rule of law[^2]

▪ Maintain satisfactory intellectual property protection[^3]

▪ Maintain robust investment guarantees[^4]

▪ Fully implement the WTO Trade Facilitation Agreement and put in place mechanisms to ensure compliance with the commitments they have undertaken

Trusted partners should exemplify “trust and reliability,” as measured by:

▪ Their national security relationship with the United States, taking into consideration their historic defense relationship with the United States and treatment as either a “friendly country” as used in the Arms Export Control Act or as “allies and partners” as used in National Defense Authorization Act laws[^5]

▪ Their status as a U.S. FTA partner, or in the case of Brazil, an updated ATEC

Trusted partners should prioritize 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 circumstances of shortages deemed to threaten national security, countries should commit to maintain transparency and to impose the least trade restrictive measures possible.

Trusted partners should pledge to cooperate and share information during crises.

▪ Cooperation and information sharing should occur on the research, development, approval, manufacturing, and distribution of new drugs to respond to disease outbreaks. This cooperation should not require the sharing of business secrets and other proprietary information. The NIH Accelerating Covid-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership offers a model for future cooperation among trusted supply chain governments and companies.

▪ Cooperation and information sharing should also occur with regard to disease outbreaks and existing treatments for these infections.
*This text box was adapted from a previous CSIS report on trusted trade partner networks and secure medical supply chains. The full report can be accessed here.

[1] The FDA can negotiate MRAs, and has with the European Union, which 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 by, in the case of the European Union, observing the EU Joint Assessment Process (JAP) of each member state’s inspectorates and sitting in on member state investigators’ inspections.

[2] For example, 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.

[3] This includes strong rights, guarantees, and protections in the following categories: patents, trade secrets, ability to commercialize IP assets, and enforcement. Additionally, it includes a transparent, objective, efficient, and independent mechanism to settle disputes regarding enforcement of IP rights and investment (preferably a local remedy).

[4] National treatment and restrictions on expropriation with adequate compensation if expropriation does occur as a baseline.

[5] “Friendly countries” generally include countries to which the United States exports defense articles and services. “Allies and partner countries” generally include countries with formal defense agreements or defense cooperation relationships with the United States, evidenced by expenditure of U.S. defense funds.

Country Profiles

MEXICO

The USMCA, which modernized the North American Free Trade Agreement (NAFTA), continues NAFTA’s zero-tariffs policy and includes the highest-standard trade rules negotiated by the three countries. Chapters on good regulatory practices and anti-corruption have been embraced by exporters in the medical sector as raising the bar considerably. Earning overwhelming approval by Congress, the USMCA stands as the most comprehensive tripartite legal structure with which to support the propagation of secure medical supply chains on the continent in the post-pandemic environment. Entering into force July 1, 2020, the USMCA includes commitments on IP rights and digital trade. At this time, it is not readily apparent how the USTR will use the USMCA to achieve improvements in securing medical supply chains to prepare for the next pandemic. As mentioned, the bilateral U.S.-Mexico High-Level Economic Dialogue (HLED) recently agreed to establish a working group to identify specific sectors to “promote competitiveness, attract investment, and reduce vulnerabilities in critical sectors.” Concrete results on this agenda, as it relates to the medical supply sector, should be a priority.

Mexico is home to the second-largest pharmaceutical market in Latin America and the twelfth-largest globally. In 2019, the country’s wholesale pharmaceutical industry reached a revenue of approximately $8.4 billion. By 2028, Mexico is projected to reach over $13 billion in pharmaceutical sales. Mexico produces several types of medicines, including antibiotics, anti-inflammatories, and cancer treatments. Mexico also supports significant local production of active ingredients and finished products. As the largest exporter of medical devices in Latin America, Mexico plays a major role in the North American medical technology supply chain—a supply chain which suffered significant disruptions during the pandemic due to uncoordinated plant shutdowns in Mexico.

Overall, Mexico was the United States’ second-largest goods export market in 2020. In 2020, the United States was also Mexico’s top source of foreign direct investment, with $100.9 billion, or 39.1 percent of all inflows (stock) to Mexico, representing a 5.2 percent increase from 2018. Moreover, uncertainty about contract enforcement, insecurity, informality, and corruption continue to hinder sustained Mexican
economic growth. Recent efforts to reverse the 2014 energy reforms and the constant attacks on autonomous and electoral organizations further increase uncertainty.

Twenty of the twenty-five largest pharmaceutical companies in the world have operations in Mexico. These include Merck, Schering Plough, Boehringer Ingelheim, Pfizer, Bayer, AstraZeneca, GlaxoSmithKline, and Roche. Recently, the robustness of the industry has also been favored by improvements in regulation, production practices, and drug approvals. From 2005 to 2014, the United States was also Mexico's largest foreign investor in this sector. Production costs in the industry are estimated to be 17 percent lower than those in the United States and the lowest among Organization for Economic Cooperation and Development (OECD) members.

While a trusted trading partner at some level, bilateral trade frictions with Mexico are deep and growing, and there are significant hurdles in advancing trade relations. For example, the biopharmaceutical industry is struggling to operate in Mexico in the face of a highly unpredictable business environment riddled with significant trade barriers that the Mexican government seems unwilling to address. Formative obstacles for businesses, including security concerns, endemic corruption, low labor productivity, and availability of suitable suppliers, have persisted for years. On the World Bank's Ease of Doing Business Index, Mexico ranked 60th out of 190 countries, just above Bulgaria. This is a significant step down from 2016, when Mexico ranked 47th.

Mexico has recently undertaken a few initiatives to become a more attractive destination for investment in the medical industry. The country's General Import and Export Taxes Law was amended in July 2020 to provide tax exemptions on exports. In February 2021, this law was further amended to make both the import and export of vaccines tax-free. In April 2022, the Mexican government is set to release its National Pharmaceutical Policy, which will be telling in how it plans to address innovation and supply chain issues in the industry. This new policy is intended to mitigate problems that have plagued the country's domestic pharmaceutical industry, including a lack of a harmonized legal framework and an insufficient national plan.

Seemingly in violation of its government procurement commitments in the USMCA, Mexico rolled out an ambitious plan to centralize government procurement in an effort to root out corruption. It also recently revised its federal procurement law to bypass the public bidding process envisioned in the agreement, in favor of outsourcing its procurement for health products to the United Nations Office for Project Services (UNOPS). As a result, U.S. manufacturers have seen significant operational challenges with the new process, including a lack of transparency in how the procurement process works, no meaningful engagement from Mexican officials that would provide more clarity, little coordination between UNOPS and Mexican government agencies, and ongoing logistical barriers that limit users' ability to accept procured goods. These issues are disrupting the flow of medical products to Mexican patients and are causing real payment challenges for U.S. manufacturers.

Mexico's Federal Commission for Protection against Sanitary Risk (COFEPRIS) has a serious backlog of procedures and approvals that stretches to back more than 10 years, affecting U.S. manufacturers and patients who suffer from the lack of availability of treatments. In Mexico, it takes 4.3 years on average for an innovative drug to become available in public hospitals, and the time to obtain a registry in 2021 was 57 percent longer than it was in 2018. Some U.S. manufacturers do not get approved in a timely fashion, while others do not get approved at all. Moreover, there is currently a serious backlog of COFEPRIS authorizing clinical trials and approving new medicines, including 36 clinical trials and 11 new medicines awaiting action, all of which have long been approved in other countries. This costly situation for industry is exacerbated by the limited communication the biopharmaceutical industry has with the agency.
Improvements in getting U.S. medicines into the hands of Mexican patients through quicker approvals would put Mexico on the radar of biopharmaceutical and active pharmaceutical ingredient companies looking to “friend-shore” to Mexico from China or other Asian countries. If Mexico is serious about working with the United States on supply chain resiliency, it should address the issues affecting the ability of U.S. manufacturers to operate successfully in Mexico. Indeed, in a recent letter sent to the USTR, Senate Finance Committee leaders Ron Wyden (D-OR) and Mike Crapo (R-ID) note that “USMCA requires that marketing authorizations be done reasonably, objectively, impartially, and transparently. . . . COREPRIS appears to be contravening these requirements, resulting in severe delays for approval of U.S. pharmaceutical products.”

Over the last three years, Mexico has also failed to enforce the biotechnology provisions laid out in the USMCA, threatening U.S. agricultural businesses and Mexican food security. In late 2021, Congressmen Adrian Smith and Jim Costa led over 70 members of Congress in sending a letter to President Biden expressing concerns about the biotech provisions of the USMCA being ignored by Mexico. The letter also calls attention to the lack of approvals for cutting-edge U.S. biotechnology products and President Lopez Obrador’s announced intent to phase out certain biotechnologies, which could signal potential rejection of current U.S. products held up in the approval process. Though agriculture is central to these concerns, lack of approval for biotechnical products has ramifications for biopharma medical products and begs questions about Mexico’s willingness to comply with additional market access and investment security provisions if the United States were to involve Mexico in a trusted partnership supply chain relationship. Congress has made clear that full implementation of the USMCA is of the highest priority.

The United States has advocated for increased transparency of government procurement regimes as a way to fight endemic corruption in Mexico, including under the USMCA and the WTO Government Procurement Agreement, which contain requirements for participating governments and their relevant procuring entities to avoid conflicts of interest and prevent corrupt practices.

In the post-pandemic era, current capacity and future private sector investment in the production of essential healthcare products in the United States and Mexico should be conceived of and supervised by governments with a view toward strengthening a regional manufacturing platform. While announcing discussions in the HLED between the United States and Mexico on the topic of securing medical supply chains is a positive move, it is important to make identifiable progress soon. Once the U.S. Department of Health and Human Services has prioritized the top 20 or 25 medications, medical devices, and items of PPE where supply chain diversification to the Western Hemisphere should be improved immediately, the HLED should task regulatory agencies in the United States and Mexico to work with the private sector to see what new investment in production capacity might be possible. Public and private sector collaboration should be aimed at the development of a practical plan. This should include the joint promotion of new, predictable production capacity in Mexico that could supplement production capacity reshored to the United States due to Buy America incentives.

Hurdles related to regulatory reform and improving the investment climate in Mexico will be enormous. It may be, however, that the Mexican government, recently under heavy domestic criticism for severe shortages of a wide variety of critical medicines, including cancer treatments, may want to turn over a new leaf. Mexico may see new value in being viewed as a trusted manufacturing platform and promising clinical trial environment for pharmaceuticals and other healthcare products.
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**CANADA**

Along with the sobering realization in Canada that vaccines and therapeutics for the pandemic were sourced almost completely from pharmaceutical firms innovating and manufacturing elsewhere, the pharmaceutical sector is now seeing renewed investment and steady growth after a long period of decline. Since the onset of Covid-19, Canada has invested in building both resiliency and capacity in its domestic biomanufacturing sectors for the specific purpose of future pandemic preparedness.

Canada scores relatively well on the World Bank’s Ease of Doing Business Index, ranking 23rd worldwide in 2020. The pharmaceutical sector has a global market share of 2.1 percent and is the ninth-largest in the world, touting a five-year compound annual growth rate of 2.4 percent. This growth is largely the result of new policies for prioritizing biomanufacturing development, externalizing R&D costs through government partnerships, certain policies to encourage investment from multinational pharmaceutical and biotech firms, and expanding clinical trials carried out by pharmaceutical firms. These factors, coupled with Canada’s growing geriatric population, extensive public healthcare spending, and sound processes for regulating medical devices make it a candidate for a trusted trade partnership model.

The Canadian health and biosciences sector has grown at a rate of **4 percent from 1995 to 2017**, and Canadian government policy aims to grow the number of firms in the sector from roughly 900 to 1,800 by 2025, focusing on high-growth firms. Key companies currently dominating the Canadian pharmaceutical market include Johnson & Johnson/Actelion, AbbVie, Novartis, Merck/Cubist, and Pfizer/Hospira. Multinational corporations are drawn to the Canadian government’s tax incentives and available funding opportunities.

Announced in July 2021, the **Biomanufacturing and Life Sciences Strategy** is the primary national policy aimed at strengthening Canada’s domestic biomanufacturing. The strategy has five pillars: (1) building strong coordinated governance; (2) strengthening research systems and talent pipelines; (3) growing business by enhancing emerging areas of strength; (4) building public capacity; and (5) enabling innovation by ensuring world-class regulation. The first pillar seeks to ensure rapid decision-making is possible with open, reliable access to expert information. The second pillar supports training and research opportunities, from universities to hospitals, to bolster education for future scientists and researchers. The third pillar leverages Canada’s Strategic Innovation Fund to close gaps in the country’s biomanufacturing supply chain. In the fourth pillar, the government seeks to take advantage of a new facility aimed at producing new biologics and vaccines of the future. Lastly, the fifth pillar attempts to harmonize regulations of biomanufacturing with the priorities of new life science firms to make Canada an attractive destination. The plan is set to receive $2.2 billion CAD ($1.7 billion USD) in funding over the next seven years.

While the government of Canada has committed significant financial support for the biomanufacturing and life sciences industries, it is unclear whether there will be lasting improvements in the post-pandemic
regulatory environment supportive of new private sector investment. Canada made strides in improving its IP environment by agreeing to provisions in the EU-Canada Comprehensive Economic and Trade Agreement agreement and the USMCA’s robust IP provisions. However, the Special 301 Report still leaves Canada on the “Watch List.” The report notes that IP concerns in Canada relate to poor enforcement regarding pirated and counterfeit goods at the border and within the country, deficient patent protection processes, and hostile patent and pricing environments for innovative pharmaceuticals.

The Canadian health technology assessment and price negotiation processes affect Canada’s attractiveness for pharmaceutical investment. The Special 301 Report specifically cites concerns about regulatory changes to Canada’s Patented Medicine Prices Review Board, announced on August 9, 2019, and now delayed until July 1, 2022. These changes, several of which are under challenge in Canadian courts, will reshape how the board evaluates patented pharmaceuticals and sets price ceilings. The changes are expected to lower overall price comparisons and thus the overall biopharmaceutical price level in Canada while adding complications to the reimbursement process. Viewed by the industry as damaging to innovation, the changes, depending on how they are finalized, can be expected to reduce the introduction of new medicines in Canada. Drug approvals in Canada often occur after those in the United States and European Union, in part because they are often submitted later by drug companies who view Canada as a relatively small market with a less “collaborative” regulatory environment.

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While the cost of labor is more expensive in Canada than the other three countries studied, it is an attractive location for reshoring due to the Canadian government incentives described above and the familiar culture, which makes it relatively easy for U.S. multinationals to navigate the market. The USMCA adds to the overall umbrella of security and predictability, including relatively straightforward recourse to dispute settlement proceedings when market access barriers do arise.

Citing public-private cooperation across the three USMCA countries on development of the new Biodefense Indoor Air Protection Systems (that traps the Covid-19 virus), Canadian trade minister Mary Ng observed: “Bolstering our deeply integrated supply chains, and decades-long collaboration through CUSMA (USMCA), will reinforce our domestic economic security and ensure that the prosperity that flows from international trade begins here, with our North American partnership, and continues to benefit our businesses, industries, people and communities.” A founding member of the Ottawa Group of advanced economies in the WTO, Canada has shown global leadership in efforts to champion open trade and supply chains for critical medical goods.

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4. The Special 301 Report is a congressionally mandated annual review of IP rights protection and enforcement across various countries. Countries that are classified as being under the Watch List represent those that merit bilateral attention to address underlying IP issues.
COLOMBIA
A strong U.S. ally, Colombia has enjoyed economic growth of 4.8 percent annually over the past five years, making it one of the fastest growing economies in Latin America. According to the State Department, Colombia’s greatest incentive for investment is perhaps its strategic location between South, Central, and North America, as well as its access to the Pacific and Atlantic Oceans. Colombia is unique in the region for its resilient institutions, private sector commitment, and overall stability that earned it membership in the OECD in 2020. In 2019, Colombia scored 67th out of 190 countries on the World Bank’s Ease of Doing Business Index, a decline from 53rd in 2016. 

Colombia’s pharmaceutical industry is substantial, ranking as the third largest in Latin America. In 2018, over a quarter of Colombian pharmaceutical sector exports were produced by multinational companies. In 2019, these exports grew at a rate of 10.8 percent compared to the previous year, underscoring the existing foreign investment and trade infrastructure that makes Colombia a suitable candidate for increased supply chain coordination with the United States. Exports from the pharmaceutical sector in 2019 reached a value of $358.4 million, while the pharmaceutical market in Colombia was worth $4.8 billion. That same year, production reached an estimated value of $2.9 billion, led by digestive and metabolic health products.

Strong government spending on healthcare (9 percent of GDP in 2020) and one of the highest health insurance coverage rates in South America help create a robust market for domestic consumption. Many American medical supply companies hold market share in Colombia, including Pfizer, Janssen, Novartis, Merck, and Unilever. However, Colombia continues to rely heavily on imports of medical goods, which in 2018 accounted for roughly 80 percent of the country’s medical device market. One study found that “input costs, logistic costs, previous experience and institutional environment affect the Colombian pharmaceutical sector’s exports.” The study also finds that the sector’s reliance on imports of raw material leads to “the domestic industry’s lack of initiative to increase domestic production of raw materials.”

The impact of China’s economic outreach to Colombia is evident in the increasing levels of bilateral trade and investment. China now ranks ahead of the United States as an import partner with Colombia. Colombia’s import partners in order are China (26.1 percent of total imports), the United States (22.9 percent), Mexico (6.1 percent), and Brazil (5.3 percent). Year-to-date imports recorded a 49.9 percent increase compared to the same period last year, jumping to $6.2 billion. Investments from China are concentrated in the oil and gas sectors and have been increasing at a slow but steady pace in recent years. In 2000, China ranked as Colombia’s 37th-largest trading partner, but by 2022 China was Colombia’s most important trading partner, mirroring an overall uptick in China’s commercial activity in the Latin American region.

The United States is Colombia’s second-largest trade partner. The United States-Colombia Trade Promotion Agreement (CTPA), negotiated in 2006 and implemented in 2012, provides a strong foundation upon which to explore an updated trusted trade partner relationship. The CPTA ensures predictability and stability in terms of applicable tariffs and substantive obligations on market access, labor and environmental standards, and investment. Further monitoring and enforcement of the labor and environmental chapters of the CTPA offer a mutually agreed negotiating structure to promote respect for good labor practices and sustainability in supply chains. Labor and environmental obligations are subject to the same dispute settlement and enforcement mechanisms as commercial obligations.

The CTPA provides for greater protection of IP rights through improved standards, including requirements for robust patent and test data protection that respect the WTO Doha Declaration on the TRIPS [Trade-
Related Aspects of Intellectual Property Rights Agreement and Public Health. The CTPA also requires the establishment of procedures to prevent the marketing of pharmaceutical products that infringe on patents.

In 2018, Colombia was designated a “Priority Watch List” country by the USTR, but the country was upgraded to Watch List status by the USTR in 2019, indicating at least some improvement in terms of IP enforcement. However, the 2021 Investment Climate Statement on Colombia by the U.S. Department of State notes that “U.S. stakeholders continue to raise concerns about Colombia’s regulation of the pharmaceutical sector, where regulatory barriers, a focus by the government on cost containment over health outcomes, delays in processing pharmaceutical registrations at INVIMA, and Congressional proposals to limit pharmaceutical IP restrict market entry and reduce the attractiveness of Colombia as a place to invest and do business.”

Colombia has more than 60 FTAs, including with the United States, the European Union, and European Free Trade Association countries. These agreements with countries around the world create a global network of open trade, emblematic of Colombia’s receptivity to international collaboration and improving its regulatory environment.

Overall, Colombia’s legal system is transparent and largely adheres to OECD norms. Colombia lags in the category of trade across borders, ranking behind Mexico, Brazil, and Argentina, highlighting that targeted regulatory changes could make it a more competitive partner within the Western Hemisphere. Although Colombia ratified the WTO Trade Facilitation Agreement (TFA), its World Bank scores remain low in the categories of import and export border compliance, underlining the importance of implementation of TFA commitments, particularly as they relate to ports. The TFA includes important provisions on accepting customs documents in electronic format, which should accelerate customs clearances. Recently the Global Alliance for Trade Facilitation introduced a risk management system for imports of medicines and medical devices at INVIMA, Colombia’s sanitary agency. The end result of the project has been to reduce physical inspections of such products (and several others under INVIMA’s purview) by 34 percent.

While there is room for progress in terms of Colombia’s fulfillment of TFA commitments, the existence of well-functioning special economic zones (SEZs) in the country makes it a suitable candidate for nearshoring. SEZs are geographically delineated areas for the purpose of customs law that offer benefits for investors operating within the zone. The zones can be designed to be (1) free trade zones (duty-free areas offering warehouse and storage facilities); (2) export processing zones (primarily aimed at foreign markets); (3) comprehensive special economic zones or industrial parks (zones that have different industries and service operations); (4) bonded areas (bonded warehouses for storage of goods without payment of duties); (5) specialized zones (science and technology or logistics parks); or (6) eco-industrial zones (focused on waste reduction and improving environmental performance). Host countries usually welcome foreign partners to share development costs, exchange information and expertise, and enhance opportunities for foreign investments.

According to the World Investment Report 2019 on SEZs, Latin America and the Caribbean have 486 SEZs, of which Colombia has 39, including 14 healthcare free trade zones and 8 health sector clusters. While forming new SEZs would enhance the competitiveness and attractiveness of the entire region for U.S. nearshoring initiatives, the existence of SEZs specific to the medical sector makes Colombia a particularly attractive partner for closer supply chain collaboration.

A persistent problem in Colombia, however, is the inconsistency of drug pricing. In Colombia, a government authority, the National Price Commission of Pharmaceuticals and Medical Devices (CNPMDM,
or Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos) determines drug pricing, including for both public and private markets. Rather than implementing uniform prices, the commission takes a subjective approach to evaluating these markets and has received significant criticism for a lack of transparency in its processes. Furthermore, Colombia’s Ministry of Health has institutionalized price controls throughout the medical market. It has put thousands of medical products under price controls, including adding 770 products to the price control list in 2020 and another 88 products in 2021. Since 2013, Colombia has followed an international price referencing methodology for pharmaceuticals reimbursements that compares drug prices of innovative and competitive medicines with prices in 17 other countries. Of significant concern to industry is a new methodology, currently under consideration, to lower reimbursement rates by taking into account generic drug prices in the definition of control prices and modifying the list of countries used for determining prices.

On January 27, 2020, the Ministry of Health ordered the CNPMDM to implement a price ceiling on 1,800 medications and chemical compounds. Pharmaceutical Research and Manufacturers of America (PhRMA) found that the drug pricing scheme was both arbitrary and nontransparent. PhRMA has also found that Colombia’s pharmaceutical sector policies suffer from substandard biologics regulation, new drug pricing methodologies that depress prices, and increased regulatory barriers resulting from the country’s National Development Plan, enacted in 2015. Creating a more uniform pricing system and updating domestic regulations to better adhere to global best practices would make Colombia’s pharmaceutical exports more competitive.

Unrest paralyzed the country in April 2021, and throughout the year Colombia experienced protests over government changes, primarily relating to tax increases, healthcare reforms, and government corruption. Across Latin America, anger about growing inequality, slowing economies, and the response to the pandemic has put left-wing governments in power in Honduras and Chile. The outcome of the presidential election in Colombia, to be held May 29, 2022, also presents the potential for an ideological swing from right to left, with a corresponding shift to less market-oriented policies and more trade protection. However, despite the political uncertainty, a report by the Atlantic Council’s U.S.-Colombia Task Force, chaired by Senators Ben Cardin (D-MD) and Roy Blunt (R-MO), found that “Colombia is uniquely positioned to receive nearshoring investments from U.S. companies looking to divest from Asia to reduce risks of future trade wars or other disruptive events like COVID-19.”

**BRAZIL**

Brazil, the world’s sixth most populous country, is the largest market in Latin America and the seventh-largest pharmaceutical market in the world. It presents a market opportunity on the scale of China for biopharmaceutical industry expansion. Brazil’s pharmaceutical market has a global market share of approximately 1.8 percent and a market value of nearly $21 billion in drug production. The medical products industry is important for Brazil’s economy in terms of value added and employment generated. Brazil has the potential to be a supplier of medical products throughout the region, including to the United States. In 2019, the pharmaceutical industry reached a production value of more than 46 billion Brazilian reals ($9.6 billion), and the sector employed over 1 million people. Estimated to grow 9 percent a year through 2023, Brazil’s market for medical devices is expected to reach $1.8 billion by 2023. In 2019, the United States was the primary destination for Brazilian exports of medical and dental devices, which exceeded $200 million in value. Unfortunately, Brazil’s medical goods exports peaked in 2011 and have steadily declined since then.

While Brazil represents a substantial market opportunity for U.S. pharmaceutical and medical device firms, its investment environment has had long-standing, endemic problems that must be addressed.
to make it more attractive for foreign firms looking to relocate from Asia to Latin America. One major disincentive is Brazil’s negative history with foreign ownership rules that forbid foreign investment in the health sector. In 2015, Brazil passed a law liberalizing foreign investment in the sector, but today Brazil’s pharmaceutical industry continues to have strong national companies. Aché Laboratorios Farmacéuticos S.A., which is 100 percent Brazilian-owned, earned approximately 3.5 billion Brazilian reals ($730 million) in revenue in 2020, an increase of nearly a third compared to 2015.

Altogether, the tax regime, political instability, and regulatory environment in Brazil make it a relatively unattractive host for foreign investment and partnerships despite its large market for medical products and considerable customer base. Brazil’s corporate tax rate is 15 percent, but it also taxes imports, exports, transactions, properties, services, income, and other assets. This taxation system is incredibly complex and burdensome, meaning tax reform would make the country more attractive for foreign investment. Brazil ranks 124th out of 190 countries in the World Bank’s Ease of Doing Business Index, just below Senegal. For comparison, Brazil ranked 123rd in 2016, underscoring persistent policy problems in the country. Despite its low score, the World Bank heralds Brazil’s progress elsewhere, particularly on cultivating a more advanced workforce. A World Bank study found that Brazil has benefited from a “demographic dividend” that saw higher numbers of increasingly educated people join the workforce. The report cautions, however, that Brazil’s productivity continues to lag compared to other Latin American countries and other regions and argues that Brazil must continue to institute additional structural reforms to ensure labor force competitiveness.

The elements of trust in the U.S.-Brazil trade relationship are sorely lacking when compared to Colombia or USMCA partners. However, a recent improvement has been the signing, on October 19, 2020, of a protocol that upgrades the ATEC, which was originally signed in 2011. As modernized by the protocol, the ATEC includes provisions similar to the USMCA on trade facilitation and customs administration, good regulatory practices, and anti-corruption. Once implemented, the protocol will reduce red tape in Brazil and improve regulatory processes, as well as serve as a foundation for bilateral engagement for improving mutual health and supply chain security in a future pandemic.

Regarding IP protection, Brazil has not taken on commitments beyond what is required by the WTO and in many areas is not even implementing its existing WTO obligations, representing a severe drawback. Patent protection policies for pharmaceuticals and protection of clinical trial test data submitted as a condition for marketing approval is lacking. While Brazil recently eliminated the prior consent requirement in the patent review process, the Brazilian supreme court revoked Article 40 of the Intellectual Property Law Statute, which provided a 10-year patent term extension. Affecting over 10,000 patent applications, this move weakens Brazil’s patent standards and only applies to pharmaceutical products and medical devices, violating nondiscrimination provisions in the WTO TRIPS Agreement.

On the positive side, the Brazilian Patent Office adopted a patent backlog plan in 2019 with the aim of eliminating the huge backlog in processing patent registrations, though the backlog of pending applications from the pharmaceutical industry has yet to improve. Important IP rights, including term restoration and regulatory data protection, are missing in Brazil. Moreover, Brazil is often cited for its need to enhance efforts to combat counterfeiting and piracy. Nonautomatic and nontransparent import licensing requirements and high tariffs hamper the export of U.S. pharmaceutical and medical products to Brazil.

Brazil also has a complicated relationship with IP enforcement actions under consideration by the United States. One of the largest users of preferential duty-free tariffs in the United States, Brazil has been on the
USTR's Special 301 Watch List since 2007. Brazil would be vulnerable to trade sanctions under Section 301 of the 1974 Trade Act were a case to be filed. U.S. trade law allows for the imposition of unilateral sanctions (usually a withdrawal of tariff benefits) for failure to maintain a sufficient standard of IP rights protection.

A new public procurement law was enacted in April 2021, and Brazil has also entered negotiations to join the WTO Government Procurement Agreement. Both the old and new procurement laws allow preferential treatment for Brazilian companies, which can disincentivize U.S. investment in the country. There are price preferences for locally manufactured products, and being a Brazilian company is a tie-breaking criterion in terms of winning procurement contracts.

The Brazilian presidential election in October 2022 will likely put President Jair Bolsonaro in a close, politically polarized contest with former president Luiz Inacio Lula da Silva of the leftist Workers' Party. If he wins, Lula could be expected to return to higher state spending and taxes, trade protectionism, and possibly a reinvigorated political and economic alliance with China. The current competitive political environment in Brazil may prompt President Bolsonaro to accelerate moves to reduce the level of Chinese involvement in the economy and establish an improved regulatory environment for medical supply companies seeking to reshore some production facilities closer to the U.S. market. The elections will occur against a backdrop of deep social and economic change in Brazil, including the damaging impact of the pandemic on the most marginalized citizens of Brazil.

The current competitive political environment in Brazil may prompt President Bolsonaro to accelerate moves to reduce the level of Chinese involvement in the economy and establish an improved regulatory environment for medical supply companies seeking to reshore some production facilities closer to the U.S. market.

To incentivize new investment in the healthcare sector in Brazil for a population struggling with the painful effects of the pandemic and to reduce uncertainties and disruptions related to future U.S. sanctions for lax IP protection, the Bolsonaro government may be willing to consider an ambitious negotiation to reset U.S.-Brazil trade relations in this sector, perhaps in the context of enhancing the newly minted ATEC. Ongoing negotiations for Brazil to join the OECD offer another possible venue to achieve commitments to improve the investment environment. Currently, OECD members are developing an accession roadmap which will incorporate priority objectives for each country. This could include addressing patent term extension, nonautomatic import licensing requirements, and regulatory data protection.

Having suffered severely during the pandemic, observers see strengthened political will in Brazil to build the local capacity capable of better addressing the next pandemic. The U.S. Chamber of Commerce points out that the Brazilian government is actively studying the impact that IP rights have on national economic output and development. In May 2021, the government released an assessment of the contribution of Brazilian IP-intensive industries to national GDP, employment, and exports. In the most recent three-year period available, these industries were found to contribute 44.2 percent of gross total value added, while employing over 19 million Brazilians, or 36 percent of the workforce.

Considering improvements in IP protection and the investment climate in Brazil, it is possible that the country, given the adoption of the right policy reforms, may one day stand as an attractive global platform.
for the production and distribution of vaccines and other medical products, not only for its own population but to the United States and the region.

Conclusion

The ongoing pandemic and the aggressive posture of China in making economic inroads in Latin America—whether through offering vaccines, providing concessional financing for infrastructure projects, or making large, reliable purchases of Latin American commodities—has forced the United States to review its domestic policy frameworks, FTAs, and regional markets. With the U.S. government now on wartime footing, improving the health security of Americans through increasing diversity of international supply of medical products will continue to be a key U.S. strategic objective. It can be expected, however, that actual improvement—meaning an expansion of U.S. trade and economic ties within the Western Hemisphere—will only be undertaken with close trading partners in the region who display a genuine, organized enthusiasm for moving their trade relationship with the United States to a new level of reciprocal benefits.

Close trading partners of the United States, such as those considered here, need a plan for incorporating their economies into readjusting global supply chains. With a plan in hand, they should consider reaching out diplomatically to the USTR with the offer to work together on bilateral government policies aimed at more diversification and redundancy of critical medical supplies. The United States should explore what support it can offer for a trusted trade partner committed to growing its own healthcare delivery capacity to be better prepared for a future pandemic.

Since the Biden administration has determined that onshoring is not realistically possible for all medical products, these countries are reasonable candidates for companies looking to build diversification and resilience into their supply chains. Proximity, a benefit now more attractive in the post-Covid economy, includes the feature of shorter, more sustainable transit times as compared to Asia.

Close trading partners of the United States, such as those considered here, need a plan for incorporating their economies into readjusting global supply chains.

In many ways, the climate for expanding trade and investment with these four countries is favorable and improving. The United State has a sophisticated system of FTAs in the hemisphere that stand as sturdy platforms upon which to add expanded commitments through mutual agreement. One or more of the four countries could be incentivized into exploring a trusted trade partnership by leveraging the following:

1. FTAs and the updated U.S. Brazil ATEC
2. U.S. expertise in the science and delivery of vaccines and other healthcare therapies
3. International standards for good regulatory practices
4. U.S. trade statutes including GSP and Special 301
5. The large size of the U.S. market

In particular, the USMCA and CTPA, combined with the geographic proximity of Mexico, Canada, and Colombia, make these countries particularly viable for increased cooperation with the United States. In contrast, Brazil has a longer way to go to improve its investment and tax environment enough to make trade negotiations a credible option. As Latin American experts Juan Cortiñas and Peter Schechter underscore, nearshoring opportunities vary by country within the Latin American region. However, among the case studies assessed in this paper, Colombia and Mexico are particularly strong contenders. Cortiñas and Schechter note that Colombia and Mexico “have more ingrained traditional and technological infrastructure
and close ties with the United States that make them more apt to be considered for these manufacturing changes.” Nonetheless, despite clear strengths of the case study countries—including close geographic proximity, business reforms to attract foreign investment, and recent regulatory reforms to support exports—persistent political problems endanger stability in Brazil, Colombia, and Mexico, but not Canada.

As countries assess measures to improve health security in the future, it will be important to look to strengthening IP protections and bringing regulatory structures up to international standards as the best way to support local innovation and creativity and obtain access to the latest technologies and medicines. The vaccines, therapeutics, and technologies that have led the global community through the pandemic are the fruits of an innovation ecosystem that relies on IP rights to foster incentives, allocate resources, form sound partnerships, and transfer technology on commercial terms. For example, effective IP rights facilitated hundreds of voluntary licensing agreements for vaccines that allowed the rapid scale-up of global manufacturing during the height of the pandemic. Data indicates that global vaccine manufacturing capacity will reach 24 billion doses by June 2022. Beyond vaccine manufacturing, there is an opportunity to move production of more medical products from Asia to Latin America, especially if countries make an organized effort to market themselves as trustworthy manufacturing platforms with strong protections for innovation and good regulatory practices.

While there is progress to be made in Brazil, Colombia, and Mexico on political stability, educational investments, and infrastructure, the Biden administration should conclude that encouraging private sector investment in these countries can play an important role in building more resilient supply chains for the United States. To build sustainable jobs domestically and throughout the region, as well as counter Chinese influence and enhance the security of medical supply chains, the Biden administration should ramp up international cooperation aimed at improving the security of medical supply chains.

A country’s true readiness and receptivity to be considered as a candidate for building a trusted supplier relationship can only be determined by full-scale diplomatic efforts aimed at identifying what provisions would make such a new relationship attractive for the potential U.S. partner. Effectively addressing supply chain vulnerabilities revealed during the pandemic will require the negotiation of innovative trade agreements, retooled government mechanisms based on lessons learned, and an enhanced political will to be better prepared for the next global health challenge.

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