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## BUILDING RESILIENT MEDICAL SUPPLY CHAINS THROUGH TRADE AGREEMENTS

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### INTRODUCTION

The COVID-19 pandemic has prompted policymakers to question whether economic globalization has left the United States overly vulnerable to foreign events and actions that could imperil Americans' access to essential drugs and medical equipment. Many in Congress—as well as the previous and current administrations—believe that supply chain resilience and security can only be achieved through reshoring of pharmaceutical production.<sup>1</sup> The Biden administration has blamed the private sector for sacrificing resilience in a relentless search for efficiency, and has advocated for various interventions and trade restrictions intended to improve resilience by having more drugs

1. Sen. Elizabeth Warren et al., Letter to Mark T. Esper, United States Senate, Dec. 5, 2019. <https://www.warren.senate.gov/imo/media/doc/2019.12.05%20Letter%20to%20DoD%20re%20pharmaceutical%20product%20supply%20chain.pdf>; Office of Sen. Tom Cotton, "Cotton, Gallagher Introduce Bill to End U.S. Dependence on Chinese-Manufactured Pharmaceuticals," Press Release, March 18, 2020. [https://www.cotton.senate.gov/?p=press\\_release&id=1342](https://www.cotton.senate.gov/?p=press_release&id=1342); Robert Lighthizer, "The Era of Offshoring U.S. Jobs is Over," *The New York Times*, May 11, 2020. <https://www.nytimes.com/2020/05/11/opinion/coronavirus-jobs-offshoring.html>.

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and drug ingredients be manufactured in the United States.<sup>2</sup>

But globalization has been vital to the development of America's thriving pharmaceutical industry. And evidence suggests that existing, market-driven supply chains are already highly diverse and have proven themselves remarkably resilient despite historic strain during the pandemic.

The most direct threat to resilience and security for medicines and medical supplies during the pandemic has come not from foreign sourcing but from the short-sighted actions of anxious governments. The pandemic has prompted the United States as well as its key partners in Europe and Asia to restrict trade in medical products and essential medicines to prevent or alleviate shortages. At best, these restrictions have been wasteful. Many of them have also been counterproductive by reducing the flexibility needed to respond effectively to new developments.

In June 2021, the Biden administration released a comprehensive study describing the state of supply chains in four key industries, including pharmaceuticals. The report advocates various policies to promote more domestic pharmaceutical manufacturing but also offers the vital observation that "it is not feasible, desirable, or realistic to expect every drug needed for American patients to be produced on American soil."<sup>3</sup> Indeed, the most valuable recommendation in the report is to "increase international cooperation and partner with allies to strengthen supply chain resilience."<sup>4</sup>

2. "FACT SHEET: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities," White House, June 8, 2021. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities>.

3. "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," White House, June 2021, p. 210. <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

4. Ibid.

There is an opportunity in the wake of the pandemic to strengthen the resilience and diversity of market-driven supply chains by improving trust among reliable trading partners. Building this trust will require international cooperation and negotiation of new reciprocal trade agreements.

We therefore urge Congress to renew Trade Promotion Authority with an explicit mandate to liberalize and expand trade in drugs and pharmaceutical ingredients with trusted partners in the supply chain. This would pave the way for a new trade pact we call the Secure Supply Chain Agreement, in which the United States and its allies commit to eliminate import tariffs, export restrictions, and procurement preferences while working to harmonize regulatory standards and marketing approval procedures.

The United States should also rejoin the Trans-Pacific Partnership (TPP) to improve America's access to key markets in Asia and to reduce the region's reliance on China. Rejoining the TPP would certainly promote America's leadership in the region—an economic and geopolitical imperative—but it would also give the United States an additional opportunity to strengthen pharmaceutical trade specifically by incorporating the commitments of the Secure Supply Chain Agreement within the TPP. The United States should also work to reach additional trusted partners through limited renegotiation of other existing free trade agreements. Finally, Congress should make pharmaceutical supply chains more secure by maintaining the competitive tax and regulatory environment that makes the United States an attractive place to invest.

## EVALUATING AMERICA'S MARKET-DRIVEN DRUG SUPPLY

By any reasonable standard, the United States is a pharmaceutical powerhouse. Most of the world's largest pharmaceutical research companies are based in the United States.<sup>5</sup> As a whole, the industry employs around 300,000 Americans involved in various research, administrative, manufacturing and sales activities.<sup>6</sup> In addition to supplying the majority of the U.S. pharmaceutical market—the world's largest by far—America's domestic manufacturers also ship enough U.S.-made pharmaceutical products abroad every year to make the United States a leading pharmaceutical exporter.<sup>7</sup>

The success of America's pharmaceutical industry depends

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5. Eric Sagonowsky, "The top 20 pharma companies by 2020 revenue," *Fierce Pharma*, March 29, 2021. <https://www.fiercepharma.com/special-report/top-20-pharma-companies-by-2020-revenue>.

6. "Occupational Employment and Wage Statistics," U.S. Bureau of Labor Statistics, last access June 29, 2021. [https://www.bls.gov/oes/2020/may/naics4\\_325400.htm](https://www.bls.gov/oes/2020/may/naics4_325400.htm).

7. Matej Mikulic, "World pharmaceutical sales 2017-2020 by region," Statista, March 9, 2021. <https://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region>.

on a high degree of specialization that is only possible in a global market. But it is possible this globalization has brought not just economic success but also greater vulnerability to foreign events and actions to the United States.

In its Supply Chain Report, the Biden administration laments a "private sector and public policy approach to domestic production, which for years, prioritized efficiency and low costs over security, sustainability and resilience."<sup>8</sup> They also warn that the United States is "dependent on China's continued supply of API," leaving America's drug supply "vulnerable to the geopolitical strategies of foreign governments" such that China "can leverage this dependency by interrupting the United States' access to these supply chains."<sup>9</sup>

Have private companies really sacrificed resilience in their never-ending search for efficiency? Is the United States dangerously dependent on Chinese ingredients? Finding the answer to these questions is more difficult than it may seem due to the complex nature of pharmaceutical manufacturing and the equally complex web of market-driven supply chains that have developed in recent decades.

At the beginning of the pandemic, R Street and others explained that there were significant gaps in the data available about the extent to which the United States is reliant on imports of finished pharmaceuticals and active pharmaceutical ingredients (APIs)—and urged policymakers not to jump to conclusions.<sup>10</sup> Fortunately, policymakers chose to follow that advice, seeking to discover more information about the source of medicines and APIs before taking more definitive action.

Under the terms of the first major aid package Congress passed to deal with the pandemic—the Coronavirus Aid, Relief and Economic Security Act (CARES Act)—the National Academies of Sciences, Engineering and Medicine were directed to study pharmaceutical and medical device supply chains and make recommendations on ways to improve resiliency.<sup>11</sup> Likewise, a provision tucked into the conference report of the National Defense Authorization Act of 2021 (NDAA) stipulates:

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8. "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," White House, June 2021, p. 7. <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

9. *Ibid.*, p. 230.

10. See, e.g., Clark Packard and Bill Watson, "Resisting Protectionism in the Pharmaceutical Supply Chain," *R Street Policy Study* No. 197, June 2020, p.3. <https://www.rstreet.org/2020/06/10/resisting-protectionism-in-the-pharmaceutical-supply-chain>; Jacqueline Varas, "U.S. Dependence on Chinese Pharmaceuticals is Overstated," American Action Forum, May 20, 2020; Andres B. Schwarzenberg and Karen M. Stutter, *Medical Supply Chains and Policy Options: The Data Challenge*, Congressional Research Service, Sept. 16, 2020.

11. CARES ACT, Sec. 3101.

the section of the National Security Strategy regarding the National Technology and Industrial base 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.<sup>12</sup>

Finally, earlier this year, President Biden issued an executive order mandating a 100-day review of the supply chains of certain products, including semiconductors; rare earth materials; pharmaceuticals and APIs; and advanced batteries.<sup>13</sup> Some of those studies are still being performed, but a report from the United States International Trade Commission (USITC) examining the medical supply was released in late 2020, which helps elucidate this debate and cut through the popular rhetoric.<sup>14</sup>

## GLOBAL AND DIVERSE

There are numerous factors that determine the best place to perform each step in the pharmaceutical manufacturing process. The final step in that process is the formulation of a finished drug product such as a pill, inhaler, injection or ointment that can be administered to or taken by a patient. But finished drugs are made by combining APIs and excipients (inactive ingredients used to add bulk or to improve stability or absorption). Those ingredients are themselves produced through various chemical processes from raw materials, which could be anything from bulk commodity chemicals to specialized biological agents.

Depending on the type of drug, market-driven sourcing decisions will hinge to varying degrees on regulatory environment, scalability, the relative importance of labor or capital, as well as proximity to research facilities, upstream inputs or distribution networks.<sup>15</sup> The USITC study helps capture the full range of the industry by analyzing trade data both by value and by volume.

Many of the newest and most expensive drugs are made in relatively small quantities using state-of-the-art technology. These drugs are more likely to be produced in the United

States or in other countries with significant pharmaceutical research industries. This reality is captured in the trade data when we look at the most common sources of drugs and ingredients by value.

For example, most drugs consumed in the United States, by value, are formulated in the United States.<sup>16</sup> Similarly, most of the API contained within drugs in the United States, by value, is manufactured in the United States.<sup>17</sup> And according to the USITC, the most common sources for imported pharmaceutical products, by value, are Germany, India, Ireland, Switzerland and the United Kingdom.<sup>18</sup>

On the other end of the spectrum are common, inexpensive drugs and ingredients that can be produced most efficiently in bulk quantities through labor-intensive processes at large chemical plants. These products are more likely to be produced, at least in part, in countries with a large, low-skilled labor force and a developed chemicals industry to make raw materials. That is why when counting by volume rather than value, the top source countries for the U.S. market are Canada, China, Germany, India and Mexico.<sup>19</sup>

Meanwhile, most pharmaceutical products fall somewhere in the middle of these extremes. As a result, there are a number of countries—such as Germany, India and the United States—that are significant producers of all different types of drugs at all stages.

Trying to assess the entire industry by looking only at trade measured by value gives excessive weight to the sourcing decisions for brand-name drugs sold at uncompetitive prices that do not accurately reflect their real value. Likewise, measuring only by volume risks over-emphasizing trade in products and ingredients with little true significance. For example, the USITC study notes that most API imports from China (79 percent by volume) are actually vitamins.<sup>20</sup>

Before policymakers attempt to force the repatriation of the medical supply chain through trade restrictions, it is worth examining how well it held up to the shock of the COVID-19 pandemic over the last year. According to the USITC report:

The United States has a large, geographically diverse pharmaceutical industry with established supply

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12. Meredith Broadbent, "COVID-19 Demand Shock and Preparedness Response: Securing Medical Supply Chains: The Trusted Trade Partner Network," Center for Strategic International Studies, Dec. 21, 2020, p. 23. [https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/201221\\_Broadbent\\_Covid19\\_Shock.pdf](https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/201221_Broadbent_Covid19_Shock.pdf).

13. Jim Tankersley and Ana Swanson, "Amid Shortfalls, Biden Signs Executive Order to Bolster Critical Supply Chains," *The New York Times*, Feb. 24, 2021. <https://www.nytimes.com/2021/02/24/business/biden-supply-chain-executive-order.html>.

14. Andrew David, et al., "COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges," United States International Trade Commission, December 2020. <https://www.usitc.gov/publications/332/pub5145.pdf>.

15. Janet Bumpas and Ekkehard Betsch, "Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines," World Bank, September 2009. <https://documents.worldbank.org/en/publication/documents-reports/documentdetail/848191468149087035/exploratory-study-on-active-pharmaceutical-ingredient-manufacturing-for-essential-medicines>.

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16. International Trade Administration, "2016 Top Market Report: Pharmaceuticals," U.S. Dept. of Commerce, 2016, p.8. [https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals\\_Top\\_Markets\\_Reports.pdf](https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals_Top_Markets_Reports.pdf).

17. Massey Whorley, et al., "Majority of API in US-Consumed Medicines is Produced in the US," Avalere, July 15, 2020. <https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-is-produced-in-the-us>

18. David, et al., p. 145. <https://www.usitc.gov/publications/332/pub5145.pdf>.

19. Ibid.

20. Ibid.

chains that proved resilient during the first half of 2020. The flexibility and number of manufacturing sites inherent in the global footprint of the pharmaceutical sector allowed firms to respond relatively quickly to demand and deliver additional medicines to aid in the response to the pandemic.<sup>21</sup>

The USITC further explained that, “producers have reduced the time needed to start commercial production, and generic drug producers, among others, have been providing contract manufacturing services to supplement production of some of the products currently used to treat patients with COVID-19.”<sup>22</sup> The report noted the resulting economic breakdown of these increases:

Domestic shipments of pharmaceuticals reached \$221 billion during January-September 2020, up 11 percent from the same period in 2019, and the capacity utilization at domestic plants reached 87 percent in the second quarter of 2020 (higher than any other time during January 2015-June 2020).<sup>23</sup>

However, despite these successes, the USITC also acknowledges that the response to the pandemic has not been perfect. They note: “While pharmaceutical manufacturers were able to ramp up production, there have been challenges in getting medicines to the right locations, at high enough volumes, and in the needed dosage forms.”<sup>24</sup>

Overall, rather than a hollowed out domestic manufacturing industry as too often portrayed by politicians and pundits, the USITC report highlights a robust and globally competitive domestic industry. Indeed, a recent report states: “Despite recent headlines, we find that pharmaceuticals are relatively less exposed [to shocks] than most other industries.”<sup>25</sup>

Similarly, a recent White House report laid out certain pillars to improve the supply chain, including “boosting local production and fostering international cooperation” and “building emergency capacity.”<sup>26</sup> While the overall document is heavy in its emphasis on domestic production, the section on pharmaceuticals and APIs is noteworthy in that it acknowledges, “it is not feasible, desirable, or realistic to expect every drug needed for American patients to be produced on

American soil.”<sup>27</sup> Indeed, the current arrangement—with an intricate web of suppliers all around the world—has led to dramatic price decreases for consumers.

The report continues:

[T]he United States must work with its like-minded regulatory partners to develop a secure and resilient supply chain that is not overly reliant on materials or manufacturing from countries that lack a shared interest in mutually beneficial supply chain arrangements.<sup>28</sup>

It then recommends that the United States work in bilateral and multilateral forums to strengthen pharmaceutical and API supply chains. This is exactly right and such actions would bring security and resiliency to the supply chain, rather than trying to repatriate the entire pharmaceutical and API supply chain domestically, which is a recipe for vulnerability and insecurity. Indeed, the Organization for Economic Cooperation and Development (OECD) released a study showing that “increased [localization] leads to GDP losses and makes domestic markets more vulnerable.”<sup>29</sup> Reshoring all the production of pharmaceuticals and APIs—and rejecting trade with close allies—does not.

## THE FOLLY OF TRADE RESTRICTIONS

Despite the exceptional performance of market-driven, global supply chains, policymakers seem convinced that trade makes drug supplies unacceptably vulnerable. This anxiety about the perceived costs of globalization has led to numerous government interventions in the United States and elsewhere to keep both production and consumption at the local level. By and large, such interventions have been not only wasteful and counterproductive, but also served as excuses for simple protectionism with no public health justification.

### Foreign Restrictions

Pandemic-induced anxiety over globalization is, ironically, a global phenomenon. The World Trade Organization (WTO) Secretariat has maintained a list of over 300 COVID-19-related trade measures taken by WTO members since February 2020. While some of those measures are liberalizing, one of the most common actions taken has been to temporar-

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21. Ibid.

22. Ibid., p. 134.

23. Ibid., p. 140.

24. Ibid., p. 133.

25. “Risk, resilience, and rebalancing in global value chains,” McKinsey Global Institute, Aug. 6, 2020. <https://www.mckinsey.com/business-functions/operations/our-insights/risk-resilience-and-rebalancing-in-global-value-chains#>.

26. Ibid., pp. 209-210.

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27. Ibid., p. 210.

28. Ibid.

29. Frank Van Tongeren, “Shocks, risks and global value chains in a COVID-19 world,” Organization for Economic Cooperation and Development, Aug. 25, 2020. <https://oecdecoscope.blog/2020/08/25/shocks-risks-and-global-value-chains-in-a-covid-19-world>.

ily restrict exports of drugs or medical equipment.<sup>30</sup> India and the European Union—two of America’s most-prominent pharmaceutical trading partners—are among the worst offenders in this regard.

In the spring of 2020, India imposed a series of temporary trade restrictions banning the export of hand sanitizers, medical equipment, and numerous pharmaceutical ingredients.<sup>31</sup> Some of the restrictions involved specifically COVID-19-related products such as remdesivir and hydroxychloroquine, but others covered standard drug ingredients, like acetaminophen, as well as hormones and vitamins.<sup>32</sup> Fortunately, most of India’s export bans have since been rescinded or loosened, and some of them lasted only a few weeks.<sup>33</sup> More recently, India has responded to a surge in COVID-19 cases by withholding exports of domestically-produced doses of the AstraZeneca vaccine originally destined for other developing countries.<sup>34</sup>

The European Union has followed a path similar to India. In the early months of the pandemic, numerous European countries imposed export bans on certain medical equipment and drugs. The original justification for the restrictions was to prevent shortages of products necessary to treat COVID-19 patients.<sup>35</sup> But some of the restricted drugs (including insulin) had no connection to the pandemic and were merely blocked to prevent price competition.<sup>36</sup>

The European Commission rightly condemned these restrictions as counterproductive measures that “hamper our collective ability to respond to the coronavirus outbreak effectively” before hypocritically issuing its own export control to ban any shipments of personal protective equipment (PPE)

from leaving the 27-member bloc.<sup>37</sup> Then just like India, the European Union tightened export licensing requirements in March 2021 to prevent exports of COVID-19 vaccine doses produced in Europe by AstraZeneca.<sup>38</sup>

## U.S. Restrictions

In the United States, meanwhile, the Trump administration used the Defense Production Act (DPA) to control the production and distribution of numerous pandemic-related products. Under the DPA, the federal government can contract with, subsidize, or simply coerce private companies for national security purposes. In many instances, the results of this intervention were demonstrably wasteful or even counterproductive.<sup>39</sup>

For instance, early use of the DPA to secure domestic production of certain medical equipment proved largely duplicative, because private companies had already begun retooling manufacturing capacity idled by lockdowns to produce ventilators and other medical items suddenly in high-demand.

In some cases, the DPA was used in a way that merely restricted exports of supplies that were already being manufactured. In April 2020, the Trump administration threatened to block outgoing shipments of N-95 respirator masks made in the United States by 3M.<sup>40</sup> The company responded publicly by noting that 3M’s U.S. facility is a vital supplier of masks to Canada and Latin America and that export restrictions would be not only inhumane but likely result in retaliation from other countries, ultimately reducing the availability of masks in the United States.<sup>41</sup> Rather than keep U.S.-made masks in the United States, it makes more sense for 3M—which had already begun ramping up PPE production in United States and foreign facilities—to produce masks

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30. “Covid-19: Measures affecting trade in goods,” World Trade Organization, last accessed June 30, 2021. [https://www.wto.org/english/tratop\\_e/covid19\\_e/trade\\_related\\_goods\\_measure\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/trade_related_goods_measure_e.htm).

31. “India bans export of protective masks, clothing amid coronavirus outbreak,” *Reuters*, Jan. 31, 2021. <https://www.reuters.com/article/us-china-health-india/india-bans-export-of-protective-masks-clothing-amid-coronavirus-outbreak-idUSKBN1ZU20A>.

32. Hannah Ellis-Peterson, “India limits medicine exports after supplies hit by coronavirus,” *The Guardian*, March 4, 2020. <https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics>.

33. “Covid-19 Temporary Trade Measures,” International Trade Centre, last accessed June 30, 2021. <https://www.macmap.org/covid19>.

34. Neha Arora, et al., “Exclusive: India unlikely to resume sizable COVID-19 vaccine exports until October,” *Reuters*, May 18, 2021. <https://www.reuters.com/world/india/exclusive-india-unlikely-resume-sizable-covid-19-vaccine-exports-until-october-2021-05-18>.

35. Chad P. Bown, “EU limits on medical gear exports put poor countries and Europeans at risk,” Peterson Institute for International Economics, March 19, 2020. <https://www.piie.com/blogs/trade-and-investment-policy-watch/eu-limits-medical-gear-exports-put-poor-countries-and>.

36. Francesco Guarascio and Matthias Blamont, “Europe’s Coronavirus export bans raise concern over insulin supplies,” *Reuters*, April 9, 2020. <https://www.reuters.com/article/us-health-coronavirus-eu-insulin/europes-coronavirus-export-bans-raise-concern-over-insulin-supplies-idUSKCN21R21Q>.

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37. Francesco Guarascio, “Exclusive: France first - Paris ignores EU calls to lift export bans on COVID-19 drugs,” *Reuters*, April 23, 2020. <https://www.reuters.com/article/us-health-coronavirus-eu-drug-exclusive/exclusive-france-first-paris-ignores-eu-calls-to-lift-export-bans-on-covid-19-drugs-idUSKCN2252HN>; Lili Bayer, et al., “EU moves to limit exports of medical equipment outside the bloc,” *Politico*, March 15, 2020. <https://www.politico.eu/article/coronavirus-eu-limit-exports-medical-equipment>.

38. Matina Stevis-Gridneff, “E.U. Will Curb Covid Vaccine Exports for 6 Weeks,” *The New York Times*, March 23, 2021. <https://www.nytimes.com/2021/03/23/world/europe/eu-curbs-vaccine-exports.html>.

39. Scott Lincicome, “Shining Much-Needed Light on the Defense Production Act,” *Cato at Liberty*, April 26, 2021. <https://www.cato.org/blog/how-many-more-kodaks-are-there>.

40. Brett Molina, “Trump blasts 3M as company says mask demand far exceeds ability to produce them,” *USA Today*, April 3, 2020. <https://www.usatoday.com/story/money/2020/04/03/coronavirus-trump-blasts-3-m-over-masks-demand-surges/2938674001>.

41. Kevin Breuninger, “It’s ‘absurd’ – 3M CEO defends coronavirus response after Trump invokes DPA,” *CNBC*, April 3, 2020. <https://www.cnbc.com/2020/04/03/coronavirus-update-3m-ceo-defends-mask-production-after-trump-invokes-dpa.html>.

where it can and freely send them to where they are needed.<sup>42</sup>

More recently, news reports revealed that the DPA had been used to award \$1.3 billion in loans and contracts to a U.S. company to make vaccine syringes. By April 2021, that company had still not constructed its factory to make the syringes and had not received approval from the Food and Drug Administration (FDA) to market them.<sup>43</sup> Meanwhile, there proved to be no syringe-related bottleneck, and the vaccine rollout progressed.

The U.S. government also took steps in 2020 to promote the long-term reshoring of drug supply chains not specifically related to the pandemic. In August 2020, the Trump administration issued an executive order imposing new “Buy American” requirements on government purchases of pharmaceuticals. All federal agencies that buy drugs are now required to “limit competition to only those Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States.”<sup>44</sup> The stated motivation for this order was a desire to “reduce our dependence on foreign manufacturers . . . to ensure sufficient and reliable long-term domestic production of these products [and] to minimize potential shortages.”<sup>45</sup>

The practical effect of the order will be to make it harder and more expensive for bureaucrats to acquire drugs needed by patients at U.S. military and Veterans Affairs hospitals.<sup>46</sup> It also creates incentives for rent-seeking businesses to adopt uneconomical supply chains solely to qualify for Buy American privileges. And when an unforeseen event does occur, those companies will be less flexible in their ability to adapt to a disruption. As such, the executive order is likely to reduce resilience and amplify shortages—the opposite of its stated goals.

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42. Mike Hughlett, “3M says it’s on track with N95 production goals,” *Star Tribune*, July 12, 2020. <https://www.startribune.com/3m-says-it-s-on-track-with-n95-production-goals/571710872>.

43. Andrew W. Lehren and Laura Strickler, “The Trump admin awarded a firm up to \$1.3 billion to make Covid vaccine syringes. Where are they?”, NBC News, April 21, 2021. <https://www.nbcnews.com/health/health-care/trump-administration-awarded-firm-1-3-billion-make-covid-vaccine-n1263872>.

44. Donald J. Trump, “Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States,” Office of the White House, Aug. 6, 2020, Sec. 2(a)(i). <https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states>.

45. *Ibid.*, Sec. 1.

46. Susan Ariel Aaronson, “More than 250 Leading Economists Warn Trump Administration: ‘Buy America’ Provision Would Harm American Response to Coronavirus,” National Taxpayers Union, May 13, 2020. <https://www.ntu.org/publications/detail/more-than-250-leading-economists-warn-trump-administration-buy-america-provision-would-harm-american-response-to-coronavirus>.

## PROPOSALS

China poses substantial challenges to the world trading system.<sup>47</sup> However, the United States can and should take steps to lessen its dependence on China for a number of products, including pharmaceuticals, APIs and other products. But that should not become a pretext for aggressive protectionism, which would raise costs for consumers and only make the supply chain less resilient. There is a smarter and more efficient way to strengthen supply chains.

Instead of trying to reshore production of all products deemed “strategic”—including, but not limited to pharmaceuticals and APIs—through trade restrictions, policymakers should work to strengthen existing trading relationships and create new trading relationships with close allies. True resilience and security will not come from autarky, but rather through diversification.

### Renew TPA

On July 1, 2021, Trade Promotion Authority (TPA) expired.<sup>48</sup> Renewed five times since 1974, TPA grants the Executive Branch the authority to negotiate trade agreements with foreign countries, which then enjoy preferential consideration in Congress (expedited consideration and not subject to the filibuster in the Senate) as long as certain requirements are met, including objectives established in the law, various timelines and reporting requirements.<sup>49</sup> As analysts recently noted:

TPA helps to solve two persistent problems in U.S. trade policy. First, it temporarily resolves constitutional tension regarding who may negotiate and enter into an international trade agreement on behalf of the United States. Second, it provides assurances to U.S. negotiating partners that an agreement signed by the president will subsequently receive a timely, unamendable up-or-down vote in Congress.<sup>50</sup>

Indeed, virtually every trade agreement the United States has entered into—from WTO agreements to regional and bilateral agreements—has been passed using TPA processes.

If policymakers are truly serious about enhancing the security of the American supply chain, the Biden administration and Congress should work quickly to renew TPA. Renewal

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47. Clark Packard, “Outcompeting Beijing: A Roadmap for Meeting China’s Commercial Challenges,” *R Street Policy Study* No. 223, March 2021. <https://www.rstreet.org/2021/03/08/outcompeting-beijing-a-roadmap-for-meeting-chinas-commercial-challenges>.

48. Halie Craig and Clark Packard, “To Save American Prosperity, Renew Fast Track,” *Foreign Policy*, April 27, 2021. <https://foreignpolicy.com/2021/04/27/trade-promotion-authority-us-economy-fast-track>.

49. *Ibid.*

50. *Ibid.*

would provide the Office of the United States Trade Representative (USTR) the space and credibility with trading partners to negotiate new trade agreements, including those designed to bolster the supply chain.

## New FTA

Using renewed TPA, the United States should work quickly to negotiate a new, limited plurilateral free trade agreement with a number of close and trusted allies (Secure Supply Chain Agreement). The Agreement should cover trade in medical products including devices, pharmaceuticals and APIs, but could also include other products deemed essential by lawmakers such as semiconductors and other essential and strategic technological products.

## Secure Supply Chain Agreement

In order to enhance the security of the supply chain, the United States should seek to negotiate a plurilateral Secure Supply Chain Agreement with trusted allies, including Canada, Mexico, the United Kingdom, Switzerland, the European Union, Japan, India, Israel, Korea, Australia, New Zealand, Taiwan and others. The trade negotiators from the participating countries should solidify an agreement that achieves the following objectives: eliminates all tariffs on finished pharmaceuticals, APIs, and other medical devices and products; expressly prohibits the use of export restrictions among the participating countries; and regulatory cooperation and harmonization for the products covered by the agreement.

The average applied tariff on medical products of WTO members is about 4.8 percent, which is significantly lower than the average applied tariff for non-agricultural products, which is 7.6 percent.<sup>51</sup> Medicines have an even lower average applied tariff—2.1 percent.<sup>52</sup> Indeed, as the WTO notes: “More than half of the [WTO Members] have no tariff in place on medicines.”<sup>53</sup> Much of this is the result of the WTO’s plurilateral Agreement on Trade in Pharmaceutical Products (Pharmaceutical Agreement), which “eliminates tariffs and other duties and charges on a large number of pharmaceutical products and the substances used to produce them, permanently binding them at duty-free levels.”<sup>54</sup> Indeed, the Pharmaceutical Agreement covers finished pharmaceuticals as well as “over 7,000 APIs and other chemical

components.”<sup>55</sup> Participating members of the Pharmaceutical Agreement include Canada, the European Union, Japan, Macao, Norway, Switzerland, the United Kingdom and the United States.<sup>56</sup> Given the already low tariff rates on pharmaceuticals and APIs, it makes sense to just eliminate them entirely.

Next, the Secure Supply Chain Agreement should expressly prohibit the use of export restrictions among the participating countries. Since the goal is to establish a reliable supply of certain strategically important products that withstands shocks, an agreement that permits export restrictions of covered products during times of crisis makes little sense. A provision explicitly prohibiting restrictions during emergencies such as COVID-19 makes a lot of sense.

Next, in order to create a true nondiscriminatory free trade zone for pharmaceuticals and APIs, trade negotiators should pursue regulatory cooperation and harmonization for the products covered. Disparate regulatory and technical standards across countries can serve as non-tariff barriers to trade that inhibit the broader, mutually shared goal of supply chain security and resiliency. Likewise, the parties should insist on expedited approval for pharmaceutical and API manufacturing facilities within the trade bloc, especially for those firms already operating facilities in the zone.

Governments are significant purchasers of pharmaceuticals and that segment of the market should not be shielded from foreign competition. Countries negotiating the Secure Supply Chain Agreement should waive protectionist government procurement schemes that favor domestic producers over foreign competitors. Though R Street would like to see the United States unilaterally waive so-called Buy American provisions, at the very least, the parties to the Secure Supply Chain Agreement should be given equal opportunity to bid on government pharmaceutical contracts within the trading bloc, including granting an exemption to Buy American requirements for all members.

## Rejoin TPP

In addition, the United States should rejoin the Trans-Pacific Partnership (TPP), which the Trump administration unwisely abandoned in January 2017.<sup>57</sup> The remaining 11 countries renamed the agreement the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and moved forward with the ambitious trade agreement without

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51. “Trade in Medical Goods in the Context of Tackling COVID-19,” World Trade Organization, April 3, 2020, p.5. [https://www.wto.org/english/news\\_e/news20\\_e/rese\\_03apr20\\_e.pdf](https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf).

52. *Ibid.*, p.7.

53. *Ibid.*

54. “The WTO’s Pharma Agreement,” World Trade Organization, last accessed June 30, 2021. [https://www.wto.org/english/tratop\\_e/pharma\\_ag\\_e/pharma\\_agreement\\_e.htm](https://www.wto.org/english/tratop_e/pharma_ag_e/pharma_agreement_e.htm).

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55. Broadbent, p. 23. [https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/201221\\_Broadbent\\_Covid19\\_Shock.pdf](https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/201221_Broadbent_Covid19_Shock.pdf).

56. *Ibid.*

57. Peter Baker, “Trump Abandons Trans-Pacific Partnership, Obama’s Signature Trade Deal,” *The New York Times*, Jan. 23, 2017. <https://www.nytimes.com/2017/01/23/us/politics/tpp-trump-trade-nafta.html>

the United States.<sup>58</sup> The agreement eliminated a number of tariffs and other non-tariff trade barriers. American firms are at a disadvantage in this vital and growing area, while American consumers face more expensive products from these countries than they would have if the United States ratified the agreement.

On top of cheaper imports for consumers—both firms and individuals—and more market access abroad for American producers, the CPTPP was designed to lessen U.S. dependence on China and provide countries in Beijing’s orbit with an alternative market of roughly similar size while strengthening supply chains with non-Chinese firms in Asia.<sup>59</sup> In essence, the CPTPP was conceived as an economic counterweight to China, which is precisely what policymakers in the United States ought to be looking for today.<sup>60</sup>

Though the United States withdrew from the CPTPP, it would almost certainly be welcomed back into the pact given its size and the preferential market access the other countries would receive into the largest economy in the world. As part of rejoining the CPTPP, the United States should insist on changes to the agreement to include the major elements of the Secure Supply Chain Agreement—elimination of all tariffs on medical goods and prohibition on export restrictions on medical goods and pharmaceutical products, etc.—in order to strengthen medical supply chains with allied countries in the Asia-Pacific region.

Withdrawing from the CPTPP was an egregious strategic error that hurt American supply chain resiliency in the Pacific and damaged the United States’ international economic leadership. Beijing was the primary beneficiary of the United States’ decision to abandon a promising trade pact. Policymakers serious about supply chain security and countering China’s commercial practices should rejoin the CPTPP and ensure that pharmaceuticals and APIs are traded freely within the bloc.

### Amend Existing FTAs

Through the United States–Mexico–Canada Agreement (USMCA), the Dominican Republic–Central America Free Trade Agreement (CAFTA-DR) and other bilateral agreements, the United States maintains preferential trade

agreements with 20 countries: Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Jordan, Korea, Mexico, Morocco, Nicaragua, Oman, Panama, Peru and Singapore.<sup>61</sup> If negotiating something similar to the Secure Supply Chain Agreement is not feasible in a relatively short amount of time, policymakers and trade negotiators should consider narrow amendments to existing trade agreements. Such narrow changes should include incorporating the major elements proposed for the Secure Supply Chain Agreement to further enhance supply chain security and resiliency among existing trading partners.

### Tax Changes

While the primary goal of policymakers interested in shoring up the security of various supply chains should be to expand and solidify trading relationships, not to engage in protectionism or autarky, there are certain changes that will make the United States a more attractive destination to manufacture certain products, including pharmaceuticals and APIs.

Under the terms of the Tax Cuts and Jobs Act of 2017, when an American firm makes investments into research and development (R&D), it can deduct those costs from its tax liability in the year in which it occurs. This is a smart way to lower costs of important R&D. However, that provision expires in 2022; beginning next year, firms must amortize the expense over a five-year period.<sup>62</sup> This means that R&D will become more expensive for American firms. If the United States wants to ensure it is a globally competitive location for pharmaceutical and API manufacturing, policymakers should make this tax provision permanent.

### CONCLUSION

Even under the extreme pressure of COVID-19, supply chains generally held up pretty well. That is especially true for pharmaceuticals and APIs. This success is a testament to the power of a healthy international trading system and relatively free markets, which bolster supply chain resiliency.

Policymakers are increasingly concerned about the United States’ economic interdependence with China and others. While there is a temptation to confront these challenges by turning inward and embracing sclerotic protectionism, that would be a mistake. True security and resiliency of supply chains, including the pharmaceutical and API supply chains, comes only through diversification. Imports from

58. Dave Sherwood and Felipe Iturrieta, “Asia-Pacific nations sign sweeping trade deal without U.S.” *Reuters*, March 8, 2018. <https://www.reuters.com/article/us-trade-tpp/asia-pacific-nations-sign-sweeping-trade-deal-without-u-s-idUSKCNIGK0JM>.

59. Clark Packard, et. al., “How to Make America’s Next Trade Policy,” *The Bulwark*, March 2, 2020. <https://thebulwark.com/how-to-make-a-americas-next-trade-policy>.

60. “Countering China and Creating Jobs: TPP 2.0,” Republican Policy Committee, April 17, 2018. <https://www.rpc.senate.gov/policy-papers/countering-china-and-creating-jobs-tpp-20#:~:text=Aside%20from%20direct%20economic%20benefits,reform%20and%20liberalize%20its%20economy.&text=If%20successful%2C%20it%20would%20further,transportation%20hub%20for%20Eurasian%20trade>.

61. Office of the United States Trade Representatives, “Free Trade Agreements,” Executive Office of the President. <https://ustr.gov/trade-agreements/free-trade-agreements>.

62. Nicole Kaeding, “Correcting the TCJA’s Mistreatment of R&D Costs,” National Taxpayers Union Foundation, Oct. 8, 2019. <https://www.ntu.org/foundation/detail/correcting-the-tcjais-mistreatment-of-rd-costs>.



allied countries can keep prices for consumers in check and enhance security. Formalized trading relationships with close allies are the best way to diversify the supply chain and enhance the security and competitiveness of the United States.

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