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RESISTING PROTECTIONISM IN THE PHARMACEUTICAL SUPPLY CHAIN

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INTRODUCTION

For about 80 years, the United States has aggressively pursued a policy of expanding overseas markets and lowering domestic tariffs and other non-tariff barriers. This process was achieved through a series of bilateral and regional free trade agreements (FTAs), as well as multilateral agreements through the World Trade Organization (WTO) and its precursor system, the General Agreement on Tariffs and Trade (GATT). Liberalizing international trade in this manner increased the U.S. Gross Domestic Product per capita by about \$7,000 and by more than \$18,000 (in 2016 dollars) per household.¹ Not only that, the poor benefitted disproportionately because they tend to “concentrate spending in more traded sectors.”² Through these agreements, American firms also were able to establish the certainty they

1. Gary Clyde Hufbauer and Zhiyao (Lucy) Lu, “The Payoff to America from Globalization: A Fresh Look with a Focus on Cost to Workers,” The Peterson Institute for International Economics, May 2017. <https://piie.com/system/files/documents/pbi7-16.pdf>.

2. Pablo D. Fajgelbaum and Amit K. Khandelwal, “Measuring the Unequal Gains from Trade,” *The Quarterly Journal of Economics* 131:3 (August 2016), pp. 1113-80. <https://academic.oup.com/qje/article-abstract/131/3/1113/2461162?redirectedFrom=fulltext>.

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needed to invest abroad, foreign firms invested here and a system of complicated supply chains quickly developed that lowered prices for consumers and enhanced the competitiveness of American firms in globalized markets.

Despite these successes, protectionist opponents on the left and right have long criticized the prevailing consensus for its effect on the domestic manufacturing base.³ “Offshoring,” critics contend, has favored multinational corporations at the expense of the working class.⁴ Critics also argue that, as a services-heavy economy, the United States is too dependent on imported products from hostile countries and that the U.S. “doesn’t make anything anymore.”⁵

But, these charges are largely untrue. Today, the United States is the second-largest exporter in the world.⁶ And, although manufacturing employment (as a percentage of the overall workforce) in the United States has declined, its peak occurred shortly after World War II and began declining in the late 1970s—“long before the North American Free Trade Agreement existed or Chinese imports were more than a rounding error in U.S. GDP.”⁷ In fact, before the outbreak

3. See, e.g., Tom Hamburger, Carol D. Leonnig, and Zachary A. Goldfarb, “Obama’s record on outsourcing draws criticism from the left,” *The Washington Post*, July 9, 2012. https://www.washingtonpost.com/business/economy/obamas-record-on-outsourcing-draws-criticism-from-the-left/2012/07/09/gJQAIjJCZW_story.html; Patrick J. Buchanan, “Is Free Trade Falling Out of Fashion,” *Buchanan.org*, Feb. 18, 2004. <https://buchanan.org/blog/pjb-is-free-trade-falling-out-of-fashion-578>.

4. Robert E. 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>.

5. Chris Wallace, “Interview with Donald Trump,” *Fox News Sunday*, Oct. 18, 2015. <https://www.youtube.com/watch?v=aXqEcUOW5J>.

6. Jeff Desjardins, “These are the world’s biggest exporters,” *World Economic Forum*, June 25, 2018. <https://www.weforum.org/agenda/2018/06/these-are-the-worlds-biggest-exporters>.

7. Scott Lincicome, “The Truth about Trade,” *National Review*, April 4, 2016. <https://www.nationalreview.com/2016/04/trade-jobs-free-trade-hurting-american-economy>.

of COVID-19, manufacturing output was near record highs.⁸ Instead, it is productivity gains and technological improvements that are the primary drivers of America's shift away from labor-intensive manufacturing, not import competition or offshoring.⁹

Despite this reality, American politicians are increasingly interested in reshoring supply chains of various products, especially those deemed "strategic" or required for U.S. national security.¹⁰ Hawkish politicians are concerned about U.S. reliance on imports from China and have pushed the United States to embrace a new era of industrial policy.¹¹ Such arguments have intensified since the outbreak of COVID-19, particularly with respect to pharmaceuticals and other products necessary to combat the pandemic. The justification is that non-allies may withhold exports of these critical products, particularly when we need them most. And, accordingly, the administration and Congress are currently considering ways to re-shore some or all of the pharmaceutical supply chain, including a blunt protectionist requirement for the federal government to purchase only pharmaceutical products that are made in the United States.¹²

Such "Buy American" proposals recently drew a stern rebuke from over 250 leading economists, including Nobel laureates and officials from previous presidential administrations, who warned in a letter organized by the National Taxpayers Union that: "The variety, supply and price of goods available to Americans will suffer under a Buy American regime. Taxpayers and patients will pay more for drugs and medical supplies."¹³ And, in fact, any such risk is unnecessary, as there are ways to responsibly increase domestic manufacturing of various pharmaceuticals and active pharmaceutical ingredients (APIs) without resorting to misguided protectionism.

What's more, to exploit this crisis as a way to radically overhaul pharmaceutical supply chains could be disastrous, especially if done in a haphazard way. For this reason, the present study first explains the costs of re-shoring pharmaceutical

supply chains and the benefits of diversity. It then dispels the dubious national security arguments made by politicians, and makes concrete recommendations for the consideration of policymakers who wish to ensure a secure U.S. pharmaceutical supply chain, including steps to responsibly increase domestic production.

DISPELLING MYTHS

In a May 11 op-ed in *The New York Times*, U.S. Trade Representative Robert Lighthizer criticized the "blind pursuit of efficiency" that resulted in "extended, overseas supply lines."¹⁴ He went on to accuse American businesses of following an offshoring "craze," as they were "swept up by the herd mentality" and a "lemming-like desire for 'efficiency'" but without adequately considering the risks that come when "long supply lines flow at the whim of local politics, labor unrest and corruption." He then claimed that the pandemic "has revealed our overreliance on other countries as sources of critical medicines" and called on policymakers to "remedy this strategic vulnerability [...] by shifting production back to the United States."¹⁵

This general antipathy toward globalization has been further energized by concerns that the Chinese government has too much power over the American medical supply. Last December, for example, four U.S. senators warned that "overreliance on Chinese API exports raises the possibility that China could terminate or raise the cost of prescription drugs."¹⁶ They further warned that the Chinese government could choose to "weaponize pharmaceuticals, by restricting exports to the United States" or "incorporating lethal ingredients in final products," and concluded ominously that this "national security threat cannot be overstated."¹⁷

In fact, such a threat is constantly and dramatically overstated, primarily because of the faulty assumption upon which it is based: namely, that our supply chain is over-reliant on China. Like all products created through complex global supply chains, understanding the country of origin for all components of a finished product can be challenging, and pharmaceuticals are certainly no exception. However, the promotion of false statistics is hardly helpful. For example, in the midst of the current pandemic, irresponsible policymakers and even mainstream media outlets persist in promoting

8. Laura Beth Harris, "Manufacturing Output Hits All-Time High, Signaling Industry's Strength," National Association of Manufacturers, July 29, 2019. <https://www.nam.org/manufacturing-output-hits-all-time-high-signaling-industrys-strength-5546/?stream=workforce>.

9. Michael J. Hicks and Srikant Devaraj, "The Myth and the Reality of Manufacturing in America," Ball State University, April 2017. <https://conexus.cberdata.org/files/Mfg-Reality.pdf>.

10. Olivia Beavers, "Momentum grows to change medical supply chain from China," *The Hill*, April 5, 2020. <https://thehill.com/policy/national-security/491119-momentum-grows-to-change-medical-supply-chain-from-china>.

11. Marco Rubio, "We Need a More Resilient American Economy," *The New York Times*, April 20, 2020. <https://www.nytimes.com/2020/04/20/opinion/marco-rubio-coronavirus-economy.html>.

12. Ana Swanson, "Coronavirus Spurs U.S. Efforts to End China's Chokehold on Drugs," *The New York Times*, March 11, 2020. <https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html>.

13. Economists' Letter to President Trump, Speaker Pelosi and Leader McConnell, May 2020. <https://www.ntu.org/library/doclib/2020/05/economist-letter-2-.pdf>.

14. 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>.

15. Ibid.

16. Sen. Elizabeth Warren et al., Letter to Mark T. Esper, Dec. 5, 2019. <https://www.warren.senate.gov/imo/media/doc/2019.12.05%20Letter%20to%20DoD%20re%20pharmaceutical%20product%20supply%20chain.pdf>.

17. Ibid.

the figure that “80 percent of our drugs come from China.”¹⁸ And, while that may sound scary (and is likely designed specifically for that purpose), it is simply false.¹⁹

To accurately analyze the source of drug imports is complicated in two important ways. One is the distinction between finished drugs and active pharmaceutical ingredients (APIs), which are the chemicals (like acetaminophen and dextromethorphan) used to make the drugs (like NyQuil) people actually consume. The second is the fact that both finished drugs and APIs are scattered across multiple product codes in national trade databases, and some of those codes include non-pharmaceutical products. It is therefore difficult to accurately estimate the true value and origin of API imports and impossible to know the origin of all APIs that are imported as existing components of finished drugs.

For at least the last 20 years, the FDA has “estimated” that imports from all foreign countries make up “approximately” 40 percent of finished drugs and 80 percent of APIs used by U.S. manufacturers of finished drugs.²⁰ But, in addition to the fact that it is unclear how the agency arrived at this estimate, the number also does not tell us where the APIs in the imported drugs are coming from. And, what’s more, any reasonable attempt to approximate these values does not indicate that anything close to 80 percent of finished drugs—or even 80 percent of the APIs consumed by Americans—are made in China. For example, we know that Chinese manufacturers supply only a small share of the APIs used to make finished drugs in the United States, because the source of those imports is recorded in U.S. trade data. According to analysis by the American Action Forum, a mere “18 percent of total active pharmaceutical ingredient imports, 9 percent of total antibiotic imports, and less than 1 percent of total vaccine imports” come from China.²¹ In reality, the largest source of imported APIs is Ireland—at about 30 percent.²² And certainly no one would credibly claim that Ireland poses any national security threat to the United States.

Moreover, in recent testimony to Congress, even the director of the FDA’s drug division stated that the agency “cannot

determine with any precision the volume of API that China is actually producing, or the volume of APIs manufactured in China that is entering the U.S. market.”²³ They do, however, have data on the location of facilities registered with the agency to produce APIs for specific approved drugs. For example, the FDA reports that there are 1,788 facilities in the world that manufacture APIs for drugs consumed in the United States.²⁴ Only 13 percent of these facilities are in China.²⁵ India and the European Union actually produce more of these APIs—at 18 and 26 percent, respectively. Twenty-eight percent of the facilities are located here in the United States.²⁶ Of course, even looking at the number of facilities does not tell us the actual volume of APIs from each country, as some facilities may be producing vastly greater quantities than others. But the data we do have does not indicate an excessive reliance on China. On the contrary, it shows that the U.S. pharmaceutical market is served by a diverse array of suppliers from all over the world, including here at home. It also shows that these market-driven supply chains are not, as Ambassador Lighthizer argues, the result of an irrational craze to cut costs at the expense of jobs. In truth, globalization has enabled the U.S. pharmaceutical industry to become a dynamic driver of economic growth in the United States.

In a global economy, it is true that the United States is not the best place to invest in large-scale, labor-intensive chemical manufacturing. But America has excelled at inventing new drugs that improve lives and at developing innovative manufacturing techniques that make drug treatments safer, more effective and more affordable. Indeed, the U.S. Dept. of Commerce’s most recent report on the state of the pharmaceutical market certainly does not describe an industry hollowed out by short-sightedness: “Large, diversified and global, the U.S. pharmaceutical industry is one of the most critical and competitive sectors in the economy.”²⁷ The U.S. market for pharmaceuticals is enormous and the United States is indeed the world’s number one importer of finished drugs. But because most drugs made in the world are not consumed in America, the United States is also a major exporter.

While the industry was developing “extended, overseas supply lines,” the value of U.S. pharmaceutical exports tripled to

18. Eric Boehm, “Why You Shouldn’t Trust Anyone Who Claims 80 Percent of America’s Drugs Come From China,” *Reason*, April 6, 2020. <https://reason.com/2020/04/06/why-you-shouldnt-trust-anyone-who-claims-80-percent-of-american-drugs-come-from-china>.

19. *Ibid.*

20. See, e.g., “Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program,” U.S. General Accounting Office, March 17, 1998, p. 1. <https://www.gao.gov/assets/230/225564.pdf>; “Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of its Foreign Offices,” U.S. General Accounting Office, Dec. 16, 2016, p. 1. <https://www.gao.gov/assets/690/681689.pdf>.

21. Jacqueline Varas, “U.S. Dependence on Chinese Pharmaceuticals is Overstated,” American Action Forum, May 20, 2020. <https://www.americanactionforum.org/insight/u-s-dependence-on-chinese-pharmaceuticals-overstated>.

22. *Ibid.*

23. Statement of Janet Woodcock, “Safeguarding Pharmaceutical Supply Chains in a Global Economy,” House Committee on Energy and Commerce, Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, 116th Congress, Oct. 30, 2019. https://energycommerce.house.gov/sites/democrats.energy-commerce.house.gov/files/documents/Testimony-Woodcock-API_103019.pdf.

24. *Ibid.*

25. *Ibid.*

26. *Ibid.*

27. International Trade Administration, “2016 Top Market Report: Pharmaceuticals,” U.S. Dept. of Commerce, 2016, p.3. https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

over \$50 billion per year.²⁸ The U.S. Bureau of Labor Statistics estimates that approximately 300,000 Americans work in the pharmaceutical industry with a median wage 56 percent higher than the national average.²⁹ This is only made possible by access to the very global network of suppliers that reshoring advocates want to eliminate.

And global supply chains have also not made the market more vulnerable to disruption—intentional or otherwise. Supply chain risk is a well-studied phenomenon, and experts have not found that reliance on domestic production and short supply lines is the best way to avoid risk.³⁰ The robustness of a supply chain (that is, its ability to continue operating when faced with an unforeseen disruption like a natural disaster) can be negatively affected by complexity because it takes more resources and oversight to maintain operations.³¹ But robustness can also be harmed by geographic concentration because a greater portion of the system is susceptible to a single incident.³² It makes sense, therefore, for companies to seek a diverse network of suppliers and potential suppliers with constant knowledge of their relative capacities. Forcing pharmaceutical companies to rely only on U.S. suppliers would likely expose their operations to greater risk of disruption by prohibiting them from adequately spreading risk.

Rather than reveal dangerous vulnerabilities, the coronavirus pandemic has actually demonstrated that supply lines for the U.S. pharmaceutical market are quite robust compared to other industries. We have seen notable problems in markets for face masks, household goods and food, but the U.S. medicine supply has been almost entirely unaffected. In fact, in its most recent update on the status of drug supplies during the COVID-19 outbreak, the FDA stated that only one drug had been added to the drug shortage list due to a pandemic-related factory shutdown in China and that “there are other alternatives that can be used by patients.”³³ The agency also identified only 20 drugs (all non-critical) with APIs sourced only from China, and none of those had reported any short-

ages.³⁴ Put simply, the evidence to date strongly suggests that the U.S. pharmaceutical supply chain is adequately diverse and robust in the face of unforeseen disruption. Efforts to re-shore all manufacturing of APIs is therefore likely to do more harm than good.

COSTS OF PHARMACEUTICAL AUTARKY

Because of the complex and efficient pharmaceutical supply chains that have developed over the years, prices of prescription drugs are lower than they would be if they were entirely manufactured in the United States. With a growing bipartisan chorus of policymakers in the Trump administration and Congress looking at ways to reduce drug prices, reshoring the entire pharmaceutical supply chain would not only undermine that worthwhile goal, but would raise drug prices.³⁵

In fact, there are a number of reasons why the United States imports finished pharmaceuticals and active pharmaceutical ingredients, which include tax laws, simple comparative advantage and access to raw materials.³⁶ Indeed, a 2011 study from the Food and Drug Administration noted:

Both India and China offer a number of cost advantages, most notably the cost of skilled labor. India in particular trains six times the number of chemists annually than the U.S. produces and companies can access this talent for 10% of the cost of the same talent in America.³⁷

The study also finds that manufacturing in India, for example, can “reduce costs for U.S. and European companies by 30 to 40%.”³⁸ These cheaper production costs mean cheaper drug prices for American consumers. If the United States were to entirely re-shore the pharmaceutical supply chain, it would dramatically increase prescription drug costs for American purchasers, including individuals, federal and state governments, hospitals and insurance companies.

Ironically, forced re-shoring could also bring about the exact result its proponents fear from Chinese interference. That is, by prohibiting American patients, pharmacists and doctors from acquiring safe and effective medicines available on the

28. “U.S. Biopharmaceutical Goods Export Volume from 2002 to 2018,” Statista, last accessed June 8, 2020. <https://www.statista.com/statistics/215814/us-biopharmaceutical-export-volume>.

29. U.S. Bureau of Labor Statistics, “May 2019 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325400 - Pharmaceutical and Medicine Manufacturing,” U.S. Dept. of Labor, May 2019. https://www.bls.gov/oes/2019/may/naics4_325400.htm.

30. Sébastien Mirodout, “Resilience Versus Robustness in Global Value Chains: Some Policy Implications,” Richard Baldwin and Simon Evenett eds., *COVID-19 and Trade Policy: Why Turning Inward Won't Work* (CEPR Press, 2020), p. 123. <https://voxeu.org/content/covid-19-and-trade-policy-why-turning-inward-won-t-work>.

31. Christian F. Durach et al., “Antecedents and Dimensions of Supply Chain Robustness: A Systematic Literature Review,” *International Journal of Physical Distribution and Logistics Management* 45:1 (2015), pp. 125-32.

32. Ibid.

33. U.S. Food and Drug Administration, “Coronavirus (COVID-19) Supply Chain Update,” Press Release, Feb. 27, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>.

34. Ibid.

35. Yasmeen Abutaleb and Erica Warner, “Trump’s support for bipartisan Senate drug pricing bill may not be enough to push it into law,” *The Washington Post*, Feb. 18, 2020. <https://www.washingtonpost.com/health/2020/02/18/trumps-support-bipartisan-senate-drug-pricing-bill-might-not-be-enough-push-it-into-law>.

36. Sally C. Pipes, “Proposed ‘Buy American’ Requirements Would Hurt Patients and the Economy,” Pacific Research Institute, April 2020, p. 6. https://www.pacificresearch.org/wp-content/uploads/2020/04/BuyAmerica_F.pdf.

37. “Pathway to Global Product Safety and Quality,” U.S. Food and Drug Administration, 2011, p. 20.

38. Ibid.

global market merely because they have a Chinese or other foreign ingredient, the U.S. government may cause the very shortages and price hikes it fears could result from malevolent foreign action. Consider, for example, the recent recall of metformin. Americans managing Type 2 diabetes spend over \$3 billion per year filling prescriptions for metformin.³⁹ After the FDA discovered potentially unsafe levels of nitrosamine in some batches of the drug, numerous drug makers pulled their metformin pills off the market.⁴⁰ But the recall is not expected to affect patients at all because, according to the FDA, “there are additional manufacturers of the metformin ER formulation that supply a significant portion of the U.S. market, and their products are not being recalled.”⁴¹ Without access to global supplies, a single instance like this of drug contamination at a manufacturing plant would severely cut the nation’s supply and force patients to go without treatment. Instead, the FDA merely advises anyone currently taking one of the recalled products to “consult with their health care professional who can prescribe a replacement.”⁴²

OVERVIEW OF CURRENT PROPOSALS

Even before the outbreak of COVID-19, policymakers had already begun proposing government interventions in the pharmaceutical chain in order to minimize or eliminate the role of Chinese manufacturing. For example, in October 2019, the House Energy and Commerce Committee held a hearing following a report from the U.S.–China Economic and Security Review Commission, which warned that the Chinese could “use U.S. dependence on China as an economic weapon and cut supplies of critical drugs.”⁴³ That report made a number of recommendations, including additional monitoring and reporting by the FDA, mandatory country-of-origin labels for API and a requirement that all federally funded health systems (including Medicare and Medicaid) “purchase their pharmaceuticals only from U.S. production facilities” subject to some broad exceptions.⁴⁴ It’s also worth noting that some of the recommendations are directed at all imported drugs and APIs instead of just ones from China, which certainly suggests that protectionism rather than national security is the true motivation behind such measures.

39. Richard Franki, “Top-selling drugs going to patients with diabetes,” *MDEdge*, March 12, 2018. <https://www.mdedge.com/cardiology/article/160612/diabetes/top-selling-drugs-going-patients-diabetes>.

40. David J. Neal, “Diabetes medicine recalled for having too much of a carcinogen. More recalls are likely,” *Miami Herald*, May 29, 2020. <https://www.miamiherald.com/news/health-care/article243081016.html>.

41. U.S. Food and Drug Administration, “FDA Alerts Patients and Health Care Professionals to Nitrosamine Impurity Findings in Certain Metformin Extended-Release Products,” Press Release, May 28, 2020. <https://www.fda.gov/news-events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin>.

42. *Ibid.*

43. “2019 Annual Report,” U.S.–China Economic and Security Review Commission, Nov. 14, 2019, p. 248. <https://www.uscc.gov/annual-report/2019-annual-report>.

44. *Ibid.*, p. 249.

Moreover, a number of bills have been proposed recently in Congress that would enact reforms similar to one or more of the report’s recommendations. The most appropriate, common-sense proposals offered so far in Congress are ones meant to improve our knowledge of the existing supply arrangement through enhanced monitoring and reporting.⁴⁵ Such knowledge may assuage rising anxiety about Chinese dominance but, even if it does not, a better understanding of the situation is crucial for government planners trying to redesign any major American industry.

In addition to this, a provision of the already enacted CARES Act calls for a report by the National Academies of Sciences, Engineering and Medicine to examine the current state of pharmaceutical and medical device supply chains and to recommend ways to improve resiliency.⁴⁶ Other bills have called on the FDA to track API production with greater detail so we can know the volume of APIs originating in every country for each approved drug.⁴⁷ Some proposals seek to promote domestic manufacturing of APIs through targeted tax breaks, grants or regulatory reform. One example of this approach is Senator Marsha Blackburn’s (R-Tenn.) “Securing America’s Medicine Cabinet Act,” which would reform the FDA’s Emerging Technology Program in order to fast-track the approval of new manufacturing methods that could help prevent supply chain disruptions.⁴⁸

A number of more drastic proposals have been offered that would actively restrict access to drugs with foreign-sourced APIs. One ambitious example is the “Protecting our Pharmaceutical Supply Chain from China Act” proposed by Sen. Tom Cotton (R-Ark.) and Rep. Mike Gallagher (R-Wis.). In addition to having the FDA better track the origin of APIs, requiring country-of-origin information on labels and giving tax breaks to companies expanding domestic manufacturing, the bill would also prohibit U.S. government entities from buying any drugs made from APIs produced in China.⁴⁹ Such a policy would undoubtedly incentivize pharmaceutical companies to source APIs from elsewhere, but it would also deny patients at VA and other federal hospitals access to drugs. The result would be healthcare decisions driven by industrial policy rather than medical needs. It would also expand the gap between private and public health systems, with the latter burdened by politically motivated inefficiencies that raise costs and reduce the quality of care.

45. See, e.g., H.R. 5982, Safe Medicine Act, §3, 116th Congress.

46. CARES ACT, Sec. 3101.

47. See, e.g., H.R. 6049, Medical Supply Chain Security Act, §2(a)(5), 116th Congress.

48. S. 3432, Securing America’s Medicine Cabinet Act of 2020, 116th Congress.

49. 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.

Sen. Marco Rubio (R-Fla.) has offered a similarly broad bill with four Democratic co-sponsors that also employs a Buy-American strategy but is less targeted at China specifically. Their “Strengthening America’s Supply Chain and National Security Act” would deny any Buy American preferences to U.S.-manufactured drugs made with foreign-sourced APIs.⁵⁰

POLICY RECOMMENDATIONS

Rather than embracing aggressive protectionism through Buy American requirements for federal pharmaceutical purchases, there are better ways to ensure the security of the supply chain and provide proper incentives to re-shore some portions of it to maintain affordable pharmaceuticals and a globally competitive industry. The following sections outline some of the most effective strategies.

Get better data and a clearer picture

As a preliminary matter, better data is needed before policy-makers can truly make informed decisions about the future of the pharmaceutical supply chain. Data exists to determine the exact portion of imported APIs used by U.S. drug manufacturers and the countries from which they come. But, there is no data to determine the portion of APIs and their countries of origin used by foreign drug manufacturers exporting to the United States. In order to rectify this, Congress could mandate the disclosure of APIs to the FDA for any drug exported to the United States by foreign drug manufacturers. If such a method is adopted, precautions should be taken to ensure that trade secrets are protected.

Likewise, as mentioned, the CARES Act, passed by Congress in March 2020, requires the National Academies of Science, Engineering and Medicine to perform a study on the security of the pharmaceutical supply chain.⁵¹ Rather than exploiting a crisis to make swift and dramatic changes without a clear picture, policymakers should wait for and then use this study to carefully craft an appropriate response.

Lead the charge for liberalization

Since World War II, the United States has been the global leader in the creation and cultivation of the rules-based trading system. The bulwark of this system is the WTO. Every president from Harry Truman to Barack Obama was largely supportive of the WTO and its predecessor, the GATT. Today,

that is not the case. The Trump administration has a well-known antipathy for the Geneva-based forum.⁵²

To be sure, the WTO’s negotiating function has been stuck in neutral for the last several years.⁵³ This is partially understandable, as new rules are necessary to cover various disciplines, such as trade in digital products, that have risen in popularity with the emergence of internet-based commerce but were not accounted for originally. With the outbreak of COVID-19, there is an opportunity for the WTO to reestablish itself as the primary forum for crafting new rules to facilitate predictable rules-based trade in pharmaceutical and other medical products. As the world’s largest economy, the United States should play a leading role in facilitating such trade negotiations.

Additionally, Phil Hogan, the European Union’s Trade Commissioner, recently proposed a global trade negotiation that seeks to “permanently eliminate tariffs on medical goods needed to respond to the COVID-19 health crisis.”⁵⁴ While lowering tariffs on pharmaceuticals and other medical supplies would be good, it does not go far enough. The larger concern during emergencies is that countries will restrict exports in an attempt to ensure sufficient quantities of certain products are available for domestic consumption. Since the outbreak of COVID-19, about 70 countries have imposed export restrictions on certain medical supplies.⁵⁵ Unfortunately, WTO rules largely work to restrict only import protectionism, not export protectionism, both of which tend to proliferate during crises and economic downturns.

For these reasons, the United States should be leading the 163 other countries in the WTO to create new rules that prohibit restricting exports of pharmaceuticals and medical supplies during outbreaks.⁵⁶ Such a move is not unprecedented; in April 2020, the agriculture ministers of the G-20 countries, including the United States, issued a pledge to prohibit food and agricultural export restrictions during the COVID-19

52. See, e.g., Lauren L. Rollins and Clark Packard, “Trump is Trying to Dismantle the WTO. That Can’t Happen,” *The Bulwark*, April 26, 2019. <https://thebulwark.com/trump-is-trying-to-dismantle-the-wto-that-cant-happen>; Clark Packard, “Trump’s Real Trade War Is Being Waged on the WTO,” *Foreign Policy*, Jan. 9, 2020. <https://foreignpolicy.com/2020/01/09/trumps-real-trade-war-is-being-waged-on-the-wto>.

53. See, e.g., Clark Packard, “Crisis and Opportunity: The Multilateral Trading System at a Crossroads,” *R Street Policy Study* No. 167, March 2019. <https://www.rstreet.org/wp-content/uploads/2019/03/Final-167.pdf>.

54. Bryce Baschuk, “Europe Seeks to Abolish Tariffs in \$597 Billion Medical Trade,” *Bloomberg*, April 16, 2020. <https://www.bloomberg.com/news/articles/2020-04-16/europe-seeks-to-abolish-tariffs-in-597-billion-medical-trade>.

55. Jason Douglas, “As Countries Bar Medical Exports, Some Suggest Bans May Backfire,” *The Wall Street Journal*, April 4, 2020. <https://www.wsj.com/articles/as-countries-bar-medical-exports-some-suggest-bans-may-backfire-11585992600>.

56. Dr. Mona Pinchis-Paulsen, “Thinking Creatively and Learning from COVID-19—How the WTO can Maintain Open Trade on Critical Supplies,” *OpinioJuris*, April 2, 2020. <https://opiniojuris.org/2020/04/02/covid-19-symposium-thinking-creatively-and-learning-from-covid-19-how-the-wto-can-maintain-open-trade-on-critical-supplies>.

50. Office of Sen. Marco Rubio, “Rubio, Colleagues Introduce the Strengthening America’s Supply Chain and National Security Act,” Press Release, March 19, 2020. <https://www.rubio.senate.gov/public/index.cfm/2020/3/rubio-colleagues-introduce-the-strengthening-america-s-supply-chain-and-national-security-act>.

51. Section 3101 of Public Law 116-136.

pandemic.⁵⁷ Likewise, during the financial crisis of 2008, the United States and the other G-20 members issued a pledge that for the next year, they would “refrain from raising new barriers to investment or to trade in goods and services, imposing new export restrictions, or implementing World Trade Organization (WTO) inconsistent measures to stimulate exports.”⁵⁸

If multilateral WTO negotiations to prohibit export restrictions of medical equipment and pharmaceuticals during emergencies are too difficult, too time consuming or face intractable opposition from, say, China, the United States could pursue plurilateral negotiations with some, but not all, WTO members. The United States would likely find willing partners with close allies like Australia, the European Union, Mexico, Canada, Japan, the United Kingdom, Taiwan, Israel and India. Such a group of close U.S. allies could agree not to impose export restrictions and other protectionist measures on medical supplies and pharmaceuticals during emergencies such as pandemics and natural disasters.

Outside the WTO context, the United States should include similar prohibitions on export restrictions during emergencies in future free-trade agreement (FTA) negotiations and consider narrowly revising existing FTAs to include such language.

Another possibility would be for the United States to rejoin the Trans-Pacific Partnership (TPP), a promising trade pact between Pacific Rim nations that President Trump abandoned.⁵⁹ A primary goal of the TPP was to establish better and more reliable trading relationships with a number of Asian countries in China’s orbit. Rejoining the TPP would therefore strengthen Asian supply chains and provide an alternative to reliance on China. As part of rejoining the TPP, the United States could insist on a provision that would prohibit export restrictions on pharmaceuticals and other medical supplies. It could also look to expand the trade bloc by negotiating accession with countries like India and Taiwan. All of these options are consistent with existing WTO obligations and are preferable to crude attempts to re-shore the entire pharmaceutical supply chain.

Offer full expensing for manufacturing facilities

However, if the goal is to re-shore some of the pharmaceutical supply chain, there are positive steps policymakers can

57. Agriculture Ministers, “Ministerial Statement on COVID-19,” G-20, April 21, 2020. https://g20.org/en/media/Documents/G20_Agriculture%20Ministers%20Meeting_Statement_EN.pdf.

58. Chad P. Bown, “COVID-19 Could Bring Down the Trading System,” *Foreign Affairs*, April 28, 2020. <https://www.foreignaffairs.com/articles/united-states/2020-04-28/covid-19-could-bring-down-trading-system>.

59. Note: the TPP moved forward without the United States. It is now called the Comprehensive and Progressive Agreement for Trans-Pacific Partnership.

take. As part of the Tax Cut and Jobs Act (TCJA) passed in late 2017, Congress provided temporary full expensing of short-lived investments through 2022, which will phase out entirely by 2026.⁶⁰ This means that when a firm makes a short-term investment, it can write off the full value of the investment from its tax liability in the year of the investment, rather than phasing it out as the asset depreciates. In order to qualify for full immediate expensing, the asset must have a cost-recovery period of 20 years or less.⁶¹

In order to make the United States a more attractive and competitive country in which to produce pharmaceuticals and APIs, policymakers should consider making full expensing permanent and applying it to long-term investments like non-residential structures or manufacturing facilities. This would provide an incentive for pharmaceutical manufacturers to open production facilities in the United States or to move facilities from overseas. Recent legislation was introduced in the House of Representatives that would provide this type of tax treatment to medical supply companies and pharmaceutical manufacturers for their non-residential real-property investments.⁶² Such a tax change is vastly superior to protectionist Buy American schemes.

Improve tax treatment of research and development costs

Currently, when an American firm makes investments into research and development (R&D), it can deduct those costs from its tax liability during the year in which they occur. This is the right policy. But under the TCJA, Congress mandated that beginning in 2022, firms making R&D investments must amortize those expenses over a five-year period. As the National Taxpayers Union Foundation has noted:

The policy will raise the cost of investments in research and development, meaning companies will be less likely to do R&D. That means less innovation and new technologies for the U.S. economy, leading to lower levels of productivity, lower wages, and a smaller economy.⁶³

In order to incentivize more domestic production of pharmaceuticals and APIs, Congress should correct the TCJA’s treatment of R&D expenses. Full, immediate expensing is vastly preferable to an amortized approach, given the time-value of money.

60. Erica York and Alex Muresianu, “The TCJA’s Expensing Provision Alleviates the Tax Code’s Bias Against Certain Investments,” Tax Foundation, Sept. 5, 2018. <https://taxfoundation.org/tcja-expensing-provision-benefits>.

61. *Ibid.*

62. H.R. 6690, The Beat China Act, 116th Cong.

63. 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-tcjias-mistreatment-of-rd-costs>.

Deregulate

The regulatory review process for building a pharmaceutical manufacturing facility can be cumbersome, time consuming and costly. If policymakers decide it is important to re-shore some portion of the pharmaceutical supply chain, the FDA should expedite and streamline the approvals of such facilities in order to eliminate costly delays and duplication.

Stockpile essential medicines

In addition to the measures already suggested, the federal government should identify and stockpile essential medicines in a deliberate and careful manner. A recent study by the Mercatus Center argues that policymakers should be utilizing the Defense Production Act to establish purchase guarantees for certain medical equipment necessary to combat COVID-19—along with targeted deregulation—in order to bolster production.⁶⁴ A similar approach could be used to secure sufficient quantities of essential drugs.

By providing purchase commitments for the essential pharmaceuticals at above-market prices for a sustained period of time, the federal government can provide the proper market-based incentives to significantly increase the supply of such drugs. Admittedly, the shelf-life of pharmaceuticals is probably shorter than protective masks, but the drugs could be purchased on a more regular basis than other medical equipment. Alternatively, companies could hold the extra stock and cycle in and out of their supplies. In other words, the government would be paying companies to have a rolling surplus of those pharmaceuticals that are deemed essential.

CONCLUSION

The simple reality is that the United States cannot—and should not—produce all pharmaceuticals domestically. Importing finished pharmaceuticals and APIs helps keep costs down. Existing pharmaceutical supply chains are diverse and produce benefits that accrue to American consumers. Exploiting the COVID-19 pandemic to haphazardly undo these supply chains would be a grave mistake that could result in higher prices or shortages of various drugs.

At the same time, if policymakers are concerned that the United States is too dependent on China for pharmaceuticals and APIs, there are steps they can take to lessen that dependence without resorting to costly pharmaceutical autarky or aggressive protectionism. The United States could go a long way toward ensuring a secure supply of pharmaceuticals by exerting global leadership through trade negotiations with like-minded allies. Likewise, policymakers can bolster

domestic production through smarter tax and regulatory policies. The current proposals put forward by the administration and members of Congress would be catastrophic. Policymakers should take a more judicious and effective approach; one based on data and practicality rather than ulterior motives.

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64. Caleb Watney and Alec Stapp, "Masks for All: Using Purchase Guarantees and Targeted Deregulation to Boost Production of Essential Medical Equipment," Mercatus Center, April 8, 2020. https://www.mercatus.org/system/files/watney_and_stapp_-_policy_brief_-_covid_series_-_masks_for_all_-_v1.pdf.