The American Medical Product Supply Chain: Will COVID-19 Drive Manufacturing Back Home?

BETH WEINMAN, GREGORY H. LEVINE, JENNA MCCARTHY & GRANT SIMS*

ABSTRACT

As the COVID-19 pandemic roiled the global economy, significant disruptions to the flow of goods and raw materials between countries emerged. Serious medical product shortages exposed the degree to which the United States relies on foreign suppliers of active pharmaceutical ingredients (API), finished pharmaceuticals, and other indispensable medical products and components. Concern about the fragility of medical product supply chains has generated rare bipartisan consensus, as policymakers of all stripes have called for measures to reduce the country's heavy dependence on foreign manufacturers. This Article begins by briefly discussing the root causes that have led many drug companies, API manufacturers, and device makers to move their operations abroad. It then outlines the potential national security and public health risks posed by the nation's significant dependence on foreign pharmaceutical and medical device suppliers. The Article also reviews measures taken during the COVID-19 pandemic to address medical product shortages, and how the pandemic has highlighted the need for comprehensive, long-term solutions to over-reliance on foreign medical product manufacturing. The Article then addresses both the Trump and Biden administrations' approaches to strengthening domestic medical product manufacturing. It concludes by considering whether the current level of scrutiny and funding to address supply chain fragility will continue after COVID-19 is no longer an immediate threat.

I. INTRODUCTION

Since early 2020, the COVID-19 pandemic has roiled the global economy, significantly affecting international trade and bringing travel to a standstill. Enormous stress on global supply chains has disrupted the smooth flow of goods and raw materials between countries, adversely affecting entire industries and product categories. Although an end to the pandemic now appears to be on the horizon with the arrival of highly effective vaccines, the SARS-CoV-2 virus has killed more than a

* Greg Levine is a partner in the Washington, D.C. office of Ropes & Gray and Chair of the Firm's Life Sciences Regulatory and Compliance (LSRC) Practice Group, which offers comprehensive FDA regulatory and compliance services, including regulatory strategy and product development advice, counsel on advertising and promotion strategy, advice on post-approval compliance issues, representation in FDA enforcement and litigation matters as well as congressional investigations, and due diligence reviews and transactional support. Beth Weinman is Counsel, and Jenna McCarthy and Grant Sims are associates in the Ropes & Gray LSRC Practice Group.

half-million people in the United States alone. The pandemic's devastating toll requires a sober reckoning with what the United States could have done better, and what the country, working with global partners, can and should do now to reduce the potential harm from future pandemics.

This reckoning will need to include an evaluation of the country's fragile medical supply chains. Although the increasingly global economy has many benefits, reliance on foreign-supplied medical products and raw materials for their manufacture was already a growing concern for U.S. policymakers before the pandemic. The severe shortages in critical medical supplies that emerged quickly in the United States once COVID-19 began to spread—including shortages of N95 respirators, laboratory testing supplies, and the drugs needed for hospitalized patients—illustrated that such concern was justified. Pandemic-related supply chain disruptions exposed the degree to which the United States and other countries rely on the foreign supply of indispensable medical products, including API, finished pharmaceuticals, and other medical supplies. In the United States, pandemic-related medical product shortages have intensified calls for measures to enhance the security and reliability of medical supply chains, with particular interest in reducing the country's dependence on foreign sources of critical medical products and raw materials by increasing domestic manufacturing capacity.

This Article addresses the causes and extent of U.S. dependence on foreign medical product manufacturing, the impact of the COVID-19 pandemic on global medical supply chains, and potential approaches to improving medical product supply chain robustness and security. It begins by discussing the incentives that have driven many drug and device manufacturers to move their operations abroad over the past few decades and the extent of the resulting U.S. dependence on foreign-made medical products, particularly API and finished pharmaceuticals. Next, the Article outlines the potential national security and public health risks posed by dependence on foreign medical product suppliers, which manifested themselves clearly during the COVID-19 pandemic and will remain a threat even as the pandemic subsides. In its final section, the Article addresses the ways in which the U.S. government has attempted to ameliorate supply chain shortages during the COVID-19 pandemic and examines potential measures under consideration to avoid or lessen such shortages when future disease outbreaks or other global crises inevitably arise.

II. GLOBALIZATION OF MEDICAL PRODUCTS INDUSTRY AND ASSOCIATED RISKS

A. Globalization of the Medical Product Supply Chain

1. Pharmaceuticals

In recent decades, the American pharmaceutical industry, like many other industries, has become increasingly global.[1] Since the 1970s, a combination of tax incentives and cost pressures has pushed many companies to move their medical product manufacturing operations away from the U.S. mainland. U.S. tax code Section 936, enacted in 1976, incentivized manufacturing in Puerto Rico by exempting

[1] Arthur Daemmrich, *Pharmaceutical Manufacturing in America: A Brief History*, 59 AM. INST. HIST. PHARMACY 63 (2017), https://repository.si.edu/bitstream/handle/10088/97768/Daemmrich%20PharmaMfg%20PharmHist%202017.pdf?sequence=1&isAllowed=y [https://perma.cc/RM5R-WBD5].

manufacturers in U.S. territories from paying taxes for corporate income generated there.[2] Over time, the possibility of significantly reduced costs attracted manufacturers to locations outside the United States entirely, further south to Mexico, and eastward to Asia.[3] Relatively low tax rates in Ireland and other European countries also made Europe an attractive destination for pharmaceutical manufacturers.[4]

A mix of factors contributes to lower production costs outside the United States, including favorable tax treatment,[5] less rigorous environmental regulations,[6] less expensive labor,[7] and cheaper real estate.[8] While these factors have resulted in the off-shoring of manufacturing for many types of products, the highly competitive market for relatively inexpensive generic drugs has exerted particularly acute cost pressures on pharmaceuticals, making their manufacture even more sensitive to cost pressures.[9]

The reshaping of the pharmaceutical manufacturing landscape has been dramatic. Since the late 1990s, the United States has imported more pharmaceuticals than it has

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[2] *See* U.S. GOV'T ACCOUNTABILITY OFF., GGD-92-72BR, PHARMACEUTICAL INDUSTRY TAX BENEFITS OF OPERATING IN PUERTO RICO (1992); Roy Avik, *Puerto Rico Can Help the U.S. End its Dependence on Chinese Pharmaceutical Ingredients*, FORBES (Mar. 16, 2020), https://www.forbes.com/sites/theapothecary/2020/03/16/puerto-rico-can-help-the-u-s-end-its-dependence-on-chinese-pharmaceutical-ingredients/ [https://perma.cc/3GSM-TANG].

[3] *Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program: Hearing Before the Subcomm. on Oversight & Investigation of the H. Comm. on Energy & Com.*, 116th Cong. (2019) (testimony of Janet Woodcock, Director, Center for Drug Evaluation and Research), https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019 [https://perma.cc/53XB-TM2C]; FITCH SOLS., UNITED STATES MEDICAL DEVICES REPORT 26 (Q3 2020).

[4] *See* Avik, *supra* note 2. *See also* Matthew Herper, *Can Anything Stop Drug Companies From Fleeing the U.S. Tax System?*, FORBES (July 19, 2014), https://www.forbes.com/sites/matthewherper/2014/07/19/can-anything-stop-drug-companies-from-fleeing-the-u-s-tax-system/?sh=63b9b1f04a37 [https://perma.cc/W6XU-G2K3].

[5] Brad W. Setser, *The Irish Shock to U.S. Manufacturing?*, COUNCIL ON FOREIGN RELS.: BLOG (May 15, 2020), https://www.cfr.org/blog/irish-shock-us-manufacturing [https://perma.cc/99F5-DBGM]; Alex Berenson, *Drug Makers Reap Benefits of Tax Break*, N.Y. TIMES (May 8, 2005), https://www.nytimes.com/2005/05/08/business/drug-makers-reap-benefits-of-tax-break.html [https://perma.cc/K8FQ-Z4YB] (describing tax breaks for pharmaceutical makers in the 2005 American Jobs Creation Act).

[6] *Safeguarding Pharmaceutical Supply Chains in a Global Economy: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 116th Cong. (2019) (testimony of Janet Woodcock, Director, Center for Drug Evaluation and Research), https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019 [https://perma.cc/SZ4E-BNTC]; *see also* Sydney Lupkin, *What Would It Take To Bring More Pharmaceutical Manufacturing Back to the U.S.?*, NPR (Apr. 24, 2020), https://www.npr.org/sections/health-shots/2020/04/24/843379899/pandemic-underscores-u-s-dependence-on-overseas-factories-for-medicines [https://perma.cc/82HY-YF3C].

[7] The World Bank has estimated that Chinese labor costs, on average, are less than one-tenth as much as labor costs in Western countries. *See* Janet Bumpas & Ekkenhard Betsch, *Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines*, WORLD BANK (Sept. 2009), https://openknowledge.worldbank.org/handle/10986/13682 [https://perma.cc/RU4J-KBBS].

[8] *See Safeguarding Pharmaceutical Supply Chains*, *supra* note 6 (noting that China has lower electricity, water, and coal costs and is embedded in a network of raw materials and intermediate suppliers); Bumpas & Betsch, *supra* note 7, at 12–13 (similarly noting lower electricity, water, coal, infrastructure, equipment, and depreciation costs in India and China).

[9] *Securing the U.S. Drug Supply Chain*, *supra* note 3.

exported.[10] Since 2011, the number and value of pharmaceutical imports have continued to rise.[11] In 2019 alone, U.S. pharmaceutical imports amounted to $128 billion, and the pharmaceutical annual trade deficit hit $74 billion.[12]

The globalization of the pharmaceutical supply chain has been particularly pronounced in the manufacture of API. Production of these crucial ingredients—compounds that give drugs their pharmacological effect—is now largely a foreign endeavor. Over the years, API manufacturing, like pharmaceutical manufacturing generally, has moved east, away from wealthier Western countries and toward growing industrial centers like India and China. Until relatively recently, for example, Italy was the largest supplier of generic API to the United States, but India has since surpassed it.[13] In some cases, this "off-shoring" of manufacturing produces huge savings. A 2011 Food and Drug Administration (FDA) report estimated that U.S. firms could save as much as thirty to forty percent on API manufacturing by moving their operations to India and China.[14] Many, including FDA, estimate that between seventy and eighty percent of the U.S. market's API is produced abroad.[15] Some API, as well as certain chemical precursors, are now solely sourced in China.[16]

Former FDA Commissioner Scott Gottlieb warned of vulnerabilities caused by significant reliance on a foreign supply of API and API starting materials, including the lack of transparency in API supply chains. According to former Commissioner Gottlieb, the United States "may not even be aware of the full scope of these vulnerabilities," and often lacks the ability to track pharmaceutical production to the level of the API and other starting materials.[17] In 2019 congressional testimony, Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), bluntly outlined FDA's limited data on API manufacturing in China and elsewhere, stating: "[W]e cannot determine with any precision the volume of API that

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[10] Steven L. Byers & Jeff Ferry, *Health, Security, Economic Benefits from Reshoring*, COAL. FOR A PROSPEROUS AM. (Mar. 17, 2020), https://prosperousamerica.org/reshoring-us-pharmaceutical-production-would-create-800k-jobs/ [https://perma.cc/43ZN-MWK2].

[11] *United States Imports of Pharmaceutical products*, TRADING ECONS. (2020), https://tradingeconomics.com/united-states/imports/pharmaceutical-products [https://perma.cc/7LPJ-BQDU].

[12] Jeff Ferry, *It's Time to Rebuild Domestic Drug Production in the US, for Both Health and Economic Reasons*, INDUSTRYWEEK (Mar. 17, 2020), https://www.industryweek.com/the-economy/article/21126380/its-time-to-rebuild-domestic-drug-production-in-the-us-for-both-health-and-economic-reasons [https://perma.cc/V8D5-32BN].

[13] Italy's API manufacturers constituted 10% of the global market in 2014. Giuliana Miglierini, *Italian API Producers Have Won the Challenge*, PHARMA WORLD (Dec. 20, 2016), http://www.pharmaworldmagazine.com/italian-apis-producers-won-challenge/ [https://perma.cc/W7YH-BAYX]; *Safeguarding Pharmaceutical Supply Chains*, *supra* note 6.

[14] U.S. FOOD & DRUG ADMIN., PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY 20 (2011), https://www.ipqpubs.com/wp-content/uploads/2011/09/FDA-Pathway-to-Global-Product-Safety-and-Quality.pdf [https://perma.cc/Z9LY-C8DJ]. Importantly, under FDA's classification scheme, establishments that produce both finished drug products and API are counted as finished drug product establishments. *See* U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: ROOT CAUSES AND POTENTIAL SOLUTIONS (2019), https://www.fda.gov/media/131130/download [https://perma.cc/4P4V-HXQ8] (updated Feb. 21, 2020).

[15] *Safeguarding Pharmaceutical Supply Chains*, *supra* note 6.

[16] Laurie McGinley & Carolyn Y. Johnson, *Coronavirus Raises Fears of U.S. Drug Supply Disruptions*, WASH. POST (Feb. 26, 2020), https://www.washingtonpost.com/health/2020/02/26/coronavirus-raises-fears-us-drug-supply-disruptions/ [https://perma.cc/KNU4-7KSU].

[17] *Id.*

China is actually producing, or the volume of API manufactured in China that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or in other parts of the world."[18] Without this knowledge, FDA cannot perform reliable "gap analyses" to better understand the nature and extent of the country's reliance on foreign-made API.[19] This lack of knowledge also impairs FDA's ability to predict how world events—from natural disasters to pandemics or war—will affect the American drug supply.

2. Medical Devices

The story of device industry globalization has been largely similar, if somewhat less dramatic. As with pharmaceuticals, desire to reduce manufacturing costs has driven device manufacturing abroad.[20] Until relatively recently, the United States held a substantial trade surplus in medical devices. But by 2017, the surplus had become a deficit of $2.1 billion, which increased further to $4.1 billion in 2018, when the United States imported more than $51.6 billion in medical equipment.[21] The number of imported medical devices increased every year from 2008 to 2018, with the exception of 2009 when the global economic crisis led to a decline in imports.[22] In 2019, the United States was the world's largest importer of medical products, responsible for 19% of global medical product imports.[23] Of that 19%, approximately 42% came from medical equipment, personal protective equipment (PPE), and other non-pharmaceutical medical supplies.[24]

B. The Risks of Overdependence on Foreign Medical Product Manufacturing

Since the end of World War II, many economists have agreed that global trade provides net positive benefits.[25] Although its benefits and costs may be unevenly distributed, in general, the benefits of trade include greater productivity, more efficient resource allocation, economies of scale, higher wages and job growth in exporting industries, and increased choice and lower prices for consumers and firms using

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18 *Safeguarding Pharmaceutical Supply Chains*, *supra* note 6.

19 *Id.*

20 FITCH SOLS., *supra* note 3, at 26.

21 *Id.* at 26, 36.

22 *Id.* at 11, 26.

23 WORLD TRADE ORG., TRADE IN MEDICAL GOODS IN THE CONTEXT OF TACKLING COVID-19 3 (2020), https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf [https://perma.cc/EBZ8-TU6K].

24 *See id.* (Table 1).

25 *See* JAMES K. JACKSON, CONG. RSCH. SERV., R44546, THE ECONOMIC EFFECTS OF TRADE: OVERVIEW AND POLICY CHALLENGES (2018), https://crsreports.congress.gov/product/pdf/R/R44546 [https://perma.cc/R8ZD-JAZS]; *see also* Gary Clyde Hufbauer & Zhiyao Lu, *The Payoff to America from Globalization: A Fresh Look with a Focus on Costs to Workers*, PETERSON INST. FOR INT'L ECON. (May 2017), https://www.piie.com/publications/policy-briefs/payoff-america-globalization-fresh-look-focus-costs-workers [https://perma.cc/XET7-44F2] ("Since the end of the Second World War (WWII), the world has gone through an enormous expansion in international trade and investment, generating unprecedented gains in wealth for the United States and its economic partners.").

imports as inputs into finished products.[26] The United States has played a leading role in establishing the global economic order, resulting in increased U.S. trade and increasing integration of U.S. markets and production with foreign nations, particularly emerging economies.[27] The increasing globalization of U.S. trade has been no less apparent in medical products industries.

Despite its well-established benefits, American policymakers have become increasingly concerned in recent years that the extent of the country's dependence on foreign manufacturing of key medical products exposes the United States to dangerous supply chain insecurity.[28] The COVID-19 pandemic has made supply chain security a matter of bipartisan concern, as dependence on foreign manufacturing has both geopolitical and public health consequences. This section highlights national security concerns raised by dependence on foreign manufacturing, the consequences of which became very clear during the COVID-19 pandemic. It then discusses the implications of such dependence for medical product quality, focusing on several recent controversies relating to drugs manufactured in China and India.

1. National Security Concerns

Over the past several years, tension in the U.S.-China relationship has consistently made headlines. The prospect of a trade war has loomed large, prompting many to wonder how such a conflict might impact critical supply chains, including those of pharmaceuticals and other medical products.[29] Reportedly, Chinese officials and academics have considered whether curtailing medical supplies such as antibiotics could be used as a tool in trade disputes.[30]

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[26] *See* SHAYERAH ILIAS AKHTAR, IAN F. FERGUSSON & BROCK R. WILLIAMS, CONG. RSCH. SERV., IF10156, U.S. TRADE POLICY: BACKGROUND AND CURRENT ISSUES (2020), https://crsreports.congress.gov/product/pdf/IF/IF10156. [https://perma.cc/E2G4-AGUS]

[27] *See id.*; *see also* Robert Feenstra, *Integration of Trade and Disintegration of Production in the Global Economy*, 12 J. ECON. PERSP. 31, 31 (1998), https://pubs.aeaweb.org/doi/pdfplus/10.1257/jep.12.4.31 [https://perma.cc/8CH8-L59N]; Robert E. Litan, *The "Globalization" Challenge: The U.S. Role in Shaping World Trade and Investment*, BROOKINGS (Mar. 1, 2000), https://www.brookings.edu/articles/the-globalization-challenge-the-u-s-role-in-shaping-world-trade-and-investment/ [https://perma.cc/KP6Z-JC4N].

[28] *See, e.g.*, Press Release, Representative Vern Buchanan Off., Buchanan Introduces Bill to Boost U.S. Drug Manufacturing (May 5, 2020), https://buchanan.house.gov/media-center/press-releases/buchanan-introduces-bill-boost-us-drug-manufacturing#:~:text=Buchanan's%20bill%2C%20titled%20The%20Securing,the%20U.S.%20Senate%20by%20Sens [https://perma.cc/5M9T-DL9H]; Press Release, Representative Robert Menendez Off., Menendez, Blackburn Introduce Bipartisan Bill to Increase US Prescription Drug Manufacturing (Mar. 11, 2020), https://www.menendez.senate.gov/newsroom/press/menendez-blackburn-introduce-bipartisan-bill-to-increase-us-prescription-drug-manufacturing [https://perma.cc/D44V-JEXL].

[29] Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China*, COUNCIL ON FOREIGN RELS.: BLOG (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china [https://perma.cc/C8ZM-RGE3].

[30] *See* Doug Palmer & Finbarr Bermingham, *U.S. Policymakers Worry about China 'Weaponizing' Drug Exports*, POLITICO (Apr. 10, 2020, 11:15 AM), https://www.politico.com/news/2019/12/20/policymakers-worry-china-drug-exports-088126 [https://perma.cc/CL66-X4SX] (noting that, in remarks delivered in March 2019, during the National People's Congress, a Tsinghua University professor and former central bank advisor stated, "We are at the mercy of others when it comes to computer chips, but we are the world's largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports, the medical systems of some western countries will not run well.").

In March 2020 congressional testimony, Rosemary Gibson, a senior advisor at the Hastings Center, outlined the acute shortages that would result if China were to use medical supplies as a "weapon of war."[31] According to Gibson, if China were to stop supplying the United States with critical drug products, the United States would experience "unprecedent[ed] deaths and social disorder on a scale never seen [here] before."[32] In addition, "[t]he civilian and military health care systems [would] collapse."[33]

2. Product Quality Concerns

In addition to worrying about the national security implications arising out of U.S. dependence on foreign manufacturing, members of Congress, FDA, and other policy analysts have also expressed concerns about the public health risks associated with sub-standard foreign-made pharmaceuticals, often in the form of low-cost generic drugs.[34] Though FDA is legally required to hold both branded and generic drugs to the same standards of safety and efficacy, questions linger over the quality of some foreign-made drugs, and some allege that cost pressures and a widespread desire for cheaper drugs have driven some manufacturers to cut corners.[35] Some have suggested that Chinese and Indian manufacturers are more likely than American manufacturers to be cited for particularly serious quality-related deficiencies.[36] By comparing FDA inspection reports (Form 483s), for example, one research team determined that "data integrity" violations were cited in 48% of Form 483s issued to Chinese facilities and 44% of Form 483s issued to Indian facilities, compared to 26% of the Form 483s issued to U.S. facilities.[37] "Data manipulation" was cited in 31% of Form 483s issued to Chinese facilities and 24% of Indian facilities, in comparison to 7% of U.S.

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[31] *Id. See also The Coronavirus and America's Small Business Supply Chain: Hearing Before the S. Comm. on Small Bus. & Entrepreneurship*, 116th Cong. (2020) (testimony of Rosemary Gibson, Author), https://www.sbc.senate.gov/public/_cache/files/1/c/1c39a1bc-f22c-4178-951e-29b92dcb2182/3AD9C94FB267763A83913E2303A6A772.gibson-testimony.pdf [https://perma.cc/3D6D-BS4J] ("Medicines in the hands of an adversary can be weaponized.") [hereinafter, Gibson Testimony].

[32] Gibson Testimony, *supra* note 31.

[33] *Id.*

[34] *See, e.g.*, Marv Shepherd, *Drug Quality, Safety Issues, and Threats of Drug Importation*, 36 CAL. W. INT'L L.J. 77, 77 (2005); Scott W. Atlas & H.R. McMaster, *Relying on Foreign Drugs is Dangerous*, WALL ST. J. (Apr. 28, 2020), https://www.wsj.com/articles/relying-on-foreign-drugs-is-dangerous-11588093635 [https://perma.cc/S99E-8SPL]; Press Release, U.S. Sen. Comm. on Finance, Grassley Presses HHS, FDA on Safety and Quality Control of Foreign Drug Manufacturing Facilities (June 28, 2019), https://www.finance.senate.gov/chairmans-news/grassley-presses-hhs-fda-on-safety-and-quality-control-of-foreign-drug-manufacturing-facilities [https://perma.cc/ASF8-ATFG].

[35] *See* Anna Edney, *How a Tainted Heart Drug Made in China Slipped Past the FDA*, BLOOMBERG (Jan. 30, 2019), https://www.bloomberg.com/news/features/2019-01-30/chinese-heart-drug-valsartan-recall-shows-fda-inspection-limits [https://perma.cc/T9K7-5GB3]; Michael White, *Generic Drugs Not as Safe as FDA Wants You to Believe*, 54 ANNALS PHARMACOTHERAPY 283, 283 (2019), https://journals.sagepub.com/doi/10.1177/1060028019881692?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed [https://perma.cc/2Z6C-M797]; *see also* Gardiner Harris, *Drug Making's Move Abroad Stirs Concerns*, N.Y. TIMES (Jan. 19, 2009), https://www.nytimes.com/2009/01/20/health/policy/20drug.html [https://perma.cc/6DY9-Z9QQ].

[36] Katherine Eban & Sony Salzman, *In Generic Drug Plants in China and India, Data Falsification Is Still a Problem*, STAT (Oct. 29, 2019), https://www.statnews.com/2019/10/29/data-falsification-still-problematic-china-india-generic-drug-plants/ [https://perma.cc/Q5AU-VE23].

[37] *Id.* The research was compiled with the assistance of FDAZilla, a data analytics company, and analyzed FDA inspection records from 2014 to 2019 in China, India, Europe, and the United States.

facilities.[38] Nearly fifty Indian manufacturing facilities were barred from shipping drugs to the United States by 2015 because of issues including alteration, falsification, or forgery of data and records.[39] The former Drug Controller General of India also stated in a 2014 interview that if he had to follow U.S. standards in inspecting facilities supplying to the Indian market, almost all of the facilities would have to be shut down.[40]

Considering that generic drugs constitute approximately 90% of all prescription drugs purchased in the United States and that the majority of generic drugs are produced abroad, such serious allegations are worrisome.[41] Media reports have questioned whether FDA's inspection regime is sufficiently robust to ensure that imported drugs meet U.S. regulatory standards.[42] Historically, FDA has struggled to meet the challenge of inspecting a growing number of manufacturing facilities, as "its resources were overwhelmed by the nation's growing dependence on generics produced abroad."[43] In addition, some are concerned that FDA's practice of giving foreign facilities advanced notice of inspections "gives plants time to clean up any evidence of unsanitary conditions, wrongdoing, or data manipulation."[44]

For its part, FDA is adamant that it holds generic drug-makers to the same rigorous standards to which it holds name brand manufacturers. Until FDA paused foreign inspections due to COVID-19, the number of annual foreign inspections had increased significantly over the past twenty years, from 242 in 2000 to 980 in 2019.[45] And every year between 2015 through 2019, FDA conducted more foreign than domestic

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[38] *Id.*

[39] Zachary Brennan, *FDA Bans Imports from Major Indian API Manufacturer*, RAPS REGULATORY FOCUS (Oct. 15, 2015), https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/10/fda-bans-imports-from-major-indian-api-manufacturer [https://perma.cc/Y362-QPRC].

[40] Sushmi Dey, *If I Follow US standards, I Will Have to Shut Almost All Drug Facilities: G N Singh*, BUS. STANDARD (Jan. 30, 2014), https://www.business-standard.com/article/economy-policy/if-i-follow-us-standards-i-will-have-to-shut-almost-all-drug-facilities-g-n-singh-114013000034_1.html [https://perma.cc/78KW-9DAF].

[41] Press Release, Norman E. Sharpless, Comm'r of Food & Drugs, U.S. FOOD & DRUG ADMIN., Statement on Continued Progress Enhancing Patient Access to High-Quality, Low-Cost Generic Drugs (Oct. 16, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-progress-enhancing-patient-access-high-quality-low-cost-generic-drugs [https://perma.cc/BMA6-RVDT]; Eban & Salzman, *supra* note 36. Indian generics companies produce one in three pills consumed in the United States, and many of these manufacturers rely on ingredients sourced from China. Priyali Sur, *The Coronavirus Exposed the US' Reliance on India for Generic Drugs. But that Supply Chain Is Ultimately Controlled by China*, CNN (May 16, 2020), https://www.cnn.com/2020/05/16/business-india/india-pharma-us-china-supply-china-intl-hnk/index.html [https://perma.cc/7M6E-M42B].

[42] Daniel J. Kevles, *The Scandal of Our Drug Supply*, N.Y. REV. (July 23, 2020), https://www.nybooks.com/articles/2020/07/23/scandal-drug-supply-bottle-lies/?lp_txn_id=1252911 [https://perma.cc/V6SH-UBH9].

[43] *Id.* ("In 1996 the agency employed enough personnel to inspect only about one hundred foreign facilities a year, a rate of roughly one inspection every eleven years for each factory. The shorthandedness worsened dramatically between 2002 and 2009, when the number of foreign facilities requiring FDA inspections soared from roughly five hundred to more than three thousand. In January 2012, in part to ease the difficulty, Congress passed the Generic Drug User Fee Amendment, which established fees for various FDA approval services and permitted the agency to use the income to increase the number of inspectors.").

[44] Eban & Salzman, *supra* note 36.

[45] *Securing the U.S. Drug Supply Chain*, *supra* note 3.

inspections.[46] In addition, according to FDA, the agency's "scientific review and assessment process for generic drug applications ensures that generic medications perform the same way in the human body, have the same active ingredients and have the same conditions of use as their counterpart name-brand medication."[47]

Nonetheless, some remain skeptical that the agency is able to ensure compliance with manufacturing quality standards abroad as rigorously as it does within the United States.[48] Such skepticism derives in part from a series of highly publicized events involving foreign manufacturers. One highly publicized episode in 2007 involved contamination of Chinese-manufactured API for the commonly used anti-coagulant heparin, which is derived from pig intestines.[49] After various manufacturers recalled heparin products manufactured with the Chinese API due to adverse patient reactions, subsequent investigations determined that many lots of the heparin API were contaminated with oversulfated chondroitin sulfate.[50] This substance is made from animal cartilage, mimics heparin's anti-coagulant activity, and is also much cheaper than heparin.[51] The contaminated heparin eventually was associated with eighty-one deaths and more than 700 severe allergic reactions in the United States.[52]

In the case of Ranbaxy, a large Indian generic drug manufacturer, allegations of data fraud resulted in the company pleading guilty to seven felonies and paying $500

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[46] *Id.* FDA's inspection authorities have evolved over the years. Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA), enabling FDA to reinvigorate its inspection regime. Following the enactment of FDASIA, FDA sharply pivoted toward foreign inspections. *Id.* As a result, the number of foreign inspections has increased significantly over the past twenty years, from 242 in 2000 to 966 in 2019. *Id.* Reflecting the shift toward overseas manufacturing, the number of domestic inspections fell from 1,016—and a high of 1,418 in 2015—to 698 during the same period. *Id.* Every year since 2015, FDA has conducted more foreign than domestic drug facility inspections, though the incidences of both have fallen in recent years. *Id.* The agency identifies sites for inspection using its Site Selection Model, a mathematical, risk-prediction model that scores each FDA-registered facility on factors such as inherent product risk, facility, and time since last inspection. *Id.* FDA then ranks establishments by their risk scores and prioritizes inspection of the most worrisome. *Id.*

[47] Sharpless, *supra* note 41 ("Generic drugs are held to high approval and manufacturing standards and once a generic medication is approved, FDA continues to monitor its safety, effectiveness and quality, including through periodic inspections of manufacturing plants, careful evaluation of post-approval changes proposed by manufacturers and thorough assessment of any adverse event reports.").

[48] *See, e.g.*, Katie Thomas, *Why the Bad Rap on Generic Drugs?*, N.Y. TIMES (Oct. 5, 2013), https://www.nytimes.com/2013/10/06/sunday-review/why-the-bad-rap-on-generic-drugs.html [https://perma.cc/4D4S-Z3KP].

[49] Gardiner Harris, *Heparin Contamination May Have Been Deliberate, F.D.A. Says*, N.Y. TIMES (Apr. 30, 2008), https://www.nytimes.com/2008/04/30/health/policy/30heparin.html [https://perma.cc/4SUX-7H6A]; *The Heparin Disaster: Chinese Counterfeits and American Failures: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy & Com.*, 110th Cong. (2008), https://www.govinfo.gov/content/pkg/CHRG-110hhrg53183/html/CHRG-110hhrg53183.htm [https://perma.cc/W6BB-BKYK] [hereinafter *Heparin Hearing*].

[50] *Baxter Issues Urgent Nationwide Voluntary Recall of Heparin 1,000 Units/ML 10 and 30mL Multi-Dose Vials*, FIERCE BIOTECH (Jan. 28, 2008), https://www.fiercebiotech.com/biotech/baxter-issues-urgent-nationwide-voluntary-recall-of-heparin-1-000-units-ml-10-and-30ml [https://perma.cc/DD2U-EDJ6]; *see also Heparin Hearing*, *supra* note 49.

[51] *Heparin Hearing*, *supra* note 49.

[52] *Id.*

million in fines and penalties.[53] Similarly, data integrity violations at an Indian facility of API manufacturer Fresenius Kabi Oncology Limited, and allegations of concealing and destroying records prior to an FDA inspection, resulted in a guilty plea and agreement to pay $50 million in fines.[54]

Another, more recent incident involving a foreign supplier took place in 2018, when FDA recalled certain generic versions of the blood pressure drug valsartan that were manufactured using API from a Chinese supplier due to contamination with N-nitrosodimethylamine (NDMA), a potentially cancer-causing chemical.[55] In 2018, FDA placed the supplier of the valsartan API, Zhejiang Huahai Pharmaceuticals, on import alert and issued a Warning Letter that identified a number of inadequacies at the plant.[56] This incident illustrates the challenges facing FDA in regulating a drug market that is increasingly global.[57]

C. Supply Chain Impacts During COVID-19

Rising concerns about the security and public health risks posed by U.S. dependence on foreign manufacturing appeared well justified in the early stages of the COVID-19 pandemic, when significant shortages of face masks, including N95 respirators,[58] COVID-19 testing supplies,[59] and drugs necessary for patients on

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[53] *Drug Manufacturer Agrees to $500 Million Penalty*, CBS NEWS (May 13, 2013), https://www.cbsnews.com/news/drug-manufacturer-agrees-to-500-million-penalty-13-05-2013/ [https://perma.cc/76N9-7YZC].

[54] U.S. DEP'T OF JUSTICE, FRESENIUS KABI ONCOLOGY LIMITED, AND ALLEGATIONS OF CONCEALING AND DESTROYING RECORDS PRIOR TO AN FDA INSPECTION, RESULTED IN A GUILTY PLEA AND AGREEMENT TO PAY $50 MILLION (2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/indian-cancer-drug-manufacturer-agrees-plead-guilty-and-pay-50-million-concealing-and-destroying [https://perma.cc/T7PY-V4CM].

[55] Maggie Fox, *FDA Recalls Are a Reminder that China Controls Much of World's Drug Supply*, NBC NEWS (Aug. 14, 2018), https://www.nbcnews.com/health/health-news/fda-recalls-are-reminder-china-controls-much-world-s-drug-n900716 [https://perma.cc/65T8-WJW2]; Press Release, U.S. Food & Drug Admin., FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity [https://perma.cc/4R72-GTHL].

[56] U.S. FOOD & DRUG ADMIN., IMPORT ALERT 66-40, https://www.accessdata.fda.gov/cms_ia/importalert_189.html [https://perma.cc/SLD7-N432] (last updated May 7, 2021); Press Release, U.S. Food & Drug Admin., FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB), Recalls (Valsartan, Losartan, and Irbesartan) (Nov. 7, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan [https://perma.cc/633L-YALH] (providing link to eleven-item Form 483 issued to firm following July-August 2018 inspection, https://www.fda.gov/media/117875/download) [https://perma.cc/D8DK-CAEX]; Letter from Center for Drug Evaluation and Research to Zhejiang Huahai Pharmaceutical (Nov. 29, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018 [https://perma.cc/3LUP-7AL4].

[57] Fox, *supra* note 55.

[58] Andrew Jacobs, Matt Richtel & Mike Baker, *'At War With No Ammo': Doctors Say Shortage of Protective Gear Is Dire*, N.Y. TIMES (Mar. 19, 2020), https://www.nytimes.com/2020/03/19/health/coronavirus-masks-shortage.html [https://perma.cc/JL62-C2MT].

[59] Nick Paul Taylor, *Widespread Shortages for COVID-19 Test Materials Persist, Poll Says*, MEDTECHDIVE (May 29, 2020), https://www.medtechdive.com/news/widespread-swab-covid-19-test-materials-shortages-persist-poll-says/578831/ [https://perma.cc/NB24-QPQB].

ventilation[60] emerged. Many countries quickly took action to restrict access to key supplies. Although its policies were subsequently modified, India restricted exports of facemasks in late January 2020, banned the export of N95 respirators in February 2020, and by March 2020, restricted the export of twenty-six API and drug products, including acetaminophen, antibiotics, and certain medical devices.[61] Similarly, in February 2020, during the first large spike in COVID-19 cases, China nationalized the production and distribution of critical medical supplies to ensure China was sufficiently equipped to slow the spread of the disease.[62] This nationalization led to shortages in importing countries, including the United States.[63] In March 2021, after facing high rates of infections and a slow vaccine rollout, India also restricted exports of the AstraZeneca vaccine.[64]

According to a Congressional Research Service report, in 2020, China, India, the EU, and dozens of other economies have imposed either limits or bans (either formal or de facto) on certain exports.[65] The report explains:

> Many of the measures temporarily restricted access to markets on which the United States depends for certain imports. These included medical ventilators (for which Singapore and China accounted for 35% and 17%, respectively, of U.S. imports in 2019), breathing and gas masks (France, the United Kingdom, and Italy, 47% combined), CT scanners (Germany,

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[60] Zachary Brennan, *FDA Reports More Shortages of Drugs Used to Put COVID-19 Patients on Ventilators*, RAPS (Apr. 13, 2020), https://www.raps.org/news-and-articles/news-articles/2020/4/fda-reports-more-shortages-of-drugs-used-to-put-co [https://perma.cc/K582-SDXQ].

[61] Chris Thomas & Neha Dasgupta, *Global Supplier India Curbs Drug Exports as Coronavirus Fears Grow*, REUTERS (Mar. 3, 2020, 4:26 AM), https://www.reuters.com/article/us-health-coronavirus-india/global-supplier-india-curbs-drug-exports-as-coronavirus-fears-grow-idUSKBN20Q0ZZ [https://perma.cc/LP92-W9SZ]; Teena Thacker, *Exports Ban Ties Hands of N95 Mask Producers*, ECON. TIMES (Feb. 12, 2020, 8:31 AM), https://m.economictimes.com/news/economy/foreign-trade/exports-ban-ties-hands-of-n95-mask-producers/articleshow/74091865.cms [https://perma.cc/ZU8Q-T79F]; David Ho, *India Starts Easing Restrictions on Med-Tech Exports, Promises Domestic Priority*, BIOWORLD (June 11, 2020), https://www.bioworld.com/articles/435737-india-starts-easing-restrictions-on-med-tech-exports-promises-domestic-priority [https://perma.cc/XNA2-D26Q]; Kirtika Suneja, *Government Bans Exports of Certain Masks, Ventilators, Raw Material for Masks, Coveralls*, ECON. TIMES (Mar. 19, 2020, 10:35 PM), https://economictimes.indiatimes.com/news/economy/foreign-trade/government-bans-exports-of-certain-masks-ventilators-raw-material-for-masks-coveralls/articleshow/74718029.cms?from=mdr [https://perma.cc/5DMV-4Z6B]. India has since walked back many of its restrictions; in April 2020, the drug and API export policy was revised after President Trump warned of potential retaliation by the United States. Neha Dasgupta & Sanjeev Miglani, *India Allows Limited Exports of Anti-Malaria Drug after Trump Warns of Retaliation*, REUTERS (Apr. 6, 2020, 7:31 PM), https://www.reuters.com/article/us-health-coronavirus-india-drugs/india-allows-limited-exports-of-anti-malaria-drug-after-trump-warns-of-retaliation-idUSKBN21O34B [https://perma.cc/B2C8-FLEV]. In May 2020, the facemask export policy was lifted, and, by August, India was permitting a limited number of N95 masks to be exported. *India Lifts Restrictions on Export of N95 Masks*, TRIBUNE (Oct. 6, 2020, 5:54 PM), https://www.tribuneindia.com/news/nation/india-lifts-restrictions-on-export-of-n95-masks-151867 [https://perma.cc/VLW6-B582].

[62] KAREN M. SUTTER, ANDRES B. SCHWARZENBERG & MICHAEL D. SUTHERLAND, CONG. RSCH. SERV., R46304, COVID-19: CHINA MEDICAL SUPPLY CHAINS AND BROADER TRADE ISSUES 15 (2020), https://crsreports.congress.gov/product/details?prodcode=R46304 [https://perma.cc/6NUF-LBNS].

[63] *Id.*

[64] Jeffrey Gettleman, Emily Schmall & Mujib Mashal, *India Cuts Back on Vaccine Exports as Infections Surge at Home*, N.Y. TIMES (Apr. 22, 2021), https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html [https://perma.cc/AL5K-BBL7].

[65] SUTTER ET AL., *supra* note 62, at 33.

> 50%), medical protective equipment made of textile materials (China, 72%), digital and infrared thermometers (China, 36%), pharmaceuticals (Ireland, Germany, Switzerland, and Italy, 53% combined), and tetracycline and penicillin (China, 90% and 52%, respectively).[66]

Other countries also took steps to ban or limit exports of facemasks, protective gear, gloves, and other goods to mitigate their own real or feared local COVID-19-related shortages.[67]

The United States has also shown willingness to impose restrictions on the exports of medical products if necessary. In the United States, the Federal Emergency Management Agency (FEMA) placed restrictions on exports of PPE, including respirators, masks, gloves, and gowns in April 2020. FEMA extended the rule in August 2020 and again in December 2020; the agency also added syringes and hypodermic needles to the list of restricted materials.[68] The COVID-19 pandemic also provided further reasons to be concerned about the quality of certain foreign-manufactured medical products. This issue arose most clearly with diagnostic tests. As demand for COVID-19 diagnostic testing surged in spring 2020, many Chinese manufacturers of diagnostic tests agreed to sell rapid tests to various European countries. British researchers discovered that the tests did not perform well, however.[69] Similar scenarios also played out in Spain and Slovakia, leading the National Medical Products Administration, China's health regulatory body, to require exporters of coronavirus tests to obtain registration certificates to clear customs.[70] From March to May 2020, FDA allowed antibody test manufacturers to perform self-validation studies; in May 2020, FDA changed its policy and required manufacturers to submit their data for agency review.[71] FDA also removed nearly thirty antibody tests from the market that did not meet the agency's standards.[72] India also purchased faulty COVID-19 antibody tests from Chinese companies and subsequently discovered that the tests varied widely in their sensitivity.[73]As described in more detail below, concerns have also emerged about filtering face piece respirators manufactured in China.

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[66] *Id.*

[67] Andrea Shalal, *80 Countries Are Hoarding Medical Supplies—Here's Why It Damages the Global Response to COVID-19*, WORLD ECON. FORUM (Apr. 24, 2020), https://www.weforum.org/agenda/2020/04/wto-report-80-countries-limiting-exports-medical-supplies/ [https://perma.cc/328G-QV59].

[68] Press Release, Fed. Emergency Mgmt. Agency, Export Allocation Rule on Medical Supplies and Equipment for COVID-19 (Jan. 22, 2021), https://www.fema.gov/fact-sheet/allocation-rule-personal-protective-equipment-exports [https://perma.cc/M6MZ-AW43].

[69] David D. Kirkpatrick & Jane Bradley, *U.K. Paid $20 Million for New Coronavirus Tests. They Didn't Work.*, N.Y. TIMES (Dec. 17, 2020), https://www.nytimes.com/2020/04/16/world/europe/coronavirus-antibody-test-uk.html [https://perma.cc/CBA9-4PGZ].

[70] Roxanne Liu, Alexandra Harney, *China Clamps Down on Coronavirus Test Kit Exports After Accuracy Questioned*, REUTERS (Apr. 1, 2020) https://www.reuters.com/article/us-health-coronavirus-china-testkits-idUKKBN21J51S [https://perma.cc/DR8W-24VW].

[71] Conor Hale, *FDA Names 28 Antibody Tests to Be Taken Off the Market*, FIERCEBIOTECH (May 22, 2020, 10:40 AM), https://www.fiercebiotech.com/medtech/fda-names-28-antibody-tests-to-be-taken-off-market-after-increasing-oversight [https://perma.cc/3CZ8-E9R3].

[72] *Id.*

[73] Emily Czachor, *India Clashes with China After Returning Order of Half a Million 'Faulty' Coronavirus Antibody Test Kits*, NEWSWEEK (Apr. 28, 2020), https://www.newsweek.com/india-clashes-

III. INITIATIVES AND STRATEGIES TO ADDRESS SUPPLY CHAIN RISKS

A. Pre-COVID-19 Measures

Even before COVID-19, concerns about supply chain globalization as a source of national security and public health risk cut across party lines. Such concerns led to multiple initiatives intended to ensure the availability of critical medical products and countermeasures, particularly during public health emergencies, whether man-made (i.e., resulting from use of nuclear, chemical, biological, or radiological weapons) or naturally occurring (epidemics, pandemics, natural disasters). In the years before the COVID-19 pandemic, the federal government initiated numerous actions to protect against shortages of critical medical products. These included efforts to accelerate research and development of medical countermeasures required during public health emergencies, stockpile critical medical products, and improve public health responses when such emergencies occur.

In 1998, the U.S. Department of Health and Human Services (HHS) created the National Pharmaceutical Stockpile—later renamed the Strategic National Stockpile—to establish a secure, readily available supply of vaccines and antidotes to help respond to biological or chemical attacks on the United States.[74] In addition to creating a national stockpile of critical goods, Congress passed legislation designed to accelerate research into and the development of medical countermeasures against biological, chemical, radiological, and nuclear agents. That law, known as the Project Bioshield Act of 2004,[75] also amended the Federal Food, Drug, and Cosmetic Act (FDCA) to grant FDA the power to issue emergency use authorizations (EUAs) based on a lower review standard for unapproved new drugs and devices, or for unapproved uses of existing drugs and devices, when necessary in an emergency.[76]

These lower emergency review standards spurred concerns about tort liability. The 2006 Public Readiness and Emergency Preparedness Act (PREP Act) further authorized the Secretary of HHS to issue an emergency declaration providing immunity from liability (except for willful misconduct) for certain claims of loss related to the administration or use of medical countermeasures.[77] PREP Act immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures, including those countermeasures subject to EUAs.[78]

Congress has continued to enact measures designed to strengthen both federal and state responses during public health emergencies. In 2006, Congress passed the Pandemic and All Hazards Preparedness Act (PAHPA), which created the Biomedical

china-after-returning-order-half-million-faulty-coronavirus-antibody-test-kits-1500719 [https://perma.cc/F8VX-WMEE].

74 Pub. L. 105-277 (1998).

75 Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 435 (2004).

76 21 U.S.C. § 360bbb-3 (2006) (hereinafter, EUA Statute).

77 *Id.* The PREP Act was enacted as part of an emergency supplemental authorization statute to address pandemic influenza (among other things).

78 *Id.*

Advanced Research and Development Authority (BARDA).[79] BARDA, an agency housed within HHS, is tasked with promoting collaboration and communication among U.S. government agencies that play a role in public health emergency preparedness.[80] BARDA supports the development of medical countermeasures through funding, technical assistance, and other services ranging from a clinical research organization network to a public private partnership that provides a domestic manufacturing infrastructure (referred to as the Centers for Innovation in Advanced Development and Manufacturing), including a fill-finish manufacturing network.[81] To date, BARDA-supported products have received a total of fifty-nine FDA approvals, licensures, or clearances.[82]

Congressional concerns about supply chain risks have not focused exclusively on medical countermeasures, however. In 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), Congress codified and expanded a prior Obama-era executive order (Executive Order 13588) to require advanced reporting of potential drug shortages.[83] The statute also granted a number of powers to FDA related to mitigating drug shortages, including strengthening FDA registration requirements for domestic and foreign drug establishments,[84] amending the FDCA to clarify that current good manufacturing practices apply also to raw materials used in the manufacturing of finished drug products,[85] and authorizing FDA to require drug importers to demonstrate a drug's compliance with the FDCA as a condition of importation.[86] In 2017, as part of the FDA Reauthorization Act (FDARA), Congress strengthened FDA control over imports by prohibiting the importation of any prescription drug not authorized and labeled by its manufacturer for marketing in the United States.[87] This provision aimed to prevent the importation of foreign unapproved versions of FDA approved drugs that might reflect indications approved by foreign regulators but not FDA, and bear foreign language labeling.[88]

As pressure to reduce the price of prescription drugs has intensified in recent years, so have concerns about cost-cutting that could jeopardize the safety and quality of medications marketed in the United States. In late October 2019, before news broke about the new coronavirus circulating in China, the Energy and Commerce Committee Subcommittee on Health convened a hearing titled "Safeguarding the Pharmaceutical

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79 Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006).

80 BARDA, MEDICALCOUNTERMEASURES.GOV, https://www.medicalcountermeasures.gov/barda/ [https://perma.cc/A3QY-3PED].

81 *Id.* (click "Core Services").

82 *FDA Approvals, Licensures & Clearances for BARDA Supported Products*, MEDICAL COUNTERMEASURES.GOV, https://medicalcountermeasures.gov/barda/fdaapprovals [https://perma.cc/9374-BDA9].

83 U.S. FOOD & DRUG ADMIN., FACT SHEET: DRUG PRODUCTS IN SHORTAGE IN THE UNITED STATES, https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-drug-products-shortage-united-states [https://perma.cc/HBV6-3BTR] (last updated Mar. 28, 2018).

84 Pub. L. No. 112-144, §§ 701, 702, 126 Stat. 993, 1064–1065 (2012).

85 *Id.* § 711.

86 *Id.* § 706.

87 Pub. L. No. 115-52, § 604, 131, Stat. 1005, 1048 (2017).

88 *Id.*

Supply Chains in a Global Economy."[89] At that hearing, CDER Director Dr. Janet Woodcock testified about the national security risks and drug quality concerns that increasing reliance on foreign drug manufacturing poses.[90] She testified about the importance of improving the information available to FDA on the extent of that reliance and recommended investing in domestic manufacturing capacity, in particular through developing advanced manufacturing techniques.[91] She also noted that a significant portion of drug shortages stemmed from drug quality issues.[92] FDA published a detailed report on drug shortages at that time, evaluating their root causes and potential solutions.[93] The report recognized the role of quality problems in driving shortages and recommended creating a rating system to incentivize drug manufacturers to invest in quality management systems.[94] FDA posited that consumers and health care plans might be willing to pay more for drugs manufactured in a facility with a mature quality system.[95]

As evidenced by the legislation and initiatives described above, concerns about emergency-related supply chain disruptions and shortages are not new. Nevertheless, they have taken on far greater urgency in the COVID-19 context. The next section of the Article describes measures taken in the context of the pandemic to address medical product shortages, many of which were prompted by the unavailability of foreign-made medical products. It then discusses longer-term policy proposals. It concludes by discussing how effective such measures and proposals may be in addressing the national security and quality concerns associated with reliance on foreign manufacturing, and whether they will lead to systemic change that will increase supply chain robustness and security in non-emergency situations as well.

B. Pandemic-Related Measures to Address Medical Product Shortages

COVID-19 quickly revealed significant weaknesses in global supply chains for important medical products. In response, the U.S. government attempted a number of measures intended to ameliorate medical product shortages, generally by employing the tools previously made available through the legislative enactments and programs discussed above. These actions have included distributing products from the Strategic National Stockpile, permitting the distribution of unapproved medical products

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89 *Safeguarding Pharmaceutical Supply Chains in a Global Economy: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 116th Cong. (2019) (opening statement of Representative Frank Pallone, Jr.), https://energycommerce.house.gov/committee-activity/hearings/hearing-on-safeguarding-pharmaceutical-supply-chains-in-a-global-economy [https://perma.cc/7FCN-BEAT].

90 *Id.*

91 *Id.*

92 *Id.*

93 *See* U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: ROOT CAUSES AND POTENTIAL SOLUTIONS, https://www.fda.gov/media/131130/download [https://perma.cc/LMP2-LLTB] [hereinafter U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES. *See also* Press Release, Norman E. Sharpless, Comm'r of Food & Drugs, U.S. Food & Drug Admin., Statement on FDA's New Report Regarding Root Causes and Potential Solutions to Drug Shortages (Oct. 29, 2019), https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages [https://perma.cc/5C4A-X82G].

94 *See* U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES, *supra* note 93.

95 *Id.*

through EUAs and other mechanisms, enhancing surveillance of the supply chain, and entering into grants and contracts to create additional sources of medical products in short supply. Unfortunately, a central lesson of the COVID-19 pandemic will likely be that these measures, while in many cases helpful, were inadequate. This section provides a brief overview of these measures and assesses their effects thus far.

1. Deploying the Strategic National Stockpile

The U.S. Strategic National Stockpile, first created by HHS in 1999 and later authorized and expanded by Congress starting in 2002, holds potentially life-saving drugs and medical supplies for use during bioterrorist attacks and other public health emergencies.[96] Early in the COVID-19 pandemic, health officials recognized that federal and state stockpiles of critically needed products, including PPE and ventilators in particular, were insufficient to meet the need.[97] The Strategic National Stockpile's supplies of surgical masks, for example, had not been replenished since the H1N1 pandemic more than a decade earlier, and many of the remaining masks were expired or in poor condition.[98] Supplies of other PPE and ventilators, distributed in response to requests from state and local governments, were promptly depleted as early as February 2020.[99] Frustrated and desperate state leaders, unsure how to obtain supplies from the federal government, resorted to Twitter messages, the media, and phone calls to the President in an attempt to procure these critically necessary products.[100] Ad hoc efforts, including a program championed by then-President Trump's son-in-law and dubbed "Project Airbridge," scavenged global markets and arranged airlifts of supplies such as N95 respirators, face shields, surgical masks, gloves, thermometers, and gowns, before winding down after several months.[101]

Plainly, stockpiling did not serve as a reliable backstop to address supply chain shortages when the COVID-19 pandemic reached the United States. Whether and how to improve stockpiling to prevent or mitigate future medical products shortages is sure to be part of the "lessons learned" debate. In the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress amended the Public Health Service Act to require that HHS include PPE, ancillary medical supplies, and diagnostic tests in

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96 G. JAMES HERRERA & FRANK GOTTRON, CONG. RSCH. SERV., IF11574, NATIONAL STOCKPILES: BACKGROUND AND ISSUES FOR CONGRESS (June 15, 2020), https://crsreports.congress.gov/product/pdf/IF/IF11574 [https://perma.cc/P5HF-WP3D]; *Strategic National Stockpile*, CHEM. HAZARDS EMERGENCY MED. MGMT., https://chemm.nlm.nih.gov/sns.htm [https://perma.cc/FZF6-FPH7].

97 ELAYNE J. HEISLER, CONG. RSCH. SERV., R46334, SELECTED HEALTH PROVISIONS IN TITLE III OF THE CARES ACT (P.L. 116-136) (2020), https://crsreports.congress.gov/product/pdf/R/R46334 [https://perma.cc/N3ZE-RZBV].

98 Daniel Joseph Finkenstadt, Robert Handfield & Peter Guinto, *Why the U.S. Still Has a Severe Shortage of Medical Supplies*, HARV. BUS. REV. (Sep. 17, 2020), https://hbr.org/2020/09/why-the-u-s-still-has-a-severe-shortage-of-medical-supplies?ab=hero-main-text [https://perma.cc/YV9K-UXDW].

99 *Id.*

100 Anita Kumar & Gavin Bade, *States Still Baffled Over How to Get Coronavirus Supplies from Trump*, POLITICO (Apr. 13, 2020, 4:30 AM), https://www.politico.com/news/2020/04/13/states-baffled-coronavirus-supplies-trump-179199 [https://perma.cc/A3BB-ZJ4G].

101 Jonathan Allen, Phil McCausland & Cyrus Farivar, *Jared Kushner's Highly Scrutinized 'Project Airbridge' to Begin Winding Down*, NBC NEWS (May 11, 2020, 4:17 PM), https://www.nbcnews.com/politics/white-house/jared-kushner-backed-project-airbridge-be-largely-grounded-n1204646 [https://perma.cc/HQY3-ZVLX]. *See also* Press Release, Fed. Emergency Mgmt. Agency, FEMA Phasing Out Project Airbridge (June 17, 2020), https://www.fema.gov/news-release/20200726/fema-phasing-out-project-airbridge [https://perma.cc/GGT4-M8L9].

the stockpile.[102] But how to choose which products to stockpile, how much to stockpile, and ultimately the purpose and role of stockpiling in responding to public health emergencies will require substantial re-evaluation in light of the COVID-19 experience. Some initial efforts have identified shortcomings in the current Strategic National Stockpile program, including its low profile and related struggle to garner sufficient resources, incomplete information and planning, and a shortage of appropriately qualified and experienced personnel.[103]

2. Permitting Distribution of Unapproved Medical Products

Throughout the COVID-19 pandemic, FDA has employed emergency powers to address short-term medical product shortages that supply chain disruptions have posed. Its primary tools for doing so have been EUAs and enforcement-discretion policies that permit marketing and use of certain unapproved and otherwise-prohibited medical products during the public health emergency. As noted above, an EUA permits an unapproved drug, device, or biological product (or an approved product for an unapproved use) to enter interstate commerce when such product is intended to meet a need arising from an actual or potential emergency, during the effective period of a declaration of emergency.[104]

On February 4, 2020, then-Secretary of HHS Alex Azar issued a declaration of emergency related to the COVID-19 pandemic.[105] Based on this determination, Secretary Azar also declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for the detection or diagnosis of the virus that causes COVID-19.[106] The Secretary later expanded upon that initial declaration to authorize emergency use of other devices, drugs, and biological products during the pandemic.[107]

FDA has used its EUA power widely during the COVID-19 pandemic to address shortages in critical medical products, authorizing the distribution and use of hundreds of unapproved diagnostic tests, testing supplies, various forms of PPE, therapeutics, and other products.[108] FDA's use of its EUA authority during the pandemic far outstripped all prior uses of that authority combined. One result of FDA's reliance on EUAs included agency staff becoming overwhelmed with EUA requests for certain product types, most notably diagnostic tests.[109]

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[102] 42 U.S.C. § 247d-6b(a)(1) (2020).

[103] Finkenstadt et al., *supra* note 98.

[104] EUA Statute, *supra* note 76. The authorization may authorize an emergency use of a product that is 1) not approved, licensed, or cleared for commercial distribution under relevant legal provisions ("unapproved"); or 2) approved, licensed, or cleared under such provisions, but which use is not under such provision an approved, licensed, or cleared use of the product ("unapproved use of an approved product").

[105] Determination of Public Health Emergency, 85 Fed. Reg. 7315 (Feb. 7, 2020).

[106] *Id.*

[107] *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (last updated May 26, 2021), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/7VV8-5BQL].

[108] *See id.*

[109] Mark McCarty, *Stenzel Mum on LDT Question, But Says FDA 'Overwhelmed' With EUA Filings*, BIOWORLD (Aug. 26, 2020), https://www.bioworld.com/articles/497061-stenzel-mum-on-ldt-question-but-says-fda-overwhelmed-with-eua-filings [https://perma.cc/Q9NL-U764].

In addition to EUAs, FDA issued enforcement policies to ameliorate supply chain disruptions that COVID-19 caused. For example, in response to severe shortages in viral transport media needed for diagnostic testing, FDA published an enforcement guidance document permitting the distribution of viral transport media without 510(k) clearance.[110] Additionally, due to low supply of compliant containers and surges in demand for oxygen and nitrogen, FDA also published an enforcement discretion policy stating that the agency would not take action against firms that fill and distribute oxygen and nitrogen intended for medical use in portable cryogenic medical gas containers not in compliance with certain FDA requirements.[111] Because they do not require product-by-product reviews like EUAs, such enforcement policies can permit more products to come onto the market sooner. But without any FDA review, the quality of such products is less well known and controlled.

FDA's use of its EUA authority and application of enforcement discretion policies succeeded in increasing the emergency availability of many medical countermeasures, but these tools have proven problematic at times. For example, FDA eventually retracted its EUA authorizing certain types of filtering face piece respirators manufactured in China after Centers for Disease Control and Prevention testing showed that the respirators did not meet National Institute for Occupational Safety and Health standards.[112] Similarly, FDA initially published an enforcement policy allowing commercial manufacturers of serological tests for COVID-19 antibodies to distribute such tests without FDA review for surveillance purposes, but later required EUAs for such tests when it discovered inappropriate promotion and poor performance.[113] Notably, when FDA later published a list of commercial manufacturers of serological tests no longer permitted under FDA's prior enforcement policy, nearly half were from Chinese companies.[114]

In short, FDA's discretion to permit marketing of unapproved products during the COVID-19 emergency has proven valuable in addressing supply chain shortages. At the same time, FDA and product developers were unprepared for such widespread use of EUAs and enforcement discretion policies. The EUA review process in some cases overwhelmed FDA, frustrating some product developers. Enforcement discretion policies allowed others to introduce sub-standard or misleadingly promoted products

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[110] U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR VIRAL TRANSPORT MEDIA DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (July 2020), https://www.fda.gov/media/140300/download [https://perma.cc/663R-3H9P].

[111] U.S. FOOD & DRUG ADMIN., POLICY FOR THE TEMPORARY USE OF PORTABLE CRYOGENIC CONTAINERS NOT IN COMPLIANCE WITH 21 CFR 211.94(E)(1) FOR OXYGEN AND NITROGEN DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 2020), https://www.fda.gov/media/136830/download [https://perma.cc/P84N-YVKH].

[112] *Id. See also* Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse (June 7, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reissues-emergency-use-authorizations-revising-which-types [https://perma.cc/NX7X-ZYUX].

[113] U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-2019 TESTS DURING THE PUBLIC HEALTH EMERGENCY (REVISED), IMMEDIATELY IN EFFECT GUIDANCE FOR CLINICAL LABORATORIES, COMMERCIAL MANUFACTURERS, AND FOOD AND DRUG ADMINISTRATION STAFF (2020), https://www.fda.gov/media/135659/download [https://perma.cc/62VE-TDEL].

[114] *See Removal Lists of Tests That Should No Longer Be Used and/or Distributed for COVID-19: FAQs on Testing for SARS-CoV-2*, U.S. FOOD & DRUG ADMIN., (Dec. 23, 2020), https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/removal-lists-tests-should-no-longer-be-used-andor-distributed-covid-19-faqs-testing-sars-cov-2 [https://perma.cc/CJ6J-8S57].

onto the U.S. market. While permitting access to unapproved products will likely continue to be necessary in future medical emergencies, the COVID-19 experience will undoubtedly offer important lessons on how best to employ these tools.

3. Enhancing Supply Chain Surveillance

Even in ordinary times, FDA maintains a surveillance program to identify and address shortages of important medical products. For example, the Drug Shortage Staff within CDER is responsible for coordinating activities related to the prevention and mitigation of drug shortages.[115] The staff conducts medical necessity assessments, considers appropriate action on inspection reports, and assesses firm proposals as they attempt to avoid supply disruption or increase production.[116] Other FDA centers have similar programs.[117]

In March 2020, Congress sought to enhance FDA's ability to manage supply chain shortages for medical products under the CARES Act.[118] The CARES Act expands the scope of existing drug shortage notification requirements. Under FDASIA, enacted in 2012, manufacturers of certain life-sustaining and other critical drugs are required to notify FDA of a permanent discontinuance or "meaningful disruption" in the supply of the drug in the United States, as well as the reasons for such discontinuance or interruption.[119] FDASIA also requires FDA to maintain a list of drugs determined to be in shortage in the United States.[120] The CARES Act reporting requirements expand the existing requirement to include "any such drug that is critical to the public health during a public health emergency determined under section 319 of the Public Health Service Act" and to require reporting by manufacturers of API for drugs covered by the notification requirement.[121] Manufacturers of life-saving drugs (and manufacturers of API for such drugs) are also required to maintain a redundancy risk management plan for each establishment where such drugs and API are manufactured.[122]

The CARES Act also requires each registered drug establishment to report to FDA annually on the amount of each drug manufactured, prepared, propagated, compounded, or processed by such facility for commercial distribution.[123] This requirement will provide FDA with new insights into the amount and sources of drug

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[115] *Frequently Asked Questions about Drug Shortages*, U.S. FOOD & DRUG ADMIN. (Nov. 13, 2020), https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q12 [https://perma.cc/C44N-ZRU8].

[116] *Id.*

[117] *Id.*

[118] Coronavirus Aid, Relief, and Economic Security (CARES) Act, S. 3548, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/senate-bill/3548/text?q=product+actualizaci%C3%B3n [https://perma.cc/8FUZ-RTJ4]; Tony Marks, *CARES Act to the Rescue . . . Phase 3 Coronavirus Bill Cares About Small and Midsize Businesses, Franchisors and Franchisees*, FORBES (Mar. 30, 2020, 5:36 PM), https://www.forbes.com/sites/tonymarks/2020/03/30/cares-act-to-the-rescue-phase-3-coronavirus-bill-cares-about-small-and-midsize-businesses-franchisors-and-franchisees/#638afa494bf9 [https://perma.cc/KQT6-WRU5].

[119] Pub. L. No. 112-144, § 1001, 126 Stat. 993, 1099 (2012).

[120] *Id.* § 1004.

[121] 21 U.S.C. § 356c.

[122] 21 U.S.C. § 356c(j).

[123] 21 U.S.C. § 360(j).

products manufactured for U.S. commercial distribution. It should also help FDA perform "gap analyses" to better predict and address potential drug shortages.

The CARES Act created similar provisions for medical devices. The statute requires device manufacturers to notify FDA in advance of a permanent discontinuance or interruption in manufacturing that is likely to lead to meaningful disruption in the supply of any device that is "critical to public health during a public health emergency declared by the [HHS] Secretary, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or for which [FDA] determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency."[124] The device manufacturer also must provide the reasons for the permanent discontinuance or interruption.[125] FDA is required to distribute information on such device shortages to appropriate organizations, unless disclosure of such information would adversely affect the public health, such as by encouraging hoarding and thus disrupting the availability of medical products to patients.[126] Additionally, the CARES Act directs FDA to prioritize and expedite review of submissions, notifications, or inspections/re-inspections if it concludes a device shortage exists or likely exists based on the required notification.[127] Finally, the CARES Act requires maintenance of a publicly available device shortage list similar to the existing shortage list for drugs.[128]

As the CARES Act provisions illustrate, the previously enacted supply chain transparency provisions of FDASIA were narrow in scope. The CARES Act provisions are more robust, but appear to have arrived too late to make a significant difference during the COVID-19 pandemic. The law's new requirements may, however, help mitigate future shortage risks implicating critical medical products. The CARES Act also has the potential to increase visibility into the amount of API and finished drug product intended for commercial distribution manufactured at registered facilities and to enhance FDA and HHS's ability to detect and prepare for potential drug and device shortages.

4. Entering into Grants and Contracts

During the COVID-19 pandemic, the government expended significant sums to facilitate increased domestic production of critical drugs and devices. Most attention has been focused on "Operation Warp Speed," an $18 billion vaccine development program.[129] Under that program, the federal government provided funding for vaccine candidates in development by a variety of pharmaceutical companies and entered into purchase contracts for vaccines significantly in advance of authorization. Entities that have received funding or contracts through Operation Warp Speed include Johnson & Johnson (Janssen), Moderna, AstraZeneca, Novavax, Pfizer, and

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[124] 21 U.S.C. § 356j(a).

[125] *Id.*

[126] 21 U.S.C. § 356j(c)(2).

[127] 21 U.S.C. § 356j(f).

[128] 21 U.S.C. § 356j(g).

[129] *See, e.g.*, John Tozzi, Riley Griffin & Shira Stein, *Trump Administration Dips into Protective Gear, CDC Funds to Fund Vaccine Push*, BLOOMBERG (Sept. 23, 2020, 6:00 a.m.), https://www.bloomberg.com/news/articles/2020-09-23/how-much-is-the-trump-administration-spending-on-a-vaccine [https://perma.cc/H6DM-K8ZJ].

Sanofi/GlaxoSmithKline.[130] Operation Warp Speed also provided funding to Regeneron in connection with manufacturing its COVID-related therapeutic, and has purchased the first doses of another COVID-related therapeutic manufactured by Eli Lilly & Company.[131] In addition to Operation Warp Speed, the government entered into contracts to spur the production of ventilators, ultimately canceling some contracts after obtaining a sufficient number of ventilators.[132]

President Biden's campaign platform also stated that he would use the Defense Production Act (DPA) to direct U.S. companies to increase production of critical products that are needed in the short term, and he would use federal purchasing power to increase domestic manufacturing capacity for designated critical products.[133] Upon taking office, President Biden invoked the DPA to bolster vaccine production, ensure greater access to COVID-19 testing, and increase supplies of PPE and other supplies.[134] President Biden also promised to make COVID-19 vaccines available to all adults by May 2021.[135] Although it was not explicitly stated, Biden's team suggested that the timeline was partially due to use of DPA powers.[136]

President Biden has also used the DPA to make good on another campaign promise: to use BARDA to increase production of vaccines and other medical countermeasures, leverage federal health care purchases, and ensure the U.S. tax code encourages onshoring of pharmaceutical supply chains.[137] In March 2021, the Biden Administration announced that it would direct BARDA to use the DPA to facilitate a collaboration between Johnson & Johnson and Merck to produce Johnson & Johnson's vaccine.[138]

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[130] SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS (Mar. 1, 2021), https://crsreports.congress.gov/product/pdf/IN/IN11560.

[131] Press Release, U.S. Dep't of Health & Hum. Servs., HHS, DOD Collaborate with Regeneron on Large-Scale Manufacturing Demonstration Project of COVID-19 Investigational Therapeutic Treatment (July 7, 2020), https://www.hhs.gov/about/news/2020/07/07/hhs-dod-collaborate-regeneron-large-scale-manufacturing-demonstration-project-covid-19-investigational-therapeutic-treatment.html [https://perma.cc/A83B-J2NC]; Press Release, Eli Lilly and Co., Lilly Announces Agreement With U.S. Government to Supply 300,000 Vials of Investigational Neutralizing Antibody Bamlanivimab (LY-CoV555) in an Effort to Fight COVID-19 (Oct. 28, 2020), https://investor.lilly.com/news-releases/news-release-details/lilly-announces-agreement-us-government-supply-300000-vials [https://perma.cc/WZD8-62RC].

[132] Michael Biesecker, *HHS Canceling Ventilator Contracts, Says Stockpile Is Full*, AP NEWS (Sep. 2, 2020), https://apnews.com/article/2f697994ea3e53eb966c58106fd96461#:~:text=The%20AP%20reported%20in%20May,under%20its%20%24489%20million%20contract [https://perma.cc/U3ZV-5ZKC].

[133] *The Biden Plan to Rebuild U.S. Supply Chains and Ensure the U.S. Does Not Face Future Shortages of Critical Equipment*, BIDEN/HARRIS CAMPAIGN, https://joebiden.com/supplychains/# [https://perma.cc/5AFQ-ELAX] (last visited June 2, 2021) [hereinafter BIDEN/HARRIS CAMPAIGN].

[134] Emma Court & Josh Wingrove, *Biden Team to Use DPA for Vaccine Manufacturing, Testing*, BLOOMBERG (Feb. 5, 2021), https://www.bloomberg.com/news/articles/2021-02-05/biden-team-to-use-dpa-for-vaccine-manufacturing-testing?srnd=premium [https://perma.cc/UC2S-K63P].

[135] Shayan Karbassi, *Understanding Biden's Invocation of the Defense Production Act*, LAWFARE (Mar. 4, 2021), https://www.lawfareblog.com/understanding-bidens-invocation-defense-production-act [https://perma.cc/7Q9Z-VN97].

[136] *Id.*

[137] BIDEN/HARRIS CAMPAIGN, *supra* note 133.

[138] Press Release, U.S. Dep't of Health & Hum. Servs., Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines (Mar. 2, 2021), https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-

While these contracts have been effective in spurring the development and production of critical products for addressing the COVID-19 emergency, they are all actions taken once the country was already in dire need of these products and supplies. The government has also entered into several contracts intended to have broader reach. These contracts also appear to be directed towards attempting to build (or re-build) sustainable domestic manufacturing capacity for certain types of critical medical products. These agreements are discussed in Section C below.

C. Longer-Term Measures: Looking Past the Pandemic

The foregoing discussion describes various efforts attempted during the ongoing COVID-19 emergency, with varying degrees of success. Other measures, some of which have been initiated and others of which have been proposed, are designed not only to address current public health crises, but also to enhance the country's ability to respond to future crises, whether naturally occurring or man-made. This section reviews a number of these proposals.

1. Buy American Executive Order and Other Executive Actions

The Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Order),[139] signed by then-President Donald Trump in August 2020, set forth a number of provisions intended to incentivize and revitalize domestic manufacturing by requiring that government agencies source "essential" medical products from domestic manufacturers when possible.[140]

The Order tasked FDA with identifying a list of Essential Medicines,[141] Medical Countermeasures,[142] and Critical Inputs[143] that are "medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms" within ninety days of issuance of the order.[144] This list was intended to be updated periodically as appropriate. FDA was also directed to take all

historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html [https://perma.cc/A46F-HQY4].

[139] Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 Fed. Reg. 49,929 (Aug. 14, 2020), https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential [https://perma.cc/334C-PSK6] [hereinafter Buy American Executive Order].

[140] *Id.*

[141] "Essential Medicines" are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of this order. *See id.* at 49,932.

[142] "Medical Countermeasures" means items that meet the definition of "qualified countermeasure" in section 247d 6a(a)(2)(A) of Title 42, United States Code; "qualified pandemic or epidemic product" in section 247d–6d(i)(7) of title 42, United States Code; "security countermeasure" in section 247d–6b(c)(1)(B) of Title 42, United States Code; or personal protective equipment described in part 1910 of Title 29, Code of Federal Regulations. *Id.* at 49,933.

[143] "Critical Inputs" means API, API "Starting Material," and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures. *Id.*

[144] The term "medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms" is not defined in the Order. *Id.*

necessary and appropriate action to "identify and mitigate vulnerabilities in the supply chain," including by:

- considering proposing regulations or revising guidance on the collection of certain information from manufacturers;
- entering into written agreements to disclose records regarding the security and vulnerabilities of supply chains;
- recommending to the President any changes in applicable law; and
- reviewing FDA regulations to determine whether they may be a barrier to domestic production and advising the President whether such regulations should be repealed or amended.[145]

Additionally, the Order directed HHS and FDA to take appropriate actions to accelerate FDA approval or clearance, as appropriate, for domestic producers of Essential Medicines, Medical Countermeasures, and Critical Inputs.[146] While the CARES Act imposed a similar requirement, the Order focused specifically on accelerating approval for domestic producers.

On October 30, 2020, FDA released a list of Essential Medicines, Medical Countermeasures, and Critical Inputs, as required by the Order.[147] As of October 30, the list contained 223 drug and biological product Essential Medicines and Medical Countermeasures, as well as ninety-six device Medical Countermeasures.[148] The Critical Inputs include API for Essential Medicines and Medical Countermeasures, as well as ingredients/components that possess "unique attributes" essential in assessing the safety and effectiveness of such products.[149] FDA is seeking public comment on the list.[150] The Order also directs the HHS Secretary and FDA Commissioner to take a variety of other actions related to ensuring domestic production of medical products, some of which have already been contemplated by FDA. These steps include issuing guidance with recommendations regarding the development of advanced manufacturing techniques;[151] negotiating with countries to increase facility inspections and increasing the number of unannounced inspections of regulated facilities manufacturing Essential Medicines, Medical Countermeasures, and Critical Inputs;[152] and refusing admission, as appropriate, to imports of Essential Medicines, Medical

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145 Buy American Executive Order, *supra* note 139.

146 *Id.*

147 Press Release, Stephen M. Hahn, Comm'r of Food & Drugs, U.S. Food & Drug Admin., FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order (Oct. 30, 2020), https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-requiredexecutive?utm_medium=email&utm_source=govdelivery [https://perma.cc/B9PX-X6N5].

148 *Id.*

149 *Id.*

150 *Id.*

151 Buy American Executive Order, *supra* note 139. This focus on advanced manufacturing is not entirely new. *See infra* Section II.A.

152 Buy American Executive Order, *supra* note 139.

Countermeasures, and Critical Inputs if the facilities in which they are produced refuse or unreasonably delay an inspection.[153]

The Order also directed federal agencies to use their respective authorities in consultation with the FDA Commissioner to procure Essential Medicines, Medical Countermeasures, and Critical Inputs through limiting competition to products produced in the United States and dividing procurement requirements among two or more domestic manufacturers, as appropriate.[154] However, these procurement provisions will not apply in certain scenarios.[155]

Members of trade groups and journalists were quick to express their criticism of the Order, even before FDA released its list of Essential Medicines, Medical Countermeasures, and Critical Inputs. The Pharmaceutical Research and Manufacturers of America, a trade association representing members of the pharmaceutical industry, expressed concern that the plan "creates even more barriers to ongoing biopharmaceutical manufacturing and innovation"[156] and will result in "less investment in U.S. innovation" and potentially "major long-term supply chain

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[153] *Id.* FDA has the power to conduct announced or unannounced inspections for cause. FDA stated in congressional testimony in June that "[w]hen the Agency has determined the need to do an unannounced inspection, FDA has conducted such operations. Over the past several years, FDA investigators have conducted unannounced inspections at foreign manufacturing facilities, including in India and China." *COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process: Hearing Before S. Comm. on Fin.*, 116th Cong. (2020) (testimonies of Judith McMeekin, FDA Associate Commissioner for Regulatory Affairs, Mark Abdoo, FDA Associate Commissioner for Global Policy and Strategy, and Douglas Throckmorton, FDA Deputy Director for Regulatory Programs), https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020 [https://perma.cc/3DZ3-WXJJ]. However, a GAO report published in June found that FDA typically preannounces foreign inspections. "While FDA inspections performed in the United States were almost always unannounced, FDA's practice of preannouncing foreign inspections up to 12 weeks in advance may have given manufacturers the opportunity to fix problems ahead of the inspection." U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-626T, DRUG SAFETY: COVID-19 COMPLICATES ALREADY CHALLENGED FDA FOREIGN INSPECTION PROGRAM (2020), https://www.gao.gov/assets/710/707345.pdf [https://perma.cc/7W9E-6WNG]. It is also worth noting that although the Order directs FDA to refuse admission as appropriate to certain imports if facilities in which they are produced refuse or delay an inspection, this refusal is already an available remedy. According to FDA Import Alert 99-32, any foreign entity can be placed on import alert if it refuses inspection. U.S. FOOD & DRUG ADMIN., IMPORT ALERT 99-32 (Dec. 2, 2020), https://www.accessdata.fda.gov/cms_ia/importalert_521.html [https://perma.cc/V8QG-Q4NG]. Under Import Alert 99-32, the refusal to permit inspection of a foreign facility or provide reasonable access to FDA's inspectional personnel, combined with other evidence, provides an appearance that the firm's products are manufactured, processed, or packed under unsanitary conditions. Those foreign factories, warehouses, or other establishments that refuse to permit entry of U.S. inspectors or other individuals to inspect their facilities will be listed on the "Red List," and their products are subject to refusal of admission.

[154] Buy American Executive Order, *supra* note 139.

[155] *Id.* The provisions do not apply if 1) the head of the agency determines that their application would be inconsistent with the public interest; 2) the relevant Essential Medicines, Medical Countermeasures, and Critical Inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or 3) the application of the section would cause the cost of the procurement to increase by more than 25%, unless applicable law requires a higher percentage, in which case such higher percentage shall apply. *Id.*

[156] Eric Sagonowsky, *FiercePharmaPolitics—After Drug Pricing Tensions, Industry Pushes Back at Trump's 'Buy American' Order*, FIERCE PHARMA (Aug. 10, 2020, 12:46 PM), https://www.fiercepharma.com/pharma/fiercepharmapolitics-after-drug-price-tensions-industry-pushes-back-buy-american-order [https://perma.cc/H7EX-GGVJ].

disruptions."[157] Leaders from the Association for Accessible Medicines (AAM), a trade association representing generic drug manufacturers, have expressed concern that U.S. generic drug prices are too low to support moving more production into the United States,[158] and that, "[w]ithout addressing the undervaluation of generic and biosimilar medicines in the U.S. with sustainable market supply plans, we simply cannot secure the domestic market and supply chain with scale and sustainability."[159] Others have critiqued the Order for undermining global cooperation and making it more difficult to obtain ingredient sources needed from abroad for the development of COVID-19 vaccines and treatments.[160] Some argued that discussions regarding repatriating supply chains should wait until the COVID-19 crisis has passed and that the United States cannot afford to invite negative responses internationally, given the need for collaboration in connection with COVID-19 vaccine development.[161]

To date, the Biden Administration has not officially revoked the Order. What role FDA's recently issued list of Essential Medicines, Medical Countermeasures, and Critical Inputs will play in future policymaking if the Order is withdrawn or significantly modified remains to be seen. President Biden's campaign platform proposed a high-level policy to mitigate supply chain issues that pledged to "immediately marshal all of the tools of the Federal government" to secure supplies, treatments, and potential vaccines to combat COVID-19.[162] Upon taking office in January 2021, President Biden signed an Executive Order titled "A Sustainable Public Health Supply Chain" directing HHS and other agencies to review the availability of critical materials, treatments, and supplies needed to combat COVID-19 and to assess whether the United States could reasonably provide such supplies in a timely manner.[163]

Additionally, on February 24, 2021, President Biden issued an Executive Order on America's Supply Chains, founded on the increasingly accepted principle that the United States needs "resilient, diverse, and secure supply chains to ensure [its] economic prosperity and national security."[164] Under the Executive Order, federal

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[157] *Id. See also* Stephen Ezell, *Faulty Prescription: Why a "Buy American" Approach for Drugs and Medical Products Is the Wrong Solution*, INFO. TECH. & INNOVATION FOUND. (June 15, 2020), https://itif.org/publications/2020/06/15/faulty-prescription-why-buy-american-approach-drugs-and-medical-products [https://perma.cc/VXC6-F5XS] (Information Technology and Innovation Foundation (ITIF) is a nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy.).

[158] Press Release, Ass'n for Accessible Medicines, Generic and Biosimilar Industry Statement on Essential Medicines Executive Order (Aug. 6, 2020), https://accessiblemeds.org/resources/press-releases/statement-on-essential-medicines-executive-order [https://perma.cc/2PL5-GWSJ].

[159] *See id.*; *see also* David Lim, *Trump Signs 'Buy American' Executive Order for Essential Drugs*, POLITICO (Aug. 6, 2020, 8:01 PM), https://www.politico.com/news/2020/08/06/trump-sign-buy-american-drugs-order-392247 [https://perma.cc/EQ4J-M75V].

[160] Sally Pipes, *Pending "Buy America" Executive Order Threatens Coronavirus Response*, FORBES (Mar. 17, 2020, 6:57 PM), https://www.forbes.com/sites/sallypipes/2020/03/17/new-pending-buy-american-executive-order-threatens-coronavirus-response/#2bb6961c22cd [https://perma.cc/VMQ2-4LPF].

[161] *Id.*

[162] BIDEN/HARRIS CAMPAIGN, *supra* note 133.

[163] A Sustainable Public Health Supply Chain, 86 Fed. Reg. 7,219 (Jan. 21, 2021), https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain [https://perma.cc/6TJK-57CR].

[164] America's Supply Chains, 86 Fed. Reg. 11,849 (Mar. 1, 2021).

agencies are currently undertaking a 100-day review to identify supply chain risks for four key product types, including pharmaceuticals, and to recommend strategies to mitigate those risks.[165] One assumption underlying this review—and undergirding ongoing policy discussions—is that reshoring pharmaceutical manufacturing will ensure greater resilience in the event of global pandemics like COVID-19, lessen dependence on foreign suppliers in countries such as China and India, and strengthen the U.S. economy by rebuilding domestic manufacturing capacity and ensuring U.S. leadership in research and development.

As we await action based on the 100-day review, it is important to avoid underestimating the protective function that global supply chains play. The United States is not immune from natural disasters or other problems that can shut down production and cause serious supply chain shocks.[166] If taken too far, consolidation of manufacturing capacity in the United States could damage global supply chain relationships and undermine efforts to strengthen supply chain security. And certainly, nations like Ireland and Mexico house significant pharmaceutical and medical device manufacturing capacity.[167] Such countries are close allies of the United States and pose little risk of using trade policy to achieve geopolitical advantages antithetical to U.S. interests.[168]

2. Contracting

As noted in Section B above, the federal government has entered into several contracts intended to foster domestic manufacturing of critical medical products. In June 2020, the Department of Defense announced that the agency had entered into a memorandum of agreement with the U.S. International Development Finance Corporation (DFC) to award and administer loans using authority under both the DPA and funds provided by the CARES Act.[169] Then-President Trump also signed an

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[165] *Id.* at 11,849–50.

[166] Consider the shortages of sterile IV saline in late 2017, after drug manufacturing factories in Puerto Rico were damaged by Hurricane Maria. *See, e.g.*, Julia Carrie Wong, *Hospitals Face Critical Shortage of IV Bags Due to Puerto Rico Hurricane*, GUARDIAN (Jan. 10, 2018, 7:00 AM), https://www.theguardian.com/us-news/2018/jan/10/hurricane-maria-puerto-rico-iv-bag-shortage-hospitals [https://perma.cc/WM85-77YH]; *How Hurricane Maria Caused U.S. IV Bag Shortage*, HARV. T.H. CHAN SCH. OF PUB. HEALTH (Feb. 28, 2018), https://www.hsph.harvard.edu/news/hsph-in-the-news/hurricane-maria-u-s-iv-bag-shortage/ [https://perma.cc/4M4N-WLQZ].

[167] FITCH SOLS., *supra* note 3, at 11.

[168] Natalie Liu, *Irish Envoy Hits Back at Call to Repatriate Big Pharma*, VOA NEWS (May 27, 2020), https://www.voanews.com/economy-business/irish-envoy-hits-back-call-repatriate-big-pharma [https://perma.cc/N487-T46X]; Roberta Jacobson & Tom Wyler, *To Counter China, Look to Canada and Mexico*, FOREIGN AFFS. (July 31, 2020), https://www.foreignaffairs.com/articles/americas/2020-07-31/counter-china-look-canada-and-mexico [https://perma.cc/3BMP-AGU7] ("[M]oving production to the United States from a region such as Asia, where manufacturing costs are lower, would be economically inefficient—assuming it is even possible. . . . There is, however, a practical alternative that would not come at the expense of U.S. competitiveness: a more economically integrated North America.").

[169] David Vergun, *DOD Partners with DFC to Protect Industrial Base from Economic Effect of Pandemic*, DOD NEWS (June 22, 2020), https://www.defense.gov/Explore/News/Article/Article/2227560/dod-partners-with-dfc-to-protect-industrial-base-from-economic-effect-of-pandem/ [https://perma.cc/W7HZ-K3ZP].

executive order authorizing this effort in May 2020.[170] Although the DFC's historic mission focused on financing private development in lower- and middle-income countries,[171] in July 2020, it issued a $765 million loan to Eastman Kodak Co. (Kodak).[172] The loan, the first of its kind under the DPA, was intended to facilitate production of "essential medicines that have lapsed into chronic national shortage," and "[o]nce fully operational, Kodak will have the capacity to produce 25% of the generic active pharmaceutical ingredients necessary for all non-biologic or non-antibacterial pharmaceuticals used in the United States."[173] A securities law controversy arose after this agreement was announced, however, leading the DFC to announce that it would not proceed with the loan.[174]

DFC has also provided similar loans to encourage domestic production of other critical medical products. In November 2020, DFC announced that it had approved a $590 million loan to ApiJect Systems Corporation to facilitate the "production of prefilled injectors that are capable of delivering almost all leading COVID-19 vaccine candidates with speed, scale, and efficiency."[175] The loan is intended to help ApiJect

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[170] Tony Capaccio, *Pentagon Teams with Finance Agency on U.S. Covid Supplies (1)*, BLOOMBERG L. (June 22, 2020, 12:25 PM), https://news.bloomberglaw.com/health-law-and-life-sciences/pentagon-teams-with-finance-agency-on-u-s-made-medical-supplies [https://perma.cc/RE3H-HSDT].

[171] *Who We Are*, U.S. INT'L DEV. FIN. CORP. (DFC), https://www.dfc.gov/who-we-are (last visited Oct. 26, 2020) [https://perma.cc/XD3Y-3UZQ].

[172] Rachael Levy, *Kodak Shifts into Drug Production with Help of $765 Million U.S. Loan*, WALL ST. J. (July 28, 2020), https://www.wsj.com/articles/kodak-lands-765-million-u-s-loan-in-start-of-medical-supply-chain-fix-11595930400 [https://perma.cc/QSK4-F3D5].

[173] *Fact Sheets: President Donald J. Trump Is Committed to Ending America's Reliance on Foreign Countries for Vital Supplies*, THE WHITE HOUSE (July 28, 2020), https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-committed-ending-americas-reliance-foreign-countries-vital-supplies/ [https://perma.cc/Y9E4-C2TW] (click "See the Screenshot View" if using the perma.cc link).

[174] After Kodak announced the loan on July 27, its shares jumped 200%. Almost immediately thereafter, Kodak was hit with a proposed securities class action alleging that the company engaged in a fraudulent scheme to artificially inflate its stock price. As a result of the class action lawsuit, the federal government determined that it would not proceed with the loan pending the outcome of the investigation. Peter Hayes, *Kodak Allegedly Touted Covid-19 Loan to Increase Stock Price (1)*, BLOOMBERG L. (Aug. 14, 2020, 8:27 AM), https://news.bloomberglaw.com/securities-law/eastman-kodak-allegedly-touted-covid-19-loan-to-bump-stock-price [https://perma.cc/R5D6-RXPN]. An investigation of the U.S. International Development Finance Corporation (DFC) by the Office of the Inspector General cleared DFC officials in connection with allegations of impropriety in connection with the award to Kodak, though it did not examine any wrongdoing by the company. An internal review conducted by a Kodak board-appointed committee cleared company leadership of insider trading allegations. Fraiser Kansteiner, *U.S. Agency Behind Kodak's Beefy Drug Manufacturing Loan Played by the Books, Investigation Finds: Report*, FIERCEPHARMA (Dec. 8, 2020, 9:45 AM), https://www.fiercepharma.com/manufacturing/us-agency-behind-kodak-s-beefy-drug-manufacturing-loan-played-by-books-investigation#:~:text=Manufacturing-,U.S.%20agency%20behind%20Kodak's%20beefy%20drug%20manufacturing%20loan,the%20books%2C%20investigation%20finds%3A%20report&text=Back%20in%20September%2C%20a%20board,plans%20to%20enter%20drug%20manufacturing [https://perma.cc/YLX4-AACC]. Kodak CEO Jim Continenza vowed in October that the company would move forward with its plan to produce drug API with or without government support. Rachael Levy, *Kodak to Push Forward on Making Drug Ingredients Despite U.S. Loan Troubles*, WALL ST. J. (Oct. 19, 2020), https://www.wsj.com/articles/kodaks-ceo-says-company-will-still-work-on-producing-drug-ingredients-11603136082 [https://perma.cc/3SA2-9B6M].

[175] Press Release, U.S. Int'l Dev. Fin. Corp. , DFC Approves $590 Million Loan to ApiJect to Expand Infrastructure and Deliver Critical Vaccines in Response to the COVID-19 Pandemic (Nov. 19, 2020), https://www.dfc.gov/media/press-releases/dfc-approves-590-million-loan-apiject-expand-infrastructure-and-deliver#:~:text=WASHINGTON%20%E2%80%93%20The%20U.S.%20International%20Develop

build out infrastructure in North Carolina enabling the delivery of a projected 3 billion vaccine doses annually and to permit the site to work with up to fifteen different drugs, vaccines, and therapeutics at the same time.[176] Within days of announcing the loan to ApiJect, DFC announced approval of a $1.1 billion loan to Ginkgo Bioworks to aid in the "expansion of its commercial biosecurity business . . . facilitating the mass production of key raw materials for vaccines and the deployment of significant [COVID-19] testing capacity."[177]

Additionally, the Trump Administration sought to boost domestic production through entering into procurement contracts with companies to produce drugs and other supplies for the federal government. In one such agreement, entered into in May 2020, the Trump Administration awarded a $354 million contract to Phlow, a generic drug company founded in January 2020 and based in Richmond, Virginia.[178] Phlow's stated goal is to help the United States secure its own strategic drug reserve through use of continuous manufacturing techniques.[179] Phlow initially worked to produce finished dosage forms that were previously in shortage, and these drugs were delivered to the Strategic National Stockpile.[180] However, Phlow has also stated that it is contributing to the first Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), described as a long-term national stockpile of API used for essential medicines intended to reduce reliance on foreign markets.[181] HHS noted in a press release that in addition to producing API, the Phlow team would expand advanced manufacturing capability by providing further capacity for producing finished generic drugs.[182] If successful, such an arrangement could help to mitigate future shortages of generic drugs. However, this contract has attracted criticism given its large size and Phlow's short track record in drug manufacturing and appears to be the subject of an

ment,to%20the%20COVID%2D19%20pandemic.&text=Our%20collaboration%20with%20ApiJect%20will,health%20and%20safety%20of%20Americans.%E2%80%9D [https://perma.cc/T8UV-G76F].

176 *Id.*

177 Press Release, U.S. Int'l Dev. Fin. Corp., DFC Approves $1.1 Billion Loan to Ginkgo Bioworks to Expand its Commercial Biosecurity Business to Combat COVID-19 on a Global Scale (Nov. 25, 2020), https://www.dfc.gov/media/press-releases/dfc-approves-590-million-loan-apiject-expand-infrastructure-and-deliver [https://perma.cc/5DRT-U27D].

178 Jacob Bell, *Little-Known Drug Manufacturer Gets Big Contract For COVID-19 Response*, BIOPHARMA DIVE (May 19, 2020), https://www.biopharmadive.com/news/phlow-barda-funding-us-drug-manufacturing/578224/ [https://perma.cc/8MP2-H734]. The contract might, if extended, ultimately be worth $812 million over ten years. *Id.* Phlow's CEO has stated that the company will focus initially on developing a "rapid surge" in manufacturing capacity for critical pharmaceuticals and ingredients.

179 *Id.*

180 *Id.*

181 *Phlow Secures $354m US Contract for Drug Supply Amid Covid-19*, PHARM. TECH. (May 20, 2020), https://www.pharmaceutical-technology.com/news/phlow-us-drug-supply-contract/ [https://perma.cc/5FV5-R3VJ].

182 Press Release, U.S. Dep't of Health & Hum. Servs., Industry Partners Expand U.S.-Based Pharmaceutical Manufacturing for COVID-19 Response (May 19, 2020), https://www.hhs.gov/about/news/2020/05/19/hhs-industry-partners-expand-us-based-pharmaceutical-manufacturing-covid-19-response.html [https://perma.cc/4KG7-2XUT]. The release further notes that "To lower production costs, reduce waste and improve yields of these ingredients, the team will use advanced manufacturing processes, including continuous manufacturing. The team will also complete a technology transfer of novel continuous manufacturing process to organizations or businesses designated by the U.S. government." *Id.*

investigation by the House Select Subcommittee on the Coronavirus Crisis (Subcommittee).[183]

As the Kodak and Phlow examples illustrate, the federal government's contracting practices during the COVID-19 pandemic have attracted some scrutiny. The Trump Administration has come under fire for awarding contracts to businesses that were inexperienced, had political connections to the administration, or failed to provide promised supplies.[184] In June 2020, members of the House of Representatives called for the Pandemic Response Accountability Committee (PRAC) to investigate first-time federal contracts.[185] The representatives cited a ProPublica analysis showing that more than half the contracts awarded to first-time federal contractors related to the COVID-19 pandemic were not subject to competitive bidding, compared with 32% of overall pandemic-related contracts.[186] The PRAC is an independent oversight committee created by the CARES Act as part of the Council of the Inspectors General on Integrity and Efficiency.[187] The CARES ACT charges the PRAC with overseeing COVID-19-related funds to prevent and detect fraud and to mitigate risks that cut across program and agency boundaries.[188] House members calling for a PRAC investigation argued that the lack of competition paired with the lack of a federal law to prevent price gouging increased the risk of price gouging and of fraud and faulty products.[189] They also stated that some companies receiving federal contracts had only formed weeks or days prior to applying for a contract.[190] In February 2021, PRAC issued an updated report discussing "top challenges in pandemic relief and response."[191] The challenges include preventing and detecting fraud against government programs and financial management of relief funding.[192]

In July 2020, another group of House members sent a letter to the HHS Secretary, Acting Secretary of the Department of Homeland Security (DHS), Secretary of

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[183] Press Release, Select Subcomm. on the Coronavirus Crisis, Select Subcommittee Releases New Evidence of Trump Administration's Failure to Address Supply Shortages (Mar. 21, 2021), https://coronavirus.house.gov/news/press-releases/select-subcommittee-releases-new-evidence-trump-administration-s-failure-address [https://perma.cc/9U58-AH6F].

[184] Press Release, Representative Jackie Speier, Rep. Speier Leads Letter Requesting PRAC Investigation into Suspect Federal Contracts (June 5, 2020), https://speier.house.gov/2020/6/rep-speier-leads-letter-requesting-prac-investigation-into-suspect-federal-contracts [https://perma.cc/ULL2-SUJJ] [hereinafter, PRAC Press Release].

[185] *Id.*

[186] *Id.*

[187] *See Our Mission & Work*, PANDEMIC RESPONSE ACCOUNTABILITY COMM., https://www.pandemicoversight.gov/our-mission (last visited Dec. 18, 2020) [https://perma.cc/EDJ4-KPS7]. Members include Inspectors General from different departments within the executive branch. The PRAC is led by the Inspectors General of the Department of Justice and the National Aeronautics and Space Administration.

[188] BEN WILHELM, CONG. RSCH SERV., IN11343, THE PANDEMIC RESPONSE ACCOUNTABILITY COMMITTEE: ORGANIZATION AND DUTIES (2020).

[189] PRAC Press Release, *supra* note 184.

[190] *Id.*

[191] PANDEMIC RESPONSE ACCOUNTABILITY COMM., UPDATE: TOP CHALLENGES IN PANDEMIC RELIEF AND RESPONSE (2021), https://www.oig.dol.gov/public/reports/PRAC%20Update%20Top%20Challenges%20in%20Pandemic%20Relief%20and%20Response%20_Final.pdf [https://perma.cc/3WFE-GVN2].

[192] *Id.*

Veterans Affairs, and Secretary of Defense stating that the Subcommittee would investigate the federal government's efforts to procure PPE, testing supplies, and other medical equipment during the pandemic.[193] The letter cited reports indicating that federal agencies had awarded contracts to businesses with no federal contracting experience, that had political connections to the administration, and that were selected without competition or transparency.[194] The Subcommittee requested documents and information from the agency heads regarding the contracts awarded by their departments, as well as plans to meet the need for the supplies.[195] In October 2020, the Subcommittee released an interim staff report regarding its six months investigating the Trump Administration's pandemic response, including reference to its investigations into "questionable contracts and loans that may be hindering the nation's ability to quickly produce and distribute protective equipment and other supplies needed to contain the virus."[196] In March 2021, the Subcommittee sent letters to HHS, DHS, FEMA, and the National Archives to follow up on the July investigation.[197] The letters highlighted new evidence obtained by the Subcommittee, including emails revealing that then-Assistant to the President Peter Navarro rushed ahead with the Phlow contract and that White House officials pushed ahead with Kodak's contract despite knowing that Kodak would need a waiver from cGMP requirements.[198]

Despite these controversies, some commentators have suggested that the federal government should make greater use of the DPA and federal contracting. Some have recommended increasing domestic production of drugs either by providing incentives for companies or through creating an emergency manufacturing infrastructure to activate during shortages.[199] In addition to entities like Phlow, nonprofit organizations like Civica Rx claim to have significant ability to produce generic drugs domestically.

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193 *Letter from Rep. James E. Clyburn, Chairman of H.R. Select Subcomm. on the Coronavirus Crisis, 116th Cong., to Hon. Alex M. Azar II, Secretary of the U.S. Dep't of Health & Hum. Servs*., HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (July 14, 2020), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-07-14.Select%20Cmte.%20to%20Azar-HHS%20Esper-DOD%20Wolf-DHS%20Wilkie-%20VA%20re%20Administration%20PPE%20Contractor%20%281%29.pdf [https://perma.cc/5MF3-P9KL]; *As Coronavirus Cases Rise, Panel Launches Investigation into Problematic Contracts for Critical Supplies*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (July 15, 2020), https://coronavirus.house.gov/news/press-releases/coronavirus-cases-rise-panel-launches-investigation-problematic-contracts [https://perma.cc/V9CS-SBTV].

194 *Letter from Rep. James E. Clyburn*, *supra* note 193.

195 *Id.*

196 HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS, INTERIM STAFF REPORT: INEFFICIENT, INEFFECTIVE, AND INEQUITABLE: THE TRUMP ADMINISTRATION'S FAILED RESPONSE TO THE CORONAVIRUS CRISIS (2020), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/InterimStaffReport10.30.20.pdf [https://perma.cc/6J7R-9X9G].

197 *Select Subcommittee Releases New Evidence of Trump Administration's Failure to Address Supply Shortages*, HOUSE SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS (Mar. 31, 2021), https://coronavirus.house.gov/news/press-releases/select-subcommittee-releases-new-evidence-trump-administration-s-failure-address [https://perma.cc/394S-777F].

198 *Id.*

199 Olga Iwona Piatek, James Chien-Min Ning & Daniel R. Touchette, *National Drug Shortages Worsen During COVID-19 Crisis: Proposal for a Comprehensive Model to Monitor and Address Critical Drug Shortages*, 77 AM. J. HEALTH SYS. PHARMACY 21, 1778–85 (2020); Esther K. Choo & S. Vincent Rajkumar, *Medication Shortages During the COVID-19 Crisis: What We Must Do*, 95 MAYO CLINIC PROC. 6, 1112–15 (2020).

Civica Rx was formed in 2018 by seven health systems in order to combat drug shortages.[200] Because Civica Rx prioritized manufacturing of antibiotics, pain management drugs, and sedatives prior to the COVID-19 pandemic, it states that it was able to assist hospitals facing shortages of these drugs as the crisis worsened.[201] Civica Rx also announced a partnership with Sandoz to manufacture critical injectable generic medicines.[202] Authors of an article from the Mayo Clinic suggest expanding the concept behind Civica Rx and turning to government manufacture of essential generic drugs long-term.[203]

To increase domestic medical product manufacturing, some groups, including AAM, have called for direct government funding and tax incentives to support construction, alteration, or renovation of facilities for domestic manufacture of medicines included on the high-priority medicines list, as well as to relocate production facilities to the United States.[204] Another approach, suggested by the CEO of U.S. Pharmacopeia, could be to provide loans to companies that specialize in complex drug or device manufacturing or emerging technologies, where the United States might have a competitive advantage, rather than attempting to onshore production of low-tech, low-value products.[205] FDA has already indicated its support for the adoption of advanced manufacturing techniques, such as continuous manufacturing rather than traditional batch manufacturing, and has highlighted the potential public health value of advanced manufacturing techniques during the

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[200] Maia Anderson, *How Civica Rx Has Responded to Drug Shortages Caused by COVID-19*, BECKER'S HOSP. REV. (May 12, 2020), https://www.beckershospitalreview.com/pharmacy/how-civica-rx-has-responded-to-drug-shortages-caused-by-covid-19.html [https://perma.cc/TMH3-TGQE]. *See* CIVICA, https://civicarx.org (last visited Dec. 18, 2020) [https://perma.cc/27VW-8BLB].

[201] Anderson, *supra* note 200.

[202] Jenni Spinner, *Sandoz, Civica RX Partner to Stem Shortage of Generics*, OUTSOURCING PHARMA (July 9, 2020), https://www.outsourcing-pharma.com/Article/2020/07/09/Sandoz-Civica-RX-partner-to-stem-shortage-of-generics [https://perma.cc/YDH5-PPZL]. Another example of a company working to address drug shortages is ProvideGx, which works with Premier Inc. and a number of hospital systems: Premier, ProvideGx. *ProvideGx*, PREMIER, https://explore.premierinc.com/providegx [https://perma.cc/HDA8-TFBT] (last visited Dec. 18, 2020).

[203] Choo & Rajkumar, *supra* note 199.

[204] ASS'N FOR ACCESSIBLE MEDICINES, A BLUEPRINT FOR ENHANCING THE SECURITY OF THE U.S. PHARMACEUTICAL SUPPLY CHAIN 7 (2020), https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf [https://perma.cc/M492-MS4A]; Andrea Shalal, Alexandra Alper & Patricia Zengerle, *U.S. Mulls Paying Companies, Tax Breaks to Pull Supply Chains from China*, REUTERS (May 17, 2020, 1:03 AM), https://www.reuters.com/article/us-usa-china-supply-chains/u-s-mulls-paying-companies-tax-breaks-to-pull-supply-chains-from-china-idUSKBN22U0FH [https://perma.cc/XZ86-3RFW]; For a discussion of the costs of building in the U.S./Western Europe vs. India, see Megan Parrish, *The Most—And Least—Expensive Places To Run A Pharma Plant*, PHARMA MFG. (Jan. 27, 2020), https://www.pharmamanufacturing.com/articles/2020/the-most-and-least-expensive-places-to-run-a-pharma-plant/ [https://perma.cc/T3ZZ-DPBE]; Kyle Blankenship, *U.S. Seeks to 'Onshore' Drug Production in Response to COVID-19. Is Pharma Even Interested?*, FIERCEPHARMA (June 3, 2020, 9:45 PM), https://www.fiercepharma.com/manufacturing/pharma-pushes-back-u-s-legislation-to-bring-drug-manufacturing-stateside [https://perma.cc/V7G9-3ZSF].

[205] *Continued Reliance on Foreign Drug Manufacturing and the Drug Supply Chain: Manageable Risk or Public Health Concern?*, FOOD & DRUG L. INST. (Sept. 16, 2020), https://www.fdli.org/2020/09/continued-reliance-on-foreign-drug-manufacturing-and-the-drug-supply-chain-manageable-risk-or-public-health-concern/ [https://perma.cc/8PL4-URBX].

COVID-19 pandemic.[206] FDA has recently entered into a cooperative agreement grant to research the risks to industry and government associated with bringing pharmaceutical manufacturing back to the United States and the potential role of advanced manufacturing technology.[207]

3. Tax Incentives

Numerous legislative proposals have also provided tax incentives or credits aimed at returning medical product manufacturing back to the United States. In light of concerns that the Tax Cuts and Jobs Act of 2017 may have created incentives for companies to send jobs overseas, Senator Debbie Stabenow (D-MI) proposed the Bring Jobs Home Act of 2017.[208] Stabenow first introduced this legislation in 2012, but it has yet to pass in the Senate.[209] The bill would amend the Internal Revenue Code to grant business taxpayers a tax credit for up to 20% of insourcing expenses incurred for eliminating a business located outside the United States and relocating it within the United States. It would also deny a tax deduction for outsourcing expenses.[210]

Legislators have proposed offering tax credits for manufacturers that operate in certain "American Opportunity Zones."[211] Other suggestions put forth in legislation include lowering the tax rate on income from domestic manufacturing and sales of API and medical countermeasures or providing credits for advanced medical manufacturing.[212]

The AAM has also proposed a variety of tax incentive measures, including a dollar-for-dollar credit against federal taxes to pharmaceutical manufacturers for 50% of wages, investments, and purchases made for manufacturing medications on the priority medicines list in the United States; an increase in the simplified R&D tax credit to 20%; and an assurance that grants provided for establishment of U.S. production of medicines are not considered taxable income.[213]

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[206] Stephen M. Hahn & Anand Shah, *Investing in Advanced Manufacturing to Support Public Health Preparedness*, U.S. FOOD & DRUG ADMIN. (Aug. 3, 2020), https://www.fda.gov/news-events/fda-voices/investing-advanced-manufacturing-support-public-health-preparedness [https://perma.cc/78WF-JB2L].

[207] Greg Muraski, *How Maryland Smith Is Helping the FDA Think About Drug Manufacturing and Risk*, UNIV. OF MARYLAND'S ROBERT H. SMITH SCH. OF BUS. (Nov. 12, 2020), https://www.rhsmith.umd.edu/news/how-maryland-smith-helping-fda-think-about-drug-manufacturing-and-risk [https://perma.cc/N7UH-57HL].

[208] *Stabenow Statement on Republican Tax Proposal*, OFFICE OF SENATOR DEBBIE STABENOW (Sept. 27, 2017), https://www.stabenow.senate.gov/news/stabenow-statement-on-republican-tax-proposal [https://perma.cc/4THY-ZMKV].

[209] *Id.*

[210] Bring Jobs Home Act, S. 247, 115th Cong. (2017). Taxpayers would also be required to increase their number of full-time employees in the United States to claim the tax cut.

[211] Press Release, Senator Tim Scott, Scott/Carter Introduce Proposal to Encourage America's Pharmaceutical Independence (May 21, 2020), https://www.scott.senate.gov/media-center/press-releases/scott/carter-introduce-proposal-to-encourage-americas-pharmaceutical-independence [https://perma.cc/9H3P-JJD7].

[212] *See Agenda for a Healthy Economy*, WAYS & MEANS HOUSE REPUBLICANS, https://republicans-waysandmeansforms.house.gov/uploadedfiles/wenstrup_one_pager.pdf [https://perma.cc/Q89T-ZLYZ] (last visited Dec. 18, 2020).

[213] ASS'N FOR ACCESSIBLE MEDS., A BLUEPRINT FOR ENHANCING THE SECURITY OF THE U.S. PHARMACEUTICAL SUPPLY CHAIN 8 (2020), https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf [https://perma.cc/AQ7D-8KEX].

4. Proposed Supply Chain Legislation

A number of bills were introduced in 2020 and 2021 to address supply chain vulnerabilities.[214] One proposal, the U.S. Pharmaceutical Supply Chain Defense and Enhancement Act, which was introduced in the Senate in July 2020 by Senators Elizabeth Warren (D-MA) and Tina Smith (D-MN), contains similarities to the Buy American Executive Order.[215] It would require both the FDA Commissioner and the Secretary of Defense to develop a list of "critical drugs," including API and starting materials, and would provide $1 billion a year for five years to BARDA to "dramatically upgrade our national capacity to manufacture 'critical drugs.'"[216] This funding would be used to contract with U.S. nonprofits and companies to help invest in the facilities, manufacturing techniques, and drug development processes needed to produce the drugs, API, and starting materials included on the list, and would use advanced manufacturing techniques.[217] The proposed law would also require the Department of Defense, Department of Veterans Affairs, HHS, and the Bureau of Prisons to purchase domestically produced drugs and provide funding to subsidize those purchases.[218] It would also create a more robust form of the annual reporting requirements included in the CARES Act by requiring drug makers to report annually to FDA information about the source of API and starting materials used to make drugs consumed in the United States and requiring FDA to issue both public and classified reports to Congress on the strength of the U.S. supply chain.[219]

Other recent bills focus on developing agency programs and directing agencies to study the effects of foreign reliance and strains on supply chains. For instance, the Strengthening America's Supply Chain and National Security Act would direct the Department of Defense to determine the extent of its dependence on foreign entities for drugs, API, and pharmaceutical components.[220] Similarly, the U.S. Pharmaceutical Supply Chain Review Act, introduced in the Senate in July 2020, would direct the Federal Trade Commission and the Secretary of the Treasury to conduct a study and report to Congress within one year on the United States' reliance on foreign countries and the impact of foreign direct investment in the U.S. pharmaceutical industry.[221] In March 2021, Senators Marco Rubio (R-FL) and Chris Coons (D-DE) introduced the National Manufacturing Guard Act of 2021, which would invest $1 billion over five

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[214] U.S. Pharmaceutical Supply Chain Defense and Enhancement Act, S. 4175, 116th Cong. (2020); Press Release, Senator Elizabeth Warren, Warren, Smith Introduce Legislation to Boost U.S. Pharmaceutical Manufacturing Capacity and End Over-Reliance on Foreign Countries for Critical Drugs (July 2, 2020), https://www.warren.senate.gov/newsroom/press-releases/warren-smith-introduce-legislation-to-boost-us-pharmaceutical-manufacturing-capacity-and-end-over-reliance-on-foreign-countries-for-critical-drugs [https://perma.cc/J3YU-ZF6C] [hereinafter Warren Press Release].

[215] U.S. Pharmaceutical Supply Chain Defense and Enhancement Act, S. 4175, 116th Cong. (2020).

[216] Warren Press Release, *supra* note 214.

[217] *Id.*

[218] *Id.*

[219] *Id.*

[220] Press Release, Marco Rubio, Rubio, Colleagues Introduce the Strengthening America's Supply Chain and National Security Act (Mar. 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 [https://perma.cc/C4DF-GAJV].

[221] U.S. Pharmaceutical Supply Chain Defense and Enhancement Act, S. 4175, 116th Cong. (2020).

years to study the U.S. government's ability to mitigate future supply chain emergencies.[222] If enacted, the law would create an Office of Supply Chain Preparedness in the Department of Commerce that would be tasked with preparing for future crises that threaten the United States' ability to produce or obtain critical resources.[223] It would also create a Supply Chain Data Exchange to enable public-private partnerships, as well as a Manufacturing Corps intended to bolster the manufacturing workforce.[224]

Some proposed legislation has focused more specifically on the United States' relationship with China. The Pharmaceutical Independence Long-Term Readiness Act was introduced in the House in November 2019 and focuses specifically on Chinese pharmaceuticals.[225] The bill would require the Department of Defense to identify vulnerabilities caused by American dependence on Chinese pharmaceuticals and to purchase only American-made raw materials, medicines, and vaccines for the military.[226]

In May 2020, House members introduced another bill, the Prescription for American Drug Independence Act. This bill would require HHS to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to establish a committee of experts regarding drug supply issues, convene a symposium to recommend strategies for ending U.S. dependence on foreign manufacturing of drugs, and report on that symposium's proceedings.[227] Representative Anna Eshoo (D-CA), one of the bill's co-sponsors, was quoted as saying that "the U.S. currently is dependent on China for the key ingredients in antibiotics and blood pressure medications, and also depends on foreign manufacturing of generic drugs, which represents up to 90 percent of the prescriptions taken by Americans," and that "[t]he U.S. must have a national strategy to eliminate foreign dependence for critical drugs and with it, Congress can move quickly to act on the recommendations of the experts."[228]

Which, if any, of these proposals will gain traction and what concrete steps the Biden administration will take to facilitate some level of onshoring and stimulate investment in domestic production is still not entirely clear. Success will likely depend on encouraging collaboration and information sharing across the government and with industry and academia. New initiatives may benefit from consideration of relevant findings from the FDA-supported research project discussed above, analyzing the risks

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[222] Press Release, Senator Marco Rubio, Rubio, Coons Lead Bipartisan Bill to Bolster U.S. Supply Chain Preparedness and Response (Mar. 19, 2021), https://www.rubio.senate.gov/public/index.cfm/press-releases?id=C231C93D-6159-4AD5-BC53-0928F567CC58 [https://perma.cc/4J7H-3TTZ].

[223] *Id.*

[224] *Id.*

[225] Pharmaceutical Independence Long-Term Readiness Reform Act, H.R. 4710, 116th Cong. (2019); Press Release, Representative Vicky Hartzler, Hartzler, Garamendi Introduce Bill to Protect Service Members from Chinese-Controlled Generic Pharmaceutical Industry (Oct. 18, 2019), https://hartzler.house.gov/media-center/press-releases/hartzler-garamendi-introduce-bill-protect-service-members-chinese [https://perma.cc/3VQW-PU4F] [hereinafter Hartzler Press Release].

[226] Hartzler Press Release, *supra* note 225.

[227] Prescription for American Drug Independence Act of 2020, H.R. 6670, 116th Cong. (2020).

[228] *Brooks Unveils Bipartisan Prescription for American Drug Independence Act*, RIPON ADVANCE (May 5, 2020), https://riponadvance.com/stories/brooks-unveils-bipartisan-prescription-for-american-drug-independence-act [https://perma.cc/28QS-GNWF].

associated with onshoring and looking at advanced manufacturing as a pathway to incentivize increased domestic drug production.[229] The results of President Biden's 100-day review should also provide important insights.

III. CONCLUSION: WHAT COMES NEXT?

The COVID-19 pandemic significantly intensified attention and scrutiny directed at the fragility of the nation's supply chain for medical products generally and the nation's reliance on foreign drug and device manufacturing in particular. Acute shortages of critical medical products have forced the United States to take a hard look at short- and long-term solutions to supply chain vulnerabilities.

Much of the attention has focused on proposals to increase domestic medical product production, even if it requires costly government expenditures. Such an approach raises a number of questions, however. For one thing, the government is currently providing large sums of money and significant human capital and other resources to boost domestic production of critical medical products. Once the pandemic is no longer an immediate threat, will this level of attention and funding persist? In a world of finite resources, such solutions may not be economically feasible due to the lack of necessary raw materials in the United States, the potentially prohibitive costs of moving manufacturing of low-margin API and generic drug products to the United States, and other factors.

Additionally, globalization of supply chains can have a protective function. Any investments in domestic manufacturing should be careful to strike an adequate balance, as too much consolidation could lead to massive shortages if a natural disaster or other problems arise that disrupt domestic supply chains. To that end, the United States should invest in domestic resources while also maintaining relationships with manufacturers in key allied foreign countries. Some level of redundancy may be inefficient yet still critically necessary.

As noted at the outset of this Article, the horrendous toll that the COVID-19 pandemic has taken on the U.S. population will require a serious and searching inquiry into what could have been done better. Such an inquiry will be multi-faceted, involving a broad set of issues relating to the country's preparedness for, and management of, serious public health threats. While it will be only one aspect of the broader evaluation, addressing the medical product supply chain fragility that the COVID-19 pandemic revealed will require serious thought and effort. Targeted solutions focused on onshoring higher technology manufacturing and a limited list of the most critical drugs and medical supplies will likely have a role, but such efforts will need to be combined with other approaches. A "9/11 Commission"-like report on the COVID-19 pandemic could help elucidate the full range of weaknesses that the pandemic has revealed, including supply chain fragility. Industry and government should examine the lessons learned from this experience and consider a broad range of solutions to supply chain fragility so that the country is better prepared for a future pandemic or other global crisis.

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[229] *See* Muraski, *supra* note 207.