Florida State University Journal of Transnational Law & Policy

Volume 31 | Issue 1 Article 5

2022

In the Danger Zone: The Call for Reshoring Pharmaceutical Manufacturing to Reduce the Vulnerability of the United States' Supply Chains to War Tactics

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Cover Page Footnote

Note

IN THE DANGER ZONE: THE CALL FOR RESHORING PHARMACEUTICAL MANUFACTURING TO REDUCE THE VULNERABILITY OF THE UNITED STATES' SUPPLY CHAINS TO WAR TACTICS

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I. INTRODUCTION

Tactics of war can take many forms, such as a surprise attack through dive bombings on a naval fleet,[1] the dropping of atomic

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1. In World War II, the United States was not prepared for the bombarding of Pearl Harbor, leading to a significant wound that led to the United States entering the war. *See* RICHARD J. SAMUELS, ENCYCLOPEDIA OF UNITED STATES NATIONAL SECURITY 572–74 (Rolf Janke, 1st ed. 2005); Christopher Klein, *How Japan's Kamikaze Attacks Went from Last*

bombs on cities,[2] or the flying of planes into a financial district.[3] As proven by the United States in World War II, blockading an adversary's access to pharmaceuticals and necessary supplies is also an effective way to damage an enemy.[4] In order to ensure the safety of a country's population, a country must surveil and ensure that such supply chains and vulnerabilities are reduced. When analyzing the vulnerabilities of the United States, the pharmaceutical supply chain is a glaring weakness to national security and public safety.[5] Currently, the United States relies on other countries for essential pharmaceuticals such as antibiotics, heparin, chemotherapy drugs, and medical supplies.[6] Should an adversary choose to injure the

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Resort as Pearl Harbor to WWII Strategy, HISTORY STORIES (Dec. 5, 2018), https://www.history.com/news/pearl-harbor-japan-kamikaze-world-war-ii.

2. The United States' entry eventually led to the very shocking but efficacious use of two atomic bombs dropped on Japan, which effectively ended World War II. SAMUELS, *supra* note 1 at 52.

3. Another effective campaign was the attacks of 9/11, which involved hijackers crashing planes into the World Trade Center and the Pentagon. The United States was on lock down. Airplanes could not leave the ground. Millions were afraid to go outside or to go to social events. The New York Stock Exchange dropped 684 points in a day. The campaign was effective at damaging the United States through economic and social upheaval. *Id.* at 50, 652–55; Marc Davis, *How September 11 Affected the U.S. Stock Market*, U.S. MARKETS (Aug. 31, 2021), https://www.investopedia.com/financial-edge/0911/how-september-11-affected-the-u.s.-stock-market.aspx.

4. SUZANNA REISS, WE SELL DRUGS: THE ALCHEMY OF US EMPIRE 15–16 (2014); Richard J. Evans, *Why Hitler's Grand Plan During the Second World War Collapsed*, THE GUARDIAN (Sept. 8, 2009), https://www.theguardian.com/world/2009/sep/08/hitler-germany-campaign-collapsed (discussing the United States' successful blocking of Germany's access to supplies).

5. Although the United States once manufactured almost all its pharmaceuticals, it now relies on other countries for many necessary pharmaceuticals, such as antibiotics and heparin. Ken Dilanian & Brenda Breslauer, *US. Officials Worried about Chinese Control of American Drug Supply*, NBC NEWS (Sept. 12, 2019), https://www.nbcnews.com/health/health-care/u-s-officials-worried-about-chinese-control-american-drug-supply-n1052376; Because United States residents rely on these finished pharmaceuticals (FPPs) and active pharmaceutical ingredients (APIs) to live, a delay or abrupt severing of the supply chain or adulteration of significant batches of pharmaceuticals would result in societal disruption as well as health impairment and potentially death to thousands or millions of Americans. Betsy McCaughey, *The Hidden Peril of Drugs Imported from China*, N.Y. POST, (Sept. 3, 2019), https://nypost.com/2019/09/03/the-hidden-perils-of-drugs-imported-from-china/.

6. Guy Taylor, *'Wake Up Call': Chinese Control of U.S. Pharmaceutical Supplies Sparks Growing Concern*, THE WASHINGTON TIMES (Mar. 17, 2020), https://www.washingtontimes.com/news/2020/mar/17/china-threatens-restrict-critical-drug-exports-us/ (discussing the potential shortage of necessary pharmaceuticals, such as antibiotics, within the United States amid the COVID-19 pandemic because of the United States' reliance on China for manufacturing); Doug Palmer & Finbarr Bermingham, *U.S. Policymakers Worry About China 'Weaponizing' Drug Exports*, POLITICO (last updated Apr. 10, 2020), https://www.politico.com/news/2019/12/20/policymakers-worry-china-drug-exports-088126 (discussing the millions of Americans reliant on pharmaceuticals from China and the vulnerability of the supply chain, such as penicillin and heparin); ROSEMARY GIBSON, CHINA RX 36–56 (2018)).

United States, this reliance could be manipulated and abused to the detriment of the health and lives of the United States' residents.[7]

For example, although China and India did not become major pharmaceutical exporters as a means to damage the United States,[8] their current exportation power could be wielded to the United States' detriment.[9] And when considering the wavering and complex relationship between the United States and China,[10] the pharmaceutical supply chains are suspect for potential manipulation or abuse. As a result, the United States must take

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7. Taylor, *supra* note 6; Palmer & Bermingham, *supra* note 6.

8. An official at the China Association of Pharmaceutical Commerce, Zhu Jianyun, suggested that it was pharmaceutical companies searching for cheaper manufacturing that led to China rising to a manufacturing powerhouse, not China seeking out those powers. Palmer & Bermingham, *supra* note 6.

9. For example, China currently manufactures the majority of the United States' penicillin supply as well as supplies for chemotherapy drugs, heparin, blood pressure medications, and doxycycline for anthrax attacks. Rosemary Gibson, *U.S. Dependence on China for Medicine Is a Major Problem*, THE SEATTLE TIMES (July 21, 2019), https://www.seattletimes.com/opinion/u-s-dependence-on-china-for-medicine-is-a-major-problem/. Overall, China is "the world's leading producer and exporter of active pharmaceutical ingredients (APIs) by volume, accounting for 20% of total global API output." WORLD HEALTH ORGANIZATION, CHINA POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 17 (2017) [hereinafter WHO China], https://www.who.int/phi/publications/2081China020517.pdf. As such, many medications reaching the United States often have APIs from China.

10. Aside from other quarrels, the United States indicted it was Chinese hackers who allegedly hacked into United States' governmental systems. The Chinese government responded by refusing continued collaboration in cyber-security workgroups. *U.S. Relations with China, 1949–2020*, COUNCIL ON FOREIGN RELATIONS (2020), https://www.cfr.org/timeline/us-relations-china. In 2020, a Harvard professor and two Chinese nationals were indicted on charges for lying to federal investigators about ties to the Chinese government. It was suggested that the Harvard professor and the nationals were attempting to steal research paid for by the United States government. *See* Veronica Stracqualursi and Sheena Jones, *Harvard Professor Among Three Charged with Lying about Chinese Government Ties*, CNN (Jan. 28, 2020), https://www.cnn.com/2020/01/28/politics/harvard-professor-chinese-nationals-arrest-espionage/index.html. In 2018 and 2019, Chinese nationals were also arrested in the United States for carrying suspected Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) materials. *See* Jerry Dunleavy, *FBI Warned about 'Biosecurity Risk' after Chinese Nationals Snuck Suspicious Vials into US*, WASHINGTON EXAMINER (Apr. 1, 2020), https://www.washingtonexaminer.com/news/fbi-warned-about-biosecurity-risk-after-chinese-nationals-snuck-suspicious-vials-into-us. Further, after United States' government officials referred to the Coronavirus (COVID–19) as the "Wuhan" or "China Virus," a Chinese official claimed that COVID–19 was possibly started by the U.S. and dropped into China to hurt the Chinese reputation. Lee Myers, *China Spins Tale That the U.S. Army Started the Coronavirus Epidemic*, THE N.Y. TIMES (Mar. 13, 2020), https://www.nytimes.com/2020/03/13/world/asia/coronavirus-china-conspiracy-theory.html. Finally, Chinese economists suggested the Chinese pharmaceutical exportation supply chain could be leveraged against the United States during the trade war. *See* Didi Tang, *China Threat to Halt US Antibiotics Supply*, THE TIMES (Mar. 11, 2019), https://www.thetimes.co.uk/article/china-threat-to-halt-us-antibiotics-supply-36tm2v2xp.

steps to reduce such vulnerabilities by reshoring the manufacturing of pharmaceuticals and diversifying supply chains in the interim.[11]

This Note discusses the history of the exportation of the United States pharmaceutical sector as well as the rise of India and China as pharmaceutical manufacturing powerhouses in Part II. Part III discusses the need for increased local production (reshoring) of pharmaceuticals within the United States and the diversification of foreign pharmaceutical supply chains. Further, within Part III, the Note will discuss the barriers to local production and diversification of supply chains. Part IV will follow with a discussion of solutions. Such solutions include incentives to increase reshoring of pharmaceutical manufacturing within the United States through pharmaceutical companies as well as other non-traditional manufacturers. Further, Part V will discuss the need to incentivize local adaption of continuous manufacturing to increase competitiveness with China. Part VI will follow with counterarguments. Part VII concludes with an overview of why reshoring and increasing local production is needed and how to encourage these processes.

II. THE SHIFTING OF THE PHARMACEUTICAL SECTOR OUTSIDE OF THE UNITED STATES TO CHINA AND INDIA

Most of the pharmaceutical powerhouses in the United States, such as Eli Lilly, began in the late 1800s and early 1900s.[12] The United States went on to solidify itself as a global power in the pharmaceutical industry during World War II by using legislative power and trade deals to control global trade of pharmaceuticals and resources.[13] For example, the United States began to shape the supply chain of cocaine, previously considered a useful medication for various injuries.[14] By striking deals with Bolivia and Peru, the United States began to block Germany from supplies and subsequently, started to become the world's supplier of cocaine.[15] The United States did not stop at just manufacturing cocaine,

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11. Such government measures were reinitiated recently through the introduction of Senate Bill 2495, Protecting Our Pharmaceutical Supply Chain from China Act of 2021. S.2495, 117th Cong. (2021). Although this bill would seemingly aid in understanding vulnerabilities, this Note makes other recommendations to improve the pharmaceutical supply chain.

12. *See* Robin Walsh, *A History of the Pharmaceutical Industry*, PHARMAPHORUM (Oct. 1, 2010), https://pharmaphorum.com/articles/a_history_of_the_pharmaceutical_industry/.

13. *See* REISS, *supra* note 4, at 47–52.

14. *See id.* at 22–25.

15. *See id.*

however, and continued to expand into other fields, leading to dominance in various pharmaceuticals' production.

Initially, the United States pharmaceutical companies used vertically integrated models of production as a means to control production.[16] Within this model, companies would do everything from research and development of pharmaceuticals to manufacturing to marketing and commercialization of the products.[17] Having the vertically integrated model, however, became much more expensive as regulations called for more complex processes for the patenting and production of pharmaceuticals.[18]

Such expenses and processes are then coupled with increased competition as others are allowed to enter the market, leading to outsourcing.[19] Pharmaceutical patents generally provide originator companies, companies initially patenting the pharmaceuticals, with several years of patent exclusivity from filing.[20] Although patent exclusivity is generally for twenty years, regulatory exclusivity is much shorter.[21] As regulatory exclusivity periods expire, generic and biosimilar companies can then apply for Abbreviated New Drug

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16. *See* Min Zhang et al., *Evaluating Outsourcing Partners' Capability: A Case Study from the Pharmaceutical Supply Chain*, 24 J. OF MANUFACTURING TECH. MGMT. 2 (2013) (citing to PricewaterhouseCoopers, Pharma 2020: Challenging Business Models- Which Path Will You Take? (2009)). "In this model, success hinges on the firm's internal abilities to identify promising new molecules, test them in large clinical trials, and promote them with an extensive marketing and sales presence."

17. *See id.*

18. *See id.*

19. With the introduction of generics, originator companies see their profits reduced, while generic companies have to cut costs to compete with thinner profit margins. *See id.* (discussing the variety of reasons why outsourcing has become more popular among U.S. pharmaceutical companies). *See also Why Outsource Manufacturing to CMO Pharmaceutical Companies?* ABBVIE CONTRACT MANUFACTURING (2021), https://www.abbviecontractmfg.com/services/expertise/when-to-use-outsourcing-in-drug-development.html; CONG. RESEARCH SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 1 (Feb. 11, 2020) (discussing the billions of dollars spent on research and development to patent pharmaceuticals).

20. *See* U.S. GOV'T ACCOUNTABILITY OFF., DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 7 (2017). Many pharmaceutical companies can retain up to twenty-five years of market exclusivity from filing due to patent extensions of five years with the Hatch–Waxman Act of 1984. Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United Stated*, JAMA INTERNAL MEDICINE ONLINE 2 (Sept. 11, 2017), doi:10.1001/jamainternmed.2017.4329. However, such time is often frustrated due to the FDA's strenuous requirements, with pharmaceutical companies having significantly less than 20 years of exclusivity when their drugs reach market. *Id.* at 2, 4 (suggesting the effective exclusivity period was found to be around 12.5 years in multiple studies).

21. During the patent exclusivity period, other companies are not allowed to "mak[e], us[e], or sell . . . the patented aspects of the drug." These other companies are also excluded from most marketing of the patented aspect or product. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 7; *See* Kesselheim, Sinha & Avorn, *supra* note 20, at 1–3; *See also* 35 U.S.C. § 271. However, as mentioned, the regulatory period is much shorter and generic companies can initiate processes before patent expiration when regulatory exclusivity expires. *See* Kesselheim, Sinha & Avorn, *supra* note 20, at 1–3.

Applications (ANDAs) and eventually begin manufacturing the pharmaceutical once approved.[22] The introduction of such generics leads to reductions in originators' profits.[23] Further, because ANDAs do not require the extensive testing that originator pharmaceuticals require, the generic market is often very competitive[24] and as a result, generic companies operate on thinner profit margins.[25] Thus, companies look for ways to cut costs, such as with manufacturing processes.[26]

Exploration led to the creation and development of contract research and manufacturing organizations (CROs/CRMOs) in emerging economies. By providing a skilled workforce with specialized services, these CROS offered ways to "reduce cost[s], improve speed, quality, and flexibility, and adjust their organizational boundaries in response to external economic pressures."[27] This led to the outsourcing of pharmaceutical manufacturing to countries in Europe and Asia.[28] Process by process was gradually outsourced, until other countries not only manufactured basic chemicals and intermediates, but also active pharmaceutical ingredients (APIs) and finished pharmaceutical products.[29]

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22. Generics are those that are similar to chemically synthesized drugs, while biosimilars are those that are similar to biologic originator drugs. *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 8. To be approved, generic companies must show that their formulary of the generic is similar to the originator "in active ingredient, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use." *Id.* Biosimilars must be "highly similar" to the approved product and "have no clinically meaningful differences in terms of safety and effectiveness." *Id.*

23. Tom Fezza, Faith Glazier & Jodi Reynolds, *Loss of Exclusivity: Strategies to Maximize Product Value*, PHARMEXEC (Nov. 9, 2016), https://www.pharmexec.com/view/loss-exclusivity-strategies-maximize-product-value.

24. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 48.

25. *See id.* (discussing the reduction in price as generic companies enter the market).

26. *See* Zhang et al., *supra* note 16, at 2; Alan S. Ryan & Frederick D. Sancilio, *Outsourcing Excellence in China and India*, PHARMA MANUFACTURING (Feb. 12, 2013), https://www.pharmamanufacturing.com/articles/2013/018/ ("The need to reduce time-to-market, boost drug discovery and squeeze costs out of pharmaceutical and nutritional products have forced U.S. companies to look elsewhere for raw materials, active pharmaceutical ingredients (APIs) and manufacturing and packaging services").

27. *See* Zhang et al., *supra* note 16, at 2. See also the statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research in *Safeguarding Pharmaceutical Supply Chains in a Global Economy, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. (Oct. 30, 2019), https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019 (suggesting among costs are "large factory site[s], . . . [and] environmental liabilities" as well as higher workforce costs in the United States).

28. Notably, China and India are countries relied upon for manufacturing through CRMOs. *See* Zhang et al., *supra* note 16, at 2.

29. *See* Sylvia M. Findlay, *Outsourcing in Pharma*, PHARM TECH (May 1, 2007), http://www.pharmtech.com/outsourcing-pharma. The authors suggested that initially basic

A. China's and India's Introduction as Pharmaceutical Powerhouses

Two notable countries that United States pharmaceutical companies turned to for cheaper manufacturing were China and India.[30] China's and India's governments helped propel companies within their boundaries into the global industry through industry design and development processes.[31] As a result, both countries boast substantial market-shares in production of APIs, with China controlling twenty percent of the global market and India controlling just over seven percent.[32]

In the 1950s and 1960s, India's government and pharmaceutical industry developed manufacturing facilities and technology to improve their foundation of pharmaceutical innovation and production.[33] After creating a strong foundation, India turned its views to tackling high income markets, such as the United States in the 1980s.[34] By using its highly integrated industry, local sourcing of low-cost APIs, and efficient production of finished pharmaceutical products (FPPs), India was able to successfully break into these markets, even with the United States' higher standards and regulatory presence.[35] By 2010, India had finished product sales of over "6 billion, increasing at an annual rate of more than 10%" and "account[ing] for nearly 20% of the global generic marketplace."[36]

China's entry into the global pharmaceutical industry came later. In the 1980s, China moved away from a "central government planning economic model to a more market-oriented model" and in 2001, joined the World Trade Organization.[37] China began seeking investors into its companies, especially its manufacturing sector, and quickly became successful in exporting basic chemicals,

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chemical processing was outsourced before moving to manufacturing of the API and now even some finished pharmaceutical products (FPPs). *See also* Ryan & Sancilio, *supra* note 26; Palmer & Bermingham, *supra* note 6.

30. *See* Zhang et al., *supra* note 16, at 2.

31. *See generally* WHO China, *supra* note 9, at 16–20; *See* WORLD HEALTH ORGANIZATION, INDIAN POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 1–3 (2017) [hereinafter WHO India].

32. *See* WHO China, *supra* note 9, at 17; Julian Issa, India's API Industry: *Exporting to the World*, GLOBAL BUSINESS REPORTS (Mar. 17, 2020), https://www.gbreports.com/article/indias-api-industry-exporting-to-the-world.

33. *See* WHO India, *supra* note 31, at 1.

34. *See id.*

35. *See id.*

36. Ryan & Sancilio, *supra* note 26.

37. WHO China, *supra* note 9, at 5.

intermediates, and APIs.[38] This market was based upon cheaper production of pharmaceutical APIs, leading to more profits for foreign global pharmaceutical companies.[39] Indeed, pharmaceutical companies found a viable industry in China with significantly lower wages, fewer environmental regulations, and lower costs related to electricity, coal, and water when compared to United States equivalents.[40] Additionally, as its industries are "embedded in a network of raw materials and intermediary suppliers," Chinese companies were further able to manufacture and export at significantly lower costs than United States' companies.[41]

As a result of these lower costs for APIs and generic pharmaceutical manufacturing, United States' companies transitioned to India's and China's manufacturing industries to reduce overall costs.[42] Although United States' residents reap the benefit by having more affordable access to generics, it also places them in a vulnerable position. As stated previously, if China (or India) decided to halt the supply to the United States, United States' residents would not have regular access to necessary pharmaceuticals.[43]

III. THE NECESSITY OF LOCAL PRODUCTION AND DIVERSIFICATION OF SUPPLY AS WELL AS BARRIERS

To reduce the vulnerability of the pharmaceutical supply, the United States must shift to local production of needed medications by reshoring pharmaceutical manufacturing.[44]

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38. *See generally id.* at 16. China has now progressed toward finish product pharmaceuticals as well.

39. *See* Ryan & Sancilio, *supra* note 26.

40. *See* Woodcock, *supra* note 27.

41. *Id.*

42. *See* Ryan & Sancilio, *supra* note 26.

43. *See* Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China*, COUNCIL ON FOREIGN RELATIONS: ASIA UNBOUND & GLOBAL HEALTH PROGRAM (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

44. "Reshoring" involves the relocating of pharmaceutical manufacturing and other processes back to the country these processes initially occurred within, such as the United States. *See generally* Jim Miller, *Will Pharma Manufacturing Move Back to the US?*, PHARM TECH: ADVANCING DEVELOPMENT AND MANUFACTURING (Mar. 2, 2017), http://www.pharmtech.com/will-pharma-manufacturing-move-back-us-0. Aside from reducing vulnerabilities due to war tactics, reshoring pharmaceuticals reduces supply issues regarding public health emergencies. Part of the issues with mask shortages and medications during COVID–19 were a result of importing masks and pharmaceuticals from outside of the country. *See* Taylor, *supra* note 6.

However, experts suggest that a shift of many needed generics would take multiple years.[45]

This stems from the barriers that stand in the way of reshoring pharmaceutical manufacturing.[46] First and foremost, costs are high to bring back pharmaceutical manufacturing. Experts suggest that opening a large-scale biologics company would cost upwards of 1 to 2 billion dollars.[47] Although generics manufacturing is substantially cheaper than biologics,[48] reshoring still comes with a significant price. Many directors and corporate boards are hesitant to take hits to quarterly earnings in order to reshore supply chains.[49] As such, one of the first hurdles would be to reduce the price of transitioning back to local production or to incentivize companies to offset losses related to reshoring manufacturing back to the United States.

Beyond the costs, determining where pharmaceutical manufacturing plants will reside is also complicated. Pharmaceutical manufacturing leads to environmental waste that must be disposed of within the Environmental Protection Agency's and state-equivalent regulations and guidelines.[50] Pharmaceutical manufacturing also calls for a good source of

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45. *See* Miller, *supra* note 44, http://www.pharmtech.com/will-pharma-manufacturing-move-back-us-0 (suggesting that to open a manufacturing facility for pharmaceuticals generally takes at least four years, while transferring a drug to another facility can take up to two years. Overall, the process of reshoring pharmaceutical manufacturing back to the United States is expected to take between 7 and 10 years).

46. Although there are barriers, reshoring comes with benefits as well, such as quick delivery of products to customers, better quality control, and more ability to customize products. Customization will play a huge part in patient-centered pharmaceuticals in the future. *See generally* Alessandro Ancarani, Carmela Di Mauro, & Francesco Mascali, *Backshoring Strategy and the Adoption of Industry 4.0: Evidence from Europe*, 54 J. OF WORLD BUS. 360, 360–64 (2019).

47. *See* Miller, *supra* note 44.

48. Avik Roy & The Apothecary, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#2e3994b718b0.

49. Steve Banker, *U.S. Manufacturers Are Not Reshoring*, FORBES (July 11, 2018), https://www.forbes.com/sites/stevebanker/2018/07/11/u-s-manufacturers-are-not-reshoring/#156dd762460 (discussing barriers to reshoring in all industries which includes the reluctance to risk large investments in overseas manufacturing). Afterall, the board's duties are to the corporation and to ensuring the longevity of the corporation. Wolters Kluwer, *Powers & Duties of Corporation Directors & Officers*, ARTICLES (Apr. 24, 2019), https://ct.wolterskluwer.com/resource-center/articles/powers-and-duties-of-corporate-directors-officers.

50. *See generally* Brian Gallagher & Dan Mollohan, *Reshoring Best Practices for Manufacturers*, INDUSTRY WEEK (Feb. 22, 2013), https://www.industryweek.com/expansion-management/article/21959734/reshoring-best-practices-for-manufacturers (discussing the need to consider environmental regulations and impact).

relatively clean water in order to achieve the necessary pristine conditions of developing unadulterated medications.[51]

Beyond these factors, companies must also consider the location due to potential weather-related disasters. For example, Puerto Rico was a significant manufacturer of many pharmaceuticals reaching the United States mainland.[52] When Hurricane Maria devastated the island, Puerto Rico's manufacturing was decimated, leading to the shutdown of manufacturing of intravenous (IV) drip bags.[53] As the United States was already suffering from an IV bag shortage, this severing of the supply chain was substantial.[54] As such, the location of manufacturing will be no small decision and will lead to limitations on potential locations within the United States.

A. Diversification of Pharmaceutical Supply Chains

While waiting on local manufacturing facilities to be arranged, diversifying supply chains would also help to reduce the reliance on a peaceful Chinese-American relationship. Instead of continuing an almost complete reliance on China, the United States should look toward countries it not only has good relationships with but also those with stable economies and those who are less likely to suffer catastrophic weather-related events.[55] Indeed, placing all of the pressure on one supply chain because the country has the lowest price situates any country in a vulnerable spot regardless of the commodity or asset and regardless of the exporting countries.[56] As some suggest, the costs of diversifying to multiple supplies would be expensive and lead to lower quarterly profits, "but it would also guarantee a modicum of stability in case of crises—whatever

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51. *See* Abdul Bake, Zubair Khalid Labu, Khurshid Jahan, *Pharmaceutical Water*, PHARMACEUTICAL GUIDELINES (Sept. 2012), https://www.pharmaguideline.com/2012/09/pharmaceutical-water.html.

52. Walecia Konrad, *Why So Many Medicines Are in Short Supply Months after Hurricane Maria*, CBS NEWS (Feb. 12, 2018), https://www.cbsnews.com/news/why-so-many-medicines-arel-in-short-supply-after-hurricane-maria/.

53. *Id.*

54. *Id.*

55. Elisabeth Braw, *Blindsided on the Supply Side*, FOREIGN POLICY (Mar. 4, 2020), https://foreignpolicy.com/2020/03/04/blindsided-on-the-supply-side/ (referencing the Fukushima earthquake and how it adversely affected pharmaceutical giant Merck by disrupting the supply chain of needed technology. Although weather phenomenon disasters have been rare, they are increasing in frequency. As a result, corporate leaders will have to consider expensive transitions to dual-supply chains to offset disastrous results of relying on a supply chain that can be destroyed by weather).

56. *Id.* (discussing the various supply chains and commodities that have been affected by crises, such as COVID–19 or earthquakes).

those crises might be."[57] Thus, should interactions with China become retaliatory, United States residents would be shielded from punitive actions.

Unfortunately, diversification also comes with complications. Other potential manufacturing sources, such as India, also heavily rely on China for much of the production of active pharmaceutical ingredients.[58] As a result, most of the countries the United States would consider transitioning manufacturing to would also need to increase manufacturing within their countries in order to take on the pharmaceutical needs of the United States.[59] Thus, diversification of pharmaceuticals coming from China will not be an easy task. However, as suggested by the Civica RX company, diversification is possible and manufacturing outside of China can produce necessary pharmaceuticals.[60] Though, to completely secure the pharmaceutical supply chain within the United States, reshoring should be the end goal.

IV. LURING THE PHARMACEUTICAL COMPANIES INTO LOCAL PRODUCTION AND INCENTIVIZING LOCAL ALTERNATIVE COMPETITORS

Transitioning pharmaceutical manufacturing back to local production is a necessary maneuver with many challenges. However, the United States government possesses enough power as well as the responsibility[61] to bring back pharmaceutical

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57. Braw, *supra* note 55.

58. Huang, *supra* note 43.

59. *See generally id.* Amid the COVID–19 virus, India is looking to take over more of the API market and limit its reliance on China. Teena Thacker, *As China Stumbles, India Plans Big Exports Push in Bulk Drugs*, THE ECONOMIC TIMES (May 1, 2020), https://economictimes.indiatimes.com/news/economy/foreign-trade/as-china-stumbles-india-plans-big-exports-push-in-bulk-drugs/articleshow/75480532.cms.

60. Civica RX partnered with Xellia out of Denmark to manufacture medications. Ben Hargreaves, *Civica Signs Its First Supplier Agreement for Antibiotics in Short Supply*, OUTSOURCING-PHARMA (May 29, 2019) https://www.outsourcing-pharma.com/Article/2019/05/21/Civica-Rx-signs-manufacturing-agreement-with-Xellia?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright; Civica RX also partnered with ThermoFisher Scientific to manufacture. Ben Hargreaves, *Civica Rx Signs 7-year Deal with Thermo Fisher*, OUTSOURCING-PHARMA (Jan. 20, 2020), https://www.outsourcing-pharma.com/Article/2020/01/20/Civica-Rx-announces-partnership-with-Thermo-Fisher; Among other places, Thermo Fisher has manufacturing sites in Ireland. ThermoFisher Scientific, *Thermo Fisher Scientific to Acquire Manufacturing Site in Cork*, Ireland, from GSK, NEWS RELEASE DETAILS (May 16, 2019), https://thermofisher.mediaroom.com/2019-05-16-Thermo-Fisher-Scientific-to-Acquire-Manufacturing-Site-in-Cork-Ireland-from-GSK; See *infra* note 116 (discussing Civica Rx's partnering with Hikma, a multi-national manufacturer).

61. Although perhaps out of the scope of this paper, the United States government has a responsibility to ensure the health and safety of its populace. The Constitution suggests that the government has the power to tax and spend to "promote the general welfare."

manufacturing to the United States. In order to successfully bring back local production of pharmaceuticals, this Note advocates for the United States to conduct the following steps: 1) use tax incentives targeting reshoring and property taxes instead of corporate tax reductions to incentivize current manufacturers to reshore; 2) use subsidies and tax incentives to incentivize investments in local continuous manufacturing; 3) use grants and prizes to increase universities' and private organizations' research into continuous manufacturing to reduce risks of investment; and 4) incentivize alternative generic manufacturers, such as hospital organizations, to increase local production. Such, incentives for alternative manufacturers includes mandating PBMs contract with local alternative manufacturers over others. These steps will increase access to local generic manufacturing of necessary pharmaceuticals and decrease the vulnerabilities of the United States' supply chain.

A. Using Taxes to Incentivize Current Manufacturers to Reshore

Tax incentives appear to be an obvious choice when incentivizing companies to reshore pharmaceutical manufacturing.[62] Pharmaceutical companies spent millions, if not billions, in developing infrastructure and plants as well as training a workforce in foreign countries to manufacture pharmaceuticals.[63] Furthermore, although the discrepancies in wages and benefits are dwindling,[64] in comparison to salaries of manufacturing workers

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Although this has not been applied to requiring pharmaceutical manufacturing of necessary medications, there is an argument to be had about the General Welfare Clause (supplemented by the Necessary and Proper Clause) or Commerce Clause applying at the federal level to such public health emergencies as COVID–19. Interactive Constitution, *The Constitution and the Corona Virus*, WE THE PEOPLE PODCAST (Mar. 19, 2020), https://constitutioncenter.org/interactive-constitution/podcast/the-constitution-and-the-coronavirus; SEAN M. STIFF, CONG. RESEARCH SERV., LSB10434, COVID-19 RESPONSE: CONSTITUTIONAL PROTECTIONS FOR PRIVATE PROPERTY, 1 (Mar. 27, 2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10434. Former President Trump used the Defense Protection Act to seize medical masks and exporting other medical equipment. However, seizing of manufacturing is a severe response, and incentives would most likely lead to better responses from the pharmaceutical industry and public. Further, it, of course, could also be argued that corporations have a responsibility to the populace, but it is more of a moral argument than a legal argument.

62. Tax incentives are often mentioned when incentivizing reshoring of manufacturing. *See* Harry Moser, *Reshoring Was at Record Levels in 2018. Is It Enough?* THE ECONOMY (July 8, 2019), https://www.industryweek.com/the-economy/article/22027880/reshoring-was-at-record-levels-in-2018-is-it-enough.

63. *See generally* Miller, *supra* note 44.

64. *See* Leigh Buchanan, *Why U.S. Manufacturers Are Turning Their Attention to 'Reshoring'*, INC. (Oct. 26, 2017), https://www.inc.com/leigh-buchanan/how-american-manufacturers-are-reshoring.html (pointing out that Chinese wages have tripled from 2005 to 2016).

in the United States, China still has a significantly lower average for salaries of manufacturer workers.[65] In order to reshore pharmaceuticals, the investments in foreign manufacturing and the costs of reshoring must be financially offset. Indeed, reshoring experts stated, "Reshoring takes place when the trade-offs between cost advantages, market and knowledge seeking, transaction costs and maintaining control are not advantageous for the firm anymore."[66]

It was thought that former President's Trump signing of the Tax Cuts and Jobs Act in 2018 would reduce costs enough to incentivize corporations, including pharmaceuticals, to reshore.[67] The act led to a reduction of the corporate tax from thirty-five percent, one of the highest corporate taxes in the world, to a seemingly competitive twenty-one percent corporate tax.[68] The goal of cutting the corporate tax was the hope that corporations would reinvest the money into the companies, including reshoring manufacturing to the United States.[69] The one-time reparation tax holiday and switch to territorial system for taxation of multinational corporations were also thought to encourage reshoring or reinvestment within the United States.[70] However, data on reshoring based on the Tax Cuts and Jobs Act suggest limited progress in reshoring manufacturing across industries.[71] The effect on reshoring of pharmaceutical manufacturing is even more limited.[72]

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65. *See* Elaine Pofeldt, *Why US Manufacturers Are Nixing the US for China*, CNBC (Sept. 21, 2015), https://www.cnbc.com/2015/09/21/why-us-manufacturers-are-nixing-the-us-for-china.html (stating that the average manufacture worker in China makes approximately $8,060 annually).

66. Steven Kinkel et al., *Measuring Reshoring Trends in the EU and the US*, MAKERS 3 (2017), https://reshoringinstitute.org/wp-content/uploads/2020/11/Measuring-Reshoring-in-the-EU.pdf.

67. *See generally* Jonathan Gardner, *Biopharma Happily Takes the Tax Cuts, But the Jobs Are Harder to Find*, BIOPHARMA DIVE (May 9, 2019), https://www.biopharmadive.com/news/biopharma-happily-takes-the-tax-cuts-but-the-jobs-are-harder-to-find/553925/.

68. *Id.*

69. Joseph Zeballos-Roig, *These 7 Charts Show Trump's Tax Cuts Still Haven't Been the Economic 'Rocket Fuel' He Promised, 2 Years after the Fact*, MARKETS INSIDER (Dec. 22, 2019), https://markets.businessinsider.com/news/stocks/7-charts-showing-trump-tax-cuts-not-economic-rocket-fuel-2019-12-1028780773.

70. Michael S. Sinha & Aarson S. Kesselheim, *The Tax Cuts and Jobs Act of 2017 and the Pharmaceutical Industry*, 46 J. OF LAW, MED., & ETHICS 806, 806 (2018).

71. Zeballos-Roig, *supra* note 69 (suggesting that there was limited GDP growth and business investments, but both were shortly lived. Further, investments did not offset the loss of tax revenue).

72. Gardner, *supra* note 67 (stating that instead of reshoring or reinvesting in the United States, pharmaceutical companies generally bought back stocks with the corporate tax savings). Interestingly, the Tax Cuts and Jobs Act also potentially breaches World Trade Organization obligations as well as the Ireland-US double tax treaty. Joe Duffy, *The US Tax Reform Impact in Ireland: Game-changer or Business as Usual?*, NEWS & INSIGHTS (2018),

This lack of reshoring based on these tax changes most likely stems from the lack of targeting the costs and burdens of pharmaceutical manufacturing.[73] Although the Tax Cuts and Jobs Acts did put available money back into the coffers of pharmaceutical companies, it did not directly impact the costs of transitioning pharmaceutical manufacturing back to the United States.[74] The law does not reduce the millions of dollars expended on Food and Drug Administration approval of manufacturing sites within the United States nor does it create an expediated process of approving the United States sites.[75] Further, it fails to increase a skilled workforce necessary to manufacture complex pharmaceuticals, and it does not directly incentivize pharmaceutical companies to develop more modern manufacturing processes, such as continuous manufacturing.[76] Instead, the Tax Cuts and Jobs Act repealed 26 U.S. Code § 199, which ironically encouraged multinational companies to manufacture in the United States.[77] By targeting these needed processes and costs, the government would be more likely to incentivize or reinforce reshoring of pharmaceutical manufacturing.

In order to incentivize pharmaceutical companies, tax credits and grants should be directed toward the local manufacturing of essential pharmaceuticals, such as those on the WHO's Essential Medicines List[78] or lists compiled by hospitals. Furthermore, not only should the government incentivize continuous manufacturing, as discussed below, but they should also offer tax write-offs related to property taxes and reshoring. Specifically, the government should re-enact 26 U.S. Code § 199, which would encourage domestic

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https://www.matheson.com/news-and-insights/article/the-us-tax-reform-impact-in-ireland-game-changer-or-business-as-usual.

73. Andrew R. Roberson, Kevin Spencer & Emily A. Mussio, *A Look at Tax Code Section 199's Last Stand*, LAW360 (Nov. 6, 2018), https://www.mwe.com/insights/a-look-at-tax-code-section-199/.

74. Gardner, *supra* note 67.

75. Such incentives as an accelerated FDA assessment which saves money can be effective if targeting specific desired achievements, such as reshoring production. *See generally* FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY 53–56 (2009) (discussing the use of prizes to reinforce achievement in pharmaceutical innovation, such as when used with orphan drugs).

76. These are all barriers suggested by surveys of why reshoring is not occurring and what would be necessary for the U.S. to reshore necessary medicine manufacturing. *See* Gallagher & Mollohan, *supra* note 50 (discussing reshoring amongst all industries). *See also* Narayan Laksham, *Q&A: Barriers to American Re-shoring*, MANUFACTURING (Apr. 10, 2013), https://www.manufacturing.net/labor/article/13057122/qa-barriers-to-american-reshoring.

77. Roberson, Spencer & Mussio, *supra* note 73.

78. *See Executive Summary: The Selection and Use of Essential Medicines, Report of the 22nd WHO Expert Committee on the 2019 Selection and Use of Essential Medicine*, WORLD HEALTH ORGANIZATION [WHO] (2019).

manufacturing.[79] When combining this historical tax write-off of nine percent with Trump's reduction of the corporate tax to twenty-one percent, those reshoring should see the United States' taxing system as more comparable to Ireland's corporate tax of twelve and a half percent.[80] This tax will specifically target reshoring instead of just placing more money into the pharmaceutical companies' coffers. The further addition of property tax reductions will increase potential locations for reshoring and incentivize companies to reshore by reducing local facility costs.[81]

B. Using Tax Incentives and Subsidies to Increase Continuous Manufacturing Development and Adoption

Certain experts suggest for the United States to compete with manufacturing conducted in China and India, the United States must update manufacturing technology.[82] One such manufacturing process that is considered the future of pharmaceutical manufacturing is continuous manufacturing.[83] Continuous manufacturing involves feeding raw materials down an assembly line of fully integrated APIs or finished pharmaceutical products.[84] In contrast, the traditional way of manufacturing pharmaceuticals

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79. A domestic manufacturing tax write-off, similar to a reshoring tax write-off, was available prior to the 2017 tax act. As such, bringing back something similar directed at domestic pharmaceutical manufacturing would be similar to a historical tax, while also targeting the behavior we want to change. *See generally* John Bentil, *How Tax Reform Will Affect the Pharmaceutical Industry*, PHARM EXEC (Feb. 15, 2018), http://www.pharmexec.com/how-tax-reform-will-affect-pharmaceutical-industry (discussing the repeal of the domestic manufacturing tax write-off).

80. *See id.* Although the corporate tax does not target manufacturing, it does combine with Research and Development tax credits to make the United States look more favorable as a place for various processes. *See generally id.* President Biden's presented plan would increase the corporate tax from 21 to 28%. *See* Michelle P. Scott, *Biden's Tax Plan: What's Enacted, What's Proposed*, INVESTOPEDIA (Apr. 29, 2021), https://www.investopedia.com/explaining-biden-s-tax-plan-5080766 (also suggesting "American corporations' foreign income generally would be subject to a tax of 21%.").

81. It should be noted that property taxes are generally state taxes and would need to be approved by states. *See generally* Agnes Shanley & Lauren Lavelle, *Lower Taxes, More Flexibility Crucial to Retaining Pharma Employment*, 33 BIOPHARM 52, 52–53 (2020). Stipulations for property tax reductions should be placed on utilization of such properties for pharmaceutical manufacturing, thus reinforcing the desired behavior.

82. Woodcock, *supra* note 27 (discussing the necessity of using advanced manufacturing to regain competitiveness with China).

83. In Jane Woodcock's testimony before Committees, she stated, "Advanced manufacturing offers many advantages over traditional pharmaceutical manufacturing, and if the United States invests in this technology, it can be used to reduce the Nation's dependence on foreign sources of APIs, increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls." Woodcock, *supra* note 27.

84. Babu Padmanabhan, *True Continuous Manufacturing*, AUTOMATION & CONTROL (Feb. 28, 2017), https://www.pharmamanufacturing.com/articles/2017/true-continuous-manufacturing/.

is batch manufacturing, in which pharmaceuticals are manufactured in discrete steps and quality testing is conducted after each step.[85]

As mentioned above, continuous manufacturing is considered the future. This stems from the fact that continuous manufacturing frequently reduces long-term costs and increases efficiency with the changes in manufacturing processes.[86] It reduces costs because of the reduction of steps and travel involved and can be modified more easily based on market fluctuations.[87] Continuous manufacturing requires less space than batch manufacturing, with experts suggesting it takes up seventy percent less space than batch manufacturing.[88] Further, automated monitoring detects errors quickly after they occur instead of after each batch and reduces human error through automation, reducing waste and potential recalls.[89] As a result of the reduction in recalls, errors, and wastes, even the FDA suggests that pharmaceutical manufacturers should invest in continuous manufacturing.[90]

However, continuous manufacturing has upfront challenges. Start-up costs are high as machines must be calibrated to function and workers must be highly skilled.[91] Furthermore, technology is

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85. *See* Sau Lee, *Modernizing the Way Drugs Are Made: A Transition to Continuous Manufacturing*, U.S. FOOD AND DRUG ADMINISTRATION (May 17, 2017), https://www.fda.gov/drugs/news-events-human-drugs/modernizing-way-drugs-are-made-transition-continuous-manufacturing.

86. *See* Clive Badman et al., *Why We Need Continuous Pharmaceutical Manufacturing and How to Make It Happen*, 108 J. OF PHARM. SCIS. 3522, 3522 (2019).

87. *See* Kamna Jhamb, *Continuous Manufacturing – Continuous Manufacturing in Pharmaceuticals: Implications for the Generics Market*, DRUG DEVELOPMENT & DELIVERY (Nov./Dec. 2019), https://drug-dev.com/continuous-manufacturing-continuous-manufacturing-in-pharmaceuticals-implications-for-the-generics-market/; The Brookings Institute, *Promoting Continuous Manufacturing in the Pharmaceutical Sector* (last accessed May 2, 2020), https://www.brookings.edu/wp-content/uploads/2015/10/meetingsummary_101915_continuousmanufacturing.pdf.

88. *See* Jhamb, *supra* note 87.

89. *See id.*; *See also* Stephen McCarthy, *Converting to a "Batch-less" World: Quality Implications of Continuous Manufacturing*, PHARMACEUTICAL PROCESSING WORLD (Mar. 26, 2019), https://www.pharmaceuticalprocessingworld.com/converting-to-a-batch-less-world-quality-implications-of-continuous-manufacturing/; *See also* Lee, *supra* note 85.

90. *See* Woodcock, *supra* note 27 (discussing the need for advanced manufacturing, such as continuous manufacturing); *See also* The Brookings Institute, *supra* note 87; *See also* Sarah Massey, *Making The Switch: Continuous Manufacturing vs. Batch Processing of Pharmaceuticals*, LIFE SCIENCE BLOGS (May 5, 2016), https://xtalks.com/Continuous-And-Batch-Manufacturing-Pharmaceuticals/ (reviewing the increase in recalls of 1200% from 2004–2015 and wastes of up $50 billion annually due to recalls and inefficiency).

91. Badman et al., *supra* note 86, at 3523; Jhamb, *supra* note 87; J. Christopher McWilliams et al., *The Evolving State of Continuous Processing in Pharmaceutical API Manufacturing: A Survey of Pharmaceutical Companies and Contract Manufacturing Organizations*, 22 ORGANIC PROCESS RESEARCH & DEV. 1160–61 (2018) (discussing the hesitation of corporations investing in continuous manufacturing because of risks associated with new technology).

still in the innovation stage and comes with significant risks when initiating continuous manufacturing.[92] As a result, although some of the major originator manufacturers are slowly transitioning to continuous manufacturing, generics manufacturers are reluctant to initiate transitioning.[93] To generic manufacturing companies, the costs and risks appear to currently outweigh the benefits.[94] However, generics switching to continuous manufacturing can reduce the estimated $50 billion spent on inefficient manufacturing processes.[95] As such, continuous manufacturing should become a more appealing method as costs increase in China and machinery begins to deteriorate.[96]

To further incentivize generic and originator companies into adapting continuous manufacturing, the government should provide subsidies.[97] Such subsidies would reduce costs of adoption of a risky, innovative technology while also enhancing the manufacturing infrastructure within the United States. Further, as with the reshoring taxes, these subsidies should be contingent on companies locally manufacturing necessary generics. This would increase generics manufacturing, would eventually offset patients' costs for buying generics,[98] and would reduce the vulnerability of the United States' supply chain.

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92. Badman et al., *supra* note 86, at 3523; McWilliams et al., *supra* note 91, at 1160–61.

93. Michael Mezher, *Continuous Manufacturing: Industry Calls for Changes to FDA's Draft Guidance*, REGULATORY FOCUS (May 31, 2019), https://www.raps.org/news-and-articles/news-articles/2019/5/continuous-manufacturing-industry-calls-for-chang.

94. *See generally id.*; Jhamb, *supra* note 87. As discussed above, the competitive nature of generic manufacturing and the lower profit margins deter generic companies from taking higher risks. *See supra* text accompanying notes 22–25.

95. *See* Shula Neuman, *Pharmaceutical Industry Wastes $50 Billion a Year Due to Inefficient Manufacturing*, THE SOURCE (Oct. 6, 2006), https://source.wustl.edu/2006/10/pharmaceutical-industry-wastes-50-billion-a-year-due-to-inefficient-manufacturing/ (referring to a study conducted by Jackson Nickerson and Jeffrey Macher). As mentioned above, batch manufacturing generally requires multiple buildings and starting and stopping multiple processes for production of a pharmaceutical. *See* Jhamb, *supra* note 87; Massey, *supra* note 90.

96. Experts suggest that most batch manufacturing equipment has a life cycle of about 4 to 12 years. *See* Jhamb, *supra* note 87.

97. Subsidies, such as grants, were mostly given to universities thus far. Pharmaceutical Technology Editors, *FDA Awards Five Grants for Advanced Biomanufacturing Research*, ADVANCING DEVELOPMENT AND MANAGEMENT (Sept. 24, 2018), http://www.pharmtech.com/fda-awards-five-grants-advanced-biomanufacturing-research. Instead, directly providing funding to pharmaceutical companies might encourage buy-in from industry players.

98. U.S. Food and Drug Admin., *New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, GENERIC COMPETITION AND DRUG PRICES, (Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

C. Using Government Subsidies and Prizes to Incentivize Universities and Private Entities to Develop Better Continuous Manufacturing

Aside from using tax incentives and grants for pharmaceutical companies, expanding grants to universities and private institutions to further develop continuous manufacturing processes and to train the workforce are also important investments.[99] Providing such grants will target two reasons for hesitation of transitioning manufacturing back to the United States: high upfront costs and risky transitioning due to newer technology and a less skilled workforce.[100]

If companies choose to reshore in order to take advantage of grants or tax incentives for continuous manufacturing, they still face the risks of transitioning to a newer technology. And experts suggest that there are very technical and significant modifications that must be made depending on the type of pharmaceutical manufactured, the size of the batch, and switching between products.[101] Indeed, changing of medications can cause differing pressures on the steel mechanisms and may cause damage if proper modifications are not made.[102] By collaborating with leaders in engineering and manufacturing processes at universities and private organizations, the government can take out some of the risk by providing needed basic research that provides further knowledge regarding risks and necessary modifications.[103] For instance, in 2018, the FDA provided five grants to universities in order to provide further research into the most effective and best practices in continuous manufacturing.[104] These grants were for the exploration of continuous manufacturing of biologics, but this type

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99. NAT'L ACADS. OF SCIS., ENG'G, & MED.; DIV. ON EARTH & LIFE STUDIES; BD. ON CHEMICAL SCIS. & TECH., CONTINUOUS MANUFACTURING FOR THE MODERNIZATION OF PHARMACEUTICAL PRODUCTION: PROCEEDINGS OF A WORKSHOP 1, 4 (Jan. 30, 2019). (discussing current grant projects to universities to increase research for advancements in continuous manufacturing. The workshop also discussed the importance of private-public partnerships to promote adoption of and innovation in continuous manufacturing).

100. Badman, *supra* note 86, at 3523; Miller, *supra* note 44.

101. Rakesh Singh Chaudhary, Ajay Pazhayattil, & Jana Spes, *Continuous Manufacturing: A Generic Industry Perspective*, ADVANCING DEV. AND MFG. (May 30, 2017), http://www.pharmtech.com/continuous-manufacturing-generic-industry-perspective.

102. *Id.*

103. U.S. Food and Drug Admin., *New Evidence Linking*, in GENERIC COMPETITION AND DRUG PRICES, *supra* note 98. (The FDA partnered with Biomedical Advanced Research and Development Authority (BARDA) to promote advancements).

104. Pharmaceutical Technology Editors, *FDA Awards Five Grants for Advanced Biomanufacturing Research*, ADVANCING DEV. AND MFG. (Sept. 24, 2018), http://www.pharmtech.com/fda-awards-five-grants-advanced-biomanufacturing-research. These could be expanded to further promote advancements.

of grant program could be expanded to increase knowledge of what modifications are necessary for various generics. Prizes should also be implemented to further incentivize efficacious practices of continuous manufacturing.[105] These prizes would provide reinforcement to better the process rather than just grants that provide funding for exploration.[106]

Furthermore, universities and private industries also hold the keys to training a skilled workforce to further reduce risks. Most pharmaceutical companies spent time and money training the workforce in China to complete very technical skills related to batch manufacturing.[107] Furthermore, as manufacturing shifted significantly to China and other countries, the skilled United States' manufacturing workforce transitioned to other jobs.[108] As a result, a skilled workforce must be trained to conduct the technical and complex tasks within continuous manufacturing.[109] Partnering with universities and technical schools to recruit skilled workers from their pools of students is necessary. Pharmaceutical companies and other private industries should supplement such programs by hiring and training students.[110] Grants from the government will help incentivize such recruitment and training of skilled workers.

V. INCENTIVIZING ALTERNATIVE MANUFACTURING COMPETITORS TO INCREASE LOCAL PRODUCTION

Aside from luring pharmaceutical companies back from China through incentives, the United States also possesses the ability to attract new local competitors into the generics industry. For example, hospital organizations are often major buyers of pharmaceuticals and as a result, are substantially affected when pharmaceutical shortages occur or medications are adulterated.[111] Hospital administration stated that surgeries and treatments

105. While subsidies such as grants can help fund projects to further knowledge, prizes can further innovation by rewarding not only exploration, but also invention of efficacious processes. *See generally* ABBOTT & DUKES, *supra* note 75, at 44, 53–54.

106. *Id.* Although not as cost-effective as choosing either a grant or a subsidy, this system provides the necessary funds for basic research while also rewarding those coming up with practical solutions.

107. *See generally* Carter Smyth, *The Viability of Reshoring Manufacturing to the U.S.*, BUS. INTELLIGENCE (Dec. 5, 2018), https://www.mbtmag.com/business-intelligence/article/13248105/the-viability-of-reshoring-manufacturing-to-the-us (discussing the barriers to reshoring to the United States for general industries).

108. GIBSON, *supra* note 6, at 282 (2018).

109. Badman, *supra* note 86, at 5523.

110. *Id.* (discussing the importance of providing ways to train skilled workers).

111. Reed Abelson and Katie Thomas, *Fed Up with Drug Companies, Hospitals Decide to Start Their Own*, N.Y. TIMES (Jan. 18, 2018), https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html.

were delayed or cancelled as a result of such shortages.[112] Additionally, with the increasing prices of pharmaceuticals, hospital organizations exhibited interest in entering the pharmaceutical generics competition to reduce costs.[113]

Indeed, in 2018, over 500 hospital organizations with over $100 million in start-up money from philanthropic groups initiated the process of manufacturing generics.[114] Named Civica Rx, this non-profit pharmaceutical manufacturer is now capable of providing needed medications to over 1,200 hospitals with up to twenty generic pharmaceuticals.[115] Although Civica Rx partnered with manufacturers around the world, diversifying their manufacturers between Ireland, Portugal, and other countries, the non-profit suggested they are dedicated to increasing manufacturing in the United States as well ensuring a safe supply chain.[116]

As such, the United States government should also engage non-traditional pharmaceutical manufacturers through incentives to increase local production. New alternative manufacturers will increase competition and should lead to lower generic prices.[117] Not only should the government use tax incentives, such as those given to traditional pharmaceutical companies, incentives and prizes should also be introduced to guide these hospital organizations into green continuous manufacturing.[118] By placing

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112. Civica Rx, *Quality.Supply.Price. How Civica Rx Aims to Solve the US Hospital Drug Shortage Crisis*, EXEC. SUMMARY (Oct. 2019), https://civicarx.org/wp-content/uploads/2019/10/Civica-Rx-White-Paper-FINAL-10.01.19-1.pdf.

113. Alison Kodjak, *Hospitals Prepare to Launch Their Own Drug Company to Fight High Prices and Shortages*, NPR (Sept. 6, 2018), https://www.npr.org/sections/health-shots/2018/09/06/644935958/hospitals-prepare-to-launch-their-own-drug-company-to-fight-high-prices-and-shor.

114. Carolyn Y. Johnson, *Hospitals Are Fed Up with Drug Companies, So They're Starting Their Own*, WASH. POST (May 6, 2020), https://www.washingtonpost.com/national/health-science/hospitals-are-fed-up-with-drug-companies-so-theyre-starting-their-own/2018/09/05/61c27ec4-b111-11e8-9a6a-565d92a3585d_story.html.

115. John George, *St. Luke's Receives First Shipment from Nonprofit Generic Drug Company*, HEALTH CARE (Mar. 5, 2020), https://www.bizjournals.com/philadelphia/news/2020/03/05/st-lukes-receives-first-shipment-from-nonprofit.html.

116. *See* Civica Rx, *Hikma and Civica Rx Sign Long-term Agreement*, CIVICA RX (July 23, 2019), https://civicarx.org/hikma-and-civica-rx-sign-long-term-agreement/ (discussing the partnership with Hikma, which has manufacturing sites in Europe and the Middle East); Civica Rx, *Civica Recognized in Senate Hearing on Coronavirus Supply Chain*, CIVICA RX (Mar. 17, 2020) [hereinafter Civica RX Senate Hearings], https://civicarx.org/civica-recognized-in-senate-hearing-on-coronavirus-supply-chain/.

117. *See* U.S. Food and Drug Admin., *New Evidence Linking*, in GENERIC COMPETITION AND DRUG PRICES, *supra* note 98.

118. *See* Luke Rogers & Klavis F. Jensen, *Continuous manufacturing – the Green Chemistry Promise?*, 21 GREEN CHEMISTRY (2019), https://pubs.rsc.org/en/content/articlehtml/2019/gc/c9gc00773c (reviewing portions of continuous manufacturing that can be done in more environmentally friendly manners).

contingencies on funding, the government is better able to influence long-lasting and efficient manufacturing processes.[119]

Aside from providing incentives for continuous manufacturing, the government should also provide incentives by encouraging or mandating that pharmaceutical benefits managers (PBMs)[120] must contract with these non-traditional generic manufacturers. These PBMs conduct negotiations with pharmaceutical companies in an effort to lower rates for patients.[121] However, PBMs are often influenced into contracting with originators companies, as these brand-name pharmaceutical companies often offer larger rebates, a main contributor of PBM profits.[122] By mandating that PBMs contract with the non-traditional manufacturers for generic pharmaceuticals for all Centers for Medicare and Medicaid Services (CMS) beneficiaries, the government could level the playing field for non-traditional entrants into the pharmaceutical industry.[123] Such was discussed during senate hearings when Civica Rx supporters suggested that more generic manufacturers would enter the market if they could be guaranteed payors.[124] This was the path the Veteran's Administration initiated by joining forces with Civica Rx.[125]

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119. As generally discussed by Abbott and Dukes, prizes can be awarded to those showing innovation that progresses advancements in areas such as green manufacturing. *See generally* ABBOTT & DUKES, *supra* note 75, at 53–54 (discussing the uses of prizes to further innovation in pharmaceuticals).

120. PBMs are third-party companies that negotiate prices and rebates with pharmaceutical manufacturers, set copays, determine formularies, as well as determine reimbursement schemes for pharmacies. *See* Elizabeth J. Seeley & Shawn Bishop, *Missing from the PBM Hearings: Value-Based Drug Reimbursement*, FIRST OPINION (Apr. 11, 2019), https://www.statnews.com/2019/04/11/pbm-hearings-value-based-drug-reimbursement/.

121. *See id.*

122. *See id.* (discussing how PBMs make profits through rebates); The higher the list price, generally the more the PBM makes in profit. See also Wayne Winegarner, *It's Time to Switch Our Pharmacy Benefit Manager*, ECONOSTATS (May 9, 2017), https://www.forbes.com/sites/econostats/2017/05/09/its-time-to-switch-our-pharmacy-benefit-manager/#11f5bc911892.

123. Although the government can step in and ensure payors for local manufacturers, this can also be accomplished by the domestic generic manufacturers contracting that partner hospitals agree to buy a certain amount from the manufacturer. *See* George, *supra* note 115 (discussing how Civica Rx partners agree to buy 50% of necessary medicines from Civica Rx for lower prices). However, the government payor's power to have PBMs buy from local generic manufacturers is significant as a common barrier to more local generic competition is guaranteed payors.

124. *See* Civica Rx Senate Hearings, *supra* note 116.

125. *See* Louis Garguilo, *CDMO-To-Hospital: A Direct Ending for Generic Shortages?*, FROM THE EDITOR (Aug. 15, 2019), https://www.outsourcedpharma.com/doc/cdmo-to-hospital-a-direct-ending-for-generic-shortages-0002. Because the VA has "U.S.-sourced-first regulations," the federal government payors can influence generic manufacturers to reshore by providing guaranteed payors first to domestic manufacturers.

VI. COUNTERARGUMENTS

Both incentivizing pharmaceutical powerhouse companies to reshore and incentivizing new entrants into the local generic manufacturing market come with significant challenges and critiques. Within these counterarguments are the benefits of pursuing more globalist relationships. Technology as well as quality can improve when countries share research and resources.[126] Further, there is some benefit in countries specializing in different processes as these countries excel at manufacturing of APIs or manufacturing of finished pharmaceutical products or improving technology.[127] And in an ideal world, one country should be able to rely on another country for upholding contracts for supplies and goods, including pharmaceuticals.[128] Unfortunately, in attempts to lower prices and strike better trade deals, countries continue to exhibit a willingness to use such supplies as bargaining chips.[129] As a result, governments cannot always count on prior trade deals as tensions sometimes flare between countries. Because resources are finite, countries may never be at a place where they openly and willingly trade resources without pressure regarding what their country receives in return. In order to ensure that supply chains for necessary supplies are kept open, countries must either diversify or must reshore essential supplies to protect their populations.

Others will argue that the costs of reshoring or the environmental impacts are too great for the United States government to bring back pharmaceuticals. However, as China and other countries increase wages and benefits to their populations, the differences in workforce costs will continue to diminish.[130] For example, China is currently increasing environmental regulations

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126. As Abbott and Dukes point out, "traditional knowledge, native skills, and natural resources can enrich the overall process to universal benefit." *See* ABBOTT & DUKES, *supra* note 75, at 287.

127. Such countries as China and India have specialized knowledge of processes that help make manufacturing efficient that other countries might not have. This can increase efficiency in processing and reduce costs. *See* David Alvaro, Emilie Branch, & Cynthia A. Challener, *Glocalization of Drug Manufacturing: Glocalization: Balancing Global and Local Concerns in Manufacturing and the Supply Chain*, PHARMA'S ALMANAC (Oct. 28, 2019), https://www.pharmasalmanac.com/articles/glocalization-of-drug-manufacturing.

128. However, as COVID–19 has shown, countries halted and disrupted exportation of materials even though companies had relied on the materials and related contracts. *See generally* Ana Swanson, *Coronavirus Spurs U.S. Efforts to End China's Chokehold on Drugs*, N.Y. TIMES (Mar. 11, 2020), https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html.

129. Chinese economists suggested that Chinese pharmaceutical companies could halt exportation of needed medications to the United States as a retaliatory measure or bargaining chip during the trade war. *See* Tang, *supra* note 10.

130. *See* Buchanan, *supra* note 64, (pointing out that Chinese wages have tripled from 2005–2016).

after seeing the effects of manufacturing on its environment.[131] As such, companies will continue to see profits dwindle as environmental regulations stiffen. Within the United States, if the pharmaceutical companies switch to greener continuous manufacturing, they can reduce their carbon footprint and create more sustainable and efficient processes that require less resources.[132] Thus, incentivizing continuous manufacturing will not only reduce costs but also should reduce problems meeting environmental regulations.[133]

Another counterargument is that reshoring will drive up pharmaceutical costs. Indeed, bringing back pharmaceutical manufacturing does potentially see pharmaceutical costs rising as costs of production will initially be higher due to higher wages of workers in the United States and the switch to more technologically advanced manufacturing.[134] However, China also currently possesses the ability to increase prices and has increased prices of certain medications and vitamins for which China controls most of the market.[135] China also currently relies on the United States for finished pharmaceutical products[136] and as such, may keep generic prices down so that Chinese residents will not see significant increases in finished pharmaceutical products coming from the United States. Nevertheless, as China improves its own finished pharmaceutical product manufacturing processes,[137] China's government will have less incentive to maintain lower exported generic prices. As such, pharmaceutical prices will most likely rise. Additionally, as their residents and skilled workforce advocate for

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131. Swarna Jayakumaran, *The Impact of China's Environmental Law on the Procurement of API and Excipients*, BEROE WHITE PAPER (July 16, 2019), https://www.beroeinc.com/whitepaper/the-impact-chinas-environmental-law-on-procurement-of-api-and-excipients/.

132. Rogers & Jensen, *supra* note 118, at 3483 (reviewing an example of green manufacturing that could be expanded to domestic manufacturing. "GlaxoSmithKline's creation of a commercial-scale continuous system in Singapore, a site that promises 50% reduction in carbon footprint and 50% reduction in costs, demonstrates the pharmaceutical industry's willingness to adapt to continuous manufacturing").

133. *Id.* (describing methods to reduce environmental footprint and methods to reduce costs).

134. *See* Buchanan *supra* note 64; *But see* Pofeldt, *supra* note 65 (suggesting that even with rising wages, Chinese Workers only make $8,060 annually); *See also* Ned Pagliarulo, *Pharma's Slow Embrace of Continuous Manufacturing*, DEEP DIVE (Sept. 24, 2018), https://www.biopharmadive.com/news/pharmas-slow-embrace-of-continuous-manufacturing/532811/.

135. *See* GIBSON, *supra* note 6, at 91–104.

136. *See* Huang, *supra* note 43.

137. *See id.*; WHO China, *supra* note 9, at 18–19.

higher wages and stricter environmental regulations,[138] China will likely be forced to raise prices to offset benefits to their workforce and the increasing manufacturing costs due to regulations. Finally, if more local competitors are introduced into the United States' generics market, prices should ideally go down.

VII. CONCLUSION

As it stands, the United States is not prepared for potential attacks on its pharmaceutical supply chain. By allowing other countries, such as China, to control substantial amounts of manufacturing without any true alternative plans in place, our supply chains of essential medications are in the same positions of the Germans' supply chains in World War II. Should China decide to halt exports, thousands, if not millions, of Americans would be in jeopardy as their health falters without necessary pharmaceuticals.

As such, the United States government must act to incentivize traditional as well as non-traditional manufacturers to initiate manufacturing of necessary medications on the United States' soil.[139] This can be achieved through the use of tax incentives and grants to encourage reshoring and utilization of continuous manufacturing as well as grants, subsidies, and other incentives for further research. Such research will reduce the risks manufacturers fear in reshoring. Further, engaging alternative manufacturers, such as hospital organizations, is also a viable method of increasing manufacturing locally and securing pharmaceutical resources. By engaging these suggestions, the United States will further protect our essential pharmaceutical supply chain from surprise and shocking attacks and will be out of the danger zone.

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138. *See* Ellen Chang, *American Companies Face Changing China Manufacturing Industry*, U.S. CHINA BUSINESS (Dec. 15, 2016), https://www.eastwestbank.com/ReachFurther/en/News/Article/American-Companies-Face-Changing-Manufacturing-Industry-in-China; *See also* Chris Devonshire-Ellis et al., *China's Rising Manufacturing Costs: Challenges and Opportunities*, CHINA BRIEFING (July 8, 2014), https://www.china-briefing.com/news/chinas-rising-manufacturing-costs-challenges-opportunities.

139. Diversification in the interim is most likely necessary until local continuous manufacturing is available.