

Faulty Prescription: Why a “Buy American” Approach for Drugs and Medical Products Is the Wrong Solution

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COVID-19 has prompted calls for reshoring of medical goods, including strict “Buy American” prescriptions. While reshoring is important, “Buy American” fails to recognize the value of the global supply chain and avoids addressing the real problem, China.

KEY TAKEAWAYS

- China’s restrictions on key medical exports in the COVID crisis expose potential gaps in the U.S. supply chain, so some in Congress and the administration now propose Buy American rules for federal purchases of medical supplies and essential drugs.
- While boosting competitiveness of U.S. life-sciences industries, achieving more manufacturing, and identifying and reducing supply chain dependencies or vulnerabilities are needed steps, a Buy American response is not the solution.
- Buy American provisions ignore the vital role that global supply chains have played in facilitating the production of lowest-cost, highest-value advanced technology products, from semiconductors and servers to pharmaceuticals and medical devices.
- Buy American provisions would only encourage other nations to introduce reciprocal and perhaps retaliatory policies, harming U.S. enterprises by limiting export opportunities in life-sciences sectors and potentially beyond.
- Buy American policies, essentially requiring local production to serve government procurement, could unwittingly reduce supply chain resiliency, while doing little to boost U.S. innovation competitiveness.
- The U.S. should push for more innovation in the biopharmaceutical manufacturing processes and introduce tax and investment incentives that would promote reshoring and the opening of new production facilities in America.

INTRODUCTION

The coronavirus crisis has exacted a terrible price on human life and livelihoods. But it has also disrupted international supply chains and exposed gaps in America's capacity to domestically produce and supply both certain medical supplies and equipment and potentially key inputs to drugs, such as active pharmaceutical ingredients (APIs). In response, some in Congress and the Trump administration have advocated Buy American mandates or preferences for domestically produced pharmaceuticals and medical products. While introducing policies to bolster America's capacity to innovate and increase the domestic supply of pharmaceuticals and medical products is certainly a laudable and desirable goal, resorting to compulsory Buy American measures both fails to recognize the value that international supply chains have brought to this sector and isn't the optimal way to achieve such objectives in any case.

Moreover, as with virtually all concerns about trade, the issue is not about globalization per se, it is about China. As such, the solution should not be to reject or restrict globalization, but to address the specific China challenge, in this case with regard to drugs, APIs, and supplies. Unfortunately, a Buy American approach would portend a turn inward, and ultimately mean that the United States does not win the race for global innovation advantage with China for medical products. Rather than that, federal policy should establish a national medical products strategy, wherein success would mean not only more domestic production, but a growing, rather than diminishing, lead over China in key biopharmaceutical and medical supply industries.

CALLS FOR RESHORING AND BUYING AMERICAN

The coronavirus crisis has exposed both challenges and threats to the U.S. medical supply chain. For instance, the Chinese government forced personal protective equipment (PPE) producers, including factories that produce equipment on behalf of Western companies, to sell every unit they made to the Chinese government when the COVID-19 epidemic was at its worst in China from late January through February 2020.¹ In April, Chinese export restrictions and customs complications left stranded in warehouses and delayed shipments of even American companies' own Chinese-manufactured, U.S.-bound face masks, test kits, and other medical equipment that was so urgently needed. U.S. companies such as PerkinElmer, which makes coronavirus testing kits, and Medtronic, which produces ventilators, were unable to import key components and final goods needed to respond to the pandemic over a crucial period in April. At the time, Chinese customs agents were prohibiting the export of medical products without certifications from China's National Medical Products Administration, on the specious grounds of "ensuring the quality of exported medical products," even though the goods had in most cases already been registered with the U.S. Food and Drug Administration (FDA).² As a U.S. State Department memo noted at the time, China's policies "disrupted established supply chains for medical products just as these products were most needed for the global response to Covid-19."³

China's restrictions on key medical supplies exports at the height of the coronavirus crisis brought into stark relief U.S. dependencies on the country as a manufacturer of both medical supplies and active pharmaceutical ingredients (the actual drugs that are subsequently formulated into tablets, capsules, injections, etc.), antibiotics, and other medicines. For instance, in 2018, China accounted for 43 percent of global PPE exports, and held a 48 percent share of the U.S. market for PPEs, in addition to supplying 39 percent of U.S. medical device

imports.⁴ As the *Pharma Letter* (an online news site covering the industry) wrote in a mid-March newsletter, “China accounts for 95% of U.S. imports of ibuprofen, 91% of US imports of hydrocortisone, 70% of U.S. imports of acetaminophen, 40% to 45% of U.S. imports of penicillin, and 40% of U.S. imports of heparin.”⁵ And while China didn’t restrict pharmaceutical exports related to the coronavirus crisis, India did, announcing on March 3, 2020, that it would stop exporting 26 drugs.⁶ Though initially the Indian export restrictions applied mostly to antibiotics, they came to include hydrochloroquine, which, though it was subsequently demonstrated to have little, if any, effectiveness in combatting the coronavirus, was believed to be a possibly important therapeutic at the time. The Indian export curbs, combined with calls in Chinese state media that the country should block exports of critical medical components and supplies to “send America into the hell of a novel coronavirus epidemic” certainly warranted sufficient impetus to focus U.S. policymakers’ attention on the resiliency and security of its medical supply chains.⁷

As such, the coronavirus crisis has raised awareness of the importance of being less dependent on foreign nations—especially upon an innovation mercantilist nation such as China—for critical medical goods, as well as on the need to increase domestic production. As subsequently elaborated and expanded upon, there have been a number of constructive proposals discussed, including collecting better data on U.S. imports of drugs and medical products, comprehensively mapping medical supply chains and dependencies, expanding research and development (R&D) investment into new pharmaceutical manufacturing processes that could make the United States more cost competitive in manufacturing drugs and APIs, and offering tax credits or investment incentives to return manufacturing to the United States.

However, one policy proposal that has gotten particular attention is a Buy American approach to federal procurement of medicines and medical supplies. Peter Navarro, President Trump’s trade adviser, recently stated, “This is an historic turning point in America’s efforts to onshore its pharmaceutical production and supply chains.”⁸ The Trump administration is believed to be in the process of preparing an executive order that would strengthen Buy American requirements for federal purchases of medicines and medical supplies, including potentially requiring the production of certain essential drugs (as defined by the World Health Organization (WHO)) in the United States.⁹ The order would eliminate current exceptions to Buy American mandates for medicines and medical supplies that allow the U.S. government to purchase foreign goods if they meet certain criteria.¹⁰ The administration may also be considering creating a “white list” of qualifying countries that would be exempted from such domestic procurement requirements. While the proposed executive order does include some useful proposals—such as identifying supply chain vulnerabilities for drugs, medical supplies, and materials, and taking steps to streamline regulatory requirements in order to expedite domestic manufacturing of APIs—these beneficial recommendations are counterbalanced by the proposed Buy American requirements.

Nor is the Trump administration alone in contemplating Buy American requirements. For instance, in Congress, bicameral legislation proposed in the Strengthening America’s Supply Chain and National Security Act would restore the Buy American Act’s intent for Department of Defense (DoD) and Department of Veterans Affairs (VA) purchases.¹¹ The Protecting our Pharmaceutical Supply Chain From China Act would go much further by “prohibiting pharmaceutical purchases from China or products with active pharmaceutical ingredients created in China.”¹² On the House side, the Pharmaceutical Independence Long-Term Readiness Reform

Act contains similar proposals, requiring the Secretary of Defense to only purchase and acquire “American-made” raw materials, medicines, and vaccines for DoD and VA. To be sure, these bills include some useful proposals worth implementing, such as tracking active pharmaceutical ingredients through an FDA registry, enhancing supply chain transparency, and including investment incentives that encourage reshoring—but they stretch too far when introducing Buy American requirements or cutting off exchange entirely with foreign nations.

HOW DEPENDENT IS THE UNITED STATES ON FOREIGN SUPPLIES?

The medical-products industry contains an array of different products, from pharmaceutical drugs of various types to antibiotics to vaccines to medical devices (e.g., ventilators) to medical supplies (e.g., N95 masks). Much of the problem in the response to COVID-19 was not that the United States did not have the capacity to produce most of these products, it was that it couldn’t quickly adapt to a surge. This was not a global supply chain problem. It was a problem that stemmed from the federal government not being willing to pay the extra costs of adding redundant capacity that most of the time will never be utilized.

But in some areas, the United States is dependent on imports. Chinese pharmaceutical firms have captured 97 percent of the U.S. market for antibiotics, and more than 90 percent of the market for vitamin C, ibuprofen, and hydrocortisone.¹³ As noted previously, Chinese suppliers have accounted for at least 40 percent of U.S. penicillin and heparin (an anticoagulant) in recent years. A December 2019 National Bureau of Economic Research study examines levels and trends in the manufacturing locations of the most commonly used prescription pharmaceuticals—off-patent generic drugs—and finds “that the base ingredients required for the manufacturing of these prescription drugs are overwhelmingly and increasingly manufactured in non-domestic locations, specifically India and China.”¹⁴ The NBER report further finds manufacturing of finished prescription drugs for the American market was equally split between U.S. and foreign suppliers, and that the share of foreign suppliers had been growing.¹⁵

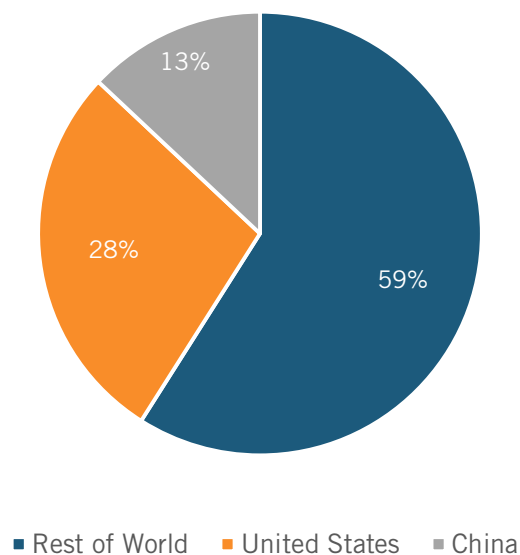
Indeed, by some accounts, the United States has also become increasingly reliant on foreign suppliers for active pharmaceutical ingredients. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research (CDER), testified before Congress that (as of August 2019), only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were located in the United States, with 72 percent of the manufacturers supplying the U.S. market located overseas, including 13 percent in China.¹⁶ Woodcock further reported that the number of registered facilities making APIs in China more than doubled between 2010 and 2019. She also noted that at least three WHO-identified essential medicines—capreomycin and streptomycin for the treatment of *Mycobacterium tuberculosis*, and sulfadiazine, used to treat chancroid and trachoma—rely on API manufacturers based solely in China.¹⁷ That said, Woodcock also noted that the United States faces severe data limitations in terms of understanding the true extent of Chinese API manufacturing, explaining that a series of data limitations means the FDA “cannot determine with any precision the volume of API that China is actually producing, or the volume of APIs manufactured in China that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or other parts of the world.”¹⁸ Indeed, for many China API manufacturing sites, the United States does not know which APIs it is manufacturing, at what volume, or where the output is headed.

It's also important to recognize that there has been more offshoring of manufacturing in small-molecule, chemically synthesized drugs, as opposed to for “large-molecule” biologic drugs that are derived from and synthesized in living tissues. Biologics are much more complex than other drugs, generally requiring much more work to purify, process, and produce, meaning that their successful production often depends on manufacturing-process innovations. It also means that a key challenge becomes ensuring quality and consistency in their production.¹⁹ Biologics account for at least 40 percent of the drugs in the U.S. biopharmaceutical development pipeline.²⁰ The complexity of biologics manufacturing means R&D and manufacturing activities are often co-located, and ensuring quality becomes a key value-driver. In contrast, cost considerations tend to be a greater driver of location considerations in small-molecule manufacturing.

But, in general, overall U.S. dependence on foreign suppliers of drugs may be overstated. In fact, 75 percent of U.S. spending on drugs goes to medicines that have been produced domestically in the United States, while an estimated 70 percent of the medicines actually consumed in the United States are manufactured domestically.²¹

Moreover, the U.S. supply chain for medicines that are imported is actually quite diverse, with more than 90 countries supplying the United States with pharmaceutical products. In 2019, 73 percent of U.S. imports of pharmaceutical products came from Europe, while 61 percent of imported APIs came from European sources. In fact, last year, the United States actually sourced 40 percent more of its imported APIs from Ireland than it did from China. As Woodcock from the Center for Drug Evaluation and Research (CDER) stated in her 2019 Congressional testimony, “CDER’s analysis shows that overall, China has only a modest percentage of the facilities able to produce APIs for the U.S. market.”²² As she noted, for all regulated drugs, China has 230 (13 percent) of the API manufacturing facilities, while the United States has 510 (28 percent), and the rest of the world has 1,048 (59 percent), as figure 1 shows.

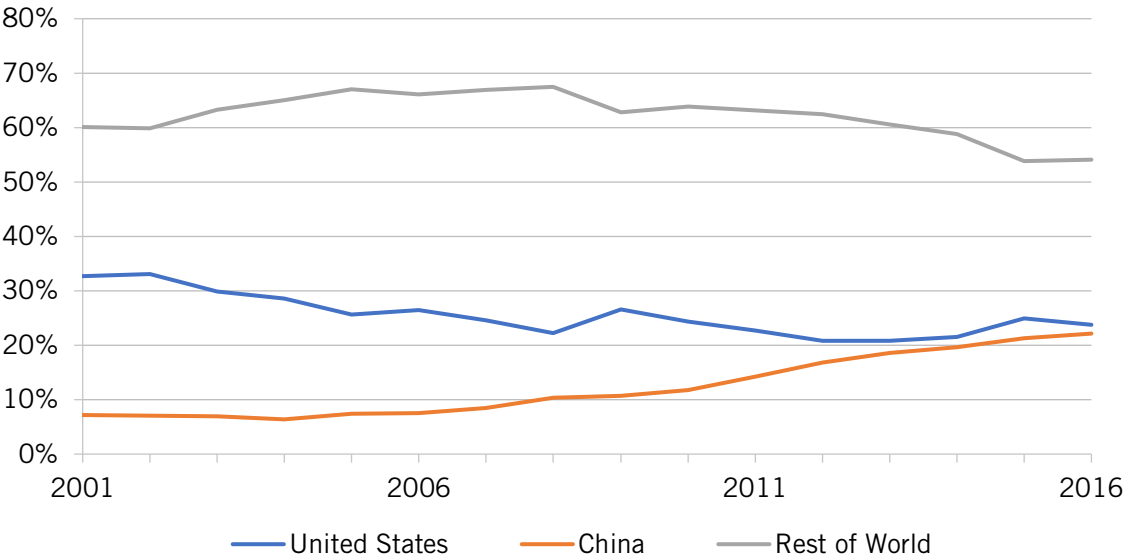
Figure 1: Percentage of API manufacturing facilities for all regulated drugs by region, August 2019²³



Those findings were reiterated in a recent study by the American Action Forum, which contended that U.S. pharmaceutical supply chains are actually fairly well-diversified. That report finds that China supplies only 18 percent of total API imports, 9 percent of total antibiotic imports, and less than 1 percent of total vaccine imports.²⁴ The report asserts that U.S. production is often understated, in part because of data limitations. For example, 70 percent of total antibiotic spending and 50 percent of total vaccine spending is on U.S.-made products. And although 80 percent of APIs were manufactured abroad in 2011, by 2019 the United States actually had twice as many API manufacturing facilities as China, and more than any other nation.

To be sure, there are key areas wherein the United States is dependent on China for particular products and inputs, just as there are in other technology areas. As such, the focus of policy, rather than putting in place wholesale reshoring policies, should be two-fold: identifying key areas of dependency, particularly with regard to China, and taking steps to boost overall medical supply industry competitiveness vis-à-vis China. This is particularly important because China is making considerable progress.²⁵ China's share of global pharmaceutical industry value added rose from 7.2 percent in 2001 to 22.1 percent in 2016, with over two-thirds of that growth happening after 2010 (see figure 2). Some of this is due to China becoming, in global terms, the leading producer (and exporter) of active pharmaceutical ingredients for drugs, accounting for between 20 and 40 percent of global output, as well being as a key generics producer.²⁶ Per a KPMG report on China's biopharmaceutical industry, "Thanks to substantial state support, the biopharmaceutical industry has enjoyed concentrated, high-speed growth over the past several years."²⁷ To be sure, China has become an increasingly serious competitor along all dimensions of the life-sciences innovation spectrum—from APIs to generics to innovative biologics—as well as a nation the United States and other nations turn to for a not-insignificant share of medical device and equipment supplies. Policymakers should certainly seek out policies to enhance U.S. competitiveness in these sectors, and reduce key dependencies and vulnerabilities (such as where China represents a sole-source supplier), but Buy American policies are not the right solution.

Figure 2: Global shares of value added of pharmaceutical industry²⁸



WHY A BUY AMERICAN APPROACH IS NOT THE RIGHT ANSWER

Even though the Buy American provisions being contemplated in administrative and legislative action would account for a relatively small share of all U.S. purchases of the pharmaceuticals or medical supplies in question, such Buy American provisions would inflict outsized harms while representing far from an optimal policy solution to addressing the challenge of U.S. vulnerability to China for drugs and other medical supplies.²⁹ There are at least four major shortcomings to this approach, as the following section elaborates.

Buy American Provisions Ignore the Benefits from Globalized Supply Chains

The first flaw is Buy American solutions neglect the importance of and significant value international supply chains have generated for the global economy, particularly with regard to the development of advanced-technology products, including medical devices and pharmaceuticals. Modern supply chains are characterized by extremely high degrees of specialization that enable the production of complex technology products at the lowest-cost/highest-capability possible. As an international consortium of think tanks recently wrote in “A Joint Declaration on the Importance of Collaboration, Open Trade, and Innovation in Tackling COVID-19,” many medicines and medical products rely on globally distributed manufacturing supply chains.³⁰ For instance, the production of the ventilators so critical to saving the lives of coronavirus patients in this crisis entails incorporating as many as 700 parts and components sourced from vendors throughout the world.³¹

Just as global trade and international supply chains have enabled the production of affordable yet highly sophisticated information technology products such as iPhones, global supply chains for medical goods and supplies help manage and control costs faced by consumers, hospitals, and medical care providers.

Buy American Provisions Would Reduce Resilience

Another benefit of international supply chains for pharmaceuticals and medical goods is they actually enable diversification of supplies, which becomes even more important in crises such as a pandemic. But if Buy American policies were to effectively force the localization of production of key pharmaceuticals or medical goods, then it would diminish resiliency and sustainability, and unwittingly expose the United States itself to shocks that could compromise the availability of key medical equipment. For instance, about 50 pharmaceutical plants were operating in Puerto Rico at the time Hurricane Maria hit in 2017, and the devastation the hurricane inflicted on the island (and some of the facilities) raised serious concerns about shortages of some critical drugs. As then-FDA commissioner Scott Gottlieb noted, “It’s a serious situation, there’s a potential for shortages in critical products.” Indeed, at the time, the FDA was “closely tracking 40 high-priority drugs that are deemed essential and could run short nationally if disruptions in manufacturing and distribution continue,” including about a dozen medications that couldn’t be produced anywhere else in the United States.³² This isn’t to say we shouldn’t actually be looking to increase pharmaceuticals production in Puerto Rico—rather, as argued subsequently, we should—but it is to argue that forcing the localization of production activity through Buy American policies is likely to produce unintended and undesirable consequences such as introducing new supply chain vulnerabilities and limiting needed geographical diversification in sourcing key components and materials.³³

Buy American Would Encourage Foreign Retaliation, Hurting U.S. Exports

Another weakness with Buy American requirements is they are only likely to encourage other nations, whether like-minded liberal, free-market democracies or unrepentant innovation mercantilists, to introduce similar policies. This dynamic is exactly why WTO created the Government Procurement Agreement: to encourage nations to open up their federal- and state-level government procurement activities for a broad range of goods and services—from information and communication technology (ICT) products to transportation and infrastructure services and equipment to medical equipment and pharmaceuticals—so their citizens can enjoy government services provided on a best-value basis driven by the forces of constructive international competition in goods and services markets.³⁴ Extending Buy American requirements would actually inflict significant harm on U.S. biopharmaceutical and medical equipment companies as other nations introduce reciprocal restrictions in their markets—a dynamic that would only be exacerbated if the effects from the coronavirus encouraged countries to introduce localization policies for other industries, such as ICT goods.

Extending Buy American requirements would actually inflict significant harm on U.S. biopharmaceutical and medical equipment companies as other nations introduce reciprocal restrictions in their markets.

To be sure, if countries are denying fair market access in medical supply procurement to other nations' enterprises, then the United States would be justified in pushing back against those practices and introducing reciprocal restrictions, if necessary. This is exactly why the European Union is now considering developing a reciprocal International Procurement Instrument that would ensure the access Europe offers to foreign countries' enterprises in government procurement activity is mirrored by the access rights their own companies enjoy in countries such as China, or even the United States.³⁵ And, in fact, the Chinese government does use discriminatory procurement practices to favor Chinese-owned firms.³⁶ For instance, China's 2016 State Council Document on the industry stated, "In principle, government procurement projects must purchase domestically produced products and gradually improve the level of domestic equipment configuration of public medical institutions."³⁷ Certainly, the United States should contest such practices, whether in direct negotiations with China or through WTO trade cases, but reciprocal restrictions on some imports from protectionist nations is a far cry from an otherwise open-market nation such as the United States extending its own Buy American requirements.

Further, if America were to introduce Buy American requirements for drugs or key medical supplies stemming from this crisis—essentially stating that a company has to produce its wares in the United States if the U.S. government is going to purchase them—that would only lend justification to the more than 80 countries that by late April 2020 had introduced export curbs or restrictions on medical supplies related to COVID-19.³⁸ Though obviously different from a "buy local" requirement, the intent is clearly the same: allow only domestic production to serve a domestic market. Such approaches should be rejected, and the United States should instead make a commitment to join Singapore and other like-minded Asian nations that have recently affirmed commitments to maintaining open supply chains for medicines and medical supplies.³⁹

Buy American Would Not Boost U.S. Innovation or Competitiveness

If the real problem is risky dependence on other nations for key medical supplies, then Buy American solutions might make some sense. But, as discussed, that is not the real challenge. The real challenge is risky dependence on China, and not just for commodity products such as masks and APIs, but going forward for new, innovative medicines. A Buy American approach not only does nothing to enable firms in America to out-compete and out-innovate Chinese firms going forward, it makes it worse. As noted, as other nations shut U.S. firms out of their markets in response to U.S. restrictions, U.S. biopharmaceutical competitiveness will decline.

THE RIGHT WAY TO INCREASE DOMESTIC PRODUCTION

The Information Technology and Innovation Foundation (ITIF) has long supported increasing domestic U.S. production of high value-added products, including medicines and medical supplies, and enhancing the broader competitiveness of these key sectors, while preserving America's role as the leading advocate for a market-based, enterprise-led, rules-governed global trading system. We also recognize that critical dependencies for medicines and medical supplies, especially when centered on non-market-based economies such as China, can present serious national security vulnerabilities that must be urgently addressed—one of the reasons why a realistic mapping of such vulnerabilities is needed.

U.S. policies should facilitate U.S. production of high value-added products, including medicines and medical supplies, while preserving America's role as the leading advocate for a market-based, enterprise-led, rules-governed global trading system.

Nevertheless, the way to achieve these objectives is through attraction, not compulsion; through innovation, rather than restrictions. In other words, America needs policies that encourage but don't compel the reshoring of production, where possible, and especially the introduction of new innovation and production on U.S. soil—all with the underlying objective of enhancing the global competitiveness of America's innovative biopharmaceutical, medical device, and medical supplies sectors. Indeed, America's biopharmaceutical sector alone contributes over \$1 trillion to the U.S. economy (about 3 percent of U.S. GDP), employs about 4 million Americans (800,000 directly, and an additional 3.2 million indirectly), and invests more in R&D (about \$97 billion annually) than any other industry, making it America's most R&D-intensive sector. Policymakers should focus on implementing proactive and constructive, but not compulsory, policies to grow the sector. This report is not intended to lay out such a comprehensive U.S. biopharmaceutical strategy, as ITIF has done that elsewhere.⁴⁰ But there are two key approaches Congress and the administration should embrace: support for production process innovation, and tax and investment incentives for reshoring.

R&D Policy for Process Innovation

As noted, policy interventions should be attuned to the specific challenges involved in the production of large- and small-molecule drugs, respectively. Public policy should direct R&D investment toward disruptive, innovation-based, advanced manufacturing processes that could shift the economics of where APIs and other drugs can be profitably produced back to the United States. In short, the United States should be looking to strategically leapfrog into better positions

in bio-based manufacturing supply chains. Such advanced pharmaceutical manufacturing production practices offer a number of benefits, including the ability to:

- more precisely control product quality, including in real time during the production process;
- rapidly respond to changes in demand, including the capacity to dynamically scale operations and to introduce adaptability and variability in producing drugs in a variety of dosages or dosage forms;
- create manufacturing platforms with smaller footprints that can even be made modular and portable to create drugs remotely in real time, such as on the battlefield or after a natural disaster; and
- manufacture medicines at lower costs than by traditional methods, with a significantly reduced environmental impact.⁴¹

The U.S. government has invested in several initiatives to advance innovative biopharmaceutical manufacturing processes. For one, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), one of America's 14 Manufacturing USA institutes, promotes the development of breakthrough biomanufacturing processes, and supports the development of standards that enable more efficient and rapid manufacturing capabilities.⁴² Effectively, NIIMBL seeks to create testbeds to pilot and validate innovative new pharmaceutical manufacturing approaches, in effect “de-risking” them before their adoption by industry. The goal is to help companies reduce the up-front capital investment they have to make in new facilities as they contemplate producing drugs before they've even completed clinical trials, or the scale of their demand is known.

A good example is NIIMBL's work with the BioPhorum Operations Group to develop a buffer stock blending skid manufacturing process for therapeutic proteins and other biomolecules that provides a flexible solution using mass flow control for small-batch processes to provide an on-demand supply of buffer solutions for biomanufacturing processes.⁴³ In essence, a buffer stock blending system represents a new manufacturing process that could obviate the need for the enormous and costly tanks in which biologics are synthesized today, potentially significantly reducing capital investment and manual-operation costs and speeding production times. NIIMBL is making up-front investments no single company could undertake on its own, with the goal of validating the potential of such production processes so they can be more widely adopted by industry—exactly what's needed to maintain and extend U.S. leadership in bio-based manufacturing processes. Another important contribution NIIMBL has made is coordinating the development of public-private technology roadmaps to drive innovation forward in gene therapy, antibody-based drugs, and vaccines.⁴⁴ As such, policymakers should continue to support NIIMBL (and the Manufacturing USA network), including by expanding funding in it (and other Manufacturing USA centers).

Another initiative is the FDA's Emerging Technology Program (ETP), launched in late 2014, which advances the adoption of innovative technology to modernize pharmaceutical development and manufacturing through close collaboration with industry and other relevant stakeholders, starting from early technology development.⁴⁵ The Emerging Technology Team (ETT) within ETP provide a gateway for the early (pre-submission) discussion of innovative technologies and

approaches—even before a candidate drug is identified—and thus supports the entry, assessment, and life-cycle management of advanced manufacturing at CDER.

The opportunity here is truly immense. A recent *Boston College Law Review* article by W. Nicholson Price, “Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing,” contends that pharmaceutical manufacturing is expensive, inefficient, and non-innovative, with firms using outdated production techniques and old plants.⁴⁶ The article estimates modern techniques could eliminate as much as \$50 billion in annual production costs.

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As Drew Endy, a member of the bioengineering faculty at Stanford University, explained, novel bio-based manufacturing processes and new bio-fermentation techniques now “make possible the biosynthesis of active pharmaceutical ingredients through bio-brewing-based processes ... we can actually leverage yeast to create a set of medicinal alkaloids,” including for many key APIs, a process which would exact far less of a toll on the environment as well.⁴⁷ As he continued, America could disrupt the currently dominant batch manufacturing processes used to make APIs with a less capital-intensive continuous-manufacturing process based on flow chemistry. As another example, CONTINUUS Pharmaceuticals is working on an integrated continuous manufacturing solution that takes raw material, creates the desired API, purifies the API, and produces the final dosage form in a single system that can operate 24/7. A prototype reduced costs by 30–50 percent, solvent use by more than 60 percent, energy costs by 50–60 percent, facility footprint by about 90 percent, and lead time from months to less than 48 hours.⁴⁸

However, as Price noted in his *Boston College Law Review* article, as part of its effort to assure the safety of marketed drugs, the FDA heavily regulates the manufacturing process used to produce them. Companies seeking approval for a new drug are hesitant to put forward new manufacturing processes the FDA has not already approved in another context. Once manufacturing has begun, the FDA must certify any changes to a previously approved process. In part, as a result, the pharmaceutical industry has not seen the dramatic improvement in quality and efficiency that other industries have experienced. CDER Director Woodcock recognized these challenges in her congressional testimony, observing:

The adoption of advanced manufacturing technologies may pose a challenge to the current regulatory framework, because most regulations were developed based on traditional batch manufacturing methods under a unified pharmaceutical quality system. As a result, FDA has launched an effort to identify and implement needed changes in the regulatory structure.⁴⁹

As Woodcock noted, the FDA actively engages with stakeholders in industry, academia, other regulatory agencies, and Congressional policymakers in identifying and addressing regulatory hurdles to the adoption of advanced pharmaceutical manufacturing practices. Congressional policymakers and the Trump administration should continue to work with the FDA on these issues, and streamline and accelerate the FDA’s capacity to evaluate and approve innovative new pharmaceutical manufacturing processes.

Tax and Investment Incentives for Reshoring

Congress should also leverage the tax code to encourage greater levels of medicines and medical supply manufacturing in the United States. For instance, Congress should reinstitute Section 936 of the Internal Revenue Code, which, when originally enacted in 1976, released pharmaceutical manufacturers from taxes on profits made in Puerto Rico and other U.S. territories. Section 936 contributed to making Puerto Rico a pharmaceutical manufacturing powerhouse, and while the biopharmaceutical sector does still contribute 30 percent of Puerto Rico's gross state product, the phase-out of the provision from 2006 to 2016 contributed to a shrinking of the sector, not to mention a 40 percent reduction in the territory's manufacturing jobs base.⁵⁰ This in part explains why the territory's economy has shrunk nearly every year since phase-out of the provision began in 2006.⁵¹

In addition to restoring Section 936, as Avrik Roy wrote in *Forbes*, Congress could create a “most-favored nation” Puerto Rican tax rate for pharmaceutical intellectual property.⁵² As ITIF has written, a number of countries have introduced “innovation” or “patent” boxes—a provision of the tax code that reduces taxes on profits derived from newly created intellectual property.⁵³ For instance, Ireland offers a special tax rate of 6.25 percent for manufacturing that is tied to intellectual property such as patents. Congress could pass legislation allowing Puerto Rico specifically to introduce an innovation box, allowing it to match the lowest such tax rate available in Europe or North America, and helping it to lure branded drug manufacturers back to Puerto Rico. While Congress could introduce a Puerto Rico-specific innovation box, ITIF has, of course, advocated that Congress should introduce an innovation box for the entire United States.

Beyond Puerto Rico-specific tax proposals, Congress could pass other tax policies to encourage reshoring activity, including in the life-sciences sector. For instance, Congress could allow first-year expensing of any costs associated with relocating manufacturing facilities to the United States. Or it could amend the existing collaborative R&D tax credit to allow companies to take a flat 20 percent tax credit when they invest in university R&D activity.⁵⁴ This is especially important because the life sciences is the largest scientific field for university R&D spending, accounting for nearly three-quarters of R&D investment by universities, or \$68.2 billion, in fiscal 2017, with \$4.8 billion contributed by industry.⁵⁵ Other steps Congress could take include restoring the orphan drug tax credit to 50 percent, and increasing the generosity of the R&D tax credit. For instance, Congress could either increase the alternative simplified credit for R&D from 14 percent to 20 percent, or expand it by enacting a three-tiered credit for qualified expenses that are 50 percent, 75 percent, or 100 percent above firms' previous three-year averages.⁵⁶

Another initiative the Trump administration is apparently considering is a \$25 billion reshoring fund for “companies that make essential goods to move production home, ensuring that even products far down the supply chain were sourced domestically.”⁵⁷ Such an approach would mirror funds created by other nations, including Japan and Taiwan. For instance, Japan is investing ¥243.5 billion (\$2.3 billion) in a reshoring fund to encourage Japanese companies to move production out of China.⁵⁸ Taiwan's comprehensive “Action Plan for Welcoming Overseas Taiwanese Businesses to Return to Invest in Taiwan” has, since 2019, brought about \$20.5 billion of manufacturing activity back from China to Taiwan.⁵⁹ If the United States considers such an approach, it should be focused in areas where it addresses genuine critical technology dependencies with China, recognizes the differing challenges involved in the production of small-

versus large-scale molecules, and ensures competitive domestic supply chains can be developed to support domestic manufacturing of such technologies on market-based terms going forward.

CONCLUSION

The Trump administration and Congress are right to focus on improving the competitiveness and innovation capacity of America's medical supply industry. But for them to be effective, they need to be bipartisan in nature and focused on making America a more attractive place for production. Indeed, proactive bipartisan policies over the past 40 years have played a pivotal role in turning the United States from a global also-ran into the world leader in life-sciences innovation. But Buy American prescriptions aren't the right approach, as they don't make the United States more fundamentally competitive in producing drugs or medical supplies. And moreover, they would risk fragmenting the global trading system while encouraging other nations to introduce similar policies that would inflict far more damage to U.S. enterprises—which would sell in foreign economies on competitive, market-based terms.

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