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ISSUE BRIEF

Proposed "Buy America" Requirements Would Hurt Patients and the Economy

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Introduction

Senior officials in the Trump Administration are preparing an executive order to expand so-called "Buy America" rules, with the goal of forcing federal agencies to purchase drugs and medical supplies exclusively from U.S. suppliers. Simultaneously, Congress is considering a range of proposals to accomplish the same goal. The leading bill among them is Sen. Marco Rubio (R-FL) and Rep. Michael Waltz's (R-FL) *Strengthening America's Supply Chain and National Security Act*.[1]

White House trade adviser Peter Navarro, championing the executive order, says the goal is to protect public health and national security.[2] Navarro has cited the current pandemic as a reason to reduce reliance on global supply chains and decouple the U.S. and Chinese economies, although he has pursued both agendas since before joining the White House in 2017.[3]

In the six weeks between February 28 and April 15, the novel coronavirus, which causes the disease COVID-19, had killed more than 28,000 Americans.[4] By August, according to the University of Washington's Institute for Health Metrics and Evaluation, more than 60,000 Americans could perish.[5]

Far from protecting public health, a Buy American executive order in this time of crisis would make much-needed drugs and medical supplies inaccessible to patients, further damage the U.S. economy, invite harmful retaliation from trading partners, and weaken the United States in its effort to fight the pandemic.

Snapshot Of An Executive Order

The draft executive order proposed by the White House has several facets, according to media reports and Navarro's public statements. It says officials must "take all possible measures" to "maximize domestic procurement of essential medicines," according to *The Daily Beast*, which obtained a draft copy of the order.[6]

To fulfill this goal, the order would force government agencies like the Departments of Defense, Veterans Affairs, and Health and Human Services to buy medicines, vaccines, pharmaceutical ingredients, and medical supplies solely from American suppliers.

In addition, the draft executive order would reinforce the administration's invocation of the Defense Production Act for medicines and vaccines, requiring American contractors capable of manufacturing these items to do so.

In short, the goal of the new order is to bring the entire pharmaceutical supply chain back to U.S. shores almost immediately. Substantial feasibility barriers exist that would make realizing this goal impossible, even if it were a good idea. A complex supply chain, developed over the course of several decades, can't be overturned and reorganized into one country overnight.

Snapshot Of A Congressional Proposal

There are a host of ill-conceived proposals currently under consideration in Congress. Chief among them is a three-pronged bill introduced by Senator Rubio and colleagues. [7]

First, it would direct the Defense Department to determine the volume of active drug ingredients being sourced from China, make an assessment of whether this poses a national security issue, and make recommendations for reducing reliance on foreign sources.

Second, it would require American biopharmaceutical companies to provide the Food and Drug Administration (FDA) with information on the volume of active ingredients being sourced from each supplier.

Finally, it would restrict the Departments of Defense and Veterans Affairs in their purchasing decisions, barring them from treating drugs manufactured in the United States that contain foreign-made active ingredients as U.S.-made.

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From Protectionism To Globalization: A Quick History

The original Buy American Act, signed by President Herbert Hoover in 1933 on his last full day in office, required the federal government to favor domestic producers when acquiring goods. It did this by compelling U.S. government agencies to choose a U.S. supplier even when a foreign supplier is offering the same product for a lower price, up to certain financial limits.[8]

In 1979, Congress passed the Trade Agreements Act, which made an exception to “Buy America” rules. It allowed foreign suppliers to compete on a level playing field for U.S. government contracts, provided their countries had trade agreements with the United States.

Beginning in 1996, qualifying trade agreements were put in place, when the United States became a party to the Government Procurement Agreement under the World Trade Organization. Under the Agreement, some 48 countries promised one another free and fair competition for government contracts.[9]

In recent decades, the U.S. supply chain for drugs and medical products, as for many other goods, became complex, diversified, and global.

Most medicines are made up of two types of ingredients: inactive components and the medically mission-critical components known in the industry as "active pharmaceutical ingredients," or APIs.

The proposed draft executive order calls APIs "critical technology" and "essential for the execution of the national security strategy of the United States."[10] Senator Rubio's bill also zeroes in on APIs. In a press release announcing the proposed legislation, his office warns against "allowing more pharmaceuticals with APIs primarily based in China to qualify for preference under the Buy American Act."[11]

The Benefits Of A Global Supply Chain

Only a modest proportion of U.S. imports of pharmaceuticals and APIs actually come from China. For finished pharmaceutical products, China accounted for just 1 percent—$1.5 billion—of U.S. imports in 2019. For APIs, China accounted for 18 percent—$1.2 billion—of U.S. imports. Combined, the United States had a $1.6 billion trade surplus with China for these pharmaceutical products and ingredients.[12]

For all WHO Essential Medicines on the U.S. market, 21 percent of API manufacturing facilities are located in the United States. Of the remaining API manufacturers supplying the U.S. market only 15 percent are based in China—the rest are located in the European Union, India, and Canada.[13] In fact, there are only three WHO Essential Medicines whose API manufacturers are sourced solely in China.

> "Within the United States, about 1,300 plants make drugs, in many cases receiving their inputs from all over the world.

An individual drug may cross borders several times during the manufacturing process, with the API originating elsewhere but final assembly in the United States.[14] Within the United States, about 1,300 plants make drugs, in many cases receiving their inputs from all over the world.[15] Under the proposed executive order, these U.S. manufacturing plants, which employ about 120,000 people, would be cut off from overseas suppliers.

The diversity of this global supply chain offers a number of advantages. Foreign jurisdictions offer companies a varied mix of benefits including tax incentives, affordable raw materials, relatively low-priced energy, and large pools of highly skilled workers. Together, these factors can result in enormous savings: A 2011 FDA report found that making an API in India can be 30 to 40 percent cheaper than doing so in the United States,[16] savings that are passed on to patients.

Being supplied by this geographically diverse network also offers an advantage when confronting natural disasters and other crises. For instance, when Hurricane Maria devasted Puerto Rico in 2017, it affected operations at some 50 pharmaceutical plants.[17] But biopharmaceutical companies avoided drug shortages by working with the FDA to source medicines from overseas plants.

In addition to medicines, many U.S. medical supplies—including gloves, protective masks, surgical instruments, and ventilators—come from overseas. In 2019, the United States imported $830 million in medical supplies from Germany, $1.1 billion from China, and $1.3 billion from Mexico.[18]

Under the proposed draft executive order, the U.S. federal agencies that supply health care to millions of seniors, veterans, and low-income families would suddenly lose access to products from overseas, with no immediate replacement.

Seizing On A Crisis

Shortly after taking office in 2017, the Trump Administration created the Office of Trade and Manufacturing Policy and appointed as its director economist Peter Navarro, author of a book called *Death by China* and a proponent of high tariffs and other trade barriers.[19] In April 2017, Trump signed the "Buy American and Hire American" executive order,[20] signaling his administration's intent to start enforcing rules that would shut foreign suppliers out of federal contracts.[21] The Administration followed up these orders with new tariffs on $370 billion worth of Chinese goods, in the process inflicting new costs on Americans of $73 billion per year, according to an analysis by the American Action Forum.[22]

In March of 2020, as the death toll from the COVID-19 pandemic mounted, Navarro made several public statements indicating that he planned to take advantage of the global crisis to advance his longstanding protectionist and anti-China agenda. He told the *Washington Examiner* that the Administration was preparing an executive order to reduce U.S. reliance on foreign-made medicine.[23] *The Daily Beast* described the draft version of the new proposed Buy American order as "similar in language and tone" to the April 2017 order.[24]

He also made his case to the *New York Times*, complaining that China dominated the drug supply chain, and saying "what we need to do is bring those jobs home so that we can protect the public health and the economic and national security of the country."[25] On April 2, Navarro again publicly touted the would-be executive order. He told a White House press briefing, "One of the things this crisis has taught us is that we are dangerously over dependent on a global supply chain."[26]

Senator Rubio has also advocated for reduced trade with China and a de-globalized supply chain since at least February 2019, more than a year before the World Health Organization declared COVID-19 a global pandemic.[27] He introduced his new bill, S. 3538, on March 19, 2020, co-sponsored by Elizabeth Warren (D-MA), Kevin Cramer (R-ND), Christopher Murphy (D-CT), and Tim Kaine (D-VA).

The Impact Of New "Buy American" Rules

Advocates for protectionist measures typically argue that they will strengthen the domestic economy, but a well-documented history demonstrates that they usually do the opposite. In general, protectionist policies such as high tariffs on imported goods distort incentives, encouraging countries to make products in which they do not have a comparative advantage.

More specifically, the proposed draft executive order would have a number of adverse effects. In the short term, since only 28 percent of plants making API for FDA-regulated drugs are located in the United States, the country would immediately experience shortages, with many medicines—from pain medicines to cancer treatments—simply unavailable and others only at exorbitant prices. This would be dangerous at any time, but especially during the current public health crisis.

New "Buy American" rules on medicine and medical supplies would also have long-term effects. The stated goal of the proposed policy is to return more drug production to the United States. However, even if this were a good idea, serious capacity barriers exist. Replacing the current global capacity requires a multi-year effort, causing persistent drug shortages as U.S.-based companies work to get new factories up and running. Moving a single drug manufacturing plant can take more than a decade and cost more than $2 billion.

Hiring qualified staff would be an even greater challenge for companies. One of the appeals of overseas drug making is the deep pool of qualified candidates in countries like India and China, which together produce almost half of all undergraduate degrees in science and engineering. The United States produces only 10 percent of the global total. The U.S. manufacturing industry already faces a potential staffing shortfall of 2.4 million between 2018 and 2028 because workers are not trained in STEM skills, according to a study by Deloitte and The Manufacturing Institute.[28] It does not appear that U.S.-based drug manufacturing can both grow significantly and be staffed by Americans without overhauling STEM curriculum and training across all levels of education.

Barring foreign suppliers from selling medicine and medical supplies to the U.S. government would also effectively withdraw the United States from its World Trade Organization commitments. This would surely invite retaliation, leading other countries to bar U.S. businesses from selling to their governments.[29]

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The United States is part of an intricate, global economy that provides numerous benefits to U.S. companies and consumers. As the U.S. government attempts to thwart off a recession, the threat of trade war escalation could weaken the country's economy for years to come.

Not surprisingly, patient groups, biopharmaceutical companies, and many U.S. political leaders were immediately alarmed by the White House push to cut off access to foreign-made medicine and medical supplies. On March 21st, a bipartisan group of 81 members of the House of Representatives wrote to senior administration officials, urging them to work with foreign governments to keep the supply of personal protective equipment for health care workers flowing. The members of Congress cited an urgent need for N95 masks, ventilators, gloves, gowns, and hand sanitizer in their states, and asked that the federal government "avoid placing any new red tape or restrictions on medical providers as they seek to obtain this equipment."[30]

A few days later, on March 25th, 89 national, state, and local organizations signed a letter to the secretaries of the Treasury and Commerce departments, noting that "such an order may delay the discovery of a COVID-19 vaccine and other treatments, worsen shortages of critically-needed medicines and medical products, and undermine prospects for economic recovery." The signatories noted that U.S. businesses cannot produce critical medical products without access to international supply chains.[31]

Keeping America Strong

The current crisis has revealed how important it is for the United States to have a secure medical supply chain. New "Buy American" laws would work counter to that goal, raising prices and intensifying shortages. However, there are ways to make sure we protect and strengthen the supply chain to improve biosecurity in the long run.

U.S. trade representatives should, for a start, continue their work to prevent other countries from violating existing trade deals. In particular, they should ensure that U.S. companies' intellectual property rights—essential for spurring medical innovation—are not undermined.

Over the long term, both the U.S. government and companies need to invest in the labor force, to make sure workers have the scientific and engineering skills to be employed in biopharmaceutical manufacturing. In the nearer term, they should embrace advanced manufacturing technologies, which can help the United States remain competitive and ensure a stable and efficient supply of the critical drugs.[32] Promising advanced manufacturing technologies include 3D printing and continuous manufacturing, in which a drug is produced in one uninterrupted flow, without breaks between processing steps. Advanced manufacturing technologies can enable smaller facilities, more efficient use of staff, and a lower environmental impact.[33]

Conclusion

The pandemic has highlighted vulnerabilities in the U.S. medical supply chain, which should be addressed by enforcing intellectual property laws, educating the next-generation work force, and investing in advanced manufacturing technology.

Expanding "Buy American" requirements is not the solution. The height of a deadly pandemic is the worst possible time to suddenly dismantle global drug supply chains. Researchers at biopharmaceutical companies are racing to develop vaccines, anti-viral treatments, and diagnostic tools for COVID-19 and explore whether any existing medicines might be repurposed. When they succeed, international collaboration will be required to source and manufacture the drugs. Only maximum cooperation will enable us, as humans, to bring our common enemy, the virus, under control.

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About the Author

Sally C. Pipes is President, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute, a San Francisco-based think tank founded in 1979. Prior to becoming president of PRI in 1991, she was assistant director of the Fraser Institute, based in Vancouver, Canada.

A celebrated speaker, Ms. Pipes regularly addresses national and international audiences on health care. A prolific writer, Ms. Pipes is a weekly columnist for FoxNews.com, a bi-weekly columnist for Forbes.com, and a contributor to the Washington Examiner's Beltway Confidential blog. Her commentary has appeared in the *Wall Street Journal, New York Times, Washington Post, USA Today, Financial Times, Los Angeles Times,* and elsewhere.

In January 2020, Encounter Books published her book *False Premise, False Promise: The Disastrous Reality of Medicare for All*, with a foreword by former Senator Tom Coburn, MD. Previously, she published three other books with Encounter, and two with Regnery. She published her first book, *Miracle Cure: How to Solve America's Health Care Crisis and Why Canada Isn't the Answer*, with a foreword by Milton Friedman in September, 2004.

In 2008, she founded the Benjamin Rush Institute, a nonprofit that unites medical students, faculty, doctors, healthcare professionals and others who believe that free enterprise and a direct patient-doctor relationship are the best means of ensuring optimal patient outcomes at affordable prices. She now serves as Board Chairman.

In addition, Pipes serves on the national advisory board of Capital Research Center, the advisory boards of the Council for Affordable Health Coverage, the California Association of Scholars, Docs4PatientCare, and the Heartland Institute. She also serves on the president's advisory council for the State Policy Network and has served as a trustee of St. Luke's Hospital Foundation in San Francisco, a board member of the Independent Women's Forum, and as a governor of the Donner Canadian Foundation.

In April 2018, she received an honorary Ph.D from Pepperdine University's School of Public Policy for her work on health care reform.

A former Canadian, she became an American citizen in 2006. She is married to Charles R. Kesler, a professor at Claremont McKenna College and editor of the Claremont Review of Books.

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