

America's Pharmaceutical Supply Chain: An Overview of the Policy Landscape and Potential Path Forward

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For several years, policy-makers and commentators have expressed concern about the resilience of the United States' pharmaceutical supply chain. Current U.S.-based manufacturing capabilities have been at the forefront of these concerns, particularly as they relate to ensuring a supply of essential medicines, such as antibiotics. Given the importance of the pharmaceutical supply chain to patients, the interest in taking steps to address these concerns has only increased during the COVID-19 pandemic.

There are growing bipartisan and government-wide calls for increasing and strengthening U.S.-based pharmaceutical manufacturing capacity. This policy discussion has focused on the Department of Health and Human Services (HHS), given its mission to enhance the health and well-being of all Americans. Specifically, the Office of the Assistant Secretary for Preparedness and Response (ASPR), created in 2006, plays a central role in preparing for, and responding to, pandemics and other public health emergencies. This includes maintaining the Strategic National Stockpile (SNS) and the Biomedical Advanced Research and Development Authority's (BARDA's) work to develop and procure needed medical countermeasures, including vaccines, therapeutics, diagnostics and non-pharmaceutical countermeasures, against a broad array of public health threats.

This alert provides a brief survey of recent government actions taken with respect to the pharmaceutical supply chain and discusses the potential path forward.

An Overview of the Policy Landscape and Previous Actions

On September 20, 2021, the Department of Defense (DoD) Inspector General (IG), released a report, *Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain*. In the report, the IG cites "senior officials from the [Defense Logistics Agency] Medical Pharmaceutical Prime Vendor Division," who assert that "if some countries decide to stop producing [Active Pharmaceutical Ingredients] or shipping them to domestic manufacturers in the United States, the results could be catastrophic..." The IG's proposed solution is to ensure the DoD pharmaceutical supply chain "has protective measures in place" to "provide a

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defensive capability against disruptions in the supply of these drugs.” The DoD’s mission is to provide the military forces needed to deter war and ensure the security of the United States. The IG’s finding that the “DoD’s reliance on foreign suppliers for pharmaceuticals is a public health readiness, and national security risk” illustrates the far-reaching impact of pharmaceutical supply chains.

The IG report is only the latest in a long line of calls for action to strengthen the resiliency of the U.S. pharmaceutical supply chain. Even before the pandemic, policy-makers had expressed concern about the durability of the U.S. pharmaceutical supply chain. On several occasions, this concern was couched within the context of global competitiveness. For example, in 2019, the House Energy & Commerce Committee’s Subcommittee on Health held a hearing during which some Members remarked about foreign dominance in the manufacturing of critical medicines. Chairwoman of the Health Subcommittee, Rep. Anna Eshoo (D-CA) cited an “overreliance on foreign production for critical medication,” calling it a “crisis” and “national security risk.” Rep. Eshoo cautioned that China’s “chokehold” on global penicillin manufacturing could allow the country to “use U.S. dependence for critical drugs as an economic weapon.” Based on these concerns, Rep. Eshoo introduced – with Republican Rep. Susan Brooks (R-IN) – the [Prescription for American Drug Independence Act](#). This legislation, which did not become law, required the convening of experts to submit recommendations to Congress regarding the pharmaceutical supply chain.

[Testifying at the hearing](#) was Dr. Janet Woodcock, then-Director of the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). Dr. Woodcock, now Acting Commissioner of Food and Drugs, stated that 28 percent of the manufacturing facilities making active pharmaceutical ingredients (APIs) for the U.S. market were located in the U.S., and the remaining 72 percent were overseas, with 13 percent in China. The number of registered Chinese facilities making APIs more than doubled between 2010 and 2019. While the FDA was unable to assess the national security implications of this situation due to a lack of data, Dr. Woodcock testified, “We do know that the U.S. drug supply is being compromised by drug shortages, in most cases triggered by manufacturing quality problems by U.S.-based as well as foreign producers.”

Following this hearing, congressional interest only increased. In December 2019, [a bipartisan group of senators](#)—Sens. Elizabeth Warren (D-MA), Tom Cotton (R-AR), Tim Kaine (D-VA), and Mitt Romney (R-UT)—wrote to then-Defense Secretary Mark Esper expressing concerns about the nation’s reliance on foreign nations for drug manufacturing. Only months later, as the pandemic hit along with concerns regarding the fragility of the pharmaceutical supply chain, this issue once again came into congressional focus. In March 2020, Sen. Cotton introduced the [Protecting Our Pharmaceutical Supply Chain from China Act of 2020](#), which would require the federal government to maintain a registry of some drugs manufactured overseas and prohibit federal health programs from purchasing drugs with Chinese ingredients, as well as institute a country-of-origin (COO) labeling program and provide tax incentives for domestic pharmaceutical manufacturing. Similarly, Sen. Marco Rubio (R-FL) introduced the bipartisan [Strengthening America’s Supply Chain and National Security Act](#), which would require the DoD to submit to Congress a classified report regarding the amount of Chinese and other foreign-source pharmaceutical products, require

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certain reporting from manufacturers and make changes to tests used to determine the COO of pharmaceuticals.

Congressional concerns regarding the DoD's reliance on foreign-sourced drugs were also reflected in language in the [Fiscal Year 2021 National Defense Authorization Act](#) (NDAA), the annual reauthorization of the nation's military spending. Specifically, Reps. John Garamendi (D-CA) and Vicki Hartzler (R-MO) included language in the bill from the duo's [Pharmaceutical Independence and Long-Term Readiness Reform Act](#) to require the DoD to review vulnerabilities arising as a result of dependence on foreign – and specifically, Chinese – pharmaceuticals. Then, in late 2020 and early 2021, DoD and HHS jointly issued contracts totaling more than \$80 million to develop domestic production capacity for certain critical APIs.

In 2021, Sens. Warren (D-MA) and Tina Smith (D-MN) reintroduced the [Pharmaceutical Supply Chain Defense and Enhancement Act](#). Among other things, this bill would require the Commissioner of Food and Drugs and the Secretary of Defense to compile a list of critical drugs, and provide \$5 billion over five years to allow BARDA to invest in new facilities, manufacturing techniques and other drug development processes.

On June 8, 2021, the Biden-Harris administration [released a report](#) based on its 100-day supply chain review, pursuant to Executive Order 14017, issued February 24, 2021. The report's findings were consistent with earlier findings, saying "the disappearance of domestic production of essential antibiotics impairs our ability to counter threats ranging from pandemics to bio-terrorism, as emphasized by the FDA's analysis of supply chains for active pharmaceutical ingredients." The report references a 2016 explosion at a Chinese API factory that manufactured "a critical antibiotic used in hospitals and for which there was already a shortage." The explosion exacerbated the shortage, leading to a shift toward other antibiotics, which "led to increases in *Clostridium difficile* infections, a serious and sometimes deadly infection." Critically, the report cited a lack of domestic production capacity for many generic antibiotics for common childhood illnesses.

Potential Path Forward

Policy-makers have determined in a bipartisan, bicameral and government-wide fashion that the current lack of domestic manufacturing of key drugs, like antibiotics, is concerning and it is likely that we will see further activity on this issue by both Congress and the Biden-Harris administration.

Implementation of the [Biden-Harris administration's supply chain report](#), referenced above, is perhaps the most likely source of activity with respect to the nation's pharmaceutical supply chain. The report included several recommendations, some with general applicability and others with specific applicability to the pharmaceutical supply chain itself.

The administration proposes that HHS will utilize existing authorities to bring manufacturing back to the United States or at least closer to U.S. borders, stating, "HHS will leverage the [Defense Production Act] process to determine the financial incentives needed to onshore or nearshore the production capacity needed for the global supply chain." However, while onshoring (moving manufacturing into the U.S.) and nearshoring (moving manufacturing to countries neighboring the U.S.) are clearly

of interest to the administration, it remains unclear whether the administration will make the significant investment needed to onshore or nearshore some pharmaceutical manufacturing.

The supply chain report also called for HHS to “make recommendations to Congress on providing the department with new authorities to track production by facility, track API sourcing, and require API and finished dosage form (FDF) sources can be identified on labeling for all pharmaceuticals sold in the United States.” While some recommendations from this report have begun to be implemented, the drug-specific recommendations await action.

Finally, the report indicated the administration will continue utilizing BARDA and other “incentive-based tools” to promote upgrades for equipment and manufacturing techniques, as well as to “reduce the barrier to entry for new manufacturers or reduce the cost to existing manufacturers looking to upgrade their facilities.” For an idea of what these “incentive-based tools” could entail, one can look to the [administration’s Fiscal Year \(FY\) 2022 budget request](#), which asks for \$823 million for BARDA, more than \$200 million over the FY 2021 enacted level. This increase would be used for expanding the agency’s “innovation efforts,” as well as “advanced development of broad-spectrum antimicrobials.” Additionally, the DoD, in partnership with HHS, through the Air Force’s Acquisition COVID-19 Task Force, recently issued a [request for information \(RFI\)](#) to learn about ways to shore up the medical supply chain to prevent future shortages. Products involved in the RFI include pharmaceuticals.

In September 2021, the administration [announced a preparedness plan](#) for future pandemics and other threats. Pillar I of the plan relates to “dramatically improving and expanding our arsenal of vaccines, therapeutics, and diagnostics,” while Pillar IV of the plan specifically relates to “stockpiles and supply chains.” The administration promised to finalize “our whole-of-government biopreparedness review” “over the next several weeks,” and details have yet to be made public.

For its part, Congress has similarly indicated a desire to improve the U.S.’ competitive posture. In June 2021, the Senate passed the [United States Innovation and Competition Act of 2021](#). Though not specifically applicable to drugs, the legislation seeks to identify and rectify supply chain gaps through the Department of Commerce, as well as support scientific and technological innovation throughout the country. Likewise, the House has advanced – but not passed – legislation designed in part to counter reliance on Chinese goods. [The Ensuring American Global Leadership and Engagement \(EAGLE\) Act](#) demands the U.S. work with European allies to “evaluate...overreliance on goods originating in the People’s Republic of China, including in the medical and pharmaceutical sectors, and develop joint strategies to diversify supply chains.”

While there is no shortage of interest in this policy issue, there are numerous costs and other challenges associated with onshoring and nearshoring pharmaceutical manufacturing operations. This includes capital costs, like purchasing land and building the manufacturing facility, as well as securing a high-quality workforce. In some cases, federal investments could be the ultimate factor for whether a manufacturer is going to pursue onshoring or nearshoring their operations, particularly for manufacturers of drugs that have low-profit margins, like generic pharmaceuticals. Ultimately, it has to make business sense. The less the federal government partners in

these endeavors, the more difficult it will be for manufacturers to grow the domestic manufacturing footprint in the United States, and the longer it will take to ensure the resiliency of the pharmaceutical supply chain.

Given that Congress continues to grapple with other policy matters, momentum on strengthening the resiliency of the U.S. pharmaceutical supply chain, including expanding domestic manufacturing of critical drugs, appears unlikely to pick back up until the second half of the 117th Congress. However, in the interim and as noted above, it is worth watching how the Biden-Harris administration responds to the growing concerns, including implementation of their supply chain report actions, and to what extent the administration prioritizes partnering in these related endeavors.

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