New U.S. Policies Expected to Spur Investor Interest in Domestic Pharmaceutical Manufacturing

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The Trump administration has taken steps in recent months to reduce the United States' reliance on foreign sources of finished drug products and active pharmaceutical ingredients ("APIs").[1] Despite a trend toward domestic onshoring of pharmaceutical manufacturing in the last few years, the U.S. pharmaceutical supply chain is still heavily reliant on foreign manufacturing. As it currently stands, more than half of finished drug products distributed in the United States—and approximately 90% of APIs for U.S. drug products—are manufactured outside the United States. The recently created Strategic API Reserve (the "SAPIR"), in conjunction with Trump administration domestic manufacturing policies and pharmaceutical tariffs, is expected to incentivize domestic manufacturing and spur investments by strategic acquirers and private equity investors.

Executive Order to Fill the SAPIR. On August 13, 2025, President Trump issued an executive order titled "Ensuring American Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve"[2] (the "SAPIR EO"). The SAPIR EO noted that "[n]early two in five prescription finished drug products are made in the United States, including many of the essential medicines. However, when it comes to [APIs], the biologically active components of finished drug products, only about 10 percent of the APIs by volume for the finished drug products used in the United States are made here."[3] In fact, the Food and Drug Administration ("FDA")

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1 For more on the Trump administration's policies and priorities impacting the life sciences industry, *see* Debevoise In Depth: The Food and Drug Administration Under the Second Trump Administration (June 18, 2025); Debevoise Update: New Combination Drugs: Assessing the Potential Impact of New CMS Draft Guidance on Pharmaceutical Companies and Investors (May 27, 2025); Debevoise In Depth: Unpacking President Trump's New Executive Order on "Most-Favored-Nation" Prescription Drug Pricing (May 20, 2025); Debevoise In Depth: Healthcare Policy in Flux: The Impact of Trump Administration Changes to HHS (Mar. 28, 2025); Debevoise In Depth: Top 10 Healthcare and Life Sciences Issues to Watch in 2025 (Jan. 10, 2025).

2 Executive Order 14336, Ensuring American Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve (Aug. 13, 2025).

3 *Id.*

found that as of 2025, "only 9% of API manufacturers are in the U.S., compared to 22% in China and 44% in India."[4]

The Trump administration expressed two primary goals in creating and ultimately filling the SAPIR. First, "[f]illing the SAPIR will . . . insulate the United States from the concentration of foreign, sometimes adversary, nations in the world-wide supply of the Key Starting Materials[5] used to make APIs."[6] Second, by preferentially purchasing domestically manufactured APIs for the stockpile, the government hopes to encourage more domestic production. The administration is focusing on stockpiling APIs instead of finished drug products because APIs are generally lower cost and have a longer shelf life.

This announcement builds on President Trump's efforts in 2020 to create the SAPIR during the COVID-19 pandemic. On August 6, 2020, he issued an executive order directing executive departments and agencies to consider a variety of actions to increase domestic procurement of "essential medicines, medical countermeasures, and critical inputs" and to identify supply chain vulnerabilities.[7] FDA published a list of "essential medicines, medical countermeasures, and critical inputs" in October 2020, and the Office of the Assistant Secretary for Preparedness and Response ("ASPR") within the Department of Health and Human Services ("HHS") later reduced the list to 86 essential medicines needed for acute patient care.[8] ASPR's list included medicines needed for rescue and/or lifesaving care, stabilizing patients in hospital continued care to enable discharge, and urgent or emergency surgery. The 2020 efforts stalled, however, and the SAPIR EO noted that "the SAPIR is nearly empty."[9]

The Trump administration now plans to fill the SAPIR. The SAPIR EO directs ASPR to develop a list of approximately 26 critical drugs vital to national health and security within 30 days and ready the SAPIR repository to receive and maintain the APIs for these drugs. ASPR must obtain a six-month supply of these APIs, with a preference for domestically manufactured APIs to the extent possible. After completing this task, ASPR must update its 2022 list of 86 essential medicines and propose a plan to obtain

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4 FDA Public Meeting Announcement: Onshoring Manufacturing of Drugs and Biological Products (Sept. 30, 2025). As of June 2025, approximately 53% of brand drug products and 69% of generic drug products have at least one manufacturer outside the United States. *Id.*

5 The foundational chemical components, raw materials or intermediates incorporated into an API.

6 Executive Order 14336.

7 Executive Order 13944, Combatting Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Aug. 6, 2020).

8 ASPR, Essential Medicines Supply Chain and Manufacturing Resilience Assessment (May 2022).

9 Executive Order 14336.

and store a six-month API supply for these drugs. ASPR must also develop a proposal for a second SAPIR to further enhance supply chain resilience.

The SAPIR has the potential to protect the United States in the event of critical medicine shortages or future tensions with foreign nations that could impact the pharmaceutical supply chain. The preference for domestically manufactured APIs could present opportunities for companies with U.S. manufacturing facilities, including the potential for long-term federal contracts. There are, of course, many outstanding questions of relevance to pharmaceutical companies and investors, such as: (1) How will API manufacturers be chosen to supply the SAPIR?, (2) When will APIs in the SAPIR be deployed, will there be attendant fees/costs, and how will manufacturers be chosen to receive the APIs?, (3) Will domestic manufacturing capacity be sufficient to fill the SAPIR, or will the U.S. government turn to foreign sources?, and (4) How often will APIs need to be repurchased given expiration dates? We expect the government to provide answers to at least some of these questions in the near future.

Executive Orders and Policies to Support Onshoring of Pharmaceutical Manufacturing Capacity, Including the FDA PreCheck Program. On May 5, 2025, President Trump issued an executive order directing FDA to reduce the regulatory burden of building domestic pharmaceutical manufacturing plants.[10] Specifically, the executive order directed FDA to streamline reviews and work with manufacturers to provide support, increase fees for and inspections of foreign manufacturing facilities, and improve enforcement of API source reporting by foreign manufacturers.

Even with reduced regulatory burdens, planning and building new domestic manufacturing facilities will take years. To address this concern, FDA recently announced "FDA PreCheck," a new program "to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States."[11]

The PreCheck program involves a two-step approach to facilitate new drug manufacturing facilities in the United States First, the "Facility Readiness Phase" "provides manufacturers with more frequent FDA communication at critical development stages, including facility design, construction, and pre-production."[12] Companies will be encouraged to submit Drug Master Files ("DMFs") containing comprehensive information on their facilities, "such as [a] site operations layout and description, Pharmaceutical Quality System elements, and Quality Management

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10 Executive Order 14293, Regulatory Relief to Promote Domestic Production of Critical Medicines (May 5, 2025).

11 FDA News Release, FDA Announces New FDA PreCheck Program to Boost U.S. Drug Manufacturing (Aug. 7, 2025).

12 *Id.*

Maturity practices."[13] The facility-specific DMF may then be incorporated by reference into a drug application, facilitating faster review. The second phase is the "Application Submission Phase," which centers on "streamlining development of the Chemistry, Manufacturing, and Controls section of the application through pre-application meetings and early feedback."[14]

Pharmaceutical Tariffs. On April 14, 2025, the administration announced the initiation of an investigation into tariffs on imports of pharmaceuticals on national security grounds.[15] This investigation can take up to 270 days, but the administration has indicated it may proceed more quickly. President Trump recently stated that pharmaceutical tariffs could reach 250%.[16] It is unclear whether a blanket tariff will be applied to all pharmaceutical products—including APIs and finished products—or whether the administration will take a piecemeal approach with tariffs tailored to product type and country of origin. Tariffs may have a disproportionately adverse impact on generic drug companies because they have the smallest profit margins and may struggle to absorb rising costs. This could lead to foreign facility closures and drug shortages.[17]

The recently announced trade framework between the European Union ("EU") and the United States includes a provision on pharmaceutical tariffs, sparing EU-based pharmaceutical facilities from the potential 250% tariffs. Starting September 1, 2025, the United States will impose a "Most Favored Nation" ("MFN") tariff rate on generic pharmaceuticals (and their APIs) sourced from the EU.[18] While it's not yet clear what the MFN rate will be, the Trump administration has said it would exceed 15% (consistent with the rate for other goods). A 15% tariff will apply to branded pharmaceuticals. Based on threats of even higher tariffs, these rates provide a modicum of relief for the EU pharmaceutical industry, which is a significant manufacturer of APIs and finished drug products for the U.S. market.

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Given the administration's policies addressed above, we expect heightened investor interest in domestic pharmaceutical manufacturing, particularly if the administration

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13 *Id.*

14 *Id.*

15 Section 232 of the Trade Expansion Act of 1962 allows the president to restrict imports of products that are found to threaten to impair national security.

16 CNBC, Trump Says Pharma Tariffs Could Eventually Reach Up To 250% (Aug. 5, 2025).

17 For more information on tariffs, *see* Debevoise in Depth: The U.S. Tariff Turmoil: Navigating the Potential Sources of Risk (June 11, 2025).

18 Joint Statement on a United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade (Aug. 21, 2025).

follows through with 250% tariffs on pharmaceuticals from certain countries. We will continue to follow these developments, and please do not hesitate to contact us with any questions.

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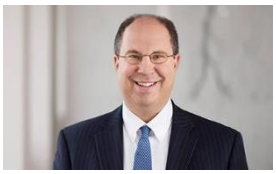

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