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Coordination and Goals for Domestic Pharmaceutical Manufacturing Initiatives

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The Duke-Margolis ReVAMP Drug Supply Chain Consortium consists of a group of experts in supply chain, manufacturing, regulatory science, national security, and drug shortages from academia, private industry, governmental agencies, and additional relevant stakeholder groups. The Consortium's mission is to generate effective policy solutions that promote a reliable drug supply chain to reduce the frequency and severity of chronic drug shortages.

This publication reflects the recommendations and analysis of Duke-Margolis researchers, which have been informed by Consortium activities and the expertise of its members. As part of Duke University, Duke-Margolis honors the tradition of academic independence on the part of its faculty, researchers, and scholars. Neither Duke nor the Duke-Margolis Institute for Health Policy takes partisan positions, and participants in our research activities are free to speak their minds and express their opinions regarding important and pertinent issues. This publication may not represent the opinions of every Consortium member. This publication is not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations.

Disclosures

Stephen Colvill serves as a board member for the End Drug Shortages Alliance and a volunteer advisor for Angels for Change.

About the Duke-Margolis Institute for Health Policy

The Robert J. Margolis, MD, Institute for Health Policy at Duke University is directed by Mark McClellan, MD, PhD, and brings together expertise from the Washington, DC, policy community, Duke University, and Duke Health to address the most pressing issues in health policy. The mission of Duke-Margolis is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. Duke-Margolis catalyzes Duke University's leading capabilities, including interdisciplinary academic research and capacity for education and engagement, to inform policymaking and implementation for better health and health care. For more information, visit Duke-Margolis website.

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Executive Summary

The medicines that Americans rely on every day are often products of complex global supply chains, with manufacturing sites in many different countries handling different stages of production. While global supply chains can enable specialization, efficiency, and access to global capabilities, they come with challenges as well:

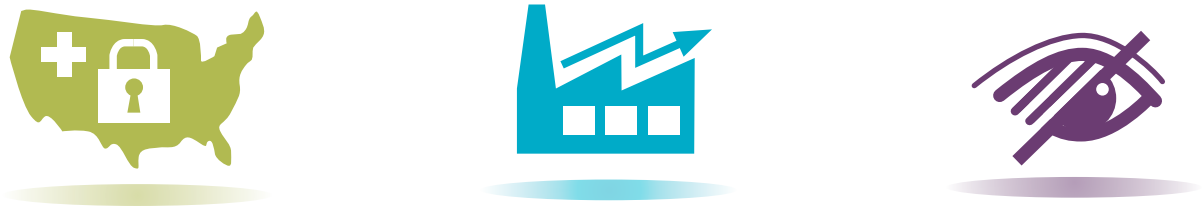
- Geopolitical risks associated with concentration of production in higher-risk countries.
- Negative impacts to local U.S. economies that could benefit from high-paying manufacturing jobs.
- Issues with regulatory oversight in some foreign countries.

Supporting a robust domestic pharmaceutical manufacturing base is a bipartisan priority for policymakers. Absent effective planning and well-defined goals, though, policy efforts to support domestic manufacturing could be expensive and generate limited benefits to public health and the U.S. economy. This policy brief describes the benefits and challenges associated with domestic pharmaceutical manufacturing, including an overview of relevant recent and ongoing policy efforts. The policy brief also outlines three high-level goals that domestic pharmaceutical manufacturing efforts can help to achieve **(Figure 1).** We then propose several SMART (Specific, Measurable, Attainable, Relevant, Time-bound) objectives that support each goal. Establishing SMART objectives can help to illuminate the policy steps that can most effectively and efficiently achieve desired goals, and SMART objectives can also be used to measure progress over time.

We recommend that the Office of Management and Budget's (OMB) Made in America Office (MIAO) and other White House offices, in partnership with HHS, DoD, VA, DOC, and other relevant agencies, direct the establishment of a National Strategy for Bolstering Domestic Production of Critical Pharmaceuticals and Associated Ingredients. We recommend that the OMB MIAO consider incorporating the goals and SMART objectives proposed in this policy brief into the National Strategy.

Benefits and Challenges Associated with Domestic Pharmaceutical Manufacturing

Figure 1: Increased Domestic Manufacturing Can Help to Achieve Three Goals



Safeguard National Health Security | **Grow Economy through Domestic Production** | **Mitigate Issues with Regulatory Oversight**

According to U.S. Pharmacopeia (USP), 12 percent of active pharmaceutical ingredients (API), 22 percent of solid oral finished dosage forms (FDF), and 45 percent of injectable FDFs for U.S. prescription medicines were manufactured domestically in 2024. A 2021 analysis found no U.S. API sources for 83 of the top 100 most-used generic drugs. Domestic manufacturing accounted for only a very minimal share of key starting material (KSM) production; in contrast, 41% of KSMs used in U.S.-approved APIs were sole-sourced from China. These analyses provide an aggregate view of how much of various stages of pharmaceutical manufacturing occurs in different regions. Within specific product categories, the percentage of volume manufactured in the U.S. is lower and the percentage of volume manufactured in high-risk countries is higher. Bolstering the domestic industrial base to ensure a higher percentage of U.S. pharmaceutical supply is produced domestically is a critical bipartisan priority, especially for APIs and critical product categories such as antibiotics. Relying on concentrated foreign sources for a significant proportion of the manufacturing of a critical drug's FDF, API, or KSMs with no emergency risk mitigation plan can create national health security risks and regulatory oversight challenges that could impact U.S. patients.[1] Domestic manufacturing can help to reduce these risks while also generating local economic benefits in the U.S.

Policymakers should develop clear, well-defined strategies for which goals they aim to achieve through support for domestic manufacturing, how proposed policies will generate progress toward those goals at a reasonable cost, and how that progress can be measured or tracked to assess success over time. Absent effective planning and well-defined goals, policy efforts to support domestic manufacturing could be expensive without a commensurate return on investment in the form of sustained improvements to supply chain security, patient access and outcomes, or economic growth. Operationalizing one new manufacturing facility can take three to five years and cost up to $2 billion dollars, and, as of 2024, U.S. patients consumed hundreds of billions of defined daily doses[2] of prescription medicines sourced from 4,839 FDA-registered foreign manufacturing sites. Opportunity costs exist, as public and private funds spent on domestic manufacturing could alternatively be spent in other areas. Prominent recent examples exist of manufacturers receiving government funds but not being able to provide sustained product availability for patients. And in many cases, utilizing existing, idle capacity will be more efficient than building new sites altogether—research suggests that underutilized manufacturing capacity exists at sites across the U.S.

[1] This policy brief focuses on FDF, API, and KSMs. Relying on concentrated foreign sources for other pharmaceutical intermediates, other inputs needed for manufacturing such as reagents, catalysts, and solvents, and other ancillary supplies such as syringes and needles can also create risk for U.S. patients.

[2] A standardized measure of average maintenance doses per day developed by the World Health Organization to assess global drug utilization.

Policymakers should develop clear, well-defined strategies for which goals they aim to achieve through support for domestic manufacturing, how proposed policies will generate progress toward those goals at a reasonable cost, and how that progress can be measured or tracked to assess success over time. Absent effective planning and well-defined goals, policy efforts to support domestic manufacturing could be expensive without a commensurate return on investment in the form of sustained improvements to supply chain security, patient access and outcomes, or economic growth. Operationalizing one new manufacturing facility can take three to five years and cost up to $2 billion dollars, and, as of 2024, U.S. patients consumed hundreds of billions of defined daily doses[2] of prescription medicines sourced from 4,839 FDA-registered foreign manufacturing sites. Opportunity costs exist, as public and private funds spent on domestic manufacturing could alternatively be spent in other areas. Prominent recent examples exist of manufacturers receiving government funds but not being able to provide sustained product availability for patients. And in many cases, utilizing existing, idle capacity will be more efficient than building new sites altogether—research suggests that underutilized manufacturing capacity exists at sites across the U.S.

Ineffective onshoring policy could introduce new vulnerabilities from concentration of production within the U.S., direct resources to domestic manufacturers that may prove to be unreliable, reduce efficiency, and limit U.S. access to global talent, capabilities, and product offerings. Other policy levers **(see Box 1)** may be complementary to domestic manufacturing in some situations and preferable to domestic manufacturing in other situations. As a result, policymakers need to establish clear goals for domestic manufacturing and identify the policy steps that can most effectively achieve those goals at a reasonable cost.

Box 1: Other Critical Pharmaceutical Supply Chain Steps

Since onshoring every component of every essential medicine supply chain is not feasible or necessarily beneficial, efforts to safeguard national security should include nearshoring and allyshoring—increasing manufacturing in partner countries close in proximity to the U.S. or closely allied with the U.S. including Bio-5 and NATO countries. As Duke-Margolis has described previously, many partner countries are similarly seeking to de-risk their pharmaceutical supply chains, so a collaborative approach can be synergistic and efficient. Or, for another example, efforts to mitigate issues with regulatory oversight could include increased funding for The FDA's Office of Inspections and Investigations and unannounced inspection pilot programs, and increased use of Mutual Recognition Agreements (MRAs) with other national regulators when possible. Other national governments and regulatory bodies have similar aims in ensuring a quality, reliable supply of essential medicines for their populations, and collaborative regulatory efforts can extend the collective reach of regulatory resources.

While increasing domestic manufacturing is a worthwhile effort for the many reasons discussed in this policy brief, increased domestic manufacturing alone may not have a significant impact on the drivers of chronic drug shortages that have persisted for decades. The most frequent cause of past drug shortages has been delays in finished dosage form manufacturing for generic sterile injectables, and many of these manufacturing delays have occurred in U.S. plants. These manufacturing delays generally are caused by market incentives that emphasize low-cost manufacturing without enough consideration for reliable supply over time, and these incentives are likely to continue to cause drug shortages regardless of manufacturing location until incentives are realigned toward reliable supply. Policy steps such as improved supply chain measurement and CMS payment reform to support purchasing from reliable suppliers are likely better suited to address chronic drug shortages than increased domestic manufacturing.

Recent and Ongoing Policy Efforts to Boost Domestic Pharmaceutical Manufacturing

Since 2020, numerous bipartisan policy efforts have been made to bolster domestic pharmaceutical manufacturing. In 2021, the White House Made in America Office (MIAO) was established in the Office of Management and Budget to help ensure that federal dollars are being leveraged to drive investment, promote good-paying high quality American jobs, and strengthen the U.S. manufacturing base. The Administration for Strategic Preparedness and Response's (ASPR) Center for Industrial Base Management and Supply Chain (IBMSC) has made many direct investments to expand domestic manufacturing capabilities, with a focus on medicines on the ASPR-ARMI 2022 Downselected Essential Medicines Needed for Acute Care list that currently have minimal U.S. sources. Executive Order 14336 on "Ensuring American Pharmaceutical Supply Chain Resilience By Filling The Strategic Active Pharmaceutical Ingredients Reserve" directs ASPR to maintain a 6-month supply of APIs needed to make 26 essential medicines, with a preference for obtaining domestically manufactured APIs. The U.S. Food and Drug Administration's (FDA) PreCheck Pilot Program aims to introduce streamlined regulatory processes for bringing online new domestic pharmaceutical manufacturing capabilities—a major focus of Executive Order 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines." The Advanced Manufacturing Technologies Designation Program, The FDA Center for Drug Evaluation and Research (CDER) Emerging Technologies Program, The FDA Center for Biologics Evaluation and Research (CBER) Advanced Technologies Team, and other FDA advanced manufacturing efforts seek to promote the uptake of technologies that can provide greater quality assurance and efficiency, and for which the U.S. has significant domestic expertise. Tariffs have also been imposed on personal protective equipment (PPE) and syringes sourced from China, as well as patented drugs sourced from certain countries (with some exemptions such as for manufacturers with "onshoring plans"). The Centers for Medicare & Medicaid Services (CMS) has implemented an N95 mask payment adjustment program to reimburse hospitals for costs of buying from domestic sources. CMS issued an Advanced Notice of Proposed Rule Making (ANPRM) to seek public comment on potential approaches to further incentivize hospitals to buy from domestic sources for PPE and essential medicines. HHS also previously recommended the establishment of a Hospital Resilient Supply Program that similarly would pay hospitals when they support a more resilient supply, including by purchasing from domestic essential medicines manufacturers that can demonstrate resilience. Through the American Rescue Plan, Congress provided $10 billion for purchasing vaccines and critical therapeutics and constructing or renovating manufacturing facilities for vaccines and critical therapeutics, along with hundreds of millions of dollars for FDA efforts to enable advanced manufacturing, resume inspections of manufacturing sites, and work to prevent shortages of vaccines and therapeutics. The Department of Defense, through research performed by the Uniformed Services University of the Health Sciences and other experts, continues to assess risks to the pharmaceutical supply chain such as those posed by reliance on foreign sources and to identify opportunities to support domestic suppliers. Most recently, ongoing hearings and developing legislation around identifying and reducing dependencies on foreign countries demonstrate Congressional interest in domestic pharmaceutical manufacturing. While many promising efforts to bolster domestic pharmaceutical manufacturing have begun, more is needed and strategic coordination is lacking.

Appropriate Goals and SMART objectives for Domestic Manufacturing Efforts

This section outlines our three identified goals that increased domestic manufacturing can help to achieve and proposes a list of SMART objectives intended to track progress toward each of the three goals.

Our proposed SMART objectives have been developed and refined through working meetings, surveys, and written feedback from Duke-Margolis ReVAMP Drug Supply Chain Consortium members and additional subject matter experts. We incorporated data on relevant historical trends and baseline rates into the objective setting process. While establishing ideal future targets for SMART objectives is challenging and subjective, being specific about these future targets is critical to enable a cohesive, focused, and efficient approach that can measure progress over time.

We have aimed to establish bold, ambitious goals while also incorporating feasibility and resource requirements. To achieve all of the proposed SMART objectives, additional resources and authorities will be required. Continuous research, workshopping, and revision of these objectives will be appropriate.

Since the authorities and expertise necessary to achieve these objectives are distributed across numerous federal agencies, interagency coordination will be critical. Policymakers leading the effort should also consider opportunities to incorporate industry perspectives from across all stages of the supply chain, as public-private partnerships will be an essential element of an effective strategy.

1. Safeguard National Health Security

Dependence on concentrated foreign sources for a significant proportion of the manufacturing of a critical drug's FDF, API, or KSMs with no emergency risk mitigation plan creates health security risks for U.S. patients. Policymakers frequently raise concerns that China could leverage its substantial role in the upstream stages of the drug supply chain to intentionally cause harm in the U.S. pharmaceutical supply. Unintentional or unexpected major disruptions—for example, a natural disaster that affects manufacturing or an infectious disease outbreak that causes spikes in demand—can also cause scarcity and shortages. Increasing manufacturing capacity in the U.S. can help to reduce the national health security risks posed by these threats.

OBJECTIVE 1

Invest in domestic manufacturing capabilities and domestic sourcing to ensure 25% or more of API volume for vulnerable medicines comes from the U.S. by 2030. Currently, only 12% of API for medicines used in the U.S. is made domestically. An increase to 25% represents a bold but achievable increase that will likely require leveraging existing underutilized capacity and speeding time to market for new capacity. This objective is aligned with the White House Office of Science and Technology Policy's 2023 "Bold Goals for U.S. Biotechnology and Biomanufacturing," and efforts have already begun to make progress towards a 25% target. USP's Vulnerable Medicines List and the API Innovation Center's National Fragility Index could be used to identify the medicines that should be prioritized and tracked.[3] An effective strategy for

[3] Later in this policy brief, we use the term "vulnerable medicines." USP's Vulnerable Medicines List and the API Center's National Fragility Index could similarly be used to identify the medicines that should be prioritized in those instances.

achieving this objective likely includes supply-side incentives to scale up domestic manufacturing capacity and increase utilization of existing sites, as well as demand-side incentives to encourage public and private purchasers to source from manufacturers that use domestic sources for their APIs. Phasing this goal to gradually increase up to an ideal steady-state target level may also be appropriate.

Box 2: The Role of Demand-Side Incentives

Supply-side incentives—such as investments in new manufacturing sites, new manufacturing lines at existing sites, and technology or equipment upgrades – are important tools in certain circumstances, such as when little to no domestic capabilities exist in a certain area. However, supply-side investments are often not well-suited for sustaining a reliable and domestically sourced supply of essential medicines over time. For generic essential medicines, intense market pressure for low prices causes manufacturers to seek lean supply chains and locations of production where costs are lower. Domestic pharmaceutical manufacturing sites sometimes operate under their full capacity due to a lack of demand.

Demand-side incentives—such as Medicare payment reform and domestic purchase preference in direct federal procurement—are important tools for sustaining a reliable and domestically sourced essential medicines supply over time. Without demand-side policy interventions, resource-constrained purchasers of essential medicines will continue to prioritize low prices in their purchasing decisions. Duke-Margolis has previously recommended how CMS payment reforms could realign health care provider incentives, creating a race to the top toward a more reliable and domestically sourced supply.

CMS payment reform offers several distinct advantages over other policy levers with regards to sustaining a reliable and domestic supply over time. For example, CMS payments are tied to the ongoing provisioning of health care, which means effective CMS payment policy can incentivize sustained availability of products for providers and patients. CMS payments also can apply to products made by many manufacturers, including manufacturers with underutilized capacity, without necessitating new individual grants or contracts with individual manufacturers. If CMS effectively incentivizes health care providers to preference reliable manufacturers, then manufacturers will have increased incentive to modernize their manufacturing and take other steps that bolster the reliability of their supply chains. In early 2026, CMS proposed implementing additional payments to hospitals that prioritize purchasing essential medicines and PPE from domestic suppliers. Duke-Margolis published recommendations for CMS to support reliable manufacturing through such payment changes—in addition to domestic manufacturing.

OBJECTIVE 2

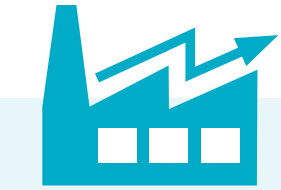
Create an emergency risk mitigation plan by 2028 for each API used in an ASPR-designated essential medicine that is currently reliant on a KSM sole-sourced from another country. USP data shows over 1,100 KSMs used in APIs for U.S. medicines are sole-sourced from a foreign country. 827 of these KSMs are sole-sourced from China, and ASPR-designated essential medicines that use these KSMs should be prioritized first. Policymakers should consider multiple options for risk mitigation, including identifying alternate routes of synthesis for APIs to remove or reduce sole-source dependency, identifying or creating alternate sources of KSMs, strategic API reserves, or ensuring availability of alternative therapies. The ASPR-designated essential medicine list represents just one subset of medicines – those that would likely have the most immediate impact on acute care if they were unavailable in case of a public health emergency or other disaster. An appropriate medium-term step would be to create emergency risk mitigation plans for other classes of APIs, such as certain chronic care medicines that are widely used or certain medicines with vulnerable supply chains, such as some pediatric medicines.

OBJECTIVE 3

Enter strategic discussions or formal strategic partnerships with four or more partner governments focused on complementary, specialized onshoring efforts by 2027. Many U.S. allies such as Bio-5 and NATO countries are assessing similar vulnerabilities and seeking to de-risk their medical supply chains, as Duke-Margolis described in our 2025 white paper, "Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of International Collaboration." For numerous reasons detailed in that paper, a collaborative international approach to these challenges will be more effective and efficient than each national government pursuing similar aims independently. The U.S. has already taken some steps toward this objective; for example, the U.S. and Japan released a Memorandum of Cooperation on Technology Prosperity in October 2025 that included an Area of Cooperation on "Securing Pharmaceutical and Biopharmaceutical Supply Chains" to "accelerate progress toward the identification and remediation of vulnerabilities". The State Department, HHS, and other federal government partners should progress the high-level goals laid out in the Memorandum towards more specific tactical steps, such as identifying specialized pharmaceutical manufacturing focus areas (i.e., the U.S. could focus on one therapeutic category of vulnerable, essential medicines and Japan on another therapeutic category) and identifying demand-side incentives that could help sustain both the American and Japanese suppliers. In some cases, identifying these specialized focus areas and demand-side incentives may be more impactful on a multilateral basis. It is in the best interest of U.S. national security and public health for the U.S. to demonstrate international leadership in this space and seek out opportunities to align formally on these goal areas with trusted partner governments.

OBJECTIVE 4

Include 50% of all APIs used in vulnerable medicines that do not have a U.S. API source in the Strategic API Reserve by 2028. An August 2025 Executive Order directed staff in the Executive Office of the President (EOP), the Office of Management and Budget (OMB), and HHS to fill the Strategic API Reserve (SAPIR) with 26 priority APIs from the ASPR-designated essential medicines for acute care list. However, more than 26 vulnerable medicines have no U.S. sources. One study found that 72% of the 94 medicines on the FDA's Essential Medicine List had no domestic API sources as of 2021, and that 83% of the most commonly used generic medicines in the U.S. had no domestic API sources. HHS should set a more ambitious goal to fill the SAPIR with a supply of API for 50% of vulnerable medicines that have no domestic source by 2028. If the 100 drugs on the USP Vulnerable Medicines List are used as the basis for identifying drug to include in the SAPIR, this objective would result in 50 drugs being included in the SAPIR. Critically, HHS should also ensure that FDA-approved fill-finish sources are available to utilize the API in the SAPIR, both in the case of an emergency and on an ongoing basis so that continuous cycling through SAPIR inventory can avoid obsolescence and reduce costs. Targeted coverage levels for the SAPIR (e.g., percentage of annual total U.S. market needs) that consider varying API shelf life should be carefully identified. When possible, extending the shelf life of existing APIs may increase efficiency. A gradual, scaled approach may help balance resilience and market stability.



2. Grow Economy through Domestic Production

Pharmaceutical manufacturers have committed to investing hundreds of billions of dollars into the U.S.'s biopharmaceutical research, development, and manufacturing industry, and supporting domestic industry and developing the domestic workforce are enduring bipartisan policy priorities. Economic growth, the creation of high-paying U.S. jobs, and an increase in the proportion of public and private capital that is invested in the U.S. can create prosperity and economic security for the U.S. While supply chain regionalization (the opposite of globalization) can decrease national security risks and have some positive localized economic impacts, regionalization also comes with negative economic consequences—U.S. exports may decrease as other regions source from their local markets, and overall global efficiency may decrease due to reductions in economies of scale and specialization. Regionalization may result in duplicative investments, higher drug prices, and reduced access. A successful approach will require maximizing positive local economic impacts, minimizing potential harm from decreased efficiency, and ensuring that public and private investments generate sustained benefits.

The CHIPS and Science Act of 2022, which incentivizes domestic manufacturing for the U.S. semiconductor industry, is one model for how policymakers can support and measure economic growth and workforce development for a critical sector of the economy like pharmaceutical manufacturing. The CHIPS Act allocated over $50 billion to promote domestic manufacturing of semiconductors, primarily through direct investment in manufacturing plants, but also with support for research and development and workforce expansion. The figures included in the objectives below are proxy examples intended to demonstrate how economic growth could be measured to assess the impact of new investments in pharmaceutical and biopharmaceutical manufacturing—these are notably different from our other recommendations around ensuring reliable U.S. patient access to quality medicines.

OBJECTIVE 1

Conduct a pharmaceutical workforce needs assessment by 2028, with analysis on workforce gaps by job type and education or training needs. Rapid expansion of the U.S. pharmaceutical manufacturing industry will create high demand for technicians, engineers, and other skilled workers. Estimating the types of jobs that the U.S. pharmaceutical manufacturing base will demand and their education or training requirements—similar to this report on the landscape of the U.S.'s semiconductor workforce—could help the U.S. take initial steps to promote workforce development and reduce the talent gap. The analysis of projected needs should consider existing federal initiatives, such as Department of Labor programs to support registered apprenticeships applicable to some pharmaceutical manufacturing technician roles, along with state- and local-level efforts to support workforce training.

OBJECTIVE 2

Establish three or more key performance indicators (KPIs) to monitor economic growth in the U.S. pharmaceutical sector by 2027. The following objectives are sample KPIs that could inform policymakers' thinking:

- **Increase the size of the active U.S. pharmaceutical manufacturing workforce by 30% by 2030.** In 2023, the pharmaceutical ingredient workforce was comprised of about 273,000 workers.[4] From an economic growth perspective, workforce initiatives should focus on high-skill, high-paying jobs that would be most beneficial to U.S. workers.

[4] See page 217 of the 2021-2024 Quadrennial Supply Chain Review.

- **Establish 200 net new[5] U.S. pharmaceutical manufacturing sites by 2030.** According to the FDA CDER's 2024 Report on the State of Pharmaceutical Quality, an average of 25 net new manufacturing sites were established in the U.S. annually from 2020-2024. With increased investment in and demand for domestically-manufactured drugs, the U.S. could establish 200 net new sites by 2030—an average of around 40 new sites each year over the next five years. Achieving a goal to establish a specific number of new sites may be an indicator that suggests economic growth, though overall economic impact will vary with each site's product type and levels of production. Appropriate priority should be given to the most critical sites.

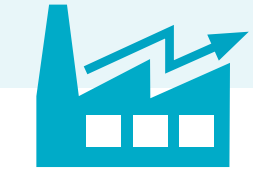
- **Increase the value of goods shipped by the U.S. pharmaceutical manufacturing sector by 75% by 2032.** As reported in the National Economic Council and National Security Council's 2021-2024 Quadrennial Supply Chain Review, the U.S. shipped $361 billion in pharmaceutical products and APIs in 2023, a 72% increase over 2018. Increasing the value of good shipped by the U.S. pharmaceutical industry by another 75% by 2032 would be a significant economic achievement. While growing the domestic pharmaceutical manufacturing base will be critical to achieve this goal, investing in research and development of new curative or transformative therapies would be equally or even more critical to achieve this goal.

Box 3: Regional Economic Impact and the Role of States in Bolstering Domestic Manufacturing

State and local economies can benefit from pharmaceutical manufacturing in their areas through direct creation of jobs and the indirect ripple effect on secondary businesses that support construction and population growth. A report from the API Innovation Center and Washington University's Center for Analytics and Business Insights (CABI) estimated that the development and commercialization of an API or generic drug could have a total economic impact of about $50 million in the state of Missouri over a 15-year time horizon.

North Carolina lawmakers have partnered with universities and local businesses for many years to support the development of the local biopharmaceutical manufacturing industry by establishing Research Triangle Park, an area dedicated to housing innovative manufacturing companies, and investing in workforce development grants with regional universities. Virginia is similarly emerging as a "hotspot" for biopharmaceutical and pharmaceutical manufacturing, with significant investments from major innovator manufacturers like Eli Lilly and AstraZeneca as well as generic manufacturers like Phlow Corporation. Virginia's Alliance for Building Better Medicine, established by a state-level grant, advanced these developments, as did partnership with the federal Economic Development Administration, which designated an Advanced Pharmaceutical Manufacturing Hub in Virginia and granted over $3 million in funding to an associated community college-led Advanced Pharmaceutical Manufacturing Workforce Initiative.

States play a vital role in establishing fertile ground for biopharmaceutical and pharmaceutical industry growth, especially through the establishment of workforce development programs. Federal efforts to support domestic manufacturing and develop a domestic manufacturing workforce should seek to support and augment these local, state, and regional efforts.



[5] "Net new" manufacturing sites is the number of sites added to the FDA Site Catalog minus the number of sites removed from the catalog.

OBJECTIVE 3

Through public and private methods, invest $100 million in training and workforce development programs for pharmaceutical manufacturing by 2029. Informed by the workforce needs assessment outlined in Objective 1, policymakers and industry should jointly invest $100 million by 2029 to bolster the U.S pharmaceutical manufacturing workforce. The CHIPS Act sets a precedent for this, investing over $200 million in funding through the National Science Foundation (NSF) to incentivize companies to prioritize semiconductor workforce development through public-private partnerships with higher education institutions and workforce training programs. An effective effort to develop the pharmaceutical manufacturing workforce should include support from the U.S. Department of Labor, Economic Development Administration, and Small Business Administration in addition to NSF.

3. Mitigate Issues with Regulatory Oversight

Regulators, policymakers, and other experts often express concerns about the rigor of regulatory oversight of manufacturing sites outside the U.S. In 2022, a Government Accountability Office (GAO) report highlighted that most FDA inspections of foreign sites are preannounced, unlike the unannounced inspections typical in the U.S., meaning that "investigators are less likely to see the true day-to-day operating environment" in foreign establishments. Between 2022 and 2024, the FDA restarted unannounced inspection pilot programs in India and China in an effort to remedy these concerns. While the FDA conducted 161 unannounced inspections in FY24 and 233 unannounced inspections in FY25, these figures still represent less than 10% of all foreign inspections during those time periods. As discussed further in the objectives below, the FDA staffing and resource challenges, along with diplomatic matters with host countries, will need to be overcome to increase the level of unannounced foreign inspections. For example, unannounced foreign inspections require the FDA staff to meet host country requirements around visas and other areas, arrange travel and lodging, and ensure translation services are available, all without alerting the manufacturing site. Addressing these issues can help level the playing field for domestic manufacturers and ensure a higher level of compliance and quality for all establishments, regardless of location.

Experts also raise concerns around the frequency of FDA inspections. In 2025, the FDA conducted 1,340 drug quality assurance inspections,[6] compared to an average of 1,760 drug quality assurance inspections per year from 2013-2019, before COVID. While use of alternative tools such as remote regulatory assessments has helped the FDA to augment its regulatory capabilities outside of inspections, the decrease in number of inspections is a concern. Given the 4,619 manufacturing sites listed in the FY2024 CDER Site Catalog, the FDA can currently be expected to inspect a drug manufacturing site about once every 3.4 years on average (if 2025 inspection levels continue). The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 and the FDA's Site Selection Model appropriately replaced a fixed minimum inspection interval (e.g., inspection once every two years) with a risk-based schedule, allowing the FDA to focus inspection resources on the most important safety risks and sites. Nevertheless, ensuring that sites are inspected at an appropriate frequency is important for public safety. And ensuring that domestic and foreign sites are inspected on a fair frequency and with equal rigor is important to help ensure a level playing field between domestic and foreign firms.

[6] The FDA inspections database accessed on May 11, 2026.

OBJECTIVE 1

Increase the proportion of foreign inspections that are unannounced rather than preannounced from less than 10% to greater than 30% by 2029. Achieving this objective would represent a substantial increase in unannounced inspections, while also acknowledging that some inspections (such as pre-approval inspections) that require specialized staff and records will always be preannounced. GAO has highlighted persistent FDA staffing challenges both among U.S.-based staff who conduct foreign inspections and staff in the FDA's foreign offices located in China and India. The FDA could expand use of Title 21 special hiring and pay authority and take other steps to help address vacancies, and additional resource support from Congress will also be needed. Interagency coordination, for example between the FDA and the State Department, will also be critical to address challenges with host country requirements discussed above.

OBJECTIVE 2

Establish U.S. sources for 50% of APIs and 50% of FDFs that are on the ASPR-designated essential medicines for acute care list and are currently sole-sourced from India or China by 2030. This objective is aligned with Objective 1 and Objective 2 in the Safeguarding National Health Security section above. Establishing new domestic sources for priority APIs and FDFs should be part of a de-risking strategy that should also include nearshoring and allyshoring, strategic reserves, and other steps. Establishing domestic sources would naturally reduce challenges with regulatory oversight in some foreign countries. A 2022 report from the Department of Defense found that seven of the 46 drugs on the FDA's essential medicines list purchased by the DoD had APIs that were solely sourced from China. Policymakers should also ensure that incentives are in place for sustained market demand for domestically-sourced versions of these products.

OBJECTIVE 3

Increase the number of annual drug quality assurance inspections, inclusive of the FDA inspections and MRA partner inspections classified by the FDA under the MRAs, by 35% or more by 2028. In 2025, the FDA conducted 1,340 drug quality assurance inspections,[7] compared to an average of 1,760 drug quality assurance inspections per year from 2013-2019, before COVID. With appropriate funding, staffing, and execution, the FDA could increase the number of drug quality assurance inspections by 30% over the next two years to meet or exceed pre-COVID levels. Based on the number of sites listed in the FY2024 CDER Site Catalog, a 35% increase in the number of drug quality assurance inspections could reduce the time interval between inspections for drug manufacturing sites from 3.4 to 2.6 years on average. Importantly, the FDA should ensure that an increased number of inspections does not result in a tradeoff with inspectional rigor. Adequate resources should still be devoted to robust inspector training and adequate time should still be devoted to each individual inspection. Achieving this goal will likely require an increase in funding and staffing for the FDA's Office of Inspections and Investigations.

OBJECTIVE 4

By 2028, increase the FDA market surveillance sampling rates of generic drugs by 300% relative to 2025 baseline. The FDA sampled 0.05% of imported drug and biologic product lines in 2025. A 300% increase would provide more meaningful data on the frequency with which the FDA observes quality imported products vs substandard imported products. A risk-based approach accounting for facility risk or adverse event reporting can help to focus resources, but random sampling of high-priority products such as medicines deemed critical to military readiness would also provide useful insights. In the case of random sampling of imported products, we are not recommending that the FDA should delay customs release for products undergoing testing, as this could unintentionally contribute to shortages. Instead, the

[6] FDA inspections database accessed on May 11, 2026.

FDA could test product obtained from market channels (e.g. wholesalers or pharmacies) or perform testing concurrent to and after customs release. Demonstrating that the FDA is actively monitoring imported products, in addition to performing robust and frequent inspections of manufacturing sites, would improve confidence in pharmaceutical quality for American patients and health care providers. To accomplish this objective, the FDA would require additional resources for their laboratories to acquire samples, establish validates test methods where needed, and complete testing.

CONCLUSION

With careful coordination, appropriate goals, and SMART objectives, efforts to increase domestic manufacturing can generate benefits for U.S. national health security, the U.S. economy, and regulatory oversight of the U.S. drug supply. While this policy brief focuses primarily on the actions that executive agencies should take to achieve these goals, success will also require Congressional action. Agencies will require some new authorities and robust, sustained funding to undertake and complete the work we recommend here—in some cases including funding increases. Focusing on appropriate goals and SMART objectives, as outlined in this policy brief, is essential to ensure these efforts and associated funding generate real and sustained impact for the U.S. drug supply.