Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of Geographic Diversification

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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 with advanced manufacturing capabilities and, ultimately, to improve patient outcomes by reducing the frequency and severity of drug shortages.

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EXECUTIVE SUMMARY

Global supply chains deliver many of the medicines on which American patients and health care providers rely. A significant proportion of pharmaceutical manufacturing, especially for active pharmaceutical ingredients, occurs abroad, including in India and China. Policymakers have expressed concerns about the risks and vulnerabilities associated with geographic concentration of manufacturing sites in these countries, including the risk of disruptions caused by geopolitical conflicts, challenges with regulatory oversight in certain countries, the possibility of theft or misuse of advanced biomanufacturing technologies, and the risks of localized disruptions due to natural disasters or other discrete events that could affect major manufacturing sites.

It's important to balance these reasonable concerns about the risks of geographic concentration abroad with an understanding of the desirable efficiencies that global drug supply chains offer. Furthermore, it's critical to recognize that reliance on manufacturing sites in foreign countries is *not* the direct or sole cause of many recent drug shortages, though it is, in some cases, related. Policymakers often have sought to relocate manufacturing sites to the U.S. – onshoring

TABLE 1: Key Considerations and Recommendations for Policies Intended to Onshore Pharmaceutical Manufacturing

Category of Policy Approaches	Key Considerations and Recommendations
Mapping, assessment, and transparency – sharing actionable information with key decision-makers	• Consolidate and share existing information to avoid redundant reporting requirements • Share data – including reliability and quality management information along with geographic location – strategically with target audiences to maximize impact
Demand-side supports – incentivizing purchasing from domestic manufacturers	• Explore opportunities to support domestic manufacturing through Medicare reimbursement for some high-risk products • Consider carefully the impact of different definitions of "domestically manufactured" drugs • Allow flexibility in purchasing from manufacturing sites abroad to avoid disruptions and ensure efficiency
Indirect investment – facilitating manufacturing in the U.S. through tax credits, workforce development, investments in academic research, etc.	• Consider whether tax incentives are fit-for-purpose based on target product classes, and whether such targeting is feasible • Leverage public-private partnerships to develop the domestic manufacturing workforce • Further the development and regulatory acceptability of advanced manufacturing technologies
Direct investment – grants, contracts,or loans from the government directly to domestic manufacturers	• Prioritize direct investments in flexible and scalable "warm base" manufacturing capacity for products essential in public health emergencies • If feasible and cost-effective, build on existing domestic manufacturing capacity • Incorporate effective strategies for long-term sustainability of domestic manufacturing sites

manufacturing – as a response to the risks detailed above, but simply relocating manufacturing sites to the U.S. will not, absent other steps, resolve the issues that have contributed to severe and chronic drug shortages in recent years. Global pharmaceutical supply chains are very complex and the risk of unintended consequences of interventions intended to shift locations of manufacturing is high. Before pursuing policies to increase domestic manufacturing of a given product, policymakers should assess what risks exist in the current supply chains for that product, how domestic manufacturing might alleviate them, and whether international partnerships to promote manufacturing of that product in diversified, geopolitically stable locations might achieve the same aims efficiently.

If a robust risk assessment shows domestic manufacturing to be a productive step to improve supply chain resilience and security for a specific product, The key considerations and recommendations in **Table 1** can guide effective implementation of different policy approaches to promoting domestic manufacturing.

In many cases and for many products, diversified global supply chains with manufacturing sites in geopolitically stable countries with robust regulatory oversight and appropriate emphasis on quality and reliability will be an efficient and effective option for ensuring supply chain resilience and security. Given complementary interests and ongoing efforts in many other regions of the world, policymakers should seek to further strategic international partnerships and coordination on drug supply chain resilience, with a focus on the following priorities:

- **Advancing regulatory harmonization –** a harmonized regulatory environment among partner countries would make participation in supply chain resilience and diversification efforts more attractive for industry. It could also enable more rapid, agile responses to public health emergencies, drug shortages, or other supply disruptions. Meaningful progress toward harmonization will likely require action from policymakers and not just regulators, as regulatory agencies may need additional funding and resources to advance the work.
- **Coordinating target products –** there is potential for alignment on critical or essential medicines lists used to guide efforts at promoting supply chain resilience and diversification.
- **Scaling production with new partners in emerging markets –** building capacity through existing partnerships in geographically diverse countries that currently have limited manufacturing capabilities is an underexplored opportunity to invest in the drug supply chain's absorptive resilience. Policymakers should seek to build upon existing health infrastructure efforts in Africa and central and southeast Asia with the long-term goals of promoting geographic diversification in drug manufacturing and harmonization in related regulations.

INTRODUCTION AND PROBLEM STATEMENT

Patients and health care providers today often rely on medicines that are manufactured and assembled throughout vast global supply chains. The United States relies on manufacturing facilities abroad for most of the active pharmaceutical ingredients (API) used in pharmaceuticals, as well as about half of finished dosage form (FDF) drugs. FDA reported in 2019 that about 32% of API facilities supplying the U.S. market were located in China and India, and only about 28% were in the U.S.

A 2022 report from U.S. Pharmacopeia (USP) showed that the proportion of API manufacturing facilities in China and India has grown significantly since 2000, while manufacturing in all other countries has reduced relatively. USP's analysis found that in 2021, 62% of new API Drug Master Files were submitted from India and 23% were submitted from China (up from 20% and 4%, respectively, in 2000), while just 4% of new filings were from the U.S. (down from 15% in 2000).[1] Policymakers frequently express

[1] Drug master files "are submissions to FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products." USP's analysis uses DMF submissions as a proxy indicator for active API facilities. Notably, these data do not capture production volumes at the active facilities.

concerns about the risks created by dependence on sites outside of the U.S. for significant portions of the drug supply (especially of API for small-molecule drugs), and as a result have increasingly considered policy actions to onshore, nearshore, or allyshore pharmaceutical manufacturing.[2] A few of the areas of risk most salient to this white paper are as follows:

- **Vulnerability to geopolitical conflict:** Experts in international relations broadly agree that there is a significant risk of a conflict between the U.S. and China in the coming decades. Such a conflict could lead to a reduction in, or an end to, the supply of key starting materials (KSMs), API, and finished drug products from China to the U.S. Without alternative sources for those products, shortages of many medicines in the U.S. could result. Other geopolitical conflicts in recent years have already affected supply chains for many critical goods.

- **Challenges with regulatory oversight in certain countries:** A September 2024 analysis of FDA data found that over 40% of sites registered to supply pharmaceuticals to the U.S. had not been inspected since before May 2019 – a backlog partially due to delayed and postponed inspections during the Covid-19 pandemic. The report showed China had the highest percentage of sites (59%) overdue for inspection of any country included in the analysis, and cited political and diplomatic challenges complicating inspections in China (though it should be noted that the U.S. had the highest *number* of sites overdue for inspections, and that FDA's Manual of Policies and Procedures includes a Risk-Based Site Selection Model that may affect inspection frequency at a given site). Germany's pharmaceutical regulators have cancelled inspections of Chinese sites due to concerns about legal entanglements under Chinese anti-espionage laws, indicating the U.S. is not the only country facing challenges with regulatory oversight.

- **Vulnerability to theft or misuse of advanced biomanufacturing intellectual property or technology:** The U.S. is a global leader in the development of innovative manufacturing methods and technologies. Heavy reliance on foreign manufacturing sites increases the risk of theft of intellectual property associated with these innovations, which could reduce those technological advantages or introduce the possibility of counterfeiting. Biosecurity experts have observed that biotechnologies can be considered "dual-use" technologies, "meaning that the same or similar techniques, manufacturing elements, and processes used for beneficial purposes could also be misused for deleterious purposes." In some cases, for example with innovative cell and gene therapies or vaccines, there is the potential for malicious misuse of the technologies for the creation of bioweapons. The development of these therapies definitionally includes the use of personal, sensitive genetic information, making the risks associated with theft of intellectual property more severe.

- **Risks of localized disruptions:** Geographic concentration in any one area increases the risk that an unanticipated event affecting the area could disrupt the supply of drugs manufactured there. Such disruptions could include an outbreak of an illness that leaves staff unable to continue production, a natural disaster that damages the manufacturing infrastructure, port shutdowns, regional conflicts, or any number of other acute emergencies. Such risks exist in any part of the world – for example, hurricanes affecting manufacturing in Puerto Rico caused at least one severe shortage, and hurricanes in early October 2024 disrupted the supply of critical injectable drugs.

It is important, however, to be clear about the extent and impact of these risks. Geographic concentration of manufacturing in certain foreign countries is not the direct or sole cause of most recent drug shortages, though it is related in some cases. Most drug shortages in the U.S. over the past 10 to 20 years have been driven by poorly aligned market incentives that prioritize lowest cost over commitment to reliability and therefore lead to frequent supply disruptions often related to manufacturing quality issues (as Duke-Margolis has analyzed extensively). The increased offshoring of manufacturing sites out of the U.S. over the same time period is primarily driven by the same

[2] As defined by USP, onshoring is the process of sourcing a company's production operations within domestic national borders; nearshoring is a strategy that involves a company shifting some or all its supply chain operations to a location geographically closer to its main market; and allyshoring is the practice of supply chain networks being focused on countries regarded as political and economic allies and where the risk of disruption from political turmoil is perceived as low.

factors – manufacturing in India, China, or other countries can be done at lower cost due to lower labor costs, lower costs of compliance with environmental regulations, and in some cases subsidies from those governments. Manufacturers operating primarily outside of the U.S. can often offer lower prices, which is what price competition encourages. Incentives for controlling costs contribute to the affordability of health care as long as prices are not driven so low as to reduce the reliability of supply.

Policymakers must therefore balance the real risks of relying too heavily on foreign manufacturing sites with the valuable efficiencies generated by global supply chains. **It is critical for policymakers to think strategically about when onshoring pharmaceutical manufacturing may improve supply chain security or reduce shortage risk, and, conversely, when it is likely to incur costs without addressing key risks. In the latter cases, policymakers should consider how international partnerships for supply chain security and resilience may be able to deliver important benefits with lower costs.**

Manufacturing of products that involves the use of particularly sensitive information or innovative technologies may be an appropriate area in which to prioritize onshoring efforts in order to protect personal and proprietary data and reduce the risk of malicious misuse of biotechnologies. Assessments of supply chains for other essential medicines or their APIs may reveal very few (or no) domestic sites able to manufacture significant quantities relative to U.S. demand, or that a large majority of supply comes from a foreign site with regulatory oversight issues – these circumstances too would suggest scaling up domestic manufacturing would be a productive step to reduce shortage risk. But in many other cases, domestic manufacturing may not be the only appropriate option for diversifying and securing drug supply, and policymakers should consider international partnerships to build a robust global manufacturing base for these essential medicines and their APIs. In still other cases, geographic locations or concentration of manufacturing sites may not be a major risk factor in the supply chain, and efforts to promote reliability and ensure robust quality management practices may be the most effective way to reduce shortage risk.

The costs and risks of policy interventions to shift the geographic locations of manufacturing sites must be weighed carefully in the decision-making process. Global supply chains are complex and fragmented, even for pharmaceutical products that are relatively well-understood. The total supply chain for a small-molecule drug that has been on the market for years may easily involve more than a dozen sites when accounting for every stage of production from KSM to API to FDF, plus manufacturing of excipients (non-active ingredients in the drug) ancillary materials such as vials, stoppers, and packaging, and delivery devices such as syringes and IV bags. Specialization of sites at each stage of the supply chain is often beneficial. A poorly targeted policy intervention could force disruptive changes at certain stages of the supply chain where there are not serious risks, or appear to improve security without meaningfully reducing risk across the supply chain as a whole.

Furthermore, simply relocating manufacturing sites back to the U.S. will not, absent other steps, resolve the issues that have contributed to severe and chronic shortages in recent years, especially of generic drugs. Wherever manufacturing sites exist, robust quality management practices and other steps to ensure manufacturing reliability over time should be a top priority for industry and policymakers.

Policy actions to increase security in the pharmaceutical supply chain through geographic diversification and onshoring can be productive and effective if they alleviate the risks listed above while promoting reliability in manufacturing and avoiding unnecessary increases in health care costs. This white paper provides recommendations for achieving these aims through bolstering a robust domestic manufacturing base and establishing strong, strategic international partnerships for supply chain resilience and security. Our recommendations largely but not exclusively apply to API manufacturing, for which the U.S. is currently more reliant on foreign supply relative to FDF manufacturing, more of which occurs in the U.S. We first review common approaches to promoting domestic manufacturing, as significant administrative and legislative effort has been undertaken in this area, and then provide recommendations and key considerations for more effective policy approaches. We then analyze nascent U.S. and international efforts to build partnerships for supply chain resilience and security, and recommend productive future directions for international collaboration.

Approaches, Recommendations, and Key Considerations for Promoting Domestic Manufacturing

In recent years, numerous policies have been proposed, and many implemented, to promote domestic drug manufacturing in the U.S. In **Table 2**, we describe several common categories of approaches policymakers have used to promote domestic manufacturing. In the following sub-sections, we provide concrete examples of each approach and key considerations or recommendations for pursuing each approach effectively. In all cases, when seeking to scale up manufacturing capacity in the U.S. or elsewhere, policymakers and industry partners should maintain a commitment first and foremost to reliable manufacturing processes with robust quality management practices.

TABLE 2: Common Policy Approaches to Promoting Domestic Manufacturing

Category of Policy Approaches	Description
Mapping, assessment, and transparency	Mapping the supply chain, assessing vulnerabilities, and sharing actionable information with key public or private decision-makers.
Demand-side supports	Incentivizing public or private purchasers to purchase from domestic manufacturers.
Indirect investment	Facilitating manufacturing in the U.S. through tax credits, workforce development, investments in academic research, or other mechanisms.
Direct investment	Offering grants, contracts, or loans from the government directly to manufacturers to pay for the domestic manufacturing of medicines.

Mapping, Assessing, and Transparency

The ability to identify vulnerabilities through mapping and to make accurate risk assessments of the drug supply chain is key to guiding efforts to boost supply chain resilience. It is necessary for regulators to support initiatives that encourage trust and transparency between government and industry for the success of mapping and assessment programs. **Appendix A** details numerous administrative actions as well as enacted and proposed legislation, to further these aims.

KEY CONSIDERATIONS AND RECOMMENDATIONS

Consolidation and sharing of existing information to avoid redundant reporting requirements: Establishing a clear understanding of the existing landscape and vulnerabilities is critical for crafting informed solutions, but a great deal of information is already reported and may be accessible, including from the policy steps described above. FDA possesses data on the locations of API and FDF manufacturing sites, though it is limited in its ability to share information since the data are considered Confidential Commercial Information. USP's Medicine Supply Map also holds a great deal of information on locations of production and other factors that may contribute to supply chain vulnerabilities and shortage risk. Wholesalers, distributors, and Group Purchasing Organizations (GPOs) also likely have valuable insights into sourcing given their roles in the supply chain, such as in negotiating, arranging purchases, and distributing products. Creating new mechanisms for enabling effective sharing of extant information with

new audiences (with appropriate protections including for proprietary data) could be beneficial, but new reporting requirements or other methods of collecting the information may be redundant in some cases.

Sharing data strategically to maximize impact: With regard to sharing information on sourcing or locations of production with new audiences, policymakers should consider whether and how the additional information is likely to change behaviors. For example, listing the country of origin on the label of a prescription dispensed at a retail pharmacy is only likely to have a meaningful impact if the consumer has a strong preference for domestically manufactured medicines (and some degree of choice between substitutable versions of the medicine from different sources). Providing the same information to a GPO or hospital procurement team might have more impact, since these entities have a larger role in selecting suppliers. Information on quality management practices at manufacturing facilities and supply chain reliability at the drug product level should also be shared as a key factor for purchasers' decision-making.

Demand-Side Supports

Government supported demand-side approaches focus on creating and sustaining demand for domestically manufactured pharmaceuticals. Policymakers have sought to further this form of support through recent Congressional proposals and executive actions, which are described in **Appendix B.**

KEY CONSIDERATIONS AND RECOMMENDATIONS

Opportunities to support domestic manufacturing through Medicare reimbursement reforms: Duke-Margolis has previously described the benefits and necessity of demand-side policy incentives that help move markets towards desired goals – specifically, rewarding providers for purchasing from manufacturers that make appropriate investments in establishing and maintaining reliable manufacturing practices for essential medicines. These same policy levers may be utilized to incentivize manufacturers to shift more manufacturing to the U.S., though policymakers should target such reforms carefully to products for which increased domestic manufacturing will meaningfully reduce security or shortage risks. Again, reliability in manufacturing should remain the top priority, and encouraging domestic manufacturing in itself does not necessarily ensure reliability.

In previous publications, we have noted that direct government purchases of drugs make up a minimal proportion of total drug purchasing in the U.S. (for retail drugs, likely less than 5% of total spending), and changing these buyers' priorities therefore may not be enough on its own to meaningfully change manufacturers' decision-making about where or how they produce drugs, though they could be a useful starting point to pilot new purchasing approaches. For example, long-term committed contracts from government purchasers could support the sustainability and reliability of some domestic manufacturers and signal the federal government's commitment to ensuring robust domestic supply of critical drugs.

In contrast, Medicare and Medicaid reimbursements cover a much larger proportion of prescription drug spending (together, about 40% of retail drug spending), so changes to the Centers for Medicare and Medicaid Services' (CMS') reimbursement policies could have a larger impact on drug purchasers' decision-making. Policymakers should consider how additional Medicare payment adjustments can enable hospitals and health systems to purchase domestically made versions of the drugs they use if those versions are available, and if U.S. manufacturers are taking steps to ensure quality and reliability in their manufacturing processes. The aforementioned Medicare Drug Shortage Prevention and Mitigation Act from the Senate Finance Committee forms a promising starting point for efforts to encourage buyers to choose manufacturers engaging in reliable manufacturing practices in the U.S., though bonus payments for buying from domestic manufacturers may not be cost-effective for all products included in the draft legislation. If reimbursement changes are implemented, CMS should coordinate with other HHS agencies such as ASPR and the HHS Supply Chain Resilience and Shortage Coordinator to ensure strategic and efficient targeting of the highest-risk products.

Encourage flexibility and diversity in purchasing to avoid disruptions: It's important to recognize also that domestically manufactured versions of many drugs are not currently available and may be costlier to make. Increased geographic diversity in the supply

chain will require years or decades to establish, so policies encouraging purchasers to buy domestically manufactured products should be targeted to products for which geographic concentration or foreign dependence creates especially high risks, with appropriate flexibilities for situations in which geographically diversified and geopolitically stable international sources can supply product efficiently with minimal risk. In general, the prudent approach is to make it more affordable and attractive to buy reliably and domestically made drugs when clear risks exist under the current supply chains, rather than to make it harder (or impossible) to buy drugs from foreign sources in general.

CALLOUT 1: Defining Domestically Made

Policies seeking to encourage more domestic pharmaceutical manufacturing, especially when using a demand-side approach, must define "domestically made" carefully. Inappropriate definitions could encourage just FDF production to shift to the U.S., where almost half of FDF production already occurs. This could lead to some cost increases without meaningfully reducing geographic concentration of upstream steps in the supply chain such as the manufacture of API and KSMs. On the other hand, stricter definitions could reduce flexibility and the potential for international partnerships for manufacturing. Some commonly used legal and statutory definitions of American made are as follows:

Buy American Act: Effective October 25, 2022, more than 60 percent of the cost of components of a good must be produced or manufactured in the U.S., and the end product must be manufactured in the U.S. This definition generally applies to direct government procurement.

Build America, Buy America Act: For manufactured products, the final product must be manufactured in the U.S., and more than 55 percent of the cost of components must be produced or manufactured in the U.S. This definition generally applies to procurement of goods used in government-funded infrastructure projects.

Made in USA Standard: A product must be "all or virtually all" made in the U.S., with no or negligible foreign content. This definition, from the Federal Trade Commission, generally applies to marketing claims about the origin of consumer goods.

Trade Agreements Act: Buy American Act standards are waived for procurements of goods above a certain price threshold from "designated countries" that are party to certain trade agreements with the U.S., essentially treating these goods the same as American-made. The goods must be "wholly the…product or manufacture of," or "substantially transformed" in the designated country to qualify.

The 2020 U.S. Federal Appeals Court case Acetris *Health, LLC v. United States* centered on the interpretation of the Trade Agreements Act (TAA) and the Buy American Act under the Federal Acquisition Regulation (FAR) regarding the procurement of pharmaceutical products by the Department of Veterans Affairs (VA). The Federal Circuit ruled that the VA's interpretation of the laws to determine the country of origin of a pharmaceutical product based on where its active ingredient was manufactured was incorrect and broadened the definition of what qualifies as "manufactured" in the U.S. to allow domestic FDF manufacturing to qualify a drug as domestically made, even if its API is manufactured abroad. This overturned previous interpretations and, according to concerns expressed by the API Innovation Center and some members of Congress, could affect efforts to promote domestic API manufacturing.

Indirect Investment and Support

Policymakers also have options to support drug manufacturing through grants to public-private partnerships, tax credits for domestic manufacturing, workforce development initiatives, and other policies that indirectly enable more domestic manufacturing. Examples of these types of policy actions are listed in **Appendix C.**

KEY CONSIDERATIONS AND RECOMMENDATIONS

Fit-for-purpose use of tax incentives: Reducing a manufacturer's effective tax rate through tax credits or other changes to tax policy can be a useful incentive to encourage more domestic manufacturing by lowering the cost of operating in the U.S. Policymakers should consider, however, whether this policy option is fit-for-purpose and whether it can feasibly be targeted toward products at higher risk of shortage or disruption due to geographic concentration and foreign dependence – given that the Internal Revenue Service (IRS) does not generally possess expertise in assessing supply chain vulnerabilities and the likelihood of drug shortages. Furthermore, a lower effective tax rate might be most compelling to a manufacturer producing high-margin branded products – this manufacturer may have more capital available for the up-front investments needed to scale up U.S. manufacturing, and more taxable profit expected in the future, therefore more benefit to be gained from the lower tax rate – and supply chains for these products tend to be more robust and reliable already. A manufacturer of generic medicines (including those producing some essential medicines whose production is highly concentrated abroad) is likely to have less capital available for up-front investments, less taxable profit expected in the future due to lower profit margins on their products, and may be less responsive to this type of incentive as a result, though the incentive may still be appealing. Depending on the product classes that policymakers hope to target, tax policy options may be a more or less effective approach, and policymakers should think carefully about these considerations and their aims. Furthermore, financial supports of any kind, including favorable tax policy, should be linked to guarantees of reliability and robust quality management practices in manufacturing overseen by FDA, and should clearly address a geographic risk.

Establishing partnerships to develop the domestic manufacturing workforce: Industry and government experts have identified the need to develop a skilled labor force as among the biggest challenges to expanding domestic manufacturing. This is especially true as domestic manufacturing will likely rely increasingly on innovative and advanced manufacturing methods with which the existing workforce may be less familiar – a 2020 study by McKinsey and the International Society for Pharmaceutical Engineering (ISPE) found that many manufacturers may already be struggling to keep their workforces' skills in line with rapidly developing technologies. Public-private partnerships provide a promising pathway to pursue the collaborative approach needed to entice and educate the required workforce to keep pace with these innovations. Policymakers should appropriate funding for, build upon, and expand efforts such as the Centers of Excellence in Advanced and Continuous Manufacturing and other partnerships between industry, government and institutions of higher education that provide experiential learning for students. Co-locating manufacturing facilities near such educational hubs may be a synergistic opportunity for industry to support and leverage these workforce development efforts.

Targeted Direct Investment

Policymakers have also used direct investment to support domestic drug manufacturing, especially through grants or contracts that can subsidize the significant costs of starting up new manufacturing sites.

The Administration for Strategic Preparedness and Response's (ASPR) Industrial Base Management and Supply Chain (IBMSC) Office has been tasked with bolstering the industrial base for medical product manufacturing, particularly for products needed in emergency response. In July 2024, the Office announced an investment of $18.5 million in two U.S. companies that will manufacture APIs for essential medicines; in September 2024 it announced another $14 million investment in the API Innovation Center for the "development and domestic production of three critical active pharmaceutical ingredients (APIs) used in the treatment of asthma, diabetes, and anxiety disorders"; and in October 2024 it announced another $17.5 million investment in National Resilience and Aralez Bio for

CALLOUT 2: Advanced Manufacturing Technologies Can Enable Growth in U.S. Pharmaceutical Manufacturing

Compared to traditional batch manufacturing methods, advanced manufacturing technologies (AMTs) offer many important advantages that are particularly critical for increasing domestic manufacturing capacity. Duke-Margolis has described previously the many benefits AMTs can generate, including increasing quality assurance and reducing manufacturing downtime when quality issues are detected, reducing per-unit production costs after initial investment, and increasing agility and flexibility in manufacturing especially for innovative therapies. Industry and government experts have also noted the improvements AMTs can achieve in terms of reducing the physical and environmental footprint of manufacturing sites – and correspondingly increasing the material efficiency of manufacturing – an area particularly important for increasing production of API in the U.S.

Given these numerous benefits, AMTs can help U.S. manufacturers remain competitive in the market with international suppliers, and indeed, about 80% of the pharmaceutical products made with AMTs are made in the U.S., per an FDA estimate as of 2021. Overall adoption of these technologies has been slow, however, due in part to uncertainty about the regulatory acceptability of implementing new technologies and to the high up-front cost of investing in them. This latter barrier is particularly challenging for generic manufacturers, who tend to have slimmer profit margins than branded manufacturers but whose products tend to be at higher risk of shortages. Policymakers therefore should prioritize the continued growth of advanced manufacturing in the U.S. with policies that help alleviate the regulatory and financial risk that manufacturers face when seeking to adopt these new technologies or methods.

advanced manufacturing of essential medicines for emergency preparedness and response. Previously, in 2020, ASPR had invested $812 million in a contract with Phlow Corporation to manufacture API for generic essential medicines. Additionally, ASPR works to secure the supply of medical countermeasures and pandemic-related medicines through programs such as the Strategic National Stockpile (SNS).

KEY CONSIDERATIONS AND RECOMMENDATIONS

Prioritize direct investments in "warm base" manufacturing capacity for products essential in public health emergencies: Investing directly in manufacturing may be particularly impactful and straightforward relative to other common approaches. It can, however, be a very costly option and difficult to scale. Given that direct financial support for domestic manufacturing of all medicines, or even all essential medicines, would be prohibitively costly and inefficient, policymakers should prioritize targeted investments in reliable, rapidly scalable manufacturing capacity for medicines that are likely to be needed for emergency response, especially public health emergency (PHE) response.

These investments should support a "warm base" of manufacturing capacity for small-molecule products essential for acute care, vaccines, monoclonal antibodies, antibiotics, and other PHE response products – the list of 86 Downselected Essential Medicines Needed for Acute Patient Care (created by the National Forum to Secure America's Supply Chain for Essential Medicines with support from ASPR and the Advanced Regenerative Manufacturing Institute) is a useful guide. Considerations should be included for different dosage forms needed by different patient populations to ensure timely access for all, including pediatric-appropriate medications for safer treatment and appropriate delivery for growing children. Manufacturing sites receiving these federal investments should be encouraged to use appropriate modernized manufacturing technologies and methods that enable them to quickly adapt to emerging needs. It may also be beneficial to encourage manufacturers to engage in risk-based inventory management practices – for example, maintaining an appropriate level of excess capacity or buffer inventory – to enable rapid scale-up to meet emergency needs without disrupting routine production or creating other shortages.

Build on existing capacity when feasible: To maximize cost-effectiveness, policymakers should seek out opportunities to scale up production from existing facilities by utilizing existing idle capacity, upgrading equipment to improve total capacity of existing facilities, or other approaches that build on already-established manufacturing capabilities when possible. A survey of 37 U.S. generic FDF manufacturing sites conducted by the API Innovation Center in 2022 found that these sites were operating at roughly 50% of their maximum capacity. Of the manufacturing sites with dormant or low-volume manufacturing lines, the survey suggested that 57% could be operational within one year and 86% could be at full production within two years. Establishing new manufacturing sites can take many years and require massive investments, so policymakers should assess, on a case-by-case basis, whether bringing idle manufacturing capacity back online may be a viable and cost-effective alternative and to what degree it is needed to address the key categories of risk described previously in this white paper.

Incorporate strategies for long-term sustainability: Finally, policymakers should think very carefully about long-term sustainability of domestic manufacturers they fund. It is critical that both the public and private partners in these ventures plan ahead for a path to viability in the market without direct government support. Efficient demand-side supports can further enable domestic manufacturing sites to remain sustainable and ready for emergency response. For example, Phlow Corporation, initially funded by ASPR's IBMSC, is actively working to establish and expand its commercial customer base. Phlow recently secured over $35 million in Series B funding, which is being used to enhance its commercial offerings and grow its contract development and manufacturing operations, known as cdmoX. Investments in networks of manufacturing partners may also generate efficiencies and enable sustainability, as in the case of ASPR's 2024 investments in the API Innovation Center and its partners at Mallinckrodt Specialty Generics, Apertus Pharmaceuticals, MilliporeSigma, and the University of Missouri–St. Louis.

Environmental sustainability is another critical consideration for the long-term viability of domestic manufacturing. Policymakers should consider funding research and manufacturing of APIs using green chemistry — a practice dedicated to the elimination of hazardous waste and conservation of resources — to support a more sustainable pharmaceutical industry and mitigate adverse health outcomes associated with chemical waste.

Supply Chain Diversification Efforts in Other Countries

Onshoring manufacturing is not the only approach policymakers can or should use to increase the security and resiliency of U.S. drug supply chains. Creating domestic manufacturing sites for all drugs used in the U.S. would be prohibitively expensive – some estimates suggest, conservatively, that it can take five to ten years and up to $2 billion to build one new pharmaceutical manufacturing facility. Furthermore, numerous nations – including many close allies of the U.S. – are taking similar measures to diversify their own drug supply chains, and these international efforts provide opportunities for productive partnerships to bolster supply chain security and resiliency for all in a complementary and efficient manner.

European Efforts

Europe is already a significant source of pharmaceutical supply for the U.S. As of 2019, 26% of all API manufacturing sites supplying the U.S. were in the E.U. (compared to 28% in the U.S.), and E.U. member states have undertaken further policy actions since then toward onshoring and nearshoring for supply chain security. The European Commission's 2019 E.U. Pharmaceutical Strategy identified risks to the drug supply chain and recommended actions to onshore and nearshore manufacturing. The EMA's "Network Strategy to 2025" includes sections on supply chain challenges specifically citing the risks to supply posed by the E.U.'s

dependence on India and China for drug supply, including increasing geographic concentration of manufacturing in those countries and limited regulatory capacity for foreign inspections. The strategy recommends building more manufacturing capacity within the E.U.'s member states and partnering with other countries for additional capacity. The EMA, together with member states, created a list of critical medicines published in 2023.

A 2023 European Parliament study mapped API production in the region and suggested methods for reshoring the industry to establish a more secure supply chain. Europe's Critical Medicines Alliance is tasked with determining how to address supply chain vulnerabilities and recommending actions to "encourage diversification," including through nearshoring, and "boost manufacturing." The E.U.'s incoming Commissioner for Health and Animal Welfare is expected to propose a Critical Medicines Act "to address the severe shortages of medicines…and reduce dependencies relating to critical medicines and ingredients," as well as continue the implementation of reforms intended to ensure a "strong, competitive, and innovative pharmaceutical sector" in the E.U.

Individual states within the E.U. are also working to increase domestic drug manufacturing. As part of France's €7.5 billion investment into its Health Innovation Plan, the French government has invested €800 million for the development and production of biomedicines through 2030, with a focus on "20 drugs to treat cancers, emerging diseases and chronic diseases, including age-related diseases." This included a significant investment in Sanofi's API production in France. As part of a $248.8 million investment in the antibiotic network in Europe, in 2023 generic manufacturer Sandoz opened a new manufacturing facility in Austria to increase production of penicillin. The company invested $160.4 million in the project to expand production, and the Austrian government invested $53 million in the project to meet the country's goals of additional domestic manufacturing of antibiotics. The U.K.'s National Health Service has publicly called on the U.K. government to onshore more manufacturing of essential medicines, and the U.K.'s Life Sciences Industrial Strategy set a goal to attract ten large and ten smaller manufacturing facilities to the U.K. over the next decade using "supportive policy and operating environment for medicines manufacturing." The UK's Vaccine Taskforce is currently undertaking work to build and strengthen the UK's vaccine supply chain by focusing on increasing domestic supply capabilities and engaging with pharmaceutical companies to invest in domestic manufacturing.

North and South American Efforts

Other North and South American governments are similarly interested in onshoring and diversifying sites of drug manufacturing. The Canadian government is investing in the revitalization of Canadian biomanufacturing. The U.S. and Canada have enacted trade agreements to facilitate trade of pharmaceutical products, improved regulatory harmonization to better align regulatory standards and reduce barriers to trade and investment, and engaged in joint research and development projects towards accelerating the development of new drugs and medical technologies. The Brazilian pharmaceutical market is also among the top ten worldwide, and the Brazilian government has encouraged the production of generic drugs, which has helped to reduce drug prices and improve access to essential medicines. Several multinational pharmaceutical companies have invested in Brazil, attracted by the country's large market and favorable business environment.

Some of these strategies and policy actions are closely aligned with the priorities of U.S. policymakers seeking to reduce geographic concentration in drug supply chains. Strategic international partnerships and coordination on drug supply chain diversification are necessary to ensure these efforts are complementary, rather than redundant.

Recommendations and Key Considerations for International Pharmaceutical Manufacturing Partnerships

The U.S. and other countries seeking to diversify their drug supply chains can reap benefits by coordinating and harmonizing their work through strategic policy and regulatory partnerships rather than competing with independent and potentially redundant efforts. International partnerships to supplement domestic manufacturing have previously proven fruitful for the U.S. in other critical industries, most notably semiconductor manufacturing. The CHIPS Act included appropriations for the State Department's CHIPS Act International Technology Security and Innovation (ITSI) Fund to enhance assembly, testing, and packing in partner countries of Mexico, Panama, and Costa Rica with additional sponsorships in allied countries such as Vietnam, Indonesia, the Philippines, and Kenya. The DOC also announced an Indo-Pacific Economic Framework for Prosperity (IPEF) Agreement which is meant to ensure a more resilient supply chain for semiconductors and other industries from partners in the region.

The U.S. has begun similar (though more nascent) efforts in pharmaceutical manufacturing, perhaps most notably the Biopharmaceutical Coalition, or Bio-5, collaboration between the U.S., EU, Japan, Korea, and India, coordinated in the U.S. by the Office of Pandemic Preparedness and Response. The Coalition will support secure biopharmaceutical supply chains especially for products used in pandemic and public health emergency response. It will focus on building resilient supply chains for APIs currently sourced in large part from China and seek opportunities for their governments and the private sector to deepen coordination on policy, regulations, R&D capabilities, and other tools.

The following recommendations and key considerations can ensure these partnerships have optimal impact on promoting geographic diversity in U.S. and global drug supply chains.

Advancing Regulatory Harmonization

As the U.S. and international partner countries work toward convergent goals related to diversifying their drug supply chains, they should seek to further regulatory harmonization as well. Regulatory harmonization can serve multiple useful purposes related to supply chain resilience and reliability. Meaningful progress toward harmonization will likely require action from policymakers and not just regulators, as FDA and other regulatory agencies may not have sufficient capacity to take on the work of harmonization absent additional funding and resource allocation.

Firstly, a harmonized regulatory environment among (for example) the Bio-5 member countries will make it easier and more attractive for industry to operate within and provide supply to those countries. It will also enable more rapid action to diversify manufacturing sites. Under the current regulatory environment, with differing regulatory requirements and individual application, inspection, and approval processes for each country, the process of qualifying a new manufacturing site can take years. If partner countries seeking to diversify their supply chains were able to establish a joint review and inspection process – even for just a specific subset of essential medicines as described in the following section – that process could be significantly streamlined and less costly. Harmonization alone would not likely be a strong enough incentive to cause manufacturers to establish or qualify new sites, but in combination with other efficient policy approaches as described in the first half of this white paper, it could have a significant influence on their decision-making processes and encourage industry participation in diversification efforts.

Secondly, a harmonized regulatory process for post-approval changes – or even the development of new, harmonized mechanisms for pre-approving contingency plans to be implemented in case of disruptions – would enable more rapid, agile response to PHEs and drug shortages. The average duration of a drug shortage as of 2023 was more than three years, up from an average of two years in 2020. This is likely due in part to misaligned market incentives but also, in part, due to the regulatory complexity of bringing new sites and suppliers online or switching production at an existing site to a new product to cover a

supply shortfall. FDA works closely with manufacturers to speed shortage response and restore availability to the U.S. market and should take a leadership role on the global stage in seeking alignment on these approaches with other national regulators. These same approaches will be valuable in responding to PHEs. The International Coalition of Medicines Regulatory Authorities (ICMRA) completed a pilot program in June 2024 that allowed sponsors to submit one post-approval change management protocol for assessment by multiple regulators, with joint hybrid facility inspections accompanying the joint application assessment. The pilot enabled the participating regulators to reach independent decisions within days of each other, with reduced burden on industry participants. The U.S. and other countries partnering to build supply chain diversity and security should build on this model to support a more nimble, resilient drug supply chain. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) are also viable fora for harmonizing elements of pharmaceutical regulation that significantly affect the resilience and reliability of global supply chains.

Coordinating Target Products

There is potential for harmonization around critical or essential medicines lists used by different regulators, and cooperation is needed for international coordinated efforts to manage supply chain risks. Regulators such as EMA and FDA have established their own lists of essential or critical medicines, so enhanced collaboration between these organizations could ensure better preparedness and response to medicine shortages. While it is beneficial for individual countries or specific regions to have their own essential medicines lists, given that health care needs vary globally, agreeing upon a shared list of priority medicines and key data needed to assess guide supply chain resilience and diversification efforts would be beneficial. A number of fora exist that could facilitate such coordination, including the World Health Organization (WHO) which has its own List of Essential Medicines that is updated biannually, ICH, and ICMRA.

Scaling Production with New Partners in Emerging Markets

Building capacity through existing partnerships in geographically diverse countries that currently have limited manufacturing capability is an underexplored and efficient opportunity to invest in the drug supply chain's absorptive resilience. Strategic partnerships with new and emerging markets in support of harmonized production could be another key element of the U.S.'s multifaceted effort to secure the global and domestic supply chain against future shortage risk, as well as strengthen alliances in the face of national security risks. The U.S. could leverage existing health care partnerships with governments and organizations in low- and middle-income countries that are not currently manufacturing hubs to support growth towards becoming API suppliers in their own regions and the global market.

Efforts are currently underway to support the development of vaccine manufacturing capacity in numerous African countries, led by the African Centers for Disease Control. Organizations such as the Clinton Health Action Initiative (CHAI), PATH, USP, Gavi, and others are supporting these efforts. Private firms including BioNTech have invested in the development of manufacturing facilities on the African continent and aim further to support capacity-building for manufacturing. Similar efforts are also underway in the Asia region. The U.S. government is already supporting a few initiatives to build manufacturing capacity in emerging markets. USAID is currently invested in the *Diversifying Asia's Pharmaceutical Supply Chain initiative,* which provides $5 million to fund Kazakhstan's and Uzbekistan's pharmaceutical manufacturing, governance, procurement regulatory systems, technology, and workforce development in the Central Asian region. The FDA and USP also cosponsored the Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue to discuss the security of the regional and global drug supply chain and USP, commissioned by APEC, developed a Roadmap for Supply Chain Security. In the near term, the U.S. government should build on the growing momentum in regions such as Southeast Asia and Africa, with the long-term goals of promoting geographic diversification in drug manufacturing and harmonization in related regulations.

CONCLUSION

Dependence on manufacturing sites outside of the U.S., particularly in China and India, for a significant proportion of the drug supply has created important risks to the stability and security of that supply – particularly for products that involve innovative manufacturing processes or sensitive IP, or products for which there are few or no alternative sources. Policymakers should assess these risks carefully on a case-by-case basis and weigh the costs and potential unintended consequences of interventions to shift manufacturing sites to the U.S. or to international partner countries. When such policy interventions are found to be an efficient and cost-effective means of alleviating supply chain risks, the key considerations and recommendations described in this brief can guide impactful and targeted efforts to promote supply chain resilience and security.

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Appendix A: Policies and Proposals for Mapping, Assessment, and Transparency

Proposal, Policy, or Program	Description of Provisions or Actions Related to Mapping, Assessment, and Transparency	Status
Executive Order 14017, America's Supply Chains	Launched an all-of-government assessment of the vulnerabilities in U.S. supply chains, with a special focus on pharmaceuticals and APIs.	Issued on February 24, 2021.
Bold Goals for U.S. Biotechnology and Biomanufacturing	Established national goals for the next two decades to advance the bioeconomy, in accordance with Executive Order 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe and Secure American Bioeconomy.* Includes a plan to "enable prediction of at least 50 percent of supply chain weaknesses" within 5 years.	Published March 2023 by the White House Office of Science and Technology Policy.
Supply Chain Center (SCC)	Created within the DOC to address supply chain challenges across sectors.	Established 2023.
Advisory Committee on U.S. Supply Chain Competitiveness (ACSCC)	Recommends policy in support of U.S. manufacturing to meet the goals of export growth, economic competitiveness, and supply chain improvements.	Established November 2011.
National Institute of Standards and Technology (NIST) Grant Competition	Funded the winners of an industry-driven consortia tasked with the development of technology roadmaps to address high-priority research challenges focused on advanced manufacturing in the U.S.	Competition announced June 17, 2021.
Supply Chain Strategies and Nearshoring Opportunities in the Americas	Outlined opportunities and recommended policy that would enable industry to nearshore manufacturing closer to the U.S. The paper highlighted industry's interest in moving some production out of Asia and the potential for more manufacturing investments in the Americas. Proposed leveraging public-private cooperation to implement trade agreements, capitalizing on existing trade agreements, establishing honest regulatory standards and anti-corruption measures, and expanding cooperative agreements or protocols with regional partners.	Published October 24, 2023.
SHORT SUPPLY: The Health and National Security Risks of Drug Shortages	Examines the health and national security risks of drug shortages in the U.S. and recommends addressing the drug shortage crisis through measures such as improving data collection and transparency, and enhancing regulatory oversight.	Published March 2023.
Coronavirus Aid, Relief, and Economic Security (CARES) Act	Expanded the drug listing and reporting requirements to give FDA greater visibility on the volume of finished drug products and APIs manufactured domestically and abroad for the U.S. market. ——— Required the National Academies of Science, Engineering, and Medicine (NASEM) to examine and report on the security of the U.S. medical product supply chain, including U.S. dependence on critical drugs and devices from other countries.	Signed into law March 27, 2020. ——— Published 2022.
Mapping America's Pharmaceutical Supply (MAPS) Act	Requires HHS, DoD, and DHS to map the entire U.S. drug supply chain from start to finish and use data analytics to identify vulnerabilities.	Introduced by Sen. Gary Peters (D-MI) on July 18, 2023. Referred to the Senate Committee on Health, Education, Labor, and Pensions.
Pharmaceutical Security Production Act	Establishes a Commission on Strengthening the Domestic Pharmaceutical Supply Chain, tasked with initiatives including the implementation of the Biomedical Advanced Research and Development Authority's (BARDA) Pharmaceutical Manufacturing in America program, strengthening domestic manufacturing workforce, and increasing federal-state coordination.	Introduced by Rep. Ritchie Torres (D-NY) on June 30, 2023. Referred to the House Energy and Commerce Subcommittee on Health.
Pharmaceutical Supply Chain Risk Assessment Act of 2023	Requires HHS, DoD, DHS, and OPPR to conduct a risk assessment of supply chains for essential medicines and identify statutory authorities available to mitigate those risks.	Introduced by Sen. Gary Peters (D-MI) on June 13, 2023. Referred to the Senate Committee on Health, Education, Labor, and Pensions.

Appendix B: Policies and Proposals for Demand-Side Supports

Proposal, Policy, or Program	Description of Provisions or Actions Related to Mapping, Assessment, and Transparency	Status
Executive Order on Ensuring the Future Is Made in All of America by All of America's Workers	Promotes enforcement of rules that encourage or require U.S. government agencies to purchase domestically made products whenever possible, including pharmaceuticals. Establishes the Made in America Office under the Office of Management and Budget.	Issued on January 25, 2021.
Domestic N95 Respirator Payment Adjustments	Provides a payment adjustment to hospitals for the cost differential associated with purchasing domestically-made N95 respirators compared with those made outside of the U.S.	Implemented July 3, 2023
Drug Shortage Prevention and Mitigation Act	Provides a small bonus payment to providers who purchase generic sterile injectable drugs from domestic manufacturers.	Draft legislation released by the Senate Finance Committee for public comment in May 2024.
Pharmaceutical Security Production Act	Creates a Commission on Strengthening the Domestic Pharmaceutical Supply Chain tasked with exploring options for CMS to support the market for domestically made drugs.	Introduced to the House by Representative Ritchie Torres (D-NY) in June 2023 and referred to the Subcommittee on Health in July, 2023.
The Pediatric Cancer Drug Supply Act of 2024	Directs HHS to contract with drug manufacturers to produce and hold inventory of essential pediatric cancer medicines	Introduced to the House Energy and Commerce Committee by Representative Anna G. Eshoo (D-CA) and referred to the Subcommittee on Health in January 2024.

Appendix C: Policies and Proposals for Indirect Investment and Support

Proposal, Policy, or Program	Description of Provisions or Actions Related to Mapping, Assessment, and Transparency	Status
FDA-NIPTE Grant Awards	$35 million grant awarded to NIPTE by the FDA that was used to "improve America's manufacturing competitiveness and create high-paying jobs at home" and "reverse the current outsourcing trends in the pharmaceutical industry in the long term by decreasing the cost of manufacture."	Awarded 2011 over a 5-year period
Economic Development Administration's Strategy Development Grant	$499,999 Strategy Development Grant that was awarded to Southeast Biotech Collaborative (SEBC) Strategy Development Consortium to develop "a regional strategy to advance biomanufacturing, biologistics, and precision population health to reduce national dependence on foreign suppliers and reduce drug shortages."	Announced October 2023
Consolidated Appropriations Act of 2023	Directed the U.S. Food and Drug Administration (FDA) to fund up to five Centers of Excellence in Advanced and Continuous Manufacturing at U.S. universities to expand research capacity for advanced manufacturing technologies, accelerate drug development to respond to public health threats, develop the domestic manufacturing workforce, and other aims.	Introduced to the House Oversight and Reform Committee in April 2021, became Public Law No. 117-328 in December 2022.
The MADE in America Act	Establishes a tax credit of 25% of production expenditures for domestic manufacturing of drugs or up to 30% if production occurs in a "qualified opportunity zones" with high poverty rates	Introduced and referred to the House Ways and Means Committee by Representative Earl Carter (R-GA) in April 2023.
State of Indiana-Eli Lilly & Company Grants	A partnership that provides up to $4.5 million in the form of incentive-based training grants. The state also committed an investment of up to $17 million in redevelopment tax credits based on the company's plans to invest around $12 billion in manufacturing in Indiana.	Announced April 2023
State and Local Government Land Purchasing	The state of Indiana redirected $88 million to support manufacturing in Boone County. $56 million will fund the acquisition of 2,500 acres of land for manufacturing, while $29 million will be directed towards infrastructure improvements.	Approved June 2024

Appendix D: ReVAMP Consortium Advisory Group

This report was informed by the work of the Duke-Margolis ReVAMP Drug Supply Chain Consortium and made possible by funding from Consortium membership fees. The following is the Consortium Advisory Group membership list as of the time of publication. We thank these members and many of their colleagues for their input and support. A regularly updated list of Consortium Advisory Group members is available on the Duke-Margolis website.

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