BUILDING A RESILIENT DOMESTIC DRUG SUPPLY CHAIN: THE PATH TO NATIONAL HEALTH SECURITY

Prepared by:
The API Innovation Center
March 25, 2025

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EXECUTIVE SUMMARY

In the past year, the API Innovation Center (APIIC) has continued to work to address an alarming issue of national importance: the United States' overdependence on foreign production for hundreds of medicines Americans rely on every day. More than four out of five of the top 100 generic medicines consumed in the United States have no U.S. source of their active pharmaceutical ingredients, or APIs — the components of the medicines that provide the therapeutic benefits. Meanwhile, about **72% of FDA-approved API manufacturing facilities** are located outside of the U.S., with many in China and India.

APIIC research has shown that U.S. drug makers lack incentives to produce the APIs for these drugs due to a combination of economic, regulatory and market factors that favor overseas production. Massive subsidies by foreign governments, lower production costs and lax government regulations have driven pharmaceutical companies to offshore API production and manufacturing. Initial costs and uncertain return on investment also hinder the adoption of advanced manufacturing technologies (AMTs) that could streamline domestic drug production. Another issue facing domestic drug manufacturers is a statutory loophole affirmed in federal court that allows companies to label products as "American-made," even if the APIs are produced overseas.

All these factors put domestic manufacturers of generic drugs, particularly, at a disadvantage. These generic drugs are the workhorses of the health care system, comprising **92% of all the medications Americans take daily**. Overreliance on foreign manufacturers puts the nation at risk of losing access to these critical medications.

APIIC's position on these issues is clear: Solving the economics that disincentivize domestic drug production will solve the problem of persistent drug shortages. For years, policymakers, industry professionals, health care professionals and patients have experienced frequent drug shortages — many attributable to vulnerabilities in the drug manufacturing supply chain. In September 2024, more than 320 essential medicines were on **an American Society of Health-System Pharmacists' shortage list** — an all-time high at that point. These shortages are a symptom of demand- and supply-side shocks that disrupt the flow of APIs and the availability of the medicines they power.

APIIC also recognizes that the existence of multiple drug shortage lists — we identified 11 in **last year's white paper** — is a missing link that needs to be addressed. While each list is created to serve a specific constituency, the existence of multiple lists fragments the nation's focus on which drugs manufacturers should prioritize to meet public (e.g., military) and private (e.g., hospitals) demand. One such list from the U.S. Food and Drug Administration (FDA) tracks shortages of essential medicines, which it defines as those most needed in U.S. acute care medical facilities for severe injuries, illnesses and urgent medical conditions. We must also track "critical medicines" — those medicines on which Americans rely daily, and, if deprived of, would be catastrophic for U.S. health security.

This white paper, the second of five planned white papers, distills APIIC's work over the past 12 months to research, advise, invest and collaborate with key stakeholders to address this critical risk. That work coalesced at its second annual plenary event on Nov. 13, 2024, in St. Louis, Missouri. There, APIIC gathered experts from across industry, nonprofit, academia and government to evaluate prior-year results and inform its recommendations for a multifaceted approach to enhancing the resilience and security of the U.S. pharmaceutical supply chain. Those recommendations included:

- **Invest Strategically:** Upgrade underused existing domestic manufacturing capacities by incentivizing manufacturers to adopt AMTs. Provide guaranteed contracts and volume commitments to encourage investment.
- **Measure and Refine:** Implement and refine the APIIC industry progress scorecard (see Appendix) to track advancements in domestic pharmaceutical manufacturing, focusing on metrics beyond cost, including quality and supply chain resilience.
- **Close the Acetris Loophole:** Address the court's interpretation of the Trade Agreement Act of 1979, which now allows finished drug products using foreign-made precursor ingredients to qualify as U.S.-made. Ensure that federal procurement practices incentivize domestic manufacturing of both APIs and finished drug products.
- **Create Central Coordination:** Identify a point agency to lead coordination among federal agencies, the states and the public-private sectors engaged in the reshoring manufacturing of drug components such as APIs and key starting materials (KSMs).
- **Create a Unified Drug Shortage List:** Consolidate the many existing lists of essential and critical medicines into a single reference point, prioritizing essential medicines and those at risk of shortage, or align on an agreed-to public-private prioritized subset of drugs critical for national health security.
- **Support AMT R&D:** Increase funding for AMT research and development, especially for generic drug manufacturers.
- **Build a Buffer Inventory:** Establish a federally supported strategic stockpile of critical medicines, including APIs and other drug substances with longer shelf lives, to mitigate shortages.
- **Prioritized Quality:** Reform the reimbursement system to incentivize domestic manufacturing of quality generic drugs and precursor ingredients. Prioritize U.S.-made drugs for FDA review, and reward U.S. manufacturers that demonstrate a consistent commitment to quality with priority preference when awarding federal procurement pharmaceutical contracts.
- **Comprehensive Approach:** Consider the entire pharmaceutical supply chain and use predictive analytics to identify and mitigate risks that lead to drug shortages.

The recommendations outlined here speak to the urgent need for a comprehensive national plan that considers the entire supply chain — from KSMs and APIs to finished drug products and their distribution. The path toward a secure and resilient domestic pharmaceutical supply chain demands deep collaboration among industry, government and other stakeholders. This is a roadmap toward a stable, secure and resilient supply of essential medicines for the nation.

ABOUT THE API INNOVATION CENTER

APIIC is the nonprofit strengthening national health security through a proven public-private partnership model. Leveraging our operational framework, APIIC unlocks its private sector network by bringing together the right set of consortium partners that ensure long-term economic viability of U.S.-based production of active pharmaceutical ingredients. Uniting government, industry and academia to advance technology and optimize underutilized manufacturing facilities, APIIC is building a more resilient pharmaceutical supply chain. APIIC's mission is to ensure that every hospital, pharmacy and patient has access to domestically produced critical medication to support national health security. APIIC is supported by grants awarded through the state of Missouri, the Missouri Department of Economic Development and the Missouri Technology Corporation. To learn more, visit: **apicenter.org**.

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ACKNOWLEDGEMENTS

The API Innovation Center would like to give special thanks to our moderators, panelists, presenters and workgroup leads for their contributions to the plenary and the resulting paper. Special thanks to workgroup leads Betsy Baer from U.S. Pharmacopeia and Elizabeth Bergman from Waters Corporation. We also thank our moderators and panel leads from the API Innovation Center for their additional support and dedication. Thank you again to our panelists, whose insights and expertise enriched the discussions, contributing substantially to the recommendations of this paper.

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I. INTRODUCTION

For many years, policymakers, health care professionals and industry experts have dealt with issues arising from the fragility of the U.S. medical supply chain and the nation's overreliance on foreign sources for APIs and finished drug products. The primary effect: frequent and persistent drug shortages affecting the availability of generic medicines, which account for more than nine out of 10 drugs that patients use every day and leaving our national health security vulnerable to future supply shocks. The vast majority of drugs consumed in the U.S., including essential antibiotics and antivirals, have no domestic source of APIs, the components of the medicines that provide the therapeutic benefits. Should our supply of APIs be disrupted, either intentionally or unintentionally, the consequences could be severe.

The COVID-19 pandemic illustrated the issue clearly as lockdowns in China and India, where most APIs are manufactured, exacerbated the supply chain vulnerabilities. The pandemic emphasized the risks of relying on long, complex supply chains as it represented a significant demand-side shock.

America is also at risk of supply-side shocks to its U.S.-based medical supply chain. One example occurred in September 2024, when **Hurricane Helene damaged a Baxter International facility in North Carolina**, leading to a major disruption in the supply of intravenous (IV) fluids. The disaster required expedited U.S. government approval for temporary imports of IV fluids, and partnerships with South Korean producers. Disasters such as Helene, or geopolitical shocks, can affect the flow of drug manufacturing components — or finished drugs — into the United States. Today, the U.S. continues to rely heavily on foreign sources for the manufacture of APIs. This dependence continues to create a significant national health security risk, affecting the nation's resilience in ensuring access to medicines.

“IN THE PAST YEAR, THE NUMBER OF DRUGS CLASSIFIED IN SHORT SUPPLY REACHED AN ALL-TIME HIGH OF 323.”

DRUG SHORTAGES BY THE NUMBERS

The United States’ dependence on foreign sources of drug and API manufacturing is underscored by the record-high number of drug shortages in the U.S. In the past year, the number of drugs classified in short supply reached an all-time high of 323. At the time of this writing, the American Society of Health-System Pharmacists (ASHP) had 237 drugs on its list. However, the numbers may differ: A variety of organizations and agencies maintain separate lists of drug shortages. At this time, the FDA’s drug shortage database listed 99 drugs as “currently in shortage.” Meanwhile, these lists do not consider drug therapies that might be classified as “vulnerable medicines,” which are drugs with a high likelihood of falling into short supply because of supply chain risks. U.S. Pharmacopeia (USP) advocates for a list of such drugs and maintains a medicines supply map for its members to monitor supply chains in order to anticipate and respond to shortages.

“We’ve not yet seen a list that combines the essential medicines list with those drugs that are important to the retail sector,” said Kevin Webb, COO of APIIC. **“Depending on which list you want to look at, you could get a different answer. In conversations with various agencies, they recognize that. There’s awareness, and now, at least it’s being discussed.”**

Recognition and awareness of the broader issue — the decline of domestic API production and its effect on national health security — extends through the halls of Congress and into the White House. In those corridors, broad bipartisan support remains for addressing the root causes, with an emphasis on building a robust manufacturing economy and bolstering national health security.

THE COMMODITIZATION LOOP

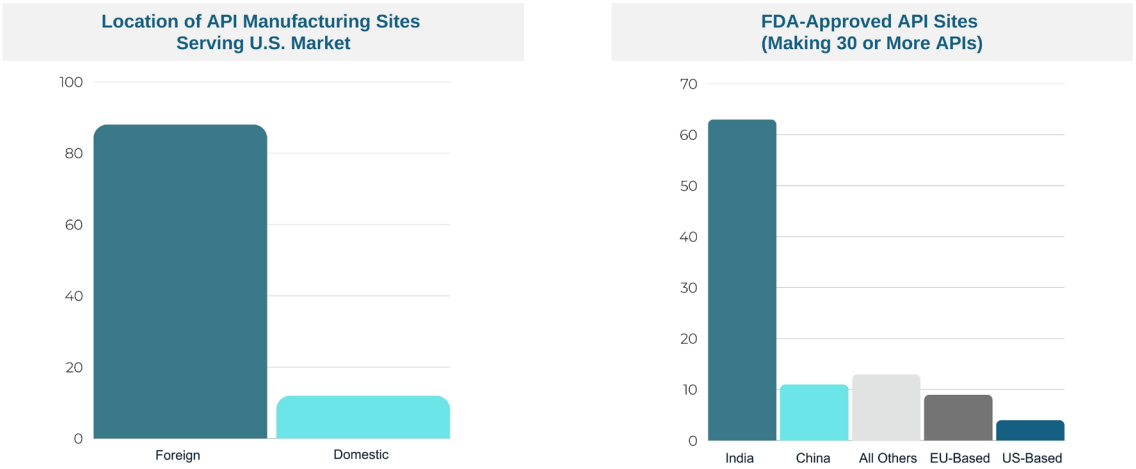
Also unchanged since APIIC's 2024 report: the reasons domestic API manufacturing has declined. Fundamentally, pricing pressure creates extremely low profit margins; domestic drug makers see poor returns on their investments in manufacturing APIs and generic medicines. The pursuit of lower production costs has driven many pharmaceutical companies to offshore API and drug production to countries such as China and India. While this has resulted in lower prices for generic medicines, it has also contributed to the erosion of our domestic pharmaceutical manufacturing base. As APIIC has previously noted, this "commoditization loop" is an economic model that disincentivizes U.S. drug manufacturers from producing APIs or generic medicines, thanks largely to a "race to the bottom" in generic drug pricing.

"There's a high cost of a low price, and it's creating havoc and fragility of our supply chain," Anthony Sardella, chair and founder of APIIC, said at the plenary event, reiterating a point **he made in congressional testimony** in May 2023. This cycle of low profitability, uncertainty in pricing and low capital availability challenges the ability of companies to reinvest in operations or adopt new technology. This lack of financial incentive results in low production and underutilized manufacturing capacity in the United States — which continues to contribute to drug shortages.

"Over the past 30 years, the generic pharmaceutical industry has consolidated and increasingly offshored its production to countries with lower labor and manufacturing costs in response to low profit margins," Sardella wrote in a **September 2022 research paper focused on underused drug manufacturing capacity. "Factors that put U.S.-manufactured pharmaceuticals at a competitive disadvantage include foreign government investments, lower offshore operating costs and labor rates, and dependency on offshore sources for raw materials."**

Where Are Our Drugs Coming From?

Less than 5% of large-scale API sites, globally, are located in the U.S. The majority of large-scale manufacturing sites are in India and China.



Source: Sardella, A., "The U.S. Active Pharmaceutical Ingredient Infrastructure: The Current State and Consideration to Increase US Healthcare Security." Olin Business School, Center for Analytics and Business Insights, Washington University, August 2021.

ECONOMIC CHALLENGES PERSIST

Plenary participant Andrew Gonce, senior vice president, commercial and strategy, of Mallinckrodt Specialty Generics, noted that the price profile for generic drugs had declined significantly. The market for many generics has become unattractive for U.S. manufacturers. The U.S. pharmaceutical industry faces an uneven playing field in the production costs for generic drugs and their APIs. Overseas manufacturers, especially in China and India, benefit from cost advantages such as government subsidies, lower labor costs and less-stringent environmental regulations. This exacerbates that "race to the bottom," in which price, rather than quality, becomes the main driver, eroding profit margins for U.S. companies. This cost advantage has made it difficult for U.S. companies to compete, leading to a decline in domestic manufacturing.

SOLUTIONS: BOLSTERING DOMESTIC DRUG MANUFACTURING

Numerous economic issues contribute to the country's national health security problem. APIIC's November 2024 plenary reviewed the ongoing issues, and raised other previously unexplored issues, providing a nuanced or more fully formed version of the persistent themes.

2024 EMERGENT THEMES

A Comprehensive National Plan

APIIC has advocated for frameworks that encourage industry adoption of advanced manufacturing technologies and public incentives to increase domestic API and generic drug production. AMTs are crucial for modernizing pharmaceutical production and enhancing the country's ability to compete in a global market. AMTs such as continuous flow manufacturing vary from traditional batch processing methods. Batch processing involves performing a series of chemical transformations in sequence in a single reactor system. Continuous flow manufacturing increases efficiency and reduces production times; improves product quality and reduces waste; lowers manufacturing costs; enhances safety through minimized exposure to hazardous materials; and provides greater flexibility and responsiveness to changing market demands. Adopting these technologies can play a pivotal role in reshoring API production to the United States. APIIC gathered industry leaders at its 2024 technology conference to explore the benefits of, and barriers to, adopting advanced manufacturing technology. Findings were further explored in **APIIC's market research report, released in February 2025**.

"It's all good until it's not, until you can't get that medicine. With the geopolitical risks, the naturally occurring disasters, all of these insults to our supply chain — building resilience needs to be a priority," said panelist Monique K. Mansoura, executive director, global health security and biotechnology, of The MITRE Corporation. **"There are times where the federal government in its own national security and economic security interest has to be part of that solution."**

Public incentives could be pivotal in revitalizing the U.S. generic drug industry and ensuring a stable supply of essential medications. Incentives could include direct federal investment in the domestic manufacturing base, such as funding for research and development to advance AMTs, improving existing manufacturing processes and developing innovative drug formulations. Or they could include grants for infrastructure development, supporting the modernization or construction of manufacturing facilities, especially those focused on producing critical APIs. Meanwhile, the Department of Defense's Office of Strategic Capital has created a loan program to attract and scale private capital for critical technology, including pharmaceutical manufacturing. Yet, while loans may be a valid investment option, the low ROI generic drug makers gain may make it difficult to repay these loans.

A national comprehensive industrial plan, however, would go beyond those two strategies — the shift to AMTs, encouraged with incentives — to encompass the following:

- **Prioritizing critical APIs:** This is essential for bolstering the U.S. pharmaceutical supply chain. Policymakers, industry leaders and health care professionals need a single, comprehensive list of critical drugs. Although other drug shortage lists exist, no one has spearheaded a coordinated effort to establish a single, national list. Such a list would require input from various stakeholders to determine the nation's priorities and should consider drugs of critical national importance; drugs that are essential or strategically important to U.S. health security; and drugs that are vulnerable to shortages or are sourced entirely from other countries.
- **Investing in workforce development:** A skilled workforce is essential for operating advanced manufacturing equipment and implementing innovative production processes. Universities and training institutions, including technical schools and junior colleges, must take the lead in developing and updating curricula and programs to address the specific needs of the industry, such as upskilling and reskilling workers to adapt to new technologies and processes. Partnerships among industry, academia and government are crucial for creating a robust workforce development strategy. These partnerships can facilitate the development of relevant curricula, provide hands-on training opportunities and ensure that training programs align with industry needs. "The demand for workforce in pharmaceutical science was diminishing because of the offshoring, and because of basically outsourcing to Asia," said panelist Vadim Gurvich, executive director, National Institute for Pharmaceutical Technology and Education. "It's very interesting to see that we made this full circle now because we're talking about how we can reshore/onshore again."
- **Strengthening supply chain resilience:** This requires several strategies.
  - **First,** develop a coordinated upstream supply chain mapping strategy to trace the origins of APIs and KSMs to identify risks and vulnerabilities. Mapping would identify where suppliers are geographically located and help mitigate the effects of a supply disruption when geopolitical and economic disruptions occur.
  - **Second,** reduce our dependence on single suppliers or geographically concentrated production locations by exploring alternative sourcing options, promoting domestic production of critical APIs and KSMs, and fostering partnerships with reliable suppliers in strategically diverse locations.
  - **Third,** focus on maintaining rigorous quality standards at every stage of the pharmaceutical supply chain, from raw material sourcing to finished drug production. Apply robust quality control measures, collaborate with trusted suppliers and leverage advanced technologies to enhance quality assurance.
  - **Finally,** rely on data-driven approaches and predictive analytics to identify potential supply chain disruptions before they occur. This will enable proactive risk mitigation, inventory management and demand planning to ensure the continuous availability of essential medications. **"Everyone's talking about supply chain resiliency and how to improve it. I think we've got a window of opportunity, policy-wise, to do it,"** panelist Joe Hill, of U.S. Pharmacopeia, told attendees. **"[U.S. Pharmacopeia is] looking at the KSMs, not just APIs, to map out where they come from, their risk profiles, those types of things. We're hopefully letting that data kind of point us in the right direction."**

- **Reforming reimbursement policies:** This strategy speaks to the demand side of the equation for drug manufacturers. Reimbursement reform would value quality, reliability and domestic production alongside cost, fostering a more sustainable and resilient pharmaceutical supply chain that can meet the needs of patients and health care providers. Today, reimbursement models often prioritize the lowest-cost medications, without adequately considering factors like quality, reliability and domestic sourcing. This creates economic instability, and disincentivizes manufacturers from investing in quality improvements, advanced manufacturing technologies and domestic production. Alternatively, reimbursement models could incentivize health care providers and hospitals to prioritize medications from manufacturers with strong track records of quality, reliability and domestic production. Tiered formularies could offer lower copayments for preferred medications, or by providing financial incentives to health care systems that prioritize these medications. Long-term contracts by health care providers could provide greater price stability and predictability of demand.

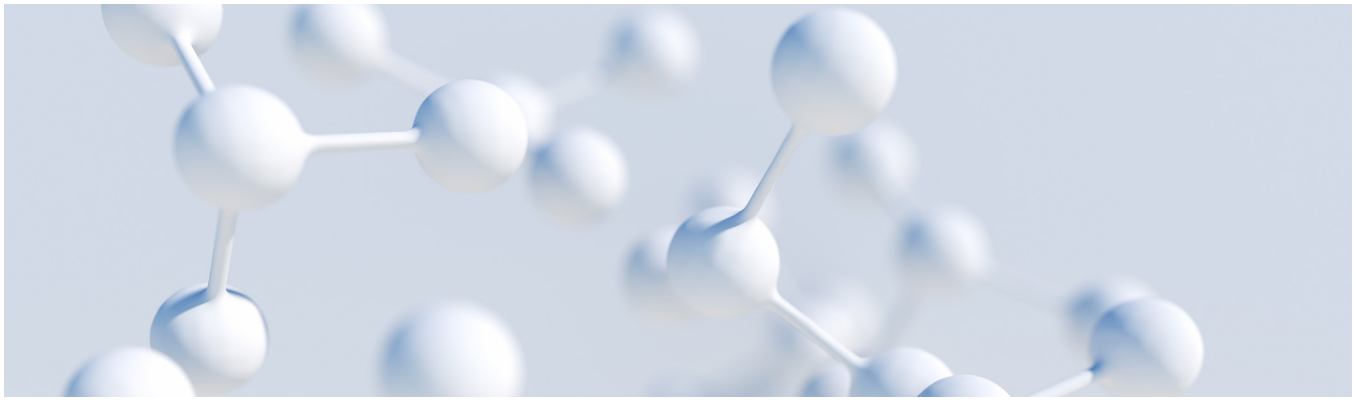
"It's not just that you have price pressure and margin pressure, but also, you have a lack of reliability in demand," said panelist Marta Wosińska, senior fellow, The Brookings Institution. "The demand is very unstable, and you don't know what you're investing in."

- **Leveraging existing infrastructure:** A significant number of existing manufacturing facilities, especially those belonging to generic drug makers, have idle production lines that could be brought back online with relatively modest investments. This issue was highlighted in a September 2022 research paper, "U.S. Generic Pharmaceutical Manufacturer Available Capacity Research Survey." **According to Sardella's report**, **"Nearly an additional 30 billion doses of essential and critical medicines could be produced in the United States without incurring the expense of building a new manufacturing plant."** This research and APIIC encourage contracting with existing current good manufacturing practice (cGMP) facilities and investing in technology transfer to enable the production of essential medications. This approach would reduce upfront capital expenditures, shorten lead times and rapidly increase domestic production capacity. Moreover, many of these facilities have decades of experience in producing pharmaceuticals, providing a valuable knowledge base and a skilled workforce.

- **Enhancing regulatory pathways:** Regulatory agencies such as the FDA should provide clear and comprehensive guidance on the use of AMTs in domestic pharmaceutical manufacturing, including outlining expectations for process validation, quality control and data integrity, as well as clarifying regulatory pathways for new technologies. **"As far as easy barriers to overcome, interestingly — and, I think, one of the biggest stigmas in the industry — is the regulatory hurdle,"** said panelist Omar Rana, associate director of MilliporeSigma. **"If regulatory agencies are willing to help us embrace new technology, there's no excuse from a regulatory standpoint taking the time-cost out of the way."** Though the FDA has **published guidance** specifically aimed at companies looking to adopt continuous flow manufacturing, including industry representation, there is a desire for the FDA to be proactive in evaluating and embracing emerging technologies and other innovative approaches that can enhance efficiency, quality and flexibility in pharmaceutical production.
    - Regulatory agencies could facilitate technology transfer and knowledge sharing among industry, academia and government by expanding workshops, conferences and training programs to disseminate best practices and promote the adoption of AMTs. The FDA could expedite approvals for products manufactured in the U.S. using AMTs, provided they meet rigorous quality and safety standards. Existing programs such as the FDA's Emerging Technology Team (ETT) and the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) should be leveraged to accelerate the review and approval of innovative manufacturing processes.

Finally, a comprehensive national industrial plan for reshoring domestic drug production would gain inspiration from other industries that have led the way in adopting AMTs. These technologies are not new; they're only seemingly new to the pharmaceutical industry. The automotive industry is perhaps best known for this strategy by making extensive use of robotics to assemble, weld and paint, or create high-precision components. Electronics manufacturers use pick-and-place machines to build circuit boards. Medical device makers use 3D printing. So does Nike, which has partnered with tech providers in prototyping and manufacturing its new shoe lines.

In the case of Toyota, the company planned to manufacture its Tundra pickup truck in Japan, and import it to the U.S. To avoid an expected 25% tariff, Toyota built a plant in San Antonio, began production in 2006, created jobs and stimulated economies in the U.S., Canada and Mexico. Generic drug makers could benefit from a two-pronged approach: direct government investment to reduce the risk of adopting AMTs (particularly in the face of pricing pressures); and commercial sustainability measures such as the previously mentioned reforms to reimbursement policies and procurement practices.



The Quality Component of Generic Medicines

The prevailing narrative that generic medications are entirely interchangeable with their branded counterparts, only differentiated by price, is a fallacy that has contributed to the fragility of the U.S. pharmaceutical supply chain. The message came through loud and clear at APIIC's November 2024 plenary: The existing system only rewards generic drug makers that can produce and sell their medicines at low cost, which doesn't always serve consumers and health care providers when those low costs force manufacturers to offshore their production and potentially risk quality. **"At the end of the day, most practitioners aren't giving much thought to where our products are made, or the quality in which they're being manufactured. And it's an unfortunate thing,"** panelist Michael Ganio, senior director, pharmacy practice and quality, American Society of Health-System Pharmacists, told plenary attendees. When faced with drug shortages, most patients don't have the liberty of caring about the quality or source of their medicines. In some cases, they need them to survive. The government must recognize and reward manufacturers who prioritize quality to ensure that all medicines are equal and accessible.

Gonce added that consumers buy only one thing at the drugstore where they can't identify the manufacturer: the medicine. Panelist Vic Suarez, founder and principal growth partner, Blu Zone Bioscience & Supply Chain Solutions, said the issue of quality control in generic drug production is a matter of trust: **"To get trust, you have to have a level of transparency, a level of reliability and a level of quality. You can have all three of those things."**

Yet, concerns about generic drug quality aren't isolated. On April 20, 2023, the industry trade journal Pharmaceutical Processing **zeroed in on drug recalls and the need for quality control**, citing issues with product contamination, sterility and undeclared ingredients:

> **"Quality issues, while cited in five recalls in January 2023, impacted 1.32 million units, demonstrating the far-reaching consequences of lapses in quality control. Examples of recent quality issues leading to recalls involve mislabeling, vial breakage, label mix-ups, dissolution test failures and incorrect labeling. For instance, Accord Healthcare recalled Daptomycin for injection in late 2022 because of mislabeling. In November 2022, Exela Pharma Sciences recalled Sodium Bicarbonate Injection as a result of vial breakage. In September 2022, a label mix-up led Golden State Medical Supply to recall clopidogrel 75 mg and atenolol 25 mg tablets."**

In December 2018, the FDA **published a news release highlighting a product recall**: The agency found that makers of the blood pressure medicine valsartan allowed a carcinogenic contaminant in the medicine. A shortage of that drug persisted for years. "Global valsartan purchases substantially decreased post-recall, highlighting the far-reaching impacts of drug shortages," according to a **January 2023 research article** published in the journal BMJ Open.

APIIC recommends incentivizing investments in quality, and *disincentivizing* the mentality that prioritizes price above all else. The FDA could consider establishing a national quality report card, highlighting those manufacturers that consistently invest in advanced and updated manufacturing capabilities while also requiring country of origin on packaging. In addition, the Center for Medicare and Medicaid Services (CMS) could prioritize medications for preferred Medicare formulary placement that are sourced from manufacturers that have demonstrated quantifiable quality objectives. This additional focus on quality would incentivize the industry to deliver continuous improvements in their manufacturing processes.

Leveraging Existing Data Resources and Expertise

Increasingly, governments, agencies, academia, nonprofits, and industry are seeking to develop large data resources to inform investments toward building a more predictive and data-driven approach to pharmaceutical supply chain management. This includes identifying and prioritizing which drug shortages to address first in manufacturing and onshoring efforts. Machine learning may be used to analyze potential routes of synthesis and identify opportunities.

"Something that often goes overlooked here is that you have so many folks — in the academic, the nonprofit and the private sectors — that have stood up so many data resources that are available for the government to leverage," said panelist Josh Narrow, director, The Conafay Group. **"As we think about all these proposals, do we need more entities set up in government to serve administrative options? That, I'm unsure about. It's a really good testament to how we can leverage existing data resources that are out there."**

Examples include:

- **Medicine Supply Maps:** USP's **map** is intended is intended to help identify, characterize and quantify supply chain risks. USP is an independent, scientific nonprofit organization that works to improve global health through public standards and related programs. Meanwhile, the University of Minnesota's **Drug Supply Map** is part of ongoing research on drug supply and market conditions. The goal is to know where drug supply is needed, where it is coming from, and what is needed to have the right facilities.
- **IQVIA Data-Sharing Model:** IQVIA is an example of a data-sharing model where wholesalers and manufacturers voluntarily report sales data through a trusted framework. This model can provide insights for critical supply chain decisions made by the federal government or purchasers/providers.
- **Cortellis Generics Intelligence dataset:** This dataset from Clarivate provides insights across the pharmaceutical sector, and it includes data on more than 64,000 small molecules and biologics, 72,000 manufacturers and marketers, 1.1 million worldwide patents and 62,000 regulatory documents.
- **Continuous Manufacturing Knowlege Center:** The National Institute for Pharmaceutical Technology & Education (NIPTE) and USP created a **continuous manufacturing database** with tools and resources to advance the adoption of continuous manufacturing. This database is an example of how knowledge management has led to partnerships that contribute to publicly available resources.
- **HHS Supply Chain Control Tower**: The U.S. Department of Health and Human Services (HHS) has shared **supply and demand data** for selected medications and is working to improve end-to-end visibility of the supply chain.
- **FDA Drug Shortage List:** The Food and Drug Administration (FDA) maintains a **list of current drug shortages** that is publicly accessible. The FDA also publishes annual reports to Congress on new and continuing shortages.

Instead of creating new entities, efforts should focus on making the most of the resources, data and expertise that already exist within established organizations and collaborations. This approach is seen as more efficient, cost-effective and strategic for addressing the complex challenges of the pharmaceutical supply chain.

Addressing the "Acetris" Ruling

This legal decision, affirmed by the U.S. Circuit Court of Appeals for the Federal Circuit on Feb. 10, 2020, broadened the definition of "manufactured" (in the context of drug production) to include activities such as compounding, mixing, weighing and measuring. Previously, under the Trade Agreement Act (TAA), the origin of a pharmaceutical was determined by where the API was made, unless a "substantial transformation" occurred. Today, a product could be considered American-made even if the API was sourced from outside the U.S. This is a problem. It undermines the intent of federal procurement policies to support domestic API manufacturing. It creates a loophole that allows foreign-made APIs to be used in products labeled as "U.S.-made." It discourages domestic API production by allowing companies to continue sourcing from overseas without penalty. It creates uncertainties in domestic API manufacturing. It hinders efforts to reduce dependency on foreign drug products. It has national security implications because it allows the U.S. to be dependent on foreign countries for essential medicines.

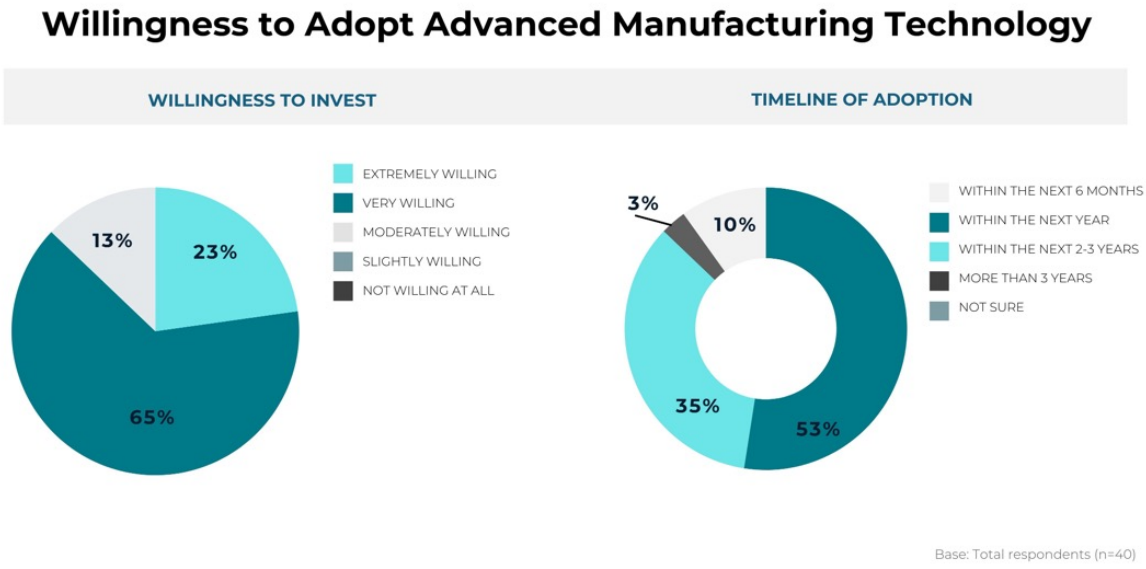
To effectively tackle these challenges, Congress must take statutory or regulatory action to clarify what "manufacture" means within federal procurement policies, and it must mean *developed domestically*. Without this clarity, foreign-made APIs will continue to be passed off as U.S.-made. However, a gradual approach to enforcing this definition is also essential: We must transform the pharmaceutical supply chain, but not by putting the supply chain at immediate risk.

The first step: The United States should create a carefully vetted, comprehensive list of APIs critical to our national security, then introduce targeted incentives to encourage domestic development and manufacturing of these APIs. Once incentives have time to take effect, these would be the first products enforced under the new definition of "U.S.-made." Systematically implementing these changes gives the supply chain time to adjust without jeopardizing the availability of essential medications. Together, these strategies — closing the Acetris loophole, taking a phased approach and introducing targeted incentives — are crucial for boosting domestic API production, decreasing reliance on foreign sources and protecting our national health security.

SUPPORTING INVESTMENT IN ADVANCED MANUFACTURING TECHNOLOGIES (AMTS)

The pharmaceutical industry has a strong familiarity with advanced manufacturing technologies. In a recent **technology adoption market survey** sponsored by APIIC, we found that 100% of survey respondents were familiar with continuous flow production technology. Further, a significant majority (88%) of survey respondents indicated that they were "willing to adopt" new technologies, with most rating their willingness a 4 or 5 on a 5-point scale. This shows a strong positive attitude toward integrating AMTs into their operations.

Though many respondents indicated a willingness to adopt AMTs within a relatively short time frame, with 53% saying their facilities would likely be ready within the next year, and a third planning to adopt the technology within two to three years, there is the realization that industry needs to overcome a host of barriers — cost being among the most significant — which may require continued government support, financial incentives and practical assistance.



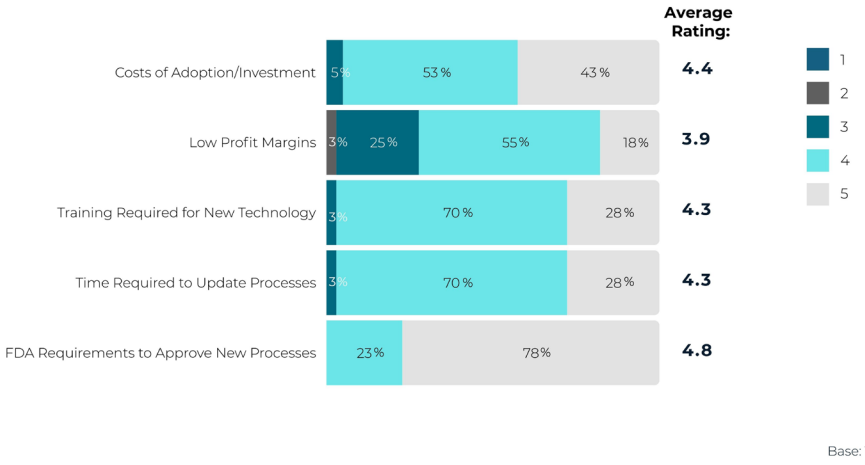
A10. On a scale of 1 to 5, what is your orginization's willingness to invest in advanced manufacturing technologies?;
A11. How soon do you think your orginization will be ready to adopt a new manufacturing technology if it proves to be beneficial?

Source: APIIC, "Benefits and Barriers to Adopting Advanced Manufacturing Technology in the Pharmaceutical Industry," Feb. 18, 2025.

"The U.S. government has to intervene in a way that it is not used to, or uncomfortable doing so," panelist Bayan Takizawa, co-founder and chief business officer of CONTINUUS Pharmaceuticals, said. **"It is important to recognize that other foreign governments have been intervening on behalf of their interest, and so the U.S. taking similar actions is not only justified, but also vital for our own national interests. Furthermore, it's going to be very hard to obtain funding from the private sector for especially those drugs that are very low-value, but still critical for American patients."**

One example to help ease the transition from batch to advanced manufacturing is an approach by Corning Inc. to apply scalable technologies that are viable and applicable at each level of demand. **"Awareness is still an uphill battle,"** panelist Jeremy West, commercial director of AFR & AFPT, Corning, told the plenary. To reduce the financial risks, Corning has developed an Advanced Flow Pharmaceutical Technologies (AFPT) lab, which will help companies assess their options without large initial investments in the equipment. This support and knowledge transfer eases drug manufacturers' adoption of AMT for commercial production.

Perceived Barriers of Advanced Manufacturing Technology



Base: Total respondents (n=40)

A9. Please rate the potential barriers to adopting advanced manufacturing technologies in your organization: (1 = Not a barrier, 5 = Major barrier)

Source: APIIC, "Benefits and Barriers to Adopting Advanced Manufacturing Technology in the Pharmaceutical Industry," Feb. 18, 2025.

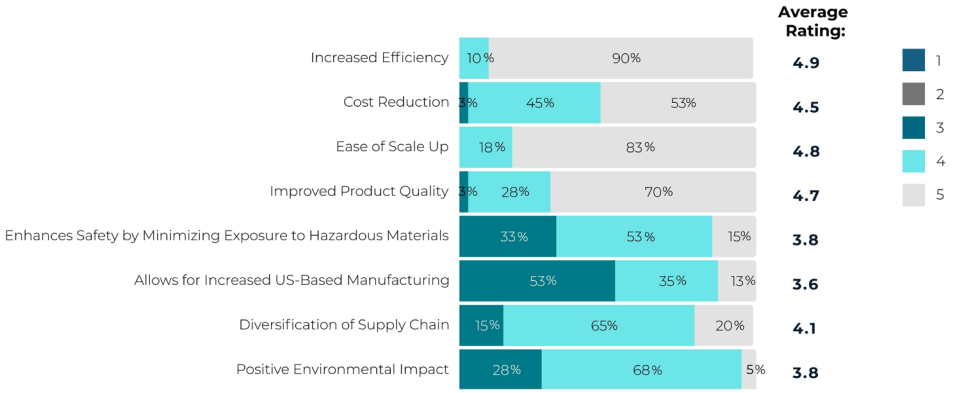
In addition to the investment cost, manufacturers cite other barriers, including regulatory hurdles and the training required to implement new technology. Regarding regulation, drug makers cite four areas of concern:

- FDA requirements: The length of time it may take to get regulatory approval for new processes, and the time required to amend regulatory filings.
- The uncertainty around regulatory agencies' views of continuous manufacturing and other advanced manufacturing techniques.
- Hesitation to change regulatory filings for fear of inviting deeper scrutiny.
- Concern that regulatory pathways for AMTs are not yet fully defined or streamlined, which could complicate the process.

Why AMTs Are Crucial

AMTs are essential for a competitive and resilient domestic pharmaceutical industry. AMTs such as continuous flow manufacturing can significantly reduce production costs, condensing processes from months to days, reducing labor costs and more efficiently using raw materials. Some estimates have shown that AMTs can reduce production costs between 30% and 50%, according to a report in Pharmaceutical Manufacturing, not accounting for the efficiencies realized by utilizing previously idle manufacturing production facilities.

Perceived Benefits of Advanced Manufacturing Technology



Base: Total respondents (n=40)

A8. Please rate the potential benefits of adopting advanced manufacturing technologies in your organization: (1 = Not beneficial, 5 = Extremely beneficial)

Source: APIIC, "Benefits and Barriers to Adopting Advanced Manufacturing Technology in the Pharmaceutical Industry," Feb. 18, 2025.

From its market research efforts, APIIC has found that the likelihood of boosting production efficiency drives the growing support for AMT adoption among industry leaders. This extends to the perception that these technologies can ease manufacturers' ability to scale up production when needed, drive down costs over the long term and diversify supply chains. Additionally, AMTs such as continuous flow manufacturing reduce batch variability — thus improving product quality.

AMTs also enable faster production timelines, which are critical for responding to drug shortages caused by supply-side surges (e.g., geopolitical shocks, closed borders, etc.) and demand-side surges (e.g., natural disasters, pandemics, etc.). The ability to quickly repurpose equipment for new molecules further enhances flexibility and responsiveness. As noted previously, continuous manufacturing can accelerate production timelines from months to days. Also noted earlier, quality concerns have emerged as an additional strategic imperative related to onshoring drug production, and AMTs facilitate higher product quality through better process control, reduced waste and more consistent manufacturing processes.

As noted in the previous section, 96% of respondents identified the cost of investment as a significant or major barrier to adoption. However, moderator Jason Rodriguez, director, division of pharmaceutical quality research II, office of pharmaceutical quality, FDA, added, **"It really is a high barrier to purchase at the time, but really, over the long term, the amount of testing or screening that you would be able to do with that is going to pay for itself more than anything else."**

In fact, 98% of respondents acknowledged cost reduction as a significant or major benefit. Over the long term, reduced production times will lower overall costs, and AMT processes will reduce waste, offering additional cost savings.

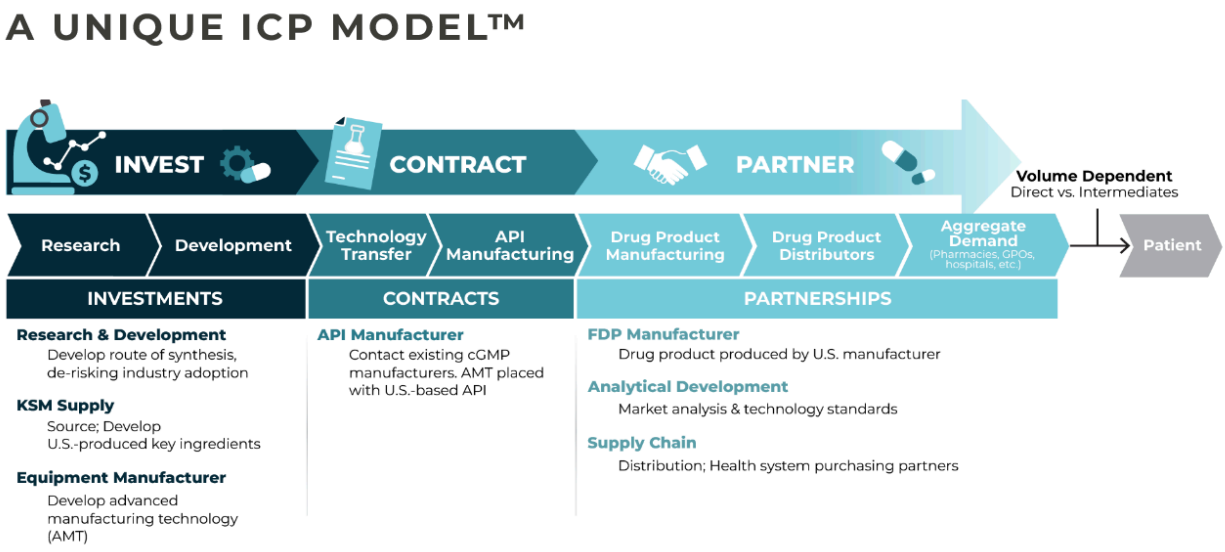
The adoption of AMTs in the U.S. creates new jobs in advanced manufacturing and stimulates the economy. The need for a skilled workforce to operate these technologies also encourages investments in education, training and workforce development programs.

Multi-Pronged Approach to Industry Adoption

APIIC's recommended approach to addressing manufacturers' concerns about adopting AMTs includes lowering costs, demonstrating efficiency, creating better regulatory pathways, providing workforce training and promoting collaboration and partnerships. For example, in the context of investment, policymakers and industry should stress the overall economic benefits, not only the up-front investment. AMTs can lead to long-term cost-effectiveness by decreasing production time and increasing efficiency.

To stimulate the U.S. pharmaceutical manufacturing base, APIIC has developed a novel model of building mini consortiums through partnership agreements to encourage and support public-private partnership and expand the production of essential and critical medications. The ICP Model™ is built on three components:

- **Invest:** APIIC invests in research and development of AMTs, including new methods for producing APIs and KSMs, and modernizing medicines. This involves working with equipment manufacturers to leverage advanced technologies.
- **Contract:** APIIC contracts with existing U.S.-based facilities that are ready and underutilized to manufacture APIs. This approach leverages existing capacity and can be implemented more rapidly than building new facilities.
- **Partner:** APIIC forms strategic partnerships with health care systems, retailers and drug manufacturers that include revenue-sharing agreements that enable long-term economic sustainability of manufacturer supply and cost for end customers.



Source: APIIC, "Benefits and Barriers to Adopting Advanced Manufacturing Technology in the Pharmaceutical Industry," Feb. 18, 2025.

This invest-contract-partner model aims to reduce up-front investment costs for companies, and to provide certainty of volume and price. **“People are willing,”** said presenter Tamara Fraley of PharmaACE, who conducted the survey in August 2024. **“The efficiency piece is the most important driver for people thinking about adopting continuous flow, but cost was the biggest deterrent. They’re worried about the investment.”** Furthermore, the market study indicated that continuous manufacturing can lead to increased efficiency and ease of scale-up, with the benefit of reduced waste.

Public-Private Partnerships

Through its ICP Model™, APIIC promotes the idea that no single company or technology will be a total solution to ensuring national health security. Collaboration will be critical to moving forward, and technology providers and pharmaceutical manufacturers, as well as government stakeholders and expert volunteers, must work together to foster greater adoption of AMTs. APIIC’s model is designed to facilitate collaborative partnerships. Indeed, APIIC’s work — and the ICP Model™ — has gained the attention of policymakers and industry for its effectiveness.

“APIIC has facilitated stakeholder partnerships with key players and innovators in the bioscience, pharma, tech and advanced manufacturing industries to create a sustainable network for the U.S. production of lomustine and other essential drugs,” California’s Institute of the Americas and the Burnham Center for Community Advancement wrote in a July 2024 strategy report on drug shortages. **“Their public-private model to build a resilient pharmaceutical manufacturing base could be a successful model for the nation,”** stated the institute’s senior advisor, John Fry.

This is significant because building and maintaining the nation’s health security requires a vast network of collaborative efforts, many of which are currently underway. **“These collaborations enable investment, economic growth, technological innovation, preparedness and national security,”** moderator Betsy Baer, senior director, U.S. Pharmacopeia, told plenary attendees. **“In addition, these collaborative efforts accelerate the development of new medicines and new advanced processes for manufacturing them.”**

Cost-sharing arrangements between public and private entities can help align funding priorities and ensure that resources are used effectively. For example, the U.S. Commerce Department's Advanced Pharmaceutical Manufacturing (APM) Tech Hub, centered in Richmond, Virginia, is a public-private partnership that seeks to accelerate the growth, innovation and sustainability of the U.S.-based pharmaceutical manufacturing industry. Other examples include:

- **ARPA-H (Advanced Research Projects Agency for Health)**, which is a government agency that funds high-risk, high-reward projects to improve health outcomes. It has a resilience office and a scalable solutions office, as well as a hub-and-spoke model for bringing together collaborators. ARPA-H aims to accelerate health breakthroughs and has a focus on strengthening the supply chain for essential medicines. The agency is modeled after DARPA (Defense Advanced Research Projects Agency).
- **The NSF (National Science Foundation) Technology Innovation Partnership (TIP),** which funds projects that are translational and solve real-world problems. The program has a regional innovation engine component that aims to invigorate local U.S. regions while building economic growth and capacity. The program provides funding to strengthen domestic manufacturing.
- **The Economic Development Administration (EDA) Tech Hubs program**, which invests in regional collaborative consortia across the country with assets and resources to become globally competitive in the technologies and industries of the future. The program is focused on driving economic growth and national security, and it brings together public, private and academic partners.
- **The Ending Drug Shortages Alliance (EDSA)**, which is a group of members from across the health care ecosystem working to solve medicine supply chain challenges via collaborative partnerships and advocacy.
- **The Duke-Margolis ReVAMP Drug Supply Chain Consortium**, which is focused on developing policy solutions to advance the reliability of the pharmaceutical supply chain.
- **The National Institute for Pharmaceutical Technology and Education (NIPTE)**, which is a nonprofit organization created in 2005 as a consortium initiative of universities. It serves as a scientific arm focused on science and a corresponding portfolio. NIPTE conducts technical and training projects, including training programs for the FDA and industry.
- **The Richmond, Virginia-area Advanced Pharmaceutical Manufacturing (APM) Tech Hub**, which was established to grow, innovate and sustain the use of AMTs to foster domestic drug and drug precursor production. Similarly, the Kansas City, Missouri, BioHub also seeks to build the world's most equitable biologics and vaccine development and manufacturing innovation ecosystem.
- **The BARDA BioMaP-Consortium**, which is a partnership of industry partners across the drug and vaccine manufacturing supply chain. The consortium aims to expand the industrial and manufacturing base for medical countermeasures (MCMs) to bolster the supply chain and America's rapid response capabilities. The consortium is funded by the Biomedical Advanced Research and Development Authority (BARDA) and is managed by Advanced Technology International (ATI). It serves as a conduit between industry and government, fostering relationships and dialogue. As of March 2025, the BioMaP-Consortium has 310 members, 11 nonprofit members and six institutions of higher education.

According to panelist Josh Marion, program manager at ATI and the BioMaP-Consortium, **"the BioMaP-Consortium is designed to help develop the relationships between industry partners, so that there's organic growth commercially, but also to create a dialogue, so the government has a well-rounded view of capability gaps and where their investment opportunities may lie."** He added that **"the program is capable of partnering with funding sponsors from anywhere within the United States government, as long as the work is within our technical domain."**

Long-Term Drug Supply Chain Management

Mapping the supply chain for domestic drug production and building strategic stockpiles — a government-funded buffer inventory of critical drugs — are critical steps toward creating resilience in the U.S. drug supply. Mapping the supply chain will allow industry leaders and policymakers to pinpoint vulnerabilities, such as reliance on single sources or foreign countries for critical materials; use predictive analytics and tools (e.g., USP's Medicine Supply Map) to forecast potential drug shortages; reveal the extent to which the U.S. is dependent on other countries for essential medicines and APIs; inform decisions on where to prioritize manufacturing efforts and investments; develop strategies to mitigate risks and enhance resilience. Beyond USP's work, organizations have launched numerous efforts to map the drug production supply chain. They include the U.S. Commerce Department's Supply Chain Center, the HHS Supply Chain Resilience and Shortage Coordinator, and the HHS Administration for Strategic Preparedness and Response's essential medicines supply chain and manufacturing resilience assessment.

With regard to establishing a buffer inventory of critical medications, existing efforts are also splintered and are in various stages of activity. The U.S. Strategic National Stockpile is part of the federal medical response, although it does not address the need for a broader national buffer stock of critical medicines that are not related to a national emergency such as a bio-terror event or pandemic. In addition, CMS seeks to address the costs hospitals incur in managing pharmaceutical shortages, and it has solicited feedback on separate payments to hospitals for establishing and maintaining access to a buffer stock of essential medicines. APIIC has also advocated for expanding the scope of the joint U.S. Department of Defense Shelf-Life Extension Program to evaluate medications beyond their labeled expiration dates. Ensuring safety and stability of these medications over extended periods could reduce waste in a buffer stock.

IV. A NEW ADMINISTRATION AND POLICY CONSIDERATIONS

In November 2024, Donald Trump was elected for his second presidential term. President Trump now has the opportunity to expand on efforts to strengthen drug supply chain resiliency and bolster U.S. national health security. As part of his first term, Trump signed an **executive order in August 2020** that was explicitly meant "to increase American production of essential medical supplies and cut down our reliance on foreign producers of medicines." The administration's "Buy American" initiatives sought to prioritize domestic production of essential drugs and medical supplies, reduce reliance on foreign sources and bolster the nation's resilience. The executive action leaned on the **1950s-era Defense Production Act (DPA)** and partnerships with private companies. The DPA authorizes the president "to allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense."

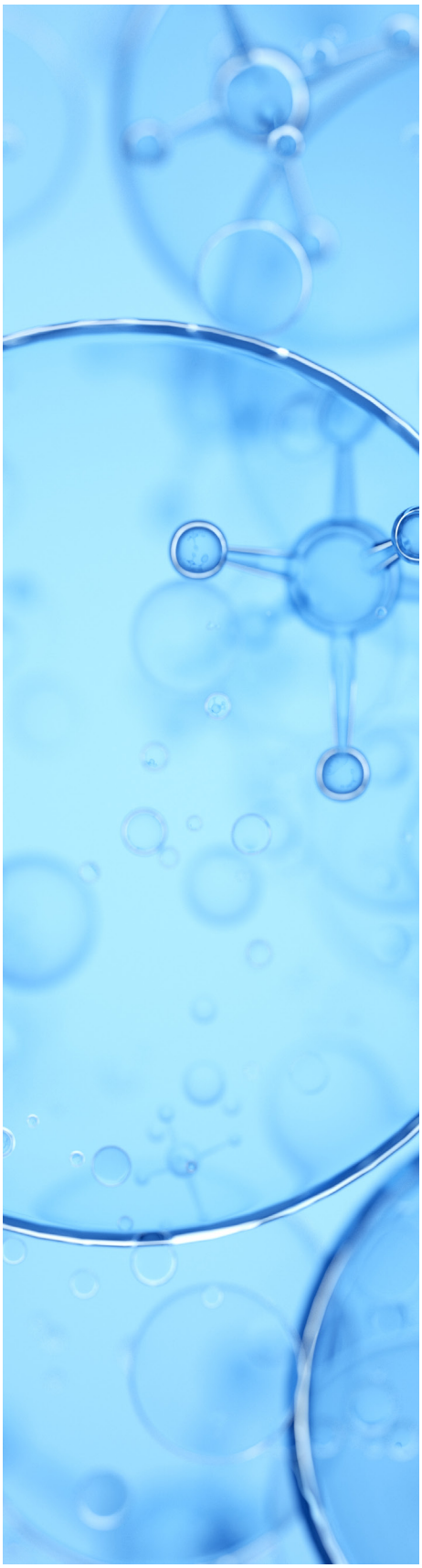
The executive order's provisions included tasking the FDA commissioner with creating a list of essential medicines, medical countermeasures and critical inputs that are essential for public health in America; limiting competition for government contracts to American manufacturers for essential items; directing agencies to prioritize permitting and approvals for domestic manufacturers; and speeding up the development of domestic advanced manufacturing for products needed for rapid response to public health emergencies and defense threats.

As the administration issued key directives to the FDA, emphasizing the critical importance of domestic production for essential medicines, Congress also demonstrated a vital, cross-party interest in addressing this pressing issue.

In June 2018, a bipartisan group of 31 U.S. Senators and 104 members of the House of Representatives sent a letter to former FDA Commissioner Scott Gottlieb, M.D., requesting his agency to thoroughly evaluate the nation's drug shortage crisis. Specifically, their letter urged the FDA to convene a task force to study the issue and identify its root causes.

In response, the FDA established an inter-agency Drug Shortages Task Force, bringing together senior officials from multiple federal agencies. As a result of the task force's efforts, the FDA released a **report on drug shortages**, published in 2019, and updated in February 2020, concluding that there was no simple solution for addressing drug shortages.

The causes include a lack of incentives to produce less-profitable drugs, little recognition or reward for manufacturers for mature quality management systems, and logistical and regulatory challenges.



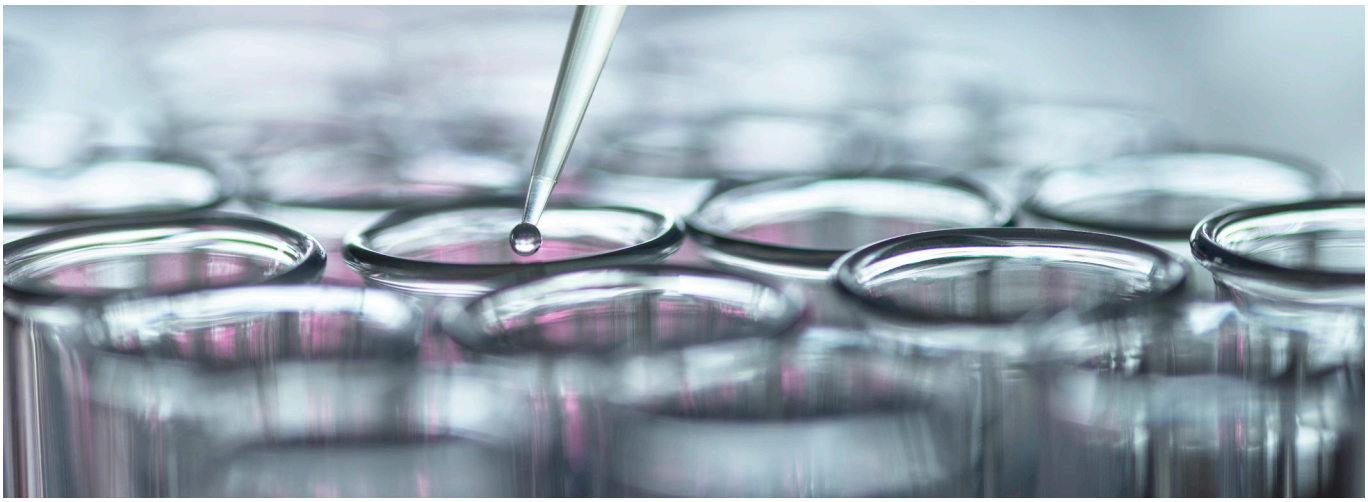
Strengthening U.S. Resiliency

The Trump Administration has made clear that an "America First" approach continues to be a policy priority, with a particular focus on trade and economic growth. This approach is built around the belief that strengthening domestic industries is not only an economic imperative, but also a matter of national security.

As outlined in the 2025 America First Trade Policy published at the start of President Trump's second term, the administration aims to prioritize "American workers, manufacturers, farmers, ranchers, entrepreneurs, and businesses" by promoting domestic production and reducing dependence on foreign supply chains. This policy is designed to level the playing field through trade measures, including tariffs, while encouraging investments in American manufacturing capacity and technological innovation.

In February 2025, President Trump announced plans to impose tariffs of up to 25% on imported pharmaceuticals. While details of the policy are not yet available, the United States remains heavily reliant on foreign-sourced APIs and the KSMs used to make them — both critical components of drug production. If implemented alongside broader economic policies that address existing gaps, these tariffs could incentivize domestic production of APIs and generic pharmaceuticals. However, a strategic approach is necessary to mitigate potential short-term supply chain disruptions where a domestic manufacturing base is not yet fully established.

The most effective path forward is to pair tariffs with a balanced approach that includes strategic investments in domestic manufacturing infrastructure and technology —creating a foundation for short- and long-term resilience in the pharmaceutical supply chain.



Building Domestic Manufacturing Capacity to Enhance U.S. National Health Security

At the heart of any reshoring effort is the need to build and expand domestic manufacturing capacity Currently, the U.S. pharmaceutical sector has substantial underutilized capacity. U.S. generic pharmaceutical manufacturing sites **surveyed by Washington University in 2022** are producing at just half of their production capacity annually, with an aggregate excess capacity of nearly 50%. This underutilization is primarily driven by high production costs, insufficient returns on investment, and an overreliance on foreign APIs, with 83 of the top 100 generic drugs lacking a U.S. source.

To address these challenges and the risk they pose to U.S. national health security, the federal government should lead a targeted investment strategy focused on:

- **Infrastructure Modernization:** Spearheading the necessary investment to upgrade existing production facilities, creating a pathway for long-term sustainability by industry with new production capacity for KSMs, APIs and finished drug products.
- **Financial Incentives:** Providing tax credits, grants and low-interest loans to encourage manufacturers to invest in domestic production.
- **Public-Private Partnerships:** Facilitating collaboration among government, industry and academic institutions to drive innovation and production efficiency.
- **Procurement Reform:** Establishing federal procurement guidelines that prioritize domestically produced pharmaceuticals to create reliable demand and stabilize production.

Additionally, direct investments through initiatives like the BioMaP-Consortium and ASPR's Industrial Base Management and Supply Chain program can further de-risk investments and catalyze production growth. These investments would not only transform idle capacity into active production but also create a resilient ecosystem that supports long-term growth and affordability across the supply chain. Such investments would be a catalyst for innovation, driven by industry to establish a model for long-term sustainability. APIIC was awarded $14 million from ASPR's IBMSC program to lead domestic development and production of three critical KSMs and APIs. This award was one of the first BioMaP-Consortium awards to reshore and strengthen domestic KSM and API manufacturing.

A Phased Approach to Market Realignment

Reshoring pharmaceutical manufacturing requires a structured, phased approach that balances the need for domestic production growth with supply chain stability. Rapid implementation of policies without careful consideration of current capacity could lead to higher costs and disruptions in drug availability.

A balanced strategy should include:

- **Gradual Implementation:** Rolling out measures in stages to allow domestic manufacturers time to scale up production and meet market demand, balanced with policy initiatives that support domestic manufacturing.
- **Targeted Exemptions:** Exemptions within federal policies or directives for producing domestic KSMs, APIs and finished drug products, where U.S. production capabilities remain limited. This will ensure that no federal action will have the unintended consequences of causing drug supply chain disruptions.
- **Risk Mitigation:** Conducting regular assessments of domestic capacity and market conditions to adjust timelines and requirements as production expands.
- **Stockpiling Incentives:** Supporting the creation of safety stocks for critical medicines to buffer against supply shocks.

This measured approach would deliver the desired supply chain resilience by ensuring that manufacturers would have a pathway to ramp up production, while affording health care providers certainty of supply.

Enhancing Market Competitiveness through Innovation and Reform

Long-term success in reshoring pharmaceutical manufacturing requires more than production capacity; it demands a competitive, innovative and skilled industry ecosystem. Without addressing underlying cost drivers and workforce limitations, domestic production will continue to struggle against lower-cost foreign competitors.

To enhance competitiveness, the federal government should prioritize:

- **Innovation Incentives:** Providing grants and tax incentives for manufacturers adopting advanced production technologies, automation and continuous manufacturing processes.
- **Regulatory Streamlining:** Accelerating FDA approval pathways for domestically produced APIs and finished drug products to reduce time to market, and lower compliance costs.
- **Transparency Measures:** Mandating country-of-origin labeling and quality records for medicines, enabling buyers to prioritize reliable U.S. suppliers.
- **Market and Tax Adjustments:** Implementing tax credits for domestic manufacturing activities to level the playing field for U.S. manufacturers.

These initiatives would not only strengthen domestic production but also ensure that U.S.-based manufacturers could produce high-quality, cost-effective medicines that would be competitive in both domestic and global markets.

By combining targeted investments, a phased approach to market realignment and initiatives to enhance industry competitiveness, the U.S. can achieve a resilient, innovative and economically sustainable pharmaceutical industry. This balanced approach ensures long-term supply chain stability, promotes economic growth and maintains affordable access to essential medicines.

Agencies and Congress Introduced Efforts to Address Reshoring Efforts

The new administration, alongside the new Congress, does not have to start from scratch in terms of developing and implementing policies to address domestic production of generic medicines. In recent years, Congress, in particular, has introduced measures to strengthen the U.S. pharmaceutical supply chain, particularly across four areas:

1. Enhancing Supply Chain Resilience and Strategic Stockpiling
2. Promoting Domestic Pharmaceutical Manufacturing
3. Improving Supply Chain Transparency and Security
4. Addressing Drug Pricing and Market Competition

While not exhaustive, the table below provides a list of previously proposed efforts to address the aforementioned areas:

FOCUS	LEGISLATION/WHITE PAPER	SUMMARY
Enhancing Supply Chain Resilience and Strategic Stockpiling	Rolling Active Pharmaceutical Ingredient and Drug Reserve Act (RAPID Act) 2023	Awards contracts requiring manufacturers to maintain a six-month reserve of critical drugs and APIs.
	Essential Medicines Strategic Stockpile Act (2023)	Creates strategic stockpiles to guarantee access to at-risk generic drugs, reducing dependence on foreign sources.
	HHS White Paper - Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States (2024)	Highlights persistent drug shortages caused by supply chain vulnerabilities and market failures, proposing initiatives like the Manufacturer Resiliency Assessment Program and Hospital Resilient Supply Program to strengthen supply chain resilience and ensure reliable access to essential medicines.
Promoting Domestic Pharmaceutical Manufacturing	Manufacturing APIs, Drugs, and Excipients in America Act (MADE Act) 2023	Provides incentives to expand and relocate manufacturing facilities for APIs, excipients and pharmaceuticals in the U.S.
	Medical Manufacturing, Economic Development, and Sustainability Act (MMEDS Act) 2023	Encourages relocation of medical manufacturing to economically distressed U.S. areas, boosting local economies.
	American Made Pharmaceuticals Act (AMP Act) 2023	Establishes a program for preferential treatment of U.S.-sourced and produced drugs under Medicare and Medicaid.
	Producing Incentives for Long-term Production of Lifesaving Medicines (PILLS Act) 2023	Introduces a production tax credit for domestically manufactured generics and biosimilars to strengthen availability.

FOCUS	LEGISLATION/WHITE PAPER	SUMMARY
Improving Supply Chain Transparency and Security	Mapping America's Pharmaceutical Supply Act (MAPS Act) 2023	Mandates HHS to map the U.S. pharmaceutical supply chain, identifying vulnerabilities and security risks.
	Drug Origin Transparency Act (DOT Act) 2023	Enhances reporting requirements for drug manufacturing origins to improve supply chain transparency.
	BIOSECURE Act (2024)	Prevents the U.S. from providing federal funds to a company of concern tied to a foreign adversary or posing a national security risk.
Addressing Drug Pricing and Market Competition	Affordable Drug Manufacturing Act (ADM Act) 2023	Establishes an Office of Drug Manufacturing within HHS to produce select generics at fair prices.
	Senate Finance Medicare Drug Shortage Prevention and Mitigation White Paper 2024	Outlines policy options to address drug shortages, emphasizing Medicare reforms for supply chain resilience.

As Congress and the Administration work to strengthen the United States' domestic manufacturing capabilities and enhance pharmaceutical supply chain resilience, these proposals provide actionable starting points. These measures offer strategies to bolster supply chain security, incentivize domestic production, improve transparency and address drug pricing challenges. By building upon these efforts, policymakers and the administration can work in tandem to develop a comprehensive approach that reduces reliance on foreign sources, mitigates vulnerabilities and ensures long-term stability in the United States' pharmaceutical industry.

V. ECONOMIC BENEFITS

Stakeholders across the political spectrum and spanning various industries have acknowledged the national health security issues inherent in our existing system of generic KSM, API and finished drug production. Reshoring pharmaceutical production in the United States also offers significant economic benefits.

In September 2024, Washington University in St. Louis's Olin School of Business drafted **an economic development study** on the impact pharmaceutical manufacturing could have on Missouri. The report focused on the importance of using AMTs, such as continuous flow chemistry, to enhance supply chain efficiency and environmental sustainability. The analysis projected that bringing the production of just 25 medicines back to the United States within five years would generate $1.2 billion in economic activity and 125 new jobs — specifically within the state of Missouri. This model is scalable, suggesting that a similar strategy would bring further economic opportunities to other states.

The study also highlighted how APIIC's public-private partnership model is designed to support the growth of a resilient domestic pharmaceutical industry by focusing on the economic viability of manufacturing. It also noted that collaboration among universities, research institutions and industry partners is valuable in achieving meaningful health outcomes.

The ICP Model™, developed by APIIC, generates significant economic impact through multiple avenues. In addition to creating jobs through direct production activities and research and development, it stimulates growth in supporting industries through equipment purchases and building out facilities. This generates indirect economic impacts, as these businesses purchase local goods and services. Furthermore, local spending by wage earners induces further economic activity. The model prioritizes local supplier purchases, which can also enhance local economies and build regional resilience. According to the Washington University study, the total economic impact is projected to be between $49 million and $51 million for a single API and drug. The model is designed to be scalable and sustainable through public and private partnerships, with a focus on reducing the need for long-term government funding.

Seeking Scalability in State Partnerships

Through its ICP Model™, APIIC has integrated investment, contracting and partnership to strengthen the domestic pharmaceutical supply chain. By connecting industry, academia and government, APIIC works to de-risk commercialization and enhance essential medicine production in the U.S. State-level investment plays a critical role. APIIC's chief partnership officer, Aaron Willard, emphasized the importance of private industry investing alongside government funds to ensure scalability and credibility.

His perspective, informed by his experience as chief of staff to former Missouri Gov. Mike Parson, underscores how targeted investments in pharmaceutical manufacturing can generate economic growth and national security benefits. The importance of state funding was supported by the economic impact study from Washington University's business school, highlighting the strategic importance of investing in advanced manufacturing infrastructure. Examples of this public-private collaboration include:

- APIIC announced in April 2024 it would use a portion of the $9.45 million grant **to partner with Apertus Pharmaceuticals** to bring the production of lomustine, a critical cancer drug, back to the United States, using advanced continuous flow technology.
- In December 2024, **APIIC contracted Missouri-based Sentio BioSciences** to develop domestic production of propofol (used in general anesthesia) and bupivacaine (a local anesthetic). Neither has a U.S. source of API.

Additionally, APIIC is working with Missouri-based manufacturers — Mallinckrodt Specialty Generics and MilliporeSigma, as well as the University of Missouri St. Louis — toward the domestic production of APIs used for drugs to treat asthma, hypertension and anxiety disorders.

VI. APIIC'S RECOMMENDATIONS: A ROADMAP TO RESILIENCE

APIIC and its founders have engaged in extensive research, advising, collaboration and analysis to address the critical challenges facing the U.S. pharmaceutical supply chain. These efforts, informed by expert opinions and stakeholder discussions, highlight the need for a strategic and multifaceted approach to enhancing domestic drug manufacturing and supply chain resilience. The recommendations presented here are based on insights gained from APIIC's ongoing research, including its market research study, its advanced manufacturing technology conference and its 2024 plenary event. This approach moves beyond the presentation of the problems to provide concrete, actionable steps for policymakers and industry leaders to take. These recommendations are a roadmap for decisive action to ensure a stable and secure supply of critical and essential medicines for the nation. They call for support from federal government policymakers, leaders in the pharmaceutical and health care industries, and the advocacy and nonprofit communities. APIIC's recommendations include:

Invest Strategically: Enhancing domestic pharmaceutical production should focus on upgrading existing facilities rather than building new ones, a costly and time-intensive process. Many U.S. drug manufacturing sites operate below capacity, with 30% of generic drug facilities running at less than 50%. Upgrading these sites with AMTs can quickly boost production and prevent permanent closures that would result in lost infrastructure, expertise and jobs. Investments in new equipment, technology transfers and workforce training are crucial, alongside guaranteed contracts and volume commitments to incentivize manufacturers, and create an economically sustainable U.S. manufacturing base. This strategy strengthens supply chain resilience, supports job creation and reduces reliance on foreign pharmaceutical sources.

Measure and Refine: APIIC should continue refining its industry progress scorecard (see Appendix) to track advancements in domestic pharmaceutical manufacturing. This tool should measure both short- and long-term efforts, including quality, AMT adoption and supply chain resilience — not just cost. Regular updates will help assess intervention impacts, address lagging initiatives and align strategies with national pharmaceutical security goals. The scorecard also serves as an accountability mechanism, ensuring progress in promoting domestic drug production.

Close the Acetris Loophole: The Acetris ruling weakens domestic drug manufacturing by allowing foreign-made precursors to qualify as U.S.-made products under federal contracts. APIIC recommends a phased approach to closing this loophole, ensuring that procurement policies prioritize U.S.-based API and drug production, while allowing time for domestic manufacturers to adapt and ramp up production. This would strengthen federal procurement integrity, reduce reliance on foreign suppliers and align federal procurement priorities with the goal of increasing U.S. national health security. Congress has shown interest in addressing this issue. In September 2024, lawmakers, including Sen. Elizabeth Warren and former Sen. Marco Rubio (now secretary of state), urged the Defense Department to act. Their proposed United States Pharmaceutical Supply Chain Review Act stalled in Congress; a related **amendment to the 2025 National Defense Authorization Act (NDAA)** was removed before passage.

Fund a Coordinator: A whole-of-government approach is essential to enhancing coordination and preventing misalignment across agencies working toward similar goals. APIIC urges the creation of a sustainably funded public entity to oversee a national strategy for reshoring drug manufacturing to enhance governmental efficiency. This entity would manage supply chain diversification, predict essential medicine needs, incentivize buffer inventories and track shortages. **While the Biden Administration's HHS supply chain resilience coordinator** was a step forward, long-term funding and clear milestones are needed to ensure accountability. Collaboration with the Department of Defense and regulatory reviews would further support reshoring efforts. The coordinator should also align federal agency priorities and integrate congressional directives, such as Sections 216 and 716 of the FY24 NDAA. These provisions focus on strengthening pharmaceutical biologics manufacturing, diversifying supply chains and improving stockpiling strategies.

Create a Unified Drug Shortage List: Consolidating existing lists of scarce and essential medicines into a single reference point would help policymakers and industry prioritize critical drugs, including military pharmaceuticals lacking U.S.-sourced APIs. Informed by public and private stakeholders, this list would support federal policies to strengthen supply chain resilience. USP's vulnerable medicines list could serve as a foundation. Additionally, funding for technology upgrades and federal authorization for data-sharing are needed to ensure effective coordination and consensus on critical drug priorities.

Support and Fund AMT R&D: Increased federal funding for AMT research is essential, especially for generic drug manufacturers struggling with low margins that discourage investment in new technologies. Direct investment would support pilot programs, advanced equipment purchases and collaborations among industry, academia and government to accelerate technology adoption. Prioritizing AMTs for domestic KSM and API production would enhance U.S. competitiveness and supply chain resilience. CONTINUUS Pharmaceuticals exemplifies AMT's potential. Its **Integrated Continuous Manufacturing (ICM) system** streamlines production by replacing inefficient batch processing, which can take 200–300 days. ICM integrates all steps into a seamless process, cutting production time to as little as two days, while improving efficiency and quality. At APIIC's November 2024 plenary, CONTINUUS co-founder Bayan Takizawa highlighted how such innovations can transform U.S. drug manufacturing.

Build a Buffer Inventory: APIIC recommends a federally supported buffer inventory of essential medicines to prevent shortages, as the National Strategic Stockpile is insufficient. This stockpile should prioritize critical pharmaceuticals and include stored APIs, which have longer shelf lives and can be quickly converted into final products. Efficient fund management and distribution systems are essential. Expanding the Defense Department's Shelf-Life Extension Program could further enhance supply stability. APIIC's proposal aligns with the Protecting Our Essential Medicines Act, introduced in December 2024, which sought to require HHS to list drug origins to address shortages, though it did not advance in Congress.

Prioritize Quality and Higher Reimbursement for U.S.-Made Medicines: Reforming reimbursement policies across Medicare, Medicaid and private insurers is key to strengthening domestic drug manufacturing. Current models favor lower-cost foreign products, neglecting the higher costs of U.S. production and quality assurance. Policies should prioritize domestically made drugs, offering higher reimbursements to providers and pharmacies that use FDA-compliant products. Preferred drug lists should be updated, and pilot programs launched to test new reimbursement models. A quality report card system beyond cGMP standards would enhance transparency and reward high-quality manufacturing. These changes would shift incentives from low-cost imports to reliable, U.S.-based production.

Be Comprehensive, Not Piecemeal: A successful strategy must address the entire pharmaceutical supply chain — from KSMs and APIs to finished drug products and distribution. Focusing solely on APIs without securing other key components fails to solve the problem. Predictive analytics, buffer inventories and transparency are essential, as are solutions to drug shortages caused by quality and manufacturing issues. Addressing the economics that disincentivize domestic development and production, and prioritizing solutions that help mitigate geopolitical risks must be part of the plan. A long-term, sustainable solution requires industry and government collaboration, along with policy changes to remove disincentives like the Acetris loophole.

Acknowledging Additional Viewpoints

While APIIC has developed specific recommendations to address drug supply chain vulnerabilities and national health security, it is also important to acknowledge alternative, supplemental or contrary viewpoints that emerged during discussions in November 2024 and research throughout the past 12 months. One significant point of discussion involves the limitations of continuous flow manufacturing as a universal solution. While beneficial for some molecules, it may not be suitable for more complex multi-step processes. Additionally, the initial cost of investment in this technology can be prohibitive, even with the knowledge that there will be cost savings in the long term. This highlights the need for a diverse approach to AMTs beyond just continuous flow and timely support that addresses the current barriers.

Another key point of contention surrounds the focus on reshoring or supply chain resilience more broadly. Some argue that reshoring is not the only answer, particularly if it is done in a way that simply replicates existing problems. The focus should be on building a robust and resilient supply chain that can withstand disruptions, no matter where production is based. This includes diversifying sources for KSMs, APIs and finished dosage forms. APIIC agrees but recognizes that the current state of overwhelming reliance on foreign manufacturers makes the country extremely vulnerable. We recognize the need for a multifaceted approach, embracing a diversified supply chain and opportunities for friendshoring. Additionally, the notion of mandating labeling or transparency about a drug's source has also raised concerns among some experts. While some see transparency as a means of empowering consumers and incentivizing domestic production, others are wary of the potential for data manipulation and the possibility of unintended consequences.

The role of government is another point of contention. While government investment is recognized as crucial, there is a caution against government overreach that could lead to inefficient spending and market distortions. Some participants suggest that the government should focus on enabling and incentivizing private sector action rather than dictating solutions. At the same time, there is broad acknowledgment that the supply chain for critical and essential medicines is vast, complex and ripe for reform. It spans from suppliers of raw materials to manufacturers, distributors, pharmacies, pharmacy benefit managers (PBMs), health care providers and, finally, patients. This complexity leads to a fragile system that is susceptible to shortages. **"There is no silver bullet, there is not one bill that magically solves this,"** Gonce said, highlighting the need for long-term government commitment.

Conclusion

The path toward a secure and resilient domestic pharmaceutical supply chain requires a comprehensive and multifaceted approach, moving beyond short-term fixes to address the root causes of the nation's overreliance on foreign manufacturing. APIIC has detailed the challenges, progress and potential solutions for reshoring pharmaceutical production, emphasizing the critical role of public-private partnerships and advanced manufacturing technologies.

The recommendations outlined here — including strategic investment in existing facilities, a unified drug shortage list, closing the Acetris loophole, funding a central coordinating entity, and prioritizing reimbursement and quality — are essential steps toward building a more robust and reliable drug supply. These measures must be implemented in tandem with a multipronged approach to industry adoption of advanced manufacturing technologies such as continuous flow manufacturing.

Crucially, a comprehensive national plan must consider the entire supply chain, from key starting materials and active pharmaceutical ingredients to finished drug products and their distribution and include a strategic stockpile of essential medicines. It is also important to recognize that the prevailing narrative that all generic medications are equivalent is a fallacy. The pharmaceutical industry, health care providers and policymakers must shift the focus from price alone to value quality, reliability and domestic sourcing, implementing reimbursement reforms that reward manufacturers who prioritize these factors.

Ultimately, securing the nation's health requires collaboration among industry, government and other stakeholders to ensure a long-term, sustainable solution. The time for decisive action is now, and these recommendations offer a roadmap for achieving a stable, secure and resilient supply of essential medicines for all Americans.

PARTICIPANTS IN THE PLENARY EVENT

The following individuals moderated or participated in panels at the Nov. 13, 2024, APIIC plenary event at Washington University.

At-Large Participants

Tony Sardella, MBA, founder and chair, API Innovation Center: Sardella is responsible for overseeing the APIIC's overall leadership and strategic planning, delivering on the commitment to strengthen the U.S. domestic drug supply chain and global competitiveness while reducing manufacturing costs. In addition, Sardella is an adjunct professor at the Olin Business School at Washington University in St. Louis, and senior advisor to the University's Center for Analytics and Business Insights. Sardella is a toxicologist by training and has authored or co-authored over 25 papers in the field of human health and environmental risk assessment prepared on behalf of government agencies and nongovernmental scientific bodies. He earned his MBA at Northwestern University.

Kevin Webb, MBA, chief operating officer, API Innovation Center: Webb has direct responsibility for business operations, programs, strategy and external engagement. He leads the APIIC's efforts at national and regional level to strengthen domestic pharmaceutical manufacturing in the U.S. Webb is a subject matter expert and featured speaker on the importance of protecting our national health security. A 30-year veteran of the health care community, he has broad, cross-functional technical expertise in government affairs, communications, manufacturing, operations, sales and brand management. Prior to the APIIC, he held leadership roles at Mallinckrodt Pharmaceuticals, Sanofi Pasteur Vaccines and Memorial Medical Center. He has an MBA from the University of Illinois and a Bachelor of Science from St. Louis University.

Panel 1: Designing a Sustainable Long-Term Drug Supply Chain

Monique K. Mansoura, PhD, MBA, executive director, global health security and biotechnology, The MITRE Corporation: Mansoura leads MITRE's efforts to strengthen U.S. competitiveness and the biotechnology sector for national and global health security. With a background in biopharma, biomedical R&D, and public-private partnerships, Mansoura has been instrumental in initiatives like the Human Genome Project and U.S. biodefense programs, including the Project BioShield Act. Her career shifted to focus on national health security post-9/11, with her work in medical countermeasures becoming a global standard. She has led cross-sector teams across biotechnology, academia and international agencies. A Research Affiliate of MIT's Laboratory for Financial Engineering, she has developed new business models to support health security. She holds a PhD in Bioengineering and an MS in Human Genetics from the University of Michigan, a BS in Chemical Engineering from Wayne State University, and an MBA from MIT. Mansoura is also a member of the Council on Foreign Relations.

Andrew Gonce, MBA, senior vice president, commercial and strategy, Mallinckrodt Pharmaceuticals: Gonce heads commercial, business development and strategy for Mallinckrodt Specialty Generics, a leading U.S. producer of essential medicines with the largest API plant in the U.S. Before joining Mallinckrodt in 2019, he worked in solid dose and sterile generic manufacturing and has spent a decade at McKinsey & Co., driving operational and quality improvements in over twenty global pharma factories.

Michael Ganio, PharmD, MS, BCSCP, FASHP, senior director, pharmacy practice and quality, ASHP: Ganio has served at ASHP since 2018, overseeing key areas in pharmacy practice such as drug shortages, compounding standards and hazardous drug safety. He holds a Pharm.D. from Rutgers University and an M.S. in health-system pharmacy administration from The Ohio State University, where he also completed a PGY1 residency. Board-certified in sterile compounding (BCSCP) and pharmacotherapy (BCPS), Ganio became an ASHP fellow in 2017. With over 20 years in hospital and health-system pharmacy, his expertise includes drug shortage management, pharmacy informatics and outpatient oncology operations. A recognized expert, he has advised at national and international forums, including the Executive Office of the President and Congress.

Aaron Willard, chief partnership officer, API Innovation Center: Willard leverages his strategic expertise and leadership to drive the partnership strategy. He is responsible for identifying and developing partnerships that align with the APIIC's mission to enhance U.S.-based pharmaceutical manufacturing, strengthen national health security and foster economic growth. He brings 20 years of experience within Missouri state government and politics. He has served as chief of staff to several Missouri House Speakers and within the U.S. Department of Commerce. Prior to the APIIC, Willard served as Chief of Staff to Governor Parson. He was key in shaping policy priorities that impacted Missouri's infrastructure and workforce development programs. He earned his Bachelor of Arts in both Economics and Political Science and Master of Public Affairs from the University of Missouri. He is currently pursuing his MBA from the University of Missouri.

Panel 2: Understanding AMTs for Domestic API Manufacturing

Tamara Fraley, client partner, PharmaACE: Fraley manages client relationships, supports data analysis and leads competitive intelligence and market research initiatives. With over 25 years in health care and the pharmaceutical industry, she provides strategic guidance for product launches, business development and market growth. Fraley's experience spans clinical practice as an RN and roles in pharmaceuticals and medical devices focused on data analysis and market research. Before joining PharmaACE, she was a senior director of market research at a major pharmaceutical firm and served as a Nurse Consultant and RN across various health care settings. She holds a B.S. in Biology, a Registered Nursing License, and a Master of Marketing Research.

Jason Rodriguez, PhD, director, Division of Pharmaceutical Quality Research II, Office of Pharmaceutical Quality Research, Office of Pharmaceutical Quality, FDA: Rodriguez oversees a team conducting research in pharmaceutical testing, including dissolution, chromatography, inhalation and transdermal analysis. He has a PhD in Chemistry from the University of Illinois Urbana-Champaign and a B.S. in Chemistry from the University of Texas-Pan American. He pioneered using portable Raman and near-infrared technologies to enhance raw material screening and develop innovative drug testing methods. He also serves as the regulatory chair for the ICH expert working group (Q3E).

Omar Rana, associate director, process and analytical development, small molecule/bioconjugation, MilliporeSigma: Rana's teams are a part of MilliporeSigma's CDMO business in both Small Molecule API and Bioconjugation sectors, responsible for the development of manufacturing processes and analytical methods for commercial operations. They support customers from discovery to commercial release and beyond, providing technical expertise throughout a product's life cycle. Rana has been with MilliporeSigma for 20 years, most of that time working in leadership roles within its Small Molecule API Manufacturing business.

Bayan Takizawa, MD, MBA, co-founder and chief business officer, CONTINUUS Pharmaceuticals Inc.: Takizawa is instrumental in CONTINUUS Pharmaceuticals' business development and strategy efforts. He has helped the company secure multiple contracts and raise funds for the development of Integrated Continuous Manufacturing (ICM) processes, most recently securing a multi-million-dollar contract from the U.S. DoD to establish an Integrated Continuous Manufacturing facility in the U.S. He holds an M.D. from Yale, an M.S. in Engineering Systems and M.B.A. from MIT, and a B.S. in Chemical Engineering from Cornell.

Jeremy West, commercial director, advanced flow reactors and pharmaceutical technology, Corning Inc.: West leads efforts to broaden the use of advanced flow manufacturing technologies in the pharmaceutical and chemical industries. His work focuses on enhancing production efficiency, promoting continuous manufacturing and strengthening the pharmaceutical supply chain through strategic partnerships. With over a decade of experience in advanced manufacturing and chemical sectors, West is a trusted leader in modernizing pharmaceutical manufacturing and supporting sustainable, scalable production. He holds a Bachelor of Science in Biology from Shorter University.

Panel 3: Public-Private Partnerships and Collaboration

Betsy Baer, senior director, federal business development, U.S. Pharmacopeia: Baer focuses on projects and collaborations with U.S. government agencies to advance supply chain resilience, advanced manufacturing, biologics, and health care quality and safety. Leveraging complementary partnerships, she drives initiatives to facilitate adoptions of new technologies that help to strengthen the pharmaceutical supply chain and global health. With over 25 years of experience, Baer previously led East Coast Business Operations for Waters Corporation and then led a new team that focused on CDMOs to expand development and manufacturing of vaccines and therapeutics during the COVID-19 pandemic. She holds a B.S. in Chemistry from the University of Virginia, and she began her career as a forensic research chemist with the FBI.

Josh Marion, program manager, medical and threat countermeasures division, Advanced Technology International: Marion leads the BARDA Biopharmaceutical Manufacturing Preparedness Consortium (BioMaP-Consortium) to bolster U.S. pandemic preparedness and the pharmaceutical industrial base. Since its founding in September 2023, he has expanded the program to over 250 member companies with nearly $800 million in funding. Previously, Marion was Deputy Director at the Composites Manufacturing Technology Center, where he contributed to the Navy ManTech program and OSD MSTP, particularly in hypersonic vehicle manufacturing. He holds an MBA and a B.S. in Mechanical Engineering from the University of South Carolina.

Kristy Hawkins, co-founder and chief science officer, Antheia: Hawkins has nearly 20 years of experience in the field of synthetic biology, focusing on yeast metabolic engineering for the production of small molecules. She did the founding work on the benzylisoquinoline alkaloid pathway while earning a PhD in chemical engineering at Caltech, and gained valuable industry experience at both Amyris and Lygos. Hawkins is an expert in tool development, HTP screening, and host strain and heterologous pathway engineering. In 2015, she began her current role as a co-founder of Antheia with Prof. Christina Smolke, and she serves as the chief scientific officer. Antheia is transforming pharmaceutical supply chains by developing biomanufacturing processes for essential medicines inspired by nature, and it recently launched its first product.

Vadim J. Gurvich, PhD, MBA, executive director, National Institute for Pharmaceutical Technology and Education, associate director, Institute for Therapeutics Discovery and Development, University of Minnesota: Gurvich is also a research associate professor in Medicinal Chemistry at the University of Minnesota's College of Pharmacy, and he serves as the associate director at the university's Institute for Therapeutics Discovery and Development. He is the executive director of the National Institute for Pharmaceutical Technology and Education (NIPTE), a consortium of 17 top pharmacy and chemical engineering schools. With more than 30 years of experience, Gurvich is an expert in synthetic organic and medicinal chemistry and chemical process development. He has led several large NIH- and FDA-funded projects, and he holds advanced degrees in chemistry, chemical engineering and business administration.

Panel 4: Regulatory and Policy Considerations

Josh Narrow, director, The Conafay Group: Narrow supports The Conafay Group's policy, coalition and non-dilutive funding teams, where he manages four coalitions and assists the federal lobbying team with Congressional and Administrative engagement. Narrow joined The Conafay Group over five years ago as an intern, fostering a keen interest in health policy and biotech funding. His experience spans both public and private sectors: He has worked on political campaigns, interned in the D.C. office of Sen. Bob Casey and served as a communications strategist for a D.C. startup. Narrow graduated cum laude from The George Washington University's Elliott School of International Affairs with a focus on global public health.

Gerren McHam, director of government and external relations, API Innovation Center: McHam builds partnerships with government and external stakeholders, overseeing workforce development, and directing cross functional projects, including grant applications and strategic planning. He also helps shape budget and policy strategies to support advanced manufacturing and reshoring critical medicine production. With over 15 years in federal and state government, McHam has served as a U.S. Senate legislative aide and as special advisor for K-12 policy in the U.S. Department of Education. Before joining APIIC, he was director of external relations at the Missouri Department of Higher Education and Workforce Development. He holds a B.S. in Political Science and Legal Studies from Clemson University.

Joe Hill, director, U.S. government affairs, U.S. Pharmacopeia: Hill has extensive experience in government relations, advocacy, health care policy and the pharmacy profession. He serves as USP's primary representative to Congress, developing and managing the organization's engagements with federal and state government agencies. He also leads USP's collaborations with key stakeholder groups on public policy issues. He previously worked at the American Society of Health-System Pharmacists as director of the Government Relations Division and as ASHP's director of federal legislative affairs, leading the society's efforts to pass legislation that would help prevent drug shortages. He is a graduate of the University of Tennessee and Indiana University of Pennsylvania.

Marta Wosińska, PhD, senior fellow, The Brookings Institution: Wosińska works in Brookings' Center on Health Policy, specializing in health care economics, with a focus on prescription drug markets and drug shortages. Her extensive government experience includes roles as director of the Bureau of Economics at the Federal Trade Commission, chief health care economist at the U.S. Department of Health and Human Services OIG, and director of economics at the FDA's Center for Drug Evaluation & Research. She also served as an economic advisor to the U.S. Senate Finance Committee. Previously, Wosińska was deputy director for policy at the Duke-Margolis Center for Health Policy, and she taught at Harvard Business School.

Vic Suarez, colonel (ret.), USA founder and principal growth partner, Blu Zone Bioscience & Supply Chain Solutions: Suarez assists biotech and life science organizations in expanding U.S. biomanufacturing through public-private partnerships. With over 27 years in the Army, he held key roles, including biotechnology advanced developer and senior medical acquisition consultant at the U.S. Army Medical Research and Development Command. Notably, he managed the Moderna COVID-19 vaccine program under Operation Warp Speed, and advanced FDA-licensed vaccines for Ebola and MPOX. A former chief of staff at Walter Reed Army Institute of Research, Suarez also advises multiple life science organizations, and he is a visiting senior fellow at the Council on Strategic Risks.

GLOSSARY

- **Active Pharmaceutical Ingredient (API):** The biologically active component of a drug that produces the intended health effects. The U.S. is heavily reliant on foreign sources for APIs.
- **Advanced Manufacturing Technologies (AMTs):** Innovative technologies that can improve production efficiency, reduce costs and enhance the quality of pharmaceutical manufacturing. These include continuous flow and on-demand manufacturing capabilities.
- **Acetris Ruling**: A regulatory loophole that redefines what qualifies as a U.S.-made end drug product, allowing products manufactured outside the U.S. to be considered U.S.-made, which undermines the incentive for domestic production.
- **Batch Manufacturing:** A traditional method of pharmaceutical production that involves performing a series of chemical transformations in sequence in a single reactor system. Batch processing includes multiple unit operations such as reaction, workup, crystallization, filtration and drying, often taking multiple days in the same reactor. Contrasts with continuous flow manufacturing.
- **Biosimilars:** Generic versions of biologic drugs that are coming off patent.
- **Biomanufacturing:** The use of biological systems to produce materials, including pharmaceuticals. Biomanufacturing can create sustainable domestic alternatives to foreign API production.
- **Buffer Inventory:** A federally supported inventory of critical drugs to mitigate the impact of shortages. These include APIs and other drug substances.
- **Continuous Flow Manufacturing:** An advanced manufacturing technology that allows for continuous production, potentially reducing costs and increasing efficiency. Contrasts with batch manufacturing.
- **Critical Medicines:** Medications that are essential for treating acute conditions and those for which there are limited or no therapeutic alternatives. Multiple lists of critical medicines exist, creating a need for standardization.
- **Essential Medicines:** Medications considered necessary for a basic health care system. The FDA and WHO also maintain essential medicines lists.
- **Finished Dosage Form:** The final form of a drug product, such as tablets, capsules or injectables, ready for administration to patients.
- **Generic Drugs:** Medications that are copies of brand-name drugs, typically available at lower costs. The U.S. generic pharmaceutical industry has faced challenges such as price erosion and consolidation.
- **Key Starting Material (KSM):** The raw materials used to synthesize APIs. Diversifying sources of KSMs is crucial for preventing supply disruptions.
- **National Health Security:** The assurance that the nation has reliable access to essential medications and is protected from threats to its health care system. Overreliance on foreign manufacturing compromises national health security.
- **Onshoring:** The process of bringing manufacturing and production back to the United States.
- **Public-Private Partnership:** A collaborative model involving the government and private sector to address issues such as drug supply chain vulnerabilities.
- **Quality Scorecard:** A system to evaluate drug manufacturers based on their compliance records, which can be used to incentivize domestic production.
- **Reshoring:** The act of bringing back manufacturing of pharmaceuticals to the United States from foreign countries.

- **Strategic National Stockpile:** A government-managed inventory of essential medical supplies for use in public health emergencies.
- **Supply Chain Resilience:** The ability of a supply chain to withstand and recover from disruptions. This involves diversifying manufacturing bases and establishing buffer inventories.
- **Substantial Transformation Standard:** A standard that defines the manufacturing processes that cause a significant change in the name, character and use of components during production. This is a component of country-of-origin rules and has been impacted by the Acetris Ruling.

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Washington University in St. Louis, Olin Business School, “Revitalizing U.S. Pharma: Evaluating the Economic and Social Impacts of Advanced API Manufacturing in Missouri,” September 2024, https://olin.wustl.edu/_assets/docs/research/APIIC-EconomicImpactReport.pdf

APPENDIX

INDUSTRY PROGRESS SCORECARD

APIIC presented the following industry progress scorecards at the Nov. 13, 2024, plenary event. These scorecards tracked industry progress over the previous year on immediate, short- and long-term efforts and were scored by the APIIC team. The scorecard serves as an accountability mechanism and will be updated and presented each year.

Immediate Actions

	ACTION 1:	ACTION 2:	ACTION 3:
IMMEDIATE ACTIONS	**Designed a coordinating entity to develop and implement a national strategy.**	**Establish a public-private partnership to represent government, industry, and patients interests.**	**Support the public-private partnership strategy with dedicated funding for the coordinating entity.**
ACTIVITY	Congress appropriated $1B for ARPHA-H first three years. Initial grants limited to biomedical health breakthroughs. HHS Supply Chain Resilience and Shortate Coordinator tasked with developing opportunities for agency coordination across drug resiliency effort. Publications from HHS focused on preventing drug shortages.	ARPA-H created as a nationwide health innovation hub-and-spoke network focused on creating and implementing solutions for Americans. BioMaP-Consortium established. Since 2019, ASPR has invested more than $325 million to develop domestic production capabilities for APIs.	NSF has issued several funding notices, ex: Regional Engines, which includes opportunities for infrastructure investments and public-private partnerships led by a coordinating entity. No grants 100% dedicated to KSMs or APIs.
SCORE	**B**	**A**	**B**

Rating Scale: Green: A (7-10 points); Yellow: B (4-6 points); Orange: C (1-3 points); Red: D (0 points)

Short-Term Actions

	ACTION 1:	ACTION 2:	ACTION 3:
SHORT-TERM ACTIONS	**Create and maintain a single U.S. critical drug list with input from various stakeholders.**	**Establish a government-funded critical drug buffer inventory.**	**Invest in upgrading existing manufacturing capacity with AMT.**
ACTIVITY	No single list established and prioritizing drugs of critical national importance.	Other than drugs maintained in the U.S. Strategic National Stockpile, no national activity taken on this reccomendation.	Some investment has been committed by ASPR via BioMaP. Office of Strategic Capital (OSC) seeks public input as it prepares to issue loans and loan guarantees for critical technology (ex: AMT) to attract and scale private capital for national security.
SCORE	**B**	**B**	**A**

Rating Scale: Green: A (7-10 points); Yellow: B (4-6 points); Orange: C (1-3 points); Red: D (0 points)

Long-Term Actions

	ACTION 1:	ACTION 2:
IMMEDIATE ACTIONS	**Continue investing in AMT to maintain a competitve edge.**	**Design a long-term drug supply chain management plan that includes diversification of sourcing for APIs and key starting materials.**
ACTIVITY	Industry willingness to invest in AMT technology. Some investment by federal government driven by some agencies including ASPR, NSF and ARPA-H. Current Congress has not passed specific appropriations to fund U.S. API development or infastructure.	Significant federal government activity to understand global supply chain map. U.S. Department of Commerce Supply Chain Center. End Drug Shortages Alliance (EDSA)'s ongoing efforts to address product shortages and new pilot to mitigate pediatric cancer drug shortages (Cancer Moonshot).
SCORE	**B**	**A**

Rating Scale: Green: A (7-10 points); Yellow: B (4-6 points); Orange: C (1-3 points); Red: D (0 points)