CROSS-SECTOR INSIGHTS INTO THE DRUG SUPPLY CHAIN: STRENGTHENING DOMESTIC RESILIENCE THROUGH PUBLIC-PRIVATE PARTNERSHIPS

Prepared by the
API Innovation Center

ABOUT THE API INNOVATION CENTER:

The API Innovation Center (APIIC) is a 501(c)(3) nonprofit corporation and public benefit organization backed by research and dedicated to ensuring a stable, U.S.-based supply of active pharmaceutical ingredients (APIs). Through public-private partnerships, APIIC unites government, industry and academia to strengthen national health security, advance novel technology and optimize underutilized manufacturing facilities. Our mission is to ensure that every hospital, pharmacy and patient has access to domestically produced critical medication. APIIC is supported by grants awarded through the state of Missouri and the Missouri Department of Economic Development. To learn more, visit apicenter.org.

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EXECUTIVE SUMMARY

Persistent fragility of the U.S. drug supply chain is caused by the country's overreliance on foreign sources for active pharmaceutical ingredients (APIs), low profit margins in generic drug production, diminishing domestic manufacturing and geopolitical uncertainties. This fragility poses a significant threat to national health security and the availability of essential medicines (API Innovation Center, 2024).

President and COO, API Innovation Center, Kevin Webb

In its role as an advocate and driver of solution-oriented action, the API Innovation Center (APIIC) continues to press for solutions to this long-standing problem. In an effort to identify comprehensive solutions, APIIC hosted a roundtable discussion on the subject of public-private partnerships (PPP) on Aug. 13, 2025. This closed-door forum convened diverse leaders from government, pharmaceutical manufacturing, health care systems and retail pharmacies.

THE GOAL:

Focus on PPPs as a key strategic tactic in mitigating the structural shortcomings in the nation's drug supply chain, and ensure reliable access to high-quality medications and drug products.

As of August 2025, 253 drugs are on the American Society of Health-System Pharmacists (ASHP) shortage list, down from a high of 323 in the first quarter of 2024 (ASHP, 2025). Yet patients across the U.S. generally remain unaware of the flaws in the pharmaceutical supply chain that may impact their ability to have a prescription filled. Furthermore, patients are often left unaware or without options when their treatments are adjusted or when significant effort is required from providers to manage disruptions in drug product availability. When patients need care, visit their doctors and receive a prescription, they expect medications that are available, efficacious and safe. The availability, efficacy and safety of these medications is affected by complex economics — particularly in the area of generic drugs, which account for 90% of prescribed medications but only about 12% of total drug spending (Association for Accessible Medicines, 2025). This imbalance between utilization and spending underscores the broken economics of the generic drug industry in the U.S.:

- **The system rewards severe price erosion in the supply chain.**
- **As prices are squeezed, domestic manufacturers cannot compete against foreign producers, which benefit from lower labor and manufacturing costs, fewer regulations, and significant foreign government subsidies.**
- **Insufficient pharmacy reimbursement for the dispensed drugs often does not cover the pharmacy's acquisition costs. This low reimbursement environment can prevent pharmacies from purchasing from any but the lowest-cost source, regardless of whether that source may be U.S.-based, reliable or susceptible to supply shocks.**
- **The poor return on investment does not support U.S. manufacturers investing in generic API manufacturing, and capital instead flows to high-margin brand-name drugs.**
- **Intermediaries such as wholesalers, group purchasing organizations (GPOs), and pharmacy benefit managers (PBMs) concentrate buying power, further driving down generic drug product prices.**

While ensuring medicine affordability is important, this opaque system prioritizes lowest cost over reliability and quality, severely compressing domestic manufacturer margins. Over-reliance on foreign API sources — over 80% of the top 100 generic medicines prescribed in the U.S. have no U.S. API source — creates a fragile supply chain, vulnerable to geopolitical risks and shocks (APIIC, 2021).

APIIC's roundtable discussions explored PPPs as a tactic to address these economic challenges while surfacing the pressure points that affect PPPs as an effective tactic to address supply chain vulnerabilities and market challenges, rather than proposing solutions. In their discussion, participants stressed the need to:

- ➜ **Ensure predictable demand and to de-risk investments in manufacturing infrastructure and technology.**
- ➜ **Shift the value proposition of generic drugs from lowest cost to reliability, quality and certainty of supply.**
- ➜ **Enhance transparency and data visibility across the drug production supply chain to foster U.S. generic drug production.**
- ➜ **Engage drug supply intermediaries, such as GPOs and PBMs, and address conflicting priorities across the whole drug supply chain to align interests and support stable, value-based contracts.**

The overarching message of APIIC's roundtable was the importance of collaboration, transparency and long-term contracts to achieve a resilient and sustainable pharmaceutical supply chain.

PART 1:

The Landscape and Pressure Points

In other forums and publications, APIIC has explored the context for the decline in domestic drug production and its causes. APIIC has characterized the existing economic model for generic drug manufacturing as a "race to the bottom" that fundamentally disincentivizes U.S. drug manufacturers from producing APIs or generic medicines (APIIC "Capacity Research Survey," 2022). This race is driven by intense pricing pressure and severe price erosion within the generic drug market, in which price, rather than quality or reliable supply, becomes the primary determinant of market success (APIIC "Resilient Supply Chain," 2025). Key elements contributing to this race to the bottom include:

Low profit margins: Generic drugs, accounting for 9 out of 10 prescribed medications, return extremely low margins (in contrast to patent-protected, branded medicines). This discourages investment in domestic API manufacturing.

Foreign cost advantage: Generic drug manufacturing has moved away from U.S. shores to other countries, where lower labor and manufacturing costs, fewer regulations, and significant foreign government subsidies render U.S. production uncompetitive.

Lack of reinvestment: The low return on investment and pricing uncertainty prevent companies from investing in advanced manufacturing technologies (AMTs) or facility upgrades or from expanding domestic manufacturing capacity.

As a consequence, the U.S. pharmaceutical manufacturing base has eroded, leading to underutilized production capacity and persistent drug shortages. It has also concentrated production of generic drugs, APIs and key starting materials (KSMs) into a select few foreign countries (Journal of Economic Perspectives, 2025). As U.S. Pharmacopeia has reported, "Geographic concentration of pharmaceutical manufacturing anywhere in the world increases the risk of vulnerability to disruption and drug shortages" (USP, 2025).

Economist and Research Officer, Federal Reserve Bank of St. Louis, Charles Gascon

THE PARAMOUNT CONCERN: PATIENT CARE

Persistent drug shortages, which have recently been as high as 323 medicines in active shortage (ASHP, 2025), represent a critical threat to both patient health and national health security. The nation's overreliance on foreign sources leaves patients vulnerable to geopolitical conflicts, natural disasters or regional health crises — which can create supply-side and demand-side pressures — directly compromising the availability of essential and often lifesaving medications. **As the single most important stakeholder, the patient absorbs 100% of the clinical care risk, facing treatment delays, less effective alternatives or even catastrophic outcomes when drugs are unavailable (ASHP, 2023).** Further, the capacity of the nation to provide basic care and protect its military is undermined by an unpredictable drug supply, emphasizing the urgent need for a resilient, domestically focused pharmaceutical supply chain (American Affairs, 2024).

This pressing reality set the stage for participants at the APIIC roundtable, where they highlighted the critical need for a clear metric to prioritize drugs for domestic production and supply chain resilience.

Director, Health and Wellness Strategic Sourcing, Walmart, Michael Edmonson, PharmD

For example, APIIC has identified at least 11 different lists of essential medicines experiencing a shortage (APIIC "Resilient Supply Chain," 2025). These lists may vary based on how different organizations define a shortage, the needs of different constituencies (e.g., military versus the general public) or the availability of reliable data. Still, roundtable participants acknowledged that the absence of a consolidated list makes setting priorities — which drugs are the most critical to produce domestically — a challenge. Participants noted tension between needing such a list and the possibility of such a list telegraphing a vulnerability to foreign adversaries. Further, some participants suggested any consolidated list should include among its criteria a link with health outcomes (e.g., increased life expectancy or reduced childhood mortality).

Roundtable Takeaway 1A: What Supply Chain Participants Need

Ensuring a reliable supply of vital medicines depends on practical solutions, and it starts with understanding what each part of the supply chain truly needs. At the roundtable, participants spoke of what they would need in an overhauled supply chain, how PPPs might provide for those needs and, importantly, what they could offer in exchange for certainty of drug supply.

APIIC has highlighted the need for a "strategic and multifaceted approach to enhancing domestic drug manufacturing and supply chain resilience" (APIIC "Resilient Supply Chain," 2025). PPPs are one facet of that approach. That strategy was made the centerpiece of the conversation at the roundtable. PPPs can provide the ability to de-risk investments and align incentives across diverse stakeholders to overcome economic and technical barriers, enabling the adoption of advanced manufacturing and the sustainable, reliable domestic production of essential medicines. Hospitals and health systems, drug manufacturers, retail pharmacies, government officials and policymakers, private and public payers, and patients are all critical stakeholders along the generic medicine supply chain. The roundtable was convened to identify what makes a successful PPP, beginning with what each stakeholder needs.

HOSPITALS AND HEALTH CARE SYSTEMS

What they face: Roundtable participants acknowledged that doctors and health care systems face uncertainty of supply, requiring a frequent need to pivot from one medication to another — sometimes without the patient's knowledge.

What they need: Thus, participants agreed that hospitals and health care systems require certainty of supply to ensure uninterrupted patient care. Their primary mission is to provide the best possible patient care, even if that means turning to alternative therapies in the face of shortages. While this adaptability preserves continuity of care, it masks the challenges hospitals face in maintaining consistent access to essential medicines, forcing them to balance proper care with constrained options.

What they could offer or support: Participants acknowledged that supply reliability may be more important than price. They noted that hospitals and health care systems prioritize a stable pipeline of essential drugs, valuing reliability and quality over the absolute lowest price, even if it means allowing relatively minor cost adjustments — although current market structures often impede this. Further, they seek predictable pricing and the ability to aggregate demand at scale. Without these resources, long-term contracts with drug suppliers — or supply chain intermediaries — are not dependable, enduring or beneficial. Health care providers also advocate for redundancy in supply channels to mitigate supply shocks from geopolitical conflicts, natural disasters and other disruptions. Their objective is to solve the drug shortage problem rather than constantly reacting to shifts in the availability of essential medications.

Senior Vice President and Chief Supply Chain Officer, BJC Health System, Tom Harvieux

RETAIL PHARMACIES

What they face: Pharmacy representatives at the roundtable said customer trust is at stake if they cannot reliably provide affordable medications.

What they need: Thus, pharmacies require certainty and reliability in supply — consistently available, in stock, on time and in full. Pharmacies also seek partners committed to domestic manufacturing, which brings products closer to patients for easier service and a strategic advantage. Like all the stakeholders, pharmacies prioritize redundancy and resilience in the production of APIs and KSMs — the building blocks for APIs — while seeking long-term agreements with suppliers to ensure stability and predictability in supply.

What they could offer or support: A low price for a medicine, while important to customers, is meaningless if the drug is unavailable when it is needed. Participants acknowledged the need to transition from a price-driven model to a value-driven model, in which value is not wholly associated with the lowest price but includes reliability of supply and the unwavering confidence of patient-customers.

DRUG MANUFACTURERS

What they face: Existing economics have disincentivized domestic manufacturing because manufacturers find it nearly impossible to gain a return on any investment in generic drug production.

What they need: At the roundtable, domestic drug makers noted that they have the capacity to produce generic drugs, yet existing economic structures make doing so unsustainable and, in some cases, nearly impossible as the result of the economic realities previously outlined. These views confirm APIIC research that fully outlined these economic forces (APIIC "Capacity Research Survey," 2022): "Leveraging available capacity … offers the ability to manufacture essential and critical medicines within the United States. But it will also be necessary to address the market factors that led the generic pharmaceutical manufacturers to increasingly offshore production capabilities in the first place."

Thus, roundtable participants discussed drug manufacturers' need for startup funding and de-risked investments to establish domestic capacity, especially given the low profit margins and high initial costs of deploying AMTs. AMTs are innovative technologies that improve production efficiency, reduce costs and enhance quality. They include methods such as continuous flow and on-demand manufacturing — crucial for domestic competitiveness and supply chain resilience.

These investments should be coupled with guaranteed, long-term purchasing commitments for production volume and price, which are essential to supporting sustainable investments in domestic capacity and innovation. Short-term or easily canceled contracts expose manufacturers to the volatility of the market and undermine any expected return on investment.

What they could offer or support: A recurring theme at the roundtable was the need for greater supply chain transparency. A new system would likely require manufacturers to share more data on their supply chains, including the origin of APIs and KSMs, which is often considered confidential commercial information. This discussion confirms earlier APIIC research: "Getting a clear picture of the API supply landscape is challenging, as supply sources are protected as confidential information for finished dose manufacturers, and there is not a transparent marketplace" (APIIC "API Infrastructure," 2021).

Because the existing market has largely commoditized generics — differentiating them by price alone — it fails to reward investments in quality or supply chain reliability. This, participants noted, is also unsustainable. **Finally, government partnerships could jump-start this process, but government involvement cannot endure indefinitely; partnerships must become commercially self-sustaining, allowing domestic manufacturers to compete with overseas facilities.**

GOVERNMENT/POLICYMAKERS

What they face: Across the board, roundtable participants acknowledged the national health security vulnerability presented by the existing economics of the generic drug supply chain. That vulnerability is represented by the overwhelming reliance on foreign sources of APIs and KSMs for the production of medicines essential to the nation.

What they need: Policymakers represented at the roundtable agreed they cannot become mired in unsustainable longtime support of what should be a commercial enterprise: the production of generic medications. PPPs require clearly defined roles, sustained alignment and mutual commitment across all partners.

What they could offer or support: The government can influence the market, not become a drug manufacturer or middleman. At the same time, policymakers crave a unified and flexible list of critical drugs — encompassing national defense, public health emergencies and common acute care — to guide strategic investments in specific products and technologies. Policymakers also need policy tools such as guaranteed, long-term contracts; targeted subsidies; favorable regulatory prioritization for domestic products; and "Buy American" incentives to better de-risk private investment and stimulate domestic capacity. **Roundtable consensus referred to predictable demand as the foundational requirement for successfully de-risking private investment in domestic manufacturing.**

Roundtable Takeaway 1B: Where the Pressure Points Lie

Given the needs of each stakeholder, an important consideration is understanding the existing pressure points. What are the challenges that stand in the way of deploying PPPs as a tactic to boost domestic drug production and insert resilience and dependability into the supply chain? Participants at the PPP roundtable identified five key areas for deeper consideration:

Skewed value proposition: The positioning of generic drugs as a commodity, with price as the sole differentiator, disincentivizes investments in domestic capacity, AMTs or improved quality. Manufacturers are not rewarded for producing high-quality or reliable supply. In the existing system, domestic manufacturers are disadvantaged against foreign competitors because the value proposition focuses almost solely on cost and reimbursement. The value proposition must shift instead from low cost to competing on value — defined as reliability, quality and certainty of supply. This price sensitivity also forestalls any conversation about health outcomes and national security.

Supply-chain opacity: This opacity prevents effective decision-making throughout the supply chain for generic medications. This refers to visibility into the source, reliability, quantity and quality of KSMs, APIs and medications. For example, under the existing system, hospitals and pharmacies, as end users, have difficulty understanding their risk exposure and how to mitigate those risks. Stakeholders, including government policymakers, cannot effectively identify choke points and vulnerabilities, prioritize national needs, or make informed investment decisions.

Misaligned incentives: All members of the pharmaceutical value chain have a role in resolving our national dependence on foreign sources of our critical drugs. Therefore, the existence of third-party intermediaries in the supply chain cannot be ignored. APIIC recognizes that the participation of third-party intermediary organizations is essential to arrive at a meaningful solution. Roundtable participants noted that these third parties typically prioritize the absolute lowest price — presumably with the wishes of end-users in mind. This manifests in practices such as spot-market purchasing and price-jumping —

further depressing prices, devaluing (or even nullifying) long-term contracts, disincentivizing investments and commoditizing the products. This tendency, coupled with the fact that generics are often more profitable abroad, diverts distribution from the U.S. The current system also fails to differentiate or reward manufacturers for quality or supply certainty, even though end purchasers, like hospitals and retail pharmacies, express willingness to pay more for reliable, long-term supply.

Unpredictable demand, policy and contracts: Manufacturers face unstable demand and sales volumes, making it challenging to justify long-term investments in domestic capacity or AMTs. This is exacerbated by current reimbursement models and policy shifts, such as changes in national priorities and strategies, which introduce uncertainty and hinder long-term planning for an industry that thrives in predictable market conditions. Moreover, long-term contracts are more the exception than the rule in the generic drug sector. Even when purchasing commitments are made, they can be easily renegotiated or canceled by third parties.

Stalled innovation: Low margins for generic drug and API manufacturers render large investments in AMTs nearly impossible. Manufacturers also face uncertainty and risk in adopting new technologies, alongside regulatory hurdles and the time required for approvals (APIIC "Benefits and Barriers," 2025). These factors collectively impede the modernization of domestic production, making it difficult for U.S. manufacturers to compete with overseas facilities — and their economically favorable circumstances — stalling crucial innovation needed for supply chain resilience.

These challenges require further and deeper solution-oriented conversations with broader representation from stakeholders across the generic medicine supply chain. APIIC remains committed to hosting further conversations about these issues. The roundtable provided an opportunity to initiate these conversations by surfacing the issues and identifying additional stakeholders.

President, Apotex USA, Christine Baeder

PART 2:

PPPs as a Mitigating Tactic

PPPs have long been acknowledged as one important strategy for the U.S. to strengthen its national health security and build a more resilient domestic generic drug supply chain. That reality is what compelled participants to gather at the August 2025 roundtable. Participants noted that the collaboration of government and industry to achieve a seemingly insurmountable goal is not without precedent. Examples can be found in sectors such as public transportation, education, IT infrastructure and others (National League of Cities, 2020). Participants spoke at length about one recent example centered on the COVID-19 pandemic.

Roundtable Takeaway 2A: How Successful PPPs Have Worked

In March 2020, the U.S. Department of Health and Human Services (HHS) invested $456 million toward research and production of Johnson & Johnson's COVID-19 vaccine candidate. Additional federal infusions into similar work by Pfizer-BioNTech, AstraZeneca and Moderna soon followed. Thus began what became known as Operation Warp Speed, unveiled to the public May 15, 2020, with the goal of delivering "300 million doses of a safe, effective vaccine for COVID-19 by January 2021" (HHS, 2020). In its fact sheet, HHS noted that funding for the operation would cost $10 billion, drawn from the CARES Act and supplemental funding through a congressional appropriation.

Participants at APIIC's August 2025 roundtable highlighted Operation Warp Speed, which they said was characterized by predictable and guaranteed demand. That was critical to the operation's success. The government infusion helped de-risk private sector investment and significantly accelerated the development, manufacturing and distribution of vaccines, therapeutics and diagnostics. A crucial factor in its success was also the establishment of a single point of direction and integration with industry, which streamlined efforts across various government agencies. It demonstrated the power of government-guaranteed demand and the rapid advancements it fostered during the COVID-19 pandemic.

APIIC has advanced its own PPP framework designed to de-risk and reshore domestic pharmaceutical production. APIIC's "Invest-Contract-Partner Model" (ICP Model™) is a framework aimed at encouraging additional PPPs through public and private investment into research and development of AMTs. Using its model, APIIC collaborates with both government and industry, facilitating contracts with existing, underutilized U.S. facilities to produce APIs and forging partnerships with drug manufacturers and end customers with the goal of entering into long-term, revenue-sharing agreements to ensure commercial sustainability.

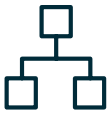
Participants at the roundtable highlighted the predictability of APIIC's model as a benefit, as well as the model's ability to "tear down stakeholder walls" and facilitate open collaboration. This was an illustration of the model's transparency, which aids in aligning incentives to deliver cost-effective patient care. Finally, participants noted its focus on seeking sustainable, end-to-end partnerships that ensure safe and reliable products rather than relying on indefinite government funding.

Roundtable Takeaway 2B: Shared Risk, Reward and Responsibility

Roundtable discussions about Operation Warp Speed and APIIC's ICP Model™ ultimately led participants to identify five characteristics that likely contribute to successful PPPs:

Director, Defense Production Act and Emergency Response Authorities Office, Center for Industrial Base Management and Supply Chain, Paige Ezernack

"Win-win" relationships within PPPs: All parties must benefit from the collaboration, aligning their incentives to collectively drive progress. Participants expressed that these partnerships cannot be seen as a zero-sum game, in which one party benefits at the expense of another. Without this mutual benefit, partnerships are unlikely to be sustainable — especially beyond political or market cycles. Ensuring a win-win scenario could eliminate inefficiency, disincentives and misaligned interests. Successful PPPs would then accelerate drug development, enable cost-sharing, drive technological advancement and foster domestic production.



Defined roles and interests: All parties — government, industry, and health care sectors — must have clearly defined rules, sustained alignment and mutual commitment to the partnership's objectives. Without a single point of direction and aligned incentives, as seen in Operation Warp Speed, efforts can be inefficient and lack the collective drive needed for progress. Defined roles foster mutual commitment and prevent a go-it-alone approach, ultimately making it possible to achieve shared goals in strengthening the drug supply chain. Broadly, those roles could be defined as:

- **Government:** Its role centers on de-risking investments (e.g., Operation Warp Speed), establishing priorities and requirements, and exerting market power through procurement and reimbursement. In the case of the generic drug pipeline, setting priorities involves acknowledging which medicines are critical and in short supply, which, as acknowledged, remains a moving target, with at least 11 different essential medicine shortage lists available. Importantly, participants acknowledged that the government cannot be drawn into solving private sector problems by serving as a long-term solution.
- **Private sector:** Manufacturers need innovation in production, adopting AMTs to create efficient production and reliable delivery. All private sector parties must commit to transparent, long-term agreements that guarantee access to and markets for generic medications in the drug supply chain.
- **Both parties:** Public and private entities must be aligned on prioritizing patient outcomes, ensuring manufacturers can effectively manage their business, reducing the dominance of intermediary organizations and building confidence through consistent, enforceable commitments.

Advance market/aggregated demand models: Advance market commitments (AMCs) are arrangements by an organization to guarantee demand — that is, the purchase of a product — when certain criteria are met. They "encourage suppliers to try to build something that should exist, but doesn't" (Works in Progress, 2024). The Gates Foundation used such a model in 2020 to jump-start the creation of a pneumococcal vaccine for underserved communities. One roundtable participant offered another example: the Pan American Health Organization, which aggregates demand and guarantees purchases of critical medicines and vaccines if specific criteria are met (PAHO, 2025). Similarly, the strategy of aggregating demand could involve fully engaging in a nascent effort by the so-called Bio-5 (the U.S., European Union, India, Japan and South Korea) to aggregate demand across multiple nations to create a larger, more predictable market for generic drugs (Duke-Margolis, 2024). This predictability is seen as essential for manufacturers to reinvest in U.S. production of APIs or generic medications. Similarly, certainty of supply is paramount; long-term contracts that commit to regular supply at predictable prices facilitate the planning and coordination required for cost-effective patient care.

Insurance-backed long-term contracts: Without an insurance piece in the background to guarantee terms, parties are reluctant to commit to long-term contracts, prompting one participant to suggest a mechanism akin to Fannie Mae — a government-sponsored mechanism that provides guarantees and liquidity in the housing mortgage market. In the drug supply chain, such an entity would guarantee certainty, stability and long-term contracts for drug production. This was seen as essential to overcome the existing malleability of generic drug contracts, which are too easily undermined by market shifts or third-party actions. Providing predictability through guaranteed purchases (similar to advance market commitments aggregating demand) is crucial for manufacturers to de-risk investments and sustain domestic production, especially for low-margin, critical drugs.

Diversified supply commitments: Partners must be committed to sourcing critical drugs, KSMs and APIs from multiple manufacturers and geographic regions, moving away from reliance on single-country origins. A strategy to aggregate demand and diversify supply would also lead to de-risking investments in manufacturing. This would also address the national security risk of depending on one or two foreign sources for essential medicines. Participants acknowledged this might increase the cost of production, but that would be the price of ensuring greater resilience in the supply chain.

Former Special Assistant to the President, Medical Countermeasures Coalition, Chandresh Harjivan

PART 3:

Considering Areas of Concern

With the opportunities of PPPs also come areas of needed attention. Without addressing these issues, efforts to address supply chain resilience for essential medicines will be hindered.

Roundtable Takeaway 3A: Open Questions

Data analytics: Roundtable participants made a strong call for supply chain transparency, leveraging digital tools such as artificial intelligence to identify vulnerabilities and inform decisions about the supply chain. The participants also had a nuanced debate about whether health outcomes should determine how essential medicines are prioritized for production. Some argued that decisions should ultimately consider public health outcomes, such as life expectancy, to assess the return on investment for health care spending. It was noted that the societal value of lifesaving drugs, such as antibiotics, is not reflected in their low market prices, and that more precise data on the impact of drug shortages on morbidity and mortality is needed to influence policymakers. While health outcomes could help in decision-making, participants acknowledged the difficulty for health care providers to designate criticality and the complexities of measuring direct impact.

Aligning priorities: The numerous drug shortage lists identifying unavailable essential and critical medicines were a recurring point during the discussion. Though existing resources such as the USP Medicine Supply Map are viewed as valuable resources, the lack of a master drug supply map was seen as both a missing link and a potential vulnerability. On one hand, roundtable participants said, a unified list would remove existing confusion, helping policymakers prioritize which drugs are most important — those essential for health security, for example, or those vulnerable to shortages or foreign sourcing. On the other hand, as one participant said, "Publishing it would tell your adversaries where the vulnerabilities are." Therefore, careful thought must be given to how the government can maintain the confidentiality of such a list while still providing industry with the necessary guidance and resources to pursue the reshoring of these medicines. One potential strategy could involve focusing sooner in the manufacturing stream on the components of generic drugs (e.g., KSMs) that have broader and more universal applications beyond drug products. That could provide cover for the government's specific intentions.

Intermediaries: While those most directly involved in the production, administration and receipt of medicines (manufacturers, health care practitioners and patients) were the focus of this initial conversation, there are also other entities in the supply chain who impact how medicines ultimately reach patients. These stakeholders, such as distributors, GPOs and PBMs, tend to manage the logistical, contractual and economic dimensions of access. Their perspectives, as well as those of public and private payers, are important considerations in future discussions on PPPs, as the agreements and mechanisms they oversee can significantly influence decision-making and help drive coordinated action across the supply chain.

PART 4:

Conclusions and Next Steps

APIIC's August 2025 roundtable underscored the need for robust PPPs to jump-start change and innovation in the U.S. pharmaceutical supply chain and to overcome the existing unsustainable economics of generic drug production. To translate insights into actionable change, APIIC will continue to drive solution-oriented conversations. The issues raised in this paper — reflecting the possible opportunities and likely challenges identified by leaders from across the pharmaceutical ecosystem — will form the centerpiece of further solution-oriented discussions at APIIC's Nov. 5, 2025, plenary event, which will include a broader cross-section of stakeholders.

A central theme from the August 2025 roundtable was the importance of the federal government's pivotal capacity to "pull through" demand that can initiate pharmaceutical supply chain reform. This speaks to the government's use of its procurement power to help establish markets, to kick-start investments and foster long-term sustainability. Participants also emphasized that government support, particularly through long-term contracts from entities like Medicare and the U.S. Department of Defense, can significantly influence private sector behavior, despite the government's relatively small purchasing volume, but should not be a crutch that artificially supports the market. The strategy — through carefully selected PPPs — aims to create a self-sustaining market in which the private sector is incentivized to prioritize domestically made products.

Participants also stressed the pervasive lack of supply chain transparency and visibility. Participants emphasized that without clear data on drug origins, KSMs and manufacturing capacity, informed decisions on investment and risk mitigation are difficult. APIIC has formally recommended that Congress and the executive branch designate a coordinating entity to develop a sustainable, long-term plan for managing the pharmaceutical supply chain, providing transparent oversight, predicting needs and tracking shortages (APIIC, "Resilient Supply Chain," 2025). This critical issue will therefore be of high interest at the upcoming plenary event.

If the role of government centers on the well-being of the nation's residents and the security of its borders, policymakers must collaborate with the private sector to:

- ➜ **Spark innovation by de-risking investments in AMTs.**
- ➜ **Establish clear priorities for critical drugs of national importance.**
- ➜ **Align incentives across the entire supply chain to reward reliability and quality.**
- ➜ **Jump-start demand through long-term contracts and purchase commitments.**
- ➜ **Redefine value in the generic drug supply chain, shifting focus from lowest price to certainty of supply, quality and resilience.**

By addressing these core challenges through sustained collaboration, the U.S. can build a truly resilient pharmaceutical supply chain that safeguards national health security.

APPENDIX I

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APPENDIX II

PRE-READING MATERIAL

APIIC leadership suggested the following reading material to participants ahead of their August 2025 roundtable discussion:

APIIC White Paper (2025): Building a Resilient Domestic Drug Supply Chain. Why It Matters: The white paper introduces APIIC's ICP Model™ (Invest-Contract-Partner) as a blueprint for reshoring API manufacturing and strengthening the U.S. drug supply chain. Frames PPPs not just as policy instruments but as economic engines to attract and sustain domestic investment.

Col. Matthew G. Clark (Defense Perspective): Collaboration With Industry – The Solution for a Sustainable Posture for Biodefense and Global Health Security. Why It Matters: Colonel Clark draws lessons from the defense and biodefense sectors, showing how enduring collaboration between government and industry can secure national health security. He underscores the tension between government support and private innovation — and how to balance these forces without overreach.

Brookings Research (2024): The Economics of Generic Drug Shortages. Why It Matters: This Brookings analysis examines the persistent issue of generic drug shortages through an economic lens. It explores how market dynamics, cost pressures and the structure of the generic drug industry create vulnerabilities in the supply chain.

APIIC Issue Brief (2023): U.S. Generic Pharmaceutical Industry: Economic Instability. Why It Matters: The brief provides critical context for why PPPs are needed in the first place. It explains the economic fragility of the generic pharmaceutical industry, including razor-thin margins, outsourcing pressures and the cascading effects on supply security.


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