# FROM FRAGILITY TO RESILIENCE: ALIGNING INVESTMENT AND PURCHASING TO SECURE AMERICA'S DRUG SUPPLY CHAIN

Prepared by the **API Innovation Center**

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# EXECUTIVE SUMMARY

In recent years, concerns regarding reliable U.S. access to critical generic medicines have shifted from a niche policy debate to a widely recognized vulnerability — acknowledged across the federal government, reinforced by experiences within hospitals and health systems, and increasingly visible to patients and those who administer therapeutics nationwide.

This shift is largely attributed to increasing attention to the issue: executive orders that have spanned at least three presidential administrations, committee testimony and legislative reports in both houses of Congress (most recently, in the U.S. Senate), scholarly research by universities and think tanks, and coverage in general-interest news publications. It was within this context that the API Innovation Center (APIIC) convened its third annual plenary event on the topic, titled "Resilience in Action: Partnerships, Policy and Progress Driving U.S. National Health Security." APIIC invited experts from academia, the pharmaceutical industry, the nonprofit sector and the health care industry to engage in guided panel discussions to consider the path through America's essential medicine vulnerability.

At its core, this vulnerability is founded on a handful of acknowledged realities. First, the U.S. is deeply reliant on foreign manufacturers for its supply of critical medicines, with a substantial share of the U.S. generic drug supply relying on key starting materials (KSMs) sourced from China and active pharmaceutical ingredients (APIs) manufactured in India. These numbers relate specifically to generic medications, which account for about 90% of the medications prescribed to U.S. patients [American Affairs Journal, 2024]. Seventy-five percent of beta-lactam antibacterials are completely dependent on China, Taiwan and India if KSMs are considered. With the last remaining domestic beta-lactam API site, Cherokee Pharmaceuticals, closing in 2026, the U.S. will become fully reliant on foreign API suppliers for this key class of antibiotics [QYOBO, Supply Dependency, 2025]. Meanwhile, more than 8 in 10 of the top 100 generic medications used by Americans have no U.S.-based source of APIs [APIIC, "Capacity Study," 2022].

Publications and public forums, including those hosted by APIIC, have outlined a string of consequences of America's drug supply chain vulnerability. For example, many have cited the "race to the bottom" toward the lowest possible price for generic medications — a reality that has positioned drug pricing as the only measure of value in the pharmaceutical supply chain. Meanwhile, the fragility of the pharmaceutical supply chain leaves it vulnerable to quality-control issues, unforeseen global events and political shocks that disrupt the availability of essential generic medications. As of late-January 2026, the American Society of Health-System Pharmacists (ASHP) reported 216 drugs on its shortage list, down from an all-time high of 323 in the first quarter of 2024 [ASHP, "Drug Shortages," 2026]. All of this threatens patients' access to the therapies they need and puts the country's national health security at risk.

In its role as contributor, convener and innovator in the pharmaceutical supply chain, APIIC hosted expert panels representing a variety of stakeholders during its November 2025 plenary. The forum was designed to move the focus on these critical health security issues from theoretical insights to concrete actions aimed at strengthening the U.S. drug supply chain. Discussion centered on shifting the value proposition for generic drugs away from lowest cost toward reliable supply and quality production. APIIC also presented its National Fragility Index (NFI) — which is a novel tool designed to bring tangible metrics to quantify supply chain risk, assess resilience and guide priorities that drive policy action. The plenary's core themes and resulting action items included:

- **Shifting the Value Proposition:** Transforming generic drug procurement by shifting market focus away from prioritizing the lowest cost toward valuing reliability, quality and certainty of supply.
- **Catalyzing Federal Procurement:** Implementing systemic procurement reform, urging federal agencies to act as "first movers" by prioritizing quality and domestic sourcing in their purchasing practices.
- **Creating Predictable Demand:** Establishing long-term, guaranteed volume contracts and advance market commitments to de-risk investments in domestic capacity and advanced manufacturing technologies (AMTs).
- **Measuring Risk for Purchasing:** Refining and implementing APIIC's proposed NFI, linking scores to procurement and reimbursement decisions.
- **Engaging Intermediaries:** Inviting drug supply chain intermediaries — such as pharmacy benefit managers (PBMs), group purchasing organizations (GPOs), and wholesalers — into conversations centered on replacing drug pricing as the sole arbiter of value.
- **Improving Data Access and Utilization:** Expanding access to existing data and enabling greater data sharing across stakeholders to support clearer, more actionable decision-making for purchasers and policymakers.

# ABOUT THE API INNOVATION CENTER

The API Innovation Center is a 501(c)(3) nonprofit corporation and public benefit organization dedicated to strengthening U.S. health security by rebuilding domestic capability to develop and manufacture key starting materials and active pharmaceutical ingredients (APIs) for critical generic medicines. APIIC is leading the development of six clinically essential APIs and brings together government, industry and academia through public-private partnerships to modernize manufacturing and activate underutilized U.S. production capacity. Our work is supported by grants from the State of Missouri, the Missouri Department of Economic Development and a federal award from the Department of Health and Human Services' Administration for Strategic Preparedness and Response. Visit **apicenter.org** to learn more.

## PLENARY PARTICIPANTS

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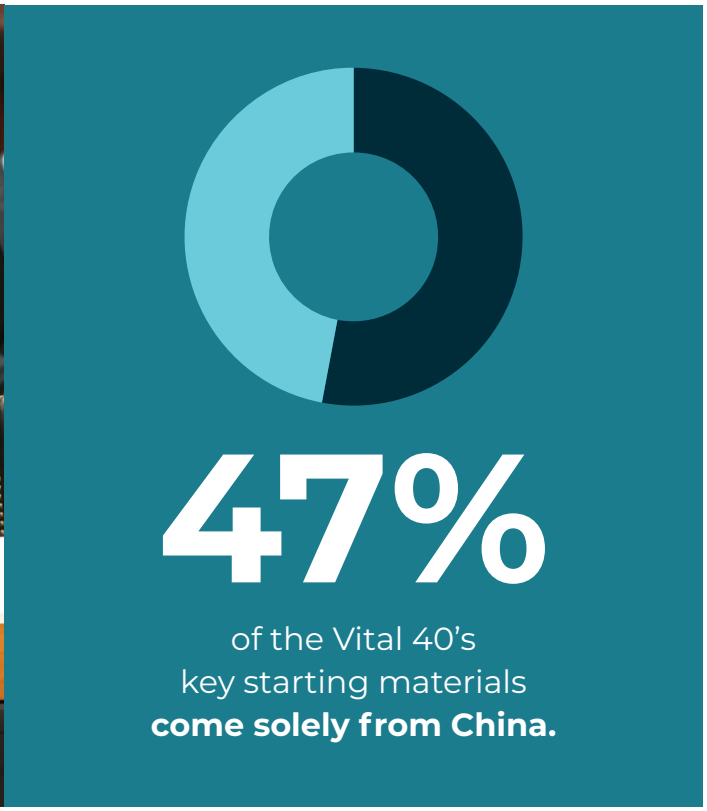
**Anthony Sardella,** MBA, founder and chair, API Innovation Center
**Kevin Webb,** MBA, president and COO, API Innovation Center

# I. INTRODUCTION: MOVING FROM INSIGHT TO ACTION

On Oct. 20, 2025, U.S. Senators Rick Scott (R-FL) and Kirsten Gillibrand (D-NY), chairman and ranking member, respectively, of the U.S. Senate Special Committee on Aging, released a 34-page **investigative report** on behalf of the Senate's Special Committee on Aging titled "Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain." The report was among the most recent in a series of activities shining additional light on the threat to patient care and national security posed by U.S. vulnerability and overreliance on foreign-made KSMs and APIs for generic medicines. The committee's report distilled prior research and testimony during two hearings before its members on Sept. 17 and Oct. 8, 2025, examining the causes, effects and possible solutions to the public health and national security threat.

Senators urged federal action to increase U.S. Food and Drug Administration (FDA) oversight and inspection of foreign manufacturers while simultaneously implementing policies to incentivize quality, foster supply chain transparency and boost sustainable domestic generic drug production [U.S. Senate Aging Committee, "Full Report," 2025]. Among the expert witnesses, senators heard from APIIC's founder and chair, Anthony Sardella, whose research the committee cited in its report. Sardella shared data from an APIIC study of its "Vital 40," a group of 40 essential medicines identified by APIIC as clinically essential, frequently in shortage, and vital


*APIIC Founder and Chair Tony Sardella testifies before the U.S. Senate Special Committee on Aging.*

to public health and national security. The APIIC study found that 47% of the Vital 40's KSMs, the precursors to APIs, come solely from China — making that nation a potential choke point for access to these medicines [APIIC, "Sardella Testimony," 2025].

2025 included a number of other noteworthy government actions, stakeholder forums and publications that continued to bring the problem to the forefront. Though not an exhaustive list, these include:

- **Aug. 13, 2025, Executive Order:** President Trump called for the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) to take several steps aimed at mitigating the nation's reliance on overseas drug makers. The mandates included compiling a list of 26 critical drugs demanding special attention; building a stockpile of APIs required to produce the identified drugs; and later expanding the list to an additional 86 essential medicines [SAPIR, 2025]. The order acknowledged that "scaling domestic API production may face barriers related to manufacturing capacity, cost competitiveness, regulatory hurdles and supply chain logistics" and that new domestic production may require "sufficient incentives and infrastructure."

- **FDA PreCheck Program:** On Aug. 7, 2025, the FDA announced "a new program to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability and facilitating the construction of manufacturing sites in the United States" [FDA, "PreCheck," 2025]. The pilot program was a response to an earlier presidential executive order calling for the streamlining of domestic drug manufacturing reviews. On Feb. 1, 2026, the FDA began accepting requests to participate in the program [FDA, "Launches PreCheck," 2026].

- **EQUIP-A-Pharma:** Announced in May 2025, this collaboration between ASPR and the Defense Advanced Research Projects Agency (DARPA) is aimed at leveraging artificial intelligence, machine learning and informatics to speed drug production, enhance efficiency, lower costs, reduce drug shortages and speed up approval for drugs [EQUIP-A-Pharma, 2025].

- **Duke–Margolis Institute for Health Policy:** An October 2025 white paper analyzes the persistent challenge of U.S. drug shortages and their underlying economic and structural drivers. The paper examines how reimbursement and purchasing incentives, particularly within Medicare, can be restructured to promote supply reliability for generic drugs and support long-term resilience and access to critical medicines [Duke-Margolis, 2025].

- **Brookings Research:** A May 2025 research paper from the Brookings Institution's Rena Conti and Marta Wosińska (a panelist at last year's APIIC plenary) sought to unravel this apparent contradiction: When drugs fall into shortage (thus tightening supply), why don't their prices rise? Their answer centers on "the inability of generic drug prices to adjust to regulatory and contracting frictions, as well as the presence of asymmetric information" [Conti and Wosińska, Journal of Economic Perspectives, 2025].

- **New Research Insights:** Research from organizations such as QYOBO continue to add to the understanding of policymakers, stakeholders and patients regarding America's overreliance on overseas sources for KSMs. For example, across all drugs sold in the U.S., 47% depend entirely on finished dosage forms and APIs from China, Taiwan and India; that number rises to 93% when KSMs are included in the calculus [QYOBO, Supply Dependency, 2025]. Late last year, Johns Hopkins University hosted a workshop by the National Academies of Sciences, Engineering, and Medicine "to determine the best 'make, buy, and invest' strategies to strengthen the resiliency of the U.S. pharmaceutical supply chain" [Johns Hopkins, 2025].

» **Growing Media Momentum:** A raft of recent articles in the popular press and trade publications suggests the issue of America's generic drug supply chain volatility is entering the public consciousness. Examples include the life sciences trade publication BioSpace ("Generic Drug and API Manufacturers Call for Onshoring Incentives) [BioSpace, "Drug Manufacturing," 2025]; The Wall Street Journal ("U.S. Supply Chains Deemed Vulnerable to Chinese Exploitation") [WSJ, 2025]; and an event on May 21, 2025, centering the issue sponsored by Axios ("Axios Event: U.S. Pharmaceutical Supply Chain Is In Crisis, Experts Say"). Among the conclusions at that roundtable event was this from Allan Coukell, chief government affairs and public policy officer at nonprofit generic drug company Civica Inc.: "You asked how close we are to a crisis, and the answer is actually we've been in a crisis for 14 years" [Axios, 2026]. These are but a few examples.

## *Harnessing Momentum*

Participants and panelists at APIIC's 2025 plenary convened with a clear awareness of the growing momentum across various stakeholders in the generic drug supply chain. At the same time, heightened scrutiny of these issues has surfaced additional challenges that hinder progress toward the goal of building a resilient, reliable supply chain for essential and critical medications.

*Paige Ezernack, director of the Defense Production Act and Emergency Response Authorities Office at the Center for Industrial Base Management and Supply Chain, participates in APIIC's August 2025 roundtable.*

At the center of this objective must be the patient, who is uniquely vulnerable as the sole bearer of clinical risks stemming from supply failures yet lacks the ability to mitigate them. Plenary experts agreed that achieving this resilience requires structural intervention that shifts value metrics from prioritizing lowest cost to valuing quality, certainty of supply and positive patient outcomes, thereby guaranteeing reliable access to the critical medicines they need.

**"This is not the patient's job to solve at all. They hold zero power,"** said panelist Laura Bray, chief change maker for Angels for Change, a patient advocacy nonprofit focused on chronic drug shortages. **"They don't decide what medicines they need. They don't know what to prescribe. This is a supply chain failure."**

In step with the demonstrated momentum around the issue of health security, the country is now presented with the opportunity to shift the narrative from crisis reactivity to strategic readiness, from merely identifying the issues to creating measurable interventions, defining success through alignment and resilience

metrics. **In APIIC's recent forums — including its August 2025 roundtable and its November plenary — systemic and operational challenges emerged that complicate efforts to secure the drug supply chain.** While they represent a variety of causes, they often lead to the same effect:

- **Price-Driven Reimbursement:** The prevailing hospital reimbursement structure and pricing models actively incentivize purchasing the cheapest possible generic medications and thus undermine investments in quality and domestic production.
- **Data Access and Utilization:** Limited access to existing data on the generic drug supply chain hinders collaboration and the development of proactive policy solutions. Plenary participants noted that data sharing remains constrained both by supply chain participants' reluctance to disclose proprietary information or intellectual property and by conflicting definitions for terms such as "shortage."
- **Misaligned Incentives:** Poor alignment among cost-driven incentives, reliable supply and predictable demand reinforces the economically destructive "race to the bottom." For example, this misalignment discourages manufacturers from investing in supply chain quality, domestic capacity and supply certainty. The prevailing opinion among many plenary participants centers on the need to engage stakeholders such as PBMs, GPOs and other intermediaries in discussion around this issue.
- **Inability to Forecast:** This poor alignment of incentives creates opacity in the upstream supply chain, preventing hospital systems, retail pharmacies and health care providers from forecasting the demand for and supply of medications.

**"You have to have trust that the stakeholders sitting at the table have the same goal in mind, and the goal can't be lowest cost,"** said panelist J'Aime Conrod, vice president of government, business and health care policy for New Jersey-based Amneal Pharmaceuticals. **"The goal is outcomes and improved patient quality of life. If we can focus on the shared goal, we can start to reframe the conversation."**


*Panelists Jim Stockhausen and Michael Ganio listen as J'Aime Conrod urges supply chain stakeholders to center the patient in all decisions.*

# II. MEASURING RESILIENCE: DATA, TRANSPARENCY AND THE NFI

What has been described, and what policymakers and stakeholders in the supply chain have acknowledged, are four challenges to the resiliency of the nation's access to its essential medicines.

## OVERRELIANCE ON FOREIGN SOURCES

The U.S. is overwhelmingly reliant on foreign sources of API and generic drug products. Studies have indicated that domestic reliance on foreign-produced generic drugs has grown substantially in the past two decades. Two examples use different metrics to draw the same conclusion. One publication by the Federal Reserve Bank of St. Louis showed a 35% decline in U.S. industrial production of pharmaceutical products and medicines from its peak in December 2006 through April 2020 [St. Louis Fed, 2020]. Another publication by the Coalition for a Prosperous America, using a different metric, showed that the U.S. imported 828,000 metric tons of pharmaceuticals in 2024 — seven times more than in 2000 [Coalition for a Prosperous America, "Dangerously Reliant," 2025]. When measured by volume, only about 10% of APIs for U.S.-consumed drug products are made domestically. Most — more than 80% — are sourced from China and India. And while India supplies about half of all generic drugs used in the U.S., Indian manufacturers rely on China for approximately 80% of the APIs they need for production [APIIC, "Economic Impact," 2024].

## POTENTIAL RISKS VIA GEOPOLITICAL SHOCKS

The risk to the nation's supply of critical medicines from geopolitical shocks is "no longer theoretical. These are coming into play, and our drug supply chain is being weaponized at every opportunity," Sardella shared with plenary participants. For example, China's ability to exert its supply chain leverage has come into play in another sector: rare earth minerals, critical components in developing military defense systems. In October 2025, the Chinese government announced "sweeping restrictions on rare earth exports [that] threaten the U.S. defense industry, providing President Xi Jinping with powerful leverage" [CNBC, "Rare Earth Restrictions," October 2025].

## PERSISTENT DRUG SHORTAGES

A symptom of supply chain shocks — either as a result of geopolitical tensions or natural disasters — is the persistent and sometimes record-setting number of drugs that fall into shortage. This shortage crisis is concentrated in the generic drug sector, which accounts for the majority of medications affected and often involves very-low-cost products: 56% of drugs in shortage in 2023 cost less than $1 per unit. Furthermore, shortages disproportionately affect critical hospital treatments: Generic sterile injectable (GSI) products are highly vulnerable, accounting for an estimated 67% of shortages overall [Senate Finance, "Wyden and Crapo," 2024]. By June 2024, the duration of shortages exceeded one year for more than two-thirds of the substances that were in short supply; for another third of substances, the duration exceeded three years [QYOBO, Shortages Analysis, 2024]. Certain critical drug classes bear the burden of this supply chain fragility, including anti-infectives and oncology drugs, illustrated by a major 2023 shortage in cancer treatment drugs that led to postponed treatments [OncLive, "Chemotherapy Shortages," 2023].

## SUPPLY CHAIN OPACITY

Plenary participants noted that stakeholders often find difficulty gauging the risks they face — in terms of manufacturing requirements, availability of raw materials, access to critical medicines, etc. — because they lack access to available data that affects their interests up and down the supply chain. This deficiency is systemic,

rooted in data silos and competing interests. This speaks to the "asymmetric information" Conti and Wosińska described [Conti and Wosińska, Journal of Economic Perspectives, 2025]. A major vulnerability is the upstream segment of the supply chain, where the U.S. government has limited import/export data regarding KSMs when they are from the same country as APIs.

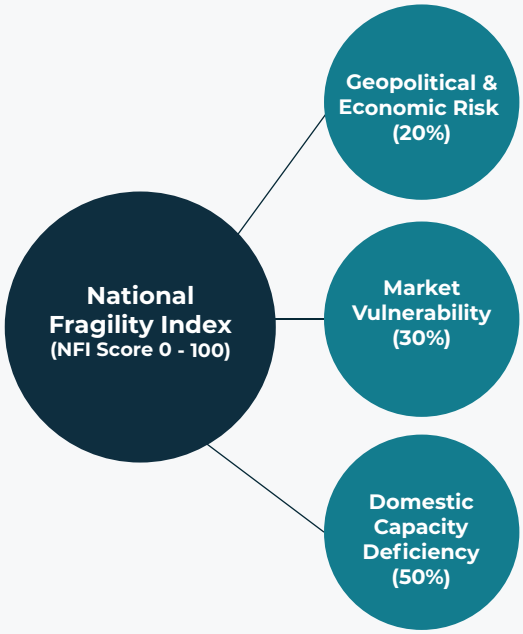
## FILLING A GAP TO MEASURE RISK

In the context of these four challenges to supply chain resilience, APIIC introduced the National Fragility Index (NFI) at its November plenary — a novel, system-wide approach designed to assess the fragility of the nation's generic pharmaceutical supply chain. Rather than measuring resilience as a static condition, the NFI is intended to identify where fragility is most concentrated, helping to illuminate vulnerabilities across the supply chain and enabling the measurement of progress toward greater resiliency. As a conceptual framework, the NFI is positioned to help inform decision-making, resource prioritization and evaluation of policy interventions aimed at reducing drug supply disruptions.

The NFI is being developed as a decision-support tool to guide manufacturers, health care systems, pharmacies and policymakers in better understanding supply vulnerabilities and areas of heightened risk. Announced in November as an experimental, evidence-based concept, participants and panelists at the plenary were invited to offer feedback on its structure and utility. As presented, the NFI is built to capture how factors such as economics, geopolitics and domestic capacity influence generic drug supply and its upstream KSMs, with the goal of supporting more informed, system-level approaches to strengthening national health security.

### A SYSTEM-WIDE APPROACH

A weighted measure of system risk based on predictive variables and outcome data

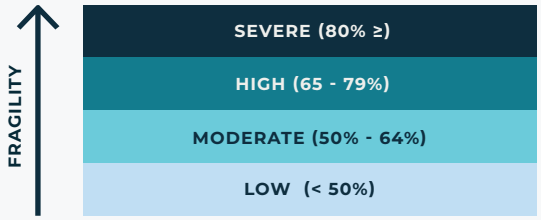



**Composite Formula**

**NFI = 0.20 (Geo) + 0.30 (Market) + 0.50 (Domestic)**

Higher NFI scores = Higher fragility & risk of disruption

**NFI Fragility Index Scale**




Validated with ASHP, FDA, & NCCN Data
High-NFI Drugs align with real world shortages
(Diltiazem, Docetaxel, Metformin ER)

## *Structure*

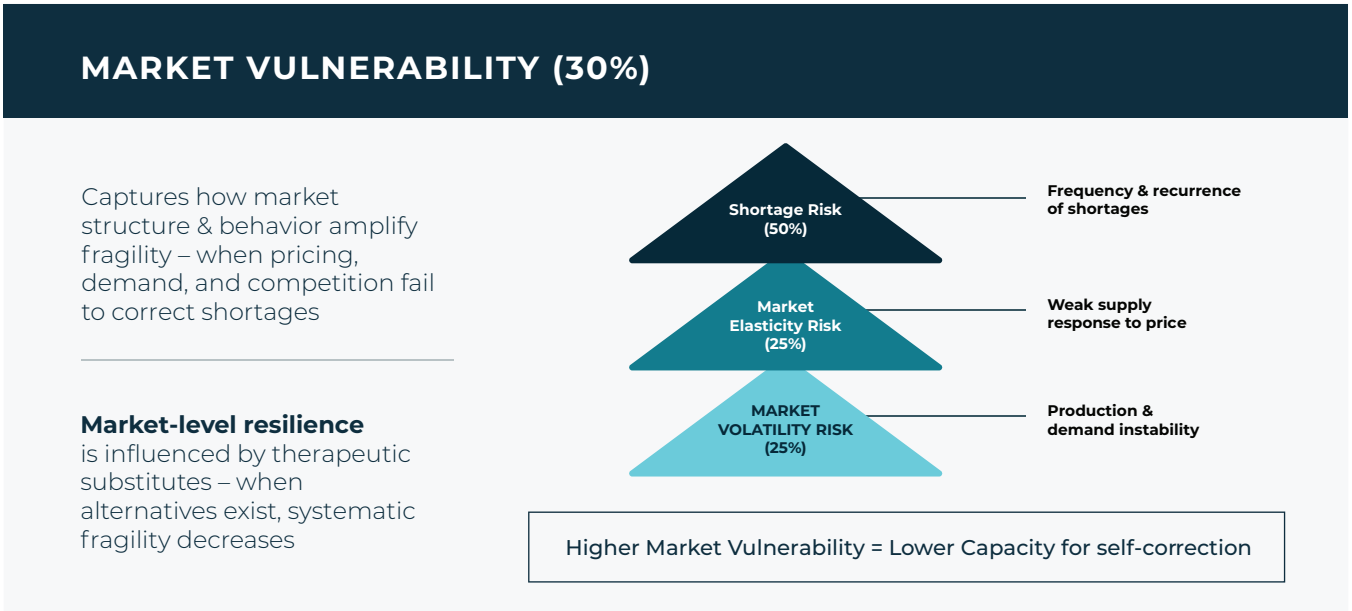
In constructing the NFI, APIIC analyzed more than 150 variables and sub-variables before narrowing the assessment tool's focus to a few specific variables that serve as the engine of the index. The tool uses those variables, spanning three weighted categories, to produce a composite score reflecting the fragility and risk of supply disruption in the U.S. pharmaceutical supply chain. A higher score means greater risk of fragility. The three components (and their sub-factors) include:

» **Domestic Capacity Deficiency (50% of the NFI ranking):** Quantifies U.S. reliance on its own manufacturing depth, redundancy and financial strength to maintain medicine supply during global shocks. Sub-factors include:

- U.S. supply coverage (40% of this component), measuring whether domestic sites can meet national demand if imports stop
- Single-site dependency (25%), measuring reliance on one or two facilities for total output
- U.S. site risk (20%), measuring domestic production capacity
- Supplier financial resilience (15%), measuring financial stability and the ability to recover or scale during shocks

» **Market Vulnerability (30% of the NFI):** Captures how market structure and behavior amplify fragility when pricing, demand and competition fail to correct shortages:

- Shortage risk (50% of this component), measured by the frequency and recurrence of shortages
- Market elasticity (25%), measuring weak supply response to price
- Market volatility risk (25%), measuring production and demand instability

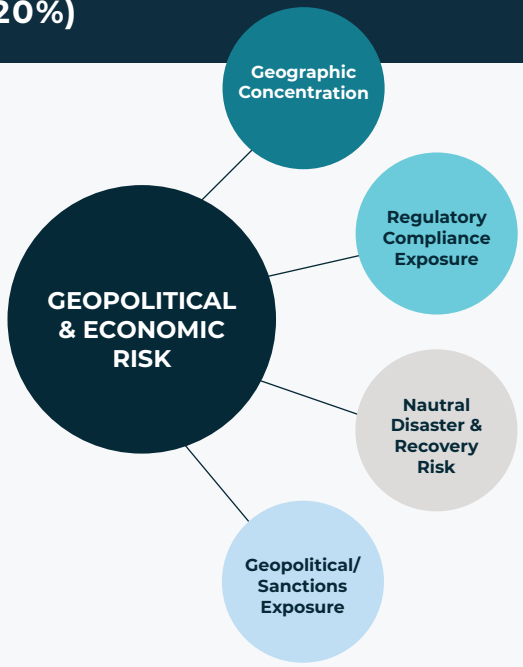


## GEOPOLITICAL & ECONOMIC RISK (20%)

Measures exposure to instability where key drug ingredients are produced – from regulatory weakness to geopolitical tension & macroeconomic instability

**Concentrated Production = Fragile Supply**
Weak regulatory oversight amplifies disruption risk
Disasters & sanctions can halt U.S. access

**Higher Score = Greater Fragility & Disruption Risk**




» **Geopolitical and Economic Risk (20% of the NFI):** Measures exposure to instability where key drug ingredients (e.g., KSMs, APIs and excipients) are produced, stemming from regulatory weakness, geopolitical tension and macroeconomic instability:

- Regulatory compliance exposure (35% of this component), measuring reliance on foreign manufacturing sites with elevated FDA quality and enforcement risk
- Geographic concentration (25%), measuring country-level concentration of API or KSM production using the Herfindahl-Hirschman Index
- Natural disaster and recovery risk (20%), measuring exposure to country-specific natural hazards and recovery capacity weighed by production share
- Geopolitical and sanctions exposure (20%), measuring dependence on supplier countries subject to trade restrictions, sanctions, export controls or heightened geopolitical tension

A composite score is calculated using a formula in which each category is multiplied by its weighting: NFI = 0.20 (Geopolitical) + 0.30 (Market) + 0.50 (Domestic). NFI scores would be interpreted as such:

» 80% or more: Severe fragility in the selected medication category's supply chain

» **65% and 79%:** High fragility

» **50% to 64%:** Moderate fragility

» **Below 50%:** Low fragility

Scoring within the NFI would be disaggregated by drug class, which would provide policymakers with the data to identify and prioritize specific molecules or drug classes that have the highest risk of disruption and would cause the most severe patient harm if unavailable. This targeted approach allows the government to focus investment and use mechanisms such as long-term purchasing agreements or specialized manufacturing support where vulnerabilities are most critical.

The NFI is a product still in the development stage as APIIC continually seeks industry and stakeholder feedback. It is proposed as a tool to guide not only policy, but inventory, purchasing and treatment decisions among other stakeholders including health care professionals and drug makers.

### *Real-World Implementation*

Participants at APIIC's plenary stress the importance of measures of "criticality" — that is, the potential of patient harm or the availability of viable alternatives — as a key component of any fragility index. Ultimately, an NFI score is intended to cover approximately 3,000 medicines and hundreds of known and unknown drivers. To pressure-test the concept, APIIC piloted it on a selection of drugs APIIC designated as the "Vital 40" — generic drugs deemed priority medicines after reviewing and synthesizing various critical drug lists. This exercise served as an experimental setting for the NFI's measurement approach. **The findings from this pilot demonstrated the index's ability to identify the most critical vulnerabilities, revealing that drug classes such as anti-infectives and oncology drugs exhibited the greatest fragility, with many falling into the severe risk category.** The pilot was validated to show that drugs scoring high on the NFI align with real-world shortages, thus demonstrating the utility of the NFI in identifying priority areas for intervention.

Participants and panelists at the November plenary viewed the NFI as a necessary and critical instrument to guide decision-making and measure resilience at a national level. Feedback centered on the need to refine the tool to ensure the index is actionable, requiring it to be disaggregated by specific drug classes rather than offering only a single national score. Panelists and participants also affirmed the need to integrate demand data (already included in the NFI's Market Vulnerability component), and further proposed addressing the fragility of dosage forms and patient impact (such as the availability of alternatives) to accurately reflect real-world vulnerabilities. Ongoing development will be shaped by the national experts and stakeholders who participated in the plenary, ensuring the NFI reflects the complexity of U.S. pharmaceutical production, distribution and regulation.

> **"Fragility is about how we avoid the market breaking. Unfortunately, our focus is that we wait until there is a crisis or a shortage, and then we work on fixing those. How do we create a sentinel system so we can see where things are starting to go in the wrong direction?"** -Dr. Stephen W. Schondelmeyer, professor and director, PRIME Institute, Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota

**"Fragility is about how we avoid the market breaking. Unfortunately, our focus is that we wait until there is a crisis or a shortage, and then we work on fixing those,"** said panelist Stephen W. Schondelmeyer, professor and director, PRIME Institute, part of the Department of Pharmaceutical Care and Health Systems at the University of Minnesota College of Pharmacy. **"How do we create a sentinel system so we can see where things are starting to go in the wrong direction?"**

Such a system would provide insights that track systemic pharmaceutical risk across all medicines using forward-looking variables, extending visibility upstream to assess the origin and vulnerability of KSMs and raw materials, to identify points of failure that threaten the continuous supply of generic drug products.

## DATA TAXONOMY AND THE ACCESSIBILITY PROBLEM

The importance of using data across all the components of the generic drug supply chain highlights a recurring thread throughout this narrative: the challenge of data use and availability. Plenary panelists generally agreed that barriers to data accessibility exist because pharmaceutical companies treat crucial information as a competitive asset. Data sharing on the source, reliability, quantity and quality of KSMs, APIs and drug products could be advantageous for decision-making. Addressing opacity concerns is immensely important because opacity prevents purchasers, policymakers and government agencies from identifying vulnerabilities, anticipating shortages, aligning incentives and effectively targeting investments to prevent systemic supply failures, ultimately placing the risk on patients.

On the subject of the availability of data to address supply chain fragility — and the opacity of available data — panelist Nick Niemeyer, APIIC's chief technology officer, said, **"If we don't have a shared model of the problem that we're solving, two people can agree that they have it solved — and yet have solved different problems. That's one of the most challenging things about complex systems: writing requirements and truly understanding what the objective is. A singular taxonomy is the goal. Building something that would have the exact same language from KSMs to finished drugs is difficult."**

### *Potential Solutions*

The plenary discussions highlighted the need for practical, nonmandatory reporting tools to bypass the difficulty of creating a universal data language. The primary proposed tool was akin to a "stoplight system," whereby stakeholders across the supply chain report their supply status using aggregated color codes (red, yellow, green) rather than proprietary figures, allowing for a shared understanding of risk without enforcing consensus on data. Bray, also an advisory board member of the Delaware-based End Drug Shortages Alliance (EDSA), told plenary attendees that EDSA was developing such a system. Its goal is to eliminate any need to agree on definitions or data disclosures to describe supply and focus on whether to sound the alarm on a particular class of drugs. "Our big thing is if we are at 25% of expected capacity, we are in challenge," Bray said at the plenary. "Everybody can just say that's a red, and you don't have to leave any kind of intellectual property out there. Then you can aggregate those stoplights. If distribution is saying they're red, manufacturing is saying they're green and hospitals are saying they're green, what's going on?"

A "pharmaceutical transparency index" was also suggested as a nonmandatory mechanism to rank and reward companies that proactively share data, incentivizing openness rather than relying solely on mandates.

While divisive, another potential solution surfaced at the plenary centering on using the Defense Production Act (DPA) as a policy lever to encourage data sharing among stakeholders for the sake of national security. Panelist Tinglong Dai, Ferrari Professor of Business at Johns Hopkins University, noted the DPA already "provides the tools for the U.S. government to ask manufacturers to provide their capacity information or even inventory information." His remarks highlighted that the federal government may not need new legislation to improve supply chain visibility but could instead rely on existing authorities traditionally reserved for emergencies. Panelists also said the White House Office of Management and Budget (OMB) was already sending letters and surveys to manufacturers, suggesting the potential use of these statutory tools.

At the same time, this proposal divided participants for a handful of reasons, raising concerns about how far the government should go in mandating disclosure of proprietary business information, underscoring the balance between voluntary collaboration and regulatory intervention. Panelists also warned that compelling data disclosures, rather than incentivizing voluntary sharing, could destabilize the market and even worsen drug shortages in the short term by encouraging stockpiling if hospital systems receive early signals of a looming shortage.

Where the issue of trust is concerned, another suggestion emerged among plenary participants: reliance on trusted, noncoercive third parties, such as academic groups, nonprofits and collaborative organizations, to overcome the persistent reluctance to share proprietary data. Rather than requiring companies to disclose sensitive information to competitors or the federal government, these neutral intermediaries could serve as data stewards — aggregating, anonymizing and translating inputs into actionable insights while protecting confidential business details. In this way, nonpartisan entities may be better positioned to establish the trust necessary for transparency and sustained cooperation. **"Trust is the fuel to transparency. Transparency is the fuel to collaboration,"** said Bray from Angels for Change.


*Tinglong Dai listens as Laura Bray emphasizes the importance of trust across the pharmaceutical supply chain.*

# III. PATHWAYS FOR PREDICTABLE SUPPLY AND DEMAND

Beyond the challenge of identifying agreed-upon metrics to measure resilience, a variety of stakeholders across the supply chain — academics, policymakers, health care professionals and industry representatives — have identified another significant barrier to stable and reliable generic drug supply. Though the specific language each stakeholder uses may differ, it tends to converge on the same idea: Incentives among supply chain participants are misaligned, leaving many of the players struggling to cope with unforeseen shifts in supply and demand. For example:

- "Under the current market and regulatory environment, incentives are not generally aligned across [supply chain] participants to ensure the necessary level of investment in resilient practices and supplier redundancy. Mismatched incentives are also associated with inadequate inventory management practices that limit safety stocks and excess capacity that would enable a swift response to increased demand or decreased supply" [HHS, "Policy Considerations," 2024].
- "Since the market does not reward quality, manufacturers lack incentives to invest in quality measures if they can sell drugs at a low cost. Manufacturers need only to adhere to the FDA's Current Good Manufacturing Practices (cGMP), but this merely sets a floor" [U.S. Senate Aging Committee, "Full Report," 2025].
- "Current generic drug payment policies and practices encourage purchasers to choose manufacturers largely based on lowest price, which creates adverse market incentives for manufacturers to keep costs down even at the expense of needed investments in supply chain resilience, reliability, and advancements" [USP, "Resilience Initiative," 2025].

This issue also emerged at APIIC's August 2025 roundtable event, which gathered representatives from health care, industry, the economic sector and the federal government to identify U.S. drug supply chain challenges and how public-private partnerships might mitigate those issues. APIIC's resulting report noted that **"manufacturers face unstable demand and sales volumes, making it challenging to justify long-term investments in domestic capacity or advanced manufacturing technologies (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."** [APIIC, "PPP Roundtable," 2025]. The following were among the key insights surfaced at APIIC's August event:


*Tom Harvieux, senior vice president and chief supply chain officer at BJC Health System, provides insight at APIIC's August 2025 roundtable.*

- **The Market Rewards Lowest Price Over Quality.** The prevailing generic drug market operates as a commodity market, in which price is the sole differentiating factor, fundamentally discouraging investment in manufacturing quality and domestic capacity. Hospital reimbursement models, such as bundled payments for long-established generics, create a powerful incentive for purchasers to acquire the absolute cheapest product.
- **Intermediaries Undermine Value-Based Contracts.** Third-party intermediaries (GPOs, PBMs and wholesalers) exercise concentrated buying power and typically prioritize the lowest price, often undercutting or quickly dissolving existing long-term agreements between manufacturers and purchasers.
- **Lack of Supply Chain Transparency Hinders Decisions.** An opaque supply chain, in which information about KSM and API origin, quality, and manufacturing capacity is often proprietary or difficult to access, makes it more difficult for purchasers (like hospitals and retail pharmacies) to differentiate products based on value factors beyond price (e.g., quality or certainty of supply).

## SHIFTING THE VALUE PROPOSITION OF GENERIC DRUGS

Discussion around misaligned incentives and unpredictable supply and demand often converges on the question of whether low cost should be the single arbiter of value for generic medications. There is now broad agreement among stakeholders that it should not. Yet due to the "race to the bottom," market incentives are not built to value any other metric as highly as cost. A central conclusion from APIIC's 2025 plenary focuses on the urgent need to shift the value proposition for generic drugs from lowest cost to reliability, quality and certainty of supply. This systemic change requires coordinated policy and market mechanisms that incentivize stable purchasing behavior and investment in resilient domestic manufacturing.

### *Establish Predictable Demand via Long-Term Contracts*

We cannot overstate how frequently participants at the November 2025 plenary brought up the notion of incentivizing long-term contracts with drug suppliers or intermediaries. This strategy was often cited as a means to mitigate unpredictable demand in the supply chain, spur investment in AMTs, build stakeholder visibility into potential shortages and align mismatched incentives among stakeholders in the generic medicine supply chain.

For example, with regard to mismatched incentives, when low cost is the primary measure of value, some stakeholders in the supply chain are easily incentivized to alter, shift or cancel contracts for the sake of a few pennies per dose. Plenary participants noted an example of the potential misaligned incentives between hospitals and third-party intermediaries — specifically referencing PBMs, GPOs and distributors. While hospitals may be willing to pay a premium for greater supply certainty, intermediaries often prioritize securing the lowest cost.

With regard to AMT investment, manufacturers must be provided with long-term, guaranteed volume contracts (ideally three years or more) to de-risk investments in domestic capacity and AMTs. While the overall clinical need for generic drugs is relatively constant, the actual market demand for a specific manufacturer is fickle and unstable; purchasers frequently switch suppliers for a price difference of a fraction of a cent. Long-term contracts would provide manufacturers with the certainty of volume and price needed to justify multimillion-dollar AMT investments.

Existing bundled reimbursement models for long-established generic drugs incentivize hospitals to buy the cheapest product. To counter this, the Senate Finance Committee had proposed creating targeted Medicare

add-on payments for providers who certify they have entered long-term contracts to acquire critical generic drugs [Senate Finance Committee, "Wyden and Crapo," 2024]. That proposal has not advanced.

With regard to supply chain transparency, better information about allocation and stock on hand could create a culture of trust and information sharing rather than an adversarial, transactional relationship. **"Right now, our buyers place orders every day. It's a surprise if it's going to show up or not,"** said panelist Erin Fox, associate chief pharmacy officer of shared services, University of Utah Health. **"That sounds crazy, but that is hospital life."**

## *Shared Risk Models*

Plenary participants also stressed that moving the generic drug market away from a "lowest cost" focus toward one centered on reliability requires stakeholders across the entire supply chain to mutually benefit from stability. Because the benefits of AMTs (such as improved quality, efficiency and supply reliability) are shared by hospitals, payers, government, distributors, manufacturers, etc., these stakeholders must also participate in the risks of standing up that capacity. As discussed by plenary panelists, such a shared risk model would de-risk investments in AMTs for generic drugs and their precursor molecules (APIs and KSMs). This model was likened to the strategic management of other vital sectors such as semiconductors and rare earth minerals, for which the government and private sector co-invest to secure national infrastructure.


This could look like using government grants, forgivable loans or long-term purchase commitments by generic drug consumers to provide the necessary economic nudge that would justify the investment in AMTs. Such a model is critical because generic drug makers typically lack the capital to invest in AMTs, which can be leveraged to build reliable, efficient and high-quality supply. By sharing the risk, partners justify the initial investment and subsequent efficiency and quality improvements. Participants at APIIC's plenary and in other forums have suggested that time-limited investments by the federal government could jump-start AMT adoption by drug manufacturers. For example, with regard to existing federal investments, the HHS Administration for Strategic Preparedness and Response (ASPR) operates its Center for Industrial Base Management and Supply Chain (IBMSC). This center "works through public-private partnerships to create diverse, agile public health supply chains and sustain long-term U.S. manufacturing capabilities." Further, IBMSC "invests in medical product industrial base capacities … to respond to future public health emergencies" and, through this work, bolsters supply chain resiliency efforts across various stakeholders, including the federal government, academia and the private sector [ASPR, "IBMSC," 2025].

**Panelists noted that achieving resilience requires a collective commitment to redefine value in our drug supply chain,** comparing this approach to those used to justify investments in other sectors critical to national security like rare earth minerals and microprocessors. For example, the signed version of President Trump's "Big Beautiful Bill Act" in July 2025 includes an expansion of Biden-era tax credits for U.S.-based semiconductor

manufacturers, rising to 35%. The goal: "Strengthen the U.S.'s domestic semiconductor supply chain and stimulate economic growth. U.S. chip developers face stiff competition from China, particularly as AI has driven up demand for data centers and consumer devices" [TechRepublic, 2025].

By treating generic medicines as part of the strategic national infrastructure, akin to semiconductors, the government absorbs investment risk, which provides the certainty manufacturers need to modernize and maintain reliable domestic supply capability. This approach signals that supply for critical medicines is a national security priority, thereby encouraging private sector participation through stable, value-based contracts. **"I was working next to the folks that were looking at electric batteries and semiconductors and rare earth elements. They had a seat at the national security table,"** said panelist Monique K. Mansoura, founder and CEO, Beacon Biostrategies, recalling her previous roles as a government leader for the ASPR medical countermeasures program and as executive director of Global Health Security & Biotechnology at MITRE. **"I think it really starts with our narrative as we talk about critical medicines [being] arguably as vital as critical minerals and rare earth elements."**

### *Single Points of Failure*

The suggestion to identify generic drug supply as a national security priority underscores APIIC's core belief that restoring domestic production for generic drugs, APIs and KSMs is critical. The challenge is not that critical medicines are manufactured abroad in general, but that overreliance on a small number of foreign sources creates a single point of failure and a national security risk. Reducing these choke points requires diversification of domestic supply. **"I'm actually really happy that my drugs come from China. I just don't want all my drugs to come from China,"** said panelist Chan Harjivan, chief strategy officer, Medical Countermeasures Coalition. **"I want them to come from Ireland, from New Jersey and from China as well. You need diversification."**

The concentration of manufacturing offshore, particularly in India and China, creates vulnerabilities to geopolitical events, such as India's restriction of exports during the pandemic. For example, the FDA has reported that 88% of API manufacturing facilities and 64% of drug products are concentrated in China and India [FDA, "Drug Shortages," 2019]. More recently, QYOBO analyzed companies holding valid U.S. Drug Master Files (DMFs) — the key submission or "secret recipe" — provided to the FDA for regulating drug components. In the first quarter of 2025, Indian manufacturers held 47% of valid DMFs, while Chinese companies held 21%. Meanwhile, U.S. companies held only 7% of valid DMFs [QYOBO, Market Trends, 2025]. **The consensus: Resilience requires supply chain diversification to mitigate risks from single points of failure, even if that diversity increases overall production costs.**

## FEDERAL PROCUREMENT AND REIMBURSEMENT AS A MARKET CATALYST

The federal government has tremendous influence over the health care markets through its purchasing and reimbursement power across the Department of Veterans Affairs, Department of War and Centers for Medicare & Medicaid Services (CMS). In fact, the federal government accounted for more than 40% of outpatient prescription drugs purchased in the U.S. in 2018. That figure does not include out-of-pocket and state expenditures for outpatient prescription drugs [CBO, "Drug Prices," February 2021].

### *Emerging Federal Policy Signals Affecting Pharmaceutical Supply Chains*

The Trump administration and Congress have already put in motion action in this policy area. In January, CMS issued an Advance Notice of Proposed Rulemaking (ANPRM) to receive public input on potential strategies to strengthen the essential medicine supply chain [Federal Register, 2026]. This notice seeks comment on

how hospitals that participate in Medicare can shore up American-made personal protective equipment and essential medicines. The notice also seeks input on a possible "Secure American Medical Supplies" designation for hospitals that demonstrate a commitment to domestic procurement and on potential payment policies to support such procurement. This effort presents an opportunity for government and industry, through participation in the ANPRM, to play an important role in shaping the future of domestic pharmaceutical manufacturing in the U.S. Given the signaling power of government reimbursement and procurement practices, the potential ripple effects of a new CMS rule could be significant.

Several areas exist in which CMS could consider how its existing authorities and payment frameworks might support greater domestic pharmaceutical manufacturing resilience, particularly for high-utilization generic medicines relied upon by Medicare and Medicaid populations. Areas of interest could include:

- **Product Transparency and Targeting:** Exploring mechanisms to recognize domestically sourced APIs at the product level and focus policies on frequently used or shortage-prone generic medicines rather than applying broad systemwide approaches.
- **Use of Existing Payment and Reimbursement Levers:** Leveraging existing Medicaid and Medicare payment structures to incentivize domestic API production while maintaining beneficiary affordability.
- **Formulary, Cost-Sharing and Provider Signals:** Using formulary guidance, cost-sharing design (e.g., Medicare Part D) or provider payment policies (e.g., Medicare Part B) to signal preference for domestically sourced generics while preserving clinical flexibility.
- **Coordination, Data and Evaluation:** Coordinating with states and other federal partners on what data collection or evaluation approaches could help assess impacts on supply chain resilience, access and cost.

In Congress, the fiscal year 2026 appropriations minibus that funded HHS included several policy provisions. Most notably, the bipartisan package includes changes affecting PBM compensation in Medicare Part D, requirements related to rebate pass-throughs in the commercial market, and new transparency and contracting standards [HR 7148, 2026]. Collectively, these provisions reflect continued congressional interest in examining pricing, contracting and transparency practices within the prescription drug supply chain and their potential implications for patient access and cost trends.

## *Leveraging Federal Procurement*

Using its policy levers, the government could act as a "first mover," prioritizing quality and domestic sourcing in its procurement and reimbursement practices. The U.S. Senate Special Committee on Aging report recommended establishing a federal buyer's market for essential medications while prioritizing American-made APIs and KSMs. A buyer's market would be a mechanism to shift the procurement decisions from a singular focus on lowest price toward reliability, quality and supply certainty. This strategy would signal that quality and supply security are valued; the federal market could influence private markets to follow suit, transforming the existing dynamic in which manufacturers face unstable demand and competition based only on cost.

Importantly, the guarantee of long-term federal purchasing contracts should be applied strategically. Procurement commitments could be tied to medicines identified as critical through objective indicators or

scorecards, such as APIIC's proposed NFI. For example, drugs scoring high on the NFI, signaling severe supply fragility, including many anti-infective, oncology and cardiovascular medicines, could qualify for preferential federal purchasing agreements or targeted investment incentives. In this way, federal procurement would not only stabilize demand but also direct resources toward the products most essential for national defense, public health emergencies and acute care needs.

## *Addressing Systemic Financial Barriers*

The existing hospital reimbursement system, particularly concerning generic drugs, creates an economic environment where buyers' (e.g., hospitals or GPOs) purchasing decisions are driven almost exclusively by receiving product at the lowest price, thereby leaving little room for discussions on efforts to establish a resilient drug supply chain that prioritizes quality and reliability. This barrier is rooted in the structure of Medicare and commercial payment models:

- **Bundling Reinforces Lowest Cost:** For generic drugs, hospitals are often reimbursed by commercial and government payers such as CMS in a bundled payment system [Journal of Economic Perspectives, 2025]. Under the CMS Inpatient Prospective Payment System and similar bundled payment models, hospitals receive a single payment for an episode of care that covers all included services and supplies, including drugs, rather than itemized reimbursement for each drug administered [CMS, "IPPS," September 2024]. This means the cost of these drugs is not paid for separately but is included as part of the overall payment for an inpatient stay or an outpatient visit.
- **Loss of Margin:** Because these drugs are not separately reimbursed, any additional cost incurred is absorbed by the hospital, reducing its margins. This creates an economic incentive for hospitals to buy the cheapest product possible.
- **Lack of Aligned Incentives with Manufacturer Practices:** The current reimbursement structure provides no incentive for hospitals to factor manufacturer practices like continuous process improvement, reliable sourcing of materials and a strong record of FDA compliance into purchasing decisions

**"If domestic supply chains are important, and we need to secure them to make sure we have less dependency on other countries, then that needs to be reflected in the payment models — how hospitals are reimbursed,"** said panelist Michael Ganio, senior director, pharmacy practice and quality, Office of Practice Advancement, ASHP. **"That will change their decision-making on purpose."**

These points build on insights from APIIC's PPP roundtable in August. There, as participants noted, the perception that generic drugs are perfectly substitutable means buyers (e.g., hospitals and GPOs) undervalue and underpay for supply chain reliability.

*Panelist Michael Ganio, senior director, pharmacy practice and quality, Office of Practice Advancement, ASHP speaks at APIIC's 2025 plenary event.*

In truth, buyers cannot accept as an article of faith that generic drugs are perfectly substitutable. A 2026 research study by Dartmouth's Tuck School of Business notes that "marketing a generic product thus only requires labelers to demonstrate bioequivalence to the brand" but goes on to point out that "the lack of transparency of supply chains means that buyers themselves cannot directly observe and reward plant-level resilience, compelling them to prioritize the lowest-priced drug" [Tuck, 2026].

Even if hospitals express a willingness to pay slightly more for reliability, the reimbursement structure makes it difficult to act on that preference. Intermediaries (e.g., PBMs) can unilaterally reset reimbursement values after a hospital makes a commitment to a manufacturer, undermining the arrangement. Panelists and policymakers agree that addressing this systemic financial barrier is necessary. Proposed solutions generally fall into two categories: federal payment reform and incentives tied to purchasing behavior. Federal payment reform initiatives could include, for example:

- **Targeted Medicare Add-on Payments:** A Senate Finance Committee proposal involved a Medicare add-on payment to providers for critical generic drugs if those providers certify that they have entered into long-term contracts for those products. This reimbursement change was explicitly designed to encourage hospitals, PBMs and GPOs to prioritize U.S.-based products and invest in supply chain stability [Senate Finance Committee, "Wyden and Crapo," 2024]. In early November 2025, HHS and CMS advanced a new payment model that "allows CMS to negotiate with participating manufacturers for lower prices, while states adopting the model will implement uniform, transparent coverage criteria. These consistent standards will give patients and providers predictable access across participating states" [CMS, "Payment Model," 2025]. This model is expected to launch in 2026.
- **Pay for Performance:** HHS has previously expressed its awareness of policy suggestions to "reward providers for long-term contracts or quality of purchasing decisions, or for preventing or reducing shortages" [HHS, "Policy Considerations," 2024].
- **Realigned Reimbursements for Compliance and Sourcing:** The government could launch pilot initiatives to increase Medicaid or Medicare reimbursements for providers that use U.S.-made generic products and purchase from manufacturers with a strong FDA compliance record. This support for domestic manufacturing practices would allow these companies to compete with overseas production.

At the same time, market- and quality-driven incentives could include:

- **Financial Incentives via Quality Scorecards:** Creating a federally operated system, such as a quality report card, that assesses the maturity, reliability and resilience of manufacturers' quality management. CMS could then prioritize medications for preferred Medicare formulary placement that are sourced from manufacturers scoring high on this quality assessment.
- **Hospital Resilient Supply Program:** HHS previously proposed creating an HRSP, which would establish financial incentives and/or penalties for hospitals based on their performance on a hospital scorecard. This scorecard would measure hospital adherence to requirements and performance in adopting practices that promote supply chain resilience, such as buying from reliable manufacturers [HHS, "Policy Considerations," 2024].
- **Long-Term Contracts as an Incentive:** The most frequent solution proposed is the use of long-term, guaranteed-volume contracts as noted above.

# IV. UPSTREAM COMPONENTS AND STAKEHOLDER ALIGNMENT

Two themes emerged during APIIC's 2025 plenary that had not been explored in depth in its two previous convenings. The first highlighted the need for greater visibility into KSMs within the generic drug supply chain to better understand vulnerabilities that are often overlooked. The second emphasized the importance of engaging all stakeholders on the demand side of the generic medicine marketplace. While patients remain central to these discussions, hospitals, health care systems and retail pharmacies have been well represented in APIIC-hosted conversations, and government purchasers (e.g., Department of War, Veterans Administration, CMS) are widely recognized as potential market-making actors. However, a key segment of the supply chain has not yet been fully engaged as a collaborator in addressing persistent drug shortages in the U.S.: intermediaries such as PBMs, GPOs and distributors.

**"I think there should be a seat at the table. We can't look at the intermediaries as an adversary,"** Conrod said at the plenary. **"We have to look at them as a partner. If the goal is reliability and low cost, this is not low cost in the beginning. This is an investment from all of us. But over time, this will pay off."**

## INTEGRATING KSMS FOR END-TO-END RESILIENCE

Similar to APIs, many KSMs lack a U.S. source and are highly dependent on foreign sources. KSMs are an under-recognized yet critical component of pharmaceutical supply chain resilience. As the foundational input to APIs and thus drug products, KSM availability, quality and geographic concentration directly determine the feasibility, scalability and security of all downstream production in the generic drug supply chain. Participants in APIIC's 2025 plenary emphasized the need for collaboration across every tier of the supply chain, noting that a resilient supply chain must include upstream components, particularly KSMs and APIs, which are still largely sourced overseas.

**"To make intelligent investment decisions to leverage our resources, both physical resources and people resources, to align that with what's required downstream with the API manufacturers, it's going to require that collaboration,"** said panelist Jim Stockhausen, business development director for KSM manufacturer FutureFuel Chemical Company. **"Has it worked up until now? No, because we are all profit driven." He went on to say that the bottlenecks are how to collaborate that way and share the value chain as well as intellectual property.**

These bottlenecks, as Stockhausen described them, were a primary concern addressed at the plenary. The lack of visibility for KSM manufacturers into the subsequent stages of the supply chain destabilizes their ability to commit resources:


*Panelist Jim Stockhausen, business development director, FutureFuel Chemical Company emphasizes that a resilient drug supply chain must include upstream components.*

- **Lack of Downstream Knowledge:** KSM manufacturers do not have visibility into final products and markets. The lack of transparency up and down the supply chain results from confidentiality practices among API manufacturers and KSM suppliers, making the initial supply chain particularly opaque to the government and downstream manufacturers. This speaks to the issue of intellectual property. Siloed communication and IP concerns have historically hindered the necessary direct collaboration between KSM, API and drug product manufacturers.
- **Impact on Investment:** Without visibility, KSM manufacturers cannot make informed investment decisions regarding their assets or personnel.

Plenary participants outlined several strategies to fully integrate KSM manufacturers by establishing committed demand, securing demand from commercial partners for the drug product and rewarding quality, thereby enabling long-term investment. Other strategies include:

- **Collaboration and Data Sharing:** Close collaboration among manufacturers of KSMs, APIs and drug products is essential to understanding vulnerabilities and constraints across the supply chain. Achieving this requires cross-tier data-sharing agreements that enable more accurate demand forecasting, improved coordination and the reduction of production bottlenecks.
- **Prioritizing Predictable Demand:** Visibility down the supply chain brings information about demand, the information KSM manufacturers need to commit resources, align investments and expand capacity.

## ALIGNMENT OF STAKEHOLDERS AND DEMAND-SIDE ACCOUNTABILITY

This unpredictability of demand was a throughline in APIIC's 2025 plenary. Demand-side opacity reduces the reliability of purchasing decisions, disrupts inventory levels and destabilizes purchasing commitments between buyers (e.g., hospitals, retail pharmacies) and intermediaries (e.g., GPOs, PBMs). Addressing this opacity is critical for manufacturers to make strategic investment decisions. In the context of manufacturing and supply inventories, panelists highlighted the "bullwhip effect," an economic principle in which small fluctuations in consumer demand can trigger disproportionately large swings in inventory levels and production orders further upstream in the supply chain. For example, when demand is fickle, a well-leveraged buyer may cancel a commitment to purchase from one manufacturer and buy from another with a lower price. This volatility leaves the first manufacturer with an inventory it must unload — likely at a lower price — further driving the race to the bottom. Strategies that might bring clarity to the demand-side of the equation included:

- **Incentivizing Long-Term Commitments:** The primary strategy to overcome opacity is to incentivize demand-side stakeholders to commit to stable, predictable purchasing patterns, thereby fostering long-term, strategic partnerships.
- **Improving Inventory Visibility:** Transparency needs to be applied to inventory management, helping the industry understand what's available in the supply chain and what is required to rapidly ramp up production. Rather than await a decades-long process to set a common taxonomy across all stakeholders, a practical solution might be a "stoplight system" that aggregates stakeholders' measurements of supply status into a shared red/yellow/green framework, helping the supply chain identify and respond to shortages without requiring consensus on terminology or revealing proprietary data.
- **Transparency for Trust and Response:** Transparency efforts must be purpose-driven, including transparency for response to crises and transparency for trust and fostering collaboration.

This last point is key, as it relates to prioritizing drug classes with highly fragile supply chains that are critical to patient care (e.g., antimicrobials, cardiovascular drugs and oncology therapies). In these cases, shortages carry a high clinical impact, severe bottlenecks exist and substitutions are much harder. Stakeholders should leverage the high clinical impact and mortality and morbidity data associated with these shortages to effectively influence policymakers. Furthermore, advocacy should focus on the economic rationale specific to these drugs:

- **Acknowledging the Negligible Cost Impact:** Consider that antibiotic courses are typically short (e.g., 14 days). Thus, doubling the price of antibiotics would have a negligible effect on overall health care costs. The product's value for money is exceptional, which could justify paying more to ensure resilience.
- **Targeting Bottlenecks:** Focus resources on drugs with the most fragility and bottlenecks, such as a KSM that feeds into various anti-inflammatory drugs.
- **Using Data Metrics:** Use tools such as the NFI, which demonstrated that antimicrobial, oncology and cardiovascular drugs are among the most fragile, to guide resources.

As discussed, all stakeholders in the U.S. supply chain for generic medicines should be seen as partners in a campaign to strengthen the nation's health care security with reliable access to essential medicines. All the partners have a seat at the table to plan and execute strategies in support of this goal. Yet all have not been given the chance to engage with the opportunity.

This level of engagement with intermediaries was called for as far back as 2019, during President Trump's first term, in an FDA report (updated in 2020) titled "Drug Shortages: Root Causes and Potential Solutions." The FDA's drug shortages task force "concluded that addressing the root causes of shortages requires the active participation of private sector players, including purchasers and intermediaries, alongside manufacturers and the public sector" [FDA, "Drug Shortages," 2019]. Among its recommendations:

- **Promote Greater Transparency in Contracting:** The inclusion of low-price clauses in contracts permits GPOs to unilaterally walk away from a contract commitment if a competitor offers a lower price. More study of these practices is needed to develop model contracts that promote reliable supply.
- **Quantify Harm:** Intermediaries and purchasers need more information on the clinical and financial impacts of shortages to make informed buying decisions, which could play a role in preventing and mitigating drug shortages.
- **Use Quality Rating Systems:** Intermediaries are central to the strategy of using a rating system to incentivize quality. A facility quality management maturity rating system could be used to inform purchasers, GPOs and even consumers about the quality commitment of a manufacturing facility. GPOs and purchasers could be required to disclose the rating in their contracts, introducing transparency and giving quality-committed firms a competitive advantage.


*Tony Sardella and Erin R. Fox listen as Monique K. Mansoura emphasizes the national health security risk created by U.S. overreliance on foreign suppliers of critical generic medicines.*

# V. CONCLUSION: COLLECTIVE CALL TO ACTION

The discussions at APIIC's 2025 plenary, "Resilience in Action: Partnerships, Policy and Progress Driving U.S. National Health Security," affirmed that establishing a stable and secure supply of critical generic medicines is an urgent national imperative. **Resilience will not emerge from any single policy or entity; it requires sustained partnership, shared risk and a collective commitment across the entire pharmaceutical supply chain to fundamentally redefine value.** The path forward demands a strategic shift from dependency to security and from crisis reaction to measurable strategic readiness.

The ultimate focus of any strategy must remain the patient, who bears the entire clinical risk of supply failures, yet holds zero power to influence a system that chronically produces shortages, risking the national health security of the nation and the well-being of untold millions. Achieving national health security requires accountability from every stakeholder and concerted action on the following measurable strategies:

## OPERATIONALIZING RESILIENCE: A COMMITMENT TO MEASUREMENT

Stakeholders in the generic drug supply chain must transition from a reliance on lagging indicators to implementing real-time, system-wide measurements that can forecast looming risks before they escalate into crises.

- **Commit to the National Fragility Index as a Guiding Instrument:** The NFI, undergoing continuous iterative refinement, is designed to identify where fragility in the supply chain is most concentrated, illuminate vulnerabilities and enable measurement toward greater resiliency. The NFI must be adopted as the critical instrument to quantify system risk, guide decision-making, and measure progress towards resilience at a national level. This commitment requires continuous development, ensuring the NFI is:
    - Actionable and Disaggregated: The NFI will be positioned to provide granular data broken down by specific therapeutic categories (e.g., anti-infectives, oncology) to target interventions and effectively guide the allocation of resources.
    - Patient Centered: Vulnerability scoring must incorporate patient impact metrics, weighing fragility by therapeutic importance, patient harm potential and the availability of viable alternatives.
- **Incentivize Data Access Through Nonmandatory Tools:** To overcome the data taxonomy problem posed by conflicting definitions of key terms such as "shortage," stakeholders must deploy practical, non-mandatory tools for supply status reporting. Plenary discussions put forth the notion of a "stoplight system" offering supply chain stakeholders (e.g., manufacturers, distributors) a way to signal risk in their portion of the market without requiring consensus on a single proprietary metric or the disclosure of sensitive intellectual property.
- **Reward Openness and Use Policy Levers:** Transparency will not occur through regulation alone, necessitating new mechanisms that reward proactive data sharing and reliability. Policy consideration should assess the potential use of Defense Production Act authority to compel necessary supply chain data for national security purposes, ensuring that critical visibility gaps are addressed.

## PATHWAYS FOR PREDICTABLE DEMAND AND REALIGNED VALUE

The persistent economic failure of the generic drug market stems from purchasing decisions driven solely by lowest cost. The centerpiece of reform must be systemic intervention that shifts the value proposition to reliability, quality and certainty of supply.

- **Establish Long-Term, Guaranteed Volume Contracts:** Long-term contracts, preferably at least three years in duration, are the fundamental prerequisite for de-risking private sector investment in domestic capacity and AMTs. These contracts stabilize demand, countering the volatile purchasing patterns that fuel the "bullwhip effect" and penalize stable manufacturers.
- **Leverage Federal Procurement as a Market Catalyst:** Federal agencies, including the VA, DoW and CMS must use their massive market influence to be first movers on the demand side of the supply chain, prioritizing procurement criteria that reward quality, resilience and domestic sourcing over mere cost. With that influence, the government can send a clear policy signal and help shape the market toward valuing security.
- **Implement Shared Risk and Reward Models:** Policy reforms must address systemic financial barriers such as the hospital reimbursement system (e.g., bundled payments for long-established generics) that incentivize purchasing the cheapest product possible. The industry must adopt shared risk and reward models through which all stakeholders — manufacturers, hospitals, payers and intermediaries — mutually benefit from the efficiency and reliability gains associated with the adoption of AMTs.

## INTEGRATING UPSTREAM COMPONENTS AND STAKEHOLDER ALIGNMENT

A successful road map to pharmaceutical supply chain resilience requires addressing gaps both upstream in the supply chain and among key downstream stakeholders whose actions often reinforce market fragility:

- **Prioritize Integration of KSMs:** KSM manufacturers, identified as a foundational and often-overlooked part of supply chain resilience, must be fully integrated into domestic strategies. Collaborative models are needed to overcome intellectual property challenges that currently bottleneck essential technical collaboration among KSM and API manufacturers and other links in the supply chain.
- **Engage Intermediaries in National Dialogue:** Key influential stakeholders must make concerted efforts to engage PBMs, GPOs and other third-party intermediaries in collaborative, high-level forums to seek alignment with the nation's resiliency goals. That means defining and establishing accountability mechanisms to ensure intermediaries contribute to solving supply chain challenges rather than exacerbating them through low-cost contracting. Focus first on targeted interventions for high-fragility drug classes, such as antimicrobials, for which bottlenecks and clinical impact are severe.

The road map to security has been drawn and informed by experts from across the supply chain. The focus is now on implementation, which demands decisive action, collective buy-in and a mission-driven commitment that places national health security above short-term economic gains.

# VI. APPENDIX

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## PLENARY MODERATORS AND PRESENTERS

### *Panel 1: Public-Private Partnerships: Building Certainty of Supply and Demand*

**Kevin Webb, MBA, president and COO, API Innovation Center (moderator):** Webb has direct responsibility for business operations, programs, strategy and external engagement at APIIC, leading its efforts at the national and regional levels to strengthen domestic pharmaceutical manufacturing in the U.S. He is a subject-matter expert and featured speaker on the importance of securing our national health security. Webb has 30 years of experience in the health care industry, with broad, cross-functional technical expertise in government affairs, communications, manufacturing, operations, sales and brand management. He is a highly respected and trusted representative of the pharmaceutical industry. Prior to working at APIIC, Webb held leadership roles at Mallinckrodt Pharmaceuticals, Sanofi Pasteur Vaccines and Memorial Medical Center, a tertiary health center in Central Illinois. He holds an MBA from the University of Illinois and a Bachelor of Science from Saint Louis University.

**J'Aime Conrod, vice president, government, business and health care policy, Amneal Pharmaceuticals:** Conrod leads the company's enterprisewide strategy to strengthen public-private partnerships that support national health security. With more than 25 years of experience in the health care sector, she drives initiatives that expand Amneal's engagement with federal and state government agencies to improve access to affordable medicines, reinforce supply chain resilience through domestic onshoring, and accelerate the development and deployment of medical countermeasures. Her leadership spans generics, biosimilars and specialty branded portfolios, aligning Amneal's capabilities with public health priorities in pandemic preparedness and emergency response. Conrod serves as co-chair of the pharmaceutical subcommittee for The Coalition for Government Procurement and is the incoming chair for AMSUS-Sustaining Members, both trade associations that support greater engagement with the federal government. She was a founding member of the AMSUS Executive Advisory Board, a federal think tank designed to bring together industry executives and federal government leaders to champion greater partnerships and drive innovation to shape federal medicine. Conrod holds a Master of Science in public health from the University of South Florida, College of Public Health, and a Bachelor of Science in interdisciplinary sciences from The Ohio State University. She holds a Lean Six Sigma Green Belt Certification from the Terry College of Business, University of Georgia.

**Michael Ganio, Pharm.D., M.S., FASHP, senior director, pharmacy practice and quality, Office of Practice Advancement, 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 a Master of Science in health-system pharmacy administration from The Ohio State University, where he also completed a PGY1 residency. Board certified in sterile compounding and pharmacotherapy, Ganio became an ASHP fellow in 2017. With over 20 years of experience 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.

**Jim Stockhausen, business development director, FutureFuel Chemical Company:** Stockhausen has extensive experience in the chemical industry, having held various management roles at companies such as The CHEMARK Consulting Group and ELANTAS PDG Inc. Stockhausen has a Bachelor of Science in chemical engineering from the University of Tennessee and an MBA from Washington University in St. Louis. Stockhausen's expertise lies in driving sales growth, managing P&L and leading new product development initiatives.

## *Panel 2: Opening the Black Box: Data Transparency in the Pharmaceutical Supply Chain*

**Chan Harjivan, MBA, MPH, Pharm.D., chief strategy officer, Medical Countermeasures Coalition (moderator):** Harjivan's career spans more than 25 years in public health, government and the biopharmaceutical industry. He has worked with nearly every major pharmaceutical company, U.S. health agency and global health organization to align priorities and accelerate the development and deployment of lifesaving vaccines, therapeutics and diagnostics. Previously, he served as a special assistant to the president in the White House, overseeing vaccines, therapeutics, diagnostics, R&D, supply chain and response plans to strengthen the nation's readiness for biological threats through strategic policy coordination, interagency collaboration and public-private partnerships. He was a key architect behind Operation Warp Speed — the historic federal initiative that developed and distributed the COVID-19 vaccine, saving $1 trillion and 3 million lives. He is also the co-founder of SaponiQx, a next-generation vaccine adjuvant company valued at $250 million on exit. Earlier in his career, he led global health practice and public sector health practice at leading consulting firms.

**Laura Bray, chief change maker, Angels for Change:** Bray is an adjunct business professor at Hillsborough Community College. Prior to academia, she worked in marketing strategy and small-business management and consulting. She graduated from University of Florida with a Bachelor of Science in business administration and from University of South Florida with an MBA. She lives in Valrico, Florida, with her husband and three children. On Nov. 24, 2018, her daughter Abby was diagnosed with acute lymphoblastic leukemia. Before that day, Bray knew very little about leukemia or childhood cancer. In April 2019, while in treatment, Abby was in need of a lifesaving drug that was part of a prolonged global shortage. This is when Bray realized that just because a proven, lifesaving medical technology exists, it does not mean a patient will receive it. For Bray, it is unacceptable that any family or patient, in a fight for survival, should be told they don't have access to the lifesaving drugs needed to fight their disease.

**Tinglong Dai, Ferrari Professor of Business, Johns Hopkins University:** Dai is a core member of the Johns Hopkins Prescription Drug Supply Chain Resource Center. His research spans health care, global supply chains and artificial intelligence. His work has been published in leading journals such as Management Science, M&SOM, Marketing Science, Operations Research, the Journal of Marketing Research, NEJM AI, JAMA Health Forum, and npj Digital Medicine. He serves as associate editor for Management Science, M&SOM, npj Digital Medicine, Service Science, Health Care Management Science and Naval Research Logistics; sits on the editorial board of Marketing Science; and is senior editor for the INFORMS Journal on Data Science and for Production and Operations Management. He is co-editor of the "Handbook of Healthcare Analytics" (Wiley, 2018) and "AI in Supply Chains: Perspectives From Global Thought Leaders" (Springer, 2025). He joined Johns Hopkins in 2013 after earning a Ph.D. in operations management and robotics from Carnegie Mellon University. He has been quoted hundreds of times in the media, including by CNN, The New York Times, NPR, The Wall Street Journal and The Washington Post. He has also appeared on BBC News, CNBC and PBS. In 2021, Poets & Quants named him one of the World's Best 40 Under 40 Business School Professors. He serves as vice president of marketing, communications and outreach at INFORMS.

**Nick Niemeyer, chief technology officer, API Innovation Center:** Niemeyer is developing and executing APIIC's technology strategy, leading the design and deployment of an innovative data solutions platform and building a strong technology team to support the organization's mission. Niemeyer has more than 15 years of experience in technology leadership, specializing in data engineering and platform development. He is an expert in driving innovation and operational efficiency across complex technical environments and has a proven track record in

scaling systems and leading high-performance teams. Before joining APIIC, Nick served as the chief technology officer at Transactly and Evolve24. He also held various leadership and engineering positions at Riot Games, Answers and Google.

## *Panel 3: Fragility Index- From Fragility to Resilience*

**Anthony Sardella, MBA, founder and chair, API Innovation Center (moderator):** Sardella is responsible for the overall leadership and strategic planning at APIIC, delivering on its 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 Olin Business School at Washington University in St. Louis and senior adviser to the school's Center for Analytics and Business Insights. He has published a series of articles on U.S. health security and the fragility of the U.S. drug supply chain and recently served as chair of the Bellwether Foundation Commission studying analytical solutions to detect the diversion of opioids in the drug supply chain. Before working at APIIC, Sardella was chief innovation and growth officer for a privately held company where he led innovation and investment efforts aimed at driving profitable growth opportunities for the portfolio. He also served as director of analytics at Monsanto Company and contributed to the development and implementation of strategies for faster adoption of Monsanto's suite of biotechnology products, all of which he can apply to revenue growth strategies for APIIC. Sardella is a toxicologist by training and has authored or co-authored more than 25 papers in human health and environmental risk assessment prepared on behalf of government agencies and nongovernmental scientific bodies. In April 1998, he was inducted as a Smithsonian Institute Laureate for his visionary work leading to significant social and economic impact in science and technology. He earned his MBA at Northwestern University.

**Erin R. Fox, Pharm.D., MHA, BCPS, FASHP, associate chief pharmacy officer of shared services, University of Utah Health:** Fox is responsible for drug information and drug policy, pharmacy informatics, purchasing, billing, 340B and antimicrobial stewardship. She also serves as an adjunct professor in the Department of Pharmacotherapy at the University of Utah College of Pharmacy. She and her drug information team have provided drug shortage information for the ASHP Drug Shortage Resource Center since 2001. Fox serves as a media resource and as an advocate for changes to improve the ongoing drug shortage situation. She has published more than 40 peer-reviewed articles related to drug shortages, including the ASHP guidelines on managing drug shortages. She is recognized as an expert in drug shortages and has received the ISMP Cheers Award and the ASHP Award of Excellence for efforts related to drug shortages. She served as a member of the National Academies of Sciences, Engineering, and Medicine Committee on Security of America's Medical Product Supply Chain. She testified at the Senate Homeland Security and Government Affairs Committee hearing on drug shortages in March 2023.

**Monique K. Mansoura, Ph.D., MBA, founder and CEO, Beacon Biostrategies:** Mansoura is a strategic adviser focused on critical issues at the intersection of biotechnology and national, economic and health security. She has technical, policy and business expertise from both public and private sectors. From 2002 to 2011, she managed strategic policy, planning and budgeting for a pioneering multibillion-dollar medical countermeasures development and acquisition program within the U.S. Department of Health and Human Services. From 2012 to 2016, she led a global program team at Novartis Vaccines and served as head of medical countermeasures and government affairs for the Americas. From 2017 to 2025, she was the executive director of global health security and biotechnology at The MITRE Corporation. She earned a Ph.D. in bioengineering and a Master of Science in human genetics from the University of Michigan and a Bachelor of Science in chemical engineering from Wayne State University and completed a National Institutes of Health postdoctoral fellowship. She also earned an MBA through the MIT

Sloan Fellows Program in Innovation and Global Leadership. She is a co-author of “Lessons from the COVID War: An Investigative Report” and is a member of the Council on Foreign Relations.

**Dr. Stephen W. Schondelmeyer, Pharm.D., Ph.D., FAPhA, professor and director, PRIME Institute, Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota:** Schondelmeyer directs a research center specializing in pharmaceutical policy, management and economics. He received a Bachelor of Science in pharmacy from the University of Missouri, a Pharm.D. from the University of Kentucky and both a Master of Public Administration and a Ph.D. in pharmaceutical administration from The Ohio State University, with a focus in health economics and behavioral epidemiology. Schondelmeyer serves as co-principal investigator of the Resilient Drug Supply Project, an initiative focused on identifying and addressing vulnerabilities in the U.S. pharmaceutical supply chain. His work involves mapping the upstream drug supply system to improve resilience, prevent shortages and inform policy solutions that safeguard patient access to essential medicines. With over five decades of experience in academia, policy research and government advisory roles, Schondelmeyer has advised Congress and federal agencies, including CMS, FDA, GAO and DOJ, on drug pricing, reimbursement and supply chain security. His work focuses on strengthening pharmaceutical supply resilience and ensuring equitable access to essential medicines.

*Panelists Erin R. Fox and Monique K. Mansoura listen as Dr. Stephen W. Schondelmeyer speaks at APIIC's 2025 plenary event.*

## GLOSSARY

**Active Pharmaceutical Ingredient (API):** The biologically active component of a drug that produces the intended health effects. The U.S. remains heavily reliant on foreign sources for APIs.

**Advanced Manufacturing Technologies (AMTs):** Innovative technologies, including continuous-flow and on-demand manufacturing capabilities, that can improve production efficiency, reduce costs and enhance the quality of pharmaceutical production. Adopting AMTs is critical for achieving sustainable cost-competitiveness for domestic manufacturing.

**Batch Manufacturing:** A traditional method of pharmaceutical production involving performing a series of chemical transformations in sequence in a single reactor system, often characterized by multiple stops and starts. This process is typically contrasted 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. This innovation can create sustainable domestic alternatives to foreign API production.

**Buffer Inventory:** A federally supported inventory of critical drugs, including APIs and other drug substances with longer shelf lives, intended to mitigate the impact of shortages. Hospitals might maintain buffer stock of critical medications to give them a runway during shortages.

**Bullwhip Effect:** A phenomenon in the supply chain in which small fluctuations in retail demand lead to massive, destabilizing swings in inventory and manufacturing orders further upstream. This unpredictability penalizes manufacturers with overages and contributes to supply chain inefficiency.

**Continuous-Flow Manufacturing (CFM):** An advanced manufacturing technology that employs a flow reactor using pumps and tubes to move reactant fluids in a continuous stream. This method significantly reduces production time, promotes safety and increases efficiency compared to traditional batch processing.

**Critical Medicines:** Medications that are essential for treating acute conditions and those for which there are limited or no suitable therapeutic alternatives. There is an acknowledged need to standardize and unify the many existing critical and essential medicine lists.

**Diversification of Supply:** A core strategy for strengthening resilience that involves intentionally sourcing critical drugs, APIs and key starting materials from multiple manufacturers and geographic regions, including from U.S., nearshore and ally-shore partners, to mitigate risks from single points of failure.

**Essential Medicines:** Medications considered necessary for a basic health care system.

**Federal Buyer's Market:** A policy mechanism designed to leverage the collective buying power of federal agencies (such as the Department of War, Department of Veterans Affairs and Centers for Medicare & Medicaid Services) to prioritize purchasing drugs manufactured in the U.S., thereby creating market stability and signaling a shift toward valuing quality over lowest cost.

**Finished Dosage Form (FDF):** 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 generic drug industry is characterized by intense price competition — the "race to the bottom" — and is subject to economic instability and consolidation.

**Intermediaries (GPOs/PBMs):** Third-party organizations in the supply chain, such as group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).

**Key Starting Material (KSM):** The raw materials or basic chemical compounds that serve as the foundation for the entire pharmaceutical supply chain and are used to synthesize APIs. KSM manufacturers were explicitly identified at the plenary as a foundational and often-overlooked component critical to achieving supply chain resilience.

**National Fragility Index (NFI):** A proposed systemwide measurement instrument designed to track systemic pharmaceutical risk by aggregating over 150 variables related to geopolitical shocks, economic factors, market vulnerability, and domestic capacity deficiency. The goal of the NFI is to proactively guide decision-making and resource allocation.

**National Health Security:** The assurance that the nation has reliable access to essential medications and is protected from threats to its health care system.

**Onshoring (also Reshoring):** The process of bringing manufacturing and production back to the U.S.

**Public-Private Partnership (PPP):** A collaborative model involving the government and private sector to address supply chain vulnerabilities and drive innovation. Successful PPPs require clearly defined roles, sustained alignment and mutual commitment.

**Quality Scorecard:** A system intended to evaluate drug manufacturers based on their compliance records, which can be used to incentivize domestic production.

**Shared Risk/Shared Reward Model:** A contractual framework that distributes the financial risk and benefits of investments — such as those made in advanced manufacturing technologies — across multiple stakeholders (e.g., manufacturers, payers, providers) to foster long-term stability and align incentives.

**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. For hospitals and patients, resilience in practice means that medicines are reliably available in the correct formulation and strength when needed.

**Transparency Index (Pharmaceutical):** A proposed accountability mechanism, analogous to models used in the fashion industry, intended to recognize and reward manufacturers for proactively practicing transparency and sharing supply chain data, going beyond basic compliance standards.

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