

## Statement of the U.S. Pharmacopeia

### Submitted to the United States Senate Special Committee on Aging

#### For the Hearing “Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans”

September 17, 2025

The United States Pharmacopeia (USP) is pleased to submit the following statement for the record on the hearing “Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans.”

USP is a private, scientific, global non-profit organization founded in 1820 when eleven physicians took action to protect patients from poor-quality medicines. Convening in the old U.S. Senate Chamber, they published a national, uniform set of guidelines for medicines called the U.S. Pharmacopeia. Today, USP employs 1,300 staff, most of whom are scientists, and works with nearly 800 scientific experts with industry, government, nonprofit, academia, and research experience who volunteer their time to establish quality standards for medicines. In addition, USP offers a range of programs to help ensure the supply of quality medicines for Americans. One such offering, the USP Medicine Supply Map, tracks the upstream supply chain of medicines and their ingredients. USP also offers verification programs to confirm the quality of ingredients in medicines and initiatives to help accelerate adoption of advanced pharmaceutical manufacturing technologies, which can support domestic manufacturing.

These programs are a core pillar of USP’s work to help strengthen the global supply chain so that the medicines, dietary supplements, and foods that Americans rely on for their health are available when needed and meet quality standards as expected and required. In addition to the scientific experts on USP standard-setting committees, USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention.<sup>1</sup> Working with this broad base of knowledge from across science and health care, USP creates standards for the quality and safety for medicines.

Safe and effective medicines, consistently manufactured according to established public quality standards, are essential to preventing disease, treating illness, and saving lives. USP’s standards and resources support innovation and access, providing shared, foundational platforms for industry to help accelerate the development of new technological solutions for the American marketplace. USP has over 6,000 standards for active pharmaceutical ingredients, drug products, and inactive ingredients used throughout the supply chain. USP creates these standards through an open, transparent process, offering the ability to update standards to adapt to new industry practices and keep up with evolving science and technology. USP also works closely with the U.S. Food and Drug Administration (FDA) and other government agencies to help ensure the quality and safety of products for Americans.

In addition to setting trusted standards, USP advances public-private partnerships that address systemic supply chain vulnerabilities, helping to safeguard access to quality medicines and strengthen national health security. This includes work with the Department of Defense (DoD), the Advanced Research Projects Agency for Health (ARPA-H), the Administration for Strategic

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<sup>1</sup> USP’s governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.

Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), and the FDA.

## Key insights to strengthen supply chain resilience and security

### Understanding factors that drive medicine supply chain vulnerabilities

More than 60% of all American adults, including nearly 90% of seniors, fill at least one prescription each year, the vast majority of which are generic medicines.<sup>2</sup> A robust supply of generic quality medicines is an essential component of our healthcare system. Unfortunately, supply chain disruptions and drug shortages persistently and substantially affect the care of American patients.<sup>3,4</sup>

**USP's Medicine Supply Map<sup>5</sup> was created beginning in 2019 to provide unique, end-to-end data and mapping of the entire medicine supply chain. USP's analysis reveals four key factors that overwhelmingly drive vulnerability in the U.S. medicine supply:**

1. **Low Prices:** Drug products with low prices, commonly older generics, have a higher risk of drug shortage.
2. **Geographic Concentration:** Drugs in which the active pharmaceutical ingredient (API) and/or the finished dose are made in a single or a few locations are more susceptible to shortages, the most extreme example being where the full supply of a particular medicine for the U.S. market is produced in only one facility.
3. **Quality Concerns:** Quality-related issues that surface in regulatory agency inspection outcomes and manufacturer recalls can also inform drug shortage risk but must be used along with other information to be actionable.
4. **Manufacturing Complexity:** Drugs with higher manufacturing complexity, such as sterile injectables, are more vulnerable to shortage. Manufacturing complexity can also be seen in certain therapeutic classes—e.g., certain antibiotics needing dedicated facilities—and in certain active ingredients that require complex chemical synthesis.

Critically, these four factors are interrelated and in combination can impact supplier decisions about whether to continue manufacturing a given drug product or to exit the market altogether. For example, manufacturing complexities increase the cost of manufacturing a medicine and can yield an unsustainable margin, especially when combined with low prices of certain drug products.

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<sup>2</sup> U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. [FastStats - Therapeutic Drug Use](#).

<sup>3</sup> U.S. Pharmacopeia. [USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024](#). 2025.

<sup>4</sup> U.S. Pharmacopeia. [USP Annual Drug Shortages Report: Economic factors underpin 2023 shortages](#). 2024.

<sup>5</sup> U.S. Pharmacopeia. USP Medicine Supply Map. [www.usp.org/medicinesupplymap](http://www.usp.org/medicinesupplymap). 2025.

Generic manufacturers stay competitive largely by reducing costs, which often means concentrating production in large facilities in lower cost jurisdictions. These market conditions often discourage investment in redundancies and quality management systems.<sup>6</sup>

This dynamic is particularly pronounced in the procurement of the most essential generic medicines, where prices can often fall below the cost of manufacturing. In this market, reliable manufacturers, particularly those operating in the United States, face considerable headwinds. Suppliers navigating these challenges are increasingly reassessing the viability of producing low-cost, high-demand medicines in the United States. They often contemplate whether to move operations outside the United States or exit the market for a particular product altogether.

These factors combine to reveal the extent of the U.S. medicine supply chain's vulnerabilities to supply and demand fluctuation, geopolitical matters, global pandemics, natural disasters, and trade disruptions. This can have lasting impact on patients, our health systems, and national security.

**Now is the time to build a more resilient and reliable medicine supply chain. In doing so, we will enhance our national security, improve our ability to respond to medical and public health crises, and most importantly, ensure that patients have access to the quality medicines that are essential for both critical and routine patient care.**

### End-to-end medicine supply chain mapping and analytics are essential for building resilience

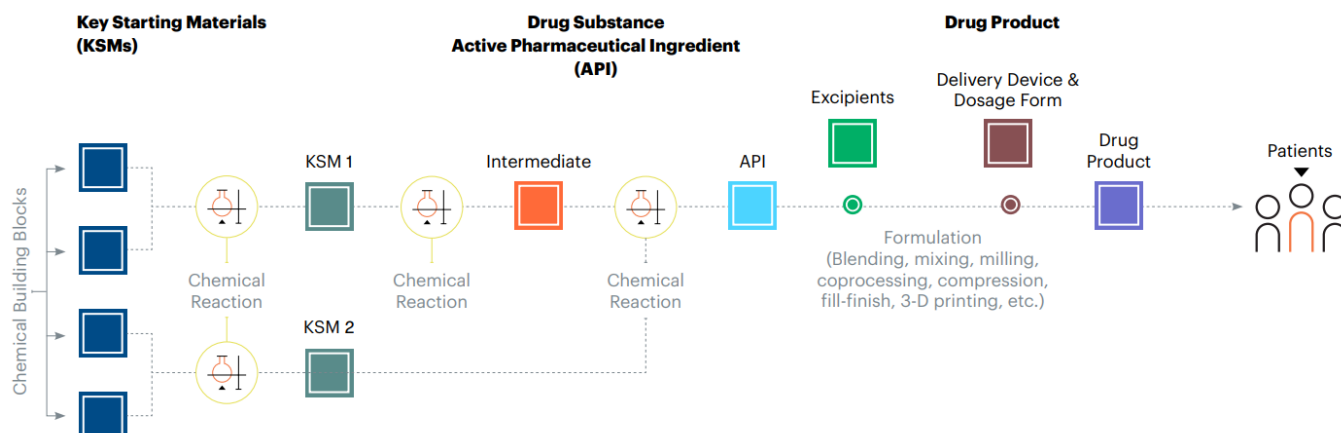
Effectively strengthening the medicine supply chain begins with our ability to understand it. The global medicine supply chain is a complex marketplace of manufacturers, suppliers, and distributors from many countries. While the globalization of the medicine supply chain has helped increase access to quality medicines at a lower cost, supply chains have grown longer, more complex and fragmented, leading to a lack of visibility and an increase in the risk to resilience. Historically, there has been little insight available into the upstream supply chain for medicines, including for key starting materials (KSMs), APIs, and finished dosage forms (FDFs).

Figure 1 is a simplified schematic depicting some of the complexity involved in the drug supply chain that begins with the KSMs needed to manufacture APIs, which in turn are necessary, along with excipients and other materials, to manufacture a finished drug product.

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<sup>6</sup> Hernandez I, Sullivan SD, Hansen RN, Fendrick AM. Cheaper is not always better: Drug shortages in the United States and a value-based solution to alleviate them. J Manag Care Spec Pharm. 2024 Jul;30(7):719-727. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11217858/>.

**Figure 1:** Simplified pharmaceutical manufacturing supply chain schematic.<sup>7</sup>



USP's Medicine Supply Map<sup>8</sup> – a data intelligence platform that maps where 94% of U.S. prescription pharmaceutical drug products and their ingredients are made, and identifies, characterizes, and predicts supply chain risk – can analyze and quantify factors linked to supply chain disruptions for drug ingredients and finished drug products. Using the Medicine Supply Map, USP analyzed the location of API manufacturing facilities as well as the manufacturing volume of APIs and FDFs to better understand the geographic concentration of production for U.S. prescription medicines. These insights include actionable information for APIs and FDFs; however, blind spots still exist in the Medicine Supply Map for the excipients<sup>9,10</sup> and KSMs necessary for many medicines. USP welcomes partnerships to fill this remaining gap.

**To more fully understand the risks affecting the U.S. medicine supply and to anticipate the impacts of policy actions and market forces, decision-makers need end-to-end supply chain data and mapping of entire supply chains for medicines.**

### Location of API manufacturing facilities

To understand the existing concentration of manufacturing for API, USP analyzed API Drug Master Files (DMFs). API DMFs identify existing geographic locations that are manufacturing

<sup>7</sup> U.S. Pharmacopeia. [USP Annual Drug Shortage Report: Economic factors underpin 2023 shortages](#). 2024. The schematic does not provide a complete picture of the supply chain; it does not include, for example, purchasers, distributors, or healthcare providers.

<sup>8</sup> U.S. Pharmacopeia. USP Medicine Supply Map. [www.usp.org/medicinesupplymap](http://www.usp.org/medicinesupplymap). 2025.

<sup>9</sup> Despite being called “inactive” ingredients, excipients play a critical role in drug development, delivery, effectiveness, and stability. Excipients comprise up to 90 percent of a medicine's volume and serve important functions, including as binders, disintegrants, coatings, preservatives, colors and flavorings. Excipients are sourced from suppliers around the world and are used for more than just the manufacture of medicines. The reliance of the pharmaceutical industry on the global excipients supply chain presents challenges for supply chain resiliency as well as quality and regulatory oversight. As such, breakdowns of critical excipient supply chains can have significant downstream effects including drug recalls and patient health impacts. For example, magnesium stearate is included in 32,060 drug products according to NIH DailyMed, including those to treat high cholesterol, high blood pressure, diabetes, and bacterial infections.

<sup>10</sup> U.S. Pharmacopeia. [USP Global Policy Position: Excipients: A Blind Spot in Ensuring Medicine Quality and Supply Chain Resilience](#). 2024.

APIs and can suggest other locations that may be likely to have additional capacity.<sup>11</sup> Not all drug products utilize APIs referencing DMFs, but the geographic analysis of DMFs can provide an overall perspective on where API manufacturing capacity might be trending.

Based on these data, India maintains the greatest API manufacturing capacity with roughly 50% of API DMF filings in 2023.<sup>12</sup> Additionally, China's API manufacturing capacity has shown a striking rise in recent years. Between 2021 and 2023, the number of DMF filings in China increased 63%, amounting to almost one-third of all filings, while India's share of new API DMF filings decreased in 2023. The European Union (EU) saw a sizeable decrease in total active API DMF share in 2023, which was likely due to an overall increase in manufacturing activities outside the EU, rather than a decrease in its own API DMF filings. Meanwhile, the United States remained at only 4% of API DMFs in 2023, which is unchanged from 2021.

### Manufacturing volume of API

Although API DMF analysis can clarify where manufacturing facilities are based, two facilities could be producing different volumes of medicines. The USP Medicine Supply Map also determines the production volume of APIs from different geographic locations to provide a picture of where current production comes from (Figure 2).

A 2024 analysis shows:

- Half of the prescription medicines API in the United States comes from India and the EU.
- Generic drugs, which make up 90% of U.S. prescription volume, primarily come from India.
- 43% of branded pharmaceutical API comes from the EU.
- The United States accounts for 12% of total API volume analyzed.<sup>13</sup>
- China contributes 8% of the total volume of API analyzed.
- There is evidence of significant dependence on China for KSMs, the building blocks of API, but further work is necessary to fully understand the supply chain of KSMs.

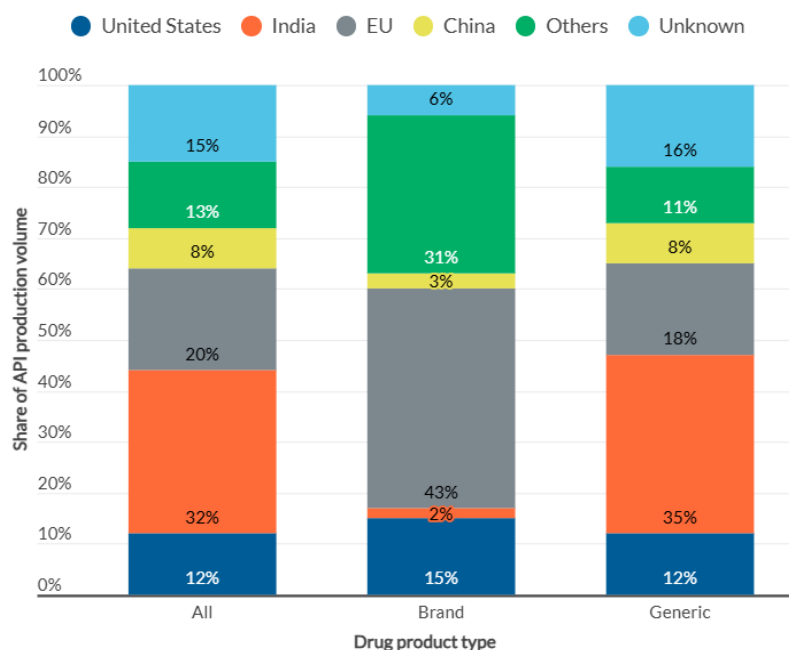
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<sup>11</sup> The proportion of DMFs in a particular location should not be interpreted as the proportion of APIs being sourced from that region. Aggregated DMF information is reflective of manufacturer site locations only, and this analysis does not contain information about the quantity produced or geographic distributions of APIs themselves.

<sup>12</sup> U.S. Pharmacopeia. [USP Quality Matters Blog: Global manufacturing capacity for active pharmaceutical ingredients remains concentrated](#). 2024.

<sup>13</sup> The analysis excluded IV fluids, such as saline. If those had been included, the U.S. contribution would have been significantly higher.

**Figure 2: API manufacturing landscape (excluding IV fluids) in 2024.**<sup>14</sup>



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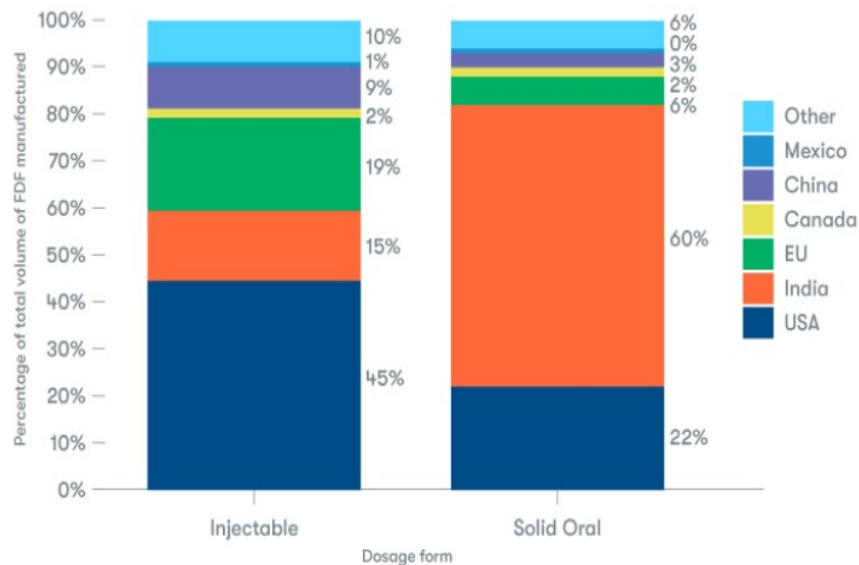
## Manufacturing volume of FDF

Using USP's Medicine Supply Map, analysis of the geographic concentration of U.S. prescription pharmaceutical finished dose forms was performed (Figure 3).

- The United States is the largest manufacturer of injectables with 45% of production volume, followed by the EU with 19% of production volume.
- For solid oral dosage forms, India has 60% of production volume, followed by the United States with 22% of production volume. Market shares have remained relatively unchanged over 2022 and 2024.

<sup>14</sup> U.S. Pharmacopeia. USP Quality Matters Blog: [Over half of the active pharmaceutical ingredients \(API\) for prescription medicines in the U.S. come from India and the European Union](#). 2025.

**Figure 3:** Manufacturing footprint of prescription pharmaceutical FDF in 2024.<sup>15</sup>



### Risk assessment analysis

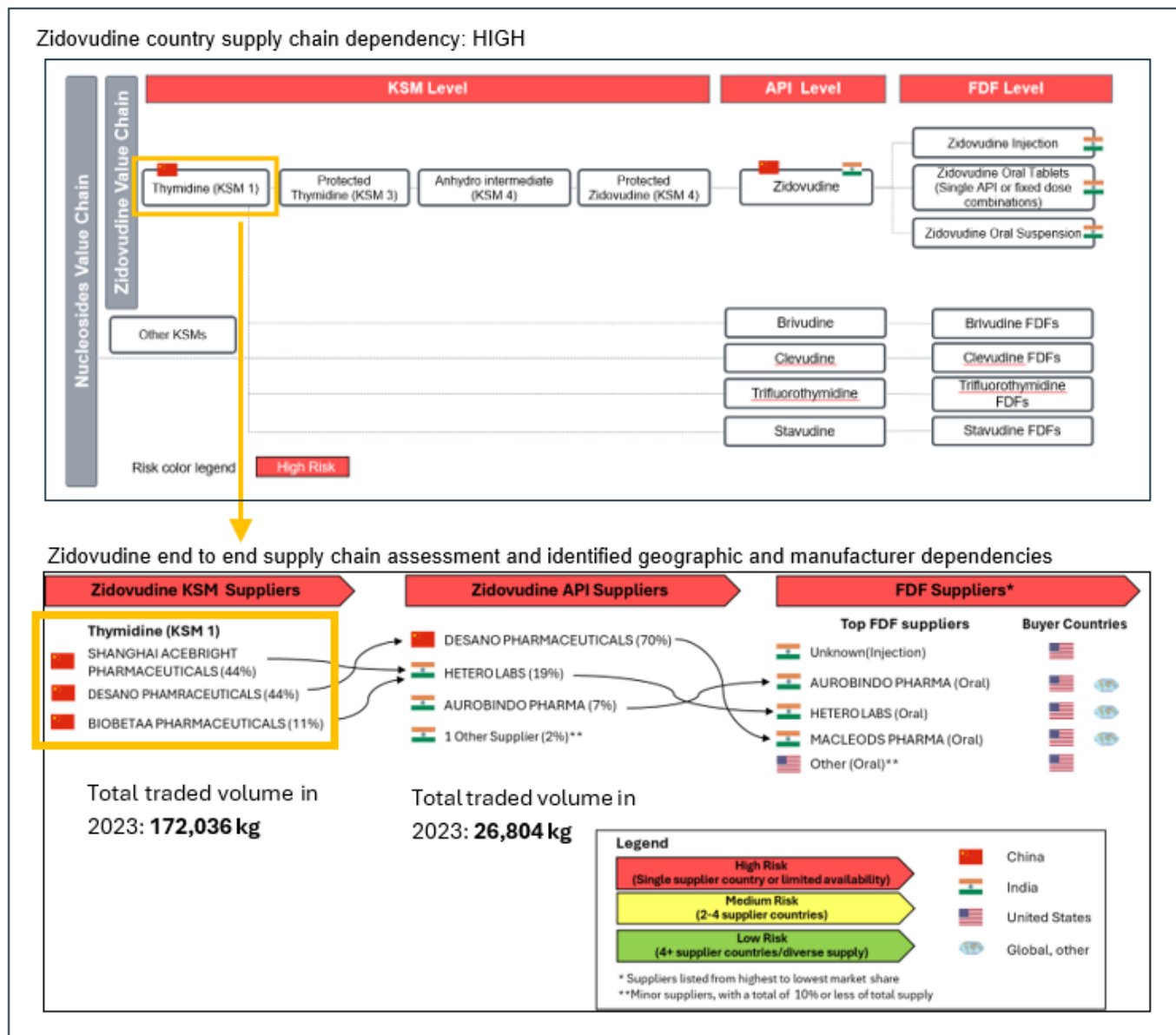
The lack of comprehensive pharmaceutical supply chain data available necessitates manual evaluation and analysis. USP is deploying scientific experts to better understand critical blind spots that remain in the knowledge of medicine supply chains and inform strategic decisions and the development of solutions. This analysis includes:

- an evaluation of the KSM and API manufacturing pathways to identify manufacturing challenges and production bottlenecks;
- a geographic and technoeconomic risk analysis to assess regional vulnerabilities, economic feasibility, and supply dependencies, enabling a structured evaluation of risk potential;
- resulting risk information that is specific to drugs or drug classes

For example, using zidovudine (a nucleoside-based antiviral medicine), analysis found a critical dependency on one KSM (thymidine) produced only in China (despite multiple API manufacturers downstream), which indicates a high vulnerability risk not just for zidovudine, but for several nucleoside-based antiviral medicines (Figure 4).

<sup>15</sup> U.S. Pharmacopeia. [USP Quality Matters Blog: India and the United States manufacture most finished medicines for the U.S. market.](#) 2025.

**Figure 4.** Zidovudine (and other nucleoside-based antiviral) supply chain components and geographic vulnerability risk analysis.



While the data presented above provides important insights into the U.S. medicine supply chain, no government agency nor any industry entity currently has a complete view of the upstream pharmaceutical supply chain (including FDFs, APIs, and KSMs). This lack of insight contributes to a limited understanding of the risks affecting the U.S medicine supply.

For example, while U.S. dependence on China for KSMs is widely acknowledged, additional work remains to fully understand this crucial but opaque part of the supply chain. **USP is currently mapping the KSMs for over 90% of the medicines tracked by our Medicine Supply Map. We expect to have this analysis completed this fall.**



Unsurprisingly, our early data shows that the United States is heavily reliant on two countries (India and China) for KSMs. Our analysis of the supply chain for the nation's most essential medicines shows a common pattern whereby 1) the majority of KSMs are produced in China, 2) provided to manufacturers in India to produce API, and 3) ultimately sold or exported for conversion to FDF in another location.

**Efforts must continue to understand supply chain risk via initiatives like the Medicine Supply Map data and analytics coupled with extensive expertise in unraveling complicated supply chain maps to provide risk assessment and intelligence. Only through a comprehensive, end-to-end understanding of the pharmaceutical supply chain can we truly unlock the targeted, cost-effective interventions to strengthen the medicine supply chain. This approach should cover all U.S. medicines, starting with the most critical products, and expand analysis beyond individual APIs to include related chemical and therapeutic classes. Doing so provides a holistic understanding of supply chain dependencies.**

## **Data- and evidence-informed policy reforms and investments can make the U.S. medicine supply chain stronger and more reliable**

Building a more resilient, reliable, and secure medicine supply chain requires manufacturing medicines in more places and in new ways—and rewarding such efforts through a deliberate incorporation of quality, resilience, and reliability, in addition to price, in contracting, purchasing, and inventory decisions. USP encourages the Committee to consider a multi-faceted approach to ensure that patients, including our nation's seniors, have access to the quality medicines they need:

1. Continuously identify the nation's most vulnerable medicines.
2. Identify alternative routes of synthesis for KSMs of the most vulnerable medicines that are or could be made in the United States or other ally countries with advanced pharmaceutical manufacturing technologies for more efficient production.
3. Establish a resiliency benchmark for the purchase of medicines, enabling private and public sector purchasers to value investments in resiliency, reliability, and quality.

## **Identification of medicines with a vulnerable supply chain will help target interventions**

USP recently published the USP Vulnerable Medicines List (VML)<sup>16</sup> – a list of medicines derived from an assessment of their essentiality, demand, and supply chain vulnerabilities – that can be used to identify medicines at risk of supply chain disruption.<sup>17,18</sup>

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<sup>16</sup> United States Pharmacopeia. [2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply](#). 2025.

<sup>17</sup> United States Pharmacopeia. [USP Global Public Policy Position: Identifying and addressing vulnerabilities in the upstream medicines supply chain to build resilience and reduce drug shortages](#). 2023.

<sup>18</sup> USP's approach borrows from the framework proposed in the article: Wosinska, M., Mattingly, T., & Conti, R. [A Framework for Prioritizing Pharmaceutical Supply Chain Interventions](#). 2023.

Leveraging Medicine Supply Map and additional data, USP conducted an analysis to identify 100 vulnerable medicines – 49 used to manage chronic conditions and 51 for acute care – to inform dialogue related to bolstering medicine supply chain resilience.<sup>19</sup> This data-driven approach accounts for the level of use by the U.S. population, public and population health necessity, the vulnerability of the medicine to supply chain disruptions, and the availability of alternative therapies. The resulting list includes a wide range of therapeutic classes of medicines as well as a variety of product types.

**USP encourages the Committee to explore legislative means for carrying out an annual cadence for assessing vulnerabilities. This could be accomplished by:**

1. Establishing a thorough, science-based mapping of the pharmaceutical supply chain, for essential medicines, from KSM to API to FDF.
2. Identifying vulnerabilities to the U.S. pharmaceutical supply chain, especially with respect to the nation's reliance on foreign and adversarial sources.
3. Requiring a yearly update to the VML and an accompanying report to Congress that provides actionable recommendations to Congress and the Administration to strengthen domestic resilience and mitigate national security risks.

Updating and sharing this critical information annually would help the U.S. government prioritize the most critical products, target investments, and inform initiatives to bolster the U.S. pharmaceutical supply chain and national security interests.

### **Innovative and scalable solutions can support greater domestic production of pharmaceutical ingredients**

Enabling economically viable domestic production of prioritized APIs and KSMs is an important element of a comprehensive effort to enhance medicine supply chain resilience and support national security. Achieving this effort requires a re-imagining of the traditional chemistry processes used along the supply chains of necessary materials due to the structural, chronic challenges associated with chemical pharmaceutical manufacturing, especially for the generic medicine supply chain.<sup>20</sup> The use of advanced manufacturing technologies—alternate synthesis pathways, continuous flow manufacturing, and advanced chemical processes—provides a strategic solution to address vulnerabilities, enhance domestic competitiveness, and safeguard public health and national security.

**Scalable solutions, beyond mapping key ingredients, to support onshoring and local production of essential drug candidates, APIs, and KSMs—and bolster rapid response capabilities within the U.S. medicine supply chain—include:**

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<sup>19</sup> United States Pharmacopeia. [2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply](#). 2025.

<sup>20</sup> Many of the structural and chronic challenges with chemical manufacturing, especially chemical pharmaceutical manufacturing, have been due to low efficiency – among the major chemical industry sectors (oil refining, bulk chemicals, fine chemicals, and pharmaceuticals) pharmaceutical manufacturing generates the least product output, with about 1 kilogram of API obtained on average from a total of 25 to 100 kilograms of raw materials input (Fortunak, 2009 doi: 10.4155/fmc.09.60). Other complexities are associated with the hazardous conditions to produce chemical products at scale. Due to these complexities, over the past few decades, the manufacturing of upstream ingredients and bulk APIs has been outsourced to lower cost and less regulated countries rather than tackling and solving the challenges.

- **Better leveraging advanced manufacturing technologies (AMTs)** – AMTs, including continuous manufacturing and flow chemistry process intensification and controls can support more efficient production of generic medicines in the United States.
- **Harnessing alternate routes of synthesis/processes** – Design economically viable alternate synthesis pathways (a form of AMT) for necessary generic KSMs and APIs so there is capability to make them in the United States or allied countries. This work requires analysis and the development of new processes to make a medicine using ingredients that are available in the United States or multiple geographies.

Building on the above example of zidovudine, USP recommends leveraging AMTs to overcome manufacturing challenges for the API and reduce reliance on a single country.

This can be accomplished by:

- Identifying an efficient pathway to synthesize KSMs like thymidine locally from widely available chemicals and then working to optimize the API manufacturing process by using flow chemistry.
- Utilizing additional AMTs to produce the medicine more efficiently—and locally—while using the domestically produced KSM and API.

USP chemists have identified an alternate pathway to synthesize thymidine and work to optimize this new process using the AMT flow chemistry is also underway.

Through a new Advanced Technologies Lab, USP is supporting the development and application of AMTs, such as those for thymidine and its APIs, to foster more efficient and expanded production of quality medicines. USP will accelerate its work with industry and regulators to advance the application of new technologies and alternate manufacturing processes including developing alternate routes of synthesis for pharmaceutical KSMs and APIs and using AMTs such as pharmaceutical continuous manufacturing. These alternate manufacturing processes will help to mitigate identified supply chain risks, and this work can help bring quality-assured products to market more efficiently, strengthen domestic manufacturing capabilities, and build national security.

Another recent example of work to re-imagine the supply chain of pharmaceutical ingredients is the ARPA-H funded Wheat-based High-efficiency Enzyme and API Technology (WHEAT) project. A consortium of partners including USP aim to establish a new way to make APIs by leveraging cell-free protein synthesis with the aid of wheat germ extract (WGE), a key raw material derived from abundantly available agricultural wheat. This project uses WGE, in conjunction with other advanced biotechnologies to circumvent challenges associated with traditional chemical manufacturing, such as low throughput and long, multi-step complex chemical synthesis. If successful, the team will demonstrate a paradigm shift in domestic API manufacturing.<sup>21</sup>

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<sup>21</sup> U.S. Pharmacopeia. [USP and Ginkgo Bioworks announce ARPA-H project to support production of essential medicines using innovative cell-free expression systems](#). 2025.

## An initiative to incentivize investment in drug supply chain resilience, reliability, and quality

In addition to the technical considerations discussed above, efforts to create a predictable, sustainable, and quality supply chain that can reliably provide critical drugs to patients must include a comprehensive assessment of the underlying market factors that influence investments in infrastructure and resilience. Economic factors play a considerable role in leading to medicine supply chain vulnerabilities and subsequent shortages of medicines.<sup>22</sup> Generic medicines account for nearly 90% of the medicines relied on by Americans and less than 15% of the U.S. expenditure on medicines.<sup>23</sup> Yet current generic drug payment policies and practices encourage purchasers to choose manufacturers largely based on lowest price.

This dynamic can weaken initiatives to strengthen supply chain resilience by limiting the ability of manufacturers to invest in new, alternate manufacturing processes, domestic production, manufacturing updates and necessary facility maintenance, quality assurance and management, or to build redundancy into supply chains.

The current purchasing and payment systems, however, lack a coordinated and collaborative means to evaluate resilience and reliability and therefore minimize and mitigate risks that affect the U.S. supply of medicines. There is a need for deliberate incorporation of quality, resilience, and reliability, in addition to price, in contracting, purchasing, and inventory decisions.

**A fundamental shift in the market is needed to align supply and demand forces to create a more predictable, sustainable, and quality supply chain that can reliably provide medicines to American patients. USP encourages the Committee to consider the development of a Drug Supply Chain Resilience Initiative (DSCRI),<sup>24</sup> which would aim to:**

- **Foster stability in the drug supply chain by providing criteria to value the resilience and reliability of manufacturers.**
- **Promote sustainable prices for generic medicines.**
- **Incentivize changes in purchasing practices with the goal of better meeting patients' needs through a reliable, safe, and resilient medicine supply chain.**

A DSCRI must include two distinct elements:

- A data-driven system to differentiate suppliers based on reliability and resilience, such as the development of an assessment or benchmark to enable purchasers to identify resilient manufacturers.
- Establishment of meaningful value-based payment and contracting reforms to incentivize supply chain resilience and reliability.

A manufacturer benchmark metric should function as a tool for decision making and consist of resilience measures, reliability measures, quality measures, as well as the base vulnerability of a drug product, which includes understanding the concentration of domestic and non-domestic manufacturing locations. Key benchmark attributes could include:

- A menu of well-established measures that are predictive of reliability and quality

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<sup>22</sup> U.S. Pharmacopeia. [USP Annual Drug Shortages Report: Economic Factors underpin 2023 shortages](#). 2024.

<sup>23</sup> Association for Accessible Medicines. [2025 U.S. Generic & Biosimilar Medicines Savings Report](#). 2025.

<sup>24</sup> U.S. Pharmacopeia. [A drug supply chain resilience initiative will better support patients](#). 2025.

- The ability of manufacturers to choose measures and combine values to reach the resilience benchmark
- A resilience determination per molecule, per manufacturer
- Experts to advise on benchmark metrics, criteria, and DSCRI details
- Data from the USP Medicine Supply Map Vulnerability Assessment and the USP Vulnerable Medicines List

Several measures are currently known and available that could be utilized, including those from the USP Medicine Supply Map; publicly available metrics from the FDA; manufacturer measures of product production, inventory, and delivery; and reputable product level quality testing data, among others.

**Without significant market and policy interventions, current medicine supply chain vulnerabilities and drug shortage trends will likely continue or worsen. A solution to bolster resiliency can be facilitated by measuring and valuing reliability and quality using a comprehensive framework like the DSCRI.**

## Conclusion

The USP appreciates the Committee for holding this hearing and the bipartisan, careful consideration of approaches to forge a more resilient, adaptable, and secure future for America's medicine supply. The well-being of millions of people and our nation's security depends on it. We look forward to working with the Committee and Congress, industry, and our scientific community to make this vision a reality.