Executive Summary

The availability of essential medicines in the United States rests on assumptions that no longer hold. What appears functional on the surface often masks deeper vulnerabilities across economic, structural, and geopolitical lines. Addressing these challenges will require long-term coordination and a broader focus on security, reliability, and public health outcomes.

Multiple structural and strategic challenges threaten the resilience, security, and sustainability of the U.S. pharmaceutical supply chain:

- The United States relies heavily on global supply chains for pharmaceuticals. While many finished drug products are imported from Europe, those supply chains are often indirectly dependent on China and India for key starting materials (KSMs) and active pharmaceutical ingredients (APIs). This creates concentrated upstream exposure that threatens national health security.
- Generic sterile injectables make up a small portion of prescriptions but are essential to hospital care. Thin margins, limited redundancy, and offshore concentration make them highly vulnerable to disruption.
- Shortages disproportionately affect generics, which account for 90 percent of prescriptions filled. These disruptions delay treatment, increase costs, and lead to reliance on unfamiliar substitutes that can result in poorer health outcomes.
- U.S. reimbursement and procurement structures reward low price over reliability. This discourages domestic production, deters investment in redundant capacity, and contributes to supply fragility.
- The U.S. lacks sufficient tools to monitor pricing distortions or trace supplier relationships across multi-tiered global supply chains. Visibility into raw material sourcing, particularly beyond the API level, remains limited. Without transparency into upstream suppliers it is difficult to identify vulnerabilities or intervene effectively during disruptions.
- FDA approvals and registered facilities give the appearance of stability, but actual production is often consolidated, offshored, or inactive, leaving the system with little surge capacity.

A new approach to procurement and production is needed, one that values predictability, resilience, and shared accountability rather than short-term cost savings.

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

The United States is the largest pharmaceutical market in the world, both in volume and total spending. According to IQVIA's The Use of Medicines in the U.S. 2024 report, more than 6.7 billion prescriptions were dispensed in 2023, and total medicine spending reached $435 billion.[1]

Several key factors are driving continued growth in demand:

- **Demographics**: An aging population is contributing to increased prescription utilization, as older adults are more likely to require multiple chronic and acute care therapies.
- **Chronic disease prevalence**: High rates of conditions such as cardiovascular disease, diabetes, and cancer continue to fuel prescription volume.
- **Expanded healthcare access** and ongoing therapeutic innovation are also expanding the treated patient population.

Both branded and generic drugs contribute significantly to U.S. pharmaceutical consumption:

- **Generic drugs** account for 90% of prescriptions filled, playing a central role in high-volume treatment of common conditions. According to the American Hospital Association, roughly 83% of drug shortages impact generic medications.[2] These shortages often delay treatment and drive up healthcare costs. In many cases, providers must rely on unfamiliar substitutes that may be less effective, more expensive, and increase the risk of medical error. Ultimately, patient outcomes suffer.
- **Branded medicines**, while representing a smaller share of prescriptions by volume, account for the overwhelming majority of pharmaceutical spending due to higher price points and specialized indications.

Generic sterile injectables, while comprising a small fraction of total prescriptions, represent a disproportionately high share of drug shortages. Key factors include:

- **Criticality**: Used widely in hospital and emergency care, often with no easy substitutes.
- **Complexity**: Require aseptic processing, cold-chain storage, short shelf life, and strict regulatory oversight.
- **Vulnerability**: Thin margins, quality issues, and a small number of producers make the supply chain fragile and difficult to scale.

Publicly available sources that document U.S. pharmaceutical demand and utilization trends include:

- The FDA Drug Shortages Database
- The USP Medicine Supply Map

[1] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

[2] https://www.aha.org/news/blog/2024-05-22-drug-prices-and-shortages-jeopardize-patient-access-quality-hospital-care

- IQVIA and IMS Health market reports
- CMS Medicare Part B and D utilization data

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

Domestic pharmaceutical production is not currently sufficient to meet U.S. demand, particularly in the generic segment. While production of branded drugs is more robust due to higher margins and more secure investment environments, the most critical supply vulnerabilities exist in low-margin, generic, sterile injectable drugs.

Despite appearing stable based on FDA approvals and registered facilities, the current system continues to fall short in practice:

- **Persistent shortages**: The U.S. continues to experience routine shortages of essential medicines, many of which are generic injectables used in inpatient care. As of April 2025, 240 drugs have active shortage bulletins listed by the American Association of Health-System Pharmacists (ASHP)[3]
- **Limited domestic redundancy**: Even when products are technically approved for multiple manufacturers, production is often consolidated or inactive at key sites for business reasons.

Generic sterile injectables sit at the intersection of volume, vulnerability, and national security relevance:

- **High utilization**: These drugs are widely used in hospital and emergency care (e.g., antibiotics, sedatives, cardiovascular agents).
- **Concentrated production**: They are frequently produced offshore or by a small number of sites, with minimal redundancy or surge capacity.
- **Disproportionate impact**: Disruptions in this category, whether from quality issues or material delays, can quickly cascade through hospital supply chains.

Taken together, the demand dynamics outlined in Question 1 and the capacity constraints described here underscore the need for better information and forward-looking analytics. Tools such as real-time demand data, supply chain visibility tools, and predictive modeling are essential to identify where U.S. pharmaceutical needs are most exposed to supply chain fragility and how to quickly react to these vulnerabilities.

[3] https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages&sort=1

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

The United States depends heavily on complex global supply chains for upstream pharmaceutical manufacturing inputs, particularly key starting materials (KSM) and active pharmaceutical ingredients (APIs). While high-value, branded finished drugs are sourced domestically and from advanced manufacturing hubs in Europe, most generic APIs and key starting materials (KSMs) come from a small number of countries, notably India and China.

Several factors define the current state of reliance on foreign supply chains:

- **Foreign concentration**: According to the U.S. Pharmacopeia's Medicine Supply Map, only 4% of API Drug Master Files (DMFs) filed in 2023 were associated with U.S.-based facilities. India held 50%, China 32%, and the EU 10%. This data reflects API manufacturing, not finished drug product (DP) production, underscoring the upstream nature of U.S. dependence.
- **Upstream exposure**: Traceability in pharmaceutical supply chains often ends at the API level. Most KSMs (the chemical building blocks of pharmaceuticals) are sourced from complex and opaque global networks, with limited visibility into origin, quality, or continuity of supply. Greater supply chain transparency will enable earlier detection of vulnerabilities and more effective mitigation, ultimately strengthening the resilience of the American supply chain.
- **Single-source risk**: Many raw materials and KSMs are sourced from a limited number of countries and producers, making them vulnerable to both geopolitical disruption and site-specific supply failures.
- **Friendly-nation opportunity**: In some cases, moving sourcing from adversarial regions to "friendly" third-nation suppliers may be feasible. However, this requires enhanced visibility across supply tiers through efforts such as supplier disclosure, traceability tools, regulatory alignment, and deeper private-sector engagement to identify viable, reliable alternatives.

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

If assessed purely based on dollar value, the United States does not import a significant share of its active pharmaceutical ingredients (APIs) or finished pharmaceutical products directly from China. Instead, most U.S. pharmaceutical imports come from other regions, particularly Europe. In 2023, 73% of pharmaceutical imports by value originated from Europe, with Ireland, Germany, and Switzerland as the primary sources.[4,5]

While China and India account for a relatively small share of U.S. pharmaceutical imports by dollar value, they play an outsized role in the global medicine supply chain. This includes supplying essential components such as key starting materials (KSMs) and active pharmaceutical ingredients (APIs), as well as a significant portion of generic medicines. While these products may not register prominently in the by dollar US trade data, they are vital to routine patient care. The concern is not the volume or cost of these imports, but the strategic risk they pose. Disruptions in the availability of even a small number of upstream components from these regions can cascade into major shortages of essential medicines in the U.S.

Publicly available sources that document import concentration and supplier dependencies include:

- The USP Medicine Supply Map
- UN COMTRADE database via Trading Economics
- FDA Drug Shortages Database
- IQVIA and IMS Health market reports

[4] https://www.reuters.com/business/healthcare-pharmaceuticals/us-pharma-tariffs-would-raise-us-drug-costs-by-51-bln-annually-report-finds-2025-04-25;
[5] https://www.beckershospitalreview.com/pharmacy/pharma-tariffs-would-raise-drug-costs-by-51b-report/?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=5544I4753201J5J

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

The U.S. pharmaceutical supply chain operates in a global market shaped by uneven competitive conditions. While U.S. manufacturers are subject to strict regulatory, labor, and environmental requirements, foreign competitors, particularly in China and India, often benefit from state-backed incentives, limited transparency, and looser oversight.

These dynamics make it difficult for U.S.-based manufacturers to remain viable in low-margin segments such as generic sterile injectables and commodity APIs. Over time, this has contributed to domestic facility closures, reduced investment, and increased reliance on foreign sources. These policies and market forces result in a "race to the bottom" pricing strategy for generics that leaves little room for redundancy or resilience. Quality-related production issues, now a leading cause of drug shortages, regularly expose these structural vulnerabilities.

The U.S. system currently lacks mechanisms to trace pricing distortions or assess systemic impacts, which limits the ability to design targeted responses.

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

One of the most damaging effects linked to artificially suppressed pricing is the erosion of transparency across the global pharmaceutical supply chain:

- **Transparency gaps**: Definitions of "supplier" and "manufacturer" are often inconsistent or misleading.
- **Shadow manufacturing**: The outsourcing of production to unaudited or undisclosed facilities makes it challenging to verify origin, quality, and regulatory compliance.
- **Information fragmentation**: Public data on supplier networks is limited and difficult to navigate; there is no single source of reliable and valid data.

ODP has had to leverage multiple external data sources to deconvolute supplier and facility relationships. These analyses are resource-intensive, offer limited certainty, and often provide only a partial view of the supply chain.

The economic impact of suppressed prices results in certain essential medications only being provided by a single supplier, poor quality medications, factory closures, and significant disruption to hospital pharmacy operations.

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

The risk of foreign export restrictions on pharmaceuticals and pharmaceutical ingredients is real and increasingly discussed as a potential strategic vulnerability. While the U.S. does not import most finished drugs directly from adversarial nations, it is heavily dependent on global supply chains that are indirectly exposed, especially through upstream inputs like key starting materials (KSMs) and active pharmaceutical ingredients (APIs).

- **Historical precedent**: During the COVID-19 pandemic, India restricted exports of 26 APIs and their formulations, including key antibiotics and acetaminophen, to secure its domestic supply.[6] In this instance, existing inventory and system buffers helped prevent widespread disruption. However, this action shows how quickly export controls can arise in a crisis and how they could trigger critical shortages.
- **Geopolitical leverage**: China has previously used export controls strategically, most notably in the rare earths sector, and could adopt similar measures in pharmaceuticals, particularly for materials that underpin India's manufacturing base.[7] A recent Wall Street Journal report suggests that export restrictions, while strategically deployed by countries like China, may also impose economic and reputational costs on the restricting country.[8]

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

The feasibility of expanding domestic pharmaceutical capacity depends on product type, economic incentives, and technology maturity. While the U.S. is a global leader in the production of branded and innovative therapies, the domestic production capacity for generic sterile injectables is often produced in a small number of centralized sites, like Pfizer's Rocky Mount Site. This concentration introduces significant supply chain risk. For example, a tornado struck Pfizer's Rocky Mount facility in 2023, disrupting the supply of dozens of hospital-critical injectables. That single site was responsible for nearly 8% of all sterile injectable medicines used in U.S. hospitals, underscoring how one disruption can cascade across the national drug supply.[9]

- **Commercial unviability**: There is often a limited domestic business model for the manufacturing of generic drugs. Margins are low and the market does not reward redundancy or resilience. Incentives like guaranteed volume commitments or long-term

[6] https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics
[7] https://www.reuters.com/world/china/china-primes-rare-earths-weapon-trade-war-escalates-andy-home-2025-04-11
[8] https://www.wsj.com/world/china/beijing-doesnt-want-america-to-see-its-trade-war-pain-1981ede8?st=LgMP4j&reflink=article_copyURL_share
[9] https://www.npr.org/2023/07/26/1190327560/here-are-the-drugs-that-could-be-in-short-supply-after-a-tornado-hit-a-pfizer-fa

purchasing agreements are largely absent. These types of measures could help encourage domestic production of vulnerable, essential generic drugs.

- **Branded vs. generic divide**: While the U.S. retains world-class capabilities in complex biologics and novel small molecules, the generic backbone of the hospital system remains largely offshore.
- **Future orientation**: Expanding domestic capacity is more feasible when paired with forward-looking technologies that will enable next-generation medicines (i.e., personalized therapies, cell and gene treatments)
- **Systemic rethink**: Strengthening generic medicine manufacturing capacity will require more than infrastructure; it will demand new and still-emerging business models that prioritize predictability, resilience, long-term value over short-term costs, and shared accountability across stakeholders. This must be coupled with advanced manufacturing and policies that value reliability and security alongside price and volume.

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

While global sourcing has helped reduce costs, it has also made the U.S. supply chain heavily reliant on imports from countries with lower regulatory, environmental, and labor standards. This foreign reliance is especially concerning for routine hospital medicines, which are often assumed to be available until a shortage reveals the fragility of the system.

Protecting high-risk, low-margin segments, such as domestic production of generic sterile injectables and APIs, requires targeted subsidies such as guaranteed volume commitments, advance market agreement or cost-sharing mechanisms. It also requires trade protections (including tariffs), and policy support in the short term that assures predictable demand and pricing stability. For example, tariffs on generic drugs could help level the playing field so that domestic production becomes more attractive.

Other countries impose tariffs and strategically reinvest the proceeds to subsidize industries of national interest, including the production of key starting materials (KSMs), active pharmaceutical ingredients (APIs), and finished drug products. These targeted subsidies reduce production costs and tilt the playing field. The United States can adopt a similar approach, but to be effective, it must be deliberate and aligned with national supply chain resilience goals.

From a longer-term perspective, policy support and government funding to implement a completely new approach to production of essential medicines is both possible and necessary. This would help create a self-sustaining new medicine production economy that is not dependent on continual government subsidy. Without intervention, these areas will remain economically unviable for domestic producers, despite their critical role in national health security.

(x) any other relevant factors.

Two structural dynamics are especially relevant to understanding why essential medicines remain vulnerable despite consistent demand and public health importance:

- **Purchasing power concentration**: A handful of group purchasing organizations (GPOs: Vizient, Premier Inc., HealthTrust Performance Group) control most of the hospital and health system procurement in the U.S. This consolidated purchasing power tends to focus on the lowest unit price, with limited consideration for resilience, redundancy, or domestic sourcing.
- **Misaligned incentives**: Existing healthcare reimbursement models reward volume and cost-efficiency, but offer little incentive for supply chain reliability or domestic production.

As a result, manufacturers frequently exit the market not because demand has declined, but because the economics of continued production are no longer viable.

One approach to addressing this misalignment is the development of new business models that directly incentivize reliability, domestic sourcing, and long-term supply stability. Models that move purchasing decisions beyond only lowest-cost considerations, reduce middlemen and instead reward availability, quality assurance, and investment in resilient capacity could help re-establish the economic conditions necessary to sustain the production of critical, low-margin medicines.