END CANCER DRUG SHORTAGES COALITION

A Consensus Statement on Drug Shortages

Background

Drug shortages are one of the most pressing problems impacting healthcare delivery in the United States today. Since 2000, there have been over 3,400 new drug shortages identified, which peaked at an all-time high of 323 in the first quarter of 2024.[i] As of June 2025, there were 253 active drug shortages in the U.S., with 42% of these shortages beginning in 2022 or earlier. Cancer medications remain one of the top five drug classes most vulnerable to shortages, with 23 active shortages reported in June 2025.[i] While not a new problem, the recent increase in cancer drug shortages has impacted hundreds of thousands of cancer patients.

Drug shortages are a multi-faceted problem with their causes being attributable to a number of factors, including supply chain vulnerabilities, economic pressures, and regulatory and manufacturing challenges. Many steps of the pharmaceutical supply chain exist outside of the United States, with a heavy reliance on China and India, to provide pharmaceutical ingredients. This offshoring of the supply chain makes the U.S. drug supply vulnerable to geopolitical tensions and trade policies.[ii] However, even those facets of the supply chain that exist within our borders are susceptible to environmental threats and natural disasters, such as hurricanes and tornados. Due to a lack of redundancy in most manufacturers' supply chains, if even one step of the process fails, the drug supply can be severely impacted. Combined with a lack of incentives for manufacturers to produce less profitable drugs like sterile injectables, and manufacturing disruptions caused by quality control issues within the supply chain, the U.S. supply of drugs is extremely insecure.[iii]

These ongoing shortages have disastrous impacts for both patients and providers alike. If a patient's anti-cancer medication is not available due to a shortage, they may need to switch medications or increase the time between doses, leading to non-optimal treatment and outcomes. These alternative therapies may result in increased toxicities or out-of-pocket costs for patients and the healthcare system. Clinical trials may also be delayed, stalled, or suspended if research treatments are unavailable due to drug shortages, stifling the incredible progress that has been made in the fight against cancer.

When drug shortages arise, hospitals and pharmacies are forced to navigate inventory challenges by forced rationing or acquiring drugs through non-optimal means. The considerable time and resources that physicians, pharmacists, and other members of the healthcare team spend managing drug shortages takes resources away from other important patient care activities. A recent study by Vizient found that in 2023, U.S. hospitals spent a combined $894 million in labor costs (estimated 20 million staff hours) managing and mitigating drug shortages, pushing 74% of surveyed institutions over budget for the year.[iv] To ensure that they have enough resources dedicated to managing drug shortages, many institutions redistribute the clinical workload of staff assigned to drug shortages to other staff members. 60% of surveyed institutions reported shifting workloads of pharmacists, without hiring new FTEs, leading to an increased workload on already overburdened and burned-out workforce.[iv]

These shortages may impact the pediatric population in different ways. For example, many of the anti-cancer agents used to treat children with cancer have been in critical supply over the past decade. Vincristine, an essential drug used to treat acute lymphoblastic leukemia (ALL), the most common pediatric

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[i] American Society of Health-System Pharmacists. Drug shortages statistics [Internet]. Bethesda (MD): ASHP; c2025 [cited 2025 Aug 19]; [about 10 screens]. Available from: https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics.

[ii] Scott D. It's about to get harder to find your prescription drugs [Internet]. Vox. Manhattan (NY); 2025 Feb 5 [cited 2025 Jun 24]. Available from: https://www.vox.com/future-perfect/398161/trump-tariffs-china-prescripton-drugs-medicine-shortage.

[iii] U.S. Government Accountability Office. Drug shortages: HHS should implement a mechanism to coordinate its activities [Internet]. Washington (DC); 2025 Apr 9. 55 p. Report No.: GAO-25-107110. Available from: https://www.gao.gov/products/gao-25-107110?utm.

[iv] Vizient. Beyond the shortage: The hidden cost of drug supply chain disruptions [Internet]. Irving (TX); 2025 Jun. 20 p. https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/0fed86e17e654732ba642464400e713f?v=323b8a49

malignancy, has been in very short supply requiring cancer centers to ration its use. There have been similar challenges acquiring methotrexate (used to treat leukemia, lymphoma, and osteosarcoma), cisplatin (brain tumors, neuroblastoma, osteosarcoma), etoposide (leukemia and sarcomas) and vinblastine (Hodgkin lymphoma, Langerhans Cell Histiocytosis). Many supportive care medications that patients are prescribed throughout the course of their treatment to help manage side effects and improve patient quality of life have also experienced shortages over the past few years, including levofloxacin, lorazepam, and narcotics/opioids used to manage pain. Shockingly, common supplies, such as empty sterile bags, syringes, and tubing sets, have also been intermittently on critical shortage, which is used to dilute countless pharmaceuticals used to treat cancer.

This document outlines what we believe to be the major factors contributing to the persistent drug shortage problem in the United States – the lack of transparency in the supply chain, the absence of incentives for manufacturers to develop high-quality and redundant supply chains, and the insecurity of the generic drug market. For each factor, we offer recommended policy solutions that the federal government should consider to help mitigate the growing number of shortages and address their root causes. We recognize that drug shortages are a multi-faceted problem that will require a multi-faceted solution. Effectively tackling drug shortages will require the collaborative efforts of drug manufacturers, healthcare professionals, patient advocacy organizations, and government agencies.

Increasing Transparency

Explanation of the Problem:

The lack of transparency throughout the pharmaceutical supply chain, from the procurement of active pharmaceutical ingredients (API) to the tracking and reporting of active drug shortages, limits the ability of purchasers, providers, and policymakers to anticipate, mitigate, and respond to supply disruptions.

Limited visibility in the supply chain starts at the beginning of the process, with a general lack of understanding of how APIs are manufactured and sourced. Over 85% of the APIs found in drugs sold in the U.S. come from foreign nations, with China and India making up the bulk of the supply.[v] Not only does this make the U.S. drug supply chain vulnerable to geopolitical threats, it also reduces the FDA's ability to have regulatory oversight of this critical step of drug manufacturing. Although domestic manufacturers are dependent upon these APIs, not all aspects of the API supply chain are visible to them. Insufficient knowledge about these processes hinders manufacturers' ability to anticipate API shortages and adjust the rest of their supply chain to respond effectively.

The increased complexity and globalization of the drug supply chain make it difficult for any parties involved to gain an adequate view of the entire drug manufacturing process from start to finish. Without this clear picture, it is nearly impossible to identify failures in quality and bottlenecks in the process. The fragmentation of the supply chain creates a lack of transparency and prevents manufacturers from appropriately assessing and managing risks.

When a product does go on shortage, the incomplete information provided to the FDA about the shortage hinders mitigation efforts. While the *Coronavirus Aid, Relief, and Economic Security Act* (CARES) Act[vi] required manufacturers to notify the FDA in advance of permanent discontinuance or interruption in the manufacturing of drug products or APIs, the inability to enforce reporting requirements results in non-

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[v] United States Pharmacopeia Quality Matters (US). Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union [Internet]. Rockville (MD): [updated 2025 Apr 17; cited 2025 Oct 16]; [about 4 screens]. Available from: https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

[vi] Coronavirus Aid, Relief, and Economic Security Act [Internet]. H.R. 748, Cong. 116 (2020). [Cited 2025 Aug 19]. Available from: https://www.congress.gov/116/statute/STATUTE-134/STATUTE-134-Pg281.pdf

compliance from manufacturers.[vii] Also, while manufacturers are required to tell the FDA that there is an expected shortage, they are not required to report the cause of the shortage or production timelines for when more drugs will become available. The FDA's lack of authority to require this information prevents them from anticipating shortages and working in a meaningful way to mitigate them.

Without insight into the causes of shortages and how long they may last, hospitals and pharmacies are unable to strategically plan and manage their stock of medications. This may lead to some institutions stockpiling or panic buying drugs when they are first notified of a shortage, leading to other institutions not being able to acquire any doses for their patients. Institutions that can afford to purchase additional inventory are advantaged in this system, while those who cannot may have to rely on acquiring drugs outside of normal purchasing channels, such as through unregulated grey markets.

Without clear insight into all the steps of the drug supply chain and reporting mechanisms in place for the FDA to gather all of the information related to a shortage, the U.S. will never be able to fully prepare for, mitigate, and prevent drug shortages. The overall lack of information inhibits manufacturers, purchasers, and regulators from employing risk management strategies, which ultimately prolongs and worsens drug shortages.

Policy Proposals:

In recent years, various policy proposals have been introduced to address drug shortages by increasing transparency throughout the pharmaceutical supply chain, including proposals from the House Energy and Commerce Committee, the Duke-Margolis Institute for Health Policy, and stand-alone legislation. Recent policy proposals that we support have included:

- Direct the FDA to report on key metrics for generic drugs and conduct inspections of new domestic sterile manufacturing facilities to improve supply chain stability.
- Mandate the FDA to properly publish and distribute information on reported supply and demand drug shortages to appropriate organizations including physicians, pharmacists, health providers, and patient organizations.
- Direct the FDA to issue draft and final guidance to manufacturers outlining information necessary to improve demand predictability.
- Enable the FDA to give civil monetary penalties to manufacturers failing to provide timely and informative notifications concerning drug shortages.
- Authorize and appropriate dedicated funding for the FDA Quality Management Maturity (QMM) program, which uses manufacturers to invest in more reliable and better-quality supply chains that meet a higher standard than current good manufacturing practice (CGMP) requirements.[viii]
- Building on the QMM program, Congressionally-directed development and piloting of a product-level Drug Supply Chain Reliability (DSCR) Program, led by an independent third party with oversight from the HHS Supply Chain Resilience and Shortage Coordinator and other federal agencies.
- Require manufacturers to provide initial notification to the FDA forty-eight hours after a sustained increase in demand for a drug, API, or excipients for six consecutive weeks; requiring a follow-up notification thirty days after the initial submission with additional information and projected duration of the interruption.
- Congressional study or investigation into how certain policies contribute to drug shortages accompanied by recommendations for preventing shortages through mark-based solutions.

[vii] Food and Drug Administration (US). Frequently asked questions about drug shortages [Internet]. Silver Spring (MD): [updated 2024 Dec 18; cited 2025 Jun 24]; [about 4 screens]. Available from: https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#:~:text=A%20notification%20concerning%20a%20permanent,or%20interruption%20in%20manufacturing%20occurs

[viii] Food and Drug Administration (US). CDER Quality Management Maturity [Internet]. Silver Spring (MD): [updated 2025 Jul 29; cited 2025 Aug 19]; [about 3 screens]. Available from: https://www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity

- Amend the Federal Food, Drug, and Cosmetic Act to require manufacturers of life-saving drugs to submit data and information to assess the stability of the drugs and determine their longest date of expiration.
- Increasing transparency from drug middlemen by requiring group purchasing organizations to disclose more information about bulk contracts, potentially reducing incentives for companies to limit drug production.

Incentivizing Manufacturers

Explanation of the Problem:

Under the current system, manufacturers are not rewarded for creating high quality, redundant manufacturing processes. This leads to a "race to the bottom," where manufacturers are competing against themselves to produce drugs at the lowest cost with the least investment possible.

Creating reliable supply chains takes a lot of time, money, and resources upfront. Redundancy requires manufacturers to build backup facilities, contract with multiple suppliers, and maintain a surplus of inventory. Drug manufacturers who operate on thin profit margins to begin with, especially in the generics space, may not have the capital to invest in building redundant systems if they are not guaranteed a greater return. The current drug purchasing system in the U.S. cares very little about the stability or quality of the supply chain, with most buyers choosing to prioritize price when making procurement decisions.[iii] Without providing some sort of financial or regulatory incentive for manufacturers to invest in a more resilient supply chain, this system is unlikely to change.

While there are some mechanisms in place to encourage quality within the supply chain, such as inspections, the FDA cannot currently require manufacturers to create contingency plans for supply chain disruptions. The lack of redundancy in the system means that one single event, such as a hurricane wiping out a factory, can take down the entire chain, and the drug supply with it.[ix] Incentives may come in the form of direct regulatory and/or economic incentives to the manufacturer, or incentives for purchasers to buy drugs produced by higher quality supply chains.[x]

Without developing an incentive for manufacturers to create a more secure supply chain, companies will have little reason to invest in redundancies and higher-quality processes. The U.S. drug supply chain will continue to remain vulnerable until steps are taken to ensure that manufacturing processes cannot be entirely disrupted due to a single-point failure.

Policy Proposals:

There have been several policy proposals in recent years that would incentivize manufacturers to invest in a more secure supply chain. This includes the Senate Finance Committee Discussion Draft from the 118th Congress, several pieces of stand-alone legislation, and a proposal from the Brookings Institute. Recent policy proposals that we support have included:

- Propose a new Medicare Drug Shortage Prevention Program, which would be a voluntary program that offers incentives for providers, manufacturers, and GPOs to adopt new contracting

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[ix] Food and Drug Administration (US). Drug shortages: Root causes and potential solutions [Internet]. Silver Spring (MD): 2019 [updated 2020 Feb 21; cited 2025 Jun 24]. 124 p. Available from: https://www.fda.gov/media/131130/download?attachment

[x] Food and Drug Administration (US), Office of Pharmaceutical Quality. Quality management maturity: Essential for stable U.S. supply chains of quality pharmaceuticals [Internet]. Silver Spring (MD): [cited 2025 Jun 24]. Available from: https://www.fda.gov/media/157432/download#:~:text=Potential%20regulatory%20and%20economic%20incentives,and%20improved%20supply%20chain%20insight.

and purchasing standards, with payments tied to supply chain resiliency, reliability, and transparency.
- Create a new tax credit to incentivize the domestic manufacturing of drugs, API, PPE, and diagnostics.
- Create a pilot program within the Department of Health and Human Services (HHS) to create a reserve supply of essential pediatric cancer drugs.
- Develop both a list of chemotherapeutic drugs that are essential for treating cancers in adults and a list of chemotherapeutic drugs for pediatric cancers.
- Authorize HHS to order drug manufacturers to distribute drugs from their buffer stocks into the commercial market in order to prevent or alleviate drug shortages.

Securing the Generics Market

Explanation of the Problem:

The majority of drug shortages in the United States occur among generic medications.[xi] However, they represent 90% of prescriptions filled in the US; 17.5% of prescription drug spending; and less than 2% of all health care spending. One of the most significant contributions of generic medicines is their lower prices. Improved affordability allows generics to reach a broader population, especially those who may be uninsured or underinsured. For instance, generic versions of anti-cancer drugs, hormonal therapies, and supportive care medications allow greater flexibility in treatment planning and allow providers to tailor treatment based on individual patient needs, preferences, and cost considerations.

The root causes of these shortages are complex but economic factors impacting the generic medications marketplace and supply chain are known drivers of shortages. The marketplace for generics operates differently from the marketplace for brand name drugs in several important ways. For example, manufacturers of generic medications are impacted by the significant presence of international generics manufacturers, who may provide these drugs for a lower cost, yet US regulators may have less authority over overseas production, including its quality. Furthermore, while not unique to generic drugs, group purchasing organizations exert significant pressure on generic manufacturers to reduce their prices. Generic medications are often subject to government-mandated drug discount programs that also apply to brand manufacturers. In the US, most generic drug manufacturers rely on other companies to produce the APIs that go into the drugs. Evidence suggests that a third of the APIs are single source (that is, they had only one manufacturing facility), and another third were manufactured by two or three facilities, suggesting that there is limited redundancy in global manufacturing of US generic APIs. Proposed tariffs on pharmaceuticals could raise production costs, which are often passed down to patients in the form of higher drug prices. These tariffs could also disrupt the global supply chain, increasing the risk of shortages—especially for lower-margin generic drugs that are highly sensitive to cost pressures. These downward price pressures can ultimately lead to reduced competition, disinvestments in quality, and a loss of supply chain resiliency. All these factors can lead to or exacerbate drug shortages.

Compared to other high-income countries, the US has historically paid less for, and used more, generics.[xi] The tough market conditions in the U.S. have driven numerous generics manufacturers out of business, leading to some manufacturers having a monopoly on the supply of certain critical medications. For example, thioguanine, an anti-cancer agent essential in the treatment of ALL, was approved for use in the United States in 1966. However today, it is only made by one company, who recently took over its

[xi] Ventola CL. The drug shortage crisis in the United States: causes, impact, and management strategies. P T. 2011 Nov;36(11):740-57. PMID: 22346307; PMCID: PMC3278171.

manufacturing and increased the cost twenty-fold. This has resulted in patients not being able to receive a drug that has been used in treatment protocols for decades and contributes to a cure rate of over 90%.[xii]

The generic drug market conditions limit competition, impact quality, and result in drug shortages, which ultimately increases costs to the healthcare system as a whole.[xiii] Therefore, supporting a resilient, high quality, accessible and stable generics market is critically important to ensure patients are able to receive the most appropriate treatments when they need them.

Policy Proposals:

There have been several policy proposals to address drug shortages and mitigate some of the economic pressures on generics manufacturers in the last few years, including proposals from the House Energy and Commerce Committee and the Senate Finance Committee as well as stand- alone legislation. Recent policy proposals that we support are listed below. Regardless of the proposal, it is critical that chosen policy solutions do not increase out-of-pocket costs for patients on their generic drugs.

- Exempting generic, sterile injectable drugs with at least one indication for a serious disease or condition that are made by more than one manufacturer from 340B rebate requirements.
- Prohibiting total rebates in excess of 100% of the drug's average manufacturer price for generic drugs in shortage or at risk of shortage.
- Requiring the Centers for Medicare and Medicaid Services (CMS) to gradually phase out the rebate reduction or waiver for drugs exiting a shortage.
- Creating a new tax credit that would only apply to generics manufacturers operating in certain Opportunity Zones across the U.S., to incentivize the domestic manufacturing of drugs, API, PPE, and diagnostics.
- Establishing grants for sterile injectable drug manufacturers to upgrade facilities to continuous or advanced manufacturing.
- Requiring the evaluation of and reporting on current Group Purchasing Organization practices and their impact on generic drug availability.

Consensus Statement:

The End Cancer Drug Shortages Coalition, a group of professional societies and patient advocacy organizations, recognizes and affirms the need to end cancer drug shortages. Mechanisms should be put in place to increase transparency across the supply chain, incentivize manufacturers to build higher quality and more redundant processes, and support a resilient marketplace for generic medications in the United States. Drug shortages are not caused by one singular issue and will not be solved using a singular policy solution. We encourage Congress and the Administration to work together to find a multi-factored solution to address the growing drug shortage problem in the United States.

[xii] Dickens DS. A soaring price, a silent fight: Thioguanine portends new access barriers to life-saving treatments for children with cancer. Pediatric Blood & Cancer [Internet]. 2024 Oct 29 [cited 2025 Aug 19];72(1): 2 p. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1002/pbc.31410

[xiii] Wouters OJ, Kanavos PG, McKEE M. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. Milbank Q. 2017 Sep;95(3):554-601. doi: 10.1111/1468-0009.12279. PMID: 28895227; PMCID: PMC5594322.

Sincerely,

Hematology/Oncology Pharmacy Association (HOPA)
American Society of Hematology (ASH)
American Society of Pediatric Hematology/Oncology (ASPHO)
The Andrew McDonough B+ Foundation
Association of American Cancer Institutes (AACI)
Association of Cancer Care Centers (ACCC)
Association of Pediatric Hematology/Oncology Nurses (APHON)
Children's Brain Tumor Foundation
Children's Cancer Research Fund
Community Oncology Alliance (COA)
KidneyCAN
Melanoma Research Foundation
National Comprehensive Cancer Network (NCCN)
Network for Collaborative Oncology Development & Advancement (NCODA)
MIB Agents Osteosarcoma
Oncology Nursing Society (ONS)
Ovarian Cancer Research Alliance (OCRA)
Society for Gynecologic Oncology (SGO)