

Testimony of
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Committee on Energy and Commerce
Subcommittee on Health
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Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security
Threats

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Summary of Testimony

Throughout the COVID-19 pandemic, we observed large-scale health care supply chain disruptions, highlighting the need to enhance the essential programs authorized under the Pandemics and All-Hazards Preparedness Act to better mitigate these supply chain breakdowns. Health care supply chain issues have a significant impact on the oncology community, largely due to shortages in critical and life-saving oncology drugs. Drug shortages can lead to delays in treatment, worsen patient outcomes, and force patients to switch to suboptimal treatments. According to the U.S. Food and Drug Administration (FDA), there are currently 11 active shortages in oncology drugs, including commonly used drugs like Cisplatin, Carboplatin, Methotrexate, and Fludarabine. Some of these shortages have persisted since 2020, impacting patient access and increasing costs. These shortages affect not only adult patients but also pediatric patients, with the most frequently used drugs for childhood cancer experiencing temporary unavailability.

The causes of these breakdowns in the drug and medical supply chain are multifaceted, involving manufacturing disruptions, quality control issues, regulatory challenges, supply chain vulnerabilities, and market dynamics. The Association for Clinical Oncology (ASCO) has been collaborating with other stakeholders to address these challenges for over a decade, identifying drug shortages as a matter of national security. ASCO presents several recommendations to address these issues in the reauthorization of PAHPA, including recommendations to improve the function and composition of the Strategic National Stockpile (SNS), improve visibility into the drug and medical supply chain and others. ASCO encourages Congress and the Administration to consider comprehensive and bipartisan legislative and regulatory solutions to address these issues and ensure individuals with cancer receive life-saving treatments. ASCO also stands ready to collaborate with the Subcommittee to swiftly advance these solutions.

Introduction

Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the Subcommittee, it is my pleasure to appear before you today to discuss this year's reauthorization of the Pandemic and All-Hazards Preparedness Act, also known as PAHPA, the Strategic National Stockpile (SNS) and the role the SNS can play in mitigating wide-spread oncology drug shortages thousands of adult and pediatric individuals with cancer are experiencing.

I am Dr. Julie Gralow, Chief Medical Officer, and Executive Vice President for the Association for Clinical Oncology (ASCO). Prior to joining ASCO, I was the Jill Bennett Endowed Professor of Breast Cancer at the University of Washington School of Medicine, Professor in the Clinical Research Division of the Fred Hutchinson Cancer Research Center, as well as Director of Breast Medical Oncology at the Seattle Cancer Care Alliance.

ASCO is a leading professional organization representing over 45,000 oncology professionals, including physicians, researchers, and other healthcare providers dedicated to improving cancer care. Our mission is to conquer cancer through research, education, and promotion of the highest quality, equitable patient care. ASCO appreciates the subcommittee's bipartisan efforts to improve the programs in the Pandemic and All-Hazards Preparedness Act to better prepare the U.S. and its health care system for future public health crises.

The COVID-19 pandemic exacerbated many long-standing access and quality issues that threaten the resilience of our nation's healthcare supply chain. It magnified the dangers inherent in failing to address gaps and deficiencies in the pharmaceutical and medical supply chains, including overall manufacturing quality. Supply chain issues can adversely impact patient care by delaying treatment, worsening patients' health outcomes, or requiring patients to switch to non-optimal treatment regimens.

Health care supply chain issues and shortages are not new issues; ASCO and other stakeholders have been working to address them for over a decade. The health care community is experiencing a significant breakdown in the pharmaceutical supply chain leading to shortages in commonly used oncology drugs. This alarming and pervasive problem is affecting patient care and outcomes. It jeopardizes the delivery of essential therapies, compromises treatment plans, and increases the burden on patients, caregivers, and clinicians.

According to the U.S. Food and Drug Administration's (FDA) drug shortage website, oncology has at least 11 active shortages. Four of the medications, Cisplatin, Carboplatin, Methotrexate, and Fludarabine, are commonly used across cancers and disease states. Fludarabine has been on the FDA's drug shortage list since 2020. Even if physicians can obtain the drug, it comes at an increased cost. If the drug is not available at all, physicians are forced to choose from suboptimal treatments to ensure patient care continues.

Today's shortages are the worst I have seen in my 30-year career. In 2022, approximately 100,000 Americans were diagnosed with ovarian, bladder and testicular cancers, cancers which may rely on Cisplatin or Carboplatin for treatment. These one hundred thousand patients may not have access to life-saving treatment. In addition to ovarian, testicular and bladder cancers (the FDA-approved indications for the platinum drugs), these agents are also commonly used in cervical, endometrial, lung, head and neck, bladder, esophageal, gastric, breast and more cancers. The number of patients potentially impacted could be as high as 500,000 in a year. The shortage impact is even felt by pediatric patients. From 2010 to 2020, eight of the 10 most frequently used drugs to treat acute lymphoblastic leukemia - the most common childhood cancer - were at some point temporarily unavailable. Beyond drugs, shortages in medical devices and supplies have also caused barriers to delivering high-quality care. In oncology, we have experienced shortages of glass vials, IV tubing, saline bags and more. Device shortages include fluid containers to dilute medications for infusion.

The cause of breakdowns in the drug and medical supply chain are multifaceted and require a comprehensive approach. Factors such as manufacturing disruptions, quality control issues, regulatory challenges, supply chain vulnerabilities, and market dynamics contribute to the persistent shortage of critical cancer medications. While some shortages may be temporary, others persist for prolonged periods, leaving patients at risk and healthcare providers struggling to deliver optimal care.

ASCO Recommendations

The reauthorization of PAHPA provides a unique opportunity for Congress to address this crisis, safeguard the health and well-being of cancer patients across the nation, and strengthen the SNS. ASCO and other stakeholders have long collaborated on efforts to improve our nation's supply chain and mitigate drug shortages. In fact, ASCO and our partners were among the first groups to identify drug shortages as a matter of national security. While progress has been made in many areas, major challenges still require policymakers' action.

ASCO and other stakeholders have developed the following [recommendations](#)¹ to guide policymakers in their efforts to address these challenges. Our recommendations are meant to provide a range of potential policy and marketplace changes to improve supply chain quality and resilience:

1. Incentivize advanced manufacturing technology and develop new continuous manufacturing technology for critical drugs and active pharmaceutical ingredients (APIs) in both foreign and domestic facilities.
2. Improve the function and composition of the SNS. Specifically:
 - a. Finalize and regularly update a list of medicines and devices necessary to respond to potential national-scale public health emergencies, which should be included in the SNS.

¹ <https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations>

- b. Increase transparency regarding the specific products and quantities of such products included in the SNS.
 - c. Expand the SNS scope to include pandemic preparedness and response.
 - d. Incentivize the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the SNS.
 - e. Implement enhancements to the Office of the Assistant Secretary for Preparedness and Response (ASPR) SNS Control Tower including improving control tower visibility in the supply chain and expanding control tower scope beyond the current 38 pharmaceutical products to additional critical medicines, including all medicines, medical devices, and personal protective equipment (PPE).
 - f. Create a workable process for SNS requests by establishing a process for planned non-emergency distributions from SNS to medical facilities of medications and devices prior to their expiration dates at discounted prices to promote practiced workflows and decrease wastage of expired and obsolete products.
3. Improve multinational cooperation and collaboration on supply chain resilience, including support for intergovernmental, regulatory, and public-private partnerships for research, development, and deployment of effective and affordable disease-tracking tools, diagnostics, therapeutics, and vaccines.
4. Incentivize manufacturers to improve quality and resilience by providing publicly available quality management ratings, reducing contamination, and identifying key starting materials, APIs, and finished dosage forms of essential medicines, including vaccines, that should have domestic manufacturing capacity to improve the resilience of the U.S. drug supply and incentivize their production without limiting access to foreign sources of the product.

5. Replicate asks for critical drug manufacturing transparency and oversight for medical devices and ancillary supplies (e.g., PPE).
 - a. The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 included drug manufacturing provisions designed to mitigate and reduce drug shortages. Amend the Act to extend similar provisions to the manufacturing of medical devices and enhance reporting requirements for device manufacturers.

In addition to the above SNS recommendations, ASCO urges policymakers to consider the following [solutions](#)² to mitigate drug, medical supply, and medical device shortages to protect U.S. national security:

1. Necessitate a notification requirement for medical product devices and equipment needed to administer medications, similar to the legislation enacted in 2012 that requires drug manufacturers to notify the FDA “of any changes in production that is reasonably likely to lead to reduction in supply” of a covered drug in the U.S.
2. Require a risk assessment of foreign source APIs.
3. Require federal government authorities with jurisdiction over national security to conduct an analysis of domestic drug and medical device manufacturing capability and capacity for critical products to assess the threat to national security.
4. Require a U.S. Government Accountability Office study to examine all aspects of the drug supply chain to determine whether any new issues are exacerbating drug shortages.

We also believe a comprehensive legislative and regulatory solution could prove to be effective. As such, we recommend that Congress and the Administration:

² <https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-security.ashx>

1. Develop incentives for drug manufacturers to have contingency or redundant production plans for their pharmaceutical products on the critical drug list. The back-up plan should include prioritizing the most medically necessary products, qualifying third party suppliers across their network, and increasing production and inventory for API and finished goods.
2. Investigate developing a system of paying suppliers to hold inventory, perhaps similar to the system employed by the U.S. Department of Defense (DoD) Defense Logistics Agency. Consider partnering with the DoD to create contractual leverage with drug manufacturers for civilian hospitals.
3. Incentivize manufacturers and work with the FDA to repackage pharmaceuticals according to the amount of medication commonly used to reduce waste.
4. Create an Office of Clinical Affairs within the Drug Enforcement Agency (DEA) for DEA personnel to be available to address the clinical aspects of medication shortages of controlled substances rather than just diversion enforcement.

Thank you for the opportunity to present ASCO's perspective. We appreciate the Subcommittee's continued efforts to enhance the health care pharmaceutical and medical supply chain to protect our national security. This is an urgent crisis, and we stand ready to collaborate with you to advance comprehensive solutions that ensure individuals with cancer receive the life-saving and life-prolonging treatments they require.