

House Energy and Commerce Committee

Oral Testimony of Julie R. Gralow, MD, FACP, FASCO, Chief Medical Officer & Executive Vice President,

Association for Clinical Oncology

Before the Committee on Energy and Commerce Subcommittee on Health U.S. House of Representatives Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats on June 13, 2023:

Chairman Guthrie, Ranking Member Eshoo, and members of the Subcommittee, thank you for the opportunity to discuss the Pandemic and All-Hazards Preparedness Act and its potential to help address the cancer drug shortages crisis. I'm Dr. Julie Gralow, Chief Medical Officer and Executive Vice President of the Association for Clinical Oncology (ASCO). Prior to joining ASCO, I was a practicing medical oncologist and professor in Washington state for 3 decades.

ASCO represents over 45,000 oncology professionals who are dedicated to improving cancer care. We appreciate the subcommittee's bipartisan efforts to improve the programs in PAHPA to better prepare the U.S. for future public health crises.

The pandemic exacerbated long-standing issues that threaten the resilience of our healthcare supply chain. While the Strategic National Stockpile and other programs authorized under PAHPA aided the health care community during the public health emergency, more must be done.

Drug shortages will worsen without intervention. This is especially true for sterile injectables, many of which are oncology drugs. These drugs are expensive to make and have a low profit margin, leading manufacturers to reduce or discontinue production. Active Pharmaceutical Ingredient sourcing is a weak point. Many manufacturers use the same API source. If that source experiences quality issues causing a production shutdown or runs out of critical components, drug shortages are a likely outcome. Visibility

into the supply chain regarding APIs is lacking; the FDA does not have authority to require manufacturers to provide API sourcing information. This means shortages can emerge without warning.

Today's shortages are the worst I have seen in my 30-year career. I'm in regular communication with colleagues at the University of Washington and Fred Hutchinson Cancer Center in Seattle. Initially they were optimistic that with dose modifications and substitutions, they had enough supply of platinum agents to ride this shortage out. However, many of the state's smaller cancer centers began running out of drug and started sending their patients to the UW, depleting their supply.

I spoke to a patient diagnosed with endometrial cancer whose team recommended a chemotherapy course that included a platinum agent. She studied the drugs and their side effects, had a game plan, and did well through the first cycle of treatment, much to her relief. Then, when arriving for her second dose, one of the agents was no longer available. You can imagine the anxiety this caused. Even when there are acceptable and proven alternatives, switching from a planned course of treatment adds fear and stress to that already caused by a cancer diagnosis.

Eleven oncology drugs are currently in shortage. Four of these - cisplatin, carboplatin, methotrexate, and fludarabine - are commonly used to treat cancer in adults and children. In 2022, approximately 100,000 Americans were diagnosed with ovarian, bladder and testicular cancers, cancers for which cisplatin or carboplatin are recommended. These drugs are also commonly used in cervical, endometrial, lung, head and neck, esophageal, gastric and breast cancers. The number of U.S. patients at risk could be as high as 500,000 a year. Drug shortage risks extend to pediatric patients as well. From 2010 to 2020, eight of the ten most frequently used drugs to treat acute lymphoblastic leukemia - the most common childhood cancer - were at some point unavailable. Beyond drugs, we have experienced essential supply shortages, including glass vials, IV tubing, saline bags and more.

Shortages place providers in a moral dilemma—prioritizing drug use for patients who are “curable” versus those who are not. Patients worry about whether they will receive their next treatment or if switching to another treatment will shorten their lives.

The PAHPA Reauthorization is an opportunity to advance solutions to improve the supply chain—especially during public health crises.

ASCO makes the following recommendations, detailed in my written statement:

1. Improve the function and composition of the Strategic National Stockpile.
2. Enhance multinational collaboration on supply chain resilience.
3. Incentivize manufacturers to improve quality and transparency.
4. Reduce reliance on other countries for critical drug ingredients.
5. Analyze domestic drug and device manufacturing capability and capacity for critical products, to avert national security threats.

I appreciate the Subcommittee’s efforts to enhance the supply chain to protect our national security and patients’ health. ASCO stands ready to collaborate with you to ensure individuals with cancer receive the life-saving and life-prolonging treatments they require. This is a crisis. Cancer patients’ lives are on the line. Thank you.