

August 25, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy & Commerce Committee
2125 Rayburn HOB
Washington, DC 20515

Dear Chair Rodgers:

On behalf of the Society of Gynecologic Oncology (SGO), thank you for the opportunity to provide comments on the Stop Drug Shortages Act discussion draft. Our members and their patients have been significantly affected by the chemotherapy shortages. We need a comprehensive solution to this problem to ensure that patients do not face the uncertainty and stress associated with a lack of access to drug therapies deemed standard of care.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our more than 2,800 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with the Foundation for Women's Cancer to increase public awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our primary mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

Undoubtedly, we are in the midst of the worst chemotherapy drug shortage in U.S. history, with 15 indispensable chemotherapy drugs in short supply simultaneously. Carboplatin and cisplatin, which have been in shortage since mid-February 2023, are first-line therapies for ovarian, endometrial, and cervical cancers. Carboplatin serves as a backbone drug for most gynecologic cancer therapies; however, similar shortage episodes over the past two decades have resulted in sub-standard cancer care. A recent survey indicated that 45% of gynecologic cancer providers are still experiencing shortages, which include methotrexate, fluorouracil, paclitaxel docetaxel, leucovorin, vinblastine, and liposomal doxorubicin. Liposomal doxorubicin is a preferred second-line standard of care treatment for patients with platinum-resistant ovarian cancer. Before the pegylated liposomal doxorubicin shortage onset, the SGO estimated that over 500,000 patients were affected by chemotherapy drug shortages. The American Society of Health-System Pharmacists (ASHP) recently surveyed that 99% of hospital pharmacists reported shortages, causing 85% to ration treatments and 84% to rely on different dosages.¹

The causes of chemotherapy shortages are complex. The recent issues with pegylated liposomal doxorubicin provide an excellent example. ASHP has listed the drug as being in shortage², while the Food

¹ <https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

² <https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=918&loginreturnUrl=SSOCheckOnly#:~:text=Pfizer%20has%20docetaxel%2010%20mg,are%20available%20in%20limited%20supply.>

and Drug Administration (FDA) reports no shortage of pegylated liposomal doxorubicin. Some SGO members have reported that they will have no new supply of pegylated liposomal doxorubicin for the next three months, which is an untenable situation for patients. Many members remain without carboplatin, cisplatin, or methotrexate.

Patients deserve better than having to wonder whether they will have access to standard-of-care cancer treatments, and SGO commends you for pursuing a legislative solution; however, we believe that the Stop Drug Shortages Act in its current form will not eliminate the root causes of the current shortages and urge you to develop a comprehensive, bipartisan solution. Specifically, SGO encourages you to consider the following when revising the Stop Drug Shortages Act to prevent future drug shortages:

- Policies that increase reimbursement to manufacturers without requiring investments to improve quality and supply chain resiliency run the risk of exacerbating drug shortages in the U.S.
- The FDA should be empowered to implement a quality management maturity (QMM) program and risk management program (RMP). Both would help improve the resiliency of the supply chain and support the production of high-quality drugs.
- Include commonly utilized, life-saving chemotherapy drugs on the FDA Essential Medicine List and empower the Administration of Strategic Preparedness and Response to oversee and respond to critical drug shortages.
- Providers need information on the quality of the drugs they purchase and should be rewarded for investing in higher-quality pharmaceuticals.
- The FDA and the public need more transparency into the root causes of drug shortages to allow them to make informed therapeutic decisions.
- Improve coordination and data sharing between federal government agencies and industry partners on pharmaceutical supply chain matters.
- Studies, as authorized, in this discussion draft provide valuable information but should not be a reason to delay a comprehensive solution further to prevent future drug shortages.

Regarding increased reimbursement to manufacturers, Sections 101, 201, and 301 increase manufacturer reimbursement in Medicaid, the 340B program, and Medicare, respectively. None of these provisions require that a portion of those funds be invested to improve the manufacture of generic sterile injectable drugs. SGO recognizes that reimbursement for generic sterile injectable drugs is extremely low, and manufacturers have narrow margins. While we support exploring mechanisms to improve reimbursement for these drugs, particularly for those deemed essential for cancer care, there is no guarantee that the mechanisms outlined in this legislation will meaningfully improve the quality of the products delivered to patients. SGO is concerned that these provisions may perpetuate existing shortages since they may incentivize the drugs to be in shortage. Therefore, we urge the committee to couple any increased reimbursements with improvements in the manufacturing process and requirements that higher quality standards be set and met.

SGO believes that the FDA needs enhanced authority to respond to and prevent drug shortages and appreciates that the committee is exploring enhanced authorities in Sections 502, 504, and 506. However, these authorities alone will not meaningfully improve supply chain resiliency. We urge the committee to consider the following comments:

- Section 502 provides incentives for an additional month of exclusivity for shelf-life extension studies. While SGO supports this additional month of exclusivity, the legislation should also provide the FDA with the authority to require manufacturers to submit studies and evaluate existing data to extend the shelf life of drugs. This authority will allow the FDA to take meaningful action in the event of a shortage by bolstering a drug's supply to ensure the drug remains safe and effective.
- SGO believes that Section 504, which would require additional reporting on generic drug active pharmaceutical ingredients (APIs) in abbreviated new drug applications, will provide valuable information on a drug to better understand the drivers behind a shortage. However, this provision does not go far enough. In addition, the legislation should authorize the FDA to require manufacturers to notify the FDA in the case of increased demand for a drug and a drug's label to include the original manufacturer and API manufacturer's information. The FDA and the public need more information about the drivers of a shortage to respond appropriately.
- In Section 506, the FDA is authorized to conduct a pilot program to conduct preapproval inspections for new domestic pharmaceutical manufacturing facilities to expedite the licensure and distribution of domestically manufactured generic drugs. SGO supports this and other mechanisms to increase the domestic production of generic sterile injectable drugs where the FDA can monitor manufacturing more closely and respond to any issues more quickly.

Additionally, SGO recommends any legislation that aims to prevent future drug shortages include the following provisions:

- **Authorize and appropriate funding for the FDA's quality management maturity (QMM) program:** QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. According to the FDA, the root cause for many drug shortages is the absence of incentives for manufacturers to strive for more than simply meeting current good manufacturing practice regulations and to develop mature quality management systems. The FDA Drug Shortages Task Force recommended creating this program for which a pilot was recently completed. The QMM rating system will help incent manufacturers to attain higher levels of QMM at their facilities and should be authorized and funded to ensure it works as envisioned.
- **Support and appropriate funding for inspection of Risk Management Programs (RMPs) for high-priority essential generic medicines, including rating the strength of the RMP, like the FDA assigns a site status after site inspections:** The FDA already has guidance on RMPs, which are designed to prevent drug shortages, yet drug purchasers lack insight regarding manufacturers' QMM and supply chain practices. A robust RMP would provide drug purchasers with meaningful evaluations of manufacturers' practices so they could purchase drugs from companies that invest in their supply chains. Given the shortages stemming from issues with generic manufacturers, an enhanced program should focus on these manufacturers.
- **Provide incentives to realign hospital purchasing practices to promote the purchase of high-quality generic drugs:** Currently, hospitals purchase drugs from group purchasing organizations (GPOs), pharmacy benefit managers (PBMs), and entities that provide the lowest prices because there are no incentives for purchasing drugs from more reliable manufacturers at higher prices. The information from the RMPs and QMM programs could be used to inform standards and best practices for contracts with GPOs and PBMs and allow CMS to establish a voluntary reporting system that would include financial rewards for purchasing drugs from manufacturers with

more resilient supply chains. A recent article from the Brookings Institution titled *"Federal Policies to Address Drug Shortages"* addresses this concept in detail.³

Again, thank you for the opportunity to provide these comments and for your commitment to addressing this issue. SGO looks forward to working with you to develop a comprehensive, bipartisan solution to this complex issue to ensure patients have timely access to the required medications. Should you have any questions or require further information, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,



Angeles Alvarez Secord, MD, MHSc
President, 2023-2024

³ <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>