

July 7, 2023

The Honorable Cathy McMorris Rodgers  
Chair  
House Energy and Commerce Committee  
Washington, DC 20515

The Honorable Mike Crapo  
Ranking Member  
Senate Finance Committee  
Washington, DC 20510

**Submitted electronically to [drugshortages@mail.house.gov](mailto:drugshortages@mail.house.gov)**

Dear Chair McMorris Rodgers and Ranking Member Crapo:

On behalf of the Society of Gynecologic Oncology (SGO), thank you for requesting information to better understand the policies driving the current drug shortages, which are having a devastating impact on our patients. We look forward to working with you to enact policies to prevent future shortages and ensure patient access to standard of care chemotherapies.

The SGO is the premier medical specialty society for health care 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.

### ***Scope of the Shortage***

As you know, there are current shortages for several chemotherapies, including cisplatin and carboplatin, which are used as first line therapies for ovarian, endometrial, and cervical cancers. Besides these gynecologic cancers, these chemotherapies are also front-line therapies to treat certain breast and lung cancers. We estimate that these shortages are affecting approximately 525,000 Americans.

SGO launched a comprehensive survey of 2,000 members on April 21 to assess the impact of chemotherapy drug shortages on hospitals across the country. The shortages are not uniform across the country since some institutions and patients have greater access than others, yet members are reporting that these shortages are affecting community cancer centers and large academic medical centers in 40 states and the District of Columbia. Our members have reported that they first began experiencing shortages of these crucial chemotherapies in mid-February. Our survey findings have revealed that a concerning 50% of respondents reported that the platinum drug shortage has impacted their ability to deliver standard-of-care therapy to gynecologic cancer patients, and 40% responded that they anticipate it will. This represents a sizable portion of the gynecologic cancer patient population, underscoring the urgent need to address these drug shortages and prevent future ones.

The survey results also revealed that 28% of physicians have had to select an alternative non-platinum containing regimen for their gynecologic cancer patients due to the drug shortages at their hospital. Over the last three decades, these alternative regimens have been shown to produce worse outcomes and negatively affect patients' survival. Additionally, 60% percent of respondents reported that they have not had to do this yet, but they anticipate they will have to. Out of the hospitals surveyed, an alarming 45% reported that they do not have a dedicated drug shortage policy in place to address the challenges posed by chemotherapy drug shortages. Fortunately, 31% of those respondents reported that a policy is currently under development. However, this still indicates a significant gap in preparedness and highlights the urgent need for healthcare institutions to establish comprehensive policies and protocols to mitigate the impact of drug shortages on patient care.

### **Potential Solutions**

SGO believes that a variety of policies that provide the Food and Drug Administration (FDA) and Assistant Secretary for Strategic Planning and Response (ASPR) with additional authority to address shortages and to support domestic manufacturing of generic drugs are required to prevent future shortages. What follows are a range of solutions that we believe when taken together will help prevent future shortages.

#### **Food and Drug Administration:**

- *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 (CGMP) 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. This QMM rating system will help incentivize 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, similar to how 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 program would provide drug purchasers with meaningful evaluations of manufacturers' practices so they could choose to purchase drugs from those companies who invest in their supply changes. Given the shortages that are stemming from issues with generic manufacturers, an enhanced program should focus on these manufacturers.
- *Lengthen drug expiration dates to mitigate shortages:* The FDA should have the authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate existing data, submit studies to the agency, and label a product with the longest expiration date—or shelf life—that the FDA agrees is scientifically supported. In addition, the FDA should be empowered to levy a civil money penalty if an applicant fails to comply. We recognize that the Department of Defense administers the Shelf-Life Extension Program, which provides for the extension of a federally stockpiled medical material's labeled shelf life after undergoing stability testing

conducted by the FDA. We recommend getting an update on this program and determining how this existing mechanism can support the prevention of generic and other drug shortages.

- *Require enhanced required reporting of manufacturing volume information:* The Food Drug and Cosmetic Act (FD&C Act) requires the reporting of manufacturing volume information, and this policy would expressly require registrants to provide data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance. The Coronavirus Aid, Relief, and Economic Security Act added a section to the FD&C Act, which requires drug manufacturers to report annually to the FDA the amount of each listed drug they manufactured, prepared, propagated, compounded, or processed for commercial distribution. However, there are still gaps in its understanding of the drug supply chain. Specifically, the information required to be submitted under the FD&C Act is insufficient to help the FDA understand which suppliers' registrants are relying upon and how reliant they are on them. Enhanced reporting would help identify vulnerabilities in the supply chain that may not be apparent due to the limited information provided currently to the FDA for application products and approved applications, and allow the FDA to help mitigate shortages by working with other manufacturers.
- *Require manufacturers to notify FDA of increased demand:* Manufacturers should be required to notify the FDA of increased demand after a sustained increase in demand for a drug, active pharmaceutical ingredient (API), or excipient for six consecutive weeks, and to provide subsequent notification 30 days after the initial submission. This policy is articulated in the *Drug Shortage Prevention Act* (H.R. 3008), but ties it to the FDA's essential medicines list, which needs to be updated to include the full range of commonly used medicines, like the chemotherapies currently in shortage. This would only address shortages stemming from surges in demand rather than disruptions in supply. However, should this policy be enacted in concert with others that require enhanced reporting about supply disruptions, it would provide the FDA with a more complete picture of drug supply.
- *Require Labeling to include the Original Manufacturer and Supply Chain Information:* The FD&C Act should be amended to provide that APIs are misbranded if they are introduced into interstate commerce and the original manufacturer and unique facility identifier are not included on the API label, other labeling, and on the certificate of analysis. Finished drug products should be deemed misbranded if the original manufacturer of the API is not included on the finished drug product label or if certain additional supply chain information is not included in the broader finished drug product labeling. This will increase supply chain accountability and transparency by ensuring APIs and finished drug products, including repackaged and relabeled APIs, have information on the original manufacturer of the API. Currently, end purchasers of repackaged API may be unaware of whether the API they purchase is adulterated (for example if it was originally manufactured by a firm that has not met drug current good manufacturing practice requirements). Lack of supply chain oversight of APIs and finished drug products can cause serious vulnerabilities in the supply chain since FDA and other supply chain stakeholders are not always able to identify the source of the drugs to address manufacturing or safety concerns and may thus lead to patient safety issues. This proposal would allow compounders, conventional drug manufacturers, and the FDA itself to quickly

identify the original manufacturer of an API that is found to be adulterated or misbranded and take appropriate action to remove inferior quality products from circulation.

#### **Assistant Secretary for Strategic Planning and Response:**

- *Require the strategic national stockpile to include essential medicines, not just medical countermeasures:* ASPR should prioritize the availability of the top essential medicines across all product types, not just medical countermeasures and pandemic-related products. Currently, ASPR focuses on emergency events such as natural disasters and pandemics. Its focus should be expanded to include the availability of top essential medicines regardless of the reason for a shortage, including a broader range of therapies like commonly used chemotherapies.
- *Refocus ASPR's mission and provide funding (especially for the new Industrial Base Management and Supply Chain office) to prioritize ensuring availability of the most essential medicines:* As discussed above, ASPR's focus must expand beyond medical countermeasures and pandemic-related medicines and emergency events, such as bioterrorism and pandemics. Essential medicines should not be limited by product type of the reason for lack of availability.
- *Mandate coordination between federal agencies, manufacturers, and stakeholders, including patients, providers, and health systems:* HHS or another agency should regularly convene representatives from ASPR, FDA, the Centers for Medicare & Medicaid Services (CMS), the Veterans Administration, the Department of Defense and other federal agencies, manufacturers, and public stakeholders, including providers and patients, to explore manufacturing and access challenges, and discuss potential policy solutions.

#### **Policies that Support Resilient Supply Chains for Generic Drugs:**

- *Provide incentives to realign hospital purchasing practices to promote the purchase of higher quality generic drugs:* Currently, hospitals purchase drugs from the 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 as well as allow CMS to establish a voluntary reporting system that would include financial rewards for purchasing drugs that come 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.<sup>1</sup>
- *Authorize tax incentives, grants, and/or loans to encourage generic manufacturing in the United States to strengthen the supply chain:* By encouraging domestic manufacturing of generic drugs, the FDA will be able to better oversee their manufacturing thereby improving the quality of the drugs produced and identifying potential quality issues before they result in a shortage. The increased funds will allow generic manufacturers to invest in new facilities and expand existing operations, adopt newer innovations, and ultimately improve the redundancy in their manufacturing processes; the lack of investment in generic drug manufacturing and the supply chain are key drivers of the current shortage. As drug shortages often are caused by quality

<sup>1</sup> <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>

issues at manufacturing facilities in the United States, these incentives should be conditioned upon achievement of quality and supply chain resilience metrics such as FDA's QMM program.

Again, thank you for the opportunity to provide these comments. SGO looks forward to working with you to enact policies that will mitigate and prevent future drug shortages. Should you have questions or require additional information, please contact Erika Miller at [emiller@dc-crd.com](mailto:emiller@dc-crd.com).

Sincerely,



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