

June 14, 2023

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf,

On behalf of the Society of Gynecologic Oncology (SGO), I am writing to express my deep concern regarding the critical shortage of chemotherapy drugs that has been affecting cancer patients across the country. As you know, there are shortages for several chemotherapies, including cisplatin, carboplatin, and methotrexate, 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. SGO recently launched a comprehensive survey of 2,000 members on April 21 to assess the impact of chemotherapy drug shortages on hospitals across the country. As of our last response received on May 18, we have accumulated valuable insights and feedback. However, considering the evolving circumstances, it is crucial to acknowledge that the drug shortages may have undergone changes, potentially presenting a different outlook. We believe that the findings of this survey are significant and warrant the attention of the Food and Drug Administration (FDA).

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.

The current drug shortages are a significant problem for our members and the patients they treat. We estimate that these shortages are affecting approximately 525,000 Americans. Our survey results indicate a distressing trend of increasing chemotherapy drug shortages, leading to significant disruptions in cancer care. The following key findings emerged from our analysis:

1. While the shortages are not uniform across the country since some institutions and patients have greater access than others, members are reporting that these shortages are affecting community cancer centers and large academic medical centers in 40 states and the District of Columbia.
2. 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

significant portion of the gynecologic cancer patient population, underscoring the urgent need to address these drug shortages effectively.

3. 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. Additionally, 60% percent of respondents reported that they have not had to do this yet, but they anticipate they will have to.
4. The survey data collected from hospitals across the country indicates that all gynecologic cancer care has been impacted by the chemotherapy drug shortages. 31% of respondents reported that all their patients with gynecologic cancer are impacted equally, 19% of respondents reported ovarian and endometrial cancers, 17% reported ovarian cancer, 9% reported cervical, vulvar, and ovarian cancers, and 7% reported cervical and vulvar cancers. This highlights the widespread nature of the issue, affecting not just one type of cancer and associated treatment but all gynecologic malignancies.
5. The survey results revealed that hospitals reported experiencing cisplatin and carboplatin shortages that first began between February 13-19. This indicates an emerging problem in the availability of these vital cancer treatments and underscores the need for immediate action to address and prevent further disruptions in the drug supply chain.
6. 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.

Thank you for your attention to this important issue. SGO is continuing to collect information from members about shortages and access at their institutions to communicate with the FDA. We are prepared to provide any additional information you may require. Should you have any questions, please don't hesitate to contact Erika Miller at emiller@dc-crd.com.

Sincerely,



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