

July 26, 2023

The Honorable Kevin McCarthy
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
Washington, DC 20510

Dear Speaker McCarthy, Leader Schumer, Leader Jeffries, and Leader McConnell:

On behalf of the Society of Gynecologic Oncology (SGO), I urge you to pass comprehensive legislation addressing the ongoing chemotherapy shortages, which are having a devastating impact on cancer patients. The Senate Health, Education, Labor, and Pensions (HELP) Committee recently reported out S. 2333, the Pandemic and All-Hazards Preparedness and Response Act, on a bipartisan basis. This critical legislation includes provisions to address drug shortages and represents an important first step to prevent future drug shortages.

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.

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 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.

As mentioned above, S. 2333 includes several provisions to help mitigate drug shortages. They include new notification procedures for manufacturers to report increased demand for critical drugs and requirements for the reporting of active pharmaceutical ingredients included in drugs to the Food and Drug Administration (FDA) as well as for the agency to report back to Congress on its shortage-related authorities and guidance documents.

SGO applauds the HELP Committee for including provisions to begin to address drug shortages in its version of Pandemic All-Hazards Preparedness Act (PAHPA) reauthorization. To prevent another drug shortage of this magnitude, a more comprehensive response that includes additional authorities for the FDA, the Assistant Secretary for Strategic Preparedness and Response, and the Centers for Medicare & Medicaid Services, among other agencies will be required. However, the HELP Committee's approval of S. 2333 represents an important first step to alleviate the challenges patients, their families, and providers are now facing accessing life-saving chemotherapies. Congress must act now by adopting FDA-related provisions to prevent drug shortages as part of PAHPA reauthorization, and SGO encourages Congress to develop and pass another comprehensive package to address the other drivers of drug shortages.

Thank you for your leadership and attention to this critical issue. Should you require further information, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,



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

cc: Honorable Bernie Sanders, HELP Committee, Chair
Honorable Bill Cassidy, HELP Committee, Ranking Member
Honorable Cathy McMorris Rodgers, Energy & Commerce Committee, Chair
Honorable Frank Pallone, Energy & Commerce Committee, Ranking Member
Honorable Ron Wyden, Finance Committee, Chair
Honorable Mike Crapo, Finance Committee, Ranking Member
Honorable Jason Smith, Ways & Means Committee, Chair
Honorable Richard Neal, Ways & Means Committee, Ranking Member