Society of Gynecologic Oncology

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June 5, 2023

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

Submitted via Regulations.gov/docket/FDA-2020-D-1057

Re: Docket Number FDA-2020-D-1057; Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act

Dear Dr. Califf,

The Society of Gynecologic Oncology (SGO) appreciates the opportunity to provide comments on Docket No. FDA-2020-D-1057; Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act. Our comments will focus on section *IV. How the FDA Communicates Information About Drugs and Biological Products in Shortage.*

The SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. Our 2,000 members, who include physicians, nurses, and other advanced practice providers, represent the entire oncology team dedicated to the treatment and care of patients with gynecologic cancers.

The SGO's purpose is to improve the care of women with gynecologic cancers by encouraging research and disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations interested in women's health care, oncology, and related fields.

The current drug shortage is of utmost concern to us and our patients. Our members are on the front lines of this difficult situation and SGO has been at the forefront of educating our members and the public on how to navigate shortages of frontline therapies used to treat gynecologic cancers. The draft guidance that has been issued is timely and we offer the following comments for your consideration.

**Notifying FDA of a Permanent Discontinuance or an Interruption in Manufacturing**

The SGO supports the FDA's guidance requiring manufacturers to notify the FDA in case of a permanent discontinuance or interruption in manufacturing. This requirement is crucial in ensuring the continued availability of drugs that are vital for patient care. By mandating such notification, the FDA can proactively monitor the supply chain and take necessary actions to mitigate any potential shortages or disruptions in delivery of care. With this, the FDA can gather valuable data that enables accurate predictability and forecasting of supply chain needs. This will protect patients and enable healthcare providers to plan and respond effectively to any changes in the availability of medications. This will also promote transparency and

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accountability in drug manufacturing, contributing to a more resilient healthcare system, ultimately ensuring patient access to care and potentially savings lives.

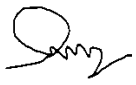
While SGO supports the FDA's proposed notification and reporting requirements, we believe that the FDA should also require manufacturers to disclose why there is a shortage. There is a pressing need for the FDA to require manufacturers to disclose detailed reasons behind drug shortages, as current regulations allow for vague explanations that hinder transparency and understanding. Patients and healthcare providers deserve clear and comprehensive information regarding the causes of drug shortages. By mandating manufacturers to provide specific reasons for these shortages, the FDA can address the root causes and develop effective strategies to predict, prevent, or mitigate future disruptions in the drug supply chain. Understanding the underlying factors, such as manufacturing issues, supply chain challenges, or raw material shortages, is crucial for developing targeted solutions and promoting accountability. It is imperative that the FDA improve disclosure requirements to ensure that drug manufacturers provide detailed explanations for drug shortages and contribute to a more reliable and resilient healthcare system.

**How FDA Communicates Information About Drugs and Biological Products in Shortage**

The SGO appreciates that FDA is providing information on how they communicate information to the public. We believe it is essential for the FDA to communicate information to the public about drugs and biological products in shortage and ensure that their website remains up to date. This transparency is vital in promoting patient safety and enabling healthcare providers to make informed decisions regarding patient care. By promptly notifying the public about shortages, the FDA allows healthcare providers to explore alternative treatment options, adjust prescriptions, or develop contingency plans. Keeping the website up to date with accurate information is crucial as it serves as a central hub for healthcare providers, patients, and other stakeholders seeking critical information about drug shortages. Additionally, an updated website allows for efficient coordination between the FDA and manufacturers, enabling them to work together to address shortages and find potential solutions. Moreover, we recommend that the FDA work with other stakeholders, such as the American Society of Health-System Pharmacists (ASHP), to align information regarding drug shortages and ensure consistency. The SGO strongly believes that open communication and an up-to-date website not only enhance patient safety but also foster trust and confidence in the healthcare community.

SGO thanks you for the opportunity to provide these comments. We welcome the opportunity to support the FDA in this work and continue this discussion. If you have any questions, please contact Erika Miller at emiller@dc-crd.com. We thank you for your consideration of our comments.

Sincerely,



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