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Statement prepared for:

U.S. House Committee on Energy and Commerce Subcommittee on Health

**Legislative Proposals to Prevent and Respond to Generic Drug Shortages
September 14, 2023**

The Association for Clinical Oncology (ASCO) appreciates the opportunity to provide this statement for the record regarding the timely and crucial hearing on “Legislative Proposals to Prevent and Respond to Generic Drug Shortages.” ASCO is grateful that the subcommittee continues to elevate the conversation on drug shortages through their legislative activities and collaborates with stakeholders to ensure the impact on patients with cancer and their providers is considered as legislative solutions emerge.

ASCO is the national organization representing nearly 50,000 physicians and other health care professionals who care for people with cancer. ASCO members are dedicated to conducting research that leads to improved patient outcomes, and we are also committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans.

The shortage of generic drugs, including vital oncology medications, poses a grave threat to the health and well-being of patients with cancer across the nation. These shortages can result in treatment delays, compromised therapeutic regimens, and increased health care costs, all of which can exacerbate the already daunting challenges that patients face. The consequences of drug shortages extend far beyond mere inconveniences; they can directly affect treatment outcomes and patient quality of life. Moreover, drug shortages highlight a break down in the U.S. pharmaceutical supply chain and can pose significant national security threats.

As noted in our past statements and response to requests for information¹²³⁴⁵⁶, ASCO firmly supports legislative efforts to prevent and respond to

¹ <http://old-prod.asco.org/sites/new-www.asco.org/files/RFI-Reponse-House-EandC-Drug-Shortage-Discussion-Draft.pdf>

² <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2023-07-06-RFI-EC-Finance-Drug-Shortages.pdf>

³ <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-JG-CEC-Testimony.pdf>

⁴ <https://old-prod.asco.org/sites/new-www.asco.org/files/SFTR-House-EandC-Drug-Shortages-Hearing-5.11.23.pdf>

⁵ <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2023-03-29-RFI-Senate%20HELP-PAHPA-Reauthorization.pdf>

generic drug shortages, recognizing the urgency of this issue in the context of cancer care. We believe that a comprehensive approach to mitigating drug shortages must encompass the following key recommendations, but encourage broad consideration of all our recommendations⁷⁸⁹:

- Enhance transparency in the drug supply chain.
- Streamline regulatory processes, including approvals to expedite access.
- Diversify manufacturing, including active pharmaceutical ingredient sourcing.
- Develop strategic reserves to offset supply interruptions.
- Stabilize the market by Incentivizing investment.
- Enhance reporting and manufacturing accountability.

The bills highlighted in this hearing incorporate some of the above recommendations and we commend you and your colleagues for further considering and advancing these proposals. ASCO specifically endorses the following:

- The *Drug Shortage Prevention Act of 2023* (H.R. 3008) introduced by Reps. Sara Jacobs (D-CA) and Cory Mills (R-FL) requires manufacturers to report when they are experiencing increases in demand, permanent discontinuance, or an interruption in manufacturing of a drug that is likely to have a meaningful disruption in the U.S. drug supply.
- The *Drug Origin Transparency Act of 2023* (H.R. 3810) introduced by Rep. Anna Eshoo (D-CA) requires manufacturers to report supply chain information, including origin details, to increase transparency in the supply chain.
- The *Ensuring Access to Lifesaving Drugs Act of 2023* (H.R. 3793) introduced by Rep. Elissa Slotkin (D-MI) requires manufacturers of life-saving drugs to submit data to assess drug stability and determine their longest supported expiration date.

ASCO also supports many provisions included in the *Stop Drug Shortages Act* (H.R. ____) drafted by Chair Cathy McMorris Rodgers (R-WA) as outlined in our discussion draft response¹⁰. We appreciate the strides taken to put forth a comprehensive legislative solution to this complex issue.

In closing, addressing drug shortages is a top priority for ASCO, our members and the thousands of cancer patients impacted. We urge this subcommittee to take decisive action to develop and enact legislation that effectively prevents and responds to generic drug shortages. By doing so, we can safeguard access to critical medications that cancer patients depend on for their treatment and ultimately improve the outlook for those battling this devastating disease.

Thank you for holding this legislative hearing and for the opportunity to provide ASCO's comments, concerns, and solutions to address drug shortages. We stand ready to work collaboratively with you and your colleagues to find meaningful solutions to this ongoing health care challenge. Please contact Megan Tweed at Megan.Tweed@asco.org with any questions.

⁶ <https://old-prod.asco.org/sites/new-www.asco.org/files/Statement-Senate-Homeland-Security-Committee-Drug-Shortages-Hearing-03.2023.pdf>

⁷ <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-JG-CEC-Testimony.pdf>

⁸ <https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-security.ashx>

⁹ <https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations>

¹⁰ <http://old-prod.asco.org/sites/new-www.asco.org/files/RFI-Reponse-House-EandC-Drug-Shortage-Discussion-Draft.pdf>