

June 25, 2020

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The Honorable Nancy Pelosi Speaker of the House of Representatives U.S. Capitol Building, H-222 Washington, DC 20515

The Honorable Mitch McConnell Senate Majority Leader U.S. Capitol Building, H-230 Washington, DC 20510 The Honorable Kevin McCarthy House Republican Leader U.S. Capitol Building, H-204 Washington, DC 20515

The Honorable Charles Schumer Senate Democratic Leader U.S. Capitol Building, S-221 Washington, DC 20510

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

On behalf of the Association for Clinical Oncology (ASCO), thank you for your continued work as you address the devastating impacts of coronavirus pandemic. ASCO is the leading professional health care organization representing nearly 45,000 clinical oncologists and other oncology professionals across the country. We believe all patients deserve access to timely, high-quality health care. Unfortunately, the ongoing COVID-19 pandemic has highlighted many issues within the United States (US) health care system that threaten patient access, including drug shortages.

For years, the medical community has experienced shortages of critical drugs that are used to treat a variety of conditions. These shortages are caused by a multitude of factors, including quality issues, manufacturer business decisions, disruptions to raw ingredient supplies, natural disasters, and other emergencies that take place in countries which house critical drug manufacturing facilities. In recent years, the US has experienced shortages in broadly used essential products such as saline, morphine, and fentanyl, in addition to products critical to smaller patient populations. For example, in 2019, the US experienced a shortage of the life-saving cancer drug, vincristine sulfate, which jeopardized the treatment of patients with cancer across the country.

We applaud Congress for including important drug shortages policies from the MEDS Act in the CARES Act. However, more needs to be done to ensure our patients and providers have access to the drugs they need. We encourage Congress to take the following actions:

- Require manufacturers to be more transparent with the Food and Drug Administration (FDA) about potential drug shortages
- Require manufacturer transparency around their sources of raw material (active pharmaceutical ingredients, API) including which state and country the API come from

- Require manufacturers of critical medications and supplies to develop a reasonable contingency plan in the event of a production interruption or shut down
- Create requirements for supply chain resiliency, including multiple manufacturing sites for important drugs and multiple suppliers of API for the same drug
- Create incentives for manufacturers to increase production when drug shortages occur

ASCO stands ready to help as you continue to work to improving the nation's drug supply chain. If you have questions related to drug shortages and how they impact patients with cancer, please feel free to contact Tyler Hanson at <a href="mailto:Tyler-Hanson@asco.org">Tyler.Hanson@asco.org</a>. Thank you again for your work on these important issues.

Sincerely,

Monica M. Bertagnolli, MD, FACS, FASCO

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Chair of the Board, ASCO Association for Clinical Oncology