AMERICAN SOCIETY OF HEMATOLOGY
2021 L Street, NW, Suite 900, Washington, DC 20036-4929 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

August 23, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair Rodgers:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on the Stop Drug Shortages Act discussion draft.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematologic (non-malignant) conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

Drug shortages—particularly for commonly used chemotherapies such as carboplatin, cisplatin, and methotrexate—are affecting the care of patients with hematologic malignancies, as well as those with classical hematologic conditions. We are pleased that you are exploring legislative solutions to this problem that affects treatment decisions, creates unnecessary stress for patients and their families as they navigate challenging health conditions, and potentially undermines the development of future therapies when drugs are not available for clinical trials. While a legislative solution cannot be enacted in time to save the lives of the patients who are currently affected, it is our sincere hope that a comprehensive solution may be developed to prevent shortages of this nature from happening again.

ASH is concerned that the discussion draft provides increased reimbursement to manufacturers without requirements that manufacturer investments be made to improve supply chain resiliency and the quality of the products being manufactured. Without these requirements, we believe that these provisions could potentially exacerbate drug shortages. Provisions to bolster the supply chain should be coupled with provisions to encourage providers to purchase drugs that meet high quality standards. Currently, providers who purchase these drugs through group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) do not have any insight into how those drugs are manufactured or their quality. The Centers for Medicare & Medicaid Services (CMS) could incentivize the purchase of higher quality drugs produced by more reliable manufacturers through a voluntary reporting system. These changes should be made in conjunction with the imposition of requirements for more detailed reporting to the U.S. Food and Drug Administration (FDA) to improve transparency and provide more detailed and actionable information for providers, patients, and the public.

Specifically, we believe that the following legislative sections will increase reimbursement to manufacturers without improving the manufacturing practices or the quality of the drugs being produced, two of the main drivers of drug shortages: Section 101 exempts certain generic, sterile injectable drugs from the Medicaid rebate requirement, Section 201 exempts certain sterile, injectable drugs from the 340B drug discount program, and Section 301 reduces the inflation rebate amounts for certain shortage drugs in Medicare. ASH respectfully requests that you reconsider providing these financial incentives without requirements that manufacturers make specific investments to improve their manufacturing practices and the quality of the products they produce. Without steps to improve the resiliency of the supply chain, there is no protection for patients who are suffering due to lack of access to lifesaving medications.

ASH provides the following comments on specific FDA-related sections in the discussion draft:

- We appreciate the inclusion of Section 506, which authorizes a pilot program for FDA to conduct preapproval inspections for new domestic pharmaceutical manufacturing facilities to expedite the licensure and distribution of domestically manufactured generic drugs. As you are likely aware, half of the cisplatin used in the United States was sourced from the Intas plant in India, which the FDA found to have significant quality control problems and was a primary driver of the current shortage. Provisions to support greater domestic manufacturing, which can be more easily monitored by the FDA, are a key piece of creating a more resilient supply chain.

- Additionally, we support Section 502, which provides incentives in the form of an additional month of exclusivity for shelf-life extension studies but believe that the legislation should go further. The legislation should be amended to also provide the FDA with the authority to require manufacturers to submit studies and evaluate existing data to extend the shelf life of drugs, which will help increase supply.

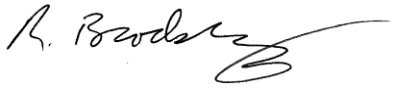
- ASH believes that Section 504, which would require additional reporting on generic drug active pharmaceutical ingredients (APIs) in abbreviated new drug applications, would also provide critical information to the FDA to allow the Agency to enact proactive measures in the event of shortages.

In addition to the provisions mentioned above, the discussion draft should empower the FDA with additional authority to better respond and mitigate future drug shortages. Specifically, the legislation should authorize the FDA to require manufacturers to notify the FDA in the case of increased demand for a drug and require that a drug's label include the original manufacturer and API manufacturer's information, which would go further than the Section 504 provision to include reporting API information in an abbreviated new drug application.

Finally, ASH appreciates the inclusion of several studies in the discussion draft including Section 202 to study penny pricing in the 340B program and evaluate which drugs have experienced shortages in the last 10 years; Section 302 on market-based pricing for shortage drugs in Medicare Part B; and Section 304 on Medicare coding for drugs in shortage or danger of shortage. However, we are concerned that directing further study of these issues will further delay the development of a comprehensive solution, ultimately hurting patients.

Thank you for the opportunity to provide these comments and for your commitment to addressing this issue. ASH looks forward to working with you to develop a comprehensive, bipartisan solution to this complex issue to ensure patients have timely access to the medications they require. Should you have any questions or require further information, please contact Stephanie Kaplan, ASH Deputy Director, Government Relations and Public Health, at *skplan@hematology.org*.

Sincerely,



Robert A. Brodsky, MD
President