



AMERICAN SOCIETY OF HEMATOLOGY

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The Honorable Kevin McCarthy
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The Honorable Hakeem Jeffries
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The Honorable Chuck Schumer
Majority Leader
U.S. Senate
Washington, DC 20510

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 American Society of Hematology (ASH), I am writing to urge Congress to take decisive action to address the ongoing problem of drug shortages in the United States. The incidence and duration of drug shortages is growing, and the shortages of critical hematology therapies lead to delays in and rationing of care, negatively affect treatment decisions, create emotional distress for patients and families, and result in worse health outcomes. We owe it to patients to find solutions to this issue.

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 diseases such as leukemia, lymphoma, and multiple myeloma, as well as classical (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.

As shortages of critical drugs persist, ASH urges Congress to act now to address drug shortages. We understand that the causes of drug shortages are complex and that there is not a single solution. As different policy solutions are considered, ASH wants to underscore the impact these shortages are having on hematology patients across the country and the need for Congress to work with FDA and other stakeholders to help prevent or mitigate future drug shortages.

Over the past several months, the shortages of blood cancer treatments such as methotrexate, cisplatin, carboplatin, as well as INFeD (iron dextran) and RETACRIT (erythropoietin) which are used to treat classical blood disorders, have significantly impacted ASH members' practice and patients. We have included a complete list of drugs that ASH members have reported are in shortage over the past 12 months in the appendix of this letter. These shortages are driving hematologists and other physicians to make difficult treatment decisions, including administering alternative and notably more intense treatment regimens. Unfortunately, these alternate regimens may result in significant toxicities, creating a host of challenges and complications for some patients.

For others, alternative treatments can lead to relapse and even death. While alternate regimens may result in positive outcomes, this entire process causes serious mental and emotional distress for patients.

In some instances, there may not be an alternate drug available. Patients with primary central nervous system (CNS) lymphoma and childhood acute lymphoblastic leukemia (ALL) require frequent administration of high doses of methotrexate. Unfortunately, hospitals have not had adequate supply of this chemotherapy, and in response, providers are forced to expedite the administration of the rituximab and high-dose cytarabine (R-HiDAC) treatment cycles, delivering these therapies earlier than standard of care dictates, while waiting for the availability of methotrexate. Unfortunately, there is no viable alternative drug to meet the needs of these specific patients.

Additionally, patient care is being delayed as hospitals are forced to triage patients to prioritize the sickest patients that cannot wait to receive treatment. Many hospitals have established criteria for priority utilization and have instituted teams and staff dedicated to addressing the shortages. Hospitals are also capping doses for patients to combat the shortages.

Future therapies and cures will be delayed because of these shortages because of their impact on clinical trials. ASH members are reporting that they must delay trials that use cisplatin due to the shortage. Additionally, physicians are being told to not accrue to trials that require carboplatin during the shortage and maximize use for patients currently on trial.

ASH members are not just navigating chemotherapy shortages. Drugs to treat classical hematologic conditions are also in shortage. For example, INFeD, an intravenous iron product prescribed to patients who cannot take oral iron supplements, was recently in short supply. This medication is the only cost-effective intravenous iron replacement that has a short infusion time and allows patients to receive the treatment in a single dose. The alternatives, Venofer and Ferrlecit, are more expensive and require administration in 2-3 separate doses, each requiring several hours for infusion. This difference affects patients' quality of life while increasing healthcare costs for both the drug and its administration. Additionally, the drug shortages are undoubtedly an increasing administrative burden. Alternatives to drugs in shortage may require new prior authorizations and delay patient care.

ASH has taken steps over the past decade to ensure timely access to safe and effective hematologic therapies by supporting statutory and regulatory changes to mitigate shortages. For example, ASH has supported providing U.S. Food and Drug Administration (FDA) with additional authority and resources to prevent and address shortages. We have also been in close contact with the FDA about shortages of hematology drugs, and have shared timely updates with ASH members about the status of shortages via the ASH drug shortage webpage and the Society's communication channels. We have also sent formal letters to FDA about critical shortages and testified at the Agency's drug shortage workshops.

ASH applauds the Senate Health, Education, Labor, and Pensions (HELP) Committee for advancing S.2333, the Pandemic and All-Hazards Preparedness and Response Act (PAHPRA), on a bipartisan basis. This critical legislation includes provisions to address drug shortages by requiring manufacturers to notify FDA about increased demand for drugs and active pharmaceutical ingredients (API) and requiring drug labels to include more detailed information about any included APIs. ASH believes that this legislation represents an important first step to prevent future drug shortages; however, more comprehensive action is needed to address the multitude of factors contributing to these shortages.

ASH urges Congress to adopt the Senate HELP approved PAHPRA reauthorization and develop additional legislative solutions to ensure patients have access to high quality medications without interruption. We look forward to working with you on this important issue. Should you have any questions, please contact Stephanie Kaplan, ASH Deputy Director, Government Relations and Public Health, at skplan@hematology.org.

Sincerely,



Robert A. Brodsky, MD

President

Attachment: Appendix noting hematologic drugs in shortage

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

Appendix

In the last 12 months, ASH members have experienced shortages for other critical drugs used in treating hematologic diseases:

- Methotrexate
- Cisplatin
- Carboplatin
- INFeD (iron dextran)
- RETACRIT (erythropoietin)
- Fludarabine
- Hydrocortisone
- Methylprednisolone
- Acyclovir
- Tocilizumab
- All-Trans Retinoic Acid (ATRA)
- Leucovorin
- Posaconazole IV
- Bacillus Calmette-Guerin (BCG)
- Fluorouracil (5FU)
- Capecitabine
- Bactrim
- Albuterol and levalbuterol
- Amoxicillin pediatric formulations
- Thiotepe
- Ketamine
- Racepinephrine inhalation solution
- Fludarabine