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**2011**

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The Honorable Fred Upton  
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House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Henry A. Waxman  
Ranking Minority Member  
House Energy and Commerce Committee  
2322A Rayburn House Office Building  
Washington, DC 20515

Re: Request for Hearing on Drug Shortages

Dear Chairman Upton and Ranking Minority Member Waxman,

The American Society of Hematology (ASH) respectfully asks you to consider holding a hearing on the current critical shortages of life-saving drugs used to treat patients with hematologic malignancies such as leukemia and lymphoma. These shortages have had a devastating impact on patient care due to the need to ration the limited drug supply, including: delaying treatment, stopping medications mid-treatment and using less effective, and at times more expensive, alternative therapies. Because the Energy and Commerce Committee has jurisdiction over the Food and Drug Administration (FDA), the Society believes that the Committee should review this situation, establish immediate actions that can be taken by the FDA and determine how this problem could be prevented in the future.

ASH represents over 16,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant hematologic disorders such as leukemia, lymphoma, and myeloma; and non-malignant conditions including anemia and hemophilia; and congenital disorders such as sickle cell anemia and thalassemia.

Although physicians have dealt with drug shortages before, the current shortage of drugs in the United States used to treat patients with hematologic malignancies has become critical and life-threatening. ASH has heard from several institutions and practices that have established stringent protocols and procedures regarding the use of certain drugs that are in short supply, such as BiCNU (Carmustine, used to treat multiple myeloma and lymphoma), Cytarabine (ARA-C, used to treat lymphoma and leukemia), and Thiotepa (used to treat lymphoma).

The most acute problem for hematology patients is the shortage of Cytarabine, the most active drug in the treatment of acute myeloid leukemia (AML). An example of what one ASH member recently reported illustrates the problem: "My hospital, like most hospitals in the U.S., has a very limited supply of Cytarabine, and we have been forced to ration the little cytarabine we have. We have decided to reserve our limited supply for pediatric patients with leukemia, and newly diagnosed AML patients. This presents a problem for management of patients with Burkitt lymphoma, or other lymphoma patients being treated with hyper-CVAD alternating with HDMTX/HiDAC. I'm wondering how to manage my patients with Burkitt's lymphoma without using high-dose Cytarabine." ASH has heard of similar problems from hematologists/oncologists across the country who are forced to make

sub-optimal treatment decisions, severely impacting the effectiveness and quality of patient care. The inability to treat Burkitt's lymphoma or AML with Cytarabine will lead to avoidable deaths.

Industry analysts believe that there are likely multiple reasons for increased shortages. Many of the shortages are of older drugs that no longer generate revenue that manufacturers consider adequate. Additional causes driving the current shortages also may be: consolidation of drug manufacturers (generic and brand); discontinuing manufacture of brand name drugs as the patent protection of the brand drug expires; GMP problems; issues with wholesalers being licensed; and increased demand. Requiring manufacturers to notify FDA of upcoming adjustments or interruptions in production and requiring expedited reinspections are options considered in S. 296, The Preserving Access to Life-Saving Medications Act, which ASH strongly supports.

While the drug shortages detailed above are affecting patients with blood cancers, current drug shortages have also had an impact on numerous other patient populations. A review of the FDA list of drugs that are considered in short supply include anesthesiology drugs and peripheral parenteral nutrition (PPN) treatments.

In conclusion, ASH requests that the Energy and Commerce Committee conduct a hearing on the problem of drug shortages, FDA's ability to address this problem and how, if possible, future shortages could be prevented.

Thank you for your consideration. Please contact ASH Government Relations and Practice Manager, Mila Becker, Esq., for additional information or with any questions at [mbecker@hematology.org](mailto:mbecker@hematology.org) or 202-776-0544.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Evan Sadler". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

J. Evan Sadler, President  
American Society of Hematology

Cc: Joe Pitts, Chairman Health Subcommittee  
Cliff Stearns, Chairman Oversight and Investigation Subcommittee  
Frank Pallone, Ranking Minority Member, Health Subcommittee  
Diane DeGette, Ranking Minority Member, Oversight and Investigation Subcommittee