



# AMERICAN SOCIETY OF HEMATOLOGY

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## 2011

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The Honorable Diana DeGette  
United States House of Representatives  
2335 Rayburn House Office Building  
Washington, D.C. 20515

Dear Representative DeGette,

On behalf of the American Society of Hematology (ASH), I write to extend the Society's appreciation for your efforts to combat critical shortages of life-saving drugs, particularly your introduction of H.R. 2245, *The Preserving Access to Life-Saving Medications Act*.

ASH represents over 16,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases, including blood cancers such as leukemia, lymphoma, and myeloma and a number of nonmalignant illnesses such as anemia (including sickle cell and thalassemia), thrombosis (including venous thrombosis, heart attack and stroke), and bleeding disorders. The patients our members treat have been especially adversely affected by recent shortages.

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 has been 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 degrading the effectiveness and quality of patient care. The inability to treat Burkitt's lymphoma or AML with Cytarabine will lead to avoidable deaths.

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. 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; Good Manufacturing Practice problems; issues with wholesalers being licensed; and increased demand.

ASH believes H.R. 2245 is an important first step in addressing the increasing problem of drug shortages, but it will not fully solve the problems we are experiencing. The Society encourages you to work with your colleagues on the House Energy and Commerce Committee to look into the causes of drug shortages and strongly supports a congressional hearing on this issue. A hearing would help illuminate the problem, by specifically examining what is causing these shortages, the impact of shortages on patient care, how the Food and Drug Administration currently addresses the problem of drug shortages, what can be done to assure patient access to needed medications, and how, if possible, future shortages could be prevented. A congressional hearing would also help to explore additional legislative strategies to address this issue, which would help strengthen H.R. 2245.

Please let us know how ASH can help you continue to build support for H.R. 2245 and a congressional hearing on drug shortages. If you have questions, or need more information, please have your staff contact ASH Research Advocacy Manager Tracy Roades at 202-776-0544 or [troades@hematology.org](mailto:troades@hematology.org), or ASH Government Relations Manager Stephanie Kaplan at 202-776-0544 or [skaplan@hematology.org](mailto:skaplan@hematology.org).

Thank you again for your leadership and commitment to this important issue. The Society looks forward to working with you.

Sincerely yours,

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

J. Evan Sadler, MD, PhD  
President