AMERICAN SOCIETY OF HEMATOLOGY
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February 14, 2012

The Honorable John Carney
United States House of Representatives
1429 Longworth House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
United States House of Representatives
1123 Longworth House Office Building
Washington, DC 20515

Dear Representatives Carney and Bucshon:

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. 3839, *The Drug Shortage Prevention Act*. The current drug shortage situation in the United States is unacceptable and requires legislative action. The shortages have caused medical treatment to be delayed and compromised and research to be slowed or halted. Most significantly, shortages have caused patients to suffer.

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 particularly adversely affected by recent shortages. For example, last year, a national shortage of cytarabine, an irreplaceable chemotherapy drug essential to the cure of acute myeloid leukemia (AML), was reported. (Cytarabine cures forty percent of patients with AML; without cytarabine, the cure rate is zero percent. This shortage affected thousands of patients who were diagnosed with AML and treated in the approximately 6-month period when cytabine was out of stock.) Currently, we are experiencing a shortage of another important drug in AML, daunorubicin and the supply of methotrexate, a critical drug in the treatment of children with leukemia, may run out in a few weeks. Scores of other leukemia, lymphoma and myeloma patients also faced shortages of life-saving treatment. Additionally, our sickle cell patients have struggled with a lack of access to hydroxyurea, the only approved drug used to treat this disease. In all of these cases, the patients may not have been able to be treated or received less effective or more toxic alternative treatments, not because of a lack of insurance coverage or because the treatment was too costly or because their doctors did not know how to treat their disease, but, rather, because the standard treatment was simply not available.

The increasing number of drug shortages has significantly affected the practice of hematology because the standard therapies frequently used include older, sterile injectable products that are particularly vulnerable to production, marketing, and other business factors that lead to shortage. Fewer firms manufacture these products, the products require complex manufacturing processes, companies may be tempted to redirect resources to more profitable products, and financial return may not justify corrective action when problems occur.

Drug shortages have also adversely affected clinical trials that are pivotal in research and treatment efforts. Trial activation has been suspended and patient accrual halted, ultimately slowing the pace of clinical research. For instance, a recently opened large Eastern Cooperative Oncology Group **(**ECOG**)** randomized clinical trial in AML involving cytarabine and daunorubicin could not accrue patients and delayed the research.

H.R. 3839 includes several of the proposals ASH has advocated for to prevent and mitigate drug shortages, including:

- Improving Regulation - During this recent spate of drug shortages, ASH has called on the FDA to improve its communication with stakeholders to ensure that current and accurate information is conveyed to all parties. The Society agrees that there is a need to improve communication between offices and officials at FDA responsible for identifying and addressing critical drug shortages. ASH also concurs with your proposal to ensure regulatory concerns are communicated and believes it is important to examine the impact of how current FDA requirements, including new testing methodologies involving more sensitive assays, may contribute to shortages.
- List of Critical Drugs in Shortage – ASH believes there is a need to protect critical drugs vulnerable to shortage. The Society has also supported the idea of developing a national drug registry for older and medically-necessary drugs to allow for better tracking the quantities and availability of these drugs. ASH appreciates your bill's underscoring of the need to solicit input from stakeholders.
- Expedited Review – ASH agrees that there should be a way to provide expedited review to applications seeking approval of a critical drug.
- Prevention of Price Gouging – The growth of the "grey market" for drugs in shortage is disturbing and must be stopped. ASH agrees with your bill's attention to addressing unlawful activities by wholesale distributors.
- Study on Feasibility of National Contingency Plan – The Society is open to pursuing options designed to prevent drug shortages. It is not clear if it would be possible to create a Federal stockpile of critical drugs, but worth studying its feasibility.

In addition to the provisions above, ASH continues to support legislative options that would increase FDA authority to require early notification from pharmaceutical companies when a factor arises that may result in a shortage; provide economic incentives to manufacturers to incentivize production of specific low cost critical drugs; and provide FDA with greater authority and resources to combat this serious problem.

ASH applauds you for introducing legislation to address the problem of drug shortages and that builds on many of the Society's recommendations. We would like to meet with you and your staff to identify ways that ASH can help you continue to build support for H.R. 3839. I will ask ASH staff to contact your office to schedule a time to meet. In the meantime, 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*, or ASH Government Relations Manager Stephanie Kaplan at 202-776-0544 or *skaplan@hematology.org*.

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

Sincerely,

Armand Keating, MD
President