



April 25, 2012

2012

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The Honorable Orrin G. Hatch
Ranking Member, Committee on Finance
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The American Society of Hematology (ASH) appreciates the opportunity to submit comments on the draft *Patient Access to Drugs in Shortage Act*. The increasing problem of drug shortages has become a crisis, taking a serious, sometimes life-threatening toll on hematology patients and negatively impacting the practice of hematology and the clinical research our members conduct. ASH commends you for developing legislation to combat drug shortages and appreciates that this draft also addresses the issue of providing economic incentives to drug manufacturers.

ASH represents approximately 14,000 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 nonmalignant illnesses such as anemias, thrombosis, and bleeding disorders. The increasing number of drug shortages has significantly affected the practice of hematology because the standard therapies frequently used to treat many hematologic conditions are 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.

ASH strongly supports the early notification and drug shortage list provisions in the legislation and the broad parameters you have included to define drugs in shortage. The Society has the following recommendations to strengthen the draft:

Inclusion of Biological Products

ASH is concerned that both biologics and biosimilar products are not mentioned within the draft legislation. Some of the most important regimens for the treatment of patients with hematologic disorders (especially blood cancers such as multiple myeloma, lymphomas, and leukemias) are biologic. The Society urges the inclusion of all biologics and biosimilar products within the defined parameters for reporting.

Inclusion of Products That Were Originally Derived from Human Tissue and Were Replaced By a Recombinant Product

ASH is particularly concerned that the reporting requirement does not include products that were originally derived from human tissue and were replaced by a recombinant product. Many of these drugs are critical to the treatment of patients with hematologic conditions and they are at risk for being in short supply. ASH recommends these products be included in the legislation.

Market Stability Incentives

Finally, as discussed in recent congressional hearings about drug shortages, ASH believes economics clearly contribute to the shortage problem. While ASH appreciates your attention to market stability incentives, the Society has questions about the impact these provisions could have and believes further study is needed to understand these provisions. Specifically, it is not clear how changing the Average Sales Price (ASP), a method of Medicare reimbursement to physicians, will effectively provide economic incentives to drug manufacturers. As these options are being further examined, ASH recommends that you consider an option modeled on the Orphan Drug Program to incentivize manufacturers' production of specific low cost critical drugs.

Thank you for your consideration of ASH's comments and recommendations. The Society appreciates your leadership on this critical issue and hopes to continue to work with you as your proposals are finalized. Please have your staff contact ASH Government Relations Manager Stephanie Kaplan (skaplan@hematology.org or 202-776-0544) if the Society can provide additional information or expertise.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Armand Keating". The signature is fluid and cursive, with a prominent loop at the end.

Armand Keating, MD
President