AMERICAN SOCIETY OF HEMATOLOGY
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The Honorable Tom Harkin
Chair, Senate Committee on Health, Education, Labor, and Pensions
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Enzi
Ranking Member, Senate Committee on Health, Education, Labor, and Pensions
379A Senate Russell Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

The American Society of Hematology (ASH) is pleased to see that provisions to address drug shortages have been incorporated into the Senate Committee on Health, Education, Labor, and Pensions (HELP) draft Prescription Drug User Fee Act (PDUFA) legislation. 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 the Committee for developing a bipartisan draft designed to address shortages of drugs that are critical for hematology treatment and research.

ASH supports many of the provisions included in the draft legislation and believes this is a helpful first step toward ensuring that patients have access to the medications they need while not compromising safety and quality of those medications. The Society strongly supports the revisions made to the earlier draft and appreciates that the Committee incorporated many of our recommendations. The Society is particularly pleased to see that the Committee incorporated the following provisions into the revised draft:

- The additional language to include sterile injectable products within the definition;
- Requiring that the Secretary to disseminate information about drug shortages to patient and provider organizations;
- Requiring enhanced inter and intra agency coordination and requiring increased and effective communication with outside stakeholders; and
- Requiring that the Strategic Plan consider the impact of drug shortages on research and clinical trials.

While we are pleased with the above improvements, the Society urges the Committee make the following revisions to further strengthen the legislation:

Inclusion of Radio Pharmaceutical Drug Products, a Human Tissue Replaced by a Recombinant Product, and Products Derived from Human Plasma Protein

ASH is particularly concerned that the reporting requirement needs to include radio pharmaceutical drug products, a human tissue replaced by a recombinant product, and products derived from human plasma protein. Many of these drugs are critical to the treatment of patients with hematologic conditions and are at risk for being in short supply. Examples of hematologic products that fall into these categories, which have already experienced severe shortages, include: intravenous immunoglobulin (IVIG) used as part of the treatment regimen for allogeneic bone marrow transplantation, chronic lymphocytic leukemia and idiopathic thrombocytopenic purpura and antithymocyte globulin used in the treatment of aplastic anemia. ASH recommends the Committee ensure these products are included in the final legislation.

Inclusion of Biological Products

While ASH strongly supports and appreciates the inclusion of both biologics and biosimilar products within the discussion draft, the Society does not think that this provision should be left up to the discretion of the Secretary. 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. It would be detrimental to a patient's treatment if a hematologist is unable to access the biologic product needed for their protocol. The Society urges the Committee to require the Secretary to include all biologics and biosimilar products within the defined parameters for reporting.

Enforcement

ASH believes simply listing the names of manufacturers who fail to comply in an annual report to Congress will not serve as an effective enforcement mechanism. Given the importance and magnitude of drug shortages on treatment and research, ASH recommends that a strong enforcement mechanism be included in the final legislation that instructs the Secretary to promulgate regulations establishing a schedule of civil monetary penalties for failure to submit a required notification.

Study Regarding National Contingency Plan

ASH recommends that the Committee consider adding a provision that directs the Secretary to coordinate a study on the feasibility of developing a national contingency plan for drug shortages.

Increased Resources for FDA

Once drugs are created, it is critical that they continue to be available. Would the Committee be willing to consider a special set aside for the FDA's Drug Shortage Program to provide adequate funding to carry out the activities authorized by this legislation?

Thank you for your attention to these important issues and your consideration of ASH's comments and recommendations. ASH believes the Committee's draft is a good first step to addressing the problem of drug shortages and that the Committee has included helpful and thoughtful provisions to combat the crisis. The Society hopes to continue to work with you. Please 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,

Armand Keating, MD
President