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Re: Docket No. FDA-2011-N-0898: Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

Dear Dr. Hamburg,

The American Society of Hematology (ASH) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the FDA's proposed rule: Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products as published in the Federal Register (FDA-2011-N-0898) on November 4, 2013. The problem of continuing drug and biologic shortages is a crisis in the United States taking a serious, sometimes life-threatening toll on hematology patients, and significantly impacting the practice of hematology and clinical research in the field. ASH understands that the causes of drug shortages are multiple and complex and that there is not a single solution. However, the Society believes that the advanced notification requirements included in Public Law 112-144, the Food and Drug Administration Safety and Innovation Act (FDASIA) are a critical step to addressing this urgent problem. ASH commends the FDA for the publication of the proposed rule carrying out these provisions.

ASH represents more than 15,000 clinicians and scientists worldwide committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma and non-malignant conditions such as hemophilia, sickle cell anemia, and venous thromboembolism. ASH membership is comprised of basic scientists, physician scientists, and physicians working in diverse settings, including universities, hospitals and private practices. The country's shortage of hundreds of drugs has particularly affected ASH member hematologists and their patients because many of the drugs and biologics most vulnerable to shortages are used to treat blood disorders.

ASH strongly supports FDA's decision to apply section 506C of the Food Drug and Cosmetic Act (FD&C) to all biological products, including recombinant therapeutic proteins, monoclonal antibody products, plasma-derived products and their recombinant analogs, blood and blood components, and cellular and gene therapy products. Biologics used to treat patients with hematologic diseases range from chemotherapeutic agents used to treat patients with blood cancers (biologics) to plasma protein therapy products and their recombinant analogs used for the treatment of hemophilia and other bleeding disorders. These treatments are vital to the delivery of care for patients with blood disorders, and the non-inclusion of these drugs would put these patients in jeopardy. In fact, patients with hematologic conditions have experienced numerous biologic shortages.

While not stated specifically in the proposed rule, ASH would recommend that the final rule make clear that biosimilars are subject to the provisions of section 506C of the FD&C Act. While the approval process for biosimilars is still under development by the FDA, ASH believes that it is important to apply the requirements of the proposed rule to biosimilars.

ASH also supports the FDA's definition in the proposed rule of "life supporting or life-sustaining" and "intended for use in the prevention or treatment of a debilitating disease or condition." ASH believes that the scope of the definitions is appropriate as we think a broad definition is important to ensure that most critical hematologic products are included in the provisions of the final rule.

Finally, ASH supports the inclusion of blood or blood components for transfusion in the proposed rule, but seeks clarification on how this will be implemented. It is not clear if reagents used to cross-match platelets for transfusion would be subject to the advanced notification reporting requirements of the proposed rule. Shortages of these reagents occurred over the past year impacting patient care provided by hematologists and blood centers. For this reason ASH asks FDA to clarify this point and include additional details in the final rule on (1) how FDA will determine if blood or blood components would be exempt from the advanced notification reporting requirements; and (2) how FDA plans to address potential shortages of the "exempt" blood and blood components.

Thank you for your consideration of ASH's comments and recommendations. The Society looks forward to continuing to work with you on this important issue. Please contact ASH Government Relations and Practice Manager, Stephanie Kaplan (skaplan@hematology.org or 202-776-0544), if we can provide additional information or expertise.

Sincerely,



Linda J. Burns, MD
President