AMERICAN SOCIETY OF HEMATOLOGY
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May 29, 2012

Representative Fred Upton (R-MI)
Chairman
House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, D.C. 20515

Representative Henry Waxman (D-CA)
Ranking Member
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, D.C. 20515

Re: H.R.5651, the Food and Drug Administration Reform Act of 2012; Title IX - Drug Shortages

Dear Chairman Upton and Representative Waxman:

The American Society of Hematology (ASH) is supportive of the work of the Energy and Commerce Committee to develop HR 5651, the FDA Reform Act of 2012, particularly your efforts to begin to address the problem of shortages of drugs and biologics. The Society, however, is very concerned that products derived from human plasma proteins and recombinant products replacing human tissue – products used for the treatment of hemophilia and other bleeding disorders – are specifically exempted from the early reporting mandate in the legislation and urges you to remove this exemption from the legislation.

ASH is the world's largest professional society concerned with the causes and treatment of blood disorders, representing more than 14,000 members who specialize in blood cancers such as leukemia, lymphoma, and myeloma, as well as serious blood diseases such as hemophilia. The country's shortage of more than 200 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.

People with hemophilia and others dependent on plasma protein therapies and recombinant products have experienced the problem of drug shortages. Consequently, ASH strongly believes that there is no reason to exempt the products our community is dependent on from the requirement that manufacturers give 6 months advanced notification to the Secretary if they plan to interrupt or discontinue making a drug and they believe that it could result in a shortage of this drug.

The Society understands the Committee agreed to this exemption because some manufacturers of plasma protein therapies and their recombinant products already report production data to FDA and to the public through the Plasma Protein Therapeutics Association (PPTA). PPTA collects production data for only 5 types of products – Plasma Derived Factor VIII, Recombinant Factor VIII, Immune Globulin (Ig), Albumin 5% and 25%. The Society notes, however, that there are an additional 20 types of plasma protein therapies and recombinant products for rarer bleeding disorders and Von Willebrand Disease that are not reported. Further, the reporting to PPTA is voluntary; not all manufacturers of plasma protein therapies and recombinant products participate in the data collection program; and, in the 13 year history of the program, there have been instances where participating companies have stopped reporting. In addition, neither FDA

nor the public is provided any information on a manufacturers' intent to stop or discontinue manufacturing of products, which could result in a shortage.

ASH believes that the reporting of production data is not a surrogate for advanced notification that a manufacturer intends to stop or interrupt production. Moreover, FDA officials have informed the Society that the manufacturers' voluntary reporting of production data is very different from advanced notification of manufacturing changes. FDA did not see any reason to exempt plasma products and their recombinant analogs from the drug shortage reporting requirements.

ASH respectfully requests that you remove the exemption of plasma protein therapies and their recombinant analogues from the advanced notification requirement in Title IX of HR 5651 so that individuals with bleeding disorders and their physicians can appropriately plan for potential shortages of these life-saving products.

If you have any questions or would like further information about this issue, please have your staff contact ASH's Senior Director of Government Relations, Practice, & Scientific Affairs Mila Becker at *mbecker@hematology.org* or 202-776-0544.

Sincerely,

Armand Keating, MD
President