



# AMERICAN SOCIETY OF HEMATOLOGY

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January 11, 2019

Scott Gottlieb, MD  
Commissioner, U.S. Food and Drug Administration  
Members of the Agency Drug Shortages Task Force  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Docket No. FDA-2018-N-3272-0001: *Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments*

Dear Dr. Gottlieb and Members of the Agency Drug Shortages Task Force,

The American Society of Hematology (ASH) appreciates the opportunity to submit feedback in response to the U.S. Food and Drug Administration's (FDA) request for comments on *Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions* (FDA-2018-N-3272-0001) as published in the Federal Register on September 10, 2018.

ASH represents over 17,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who provide care to patients in diverse settings including teaching and community hospitals, as well as private practice. Many of the patients our members treat have been adversely affected by recent shortages.

ASH commends the FDA for developing the Agency Drug Shortages Task Force and taking recent steps to understand why drug shortages continue and identify potential solutions to address the underlying causes. Additionally, the Society appreciates all the prior steps that the FDA has taken to help combat shortages including, but not limited to, the establishment of the drug shortage database, timely drug shortage email notices, expedited reviews of critical therapies, and the quick responses from staff in the FDA's Drug Shortage Program. Despite these changes, hematologists continue to see shortages of therapies, both hematologic and supportive care drugs. Some critical hematologic shortages that ASH members have seen over the past year are therapies that have no alternatives, such as etoposide and methotrexate. These are crucial therapies for hematologic patients who could die without access to these medications. Over the past year, ASH has received calls from hematologists experiencing drug shortages and requesting help in finding supplies of the drugs.

The Society would like to highlight the following points to emphasize how critical we believe the problem of drug shortages to be:

**Treatment Decisions** - Physicians have had to choose therapies that are not the standard treatment protocol not because the patient lacks coverage, or because of prohibitively high costs, or because they are not sure how to treat, but, rather, because the standard treatment

## 2019

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is not available. As a result of shortages, some patients have received less effective or more toxic alternative treatments, in some cases leading to serious complications.

- **Rationing Care** – As a result of short supplies of some medications, institutions and practices have had to establish policies to prioritize and ration the use of certain drugs.
- **Increased Costs** – Because of shortages of generics, practitioners have been forced to choose more expensive treatments.
- **Emotional Impact** – Changes to treatment plans, including rescheduling and reworking treatments because of shortages, can make patients suffer emotionally at a time they are embarking on a major therapy regimen.

The recent, but now resolved, shortage of etoposide is a prominent example of therapy that was in shortage without an alternative. This is a chemotherapeutic drug that is a crucial component, without alternatives, in treatment regimens designed to be curative for life-threatening conditions including leukemias and lymphomas. Etoposide is a mainstay of the regimen known as dose adjusted EPOCH widely used to treat a highly aggressive form of diffuse large cell lymphoma. The etoposide shortage in particular had a major impact on bone marrow transplant (BMT) programs across the country. It is a critical therapy for transplant conditioning chemotherapy regimens. During the shortage ASH members were concerned about how to manage patients in need of this therapy, especially for severe and time-sensitive cases when no alternatives were available.

The drug shortages have caused medical treatment to be delayed and compromised, but most significantly, shortages have caused patients to suffer. ASH urges the FDA to continue to work with stakeholders to identify and implement solutions as soon as possible. As different remedies are considered, ASH would like to offer itself as a partner and resource. Please contact ASH Senior Manager of Government Relations and Public Health, Stephanie Kaplan ([skaplan@hematology.org](mailto:skaplan@hematology.org) or 202-776-0544), if the Society can provide additional information or expertise.

Sincerely,



Roy L. Silverstein, MD  
President