September 19, 2019

Norman E. Sharpless, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter Marks, MD, PhD
Director
Center for Biologics Education and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Sharpless and Marks,

On behalf of the American Society of Hematology (ASH), I am writing to express the Society’s concerns regarding the critical shortage of unfractionated heparin and to encourage the U.S. Food and Drug Administration (FDA) to take the steps needed to address the shortage in a timely manner.

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.

The Society has recently heard from ASH members across the country who have reported about the critical nature of the shortage of unfractionated heparin in their region and the challenges they are facing as they manage patients who are in desperate need of this therapy. Heparin is used by hematologists to treat blood clots, as well as used prior to surgical procedures to reduce the risks of blood clots. Outside of hematology, heparin is also used as a polytherapeutic for overdoses, kidney dialysis, open heart surgery, and angina. Because of its many uses and low cost, heparin is essential for hematologists. While there may be alternative therapies to use in place of unfractionated heparin as an anticoagulant choice for prophylaxis or treatment, such as for venous thromboembolism, unfortunately, there are no substitutions for heparin for cardiac procedures or surgeries.

According to reports from ASH members in the Boston area, supply for unfractionated heparin is on extreme restricted usage and the region has less than a one-month supply left. Unfortunately, the reports from Boston are not isolated and we are hearing similar reports from other ASH members about how physicians are forced to choose therapies that are not the standard treatment because of lack of availability. Hospitals and institutions across the
ASH recognizes that the causes of this shortage are multiple and complex and there is not a single solution; however, the Society encourages the Agency to explore all options under its authority to find an interim supply of this therapy for critical cases as the shortage is being resolved. We would also ask the Agency to provide guidance to providers during this shortage period.

ASH specifically is seeking your response to the following questions:

- Does the FDA have a mechanism in place to determine the available supply and inform clinicians about how to access it in a life-threatening situation?
- Do you have any information about an emergency supply or the projected timeline for the shortage that we can relay to providers who are managing patients in critical need of the therapy?
- Do you have any more information on when additional supply will be available?
- Is there anything that ASH can do to help with this situation?

This shortage has caused medical treatment to be delayed and compromised, but most significantly, it has 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 Deputy Director, Government Relations and Public Health, Stephanie Kaplan at skaplan@hematology.org or 202-776-0544, if the Society can provide additional information or expertise.

Sincerely,

Roy Silverstein, MD
ASH President