



March 20, 2020

The Honorable Stephen M. Hahn, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

AABB, America's Blood Centers and the American Red Cross request you include challenges to the nation's blood supply in your response to the request from the House of Representatives Committee on Energy and Commerce on the potential impact the novel coronavirus (COVID-19) could have on the supply of safe drugs and other medical products.

Maintaining a safe and adequate blood supply during this epidemic continues to be a critical public health objective. The blood supply is safe because, as FDA continues to acknowledge, "[i]n general, respiratory viruses are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus. Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10)."

However, as COVID-19 continues to spread, the virus is beginning to adversely impact blood donations. As a result of COVID-19, businesses, schools, and the public have responded with several social distancing efforts. While these efforts are intended to limit the spread of COVID-19, closed business campuses, high schools and universities, as well as cancellations of gatherings by churches and community organizations have resulted in many canceled blood drives. As of March 16, the blood industry has seen more than 4,000 blood drives cancelled, resulting in some 130,000 fewer blood donations due to coronavirus concerns.

COVID-19 is quickly evolving and has the potential to result in even more blood drive and individual donor appointment cancellations, fewer healthy donors available to sustain the blood supply and potential absenteeism among blood centers' staff, which may limit the ability to draw and process blood. While efforts to extend the blood supply are being considered and implemented, we are concerned that the impact of these blood management strategies may not be sufficient to make up for the loss of donors. Further, for many patients – such as cancer patients, those with blood disorders, trauma victims, and others – the need for blood will continue even as the COVID-19 outbreak grows.

In addition to being a lifesaving treatment for patients, donated blood is needed to manufacture reagents, which are used to type and label a unit of blood, and to determine the

patient's blood type and red cell antibody status. Manufacturers of reagents are beginning to see slower deliveries of units from their blood center suppliers. If manufacturers are unable to obtain sufficient volumes of fresh blood products to manufacture reagents, blood collected for patient transfusion cannot be tested, labeled and shipped to hospitals, hospitals will experience a profound lack of inventory for transfusion, and will be unable to type and screen patients for necessary transfusions.

Blood collection, testing, and storage requires a variety of other supplies that must be available. For example, blood bags, filters, sterile fittings and other disposable products are all medical devices sourced from a limited number of suppliers and differences between these products may preclude easy substitutions. Additionally, various types of personal protective equipment and sanitation supplies are important for continued blood donation activities, however, shortage concerns are ongoing throughout the health care system.

We encourage you to remind Congress that the supply chain for blood begins with donors in the community. Blood has a short shelf life, up to 42 days for red blood cells but only five days for platelets. Thus, blood must be constantly and regularly collected from healthy individuals to sustain the nation's blood supply, a critical public health resource. We also recommend that you reinforce that (1) blood donation is safe, (2) blood drives are not "social gatherings" or "mass gatherings, and (3) blood donation can and should continue even while social distancing measures are in place.

The blood community has established mechanisms and focused resources to ensure a safe, robust blood supply, however, COVID-19 has the potential to wreak havoc on blood collections as public health measures are implemented nationwide. The entire blood community is united and undertaking massive efforts to educate the public about the safety and necessity for blood donation, supported by federal, state and local government officials actively encouraging donations. However, more is necessary. Blood drives are key to the supply chain for blood and are being adversely impacted by the COVID-19 outbreak. Thus, governmental support is required to encourage all healthy individuals to donate blood and to ensure that the entire blood supply chain is intact.

Sincerely,

Debra BenAvram  
Chief Executive Officer  
AABB

Kate Fry  
Chief Executive Officer  
America's Blood Centers

J. Chris Hrouda  
President, Biomedical Services  
American Red Cross