America's Blood Centers®
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Peter Marks, M.D., Ph.D., Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Nicole Verdun, M.D., Director
Office of Blood Research and Review, CBER
Food and Drug Administration
10903 New Hampshire Avenue
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Re: Temporary Blood Guidances in Place During COVID-19 Pandemic

Dear Drs. Marks and Verdun:

On behalf of America's Blood Centers (ABC) and our member blood centers, we appreciate the FDA's efforts to maintain a safe and robust blood supply during the COVID-19 pandemic. The ability of blood centers to provide blood components to hospitals in support of patient care, while experiencing significant challenges in collections, was aided by the issuance of three guidances in April 2020:

- Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency;
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission;
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.

The alternative procedures guidance indicates that FDA "intends at a later date to consider whether permanent changes to the applicable regulations would be appropriate" and will "provide further notification when the alternative procedures are no longer in effect." The malaria and HIV guidances state that they are "intended to remain in effect for the duration of this public health emergency" but FDA "expects that the recommendations set forth in this revised guidance will continue to apply outside the context of the current public health emergency. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with an updated guidance that incorporates any appropriate changes based on comments received on this guidance and the Agency's experience with implementation."

We are in favor of making all three guidances permanent (beyond the expiration of the public health emergency), a course of action that will continue to promote a robust blood supply while maintaining its safety. Given the wording about future plans beyond the declared public health emergency however, we are concerned about the potential impact of any "gap" in guidance once the public health emergency has expired. For example, it would place an undue burden on centers if they were required to revert back to previous pre-pandemic requirements and then potentially change yet again if the pandemic guidances are evaluated and made permanent. We would appreciate understanding your plans to avoid such a situation.

Our member centers have been responsive and agile during the course of the pandemic. The operational changes necessary to implement these three guidances, while swiftly applied, involved substantial changes to SOP and blood establishment computer systems. Additionally, donors have shown

appreciation for the revised qualifications, and many units were saved with the allowance for release of blood components that would previously have required discard regardless of whether safety of the donor or patient was unaffected.

Thank you again for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer