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February 8, 2023

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
Silver Spring, MD 20993-0002

Re: **Docket No. FDA-2022-D-0588,** "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry"

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. Throughout 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 several guidances in April 2020, including "Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency" (Alternative Procedures Guideline). We appreciate FDA's issuance of guidance documents to extend many of these changes after the expiration of the PHE.

However, while FDA released a draft guidance entitled "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements" (Draft Guidance) in May 2022, which would allow the recommendations set forth in the Alternative Procedures Guideline to continue to apply outside the context of the public health emergency (PHE), this Draft Guidance has not yet been issued as a final guidance. ABC did submit joint comments in collaboration with the Association for Advancement of Blood and Biotherapies (AABB) and the American Red Cross (ARC) in response to the Draft Guidance.

With the impending end of the Public Health Emergency (PHE), which the White House stated will terminate on May 11, 2023, we urge the timely finalization of this Draft Guidance.

If this guidance is not finalized before the expiration of the PHE on May 11, blood centers will be forced to again modify their systems to revert to the previous requirements. Such a change will require blood center resources, including staff time, be dedicated to this over other priorities, only to have to again make modifications when the guidance is finalized. This additional burden has the potential to interfere

with blood centers' ability to efficiently implement other changes that would need to be made, including the change required to adopt the draft Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.

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