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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Rm 1061
Rockville, MD 20852

Submitted via https://www.regulations.gov

Re: Docket No. FDA-2023-N-5653, "Draft Report and Plan on Best Practices for Guidance."

Dear Dr. Califf:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian, blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

ABC appreciates FDA's solicitation of input on initiatives that FDA should consider to improve its processes for the issuance of guidance documents. As stated in the Draft Report and Plan on Best Practices for Guidance (Draft Report), "[w]hile FDA has significantly improved its best practices for efficient prioritization, development, issuance, and use of guidance documents over the years, FDA continues to explore areas for enhancement."

Specifically, in FDA's request for comments on the Draft Report, the agency is seeking input "on whether there are any additional circumstances, categories of guidance documents, or topics for guidance for which it may be appropriate and consistent with the FD&C Act and FDA's GGP regulation for FDA to consider issuance as a Level 1 guidance document for immediate implementation without prior public comment." In response to FDA's request, ABC provides the following recommendations.

I. ABC strongly recommends that FDA develop draft guidance documents for implementation under emergency conditions, and provide these documents to blood centers in advance, so blood centers can reconfigure and validate their Blood Establishment Computer Systems (BECS), update their standard operating procedures (SOPs), and train their staff in preparation for immediate implementation, should the need arise.

ABC applauds FDA for allowing multiple flexibilities during the COVID-19 Public Health Emergency (PHE). As noted in the Draft Report, "on April 29, 2020, the Secretary issued a [Paperwork Reduction Act] (PRA) waiver that applied to information to be collected by FDA to evaluate various ways to maximize the number of healthy individuals who can donate blood to facilitate its response to the PHE. The information collected pursuant to this PRA waiver supported the development of guidance

documents intended to address blood shortages, such as the guidance on "Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency [Alternative Procedures Guidance]."

The PHE led to dramatic reductions in the number of donations due to social distancing and the cancellation of blood drives. To help address the need for an increase in the number of donations, the FDA modified policies regarding the eligibility of certain donors, based on recently completed studies and epidemiologic data, without compromising the safety of the blood supply. The ability of blood centers to provide blood components to hospitals in support of patient care, while experiencing substantial challenges in collections, was significantly aided by these guidance documents, which FDA published for immediate implementation in April 2020. They included the Alternative Procedures Guidance, in addition to the Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (HIV Guidance), and Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.

These guidance documents were implemented without prior public comment because the FDA determined that prior public participation for the guidance documents was not feasible or appropriate. However, these guidance documents remained subject to comment in accordance with FDA's good guidance practices. ABC provided comments on the HIV Guidance in June 2020, requesting an immediate technical correction to the Guidance, noting that, "[b]ecause of the [identified] inconsistency, some blood centers are waiting for FDA clarification before they implement the guidance, thereby losing a valuable opportunity to expand the donor pool and reenter otherwise eligible donors during this public health emergency." In August 2020, FDA made the changes ABC requested, and updated the recommended deferral for individuals, eliminating the inconsistency, thereby allowing blood centers to implement the guidance. Overall, it took months for blood centers to implement the change from a 12-month to a 3-month deferral, since blood centers had to reconfigure and validate their BECS, put new SOPs in place, and train their staff. If FDA had provided the draft guidance in advance, blood centers could have reconfigured and validated their BECS, developed SOPs in advance, trained their staff, and implemented the change far more quickly.

As FDA noted in the Draft Report, "The facts and circumstances surrounding COVID-19 and the COVID-19 PHE enabled FDA to rapidly disseminate Agency recommendations and policies related to COVID-19. These flexibilities were critical to the significant work FDA accomplished during the COVID-19 pandemic." The release of guidance documents for immediate implementation, as described above, serves as a model for the immediate implementation of certain Level I guidance documents.

ABC strongly recommends that FDA develop draft guidance documents for implementation under emergency conditions, and provide these documents to blood centers in advance, so blood centers can reconfigure and validate their BECS, update their SOPs, and train their staff in preparation for immediate implementation, should the need arise. Additionally, in the event FDA decides to release draft guidance documents for immediate implementation that have not already been provided to blood centers, FDA should look to the Level I guidance documents provided during the PHE for immediate implementation, which provided less stringent requirements for blood centers to follow. This allowed blood centers to implement the new, less stringent guidance documents, or maintain the more stringent requirements already in place, allowing blood centers flexibility until they developed the necessary SOPs, without compromising the safety of the blood supply. If FDA does provide level 1 guidance documents without prior public participation, FDA must provide for public comment upon publication and take the public comments into consideration.

II. ABC recommends that FDA provide additional information in CBER's annual Guidance Agenda regarding the specific topics to be addressed in the Level 1 planned guidance documents.

ABC greatly appreciates FDA's publication of the Center for Biologics Evaluation and Research (CBER) Guidance Agenda at the start of each year. This information is important to blood centers, as it allows them to strategize and plan operational changes needed to implement new or updated guidance documents. However, the information provided in the Guidance Agenda is minimal, and does not provide insight into the specifics of the issues FDA plans to address. ABC recommends that FDA provide additional information in CBER's annual Guidance Agenda regarding the specific topics to be addressed in the Level 1 planned guidance documents. We recognize that CBER is not bound by the list of planned guidance documents, nor would the Center be bound by any details they provide. However, this additional information would allow blood centers to begin strategizing around the implementation of potential changes to their operations.

ABC appreciates the opportunity to comment on the Draft Report. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

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

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer