



Advancing Transfusion and
Cellular Therapies Worldwide



March 02, 2016

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

Submitted via <http://www.regulations.gov>

Re: Docket No. FDA-2014-D-2175, “Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus” draft guidance.

Dear Dockets Manager:

We appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) on the draft guidance titled “Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus.”

Our organizations appreciate the concern for recipient safety that the FDA seeks to address as we work toward that goal in our daily operations. The blood community responded effectively and rapidly to the West African Ebola outbreaks by developing AABB Association Bulletin #14-08, dated October 14, 2014. We appreciate the FDA liaisons to our committees and task forces who contributed to that initiative. However, we do not believe the effort that will be expended in implementing the extensive recommendations contained in this draft guidance matches the risk that Ebola virus presents to the US blood supply. We strongly maintain that the voluntary approach to self-deferral via predonation education used during the recent outbreak in West Africa was the correct and proportionate response to the risk and that interventions beyond that are not justified.

Further, the recommendations in this draft guidance drive blood centers to web pages maintained by the Centers for Disease Control and Prevention (CDC), for purposes other than blood collection, that

- do not contain all of the information needed to implement the recommendations,
- change frequently, and
- do not highlight the updated information corresponding to Alert Notices.

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We recommend that the FDA and the Office of Blood, Organs and Other Tissue Safety at CDC collaborate with the blood community to ensure the necessary information is available to assess blood donors in compliance with FDA recommendations.

The AABB Donor History Questionnaire (DHQ) “Blood Donor Educational Material” was developed by the AABB Donor History Task Force to provide the donor an overview of the donation process and standard information about

- the importance of accurate and complete answers on the “Donor History Questionnaire,”
- important eligibility information about medications, travel and risk behaviors for transmission of disease from the donor to the patient that do not vary significantly over time as do time-limited epidemics,
- the various steps in the collection and testing of the donation, and
- what happens after the donation process.

The document was not designed to target relevant transfusion-transmitted infections, one-by-one, as they appear on the horizon, and must not be reoriented for that purpose. As previously proved with Ebola virus, and is currently being implemented with Zika virus, we have shown that a facility’s additional educational materials, not integral to the FDA-accepted materials, can be used for these purposes. We recommend that compliance with relevant FDA recommendations be allowed via facility educational materials that are a part of the facility’s standard operating procedures, as was done with AABB Association Bulletin #14-03.

Comments to specific recommendations in the guidance document are arranged in the following format:

Section – language from draft guidance reprinted.

Recommendation or Request for Clarification – recommendation or clarification request.

Rationale/Supporting Information – rationale in support of the recommendation /clarification request.

III. Recommendations

A. Donor Educational Material and Donor History Questionnaire

1. Donor Educational Material

We expect very few individuals with a history of Ebola virus infection or disease to present as blood donors. When there are no countries classified as having widespread transmission of Ebola virus, self-deferral of donors with a history of Ebola virus infection or disease should provide sufficient protection. You may update your donor educational materials to instruct donors with a history of Ebola virus infection or disease to not donate blood or blood components.

Recommendation – We recommend that the FDA finalize the guidance with only a self-deferral recommendation for periods when there are countries classified as having widespread transmission of Ebola virus.

Rationale – The AABB DHQ “Blood Donor Educational Material” should not be used to target discrete outbreak risks to the US blood supply such as those theoretically posed by Ebola virus. These materials are not used to permanently defer a donor for a criteria that does not appear on the questionnaire. “Blood Donor Educational Materials” should be used to remind donors of the risk exposures they are likely to have that will impact patient safety and to provide some information to the donor about the donation process. It is well known that donors devote limited time and attention to the education/information provided to them during the donation process. The blood community has proven that topic-specific educational materials work well with outbreak risks; e.g., AABB Association Bulletin #14-08 Deferral for Blood Donation of Persons Under Public Health Surveillance for Possible Exposure to Ebola Virus. In future outbreaks this process should again be sufficient to mitigate the risk being addressed.

III. Recommendations

A. Donor Educational Material and Donor History Questionnaire

2. Donor History Questionnaire

In the event that one or more countries is designated as having widespread transmission of Ebola virus...

b. A history of residence in or travel in the past 8 weeks to a country with widespread transmission of Ebola virus disease or cases in urban areas with uncertain control measures. (See <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distributionmap.html>).

Recommendation – We recommend that the FDA work with the CDC to provide the necessary information on the web page for blood centers to defer donors as recommended by FDA guidance. The current CDC web page does not provide the chronological history of transmission in a country. As of December 29, 2015 all of the West African countries were cleared from the list of countries with widespread transmission. No timeline is provided to know when widespread transmission commenced and ended. The same may be true of the data fields for “urban areas with uncertain control measures.” These data fields were not used in the 2015 outbreaks. Further, as noted above, we believe self-deferral through the facility educational materials as used during the recent West African epidemic is sufficient to protect the safety of the US blood supply.

Rationale – Blood centers cannot apply appropriate deferral periods utilizing current data fields on the CDC webpage.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half 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. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments. We look forward to continuing to work with the FDA on patient and donor safety initiatives. Questions concerning these comments may be directed to acarrgreer@aabb.org.

Sincerely,

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