



March 18, 2020

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-2012-D-0307, “Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt Jakob Disease by Blood and Blood Components” Draft Guidance, January 2020

Dear Dockets Manager:

AABB, America’s Blood Centers (ABC), the American Red Cross (ARC), and the Armed Services Blood Program (ASBP) are jointly submitting comments to the Food and Drug Administration (FDA) on the January 2020 Draft Guidance, “[Recommendations To Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt Jakob Disease by Blood and Blood Components](#)” (the 2020 Draft Guidance). These comments on the draft guidance were prepared by members of AABB’s Transfusion Transmitted Diseases Committee, Donor History Task Force, Regulatory Affairs Committee and interested parties from ABC, ARC and ASBP.

We have the following comments:

Comment 1: Recognition of CBER’s Regulatory Reform

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Our organizations are extremely pleased with the agency's updated donor deferral policies related to current risk for Creutzfeldt-Jakob Disease (CJD), variant CJD (vCJD), sporadic (sCJD), and iatrogenic CJD (iCJD).

We are deeply grateful to CBER/OBRR for this new direction and the decision to restore donation opportunities for many new and returning donors, most notably those who were deferred for time spent in Europe during military service, along with their dependents. This draft guidance is evidence of CBER's stated commitment to reevaluate and update regulations and recommendations.

Comment 2: Section III. A. 1, Donor Deferral for Receipt of Human Growth Hormone (hGH), and Reentry Options under Section IV. A. 3.

We agree with:

- FDA's conclusion in III. A. 1. that "...Because the risk exposures to hGH occurred prior to 1977, it is unlikely that any additional cases of iCJD will occur in this cohort"
- the resulting decision to "remove hGH from their medication deferral lists used in donor screening."

In the corresponding recommendation in Section IV. A. 3, FDA states:

"...Accordingly, donors who were previously deferred for certain risk factors for vCJD and CJD may now be eligible based on the revised recommendations in section IV of this guidance, except as follows:

- Donors previously deferred for receiving hGH are not eligible for reentry..."

Request for clarification of rationale for reentry recommendation in IV. A. 3:

In the final guidance, please provide the rationale behind CBER's risk-based decision to remove hGH as a reason for donor deferral without permitting reentry options.

Likewise, please provide guidance and similar rationale for potential iatrogenic exposures to sCJD. We recognize that the number of affected donors in both cohorts is very small and there is lack of evidence of transfusion transmission.

We have no additional comments on the recommendations found in Sections IV. A through C because they are clearly presented and consistent with the rationale described in Section III.

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

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical

technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, ABC 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 ARC 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.

Since 1962, the Armed Services Blood Program has served as the sole provider of blood for the United States military. The ASBP's mission is to provide quality blood products and services for all worldwide customers in both peace and war. As a division in the Defense Health Agency's Combat Support Directorate, we focus on equipping the warfighter with lifesaving blood and blood products needed on the battlefield as well as in military treatment facilities with 20 blood donor centers worldwide. Working as a joint operation, the ASBP collects, processes, stores, and distributes blood and blood products to service members and their families worldwide. Since the ASBP's inception, more than 1.5 million units of blood have been provided to treat battlefield illnesses and injuries. While ASBP blood recipients are most often thought of as a deployed service member injured in the line of duty, we also support the peacetime needs of military personnel and their families.

Sincerely,

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