



## A Joint Statement to the Food and Drug Administration's Blood Product Advisory Committee

18 November 2016

“Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus,” August 2016 Guidance Document

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Chair, AABB Transfusion Transmitted Diseases Committee

AABB, America’s Blood Centers and the American Red Cross appreciate the opportunity to present this statement focused on the August 2016 guidance “Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus.” AABB’s Transfusion Transmitted Diseases Committee and its Arboviruses subgroup assisted in drafting this statement. America’s Blood Centers and the American Red Cross provide representatives to the TTD Committee.

We recognize the nature of the worldwide Zika-related health emergency and are supportive of the objective of HHS to minimize or prevent infection from blood transfusion, particularly of pregnant women, with the consequent risk of harm to the fetus. While we support the delivery of the safest possible blood products and services, we are concerned about the processes used to develop and implement the Guidance, the balance of resource commitment to potential benefits, and the potential for future expectations for blood donation testing.

The agency-issued recommendations were linked to several regulations and utilized authority outlined in the May 2015 final rule “Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use,” making the content of the Guidance a non-negotiable mandate. The Guidance appears to be based upon an extreme interpretation of the precautionary principle and rejects the concept of “tolerable risk”. However, it should be noted that a primary tenet of the principle is that action should be taken only if it will not cause harm. In the absence of any formal risk assessment and since the blood community was not consulted during the development of the Guidance, we do not believe that this aspect was fully evaluated. Further, responsible commentary on the precautionary principle advocates against policies based

upon zero-risk and calls for a response that is proportionate to the risk and is commensurate with measures previously undertaken in similar circumstances. In this context, we recognize that the current circumstances are extraordinary, with little or no precedent, but are nevertheless concerned that there has been no public quantitative assessment of the potential risks, benefits or resource usage required in the Guidance. We consider this wholly inappropriate at a time when both healthcare and public health resources are limited.

As noted, the lack of consultation with the blood community in the development and issue of the Guidance is of particular concern. No attempt was made to determine whether the Guidance could be implemented by the blood community in the required time frame without adverse effects on the safety and adequacy of the blood supply. Neither was any attention given to the resources required to implement the requirements of the Guidance. Lastly, estimates are that the program will incur direct costs well in excess of one hundred million dollars per year. This sum must be measured against a responsible estimate of the potential benefits accruing from implementation of the Guidance. Further, the investigational new drug cost recovery regulations under which centers can bill for this testing (21 CFR 312.8) allow recovery only of the direct costs of testing. Approximately 30% of the total cost is indirect and not allowed under cost recovery of this nature. If this were a licensing clinical trial, for example, both direct and indirect costs could be captured. Thus, the costs for this FDA mandate are not fully recoverable.

We strongly recommend that FDA establish a continuing formal, public review of the policies recommended in the Guidance, with the specific objective of modifying the Guidance to achieve an appropriate balance of benefits and resource usage.

Despite these concerns, the blood community has risen to the challenge and we believe that we, and our suppliers, should be commended. However, we wish to emphasize that this should be viewed as a unique response. Neither we, nor the FDA can yet determine the concrete benefits and associated adverse effects of implementing this Guidance. For example: ongoing safety and quality-related projects were put on hold; laboratories were reconfigured; and, we are burdening our hospitals with another IND cost recovery increase without concomitant data demonstrating efficacy. Every collection site having testing performed under one of two investigational protocols is also required to have institutional review board approval of the protocol and all documents that interface with human subjects; this task alone has been especially burdensome and challenging to the FDA required timeline. We do not believe that, under current circumstances, the blood community could be expected or able to repeat a response to another regulatory expectation of this nature.

Thus, in closing, while we support efforts to minimize or prevent transfusion-transmitted Zika virus infection, our concerns focus on the lack of transparency of this Guidance process when there were ample opportunities for fruitful interaction with the blood community. We are also concerned about the balance between the cost and overall value of this initiative. Finally, we are uncomfortable with the precedents that this process appears to have established.

Thank you for the opportunity to offer these comments.

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, 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.