Advancing Transfusion and Cellular Therapies Worldwide

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American Red Cross

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VIA email

Dear Sirs,

Blood establishments currently do not have a method to comply with certain recommendations contained in the February 2016 guidance document titled "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion Transmission of Zika Virus." The relevant guidance language/recommendation is reprinted here.

Page 3, Section III, Recommendations:

> For the purpose of this guidance, an area with "active transmission of ZIKV" is an area included on the CDC website listing of countries and U.S. states and territories with local vector-borne (i.e., mosquito-acquired) transmission of ZIKV: http://www.cdc.gov/zika/geo/index.html.[3]
>
> Footnote [3] In general, an area is considered to have active transmission of ZIKV when locally transmitted, mosquito-borne ZIKV has been reported.

Two months after publication of this guidance, and despite the best efforts of numerous parties, there is no consensus definition of "an area with active transmission of ZIKV" that will be used by local jurisdictions in the United States and the District of Columbia (the United States). Nor is there any credible evidence that the jurisdictions will report their determination of activity to the CDC or any other location that will be publicly accessible to blood establishments in near real-time to assure maximum transfusion safety and compliance with the guidance.

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We – AABB, American Red Cross, and America's Blood Centers – are growing more concerned as the weather continues to warm toward active mosquito season in more areas of the United States. Crisis-mode management should be avoided at all costs and we ask you to use all of the resources at your disposal to support resolution of this serious problem.

We believe it will be helpful if the FDA would publicly define areas of active vector-borne transmission to be used to activate blood safety interventions recommended in the FDA guidance document. We further believe that the agency is aware of efforts within the Council of State and Territorial Epidemiologists to develop a consensus definition for use by and within the States and believe this definition is a good starting point for the agency. Considering the range of the mosquito vector, a far smaller geographic area than "state" is needed. Zip codes have proven to be useful to the blood community in the West Nile virus model. A cluster of zip codes may be a reasonable solution, although we do not understand why a single zip code is perceived to be a privacy issue.

It is essential to have real-time reporting of areas of active vector-borne transmission to assist blood establishments in other locations to implement appropriate travel deferrals and assure the safety of outsourcing programs.

The FDA should also be open to an alternative resolution to the possibility that all the information needed by blood centers may not be reported by the States to the CDC web site. The agency should consider what the acceptable alternatives may be and make this information publicly available.

Lastly, we request the agency to identify the methodology that will be used to "detrigger" areas of active transmission.

Sincerely,

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