



January 24, 2020

James Berger, Designated Federal Officer for the TBDWG
Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Mary E Switzer Building
330 C Street SW, Suite L600
Washington, DC 20024

Re: Written Public Comment – January 28-29, 2020 Meeting of the Tick-Borne Disease Working Group

Dear Mr. Berger,

The undersigned organizations support the critical work being done by the Tick-Borne Disease Working Group (TBDWG). Vector-borne diseases, including tick-borne diseases, create multifaceted and interdisciplinary public health challenges. We appreciate the TBDWG's plans to address the risks associated with tick-borne diseases and applaud policymakers' commitment to addressing tick-borne diseases through the recently enacted Kay Hagan Tick Act. We hope that the ongoing efforts of this Working Group and the efforts resulting from the Kay Hagan Tick Act will improve our understanding of existing tick-borne diseases, enable the rapid detection of new disease agents, result in effective prevention and improve the public's health.

Blood transfusions are medically necessary, routine treatments for patients with chronic health conditions, life-saving therapies for patients who experience blood loss from trauma or surgery and must be available in emergencies. A variety of human cells, tissues, and cellular and tissue-based products (HCT/Ps) are used as cellular therapies and other biotherapies to treat different diseases or conditions. For instance, hematopoietic stem cells are used to treat leukemia, lymphoma and sickle cell disease.

As the TBDWG recognized in its 2018 Report to Congress, tick-borne pathogens are quite diverse, and methods of transmission differ. While there is evidence that some existing tick-borne diseases can be transmitted via blood transfusions, other tick-borne diseases have not been linked to blood transfusions or therapies involving HCT/Ps. For example, despite the prevalence of Lyme disease in the general U.S. population, we have not seen evidence that Lyme disease can be transmitted via blood transfusion or therapies involving HCT/Ps. We are encouraged that the efforts of the TBDWG and resulting activities have the potential to add to the evidence and result in improved, evidence-based policymaking that reflects documented risk.

Thus, as detailed below, we encourage the TBDWG to include in its report to Congress the following recommendations to ensure that current, evidence-based policies protect the safety and availability of the nation's blood supply as well as HCT/Ps:

1. Ensure that surveillance and research findings are shared with the Food and Drug Administration's Center for Biologics Research and Evaluation in a timely manner to inform evidence-based policies.
2. Recognize gaps in research related to the impact of tick-borne diseases on the blood supply as well as on cellular therapies and biotherapies.
3. Consult with individuals with expertise in the impact of tick-borne diseases on the safety and availability of blood and HCT/Ps.
4. Encourage the safety and availability of blood and HCT/Ps to be integrated into the national strategy for tick-borne diseases.

We recommend that surveillance and research findings be shared with the Food and Drug Administration's Center for Biologics Research and Evaluation in a timely manner to inform evidence-based policies.

Our organizations appreciate the TBDWG's efforts to ensure interagency coordination related to tick-borne diseases and believe that continued communication and coordination between Federal agencies and departments is essential for implementing evidence-based policies that protect the public's health. We urge the TBDWG to recommend that the Center for Biologic Evaluation and Research (CBER) at the Food and Drug Administration (FDA) be given the opportunity to provide input into the design and implementation of surveillance, research, programs and other activities so that these efforts can be used to inform and update evidence-based policies impacting the blood, cellular therapies and biotherapies communities. Similarly, surveillance and findings from other programs and activities, including an absence of evidence implicating transmission risk, should be shared with CBER in a timely manner so that the policies regulating blood, cellular therapies and biotherapies are continuously aligned with current epidemiology and research findings.

For instance, FDA's "Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry" takes a risk-based, regional approach to regulating blood donations.¹ Currently, FDA requires blood collection establishments to test blood donations when collected in 14 states (Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin) and Washington, D.C. Given that the epidemiology of tick-borne diseases is continuously evolving,² we support the TBDWG's 2018 recommendation to "fund studies and activities on tick biology and tick-borne disease ecology, including systematic tick surveillance efforts particularly in regions beyond the Northeast and Upper Midwest."³ We believe that the studies and surveillance efforts championed by the TBDWG can be used to inform FDA's current and future policies.

As another example, novel and emerging tick-borne disease agents present significant challenges to FDA as well as to the blood and cellular therapies/biotherapies community. We support the Working Group's 2018 recommendation to "fund systematic studies and activities to identify and characterize novel tick-borne disease agents in the United States," and believe that these studies and activities should specifically address risk for transmission of novel tick-borne disease agents via blood transfusion or by HCT/Ps. Findings from such research and surveillance efforts, including evidence indicating an absence of

¹ Food and Drug Administration, Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis, Guidance for Industry (May 2019), available at <https://www.fda.gov/media/114847/download>.

² Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System, Weekly Tables of Infectious Disease Data. Atlanta, GA. CDC Division of Health Informatics and Surveillance. Available at: <https://www.cdc.gov/nndss/infectious-tables.html>.

³ Tick-Borne Disease Working Group: 2018 Report to Congress, available at <https://www.hhs.gov/sites/default/files/tbdwg-report-to-congress-2018.pdf> (last visited January 9, 2020).

risk, should be made immediately available to CBER to ensure that evidence-based policies are (1) implemented and continuously updated to protect the safety and availability of blood and HCT/Ps; (2) not overly burdensome in the absence of data implicating blood or HCT/Ps; and (3) support the availability of blood and HCT/Ps.

We recommend that the TBDWG specifically recognize gaps in research related to the impact of tick-borne diseases on the blood supply as well as on cellular therapies and biotherapies.

Investing in research is critical to preventing and mitigating the impact of tick-borne diseases. Comprehensive, timely surveillance data coupled with improved risk mitigation strategies, early diagnostics and additional treatment approaches can improve the public's health and lessen the burdens associated with tick-borne diseases. We appreciate that the TBDWG's 2018 Report to Congress highlighted the following needs and gaps in research, and believe that these areas remain challenges and research priorities today:

- Improve early and accurate diagnosis and treatment.
- Strengthen national surveillance.
- Understand the immunological mechanism (for example, the pathogen-host interaction) of immune protection for Lyme disease and other tick-borne diseases.
- Develop new rapid and accurate lab tests.
- Develop antibiotic combination and/or therapeutic options for treating acute and persistent illness.
- Encourage the development of strategic plans for tick-borne disease Federal investments.
- Dedicate funding to tick-borne diseases and evaluate related activities using performance indicators and clear metrics for success.
- Characterize how tick-borne disease affects U.S. national security, military readiness, and the health and wellness of active duty Servicemembers, Veterans, and their families.

Potential risk of transmission through blood and HCT/Ps should be considered in each of these research areas. For example, we agree that the absence of reliable, national surveillance data is quite problematic and limits the nation's ability to understand the epidemiology of tick-borne diseases. Enhanced national surveillance that tracks tick and human activities, including where and how specific tick-borne diseases are acquired (i.e., community, travel, via blood transfusion, via HCT/P, etc.), is key to developing and adopting evidence-based policies and procedures that are proportional to documented risk, mitigating the risks of these vector-borne diseases, and ensuring the availability of blood and HCT/Ps.

In addition, we believe the TBDWG should recommend economic studies and activities related to the costs associated with preventing transmission and mitigating the risk of tick-borne diseases. For example, screening and testing blood for transfusion-transmitted babesiosis is a crucial public health function carried out by blood operators in select states. The current funding model is flawed and is not aligned to support this public health role. We believe that it is important to understand the economic impact of this type of public health activity, and to dedicate funds and develop reimbursement policies to support the function.

As the TBDWG continues its important work in shaping U.S. policy and activities related to tick-borne diseases, we encourage the group to consult with individuals with expertise in the impact of tick-borne diseases on the safety and availability of blood and HCT/Ps.

We recommend that the TBDWG engage with individuals from the blood and HCT/P communities who are uniquely qualified to support the efforts of the TBDWG and provide expertise on blood transfusion safety as well as transmission of diseases via HCT/Ps. For example, such individuals could provide the working group with epidemiological and clinical research expertise related to blood donor collections and screening processes, expertise related to transmission by HCT/Ps, as well as a robust understanding of operational considerations associated with risk mitigation.

We encourage the TBDWG to recommend that HHS appoint new members to the TBDWG or at a minimum, solicit input from external advisors, so the ongoing and future work can inform policies and practices that protect the safety and availability nation's blood supply and HCT/Ps.

The safety and availability of blood and HCT/Ps should be integrated into the national strategy for tick-borne diseases.

We are encouraged that the Kay Hagan Tick Act dedicates funding for activities related to vector-borne diseases and requires HHS to develop a national strategy to address vector-borne diseases, including tick-borne diseases. We hope that HHS will use the important work being done by the TBDWG to inform this strategy, identify gaps and develop strategic goals and benchmarks related to addressing vector-borne diseases. Additionally, we believe HHS should consult with experts from the blood and cellular therapies/biotherapies community to ensure that the national strategy, identified gaps, strategic goals and benchmarks consider blood and HCT/P safety and availability in a manner consistent with the above recommendations.

If you have any questions or need additional information, please contact Leah Stone at lmstone@aabb.org or 301-215-6554.

Sincerely,

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