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American Red Cross

July 17, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

On behalf of the undersigned groups representing the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, we request that as you review the federal advisory committees as required by the Executive Order issued on June 14, 2019, you support the current structure of two distinct federal advisory committees charged with making recommendations related to the safety and availability of our nation's blood supply.

A safe and robust blood supply is an essential component of the U.S. healthcare system. Unlike other pharmaceuticals and biologics, blood cannot be manufactured and stored to consistently meet demands. Instead our healthcare system relies on the continuous availability of non-remunerated donors to meet the ever-present and emergent needs of acute care patients and those with chronic disease conditions.

Ensuring a safe blood supply with sufficient inventory today and in the future requires a multi-disciplinary, multi-agency approach as the blood supply plays a role in the nation's health care system, public health capabilities, and emergency preparedness and response. Current federal advisory committees with jurisdiction over issues impacting the nation's blood supply include the Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) and the Food and Drug Administration (FDA) Blood Products Advisory Committee (BPAC). Together, ACBTSA and BPAC encompass a comprehensive approach to the collection and manufacture of blood and blood components that is inclusive of donors, patients, and industry.

These two advisory committees have distinct roles within the statutory authority and limitations of each agency. We believe that HHS should ensure that each of these committees are preserved and the public forums continue to exist to fully inform and advise federal authorities about blood safety and availability.

To meet their respective charges, ACBTSA and BPAC are composed of different stakeholders with various expertise. Both committees hold open meetings and encourage public input. ACBTSA's membership includes medical and technical expertise, patient advocacy groups, provider organizations, and HHS officials representing the array of areas within HHS impacted by blood products, including the Centers for Medicare and Medicaid Services (CMS),

Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), and National Institute of Health (NIH) . BPAC's focus on the safety, purity and potency of the blood supply is supported by medical and technical professionals with expertise unique to blood manufacturing and transfusion medicine,.

Below are some areas of jurisdiction for the two committees:

- ACBTSA is charged with unique objectives and duties that focus on important issues related to sustainability of the blood supply, such as cost, which BPAC is unable to consider under their current statutory authority. The work of ACBTSA fills a void that cannot be addressed by BPAC where conflicts of interest would exist for the BPAC members. ACBTSA sets its own agenda and as such provides advice on a wide array of policy issues, including public health issues impacting the blood supply, broad ethical and legal issues, assessing economic factors impacting the blood supply, risk communications relating to blood transfusion and tissue transplantation; and assessing infectious disease transmission issues for blood, organs, blood stem cells and tissues.

- BPAC reviews and evaluates available data at the request of FDA/CBER, and through robust evaluation of donor health and risk, provides an opinion to inform FDA/CBER's regulatory approach concerning the safety, effectiveness, and appropriate use of blood and products derived from blood or biotechnology that are intended for use in the diagnosis, prevention, or treatment of human diseases. Examples of BPAC's work includes evaluations of infectious disease risk in donors, evaluations of eligibility relating to the donor health, robust donor deferral and the promising new applications for pathogen inactivation technology, as well as other highly technical evaluations. As an aside, we believe that BPAC may be exempt from the Executive Order under Section 5, since it is charged with advising the Commissioner of FDA "in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility."

The important and distinct roles of both committees is illustrated through their recent work. For instance, BPAC recently advised the FDA Commissioner on regulatory options for emerging risks to the blood supply posed by Zika virus infection and babesiosis. BPAC also responded to specific questions from CBER in support of "risk control strategies" for platelets to enhance detection of bacterial contamination, resulting in decreased patient risk for adverse events and fatalities. As another example, the ACBTSA is currently working to advise the HHS Assistant Secretary for Health on the resilience of the blood supply amid a shifting donor base, increasing complexity of safety and technology measures, and economic challenges as well as considering acceptable risk tolerability for infectious diseases.

The functions of these unique advisory committees are essential to ensuring highly complex regulatory and policy decisions will support a safe and robust supply of blood sufficient to meet ongoing and emergency needs of Americans across the country. We encourage you to maintain these committees of experienced experts so they can continue to provide strong advice

on the state of the nation's blood supply and advocate for the needs of donors and transfusion recipients.

If you have any questions, please contact Leah Stone (lmstone@aabb.org, 301-215-6554), Diane Calmus (dcalmus@americasblood.org, 202-654-2988) or Julie Manes (Julie.manes@redcross.org, 202-417-5147).

Sincerely,

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