Congress of the United States
Washington, DC 20515

February 16, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Robert M. Califf, M.D.
Commissioner
United States Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Secretary Becerra and Commissioner Califf,

In December, 2020, the Food and Drug Administration (FDA) issued a Final Guidance document addressing an urgent public health matter: bacterial contamination in platelet transfusion. Because platelets are stored at room temperature, they are particularly susceptible to bacterial growth. Bacterial infiltration of platelet donations can and does lead to fatal septic reactions in vulnerable patients; as a result, these donations must be screened and/or treated for potential contamination.

In its Final Guidance, titled "**Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion**," FDA offers the market three avenues for compliance, each with unique benefits, risks, and costs. The agency does not characterize any option as better than the others, providing hospitals freedom to select the solution best suited for their particular needs and resources. FDA provided these choices because it recognized that hospitals have different patient populations, supply chain concerns, and operational and economic priorities and feasibilities, many of which are driven by geographic location. For example, rural hospitals with limited access to blood products supply may prefer a platelet product with a longer shelf life and that contains more concentrated amounts of platelets - both factors which vary depending on how platelets are tested and treated for bacteria.

We are concerned that many, if not most, health care providers are not being afforded the ability to select between FDA's three accepted options. First, a significant percentage of market share is

held by a few blood collectors, including the American Red Cross. Further, it is not uncommon for geographic regions to have access to only one blood collector. As a result, hospitals may be required to accept platelets prepared to the blood collectors' choice, regardless of expense or work force requirements.

Others have also expressed profound concern that decisions by blood collectors will limit provider decision making. Leading transfusion medicine professionals submitted a public letter to the FDA dated November 25, 2020, and the principal professional association for transfusion medicine, the Association for the Advancement of Blood & Biotheraphies (AABB), issued Bulletin #21-02 on June 2, 2021. Each of these communications addresses the impacts of Guidance implementation, emphasizing strongly the need for hospitals to have a choice as to how they will reduce the risks addressed by the Guidance.

In addition, FDA announced in email correspondence to the blood banking and medical community dated December 2, 2021, that since 2019, the FDA is aware of three cases, including two fatalities, involving Pathogen Reduced "PR" and treated platelets. The agency also disclosed that "additional reports" of sepsis associated with PR platelets are "under investigation," demonstrating "that it is important for blood establishments and transfusion services to recognize the residual risk of bacterial contamination of platelets, including pathogen-reduced platelet components." Given this significant and concerning development, it is imperative that additional measures be taken to ensure choice for health care providers.

We share FDA's desire to ensure provision of safe, timely, and effective blood transfusions to patients in need by offering providers flexibility in managing their care. As a result, we ask that FDA consider whether additional actions are necessary to preserve the benefits of choice and competition among those complying with the Guidance, in order to best serve patients and communities.

Sincerely,

Earl L. "Buddy" Carter, R.Ph.
Member of Congress

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