



Advancing Transfusion and
Cellular Therapies Worldwide



April 18, 2019

The Honorable Nita Lowey
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Sanford Bishop, Jr.
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Kay Granger
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Jeff Fortenberry
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Lowey, Granger, Bishop and Fortenberry:

On behalf of the undersigned organizations representing the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, we are writing to support the proposed funding included in the White House's fiscal year 2020 budget request that would encourage the development of pathogen reduction technologies (PRT). Today's blood supply is safe. However, the development, implementation, and adoption of this technology can further enhance the safety of the nation's blood supply by reducing the risk of existing and emerging infectious agents while potentially reducing the rate of blood donor deferrals and/or testing requirements. To facilitate widespread use of PRT, it is imperative that the development and optimization of PRT be agnostic to both apheresis and whole blood collection methodologies allowing all blood components collected and distributed in the United States to benefit from the improved safety profile. We support FDA's commitment to developing new PRT products that are efficacious, safe and cost effective.

Current PRT uses chemical and/or physical processes to inactivate infectious disease agents (parasites, bacteria and viruses) from blood for transfusion. PRT has the potential to benefit both the safety and availability of the blood supply, while also allowing a simpler solution to provide hospitals with a ready-to-transfer blood component. PRT improves patient safety by reducing the risk that existing infectious agents could be transmitted to patients through blood transfusion and that emerging infectious agents could go undetected. In addition, PRT has the potential to expand the donor base by mitigating the loss of otherwise qualified donors who may have behavioral or geographic risks for infection. For example, thousands of otherwise healthy donors are not permitted to donate after traveling to areas with malaria. Additionally, other donors are lost due to false positive tests for infections, some of which FDA believes can be eliminated after the widespread use of PRT. Notably, PRT is important to the military. In theatre, the military must

often collect blood in geographically distant locations without the ability to test for infectious diseases from military personnel who are exposed to local infectious diseases such as malaria.

FDA has approved one PRT for use on platelets and plasma collections, with others in various stages of development. Current PRT solutions are expensive, result in product loss, and contain narrow guard bands that inhibit wide scale production. We support FDA's dedication and request for funding to advance PRT, simply and inexpensively, without disruption to blood collectors or hospitals operations and we ask that ongoing efforts be applied agnostically to all collection approaches maximizing safety and widespread adoption for all blood component products.

We support FDA's request to advance new blood safety technologies and highlight that non-profit blood centers are facing significant financial challenges. It is laudable that FDA acknowledged that "by addressing both a variety of known pathogens and offering protection against many emerging pathogens, the application of a simple, safe and effective pathogen reduction technology potentially could measurably increase the safety of the blood supply while reducing cost." We believe that Congress will need to dedicate additional funding to evaluate the impact of new technologies and policies on the economics of the blood system and the stability of the blood supply.

In the interest of patient safety, ease of hospital transfusion use, and the availability of a robust supply of all blood components, we remain supportive of PRT. We strongly urge you to adopt the proposed funding to support the development and optimization of pathogen reduction technology across all collection methodologies. Should you have any questions, please contact AABB (Leah Stone, lmstone@aabb.org, 301-215-6554), America's Blood Centers (Kate Fry, kfry@americasblood.org, 202-654-2911) and American Red Cross (Julie Manes, julie.manes@redcross.org, 202-417-5147).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

James C. Hrouda
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