



A Joint Statement to the Food and Drug Administration's Blood Products Advisory Committee

December 8, 2022

Support for FDA's Research Programs
Protecting the Safety and Availability of Blood and Biological Products

AABB (Association for the Advancement of Blood & Biotherapies), America's Blood Centers, and the American Red Cross appreciate the opportunity to provide a statement of support for the research programs conducted by two laboratories within CBER/OBRR's Division of Emerging and Transfusion Transmitted Diseases (DETTD); the Laboratory of Emerging Pathogens, and the Laboratory of Molecular Virology. The unprecedented level of blood safety we currently enjoy is a direct result of the robust research of these expert career scientists and programs. Additionally, the important work of these researchers supports the safety of other biological products regulated by CBER.

AABB requests adequate, sustained, and dedicated funding for CBER/OBRR/DETTD to support the hiring and retention of expert staff, and the capacity and infrastructure of FDA's research programs which are essential to ensuring the continued safety of the nation's blood supply. This funding would directly support CBER's mission to protect the public against the threats of emerging infectious diseases and bioterrorism. These research programs have made groundbreaking contributions in the field of emerging infectious disease agents which have threatened the safety of the blood supply. Successful mission-related efforts have significantly reduced the risk of transfusion-transmitted human immunodeficiency virus, viral hepatitis, anthrax, *Babesia*, *Trypanosoma cruzi*, and other infectious agents. Equally important, this research helps to ensure an adequate blood inventory by supporting evidence-based decisions to prevent unnecessary donor deferrals when data shows an infectious disease agent does not pose a risk for transfusion transmission.

Regulatory science research is fundamental to FDA's ability to proactively identify, understand, and effectively respond to potential threats, ensure blood safety, and provide effective regulatory review of biological products. This research performed by OBRR/DETTD also provides important information necessary to support evidence-based decisions regarding infectious disease transmission risk for other biological products regulated by CBER's Office of Tissue and Advanced Therapies, ensuring the safety and availability of cellular therapies and biotherapies which are growing at a rapid pace.

The importance of the role of these researchers cannot be overstated. Their work encompasses not only the primary research efforts of the Principal Investigators and other scientists, but also regulatory review responsibilities aimed to support DETTD's regulatory mission "to drive that risk to the lowest level reasonably achievable without unduly decreasing the availability of this life saving resource," as noted on the FDA website. Researchers are also responsible for

developing policy, guidance documents with recommendations for blood donor screening questions and tests, diagnostic devices, and providing scientific and technical advice to other Agencies and Government entities (e.g., CDC, CMS, DoD, DHHS). In closing, it is vital to attract and retain career research scientists with critical scientific expertise within the FDA, and adequately fund the agency's research to facilitate the assessment of interventions that ensure the continued safety of the blood supply and support effective, efficient regulatory review of lifesaving blood and biological products.

AABB is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. For the past 75 years, AABB has worked collaboratively to advance the field through the development and delivery of standards, accreditation, and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available, and effective worldwide.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer this statement.