Statement from American Plasma Users Coalition (APLUS) on Proposed Change from Identity-Based Deferrals to Individual Risk Assessment for All Potential Blood Donors

(Washington, D.C.) On Friday, January 27th, the Federal Drug Administration (FDA) announced a proposed draft guidance that would implement an individualized risk assessment for all potential donors regardless of their sexual orientation or the gender of their partners. This comes after many years of attention on the deferral criteria for men who have sex with men (MSM). The undersigned members of the American Plasma Users Coalition (APLUS), which represents end users of blood and plasma products, issue the following statement in support of this draft guidance from the FDA:

The transition to an individual risk-based assessment for all donors is a welcome change in the management of the U.S. blood and plasma supply and is one that our organizations support. We have long stated that prior donor deferral policies were suboptimal and that we support any science-based policy changes that can reduce discrimination and increase the number of potential donors, while ensuring that the risk to end users of America's blood and plasma supply is not elevated. We look forward to reviewing the forthcoming data from the ADVANCE Study, on which the FDA has partially relied, to make this change.

We are encouraged to hear from the FDA that they are continuing to monitor data around the potential inclusion of blood donors who are using pre-exposure prophylaxis (PrEP) and may expand donor pools once data can inform such a potential move. We look forward to working with and continuing the dialogue with the FDA and other stakeholders regarding expanding eligible donors, if and when sufficient data is available and technology and logistical capacities of America's blood donation centers allow.

Finally, we wish to address the promise of pathogen inactivation. In 2010, APLUS called for a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components. It has long been recognized that robust pathogen reduction is the “Holy Grail” of blood safety. Donor selection and donor screening are the only gatekeepers to prevent infectious units from entering the system and screening tests are only available for some pathogens. Pathogen inactivation is one of the key components of advancing blood safety that could increase safety while allowing further changes to donor deferral policies. We look forward to working with the FDA to advance the promise of pathogen inactivation technology which may well support further revision to donor deferral policies.

We are pleased the FDA undertook the studies necessary to validate an individual risk assessment for all donors, regardless of sexual orientation or gender identity, and hope it will continue to conduct the research necessary to expand the donor pool and increase the supply of safe whole blood, blood components, and blood products, while ensuring the safety of products for end users."

The American Plasma Users Coalition (A-PLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. Together our coalition represents more than 125,000 Americans living with chronic disorders who depend upon plasma protein therapies to lead healthy, productive lives. Please direct follow-up questions or inquiries to Nathan Schaefer of the National Hemophilia Foundation at nschaefer@hemophilia.org.

Sincerely,

American Plasma Users (APLUS) Coalition Members:

Alpha-1 Foundation

GBS I CIDP Foundation International

Hemophilia Federation of America

Immune Deficiency Foundation

National Hemophilia Foundation

World Federation of Hemophilia