June 11, 2012

Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services (HHS)
1101 Wootton Parkway
Tower Building, Suite 250
Rockville, MD 20852

RE: Docket No. HHS-OPHS-2012-0003

To the Department of Health and Human Services,

The American Plasma Users Coalition (A-PLUS) commends the Department of Health and Human Services’ (HHS) for releasing a request for information (RFI) on the design of a pilot operational study to assess alternative blood donor deferral criteria for men who have sex with men (MSM) in the U.S. 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. The Cooley’s Anemia Foundation represents individuals with thalassemia, who depend on blood transfusions to treat their condition. As end users of blood products and plasma protein therapies, our organizations greatly appreciate the opportunity to comment on the design of the pilot project.

A-PLUS is pleased with the progress the Department of Health and Human Services has made since the HHS Advisory Committee on Blood Safety and Availability (ACBSA) recommendations on donor deferral were adopted in June 2010. At that time, A-PLUS acknowledged that the scientific basis for the permanent deferral for men who have had sex with a man (MSM) required review, though we believed that available scientific knowledge was inadequate to establish an alternate deferral policy. We are pleased that the appropriate federal agencies are undertaking the necessary research to allow for a science-based evaluation of the deferral policy and how any potential changes will impact the overall safety of the blood system.

We concur with the conclusions of the ACBSA that the current deferral system is sub-optimal and continue to recognize and empathize with the position of those advocating for revision of the current donor deferral policy. We acknowledge that by design, public health policies can be discriminatory and that discrimination can be acceptable when in the service of public health such as the protection of the end users of our nation’s blood supply. That said, it is important to ensure that the policies adopted are the least onerous to a given community or group. Optimally, the research underway will allow for an adjustment in the donor deferral criteria, which is based on scientific and epidemiological evidence, as well as lessen the stigmatization and discrimination of the target donor populations.

The proposed pilot study is an important complement to other research projects related to this issue. The three research studies currently underway (NHLBI REDS II Study on TTD risk in current donors, NHLBI REDS III Study on attributes and behaviors of MSM toward the donation screening process and motivation of donors, and the NCHS study on the cognitive evaluation of the donor history questionnaire (DHQ)), along with the conclusions of the FDA workshop on quarantine release errors all will provide important
information in the re-evaluation of the donor deferral policy. The collection of research initiatives must be evaluated in aggregate to provide understanding of the risk implications of a policy change. The scope of this proposed pilot study in combination with the others will be useful in determining if a behavioral based screening process would preclude high risk donors and not increase the overall risk to the blood supply.

We believe that the proposed pilot is all the more relevant in light of the recently published report (May 2012) from the Centers for Disease Control and Prevention (CDC), CDC Fact Sheet on HIV among Gay and Bisexual Men. In this report it was noted that many gay and bisexual men with HIV do not know they have HIV, especially MSM of color and young MSM. Of MSM who test positive for HIV in 2008, 44% did not know they were infected. Among those infected, young MSM aged 18 to 29 (63%) and racial/ethnic minority MSM (54%) were likely to be unaware they had HIV. We also take note of the aging of the U.S. population and consequent greater recruitment and retention efforts placed on younger Americans as blood donors. Persons who do not know they have HIV do not get medical care and can unknowingly infect others. Taking into account this background information and the fact that in 2009, MSM accounted for 61% of all new HIV infections, this proposed pilot study is of profound importance in assessing any policy change in the deferral interval for MSM donors.

**Donor Screening and Testing**

A key element of the proposed research is to segment the MSM population into high and low risk donors. We agree that it may not be appropriate to continue to consider MSM as a homogenous group. The use of enhanced donor screening tools (a pre- or post-test blood test, enhanced DHQ or combination of these) could establish a pathway allowing for a controlled entry of previously deferred high-risk donors. The pilot study could illuminate which MSM may be added to the donor pool without increasing risk to the blood supply.

We support the validation and use of an enhanced DHQ, which could include a more in-depth interview or sub-set of questions for target donor populations based upon a donor’s initial responses to the standard DHQ. This would aid our understanding of donor compliance, cognitive understanding and veracity in DHQ responses. However, we also note the challenge in implementing a behavior-based deferral system since donors can only report on their own behavior, not that of their sexual partners. Questions about the number of sexual partners, monogamous behavior and high-risk practices may all prove relevant.

The RFI discusses several options for implementing a pre- and/or post-donation blood test. A pre-screening test would allow for an understanding of the estimated prevalence of HIV in the donor population and aid in the cognitive understanding of a DHQ whereas a post-screening test would provide additional information relative to the risk of incident infection. While a combination of a pre- and post-test sample would provide the most complete picture of prevalence and incident infections we are reluctant to call for implementing both tests, since we anticipate this would create significant burdens on blood centers, negatively impact recruitment for the study and potentially increase an unknown risk for the end-user.

We have two concerns about the use of a post-donation test strategy, in which donations from MSM would be quarantined until after the donor returns to the blood facility for a post-donation test. It is probable that many donors will not return for their post-donation testing at precisely the time between the end of the window period for the Nucleic Acid HIV test (12 days) and the expiration date of the red blood cells (14 to 42 days). Platelets have a typical shelf life of seven days which would already render them unusable in this scenario. If donors return and have a negative HIV test after this expiration period, the plasma from the blood could still be used. Since only the plasma would be usable in this scenario, we believe that the implementation of a post-donation test strategy may result in a disproportionate share of the donated
blood serving only the plasma users community, which would not only not benefit the many Americans who need red blood cells, but also concentrate the risk of any unknown pathogens in our communities.

We do support the implementation of a pre-test strategy. In our 2010 testimony we noted our belief that a “pre-test” might be coupled with an enhanced donor questionnaire to allow for a more complete “pre-screening.” Such a system could prove useful to collect additional donor information on high-risk behaviors. Using marker viruses such as HIV and hepatitis, one might then be able to identify a subgroup of donors appropriate for continued long-term deferral or narrow the deferral to the segment of donors with high-risk behaviors.

We are also mindful, given the high percentages of MSM that do not know their HIV status, of the potential for test seeking behavior in the donation setting and are uncertain of the capacity of blood collection centers to provide suitable education and counseling programs to those who present with HIV. Careful consideration will need to be given to the blood collection centers or organizations selected to participate in the pilot. Akin to the design of REDS, it may well be prudent to focus the initial pilot in a few large centers to ensure appropriate controls and systems are in place to manage the complexity of the study.

**Donor Deferral Periods**

We believe that the research study should determine an appropriate deferral period that does not increase overall risk to the blood system and that any movement to relax the current donor deferral policies should proceed in a step-wise manner, as follows.

First, we believe that the study should accept all MSM donors so as to evaluate the corresponding risk associated with various behaviors. As mentioned above, an enhanced donor questionnaire should be implemented and it will be critical to evaluating whether a behavior-based screening method is effective. We are concerned that if a specific deferral period is chosen in the study design, the study will only show whether or not there is an increased risk to blood safety for this period. If you implement this strategy, then we would request that the blood collected as part of the pilot study not be distributed into the blood supply or destined for fractionation. The blood should be considered as study material and discarded after the research is concluded. Including a variety of MSM will help the pilot project to determine an optimal deferral period.

Second, when evaluating what deferral period would not increase risks for users of blood and blood products, we believe that the FDA should not only evaluate the risk of HIV, but also new, known or potentially sexually transmissible pathogens. We acknowledge that the window period for HIV NAT testing has narrowed significantly since the original deferral was put in place, and so a deferral interval of 5 years, 1 year, 6 months or a behavioral-based deferral in combination with a time interval may be achievable. However, if it is concluded that other pathogens could follow similar pathways as HIV, then there would be reason to be more conservative in establishing a new deferral period.

Third, in light of the risk of unknown pathogens, we request that any deferral period allow for a margin of safety. A longer deferral period of 5 years or possibly 1 year would allow for a new pathogen risk arising in MSM donors disproportionately to be reduced in the blood supply. We wish to emphasize that the donor deferral period should not be tailored just to respond to the risk of HIV transmission but rather we support a holistic approach.

Finally, we propose any change be implemented in a phased approach allowing for careful control and monitoring of risk. All stakeholders agree on the need for the safest possible blood supply, and we request that any change be phased in so as to ensure that blood establishments, donors and end users of blood and
blood products fully understand the changes and will be able to implement the new policy effectively, including the development of appropriate donor educational materials and counseling services if required.

**Conclusion**

For the pilot study to be useful in determining whether research supports changing the donor deferral policy for MSM, we believe that it should include an enhanced donor history questionnaire to better understand MSM behaviors coupled with a pre-donation blood test; and no specific deferral period so as to link behaviors with risk factors. We hope that the pilot study will help us determine which donor screening and testing strategies is most effective on a permanent basis. We recognize this is a research initiative, and so it will likely be burdensome to participants, but believe the rigor is necessary to inform us about the most optimal policy.

We also view the pilot study is a first step in a process that will ultimately lead to an overall review of US donor deferral policies and the efficacy of current conceptual and operative assumptions regarding donors, donor populations and their individual behaviors. We remain concerned that we have yet to address existing risks to the blood supply that are not effectively addressed in the current donor questionnaire and screening procedures.

In looking beyond the pilot study to a national ramp-up of incoming new donors it is important to recognize the operational issues that can and will arise at blood centers across our nation and to ensure additional tracking measures to ensure new donors are monitored closely as they re-enter the system. In closing, please be mindful that any changes in policy or regulation concerning the blood supply have consequences in other areas of the overall blood system.

Thank you again for the opportunity to submit comments. If you have any questions or need further information, please contact Mark Skinner at mskinnerdc@gmail.com.

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
GBS/CIDP Foundation International
Committee of Ten Thousand
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
National Hemophilia Foundation
Patient Services Incorporated
Platelet Disorder Support Association

and

Cooley’s Anemia Foundation