AMERICAN PUBLIC HEALTH ASSOCIATION
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June 12, 2015

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

SUBMITTED VIA: Regulations.gov

ATTN: Docket ID FDA-2015-D-1211-0001; Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

On behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, I write to thank you for the opportunity to comment on the Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. APHA shares the broad goals of updating the recommendations to better reflect the latest science and enhance our nation's blood supply. The proposed recommendations provide an excellent history of how men who have sex with men were indefinitely excluded from blood donations, demonstrating our limited understanding of HIV transmission at the time. We have made enormous progress in our medical and scientific understanding of HIV and our ability to treat and detect the virus since the time of the original mandate. It is because of this progress and advancement in knowledge and technology that we believe the proposed recommendations are scientifically unwarranted. We recognize that the recommendation to move to a 12-month deferral policy is a step forward relative to the current policy. However, such a recommendation continues to prevent low-risk individuals from contributing to our blood supply and maintains discriminatory practices based on outdated stereotypes. Instead, we strongly urge FDA to issue guidance that is grounded in science to ensure a safe and robust blood supply.

We are pleased to provide the following comments for consideration as FDA works to finalize the guidance.

Improved blood banking practices and technology help minimize risk

As cited by FDA in the draft guidance, the use of donor education material, specific deferral questions and advances in donor testing have reduced the risk of HIV transmission from blood transfusion to an estimated residual risk of one in 1.47 million transfusions.[1] Nucleic acid-

[1] U.S. Food and Drug Administration, Revised recommendations for reducing the risk of human immunodeficiency virus transmission by blood and blood products: Draft Guidance for industry. http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

amplification was first used in the U.S. as an investigational screening test in 1999 to test blood for HIV-1. Analysis of donations during the first three years of nucleic acid screening found 12 units confirmed to be positive for HIV-1 RNA among 37,164,054 units screened, or one in 3.1 million donations.[2] Currently the nucleic acid-amplification test is able to confirm the presence of HIV infection within 11 days of infection. NAT accuracy, specificity and sensitivity is high and is the screening method used by 98 percent of tested blood donations.[3] The older, but still in use, antigen reactive assay test is used in the remaining collection sites and its results show infection, on average, within 25 days from point of infection although there is a range from 2-8 weeks. Given the already wide-spread use of NAT for blood screening, it could easily be required of all collection sites. This would mean that the window of possible infection would be less than 11 days in which blood components could, conceivably carry risk.

The 12-month exclusion is arbitrary

The selection of a donation deferral time period of 12-months is not based in science but appears to be modeled after other countries' choices and fears. For example, the Blood Donor Screening Group of the United Kingdom states that there may be risk from new or currently unknown infections, which may have lengthy periods of dormancy.[4] It does not serve the public to make public health decisions based on unknown threats. In its proposed guidance, FDA cites this same British study among the research used by other countries for deferral policies.[5,6] It also discusses the outcomes of meetings by FDA's Blood Products Advisory Committee in which it is implied that a one-year deferral was the compromise to lessen the severity of a lifetime deferral based on actions, studies and surveys in other countries. No specific scientific rationale is provided to justify the 12-month exclusion.

As demonstrated above, today's NAT testing is highly accurate, specific and sensitive and when fortified with a proper behavioral risk-based donor health questionnaire, donor education and broad improvements in public health to reduce HIV transmission any deferral period exceeding the window of possible non-detection by NAT is therefore unfounded.

Improving the safety of the blood supply through objective risk-based assessment and eliminating discrimination

The FDA proposal details the disproportionate risk of HIV that is present among different populations. While it is accurate to state that MSM have borne a disproportionate HIV disease burden, it is not pertinent or productive to focus on a specific population. Rather, we urge FDA

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[2] Stramer, S.L., Glynn, S.A., Kleinman, S.H., Strong, D.M, Caglioti, S, Wright, D.J., Dodd, R.Y., & Busch, M.P. (2004). Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. *New England Journal of Medicine, 351*(8), 760-8.

[3] Ibid.

[4] United Kingdom Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). *Donor Selection Criteria Review.* (2011).

[5] Benjamin, R.J., et al. (2011). Deferral of males who had sex with other males, *Vox Sanguinis, 101*: 339-67.

[6] Custer, B., Sheon, N., Siedle-Khan, B., Pollack, L., Spencer, B., Bialkowski, W., D'Andrea, P., Sullivan, M., Glynn, S., & Williams, A. (2014). NHLBI Recipient Epidemiology and Donor Evaluation-III (REDS-III), Noncompliance with the men who have sex with men (MSM) deferral among U.S. male blood donors, Blood Donation Rules Opinion Study (BloodDROPS).

to follow the science of how HIV is transmitted and focus on behaviors rather than a population-based focus by using an objective, risk-based pre-screening questionnaire to determine the use of a deferral period.

Additionally, the proposed guidance notes that in the context of the DHQ gender is "taken to be self-identified and self-reported. In instances where a donor has asserted a change in gender identification, medical directors may exercise discretion with regard to donor eligibility."[7] We are concerned that this could open the door for discrimination and insensitive treatment of the donor by allowing local jurisdiction to make decisions related to transgender individuals. If there are concerns regarding current medications or general health, this information should be collected in the DHQ as with all donors.

Missed opportunity to enhance a safe blood supply

Instead of protecting and enhancing the nation's blood supply, a 12-month deferral represents a missed opportunity to save the lives of people in need of blood. According to the Williams Institute it is estimated that full elimination of a ban would result in 4.2 million newly eligible donors and an estimated 615,300 additional pints of blood donated each year increasing the total annual blood supply by 4 percent.[8]

In conclusion, APHA strongly endorses the need to update the guidance and urges FDA to base the revisions on sound, up-to-date science. Thank you for the opportunity to share our recommendations to improve upon the draft guidance and contribute to well-informed health policies.

Sincerely,

Georges C. Benjamin, MD
Executive Director

[7] FDA, Revised recommendations for reducing the risk of human immunodeficiency virus transmission by blood and blood products: Draft Guidance for industry.

[8] Miyashita, A. & Gates, G.J. (2014). Update: Effects of lifting blood donation bans on men who have sex with men. The Williams Institute. http://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Ban-update-Jan-2015.pdf