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Leslie Kux, JD
Assistant Commissioner
U.S. Food and Drug Administration
Office of Policy, Planning, Legislation,
and Analysis
10903 New Hampshire Avenue
White Oak Building 32, Room 4232
Silver Spring, MD 20993

Re: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus
Transmission by Blood and Blood Products; Draft Guidance for Industry

Dear Ms. Kux:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the U.S. Food and Drug Administration's (FDA) draft guidance for industry regarding revised recommendations for reducing the risk of transmission of Human Immunodeficiency Virus (HIV) through blood and blood products. The AMA commends the FDA for taking this important step to update policy for protecting the nation's blood supply in keeping with the best available scientific evidence and the best ethics practice in public policy, in light of the evolving epidemiology of HIV and risk to blood safety.

The AMA believes that the draft revised recommendations for deferral treat blood donors at risk for transmitting blood-borne infections, including HIV, in a fairer and more consistent manner, in keeping with principles for ethically well-grounded policy. The revised recommendations extend the opportunity to participate in the socially valued activity of voluntary blood donation to the widest population of donors consistent with the FDA's primary charge to ensure the safety of the blood supply. In doing so, the revised recommendations minimize unintended, ethically problematic effects of stigma and discrimination associated with lifetime deferral of blood donation by men who have sex with men (MSM).

At the same time, however, the AMA also encourages the FDA to promote additional research into behavioral factors associated with transfusion transmissible infections (TTIs), with the ultimate goal of assessing the effectiveness of individual risk assessment as a preferred strategy

for donor deferral. The ethical ideal for public policy in this area should be to transition away from policy that defers categories of persons based on attributing to all members risks associated with a population and toward policy that defers individual donors on grounds of evidence-based risk assessment. As a corollary, we encourage additional research to improve the effectiveness of donor history questionnaires as both a complement to donor education materials and a tool to identify ineligible donors in a fair and respectful manner. We strongly urge the FDA to work to further improve the important balance among ensuring health equity, engaging with high-risk populations, and protecting the safety of the blood supply.

We applaud the draft revised recommendations for recognizing that blood donation is a “teachable moment” at which to educate prospective donors about the risks of TTIs to themselves and others, as well as the importance of self-deferral in the FDA’s overall strategy for protecting the blood supply. We urge the FDA to provide more specific guidance for industry; however, with respect to key issues that should be addressed in donor education. Research has shown that MSM donors fail to self-defer for a variety of reasons. These include believing their own blood is low risk, discounting sexual experiences that would bar donation, placing undue confidence in the reliability of blood screening, and being unaware of or misunderstanding deferral criteria.^{1,2,3} Some perceive existing lifetime deferral to be unjust.¹ Donor concerns about confidentiality, particularly about inadvertent self-disclosure in public settings of blood donation, are also important.¹ To promote self-deferral effectively, donor education must address these concerns explicitly.

We urge the FDA to encourage the blood supply community to draw on educational resources available in the HIV and public health communities and to engage these communities actively in reviewing updated donor education materials. Enhanced materials will not only serve the interests of blood safety, but can also have the added benefit of providing health education to individuals who may be most in need of it. Ensuring that information about testing and health services is available to individuals who are ineligible to donate would likewise serve broader goals of public health and individual well-being. In addition to donor education, providing a safe, private environment for self-disclosure that reduces the likelihood of stigma or embarrassment, e.g., by providing for computer-assisted donor history questionnaires, can help promote candor and self-deferral.

The AMA encourages the FDA to continue to advance public policy in this area. Identifying and acting on opportunities to enhance all components of U.S. strategy to ensure blood safety is fully consistent with the mission of the FDA and with the goal of ensuring that blood policy

¹ Grenfell P, Nutland W, McManus S, et al. Views and Experiences of Men Who Have Sex with Men on the Ban on Blood Donation: A cross Sectional Survey with Qualitative Interviews. *BMJ* 2011; 343:d5604.

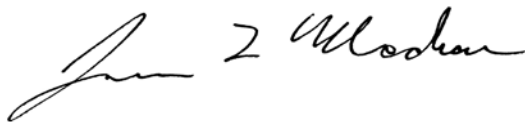
² Lee S-S, Lee C-K, Wong N-S, et al. Low Compliance of Men having Sex with Men with Self-Deferral from Blood Donation in a Chinese Population. *Blood Transfus* 2014;12:166–171.

³ Liszewski W, Becerril J, Terndrup C, et al. The Rates, Perceptions, and Willingness of Men Who have Sex with Men to Donate Blood. *Transfus* 2014; 54:1733–1738.

implements the least restrictive, most even-handed means to achieve this goal. The further development and adoption of pathogen reduction technologies as a key component of a comprehensive approach has the potential to enhance blood safety significantly.³ These technologies can address concerns about donation during the “window period,” when a TTI cannot be detected by available screening technologies, and can minimize the risk posed by emerging infections for which screening is not available. We, therefore, urge the FDA to support research in this area.

Ensuring the safety of the blood supply is of paramount importance. The AMA welcomes the opportunity to engage with the FDA in the agency’s ongoing efforts to achieve that goal through a comprehensive approach that takes advantage of emerging technologies and embodies the core principles of strong ethical policy for public health.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

⁴ Snyder EL, Stramer SL, Benjamin RJ. The Safety of the Blood Supply—Time to Raise the Bar. *N Engl J Med* 2015; 372(20):1882–1885.