July 13, 2015

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Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry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Medical Association (AMA), I appreciate the opportunity to comment on the U.S. Food and Drug Administration’s (FDA) draft guidance for industry regarding revised recommendations for reducing the risk of transmission of Human Immunodeficiency Virus (HIV) through blood and blood products.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

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1 Grenfell P, Nutland W, McManus S, et al. Views and Experiences of Men Who Have Sex with Men on the Ban on
3 Liszewski W, Becerril J, Terndrup C, et al. The Rates, Perceptions, and Willingness of Men Who have Sex with
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.¹ 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,

James L. Madara, MD

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