AMA
AMERICAN MEDICAL ASSOCIATION

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Bryan Emery
Center for Biologics Evaluation and Research
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Blood Products Advisory Committee Meeting [Docket No. FDA-2014-N-1617]

Dear Mr. Emery:

Please find attached a copy of the most recent position statement of the American Medical Association (AMA) on the issue of the current blood donor deferral policy for men who have had sex with another man (MSM) even one time since 1977. It reflects the official policy adopted by the AMA's House of Delegates based on reports and analyses developed by the AMA's Council on Science and Public Health and the Council on Ethical and Judicial Affairs. This statement is submitted for consideration by the Food and Drug Administration's Blood Products Advisory Committee, in conjunction with the meeting scheduled for December 2-3, 2014, at which the Committee will meet in open session to hear scientific data related to the reconsideration of the current blood donor deferral policy for MSM.

Sincerely,

James L. Madara, MD

Attachment

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Statement of the

American Medical Association

on

Blood Donation by Men Who Have Sex with Men (MSM)

The American Medical Association (AMA) is pleased to submit this statement for the Food and Drug Administration's Blood Products Advisory Committee meeting. The AMA strongly supports, on both scientific and ethical grounds, eliminating current public policies that require lifetime deferral of blood donation by men who have sex with men (MSM). This position was adopted by the AMA's policy-making body—the House of Delegates—after its careful consideration of two key reports by AMA councils addressing the lifetime deferral issue.

In 2008, a report by the AMA's Council on Science and Public Health concluded that a change in policy relating to blood donation by MSM was scientifically supportable, "based on [then-existing] scientific evidence and risk assessment models." Three years later, in a 2011 report on the ethical and social implications of deferral policy, the AMA's Council on Ethical and Judicial Affairs (CEJA) observed that policies intended to anticipate and prevent harm to the public, such as policies governing blood donation, must be both scientifically *and* ethically sound. In CEJA's view, mandatory lifetime deferral of blood donation by all men who have sex with men is not ethically sound. Policy adopted by the AMA's House of Delegates in 2013 supports revising existing policy and practice designed to ensure the safety of blood products, and states that "our AMA supports the use of rational, scientifically based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their level of risk and opposes the current lifetime deferral on blood and tissue donations from men who have sex with men."

Donor screening and deferral based on responses to questions about risk behaviors is one part of a more complex approach to protecting the blood supply. When donated blood can be tested directly, risk behaviors are not relevant—each infected donor poses the same detectable risk outside the "window period" for transmission of the given disease. Current policy mandates screening of all donated units by nucleic acid testing, which can identify infected units within 11 days of transmission of HIV.

Current screening questions are not able to distinguish between individuals who are at lower or higher risk for infection in categories of "at risk" donors. Current deferral policies permit some potentially high risk donations while preventing some potentially low risk donations. For example, gay or bisexual men known to be HIV-negative who are in monogamous same-sex relationships are prevented from donating blood, yet a woman with multiple sexual partners of unknown status, who thus should be considered high risk, is not deferred because screening questions do not target this behavior.

Moreover, behavioral screening questions de facto define categories of persons. Questions that pick out behaviors that are socially disvalued, such as intravenous drug use or male same-sex sexual activities, can reinforce negative stereotypes and stigma. Prohibiting MSM from donating blood sends a demeaning message that all gay or bisexual men should be treated as if they have HIV. Further, mandatory deferral of donation prohibits MSM from engaging in the socially valued activity of donating blood.

Current U.S. policy requiring deferral of donation by men who have sex with men does not meet the condition of treating like risks alike. Rather, the policy construes HIV/AIDS as a uniquely serious threat to recipients of blood products. This policy fails to recognize significant advances in treatment for HIV. To justify treating HIV differently from other blood-borne diseases, for example, Hepatitis C, as a matter of public policy requires comparing not only relative risk of transmission, but also the relative morbidity and mortality associated with each condition and the availability, cost, and burden to patients of treatment.

Current U.S. policy and practice with respect to screening and deferral of blood donors fails to treat comparable risks to blood safety in a consistent manner, may unduly restrict the opportunity of some populations to engage in the socially valued activity of blood donation, and perpetuates unfair stereotypes even if it is not discriminatory in intent.

November 2014