

March 4, 2010

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write today to express our concerns regarding outdated, medically and scientifically unsound deferral criteria for prospective blood donors. With hospitals and emergency rooms across the country in constant and urgent need of blood products, we believe certain blood donor deferral policies should be reviewed and appropriately modified and modernized while ensuring the blood supply meets the highest possible standards that we all expect in America.

The American Red Cross, America's Blood Centers, and AABB reported before an FDA-sponsored workshop on March 9, 2006 that the ban on men who have had sex with other men (MSM), even once, since 1977 from ever donating blood "is medically and scientifically unwarranted." Then in 2008, the Council on Science and Public Health at the American Medical Association also advocated modifying the lifetime deferral requirement for MSM. We all recognize the practical and well-intentioned origins of this ban, first established in 1983 at the height of the HIV/AIDS crisis when modern screening procedures and advanced testing methods for HIV were yet to be developed. Standards and selectivity is of course necessary to protect the blood supply.

We live in a very different country than we did in 1983. Today, the high-risk behaviors associated with HIV contraction are more fully understood and dramatic technological improvements have been made in HIV detection. Collecting facilities now screen all donors for history of certain high-risk behaviors, and FDA regulations determine that all donated blood be analyzed by two highly accurate screening tests; one for antibodies to HIV-1/2 and HIV-1 Group O variants, and the other for the actual sequences of the virus using molecular technologies. As a result, the blood banking community believes that the lifetime deferral is no longer necessary to protect the integrity of the blood banks.

It is our understanding that there is a window period of up to three weeks following a person's initial exposure to HIV during which infection may be missed by the blood tests. It is this window period that rightfully serves as the scientific basis for a deferral period for prospective donors deemed to be of high-risk for HIV. Similar approaches and deferral periods are used to prevent window-period transmission of Hepatitis B and Hepatitis C by blood transfusion. However, there is a clear and unscientific double standard embedded in the current deferral rules for potential exposure to HIV.

Reflecting the dangers associated with the window period, prospective donors who have engaged in heterosexual sexual activity with a person known to have HIV are deferred for one year. At the same time, male donors who engaged in protected homosexual sexual activity with a

monogamous partner 26 years ago are deferred for life. The FDA-imposed lifetime ban for men who have sex with men does not fall in line with the one-year deferral required for high-risk heterosexual behavior, nor does it correspond in any way to the window period. The ban also does not distinguish between safe and unprotected sexual activity. As a result, healthy blood donors are turned away every day due to an antiquated policy and our blood supply is not necessarily any safer for it.

With the safety of the blood supply as our top concern, our examination of the deferral process has brought to our attention a second issue that we believe requires your consideration. It is our understanding that there are rapidly rising rates of new HIV infections among certain segments of the heterosexual population. While the screening and testing procedures are rigorous for certain high-risk behaviors, there is no expressed concern with unprotected heterosexual sex during the window period in which the administered HIV tests are unreliable. Unprotected sexual activity, whether homosexual or heterosexual, is recognized as a significantly higher risk behavior for HIV transmission than protected sexual activity. We urge you to take this important distinction into consideration when reexamining possible changes to deferral policies.

The safety, availability, and integrity of our nation's blood supply are vital. For these reasons, we agree with the American Red Cross, America's Blood Centers, AABB, and others that the time has come for the FDA to modify the lifetime deferral for MSM to be consistent with sensible health and safety policy and with FDA deferral guidelines for high-risk heterosexual behavior. We request that you initiate a review of the lifetime deferral requirement for men who have sex with men wishing to donate blood and that you reexamine the deferral criteria for all blood donors to ensure all high-risk behaviors are appropriately addressed.

Thank you for your leadership in promoting public health and safety. We look forward to working with you on this issue.

Sincerely,

John Kerry
United States Senator

Kirstin Gillibrand
United States Senator

Dick Durbin
United States Senator

Daniel Akaka
United States Senator

Sheldon Whitehouse
United States Senator

Sherrod Brown
United States Senator

Frank Lautenberg
United States Senator

Bob Casey
United States Senator

Bernie Sanders
United States Senator

Russ Feingold
United States Senator

Mark Udall
United States Senator

Al Franken

United States Senator

Maria Cantwell
United States Senator

Carl Levin
United States Senator

Tom Harkin
United States Senator

Mark Begich
United States Senator

Rolland Burris
United States Senator

Michael Bennet
United States Senator