

## FDA Remains Firm on Lifetime Blood Donor Deferral for Gay Men

The Food and Drug Administration has rejected arguments in an April letter by seven members of Congress who asked the agency to reconsider the lifetime blood donation deferral for gay men in favor of a one-year deferral policy.

In March, Rep. Diane Watson, (D-Calif.) circulated the letter to fellow lawmakers and then sent it to both acting FDA Commissioner Frank M. Torti, MD and new FDA Commissioner Margaret Hamburg, MD. The letter said the behavior-based blood donation deferral policy “relies on generalizations to justify a double standard for MSM [men who have sex with men] compared to heterosexual donors who engage in high-risk sexual activities.” Other co-sponsors were Reps. Raul Grijalva (D-Ariz.), Jerrold Nadler (D-N.Y.), Michael Honda (D-Calif.), Luis Gutierrez (D-Ill.), Robert Wexler (D-Fla.), and David Price (D-N.C.)

On Monday, Rep. Watson received a response from Stephen R. Mason, acting assistant commissioner for Legislation at FDA, stating that the policy is based on risk alone but the agency will “continue to reevaluate donor deferral policies as new data become available.”

“A current risk assessment model suggests that adoption of even a conservative five-year deferral for MSM might result in up to one to two additional HIV transmissions per year,” the letter said. “This would represent approximately a 17-34 percent increase over the current rate of transmission of HIV through the blood supply.”

He also pointed out that some “patient groups who represent a significant number of blood product recipients (e.g., the National Hemophilia Foundation and the Committee of Ten Thousand) also support continuing the present policy at this time” and that it is consistent with the policies of many other countries.

Rep. Watson’s letter argued that a one-year deferral policy has been successfully implemented in several countries with no indication of an increased risk of HIV transmission.

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### Gay Deferral Still an Issue At California Universities

University of California Berkeley’s student senate last month passed a bill labeling the current Food and Drug Administration deferral policy for gay men “discriminatory.” The bill contains a provision that will no longer permit Associated Students of UC (ASUC) Berkeley funds to go toward blood drives, though the drives are still allowed to take place on campus.

The action comes in the wake of a blood drive ban by California State University San Jose’s administration on the basis that the FDA ban violates the university’s nondiscrimination policy.

Though UC Davis has yet to pass such a regulation at either the student government or administration level, there is tension regarding current practices. “Nobody is against blood drives,” said ASUCD Senator Mo Torres, who spoke against discriminatory blood drives in his fall election campaign. “[But] to uphold the UC Davis Principles of Community, we must ensure that organizations do not come onto our campus and discriminate against our students.”

By banning men who have sex with men, regardless of the individual’s HIV status, the FDA “creates the illusion that the blood will be safer because of it,” he said. “However, under the current policy, a man who exclusively has sex with women but is extremely promiscuous and engages in risky sex practices – without protection – is able to donate with no problem. How is that individual at any lesser risk for HIV than a man who exclusively has sex with men, but is in a monogamous relationship and always uses protection?”

BloodSource, based in Sacramento, conducts most UC Davis on-campus drives. In response to such questions, the blood center is working with the federal and state authorities to find funding to conduct more research, said Leslie Botos, vice president of Public Affairs at BloodSource.

Research is being conducted in the UK questioning whether gay men are at a greater risk for such diseases, Ms. Botos said. “If this deferral changes without science to guide it; [and] *if* the emotional voices are wrong and *if* indeed men who have had sex with men are at a greater risk for getting HIV and then passing it on if they were a donor – it would set back every bit of progress made by the gay community since 1985,” Ms. Botos said. “I don’t think anyone in that community would want that to happen.” (Sources: *The Daily Californian*, 5/6/09; *The California Aggie*, 5/26/09)

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Jillian Schlotter, legislative assistant for Rep. Watson, said the FDA letter probably will not settle the matter.

In 2006, America's Blood Centers, the American Red Cross, and AABB asked FDA to review the policy, and proposed deferring MSM within 12 months of sexual activity. They argued that the likelihood of receiving a unit of HIV-infected blood was one in 2 million and that blood centers now use nucleic acid testing, which detects HIV and hepatitis earlier than older testing methods. (Source: GalleryWatch, Watson letter, accessed 5/21/09)