

NOVEMBER 13, 2003

SCHAKOWSKY CALLS ON FDA TO LIFT LIFETIME BAN ON BLOOD/BONE MARROW DONATION BY GAY AND BISEXUAL MEN
WASHINGTON, D.C. - In a letter to the Food and Drug Administration (FDA), U.S. Representative Jan Schakowsky (D-IL), a member of the Energy and Commerce Committee, expressed her concern about the *"antiquated and discriminatory system of screening for blood donors,"* adding that banning gay and bisexual men from donating blood *"appears to be a case of ideology being placed before science."*

Schakowsky questioned why a *"gay man in a monogamous relationship poses the greatest risk and should be singled out for a lifetime ban on blood donation,"* while a *"heterosexual man who has visited prostitutes or has had intercourse with an HIV positive individual, is only banned for 1 year."*

Schakowsky called on the FDA to provide *"the scientific basis upon which the FDA is basing the lifetime ban on blood donations from HIV-negative gay and bisexual men,"* especially when Nucleic Acid Testing (NAT) for HIV has cut the window of time between infection and detection to a matter of days.

In the letter, Schakowsky explained that this issue was brought to her attention by *"one of my constituents, a gay HIV-negative man who has been in a committed, monogamous relationship with another HIV-negative man for 12 years."*

□ □ The constituent, who was a potential bone marrow donor for a five-year-old boy in need of a life-saving transplant, was turned away because he is a gay man and is banned for life from donating blood.

"Lifting the ban on gay and bisexual men would result in an estimated 62,300 additional blood donors," Schakowsky wrote. □ She concluded, *"Unless you can provide me with scientific data that justifies the lifetime ban on blood donations from gay and bisexual men, I remain convinced that the ban should be lifted so that the eligible pool of potentially life-saving donors may be expanded. □ Given the urgency of this situation, I look forward to your response by November 24, 2003."*

Below is Schakowsky's letter to FDA Commissioner Mark McClellan:

November 10, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Dr. McClellan:

I am writing to express my concern at what appears to be an antiquated and discriminatory system of screening for blood donors. We must ensure that our blood supply is safe, and at any time, 30-40 percent of the American public is prohibited from donating blood during the time in which they might pose a risk. Persons with cold or flu symptoms are banned until symptoms abate; persons recently undergoing dental work are banned for 72 hours; persons with tattoos are banned for 12 months. One group that is singled out and banned for life from donating blood is gay and bisexual men. This appears to be a case of ideology being placed before science and the result may have serious consequences for numerous patients in need of blood product donations.

Please provide me with the scientific basis upon which the FDA is basing the lifetime ban on blood donations from HIV-negative gay and bisexual men. In the absence of scientific evidence in support of this policy, I strongly believe that the FDA should reconsider the ban so that the pool of eligible, potentially life-saving donors can be expanded.

This issue was brought to my attention by one of my constituents, a gay HIV-negative man who has been in a committed, monogamous relationship with another HIV-negative man for 12 years. He was contacted to be a potential bone marrow donor for a five-year-old boy in need of a life-saving transplant. He began the process of testing to determine whether he would be a match. However, the day after filling out his health questionnaire, he was told that no further testing would be done because he was a "man who has had sex with another man, even once, since 1977." Because he is a gay man, he has been banned for life from donating blood and bone marrow. As a result, the five-year-old boy may have to wait for the transplant that can save his life.

I understand the importance of ensuring a safe blood supply. During the late 1970's and early 1980's, the early years of the HIV/AIDS epidemic, gay men were discouraged from donating blood, and in 1985, the FDA turned this recommendation into regulation. At the time, those recommendations and regulations were prudent. Now, over two decades into the HIV/AIDS epidemic, we have a greater understanding of HIV and much has changed in the ways in which we approach the epidemic. However, the FDA's position on blood donations from gay men has not changed.

We are in a very different place today than we were twenty years ago. Today, Nucleic Acid Testing (NAT) for HIV has cut the window of time between infection and detection to

a matter of days. Whereas antibody testing can take weeks or months to detect HIV antibodies in the blood, NAT takes as little as 4 to 5 days to detect HIV RNA. Moreover, blood banks have been using NAT since 1999. The American Association of Blood Banks, whose facilities collect virtually all of the blood donated in America, requires its members to use NAT. As such, we can be certain, within a few days, that blood donations are safe.

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The advent of NAT technology represents an important step in ensuring a safe blood supply and an opportunity to reexamine FDA regulations that are almost 20 years old and clearly out of date. HIV is no longer a "gay disease." HIV affects all segments of society, with the rates of new HIV infections rapidly increasing among heterosexuals. Every unit of blood collected has the potential to be HIV-positive, which is why NAT is crucial. The targeting of gay men for a lifetime ban on blood donation does not appear to be scientifically sound at this point in time. Rather, this ban appears discriminatory and supportive of the false stereotype that HIV affects only gay men.

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A gay man who has consistently tested negative for HIV and who has had only one protected sexual encounter with another man can never donate blood. However, a heterosexual man who has visited prostitutes or has had intercourse with an HIV positive individual, is only banned for 1 year. A woman whose HIV serostatus is unknown and who has engaged in risky sexual acts with multiple partners is not banned at all. I am aware of no scientific evidence proving that, out of these three scenarios, the gay man in a monogamous relationship poses the greatest risk and should be singled out for a lifetime ban on blood donation.

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Most troubling is that, if there is no scientific justification for a lifetime ban, this policy may be preventing persons in need of bone marrow transplants from receiving available help they need to survive. It is estimated that more than 30,000 people are diagnosed with fatal blood disorders annually. Approximately 30 percent of those patients have compatible family donors. The remaining 70 percent must rely on unrelated donors, and finding a match is often difficult. As a result, patients may die due to the absence of a compatible marrow donor. This lack of compatible donors is made more severe by the lifetime ban on gay men. Like the five-year-old boy who will not be able to benefit from my constituent's bone marrow donation, patients will continue to search for donors from an unnecessarily limited pool. It is this limited pool that could be the difference between life and death for patients with fatal blood disorders.

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I am not alone in my desire to see FDA policies changed. Both the American Association of Blood Banks and America's Blood Centers support lifting the lifetime ban on donations from gay and bisexual men. FDA's own Blood Products Advisory Committee narrowly voted against changing the policy, with a 7-6 vote and five members absent.

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The advances in blood-screening technology have furthered the safety of our blood supply and we no longer need to deny those suffering from fatal blood disorders because of unscientific bias in donor eligibility policy. Lifting the ban on gay and

bisexual men would result in an estimated 62,300 additional blood donors. This significant increase would help to decrease our blood shortage and likely increase the pool of bone marrow donors.

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Unless you can provide me with scientific data that justifies the lifetime ban on blood donations from gay and bisexual men, I remain convinced that the ban should be lifted so that the eligible pool of potentially life-saving donors may be expanded. Given the urgency of this situation, I look forward to your response by November 24, 2003.

□

Sincerely,

□ □

**Jan Schakowsky
Member of Congress**