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The Washington Blade

SERVING THE NATION'S CAPITAL SINCE 1969

FDA may develop strict rules on Gay sperm donations

by Peter Freiberg

The U.S. Food and Drug Administration (FDA) is considering promulgating regulations for sperm banks that would ban Gay men from being anonymous donors and make it more difficult for Gay men to father children with a woman they already know, according to a group of activists and sperm bank directors.

In a May 17 letter sent to 300 Gay and alternative publications, the authors of the letter say the regulations under consideration would bar any man who has had sex with another man in the preceding five years from being an anonymous sperm donor.

The FDA proposals would have an impact not only on anonymous donors but also directed donors — men who wish to father a child with a woman they know and who

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FDA may prevent Gay men from donating

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have tested negative for HIV and other diseases — as well as Lesbians, many of whom prefer known donors to be Gay men, according to sperm bank officials.

Currently, there is no requirement for freezing and quarantine of the sperm donation of a directed donor, and fresh (unfrozen) sperm can be used. But the rules being considered would require both Gay and straight directed donors to have their sperm frozen and quarantined for six months, and then be re-tested for HIV before their sperm can be used. According to the letter writers, only one in six men have sperm strong enough to survive the freezing process well enough to be useable for insemination. Applying the proposed test-freeze-quarantine-test rule on directed donors, too, they said, would "effectively prevent" 84 percent of Gay male directed donors "from the possibility of having children." (The sperm of those 84 percent might be made suitable for insemination, noted the letter writers, but only through expensive high-tech methods.) "Under these regulations," the authors say, "heterosexual men may have multiple sexual partners and be acceptable. However, Gay men in a long-term, mutually monogamous relationship would not."

Currently, there are no national regulations governing sperm donors, only guidelines from the Centers for Disease Control and Prevention (CDC). Fertility industry standards, according to the letter's authors, require anonymous donors to be tested for HIV antibodies, after which their sperm donations are frozen and quarantined for six months. Donors are then re-tested for HIV antibodies before their sperm is released for insemination.

The HIV "window period" — the time between the moment HIV enters a person's body and the person's immune system begins to produce antibodies to HIV (and, thus, tests positive on the HIV antibody test) — is one to three months. That, the letter notes, is much less than the six-month quarantine for sperm. If the sperm donor tests negative on both tests, then the retest confirms with considerable certainty that the original sperm donation was HIV-negative.

"In light of the effective screening procedures already in place," the letter says, "and because there is no scientific or medical basis for excluding Gay donors, such a ban would be discrimination."

In a 40-minute interview yesterday with the *Blade*, FDA officials confirmed that a proposal drawn up the agency — and which must be approved by Health and Human Services Secretary Donna Shalala before being announced — would bar men who have had sex with men in the last five years from being anonymous donors.

In explaining why FDA is considering the regulations, Dr. Jay Epstein, of the FDA's Center for Biologics Evaluation, said the incidence of sexually transmitted diseases (STDs), including HIV, is still "very high" among Gay men.

But Epstein asserted, "We do not ban a class of people. We ban individuals who have particular behavior risk histories. There's no categorical labeling of the pop- we're focusing on behavioral risk factors that are established in the scientific literature."

Epstein said the FDA believes that a combination of screening — to exclude Gay men and other high-risk individuals, like men who have had sex with prostitutes in the previous five years — followed by testing of sperm donors who have made it through the screening process is the most

Leland Traiman said the directed donor rule would "affect Gay people much more than straight people."

effective way to bar transmission of STDs, including HIV.

"We want the best possible screening and we want the best possible testing," Epstein said.

But the authors of the May 17 letter argue that screening out all Gay men as anonymous donors, including healthy ones, is discriminatory. One signer, Maura Riordan, executive director of the Sperm Bank of California in Berkeley, a nonprofit facility where two-thirds of the clients are Lesbian, says the rules being weighed by the FDA would mirror those of the most restrictive state in the country, New York.

"By saying that, even if a man tests negative and his samples are screened and cleared, that we still can't use him," Riordan says, "even if he's participating in mutual masturbation with another man, that doesn't make sense to me."

Kate Kendell, executive director of the National Center for Lesbian Rights, also signed the May 17 letter.

"The folks at the FDA would have to have never read a newspaper in 20 years or be hopelessly ignorant and misguided, to think that excluding Gay men as donors in any way makes a sperm bank any more safe," said Kendall.

Leland Traiman, owner and executive director of Rainbow Flag Health Services and Sperm Bank in Oakland, Calif., and the organizer of the May 17 letter, said the directed donor rule being considered would "affect Gay people much more than straight people." The reason, Traiman said, is that the proposed regulations exempt from quarantine and freezing donations from sperm donors who are sexually intimate with the woman who is to receive the sperm donation.

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FDA sperm ban denounced

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Since very few Gay men are sexually intimate with the women they want to donate sperm to, Traiman says, their sperm would have to go through "this freezing and quarantine period, which only one out of six men's sperm survives."

The FDA's Epstein defended the six-month freezing, quarantine, and retesting requirement for directed donors, saying it is not sufficient to rely on sexual histories given by prospective donors, even if that donor tests negative for HIV when he first donates sperm.

"Say you are a Gay man," he says. "You donate for your known Lesbian friend. The problem may be that the partner of the semen donor has had an affair; this may be unknown to the sperm donor." The donor could test negative, but that could be because the test is given in the "window period."

Traiman and others maintain that the fact that the donor and recipient know and

Maura Riordan of the Sperm Bank of California said that the FDA's rules would mirror those of New York state.

trust each other and that the donor tests HIV-negative affords sufficient protection against HIV transmission and is reason enough for the FDA to refrain from intruding into the private family planning arrangements of the two people.

But Epstein disagrees.

"We have to make tradeoffs," said Epstein. "The tradeoff here is that we're protecting hundreds of thousands of women, probably against a fairly low risk ... but the risk is not zero, and it can be significantly lowered by quarantine and retest."

In addition to Traiman, Riordan, Kendell, the letter was signed by Robert Kim of the American Civil Liberties Union of Northern Califorinia and Jennifer Pittman, policy and program associate at the Gay and Lesbian Medical Association.

Once the FDA proposal is published in the *Federal Register*, the public will have the opportunity to comment before the regulations are adopted. Epstein said the agency would be "open" to making changes, but he said he did not know when the regulations would be published.

"If you have data that supports arguments, we tend to be more swayed [by data] than we are by opinions."

The FDA, Epstein asserts, has "understood and sought to address the concerns of the Gay male and Lesbian community. We do not think the six-month quarantine [for directed donors] is scientifically unsound, or that it creates an unreasonable burden."

Christopher Anders, the ACLU's legislative counsel in Washington, says that in the April *Federal Register* the FDA gave a target date of June 1999 for formally proposing regulations that will include suitability of sperm donors.

Anders says the FDA has long been examining ways to regulate the sperm bank process. He says it is premature to comment on any possible FDA proposal.

"This is an extremely early stage in the rulemaking process," Anders says. "The FDA has not put out a proposed rule yet; when they do, there will be plenty of time for health care groups, for Gay/Lesbian groups and anyone else ... to comment.

"Agencies are very often very willing to say they didn't get it right the first time," Anders says. "We'll be working, as will a lot of people, to encourage them to get it right."

But the letter signers are trying to head off the FDA before the proposal is published. "At that point, it's already kind of late in the game," says Kim. "The key is to really have the public involved before something gets set in stone for comment."

Even without national regulations, there are only two sperm banks in the country that accept Gay men as donors, activists say: Traiman's for-profit facility, which primarily serves Lesbians wishing to get pregnant, and the Sperm Bank of California, where an estimated two thirds of the 300 to 400 women who come through the doors each year are Lesbian.

A major reason why most sperm banks bar Gay men, Traiman says, are the CDC's 1994 recommendations. These guidelines state that "regardless of their HIV antibody test results," men who have had sex with another man in the preceding five years should be excluded from donating organs or tissues, including sperm.

Among the states, only New York flatly bans Gay men as sperm donors, according to Riordan, although Maryland also places restrictions. But because New York women are such a large potential client pool, many sperm banks are licensed by New York and agree not to accept any Gay men as donors, says Riordan.

That policy, says Kendell of the National Center for Lesbian Rights, has made it very difficult for Lesbian couples — many of whom want to use Gay men as donors — to use a Gay male directed donor through a facility where the sperm is tested, frozen and retested.

"They end up using fresh sperm or sperm from a known donor who was not able to go through the testing," entailing "perhaps some risk," says Kendell.

Like other sperm banks, the 17-year-old Sperm Bank of California went along until a few months ago with New York's ban on Gay donors. But Riordan says the state has now agreed that as long as she doesn't ship Gay donors' sperm samples to New York, she can keep her New York license, which she says "is seen as prestigious in the industry."▼

HHS NEWS

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REINVENTING THE REGULATION OF HUMAN TISSUE

The Food and Drug Administration today announced a plan for a new, comprehensive regulatory framework for products derived from cells and tissues that would protect the public health through innovative common-sense government oversight. Today's proposal is the FDA's sixth reinvention reform as part of the Clinton Administration's Reinventing Government Initiative.

"This new regulatory framework, developed after discussions with industry, academics and professional groups, will allow greater flexibility and innovation in this promising field of medicine," said Vice President Al Gore. "At the same time, safeguards are maintained to protect the public health."

"Human tissues have wide uses in medicine, including skin replacement after severe burns, tendons and ligaments to repair injuries, and corneas to restore eyesight," said HHS Secretary Donna E. Shalala. "Now that science is providing even more new ways of using tissues, FDA has developed an innovative regulatory approach to allow these novel products to benefit patients as soon as possible."

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In recent years, scientists have developed innovative methods of manipulating and using human cells and tissues for therapeutic purposes. For example, using somatic cell therapy, scientists are studying how to manipulate and use human cells to treat viral infections (including HIV), Parkinson's disease, and diabetes. Other tissue research includes the treatment of diseases and medical conditions by using "cord blood" (from the placenta and umbilical cord) and processed structural cells and tissues.

This new regulatory framework, which provides a tiered approach with the level of regulation proportionate to the degree of risk, focuses on three general goals:

- preventing the unwitting use of contaminated tissues with the potential for transmitting infectious diseases;
- preventing improper handling or processing that might contaminate or damage tissues;
- and ensuring that clinical safety and effectiveness are demonstrated for certain cells and tissues. These include highly processed tissues, as well as those that are used for other than their normal purposes, those that are combined with non-tissue components, and many that are used for metabolic purposes (such as to treat diabetes).

This tiered approach will impose little or no regulation for some products, with the degree of oversight increasing with the potential risk, so that extensively processed and novel products

would require FDA's approval before they could be marketed. All tissue processing facilities would be required to register with the FDA and to list their products, and all labeling and promotion of these products would have to be clear, accurate, balanced, and non-misleading.

In designing this new approach, FDA focused on five broad public health and regulatory questions: (1) How can the spread of communicable diseases be prevented? (2) What processing controls are needed to prevent contamination and preserve the integrity of cells and tissues? (3) How can clinical safety and effectiveness be assured? (4) What labeling is necessary, and what kind of promotion is permissible, so that the product may be used properly? and (5) How can FDA best monitor and communicate effectively with the cell and tissue industry?

The following examples show how the tiered approach would work:

- FDA would not regulate cells and tissues removed from and transplanted into the same person in a single surgical procedure.
- For most conventional and reproductive tissues that are minimally processed and used for their normal functions, FDA's oversight would focus on proper handling and on ensuring that the products are not infectious.

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Registration, product listing, and adverse event reports would be the only submissions required.

- FDA would require that all tissues (except those removed and transplanted back into the same patient in one surgical procedure) be handled according to "good tissue practices." FDA would also prescribe procedures for testing the tissue for infectious agents and screening the donor about potential exposure to disease agents.
- For tissue stored for use in the same person from whom it was obtained (or in a sexually intimate partner of a reproductive-tissue donor), FDA would recommend but not require that similar testing and screening procedures be followed. To protect health care workers, FDA would also require labeling according to whether the tissue poses a potential biohazard.
- For most tissue transplanted from one person to another, FDA would require infectious disease testing, donor screening, and processing controls.
- For some tissues, FDA would require controlled clinical trials and pre-market approval to demonstrate safety and effectiveness. This requirement would apply to tissues and cells processed to alter their biological or functional characteristics; tissues and cells used to perform other than their normal functions; many tissues and cells used for

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metabolic purposes; and tissues and cells that are combined with medical devices, drugs, or other biological products. Somatic cell therapy and gene therapy would be covered by this category of regulation, as would many forms of stem cell therapy.

FDA's current regulation of unmodified or minimally modified tissues that traditionally have been used for replacement purposes (such as bone replacement) focuses on preventing the spread of communicable disease. In December 1993, FDA issued an interim final rule that required the testing of tissue donors for certain transmissible disease such as HIV infection and hepatitis, as well as the screening of donors for behavioral risk factors. FDA intends to finalize these requirements soon. finalized The requirements for this new regulatory framework would be phased in over the next two to three years.

The new regulatory framework does not include whole organs or minimally-manipulated bone marrow, which are both regulated by the Health Resources and Services Administration. It does not cover blood products -- such as whole blood, red blood cells, platelet and plasma -- for transfusion or animal-derived tissues, which FDA regulates under existing authorities. Additional products covered by other regulations and standards include human milk, collagen, and growth factors.

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