

Rainbow Health Services

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
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Comments on:

Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

It is a sad fact that, from time to time, the FDA abandons science and simple reason for politics. In doing so the FDA abandons it's role to safeguard the health of our citizens and jeopardizes public health with misinformation. The most famous example of this is the FDA's declaration that Canadian pharmacies are not as safe as American pharmacies. Not only do they have no scientific evidence to support their claim, it is so far beyond reason that, thankfully, our average citizen dismisses it out of hand. Indeed, several States governments have ignored the ban and Vermont is suing the FDA over this.

So it is with this Guidance document when it declares a ban on Gay sperm donors. Thankfully, the FDA, realizing the case for this position was scientifically nonexistent, has not put this in a regulation, which has the force of law, but a Guidance document, which is not legally binding. Nonetheless, this document is an intimidation tool designed to mislead the public by perpetuating bigotry. The most potent arguments against this proposal are from scientists from the Centers for Disease Control as well as testimony the FDA itself presented before their own Blood Products Advisory Committee and the FDA's failure to have their own Advisory Committee sustain their position. Equally compelling, a United States Supreme Court ruling which would invalidate the FDA's assertion if it had been in a regulation with the force of law.

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All sperm banks initially test donors, freeze the donor's sperm for six months, then retest the donor's blood after the six months quarantine before the sperm is used for insemination. If a person is infected with HIV, hepatitis or syphilis it may take as long as three months to show up in a blood test. Sperm banks keep sperm in quarantine for six months. If a donor is negative six months after donating then we are sure he was not infected at the time he donated. This two -phase testing scenario is a universal precaution used on all donors. Common sense suggests this works equally well regardless of one's sexual orientation. Common sense is correct. Tom Spira, M.D., Assistant Chief for Medical Science for the CDC, said, "I would not, categorically, want to exclude them (gay men) since we have appropriate testing. If you do so, I believe, you gain a false sense of security." Charles Schable, Chief of the AIDS Diagnostic Laboratory at the CDC, said, "If one is freezing the sperm and retesting the donor after six months the only reason to apply that criterion (banning Gay donors) of semen donors is homophobia." (Since making that statement Charles Schable has been promoted within the CDC.)

In December 1997 the FDA's Blood Products Advisory Committee discussed the possibility of allowing Gay men to be blood donors from which they are presently banned. Unlike sperm, blood cannot be frozen for long periods, so the absolute safety of a sperm bank's two-phase testing cannot be used. The FDA's own expert witness, Andrew Dayton, MD, PhD, said that if blood banks were to use a "two-phase testing scenario" on Gay blood donors, "This would basically have the effect of dropping the (HIV) prevalence problems to zero." The "two-phase testing scenario" Dr. Dayton described was less stringent than the one presently used by sperm banks.

In December 2001 the FDA's Blood Products Advisory Committee had six hours of presentations about the issue of Gay men being sperm donors. All the invited speakers were given at least one hour to present their point of view. Only the FDA could invite speakers to make presentations. I was the only invited speaker whose name was not on the agenda. At the meeting I was told that I would be limited to ten minutes during the public comment section. The Committee failed to sustain the FDA's position against Gay sperm donors. Indeed, the Committee tried to go outside its usual practice and a motion was made that Gay sperm donor be allowed. However, statements by FDA employee, Jay Epstein, gave the impression that this issue would be brought up again at a later date for a vote and the motion was withdrawn. The meeting was abruptly adjourned cutting off discussion. Jay Epstein has since stated there is no plan to bring the subject up again. Please read the meeting transcript to verify this account.

Finally, the FDA denies that they are targeting Gay men for discrimination. Indeed, their Guidance language never mentions Gay or homosexual men. Instead it says "men who have had sex with another man" (aka MSM's) should be excluded. The FDA

has consistently said, "Excluding MSM's does not discriminate against Gay men but simply excludes certain behaviors." Like the argument against Canadian pharmacies, the average citizen dismisses this argument as silly. Engaging in sex with another man is what defines Gay men. To state this does not discriminate against gay persons as a class is absurd. Supreme Court Justice Sandra Day O'Connor agrees. In her concurring opinion with the majority in *Lawrence v. Texas* she writes:

"Texas argues, however, that the sodomy law does not discriminate against homosexual persons. Instead, the State maintains that the law discriminates only against homosexual conduct. While it is true that the law applies only to conduct, the conduct targeted by this law is conduct that is closely correlated with being homosexual. Under such circumstances, Texas' sodomy law is targeted at more than conduct. It is instead directed toward gay persons as a class. 'After all, there can hardly be more palpable discrimination against a class than making the conduct that defines the class criminal.'"

The FDA lists numerous reasons to deferred a donor, mostly because of possible exposure to infectious disease. Many have only a 12 month deferral period. Only three have a five year deferral, Gay men, intravenous drug abusers, and prostitutes. The Guidance would allow a heterosexual man who has had sex with an HIV infected woman to donate 12 months after his sexual encounter but would not allow a Gay man in a long term mutually monogamous relationship with an uninfected partner to donate until he had been celibate for five years. Clearly, Gay men are grouped in a punitive fashion with criminals such as IV drug abusers and prostitutes. Not only does the FDA lack any evidence for this classification on safety grounds, the Supreme Court has ruled that Gay men are not criminals.

What the FDA fails to include in the Guidance is almost as disturbing as the bigotry that is included. There is no exclusion or deferral for a history of unprotected sexual behavior with multiple partners. Nor a recent history of sexually transmitted infections such as gonorrhea and chlamydia. Interestingly, Justice O'Connor points us in the right direction again:

"When a State makes homosexual conduct criminal, and not 'deviate sexual intercourse' committed by persons of different sexes, 'that declaration in and of itself is an invitation to subject homosexual persons to discrimination both in the public and in the private spheres.'"

To paraphrase Justice O'Connor:

When the FDA makes homosexual conduct exclusionary, and not 'unprotected

sexual behavior with multiple partners' committed by persons of different sexes, that declaration in and of itself is an invitation to subject homosexual persons to discrimination both in the public and private spheres.

Equally disturbing as perpetuating this unscientifically founded discrimination is the "false sense of security" the FDA gives the public by excluding Gay men, regardless of their behavior, while approving almost all heterosexual men, regardless of their behavior.

Clearly, what is needed is universally applicable safe sex guidelines for all donors regardless of sexual orientation. The FDA's regulations appropriately gives that responsibility to the medical director of the tissue or sperm bank. And there it should stay without further intimidation by the FDA in the guise of this Guidance.

Guidance documents do not have the force of law. Unfortunately, this Guidance document will be used as a tool of intimidation. This intimidation has already begun with the FDA itself. Days after the tissue transplantation regulations and this Guidance were released I spoke with an FDA information officer. She told me that the new regulations, released on the same day as this Guidance, prohibited the use of Gay sperm donors. It was only when I pointed out to her that the anti-Gay prohibition was not in the regulation but in the Guidance that she conceded her mistake.

I call on all medical personnel who are involved in fertility care to follow all reasonable safety precautions and screen all donors INDIVIDUALLY for their risk factors and disregard this scientifically unfounded and bigoted suggestion by the FDA. It is important to remember that Guidance documents do not have the force of law.

If the FDA and it's employees try to force medical professionals to follow this unscientific, illegal and unconstitutional Guidance as if it were regulation they will be challenged both institutionally and personally for abuse of their office as guardians of public health.

Sincerely,

A handwritten signature in cursive script that reads "Leland Traiman".

Leland Traiman, RN/FNP