



Docket No. 97N-484S

1823 '00 JAN -5 10:16

November 22, 1999

Harriet Rabb, Esq.
Marcy Wilder, Esq.
Department of Health and Human Services
200 Independence Ave. S.W.
Washington, D.C. 20201

Re: FDA Proposed Regulations

Dear Ms. Rabb and Ms. Wilder:

Thank you once again for taking the time to meet with me and my colleagues to discuss what were then the not-yet-seen proposed FDA regulations regarding suitability of donors of human cellular and tissue based products, including reproductive tissue.

On behalf of the Gay and Lesbian Medical Association, Human Rights Campaign, Lambda Legal Defense and Education Fund, Rainbow Flag Health Services & Sperm Bank, Sperm Bank of California and the National Center for Lesbian Rights, I write to address our concerns that appear borne out by the language of the proposed regulations at Federal Register Vol. 64, No. 52696 (September 30, 1999). However, we continue to labor under some disadvantage in not yet seeing the critical guidance document that will accompany the regulations. I write today to reiterate our areas of concern in the hope that the guidance document can be reviewed prior to the official notice and comment period to address the issues we raise.

As we understand it, it is the guidance that will set forth the suitability criteria for sperm donors and will codify who may be eligible for sperm donation and who will not. It remains our concern that the guidance will simply adopt, as to sperm donors, the 1994 CDC guidelines, which ban any men who have had sex with men (MSM) within the preceding five years from being blood or tissue donors. The designation of MSMs as unsuitable donors operates regardless of the results of any HIV test, the sexual behavior of the potential donor and with no accounting for the fact that the blood of the donor can be tested, and that semen, unlike other types of tissue, can be stored in quarantine for six months until the donor is retested. Simply put, we believe that the guidance should not designate MSMs as unsuitable sperm donors without adequate scientific support. Moreover, in reviewing the guidance document, the FDA should consider the reliability of current mechanisms designed to prevent the transmission of HIV through reproductive tissue donation, including the quarantine and re-test procedure.

National Office

870 Market Street

Suite 570

San Francisco

CA 94102

Telephone: 415 392 6257

Fax: 415 392 8442

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According to our information, the FDA is free to either adopt the CDC guidelines without change, or make modifications as deemed necessary and rational based on current scientific knowledge. We would encourage the FDA to evaluate separately the categorical designation of MSMs as unsuitable donors for reproductive — and only reproductive — tissue.

As we discussed in our meeting, the precautions and testing protocols that exist for reproductive tissue make it decidedly different from blood or other tissue, thus calling into question the efficacy and necessity of applying to sperm donation the same restrictions on MSM donors that apply to blood and other types of tissue donation.

We respectfully request that you prevail upon the FDA to assure the guidance document does not adopt overly stringent criteria not supported by current scientific knowledge. We appreciate your interest in this important issue. If you need any additional information or assistance please let me know.

Sincerely,



Kate Kondell
Executive Director

cc: Doni Gewirtzman (Lambda Legal Defense & Education Fund)
Barbara Menard (Human Rights Campaign)
Maureen S. O'Leary (Gay & Lesbian Medical Association)
Maura Riordan (Sperm Bank of California)
Leland Traiman (Rainbow Flag Health Services & Sperm Bank)

26 December 1999
210 Monte Diablo #303
San Mateo, CA 94401
email: leland@gayspermbank.com

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Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
email: FDADOCKETS@oc.fda.gov

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I have been asked by Kate Kendell, the author of the enclosed letter, to submit it as part of the notice and comment period for Docket No. 97N-484S. She was unable to submit it herself because of the Christmas Holidays.

Sincerely,



Leland Traiman

RAINBOW FLAG HEALTH SERVICES
LELAND TRAIMAN, R.N./F.N.P.
543 A 30th STREET
OAKLAND, CA 94609



DOCKET MANAGEMENT BRANCH (HFA 305)
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, RM 1061

Rocky
20857/0001

