

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

0775 '99 DEC 30 19:57

Re: Docket No. 97N-484S

Via Fax and US mail

December 28, 1999

Dear Docket Management Branch Officers:

On behalf of the Gay and Lesbian Medical Association, the Sperm Bank of California, and Rainbow Flag Health Services and Sperm Bank, we are writing to suggest language for the FDA to consider in formulating its final regulations of Federal Register Vol 64, No 52696 (September 30, 1999). You have received previous letters from us written in coalition with the American Civil Liberties Union, the National Center for Lesbian Rights, Lambda Legal Defense and Educational Fund and the Human Rights Campaign, however, our group felt that it was most appropriate for the medically oriented organizations to suggest specific language changes. We believe that if our suggestions are instituted the public's health will be fully protected without infringing on the civil and reproductive rights of any Americans.

Before we proceed with our suggested language we are compelled to comment that much of the problem with the regulations has arisen because of the integration of reproductive tissues with other kinds of tissue donation. Reproductive tissue donation is unique. Unlike blood and organ donation, donations of some reproductive tissue can be frozen and quarantined for extended periods of time. This makes anonymous sperm donation much safer than other types of tissue donation; a fact the FDA has yet to recognize.

More importantly, to date the FDA regulations have failed to allow for the ultimate result of reproductive tissue donation. Reproductive tissue produces children who have an inextinguishable biological connection to the donor, and this raises both ethical and civil rights considerations in a way that blood and organ donation does not. Until this omission is rectified, it is impossible for our organizations to accept the present proposal in good conscience. We hope the FDA will consider our suggestions as a possible remedy for this difficult and complicated issue.

The proposed regulations only define two types of donation: directed and anonymous. In actuality, reproductive tissue has three kinds of donation: directed and two distinct types of anonymous donation, each of which must be handled differently. Of the two types of anonymous donation, one is an anonymous donation that will forever be anonymous; and the other reveals the identity of the donor to the child and/or the mother at some point after birth. For our purposes we will refer to the latter donors as Identification Revealed Donors.

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I. Directed Donors

It is unacceptable to require Directed Donors to freeze and quarantine their semen for six months and go through retesting before their sperm can be used. The medical literature is quite clear that the freezing process dramatically decreases sperm viability and results in a marked decrease in pregnancy rates ¹. The success rate of frozen sperm with women over 40 years of age is especially poor. Moreover, female fertility can decrease rapidly after age 40 and waiting six months may mean missing their only opportunity to conceive ².

Our first suggestion refers to Directed Donors and §1271.90 (a) (2). Some have suggested that the term "directed donor" be inserted into this section along with "sexually-intimate partner." We do not find this appropriate. It is imperative that both sexually intimate partners and Directed Donors be appropriately screened. This should be required and not suggested. It is inappropriate to presume that sexually intimate partners have already been exposed to possibly infectious bodily fluids and are not in need of testing. Through the use of condoms or by engaging in sexual activity other than unprotected genital intercourse they may have escaped exposure to each other's bodily fluids. Additionally, a person infected with HIV may be unaware of their infection or may be hiding it from a partner and may not have, as yet, infected their partner. Therefore, it is appropriate to require all donors to be screened.

California's Health and Safety Code 1644.5 is a clear working example which answers all of these concerns. Using that as a model we are proposing the following replacement wording for §1271.90 (a) (2):

Reproductive cells or tissue may be donated by a directed donor or a sexually-intimate partner of the recipient for reproductive use if;

(i) the donor has been tested for relevant communicable disease agents as defined in §1271.3 (y); and

(ii) if the donor is found positive for hepatitis B surface antigen then the recipient must show immunity to hepatitis B by the presence of hepatitis B surface antibody, and;

(iii) if the donor is found positive for syphilis then it must be documented that the donor has been treated and is no longer infectious; and

(iv) if the donor and the recipient sign a document affirming that each comprehends the medical repercussions of using fresh, unquarantined reproductive tissue for conception and that each consents to it and that if any of the tests listed in (i) above are reactive that both comprehends the medical repercussions of using reproductive tissue from a reactive donor and that each consents to it. Copies of the document shall be placed in the medical records of the donor and the recipient.

In keeping with our suggestion that all donors be screened, the phrase, "Except as provided under §1271.90" should be changed to "Except as provided under §1271.90 (a) (1)" in the following places: §1271.75 (a) (1); §1271.75 (a) (2); and §1271.75 (b).

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II. Anonymous and Identification Revealed Donors

The proposed regulations state that a future guidance document will define a donor's exclusionary "risk factors." However, we are addressing this here because of repeated statements from the FDA that "men who have sex with men" (MSM) will be excluded from the donor pool. It is unacceptable that men who have had sex with another man in the last five years may be excluded from the sperm donor pool. There is no scientific justification for this given a six month quarantine period which is double the HIV window period.

At the FDA's Blood Products Advisory Committee of December 11, 1997, which discussed relaxing blood donation restrictions, Dr. Andrew Dayton M.D. Ph.D., spoke of a "two-phase testing scenario." He said that if blood banks were to adopt this scenario that "this would basically have the effect of dropping the (HIV) prevalence problem to zero." Dr. Dayton's suggested scenario is already standard practice in sperm banking facilities.

We are concerned that the FDA will borrow the text of the CDC's "Behavior/History Exclusionary Criteria" as it appears in the CDC's "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs" (MMWR, 5/20/94). These criteria exclude all tissue and organ donation from: "Men who have had sex with another man (MSM) in the preceding 5 years."

If the FDA is inclined toward classifying MSM's as donors with "risk factors" and therefore, unsuitable for most kinds of tissue donation, then we recommend the following language be adopted in the proposed guidance document: "Except for reproductive tissue which has been quarantined for 6 months and the donor retested and found negative for HIV 1 and HIV 2, men who have had sex with another man in the preceding 5 years."

The above option is our preference. However, a second option would add language to the present proposed regulations by recognizing Identification Revealed Donors as distinctly different than Anonymous Donors. This could be accomplished by clearly defining the term "identification revealed donors" under §1271.3 and inserting "identification revealed donors" in §1271.75. Suggested language to accomplish this under §1271.3 is: Identification Revealed Donors means donors of reproductive tissue whose identity is unknown to the recipient at the time of insemination but may be revealed to either the recipient and/or the child(ren) resulting from that insemination after the child(ren) is born.

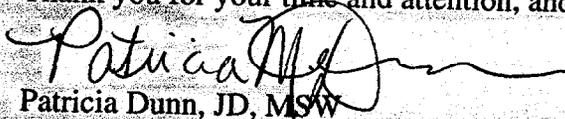
With this definition in place, §1271.75 could be changed to read (underlined is added): §1271.75 Donor screening. (a) (1) Except as provided under §1271.90 (a) (1) and except for identification revealed donors of reproductive tissue with regard to risk factors, the relevant medical records of a donor of cells or tissue for a human cellular or tissue-based product shall be reviewed for risk factors for and clinical evidence of relevant communicable disease agents and diseases including, at a minimum, the following....

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The Gay and Lesbian Medical Association, the Sperm Bank of California, and Rainbow Flag Health Services and Sperm Bank are of the opinion that open, honest dialog will strike the right balance between protecting public health and preserving reproductive choice. We have proposed these language changes to assist the FDA in accomplishing its goal of protecting public health while insuring the reproductive and civil rights of all Americans.

Please contact us if you have any questions or concerns or require additional information or documentation.

Thank you for your time and attention, and we look forward to hearing from you.



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Endnotes

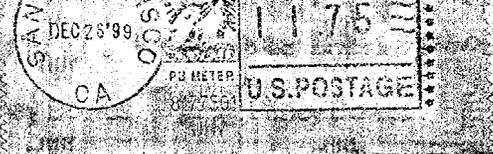
¹ See RS Sidhu et al. Effects of Cryopreserved Semen Quality and Timed Intrauterine Insemination on Pregnancy Rate and Gender of Offspring in a Donor Insemination Program. Journal of Assisted Reproduction and Genetics 1997; 14: 531 at 534 (“[c]ompared to fresh semen, frozen-thawed semen has a diminished capacity to achieve pregnancy after donor

insemination"); BM Kang & TJ Wu, Effect of Age on Intrauterine Insemination with Frozen Donor Sperm, *Obstet Gynecol* 1996;88:93-8 at 93 ("quarantined, cryopreserved sperm results in a decreased cycle fecundity compared with fresh semen"); W Byrd et al, Intrauterine Insemination With Frozen Donor Sperm: A Prospective Randomized Trial Comparing Three Different Sperm Preparation Techniques, *Fertility & Sterility* 1994;62:850-56 at 851 ("[c]ryopreservation of sperm results in cryodamage to the spermatozoa and decreased fecundity of the spermatozoa"); WW Hurd et al. Comparison of Intracervical, Intrauterine, and Intratubal Techniques for Donor Insemination, *Fertility & Sterility* 1993;59:339-42 at 339 ("[u]nfortunately, the cycle fecundity rates after intracervical insemination (ICI) with cryopreserved sperm is less than half that found after insemination with fresh semen"); PB Marshburn et al. Spermatozoal Characteristics From Fresh and Frozen Donor Semen and Their Correlation With Fertility Outcome After Intrauterine Insemination. *Fertility & Sterility* 1992;58:179-86 at 185 ("[t]he frozen-thawed semen compared with fresh semen has a diminished capacity to achieve pregnancy after donor insemination"); W Byrd et al. A Prospective Randomized Study of Pregnancy Rates Following Intrauterine and Intracervical Insemination Using Frozen Donor Sperm. *Fertility & Sterility* 1990;53:521 at 525 ("cryopreserved sperm have a lowered fecundity rate when contrasted to fresh sperm. It is assumed that this decrease is primarily because of damage to the sperm during processing and freezing"); CA Brown et al. Improved Cryopreserved Semen Fecundability in an Alternating Fresh-Frozen Artificial Insemination Program. *Fertility & Sterility* 1988; 50:825-27 (finding that fresh semen had a superior fecundability rate to frozen semen). MA Richter, Artificial Donor Insemination: Fresh Versus Frozen Semen; The Patient As Her Own Control, *Fertility & Sterility* 1984;41:277 at 279 (confirming "the general belief that fresh semen is more effective than cryopreserved semen in producing pregnancies"). BA Keel et al. Effects of Cryopreservation on the Motility Characteristics of Human Spermatozoa. *Journal of Reproduction & Fertility* 1987;81:213-220 at 215 ("[c]ryopreservation resulted in significant . . . reductions in [sperm] velocity, motility, motility index and motile density").

² See BM Kang & TJ Wu, Effect of Age on Intrauterine Insemination with Frozen Donor Sperm, *Obstet Gynecol* 1996;88:93-8 (finding that the age of a recipient is a significant predictor of fertility outcome for intrauterine insemination of frozen donor sperm).

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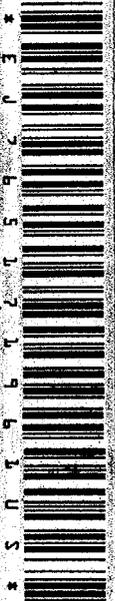
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