



**THE SPERM & EMBRYO BANK OF NEW JERSEY, INC.®**  
**SEBNJ**

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Divisions of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, Maryland 20852

Docket No. **1997N-0484T**

Human Cells, Tissues and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling

Re: **Interim final rule (IFR) filed**, by Jeffrey Shuren May 24, 2005 and put into effect May 25, 2005  
21 CFR Part: 1271

**Corporate background information:**

BioGenetics Corporation, The Sperm Bank of New Jersey, Inc. and The Sperm Bank of New York, Inc. are independent privately owned businesses. The tissue banks as an entity have gathered ample "day to day" business experience with regards to the storage and maintenance of cryopreserved human tissues. Our experience and exposure to the various needs from our non-professional and professional clients has helped us in responding to the "solicitation" by the FDA for comments regarding the IFR to Part 1271 and to the potential benefits, risks, and any other direct or indirect effects these proposed changes may have.

In our opinion certain changes proposed if applied will create an even higher risk in the day-to-day management operation of any tissue bank. We propose several recommendations for amendments which include higher specificity in the regulations and increased safety precautions. Our overall comments pertaining to the following IFR changes presented below in bold are:

**FDA position regarding making certain changes:**

***"in response to comments from affected interested persons regarding the impracticality of complying with certain regulations as they affect particular HCT/Ps"***, as described by the IFR (p. 29949).

The concerns regarding these changes proposed in the IFR from our tissue bank's perspective, may though, should not differ from those of assisted reproductive technology centers i.e. *in vitro* fertilization programs, or these so called interested persons.

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## **FDA position regarding specimen collection:**

The IFR deletes the statement in 1271.80 (b) regarding specimen collection at the time of recovery, because, ***“we are aware that this has been interpreted to mean that a specimen collected from a donor on the day of donation is superior”***.

Our recommendations regarding the objective of section 1271.80 (p.29950) pertain to the timing of specimen collection and which tests to use given the availability of FDA approved testing kits.

It is clear that testing donors of sperm, oocytes and embryos at the time of donation is “superior” because the results from these samples will be the most recent and conclusive.

As reviewed in NIH News on Wednesday, August 18, 2004, Nucleic Acid Amplification Testing, herein referred to as NAT, has been approved for use by the FDA since 2002. ***“NAT can detect HIV and HCV infections in blood donors earlier than other screening tests because it detects genes rather than antibodies or antigens”***.

The FDA is also aware, and states, that appearance of antibodies and therefore detection of antigens requires time for the donor to develop an immune response. Detection of antigens requires more time until higher levels of virus appear in the blood stream. Donors can test negative for antibodies prior to, at and after collection.

In addition, the American Association of Tissue Banks (AATB) recommends, in their guidelines for accredited tissue banks, that all donors be tested within 7 days of collection.

The IFR also states that ***“in the donor eligibility rule, we permit collection of the donor specimen up to 30 days before recovery”***.

The “window” period between exposure to the virus and antibody production may occur during the course of the 30 day HCT/P collection period proposed. NAT decreases this “window” to approximately 10 days for HIV1 and HCV.

In the IFR the FDA clearly states that ***“screening and testing of semen and oocyte donors is recommended given the potential risk that such tissue, like any other cell or tissue derived from the human body, could transmit communicable disease” (p. 29951)***.

Therefore, we recommend all donors be screened as per the algorithm developed by the FDA and presented in the FDA Talk Papers (September 2001, p. 5). In addition, we strongly recommend a quarantine period of 6 months for any HCT/P from directed donors, open identity and anonymous donor. We also recommend mandatory retesting of egg donors (for donated embryos created using a donor egg) as well as embryo donors (male and female gamete donors) prior to transfer.

## **FDA position regarding donor eligibility and labeling of specimens.**

In section 1271.90, the FDA loosely states ***“when possible, testing and screening of sexually intimate partners who later decide to donate embryos should take place before transfer of the embryo to the recipient”***. The recommendation is based on the statement ***“this will enhance the availability of embryos for donation”***

We urge that all types of donors; client depositors, directed donors, intimate partners, married donors, anonymous donors and autologous donors be tested. The IFR is making an exemption to a previous exemption in **1271a** in which donor eligibility was established for married couples creating embryos and determined that they did not need to be tested.

The FDA is aware that couples who create embryos and cryopreserve them, may later decide to donate them. Therefore the FDA only recommends, that “when possible, appropriate measures should be taken to screen and test the semen and oocyte donors couple creating embryos) before the transfer of the embryo to a recipient” (IFR p. 29950). We strongly urge that screening of any donor be done near or at the time of collection. Even, if the testing is postponed until a period after the creation and/or cryopreservation of the embryos. The issue that is of most importance is that these cryopreserved embryos (and HCT/P’s) are usually stored in large tanks of liquid nitrogen. There are thousands of frozen embryos and sperm vials already commingling from donors that haven’t been tested. There is reported evidence that some viruses can live through extreme temperatures, such as the environment produced in these tanks. Currently many assisted reproductive technology (ART) centers are cryopreserving oocytes and embryos in an open system that exposes these cells directly to liquid nitrogen (vitrification). It has been reported that hepatitis B (Fountain et al., 1997) and bovine hepatitis virus (Bielanski et al., 2000) can be transmitted through liquid nitrogen contamination. Therefore, this puts recipients, cryostorage centers and ART facilities at risk.

The IFR advises that all samples that have been frozen from donors that were not tested be labeled with ***“WARNING the donors were not tested”... “that the patient be advised of communicable disease risks and so that the physician can discuss with them these potential risks”***; Section 1271.90 (p. 29951). Also, it states that ***“if it is not possible to label the specimen, that is should be stated in the accompanying paperwork”***.

We understand that this is merely advice and do not believe it could be enforced in a court of law and would only mare torte cases.

With regards to having paper work reflect ***“WARNING the donors were not tested”***, paperwork gets lost or ignored, for example; cigarette companies put warning labels on cigarette packs and still people smoke, get sick and sue; even if it is due to second hand smoke.

Therefore, applying a warning label to untested HCT/P donors puts any cryostorage facility at risk of having to defend itself in front of a jury or in a court of law. We feel that all cryopreserved HCT/P specimens from a donor that has not been tested not be donated unless the donor is found and tested. This is most prevalent in cases of embryo adoption.

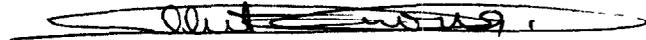
Finally, we are not attempting to define or describe an eligible / ineligible donor, our issues stem solely in regards to any HCTP "donor" seeking cryopreservation.

Any individual intending to cryopreserve his/her HCT/P's must be tested using the FDA algorithm discussed above and this testing should not be done more than 7-10 days prior to cryopreservation or within a short period thereafter as well as all subsequent required testing for the release of specific HCTP and applicable quarantine periods should be enforced.

Last but not least, our comment as to what to do with all of those thousands of stored or abandoned embryos? These embryos could be technically "available for adoption" yet most couples elect not to put them up for adoption. Cryostorage facilities are currently burdened with the maintenance and care of the embryos and often do not receive payment for these services. In turn, they find themselves unable to dismiss the legal responsibility associated with the storage of abandoned embryos as well as other HCT/P's.

Our recommendation is for the federal government through the powers of this agency to apply a combination of laws and regulations as applied under the U.K laws and provided by The NY State Department of Health Tissue Banking regulations in regards to abandonment / or nonpayment for HCTP storage.

Respectfully;



Albert Anouna, HCLD  
Director / CEO



Anna Błaszczyk, Ph.D.  
Director Technical Services

cc: NY State Department of Health Blood and Tissue Resources  
American Association of Tissue Banks

Fountain, D., Ralston, M., Higgins, N., Gorlin, J. B., et al., (1997). Liquid nitrogen freezers: A potential source of microbial contamination of hematopoietic stem cell components. *Transfusion* 37, 585-591.

Bielanski, A., Nadin-Davis, S., Sapp, T., Lutze-Wallace, C. (2000). Viral contamination embryos cryopreservation in liquid nitrogen. *Cryobiology* 40, 110-116.