May 7, 2001

Dockets Management Branch (HFC-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, Docket No. 97N-484P

I am a member of the Reproductive Council of the American Association of Tissue Banks. ReproTech, Ltd. is an AATB accredited cryobank providing long term cryostorage for reproductive tissue cryopreserved by another facility. ReproTech, Ltd. is currently storing client depositor (individuals storing their specimens for their own use) semen and embryos. I appreciate the opportunity to provide comments on FDA's proposed rule establishing current good tissue practice (cGTP) requirements and inspection/enforcement provisions for human cellular and tissue-based products, published in the Federal Register on January 8, 2001. I have listed my comments under the corresponding Proposed Section:

Proposed Section 1271.260(b)

This proposed section address the issue of acceptable storage conditions (temperature, length of time) to ensure product function and integrity, prevent deterioration and to inhibit growth of infectious agents. I am asking for clarification that these provisions would not require individual storage facilities to validate storage temperature or length of storage. Our industry has, with experience, established ranges of storage periods and temperatures for reproductive tissue.

In subsection (b)(2) I recommend removing the phrase "..ensure product function and integrity..". The phrase "product function and integrity" is undefined and dependent on many factors beyond the control of a storage facility such as ReproTech, Ltd. or the processing facilities who transferred crypresevered tissue to ReproTech, Ltd. for storage. I recommend that FDA delete references to "function and integrity" in all proposed sections of Docket No. 97N-484P.

97N-484P C40

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Proposed Section 1271.290

Distinct Identification Code

This proposed section indicates that except for autologous or directed donations the coding of the tissue must not include the donor's name. At the request of some of our embryo storage clients, ReproTech, Ltd. provides an anonymous embryo donation program. Due to personal reasons, these potential donors are unable to choose destruction as the method to terminate the storage of their embryos. Following qualification of potential embryo donors, ReproTech, Ltd. assigns a specific code to the embryo donors (anonymous donation) that does not include the individuals names, social security numbers or other identifying information. However, the labeling of the vials or straws that contain the cryopreserved tissue usually has the individuals names. The vials or straws would have to be thawed to allow the re-labeling of the vials or straws. That would certainly affect the integrity of the tissue and after re-freezing render the embryos non-vialble. We take great care to ensure that the physician receiving the labeled vials or straws is aware of the labeling and that measures are taken to prevent the recipient of the donor tissue from observing the donors names on the containers.

I am recommending that proposed section 1271.290 (b) allow for anonymous embryo donors names on the cryopreserved tissue containers. We acknowledge that recipients of anonymous donor embryos will only be provided documents which identifies the embryos donors with a non-identifying code. Without this change anonymous embryo donation would be impossible to complete and embryo client depositors will have only the choices of destroying their embryos or continuing storage of their embryos even though they will never use them.

Thank you considering my comments.

Sincerely,

Russell Bierbaum

Russell Bierbaum
President

RCB/hkh

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