



# The Sperm & Embryo Bank of NJ, Inc.<sup>®</sup>

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February 24, 2000

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

Re: Docket #97N-484S Federal Register / Vol. 64. No. 189

Subject: Tissue Bank's Rights to Destruction and Disposal of  
Reproductive Tissue

Dear Sir/Madam,

Often enough we gain our experience on a learning curve through our personal experience or the experience of others. Although this subject matter does not relate directly to the content of the proposed rule it may apply indirectly or toward future regulatory actions by the Department of Health and Human Services.

This issue that I bring to the forefront is both in a form of comment and recommendation. Reproductive tissue banks have always been faced with the fiduciary responsibility of safeguarding a tissue for client depositors. However, when client depositors face tissue banks with many variances of non-compliance, they, the sperm banks, are faced with the possible lifetime legal burden of maintaining in storage a reproductive tissue. Although there is no consensus on how long should or must a reproductive tissue bank maintain these reproductive tissue, a legal document in the form of a contract has been historically used by most commercial sperm banks, to contain language that would define time lines wherever appropriate. Each individual commercial sperm bank has created their own formatted contract to include language defined by their legal counsel. Such legal language made it clear as to the responsibility of both the tissue bank and the client depositor giving each a fair amount of time to cure any differences.

It appears to me that no such element has been introduced in the proposed rules published in Vol: 64 #189 in September 1999.

I think the time is appropriate for the FDA and other regulatory agencies to enact such a rule to provide clear-cut relief for both the reproductive tissue banks, who have willingly taken on many responsibilities to provide the Client Depositors such a service, and those who have entrusted reproductive tissue banks with what is considered their most valuable assets and hopes.

Reproductive tissue banks nationally accept the responsibility the client depositors have given us, however, all responsibilities are shared with the parties under contract. When a party to a contract remains uncooperative or uncommunicative, it leaves the tissue banks the difficult decision when to enforce the contract provisions and will their actions be subject to possible litigation.

I urge the Department to look into this matter and create a section in the proposed rules to be equitable to all parties, as there do not appear to be any statute or regulations that apply.

Yours Respectfully,



Albert Anouna, BLD  
Director/CEO

Cc: Jeanne V. Linden, M.D., M.P.H. Director, Blood and Tissue Resources  
New York State Department of Health  
Chairman, The New York State Task Force on Life and the Law  
Board of Governors, American Association of Tissue Banks  
Ethics Committee Chair, American Association of Tissue Banks  
Reproductive Council Chair, American Association of Tissue Banks  
Ruth Solomon, M.D., Director of CBER - OBRR  
Wendy Taylor, Desk Officer for FDA

AA/lhc

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