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07 May 2001

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

RE: Docket No. 97B-484P – Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Basked Products; Inspection and Enforcement:

Dear Ladies and Gentlemen:

I would like to thank the FDA personnel for the effort that was put into the preparation of the above referenced document, which is thorough and clearly delineates current issues and practices in tissue banking. I understand the American Association of Tissue Banks offered specific comments on the documents so there is little reason for repeating these or dealing with these individually. However, I would like to comment on one specific issue, i.e. that dealing with pooling of tissues during their processing.

It is our opinion that pooling of donor tissues which has not been previously done by the tissue banks in the U.S. is an unacceptable practice, which jeopardizes donor-recipient relationship principle on which the entire transplantation practice is based. It may also pose an unacceptable risk to the patients.

When a request for tissue donation is made it usually carries an implication that tissue will be transplanted into a given recipient. Citizens of the U.S. would most likely not look kindly on donated tissues being mixed in factory like manner to produce a product containing tissues from dozens of individuals.

The threat to patients is that should there be a transmission of disease with the allografts produced from pooled donors the same would be inflicted on several hundred recipients. Tracing back to the source of the problem would be impossible. At particular risk would be women of child bearing

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age who are Rh negative and who should not receive transplants from Rh positive donors because of the possibility of sensitization.

The data presented by an organization engaged in pooling of cadaver tissues and stating they may be granted and exemption by the FDA for their practice, regarding the efficacy of their sterilizing technique is not all inclusive and subject to scrutiny. All experiments were performed on artificially contaminated specimens and not on specimens of bone from individuals with sporeforming organisms as one frequently encounters in the actual setting. In addition, to date no completely fool proof sterilization process, which, among other things would eliminate infections such as CJD agent, has been devised.

Scientific and professional literature does not present data indicating clinical efficacy of musculoskeletal allografts processed in this manner.

Finally in considering the entire issue one can find no reason, other than financial advantage, to allow this practice.

Sincerely,

Theodore Malinin, M.D.
Professor of Orthopaedics and Rehabilitation
and Director, Tissue Bank

Align to

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