

THE NEUROSURGICAL CENTER OF SOUTHWEST VIRGINIA  
DOCTORS OF NEUROLOGICAL SURGERY

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GENERAL NEUROSURGERY  
PEDIATRIC NEUROSURGERY  
SPINAL SURGERY

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

RE: Proposed Regulation of Allograft Tissues

To Whom It May Concern:

Please be advised that I am currently a practicing neurosurgeon and have used tricortical iliac crest allografts for over 19 years in my practice of neurosurgery. The efficacy and safety provided by present bone bank regulations is more than adequate. I don't believe any further regulation is required for **allograft** tissue, and I am not sure where this thrust is coming from, as there have not been any problems up until this date, with already proven efficacy of fusion bone with a good safety record. I worry that any change in regulating to satisfy pre-market requirements, clinical trials, or other regulatory documents, would be of detriment to the health of patients, as precluding their availability of **allograft** tissue. I wonder where the thrust for this is coming from; if it is financially motivated by competitors in the field. I wish to go on record saying that I have been using **allograft** all this time, have been more than happy with the quality assurances provided by the bone banks and their care, and I don't feel any further regulation is necessary for **allograft** tissues.

Please refer to docket #97N-484S.

Yours truly,

Laurence I. Kleiner, M.D.

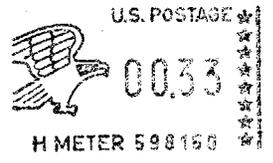
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