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The Division of Orthopaedic Surgery of Eastern Virginia Medical School

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July 24, 2000

Ms. Kathy Eberhart  
Food & Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike, Suite 200 North  
Rockville, Maryland 20852-1448

Dear Ms. Eberhart,

I understand that CBER and CDRH are sponsoring the open public meeting on "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair" on August 2, 2000. I will not be able to be present at the meeting, but I would appreciate your incorporating the following statement in the information to be considered at the meeting.

As an orthopaedic spine surgeon for many years, I have been using allograft bone material in my surgical cases for anterior cervical fusions. I also frequently use threaded bone dowels supplied by the Florida Tissue Bank for stability and fusion when performing anterior lumbar interbody fusions.

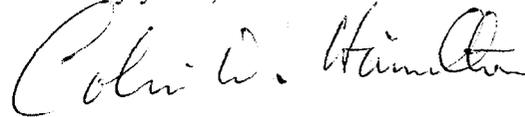
I understand that there is a proposed FDA regulation which would require regulation of some types of allograft bone material as medical devices. I greatly fear that if this type of regulation were enacted, the tissue banks which supply these needed human bone products would be unable to sponsor the same types of clinical trials and submit lengthy regulatory documents which are required for spinal implants. I fear that if this kind of FDA regulation were made mandatory, the supply of the above-mentioned bone products would be eliminated, which would have disastrous consequences for my patients who need them. We already have a nationwide shortage of iliac crest wedges so that I presently have to do an additional operation to harvest autograft bone for many of my neck surgery patients.

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I respectfully request that there be no FDA regulation to regulate allograft bone products as medical devices. I would be happy to supply any additional information regarding this issue at your request.

Sincerely yours,

A handwritten signature in cursive script that reads "Colin W. Hamilton".

Colin W. Hamilton, M.D.  
Clinical Assistant Professor,  
Orthopaedic Surgery  
Eastern Virginia Medical School

CWH/dh

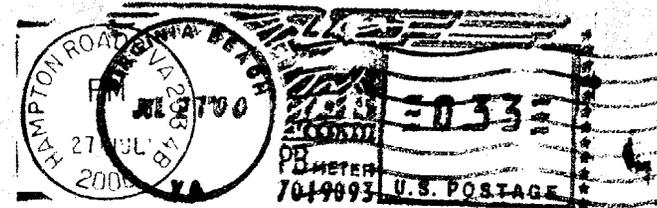


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