



**Department of Orthopaedic Surgery**

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August 3, 2000

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

Dear Ms. Eberhart:

I am writing to you with reference to proposals to regulate allograft tissue. I have very severe concerns vis a vis proposed regulation which initially appeared in September 30, 1999 issue of the Federal Registry.

I have used structural allograft tissues for spinal fusions for many, many years. Their efficacy used properly in the anterior column of the spine are as good as structural bone harvested from the patient's own iliac crest. We have done a prospective study looking at this.

The use of allograft bone considerably increases patient morbidity and cost.

The development of bone dowels, bone ramps, and other bone products including demineralized bone such as Grafton have proven themselves to be very efficacious in the field of spinal surgery.

I do not feel that the families of patients would be upset to know that their diseased relative's bone was being used to aid other people. I would see nothing wrong with an altered consent form but I do not see the need for any alteration in the Federal regulations with reference to the use of tissues such as bone. The use of bone allografts and other musculoskeletal allografts works extremely well vis a vis safety issues which are regulated by the FDA. Further regulation is unnecessary either for efficacy or safety.

The orthopaedic literature is replete with the value of bone allografts. I am concerned that further regulations will curtail supplies which we rely on for treating our patients and will put unnecessary burden on society. It is my firm belief that no further regulation is necessary.

Yours truly,

John P. Kostuik, M.D.  
Professor of Orthopaedics-Neurosurgery  
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JPK:hbk

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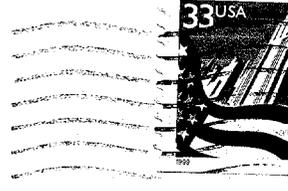
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