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Fellow American Board of Orthopaedic Surgeon

December 22, 1999

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

Re: FDA proposal to regulate allograft tissue (Docket No. 97N-484S)

Dear ladies are gentleman:

I'm an orthopedic surgeon who has been practicing orthopedics for approximately 40 years. My practice is still very active and I frequently use bone graft material from bone banks.

I note that there is the current proposal to regulate bone banks which provide tissue, i.e. bone grafts, for our patients in orthopedic surgery. The proposal has been made to increase safety in providing bone grafts for patients.

On paper this sounds like a good idea. In my opinion, however, it would create another government bureaucracy which would lead to curtailment of current supplies of bone products, increased cost, and would limit supply of these products.

I've been using bone grafts from bone banks for 40 years. I've used them in thousands of cases. I've never personally seen complications secondary to the bone graft from the bone banks. Although I'm in favor of public safety and particularly the safety of patients, I think that the regulations are unnecessary, would be costly, and would limit the supplies of necessary materials. Increase safety would not be provided.

For the above reasons, it's my opinion that the proposal to regulate allograft tissue should not be approved.

Sincerely


Howard Shortley M.D.

97N 484S

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