

DEPARTMENT OF NEUROSURGERY  
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APPOINTMENT BY REFERRAL ONLY

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July 16, 2000

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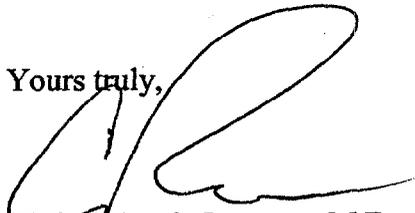
Kathy Eberhart  
Food & Drug Administration  
Center for Biologics Evaluation & Research  
1401 Rockville Pike, Suite 200 N  
Rockville, MD 20852-1448  
HFM 42

Dear Ms. Eberhart:

It has come to my attention that the FDA has announced that public hearings will be held to discuss the proposed regulation of bank bone as a medical device. I would like to ask you to review the enclosed letter that I sent to the FDA in December 1999 on this issue. I would also like to again reiterate my belief that to change the designation of bank bone to a medical device will do nothing to enhance patient care. It will without question have a decidedly deleterious effect on patient care.

Your review and consideration of my concerns is greatly appreciated.

Yours truly,



Christopher S. Rumana, M.D.

Enc. December 6, 1999 FDA Letter

0010-1380

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December 6, 1999

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Document Management Branch (HFA-305)  
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Rockville, MD 20852

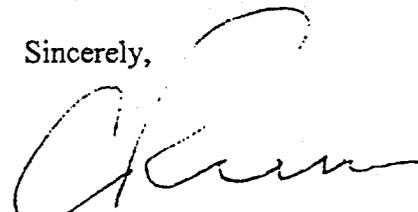
RE: Docket #97N-484S  
*Proposed Regulation of Bank Bone as Medical Device*

To Whom It May Concern:

I am writing to register my opposition to the proposed FDA regulation of bone allograft. Bone is a natural substance, a tissue. Obviously, FDA regulations are critically important for the safety of bone; however, bone is not a medical device. Significant regulation of bone allograft as a medical device will likely cause a massive rise in the cost of surgery requiring bone grafting and will markedly diminish the supply of bone for use in medical procedures. As a neurosurgeon who performs many spine fusion procedures, I can attest that medical care will be greatly impacted and the proposed changes would lead to much poorer medical care for our patients.

I believe that the proposed changes are not in the best interest of patient care and safety. Thank you for considering my concerns regarding this matter.

Sincerely,



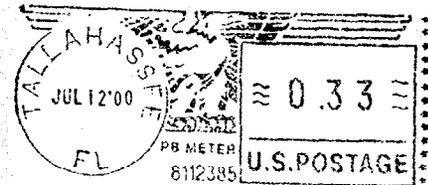
Christopher S. Rumana, M.D.

97N-484S

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**RETURN SERVICE REQUESTED**



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*FDA Center for Biologics*  
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*1401 Rockville Pike, Suite 200N*  
*Rockville, MD 20852-1448*

20852/1448

