

Bryan S. Givhan, M.D.



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Rick L. McKenzie, M.D.

December 16, 1999

Food and Drug Administrations
Document Management Branch
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

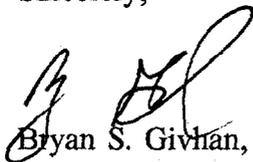
Dear Sirs:

I'm writing a letter to express my concern about the FDA proposal to start regulating allograft tissue. In my practice as a neurosurgeon, we use a significant amount of allograft bone tissue for cervical and lumbar spine fusion procedures. This tissue is obtained through tissue banks and has been thoroughly tested for any kind of viral or bacterial disease. This tissue is implanted and is very useful in our practice. If this is not available, then we are going to have to harvest bone from our patients, which will be more expensive, and associated with morbidity for the patients.

I would be strongly opposed to any further regulation of this type tissue, especially regulating this tissue as an implantable device. I understand that there is some push toward this based on some of the medical implantation companies trying to gain sales advantage for their particular implantable products. I think this would be a major mistake in that the majority of the implanted allograft tissue that is used in my practice, and the practices of many others, is not sold by these companies but comes directly through tissue banks. This is certainly not in any way any sort of medical device.

I would appreciate your consideration in this matter. If I can provide any further information or assistance, please don't hesitate to contact me.

Sincerely,



Bryan S. Givhan, M.D.

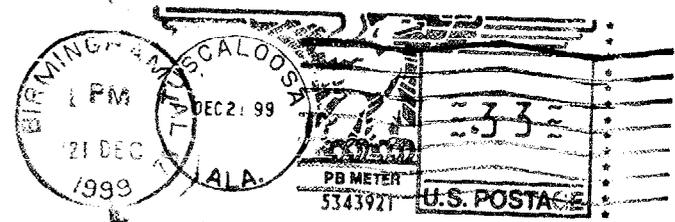
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