

NEUROSURGERY, INC.

A Division Of Physicians Care Of Va., P.C.

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(Retired)

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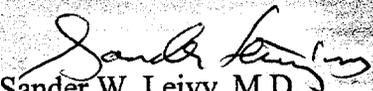
Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North
Rockville, Maryland 20852-1448
HFM 42

TO WHOM IT MAY CONCERN:

I am a neurosurgeon in Roanoke, Virginia who has been quite concerned over the recent FDA proposal to regulate allograft tissue as a medical device. Allograft bone has been used for years to help with bone fusion by different medical specialties. I believe it is wrong to regulate this as an actual medical device, as it is more consistent with the definition of a tissue and not a device. This has proved to be an important adjunct to obtain bone fusion in our patients and limiting its use could severely hamper our ability to take care of these patients. I do not believe that the shape of the bone being used, whether it be a block of bone, a dowel or threaded dowel, etc. at all would change how the graft interacts with biologic tissues, and again, years of use have proven no detrimental affects with the placement of these grafts, especially with appropriate regulations for testing of infectious disease along with donor screening.

I thank you for your attention to this matter.

Sincerely,


Sander W. Leivy, M.D.

SWL/lt
DD: 7/7/00
DT: 7/10/00

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