

CENTRAL OHIO NEUROLOGICAL SURGEONS

MARK A. FULTON, M.D.  
RIVERSIDE MEDICAL BUILDING  
3555 OLENTANGY RIVER ROAD  
SUITE 3030  
COLUMBUS, OHIO 43214  
PHONE: (614) 268-5531  
FAX: (614) 268-5611

DAVID YASHON, M.D., F.A.C.S., F.R.C.S. (C.)  
EDWARD S. SADAR, M.D., F.A.C.S.  
THOMAS HAWK, M.D., F.A.C.S.  
MARK S. FLEMING, M.D.  
REBECCA P. BRIGHTMAN, M.D., F.A.C.S.  
BRADFORD B. MULLIN, M.D.  
WILLIAM R. ZERICK, M.D.  
MARK A. FULTON, M.D.

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Food and Drug Administration  
5630 Fisher's Lane  
Room 1061  
Rockville, MD 20852

RE: Docket No.: 97N-484S

Dear Sirs:

I am writing as a spinal surgeon who frequently uses allograft bone in multiple surgical techniques for degenerative, traumatic and cancer related spinal conditions.

It has come to my attention that there have been recent proposals regarding the re-classification of allograft bone as a medical device that would further regulate these materials and subject them to tighter FDA controls.

I would argue that this is unnecessary bureaucratic regulation that would have little patient benefit and significantly raise the costs of these supplies. Most allograft tissues are used by surgeons in such a manner that they are essentially custom devices for each individual patient. Very rarely do two allografts have exactly the same structure or function in two separate patients.

Although I certainly agree that there is a potential for harm to patients by the improper use of allograft materials, I think a more appropriate bureaucratic step may be to regulate which surgeons have appropriate training in the use of these materials rather than to manage the materials themselves.

I hope that you would please consider my opinion on this matter and not advance the regulatory involvement with allograft tissues, specifically bone graft materials.

I thank you for your attention to this. If you have any questions, please feel free to contact me.

Sincerely,



Mark A. Fulton, M.D.  
Central Ohio Neurological Surgeons  
Columbus, Ohio  
MAF/kk

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MARK A. FULTON, M.D.  
RIVERSIDE MEDICAL BUILDING  
3555 OLENTANGY RIVER Rd., SUITE 3030  
COLUMBUS, OHIO 43214

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