

NEUROSURGICAL CARE, INC.

463 WORCESTER ROAD • SUITE 103  
FRAMINGHAM, MA 01701

2281 '00 JAN -6 AIO :26

508-875-2050  
FAX 508-875-1965

RONALD W. MORTARA, M.D., F.A.C.S.  
Chief of Neurosurgery, MetroWest Medical Center  
Associate Professor of Neurosurgery,  
Boston University School of Medicine

December 16, 1999

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

Re: Docket No.: 97N-484S

Dear Sir:

I wish to express my views against the proposal to allow the FDA to regulate allograft as medical devices, as has been proposed in the September 30, 1999 Federal Register. I commonly use allograft bone and fascia lata in my practice, obtain this from qualified tissue banks, and feel that regulation and administration of the tissues involved would be inappropriate, as it would be an excessive taxpayer expense for no benefit.

The tissue banks I use are qualified professional organizations and have provided good service. The tissues used are not devices but rather natural tissues not invented by man. Regulating these devices would only increase their cost and slow down the progress made in their use.

Feel free to call me should you wish further information. I appreciate your help with this matter.

Sincerely yours,



Ronald W. Mortara, M.D.

RWM/SD:jem

97N 484S

C410

NEUROSURGICAL CARE, INC.  
463 WORCESTER ROAD • SUITE 103  
FRAMINGHAM, MA 01701



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

20857+0001

