

**PIEDMONT
NEUROSURGERY, P.A.**

David M. Jones, M.D.
Mark J. Marchese, M.D.
A. Gregory Rosenfeld, M.D.
BOARD CERTIFIED NEUROSURGEONS

0773 '99 DEC 30 A9:57

December 16, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockfield, MD 20852

RE: DOCKET #56797N-484S

Gentleman:

It has just recently come to my attention that there is a proposed FDA regulation which would allow the FDA to regulate some types of allograft tissue as medical devices.

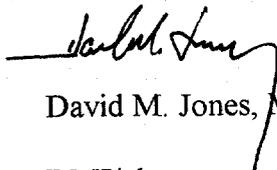
I am a neurosurgeon who frequently uses banked allograft tissue, both bone and dura. I particularly use a great deal of banked allograft bone in my practice.

The FDA already regulates the safety of tissue banks, and the supply of tissue has been met well in my experience by the private sector, such as the tissue banks Life Net, and Musculoskeletal Transplant Foundation.

I think it is a mistake to regulate these bone allografts as medical devices. Their safety is already well documented, and I think that additional regulatory restrictions imposed on this material would simply dramatically increase expenses and significantly curtail supply. Ultimately, patients would suffer the consequences of this further regulation which is completely unnecessary.

If the system is not broken, please don't try to fix it.

Sincerely,



David M. Jones, M.D.

DMJ/gh

Hickory
Eastway Plaza, Box 108
1899 Tate Boulevard SE, Suite 2108
Hickory, NC 28602
phone 828-327-6500 fax 828-327-4700

C311
Morganton
137-B West Parker Road
Morganton, NC 28655
phone 828-437-2022 fax 828-437-2141

17N 484S

RECIPIENT:

The sender has requested notification upon delivery. Immediately upon receipt, please telephone:

Name: _____
Tel. No.: () _____



0000

U.S. POSTAGE
PAID
HICKORY, NC
28603
DEC 28 '99
AMOUNT

\$11.75
00029692-02



**EXPRESS
MAIL**

UNITED STATES POSTAL SERVICE

www.usps.gov



**EXPRESS
MAIL**

UNITED STATES POSTAL SERVICE™

POST OFFICE TO ADDRESSEE

ORIGIN (POSTAL USE ONLY)

PO ZIP Code	Day of Delivery <input type="checkbox"/> Next <input type="checkbox"/> Second	Flat Rate Envelope <input type="checkbox"/>
Date In Mo. Day Year	<input type="checkbox"/> 12 Noon <input type="checkbox"/> 3 PM	Postage \$
Time In <input type="checkbox"/> AM <input type="checkbox"/> PM	Military <input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee
Weight lbs. ozs.	Int'l Alpha Country Code	COD Fee Insurance Fee
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Acceptance Clerk Initials	Total Postage & Fees \$

DELIVERY (POSTAL USE ONLY)

Delivery Attempt Mo. Day	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Delivery Attempt Mo. Day	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Delivery Date Mo. Day	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Signature of Addressee or Agent		
X Name - Please Print		
X		

CUSTOMER USE ONLY

TO FILE A CLAIM FOR DAMAGE OR LOSS OF CONTENTS, YOU MUST PRESENT THE ARTICLE, CONTAINER, AND PACKAGING TO THE USPS FOR INSPECTION.

WAIVER OF SIGNATURE (Domestic Only) Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY Weekend Holiday

Customer Signature

FROM: (PLEASE PRINT)

PHONE () _____

TO: (PLEASE PRINT)

PHONE () _____

14FA-305
5630

1061

FOR PICKUP OR TRACKING CALL 1-800-222-1811

www.usps.gov



Label 11-B July 1997

Addressee Copy

