# THE JOHNSON NEUROLOGICAL CLINIC, INC.

SPECIALIZING IN MEDICAL & SURGICAL DISEASES OF THE NERVOUS SYSTEM

JNC

JAMES A. JOHNSON, M.D.
1933-1991

NEUROSURGERY
RUSSELL H. AMUNDSON. M.D.
MICHAEL B. HUSSEY, M.D., F.A.C.S
VICTORIA C.D. NEAVE, M.D.
SAUL S. SCHWARZ, M.D., F.A.C.S.

NEUROLOGY
GREGORY D. MIEDEN, M.D., Ph.D.
J, KEITH MILLER, M.D., F. A. A. N.
S. SCOTT STEWART, M.D.
LEANNE K. WILLIS, M.D.
RAYMOND S. KANDT, M.D.
MICHAEL D. APPLEGATE, M.D.

PHYSICAL MEDICINE - REHABILITATION
KATHLEEN M. BXRFOOT, M.D.
KIRSTEN G. D'AMORE, M.D.

HIGH POINT, NC 27262
606 NORTH ELM STREET
OFFICE: (336) 889-8877
NEUROSURGERY FAX: (336) 889-7850
NEUROLOGY FAX: (336) 885-2060

ASHEBORO, NC 27203
2 16A FOUST STREET
OFFICE: (336) 629-3500
FAX: (336) 629-3521

LEXINGTON, NC 27292
100 HOSPITAL DRIVE
OFFICE: (336) 248.8083
FAX: (336) 224-0006

THOMASVILLE, NC 27360
1213 LEXINGTON AVENUE
OFFICE: (336) 475-0113

KERNERSVILLE, NC 27284
CENTRAL TRIAD MEDICAL PARK
222 BROAD STREET
OFFICE: (336) 993-2500

NEURODIAGNOSTIC SERVICES
(336) 887-3091


6585 '99 DEC -3 P1:41

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

November 30, 1999

Dear Administrative Staff,

I am writing to dissuade consideration of further FDA regulation of surgical allograft bone usage. I understand that the FDA already has set guidelines for the safe preparation and packaging of bone grafts for the purpose of intraoperative implantation, and we have not seen any problems with their use. It is customary and routine in our neurosurgical practice in North Carolina to use 4 to 10 or more of these grafts a week in the performance of cervical spine fusion surgery, to our patients' great benefit. To relabel allograft bone as a "medical device," requiring further regulatory testing and approval, is misguided and can only interfere profoundly with well-established, standard of care surgical practice, and sabotage our safe and painless source of fusion material for our patients.

Please feel free to contact me for further clarification of this issue, from a busy private practice perspective.

Respectfully submitted,

Saul S. Schwarz, MD FACS
Chief, Surgical Section, High Point Regional Hospital
Neurosurgeon, Johnson Neurological Clinic

97N 484S

C235

The Johnson Neurological Clinic, Inc.
"SPECIALIZING IN MEDICAL & SURGICAL DISEASES OF THE NERVOUS SYSTEM"
606 NORTH ELM STREET. HIGH POINT, NC 27262

ADDRESS CORRECTION REQUESTED

HIGH POINT NOV 30 '99 NC
PB METER 8342722
0.33
U.S. POSTAGE

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

20857-0001