



John B. Mazur, M.D.

Certified by
The American Board of Spine Surgery &
The American Board of Neurological Surgery

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July 13, 2000

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

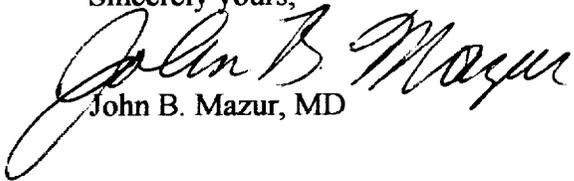
Dear Mrs. Eberhart:

I am writing concerning the use of allograft and its possible future FDA regulation. In 25 years of practice of spinal surgery and in over 1,000 cases of placement of bone allograft, I have had no complications referable to the bone graft. There have been no cases of infection transmitted with this bone graft. My colleagues have similar experiences.

There is no justification for regulation of allograft. This regulation would only increase costs both for the Food and Drug Administration and therefore the taxpayer, and also for the potential recipients of allograft, the patient population in general. With these increased costs will be a loss of innovation as newer uses of allograft will come less rapidly. I strongly feel that allograft material should not be regulated as a medical device.

Thank you again for your consideration.

Sincerely yours,


John B. Mazur, MD

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302 Randall Road, Suite 308
Geneva, IL 60134
630-262-1210

1315 N. Highland Ave., Suite 105
Aurora, IL 60506
630-892-2797
FAX 630-859-2378

610 Plaza Drive, Unit #4
Sycamore, IL 60178
815-895-8422

Toll Free: 1-877-SPINE04
1-877-774-6304

www.thespinespecialist.com



The Spine Specialist S.C.
1315 N. Highland Ave. Suite 105
Aurora, IL 60506



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20852-1428

