

MEDICAL NEUROLOGY

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November 30, 1999

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

RE: Docket #97N-484S

Dear Sir:

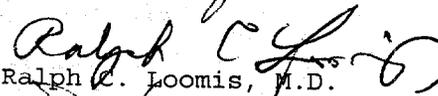
This letter is in opposition to proposals regarding the FDA regulation of some types of allograft bone used as medical devices.

Placing further regulations beyond what is placed on bone tissue used routinely for surgical purposes would increase the cost of surgery to the patient and their insurance carriers and might even decrease the availability of such devices by diminishing the supply since some companies might not continue to be involved with the production and development of new and better ways for treating the many spinal problems which we are involved in treating.

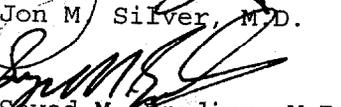
Please do not place more restrictions, regulations and requirements on the production and supply and development of these devices.

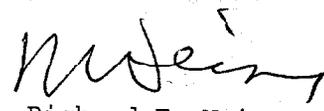
Yours Sincerely,

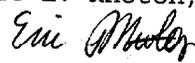

Lary A. Schulhof, M.D.

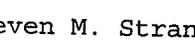

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November 29, 1999

**FDA PROPOSAL TO REGULATE
ALLOGRAFT TISSUE**

Dear Doctor:

I am writing to you today to inform you about another proposed FDA regulation that appeared in the September 30, 1999, issue of the *Federal Register*. The wording used in the proposed FDA regulation, if accepted, could allow FDA to regulate some types of allograft as medical devices.

As you are aware, bone banks currently provide bone as tissue, for which the FDA regulates the safety. However, bone banks likely do not have the resources or the expertise to satisfy the FDA's pre-market requirements, such as sponsoring clinical trials and submitting lengthy regulatory documents. This may lead to a curtailed supply of bone products on which you rely for treating patients. The potential implications of FDA's regulatory actions with this proposal are staggering.

As part of the rule-making process, the public is allowed to comment on such proposals. I encourage you to do so, since you probably use banked tissues in your practice. Public comments must be submitted by **December 29, 1999**, to the following address:

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

Please reference **Docket No. 97N-484S** so that your comments will be filed properly. If you have any questions or need additional information, including a copy of the proposal with the specific definitions, please do not hesitate to call my office at (800) 763-2667. Thank you for your interest in this issue.

Best regards,

Ron Pickard

When Life Depends on Medical Technology



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