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December 17, 1999

**RE: FDA Proposal To Regulate
Allograft Tissue
Docket No. 97N-484S**

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

To Whom This May Concern:

I am writing to express my opposition to the proposal by the FDA to regulate allograft tissue for use as medical devices. I am a Spinal Surgeon and I use structural bone allograft as well as morselized bone allograft for achieving spinal fusions in patients with a variety of spinal conditions.

Other options for performing anterior interbody spine fusions include use of metal interbody cages which are already regulated by the FDA. I use structural bone allograft in a variety of shapes, and the fact that it may be used to help support the spine during a healing fusion, should not necessitate that this bone be regulated by the FDA.

The simple fact that structural bone allograft is used in some of the same applications as metal interbody fusion cages is not adequate reason to change the regulatory status of allograft tissue. As you know, these allograft tissues are biocompatible and become completely replaced by the patients own host tissue after a certain period of time. This offers obvious advantages. This is significantly different from metal interbody fusion cages which remain essentially unchanged for the life of the patient.

It is confusing to me to think why the FDA would even consider regulating this type of allograft tissue. In addition, research studies performed on the risk of infectious transmission from use of donor bone tissue have shown infection rates to be extremely rare, and confined to the use of fresh, frozen allograft.

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I respectfully submit these comments and I hope that they have some influence on your decision making process.

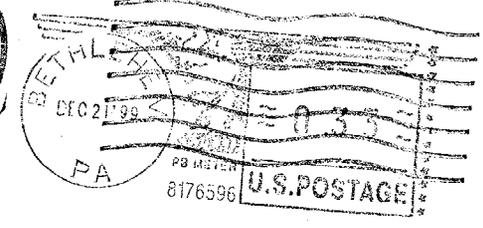
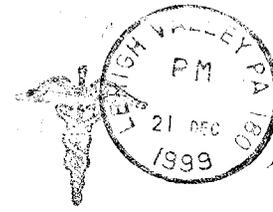
Sincerely,

A handwritten signature in cursive script that reads "Stephen Falatyn".

Stephen P. Falatyn, M.D.

SPF:sgk

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