

CENTRAL OHIO NEUROLOGICAL SURGEONS

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To Whom It May Concern:

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

If this regulation includes allografts from human cadavers that are to be used in anterior cervical fusions than I would strongly recommend that no such regulation would be necessary. We have used this material for ten years and it has been to the great satisfaction of the neurosurgeons and the orthopedic surgeons utilizing the material. Over twenty years ago we were using bovine bone for the anterior cervical discectomy and fusion and found it to be an excellent material. However, the Bureau of Implants and Devices took over control and went through a long and redundant process of testing. It took a great deal of time and tomes of paper as well as expensive testing to go through a study which we felt to be necessary as we had utilized the material very successfully for over ten years. I would hope that we are not in a similar situation now where such a form of regulation would be mandated.

Following this continuation of the bovine material, we went back to harboring the grafts from the individual patients and utilized autogenous grafts from the iliac crest of those undergoing the surgery. This required a second operation and a great deal of pain and suffering. It was absolutely not necessary. Ninety-eight percent of the patients that I have elect to use the bone bank iliac crest and it has been an excellent material. I have been utilizing this material for well over ten years and have not had a single rejection. The system works as it is set up presently and I see little reason to interfere with it in any way.

Sincerely,


Thomas J. Hawk, M.D.

TJH/cc

Dictated but not proofread by doctor.

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