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Director, JFK Neuroscience Center

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July 10, 2000

Kathy Eberhart
Food & Drug Administration
Center for Biologic Evaluation and Research
1401 Rockville Pike, Suite 2000
North Rockville, Maryland 20852-1448 HMF42

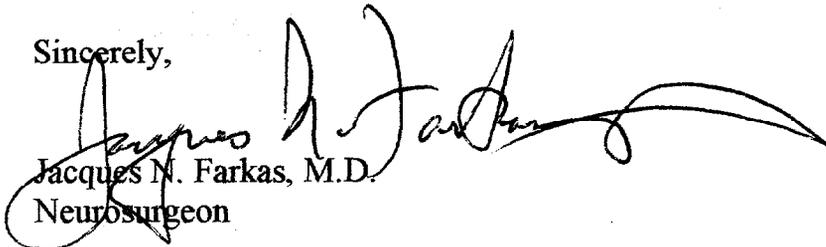
RE: RECLASSIFICATION OF HUMAN ALLOGRAFT TISSUES

Dear Ms. Eberhart:

I am writing you in regards to a proposed FDA regulation for reclassification of human tissue allografts. As a practicing neurosurgeon, I have been using bone allografts for many years. In my own personal anecdotal experience, there have been no associated complications with the use of this material. It is a tremendous adjunct in performing surgical reconstructive procedures in my practice. It is of tremendous benefit to patients. I believe the literature supports the safety and efficacy of its use over many years.

With this letter, I am enclosing the position paper on the use of bone dowels from human tissue of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. I believe this supports my position. Therefore, I strongly urge you not to reclassify human tissues and medical devices. If this proposed regulation is passed, then this regulatory requirement would place an extreme burden on bone banks which would probably result in there being a shortage of bank bone available for surgical use. This will have a great impact on public health. Surely, you see the logic here and will reject this proposed onerous regulation. Awaiting your reply.

Sincerely,



Jacques N. Farkas, M.D.
Neurosurgeon

JNF/jsc

Enclosures

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Dictated but not read.

Diplomate American Board Neurological Surgery

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