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The Document Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Gentlemen:

As a professor of neurosurgery, I strongly endorse the position paper on the use of bone dowels from "human tissue" prepared by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. Essentially, surgeons have used human bone products processed and preshaped for spine surgery for a number of years. These materials already have very appropriate regulation for infectious disease testing, donor screening and record keeping. The reduction in pain and disability and the excellent results associated with surgery using these products is documented and appreciated by all patients undergoing surgery for spinal conditions. There is no practical or medical reason for the reclassification of these products from human tissues to medical devices as is being proposed by the FDA.

I will be unable to attend the August 2nd panel but wish to register my strong objection to the proposed FDA plans as they are not only unnecessary but will interfere with patient care particularly patient discomfort.

Sincerely,

James T. Robertson, M.D.
Professor

JTR:bwb

copy: Senator Trent Lott
Senator Thad Cochran
Rep. Roger Wicker

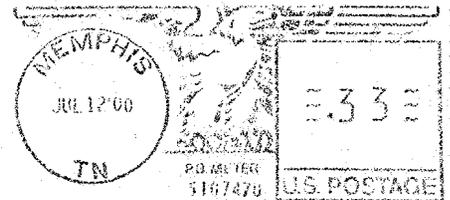
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