



March 6, 2007

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005P-0121

Dear Sir or Madam:

I am writing to express my support for the FDA's decision to accept the recommendation of the Orthopaedic and Rehabilitation Devices Panel to retain non-invasive bone growth stimulators in Class III. I am a neurosurgeon in Harrisburg, Pennsylvania. As part of my training I also completed an orthopedic spine fellowship, and with this background I enjoy a very busy spinal surgery practice at the Pennsylvania Spine Institute. The use of bone growth stimulators for multilevel fusion and pseudoarthrosis is instrumental to my practice. On a daily basis I am referred patients that have a history of failed spinal surgery or have significant risk factors such as smoking. It is in this type of difficult clinical scenario that I use bone fusion stimulators.

I appeared at my own expense at the Panel meeting in June 2006 because of my serious concern about the risk that reclassification will pose for patients for whom these devices are potentially most beneficial. I was heartened to hear members of the Panel echo this concern, and I am even more pleased that the FDA now agrees.

My statement to the Panel appears at pages of 247-53 of the meeting transcript. At the meeting I explained that I do two to three lumbar spinal fusions a week and another two multi-level cervical fusions per week. These are serious operations, with potentially life-threatening complications if fusion is not achieved. A failed fusion is usually associated with significant pain, serious morbidity, and usually leads to further surgery, all of which exposes the patient to considerable added risk. To minimize these risks, I use bone growth stimulators, particularly for high-risk patients.

My concern with the reclassification petition – simply stated – is that it disregards the interests of patients. As recognized by the Panel, and by the FDA in its January 17, 2007 Notice, research to date has not shown exactly how bone growth stimulators work, or what effect even small changes in design may have on their effectiveness. The devices that are currently on the market have all gone through extensive clinical trials to demonstrate their efficacy. The reclassification petition proposes no meaningful alternative to evaluate safety and effectiveness and, if granted, would permit devices to be marketed with no demonstration of effectiveness. Bone growth stimulators are safe only if they work. The risk of ineffective devices is a higher rate of failed fusions, with significant associated morbidity concerns.



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Other physicians who gave statements at the Panel meeting (Drs. Friedlaender, Kahanovitz, Aaron, Lane, Einhorn) were also opposed to reclassification, essentially for these same reasons. All believed reclassification would be a disservice to patients, and some believed it would be unethical. The Panel members who practice medicine agreed. No Panel member with an M.D. voted in favor of reclassification. As observed by Dr. Jay Mabrey, an orthopedic surgeon from Baylor University, “an ineffective device with a painful non-union constitutes a substantial impingement upon that patient’s overall health.” (Tr. 334)

Like many other doctors, I rely on the FDA as a partner in my efforts to assure safe and effective patient care. I specifically rely on the FDA to only approve a bone stimulator device if it has been tested to be safe and effective. It is simply not known how a change to the device output due to device modifications may impact the clinical response to treatment. If I use a device that is not clinically effective, I will have a higher failed-fusion rate with associated increase in morbidity. I applaud the agency for its decision thus far to retain bone growth stimulators in Class III, and urge it to take the next step of denying the reclassification petition. This is the only course that will assure safe and effective treatment, and it is the right course for patient care.

Respectfully yours,

A handwritten signature in black ink, appearing to read "William Beutler". The signature is fluid and cursive, with a prominent flourish at the end.

William J. Beutler, M.D.