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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 in favor of the FDA's decision to accept the recommendation of the orthopedic and rehabilitation devices panel to refrain from down classifying bone growth stimulators to class II devices.

As a spine surgeon, I am a frequent user of bone growth stimulators. These devices are particularly useful for high risk patients with compromised healing abilities such as patients with diabetes, obesity, prior surgeries, osteoporosis, and smokers.

The petition to re-classify bone growth stimulators was alarming and it could have had a detrimental impact on patients. Both the panel and the FDA have pointed out that research on bone growth stimulators remains ongoing in many respects. Current devices on the market have been extensively evaluated in clinical trials for safety and efficacy. Even a small change in the product design can impact the quality and final result of the treatment with the device.

If a device were to be introduced to the market without the proper clinical evaluation, the consequences could include higher rates of failed fusions with associated morbidity concerns, as well as increased financial burdens to the patients and the insurance carriers. Not only would such an action be a disservice to patients, but its ethical basis would be suspect.

I rely on the FDA to provide safe and effective patient care. As an orthopedist, I rely on the FDA specifically to only approve a bone growth stimulator that has been tested and proven to be both safe and effective. Once again, for all of the reasons listed, I strongly agree with the agency for its decision to keep bone growth stimulators as class III devices and taking the next action of denying the reclassification petition, as it is the only course that will ensure effective treatment, safe treatment, and proper patient care.

Sincerely,

Paul A. Glazer, M.D.

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