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June 28, 2005

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

Subject: FDA Docket 2005P-0121/CCP 1
Comments in Opposition to the Reclassification of Non-Invasive Bone
Growth Stimulators

To Whom It May Concern:

The purpose of this letter is to state my opposition to the reclassification of external bone growth stimulators from Class III to Class II. In addition to 35 years experience as an orthopedic spine surgeon at State University of New York, Upstate Medical University, I have worked with the FDA on many occasions, consulting on several orthopedic panels, and I have also worked with Dr. Becker on electrical stimulation on wound healing with Bacteriostatic effects. Therefore, I would like to express my opinion as a leader in the area of spine research.

The mechanism of action of the various bone growth stimulator technologies is not yet fully understood. While we have strong clinical evidence of the effectiveness of these products, the cellular response to the external stimulus has not been fully elucidated. Research has shown that variations in the device's output can yield varying results, such as no clinical benefit at all. Safety and effectiveness must be proven with a well controlled, statistically valid clinical study.

As a former president of the North American Spine Society (NASS), and an active member of the International Lumbar Spine Society (ISSLS), I am aware of research on the cellular pathways affected by exposure to external electrical stimulation. Although current clinical applications are well developed in orthopedic applications, specifically nonunion and spinal fusion, the effects of these electrical fields have also been shown to induce changes in many other tissue types including ligaments, tendons, soft tissue, and vascular tissues. That research is on-going.

2005P-0121

C1

Page 2
June 28, 2005

The reclassification of these devices from Class III to Class II implies that the technologies are well understood and somewhat static. I do not feel this is the case with electrical and electromagnetic stimulation as yet. Given the differences in the BGS technologies, they cannot be considered as a single generic type of device and I urge you to maintain the rigorous Class III standards for these technologies.

Sincerely,

A handwritten signature in black ink, appearing to read "Hansen". The signature is fluid and cursive, with a large initial "H" and a trailing flourish.

Hansen A. Yuan, M.D.
Professor, Department of
Orthopedic and Neurological Surgery

HAY/ss

cc: Miriam Provost, Ph.D.
Food and Drug Administration/CDRH
Division of General, Restorative, and Neurological Devices
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