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Re: FDA Medical Devices Advisory Committee Panel Meeting on Reclassification of Noninvasive Bone Growth Stimulators

Dear Commander Garcia,

I am writing regarding the September 8, 2020 meeting of the Medical Devices Advisory Committee, Orthopaedics and Rehabilitative Devices Panel. My comment concerns the Panel's consideration of potential reclassification of noninvasive bone growth stimulators (BGS devices) from Class III to Class II. I strongly recommend that the FDA maintains the Class III classification for these important clinical devices.

I am a Board Certified Orthopaedic Surgeon and Hand Surgeon and work in a tertiary care environment. Therefore, I manage many complex cases involving challenging fractures in adults and children, including those which have poor local healing environments (such as those with associated soft tissue injuries which can compromise blood flow, critical to fracture healing) or those that are delayed unions or nonunions (ie. those fractures that have demonstrated a lack of healing over time). In such cases, the use of a BGS can be an important adjuvant to the stimulation of bone healing. As a treating physician, it is vital to me to know that any BGS device I prescribe will have been proven to be safe and effective through robust clinical studies and application of FDA's most stringent, Class III regulatory controls. The clinical consequences of ineffective or unsafe BGS devices are far too great to support anything less than FDA's highest level of regulation.

As there are many factors that contribute to bone healing, in the absence of scientific evidence for a BGS to contribute to the bone healing process it would be difficult to confirm that bone healing is the result of the physiologic effects of the BGS – presenting the real risk of a BGS market where many claims could be advanced without scientific support, leading to poor patient outcomes, inefficient use of medical resources, and unnecessary financial burden on the healthcare system.

For patients with fractures to be treated with BGS devices, these devices are of critical clinical importance. The risk of a device that is not efficacious is simply unacceptable. For example, fracture non-unions are chronic medical conditions with debilitating, lasting adverse effects on not only patients'

physical health, but also their mental health and quality of life. Consistent with my experience, the clinical literature documents that the adversity experienced by patients with non-unions (e.g., of long bones) in these regards is comparable to that of patients with end-stage hip arthrosis and worse than that of patients suffering congestive heart failure. The frequency of this is greater for patients with common co-morbidities, such as those who are smokers, diabetics or obese, or those for whom a local healing environment is less than ideal such as following an infection or soft tissue injury.

BGS are high-stakes devices. Patients and clinicians thus deserve and need to have the greatest assurance of their effectiveness and safety. BGS devices encompass a range of distinct technologies, waveform parameters, functionalities, designs, dosimetries, and intended uses. Given the nature of and dissimilarities among BGS devices, a single set of special controls could not reasonably assure the safety and effectiveness of each distinct type of BGS device. Even minor changes to BGS devices may profoundly impact their safety and effectiveness in unknown ways that render Class III controls, such as rigorous clinical studies and pre-approval manufacturing review, necessary. While Class II standards such as "substantial equivalence" of technological characteristics are appropriate for many devices, because of the complexities and uniqueness of BGS waveforms, these devices do not lend themselves to proof of effectiveness and safety merely by the appearance of similar technical characteristics. Instead, device-specific data, including clinical data, and the strictest levels of FDA review are the only mechanisms sufficient to ensure that BGS devices will, in fact, perform as intended. BGS devices should therefore continue to be regulated in Class III.

I appreciate your work relative to matters of public health and health policy and would be happy to discuss if needed. I appreciate FDA's thoughtful consideration of this personal opinion by a clinically active orthopaedic hand surgeon.

Sincerely,

Fraser J. Leversedge, M.D.

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cc: James Swink (James.Swink@fda.hhs.gov)
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