

THE CHATTANOOGA CENTER FOR PAIN MEDICINE

PRECISION DIAGNOSTIC & THERAPEUTIC INJECTIONS

CONSULTATIVE EVALUATION & MEDICAL MANAGEMENT

IMPLANTATION OF PAIN CONTROL SYSTEMS

403 W. CATLIN, MD -3 P2:56

DIPLOMATE OF THE AMERICAN BOARD OF PAIN MEDICINE

DIPLOMATE OF THE AMERICAN BOARD OF ANESTHESIOLOGY
SUBSPECIALTY CERTIFICATION IN PAIN MANAGEMENT

DIPLOMATE OF THE AMERICAN ACADEMY OF PAIN MANAGEMENT

October 20, 2000

Dockets Management Branch (HFA-305)
U.S. Food & Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sirs,

I am writing you in STRONG SUPPORT of the FDA's intention to reclassify totally implantable spinal cord stimulators from Class III to Class II. Such a move would improve the availability of new equipment to treat patients with pain to a much greater degree. The technology has been on the "benches" of both major companies and have stalled because of unnecessarily intense scrutiny prior to release of the equipment. It is not only driving up the cost of medical care, but markedly delayed by years, access to equipment which would improve the physician's ability to control pain.

Spinal cord stimulator devices are modestly complex, but certainly well proven, having been on the market and used extensively for over a decade. Because they utilize very small sources of power, the ability to damage a patient is essentially nonexistent. When appropriately implanted into a patient, the systems are totally and completely explantable, should that need ever arise, leaving the patient in essentially the same anatomical state as they were prior to the trial and/or permanent implantation of the stimulator system. Therefore, unlike drugs which have the potential of doing damage to body parts, e.g., heart valves or orthopaedic prosthesis, such as hips and knees, which require the removal of the end of a bone prior to implantation of the device, a spinal cord stimulation system is totally different. The electrodes can be implanted safely, the vast majority of the time through a needle, just like an epidural catheter a lady has at the time she undergoes epidural placement for labor and delivery. And, in fact, when the electrodes are placed, the procedure is performed in the operating room with due respect to sterility and with fluoroscopy visualization. Therefore, the utilization of spinal cord stimulation equipment cannot be seen as an analogous to other types of implantable devices, because it simply is not. Granted, there are some risks that declassifying spinal cord stimulation systems from 3 to 2 would make it slightly easier for unproven companies to submit "equivalent devices," and would reach the market without acceptable testing.

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However, I have more faith in the FDA than to not be able to identify such a device, and for the small risk that is posed, the value of having new equipment rapidly available for utilization for patient care far outweighs the small risk of this non-destructive reversible and totally explantable technique. In the long run, it will probably bring down the cost of the devices, making them more "in the reach" of patients who are now not able to afford them.

Therefore, I would strongly urge you to ignore cries to the contrary. I believe the FDA has made a good and wise decision, and should stick to it.

Thank you for your careful consideration of my comments. Should you have any questions, please do not hesitate to let me know.

Sincerely,



Roger W. Catlin, M.D., DABPM
Medical Director

RWC:rt October 20, 2000

cc: Don Harrison
Christopher Chavez, President, ANS