

# THE PHYSICIANS'

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September 27, 2000

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Dockets Management Branch (HFA-305)  
United States Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Marc J. Kornfield, M.D.

Dear Sir or Madam:

Charles A. MacNeill, M.D.

I am a physician practicing pain medicine for more than twenty years having implanted more than 150 spinal cord stimulators (SCS) during this time. I take strong opposition to the FDA intention to reclassify totally implantable spinal cord stimulators from Class III to Class II. Such a move would eliminate critical checks and balances that help promote patient safety.

John G. Porter, M.D.

Randy F. Rizor, M.D.

In my years of implanting I have found that such SCS devices are extremely complex. They involve highly intricate and specialized circuitry and a power sources that are totally implantable with leads surgically placed and secured in the spinal area. The devices themselves are as complex as the procedure to implant them.

Darrell N. Simone, M.D.

David R. Walega, M.D.

I am deeply concerned that the potential reclassification of this device to Class II opens the door to allow a lower standard of product in the market that could potentially endanger the lives of patients. As a physician who treats chronic pain patients on a regular basis, I am concerned for their safety as well as the integrity of my practice.

Patti Chambers, RN

Susan Heurich, MS, RN, FNP-C

Even with implantable SCS devices already approved by the FDA, not all safety features are well understood. To insure patient safety, it is critical to have manufacturing checks for any potential manufacturer of these devices.

Steve Kilgore, LCSW

John Lumpkin, RPT

I would note that in 1995, FDA itself deemed these devices "potentially high risk". The fact that the agency is planning to downgrade them now is cause for great concern.

Sharon Najeway, RN

I firmly believe that reclassification of these devices compromises the integrity of the entire class, a misstep that undoubtedly will jeopardize future patients (many of whom have lived with serious pain for years) from potentially receiving the only therapy that could help them.

Mary Paris, RN, CS

Cher Riddell, LPC

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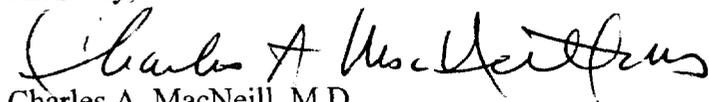
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United States Food and Drug Administration

The FDA classification level III, with the corresponding PRE-MARKET APPROVAL, is imperative to protect the safety of patients receiving these complex, technologically advanced devices.

Thank you very much for your careful consideration of my comments. If you have any questions or if I can provide any additional information, please do not hesitate to call. I can be reached at 404-256-0536.

Sincerely,



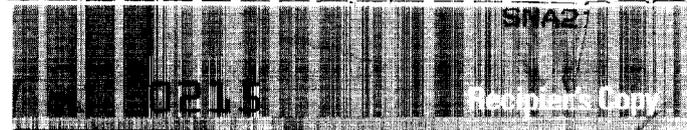
Charles A. MacNeill, M.D.

Clinical Professor of Anesthesiology and Pain Medicine  
Emory University School of Medicine  
President, The Greater Atlanta Pain Society  
Director, The Physicians' Pain and Rehabilitation Specialists of Georgia

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