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12 August 2011

Nancy K. Stade  
Deputy Director for Policy, Center for Devices and Radiological Health  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2011-N-0504 – Please post for public viewing**

Dear Ms. Stade:

I would like to take this opportunity to respond to the "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator" published in the Federal Register on 8/8/11. I am far beyond horrified by your egregious act against the many thousands of patients whose lives have not only been maximally improved with the prescribed use of Cranial Electrotherapy Stimulation, but saved from the ravages of Big Pharma and a lifetime of medication dependency and tremendously diminished quality of life.

Though I have lectured widely on the subject of Alpha-Stim Cranial Electrotherapy Stimulation on a national basis, I have no financial interest in Electromedical Products International and do not sell or rent this medical device in order to avoid conflictual relationships prohibited by Ohio Psychology Law.

As a Diplomate in Pain Management and licensed clinical psychologist, I have utilized Cranial Electrotherapy Stimulation since 1991, in hospital-based pain management programs, private practice, and the wartime theaters of both Iraq and Afghanistan, in each and every case, with unequivocally positive results and no less than negligible exceptions. Almost every single one of my private practice patients is now in possession of their own personal Alpha-Stim SCS device after years of battling the insurance industry and the Bureau of Workers' Compensation to assure that each of my patients received the most effective and beneficial treatment available to date anywhere in the world, as an adjunct to both traditional and holistic treatment approaches. Without exception, there is very simply, no more powerful form of therapeutic intervention, either as an adjunct or a stand alone form of treatment, than Alpha-Stim CES. This device is one of the most researched medical devices in today's market as you are clearly aware, and has stood the test of time in that it has been legally on the

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market in continuous distribution for 30 years with a flourishing research base and growing utilization by the Department of Defense because it works so rapidly and so effectively.

The very same holds true in my own practice and during my three overseas deployments in support of Operations Iraqi Freedom and Enduring Freedom. In the latter case, this was under the worst possible conditions that any human being should ever be forced to tolerate. When productive sleep or any degree of sleep was elusive, Alpha-Stim CES was the answer in every case, with one single exception. When anxiety and panic prevented Soldiers from being able to perform critical missions, the response to Alpha-Stim CES was rapid and entirely effective, acting as an unequivocal force multiplier. In the face of desperately depressed Soldiers consumed with overwhelming misery and despair, the rapid and progressive effects of Alpha-Stim CES made it possible for these Soldiers to perform their missions and to exceed standards and expectations. Most importantly, with respect to PTSD, often rampant in the wartime theater, Soldiers were enabled to remain on mission, avoiding medevacuation to higher levels of care and to be returned to home station in the U.S., with exceedingly negative and dire consequences. I would freely testify to these facts in any legal proceeding and gladly.

To deny access to the multitudes of patients, military personnel, and veterans who have derived significant or even modest benefits from CES, is no less than a crime against humanity in my estimation. You are its primary accomplice to damages that will render tremendous and unnecessary suffering among these infinite numbers of patients who prefer not to shuffle through life stuporously as the result of medication side effects. For all intents and purposes, for those who can no longer subsist under these prescriptive conditions, there is too often, no acceptable course of action remaining other than the taking of their own lives. One need not look any further than the explosive and record-breaking numbers of suicides within the population of returning veterans and the Army as a whole to know that this truly is the case. I hope that you own a conscience, Ms. Stade, as the deleterious impact of your decision is immeasurable and will unquestionably potentiate an endless series of damages to those so urgently in need of Alpha Stim CES. In effect, this amounts to a shotgun blast to the face.

The views and opinions expressed in this letter are those of the author of this correspondence and do not reflect the official policies of the United States Army, the Army Reserves, the Veterans Administration, or the Department of Defense.

Yours most sincerely,

*Kathy Platoni*

Kathy Platoni, Psy.D.

COL/MS/USAR

Army Reserve Psychology Consultant to the Chief, Medical Service Corp.