

Letters From Practitioners

Who Mentioned the Amount of Patients They Treated

Secretary's Correspondence

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT**

OS#: **082220111050** *Date on Letter:* **8/15/2011**

From: **Shealy, C. Norman (5607 S. 222nd Rd.)**

City/State: **Fair Grove MO** *Date Received:* **8/22/2011**

On Behalf Of: **,** *Type:* **General Public**

Subject: **The FDA is on the verge of banning safe, effective Cranial Electrical Stimulation for the treatment of depression, which has been in use since 1975. Writer has personally treated 30,250 patients without a single complication. Writer requests a Congressional hearing to prevent the banning this procedure.**

Synopsis:

Subject Tags: **None**

Assigned to: **FDA**

PC: **Gloria Overholser** *Date Assigned:* **8/22/2011**

Action Required: **Direct Reply** *Date Reassigned:*

Reply Due Date: **9/5/2011**

Info Copies To:

Interim (Y/N): **No** *Date Interim Sent:*

Comments:

File Index: **PO-4-6** *CCC:* **Laura O'Neill**

C. Norman Shealy, M.D., Ph.D.



August 15, 2011

Kathleen Sebelius, Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Madam Secretary:

The FDA is on the verge of banning safe, effective Cranial Electrical Stimulation for the treatment of depression, which has been in use since 1975.

<http://www.federalregister.gov/articles/2011/08/08/2011-19957/effective-date-of-requirement-for-premarket-approval-for-cranial-electrotherapy-stimulator>

I have personally treated 30,250 patients, **without a single complication.** See enclosed.

Meanwhile, in the July 2000 JAMA, it was reported that there were a minimum of 106,000 deaths from prescription drugs each year – about 300 Americans killed by prescription drugs every day! There have been three major articles, including one in the NEJM, that show that 75% of the NEGATIVE research papers on antidepressant drugs were not published, so that if they had been, drugs are reported to be 42% effective with a complication rate of 25%

I request a Congressional hearing to prevent this travesty.

Yours very truly,

A handwritten signature in black ink that reads "C. Norman Shealy".

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President, Holos Institutes of Health
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Psychological Services

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September 20, 2011

Nancy K. Stade

Deputy Director for Policy, Center for Devices and Radiological Health
Division of Dockets Management (HFA-305)
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Rockville, MD 20852

Re: Docket No. FDA-2011-N-0504, Federal Register, Vol 76, No. 152, pgs 48062-48070. Proposed Rule: Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator.

Dear Ms Stade;

In regard to my background, I have been using cranial electrotherapy with the Alpha-Stim 100 and/or the SCS and all the previous versions since 1982. In my private practice, I have treated more than 12,000 patients in my career and 70 have been treated using these various electrotherapy devices. Which is to say more than 21,000 CES (Cranial Electrical Stimulation) treatments. I have published four articles in a number of national journals such as the American Journal of Electromedicine and the Journal of Neurotherapy concerning Cranial Electrotherapy Stimulators because I have been so impressed with the positive treatment effects of Cranial Electrical Stimulation. In addition I have been quite successful in treating State Police and Municipal Policemen in Pennsylvania after Critical Incidents using CES. I have also been successful in treating patients using CES with PTSD especially veterans returning from Vietnam, Iraq, etc. Using CES, I have been quite successful in treating acute anxiety, panic attacks, headaches, neck and shoulder pain, autonomic pain and discomfort, depression, and sleep disorders. In addition, I have found CES quite useful in working with reducing or eliminating various addictions such as smoking, marijuana, and other

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depressants drugs legal or otherwise. I used it successfully to reduce the pain with a mild case of shingles on myself as an experiment and have suggested it to others with over a 50% success rate. Many of my patients like the machine so much that they purchase their own Alpha-Stim during treatment or at the end of treatment to guard against relapse in the above disorders. Finally, I practice what I preach since I own my own unit (an Alpha-Stim 100) to calm myself at home when I get upset. (I am quite healthy otherwise and do not take any medication, but find that my job can be stressful at times. Ten minutes is all I normally need.) I believe that this qualifies me as a Licensed Clinical Psychologist with significant human experience with these devices.

I have been amazed by the consistently excellent results and nearly total absence of negative effects. The vast majority of my patients go into a deep state of relaxation within 1 to 2 minutes of treatment. It even amazes them how fast they feel relief from anxiety, etc. Some take longer, but I have had only 5 or so patients state that they do not feel any positive change during their first treatment, something that I find extraordinary. I have never had such a positive effect with any other treatment that I have ever tried in 40 years as a Clinical Psychologist. I have only had a few patients that would not try it so I had to use other approaches. Only two patients found that even the smallest electrical stimulation was too strong for them so CES was not useful. They however, had no negative effects otherwise since I saw them for a number of visits and asked them. Probably 10-15% do feel "woosy" that is they say that feel light-headed for a few seconds if I start them at a higher intensity than is helpful. I tell them that this may occur and all I have to do (or they have to do) is reduce the intensity and they are fine. I have some patients that use the CES unit for hours/day due to the pain reduction that it induces.

Based on these experiences, I will now respond to your request for comments:

It is obvious to me that the FDA's current position of demanding a new PMA for the CES is totally biased against CES. I remember that the FDA received a PMA from the Alpha-Stim company in 1995, yet has not made the appropriate response of making it available to everyone in the US over-the-counter as it is throughout the world right now. I have psychologist friends in Europe, China, and Japan who tell me they can buy these machines over-the-counter.

The inaccurate FDA reviews on CES particularly upset me since they reviewed

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one of my published studies. The review states: the "Overcash study" used a rating scale that was not validated. If the FDA had read my study (in the American Journal of Electromedicine), they would have found that I used objective psychophysiological measures of anxiety " cardiovascular response (temp), glandular responses (EDR), and electromyography (EMG). All of these are accepted and validated approaches to measuring anxiety. A Numerical Visual Analog Scale (NVAS) was used to obtain a subjective measure of anxiety from the subject. Validity for the NVAS in the study of anxiety is well established in the research literature. The FDA comment on the rating scale used in this study is **false**.

Next, I have heard from other psychologists that some risks are mentioned from patients such as skin irritations and headaches. These have never been mentioned by all my patients and my psychologists friends state that they are very rare, very minor, and/or disappear when treatment ceases. This should not be a problem in regard to the availability of treatment. Seizures have been mentioned by the FDA, but the Alpha-Stim has not been shown to cause seizures in 30 years of use. Finally, FDA states: "potential adverse effects from electrical stimulation of the brain." I have researched this myself and found that electrical stimulation of the brain by these devices have been well studied and the effects are known. Pharmacology's effects on the brain are not fully understood. In 30 years of use with no problems, it is clear to me that these "adverse effects" are figments of the FDA's imagination. I will use the CES on myself for the rest of my life with no fear of the imaginary effects. When you compare these so called "risks" to the actual risks of many FDA-approved psychiatric drugs used to treat anxiety, addiction, depression, pain, PTSD, sleep disorders, etc you will see that CES is benign. I am in the process of slowing down and eventually retiring from Clinical Psychology after 40 years in practice. I believe that the American public would be well served by the FDA to allow open access to CES treatment and publish legitimate information concerning CES's usefulness in treatment.

Sincerely,

Stephen J. Overcash, Ed.D.
Consulting " Clinical Psychologist

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Aug 22, 2011

Nancy K. Stade
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Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

Dear Ms. Stade,

I have been using cranial electrotherapy stimulation with the Alpha-Stim daily in my medical practice for the past seven years. I have treated an average of 5 to 10 people a day during this period, which is to say more than 12,000 CES treatments in my office. This qualifies me as a physician with significant human experience with this device. I have been amazed by the consistently excellent results and the nearly total absence of negative effects.

Within thirty seconds of treatment, half the patients go into a deep state of relaxation, even if they were anxious in the beginning. Most of the other half become very relaxed after five to fifteen minutes. One in ten gets little or no effect. One or two in one thousand don't like it, but there is no harm. A twenty minute treatment typically keeps the anxiety away all day.

I have observed in my practice daily for seven years that CES with Alpha-Stim also reduces or totally relieves headaches, neck and shoulder pain, autonomic related pain such as bladder cramps, menstrual cramps, and abdominal cramps. I have seen it stop long term attacks of shingles pain on numerous occasions, no failures. I have seen it stop the pain of Complex Regional Pain Syndrome on numerous occasions. I have seen it block a migraine when used early in the attack, perhaps fifteen times or more, in my office, without failure.

Based on the work of Meg Patterson, MD, who had developed a cranial electrotherapy treatment for addiction (1), I was looking for an opportunity to try Alpha-Stim on someone wanting to get off drugs. I eventually was visited by a patient who wanted to get off methamphetamine "today,"

after four years. Alpha-Stim treatment totally took her cravings away, and there was no withdrawal. It worked like magic! Wanting to test this further, I asked cigarette smoking patients if they would mind if I tried to take away their cigarette craving. Most agreed to try it. I kept track of results. In 97% of smokers, within two minutes of treatment with Alpha-Stim, the craving was totally gone. (2) During the five + years I've been studying the cigarette addiction treatment, I've had the opportunity to test cravings for all the addictive drugs, both legal and illegal, including SSRI's. Alpha-Stim either totally takes away the cravings and eliminates the withdrawal, as appears to happen with cigarettes and methamphetamine, or greatly reduces the time and severity of withdrawal. More testing is obviously needed for this application. I know that FDA will endorse anything safe that will help people stop smoking.

Based on these experiences, I can now respond to your request for comments:

FDA's current position of demanding a new PMA for CES is totally biased against CES and CES manufacturers, particularly Alpha-Stim. FDA has already received a PMA from Alpha-Stim in 1995, and has not made the appropriate responses that would truly benefit the American citizenry -- to make this easily available to everyone! By any reasonable standard, after 30 years on the market, FDA should declare CES is now OTC/over-the-counter, just like it is throughout the rest of the world.

FDA knows very well, from the PMA submitted on Alpha-Stim in 1995, from post-marketing surveys from the company, and from the lack of any consumer complaints in thirty years of use and research, that Alpha-Stim is both safe and effective.

FDA's proposal is full of words, citations of regulations, and opinions, but it totally obscures the truth. The "Summary of Data" basically alleges poor quality of research on CES, or that good quality of research was with the wrong kind of patient for treating anxiety! It makes excuses for claiming that there is not enough evidence to support the positive therapeutic effect of CES. This "conclusion" in fact appears to have been FDA's position from the start. The conclusion is not based on the facts. Research and clinical experience find that Alpha-Stim CES is effective and safe.

In "Summary of Data," in two places, FDA mentions studies treating withdrawal and addiction. Yet FDA callously and effortlessly sets these aside because it is not representative of the general population with anxiety. As I have found using Alpha-Stim for cigarette and all other drug cravings, this is a remarkable treatment device. Instead of ditching these studies as irrelevant, if FDA truly had the benefit of the American public at heart, they would be funding or calling for the funding of using Alpha-Stim for treating cigarette and other addictions, and for more widespread use of treating anxiety. Only a negatively biased FDA could justify the actions taken over the years relative to CES and Alpha-Stim.

FDA's bias is clear in the segment, "Risks to Health," which lists 6 items. First, "Worsening of the condition being treated—If the device is not effective and the patient is not treated in a conventional manner, the patient's psychological condition may worsen." In fact, the problem is the opposite. Because FDA has been blocking wider usage of this amazing, very effective technology, people are getting worse because they can't get the treatment.

Then some true risks are mentioned, headaches and skin irritation, which are very, very rare, or very minor, or at worst, disappear when treatment ceases. The rarity and tininess of these problems are not sufficient to get in the way of the availability of this treatment.

Seizures are mentioned as a risk, but Alpha-Stim has not been shown to cause seizures in thirty years of usage.

Finally, as a risk: "Potential adverse effects from electrical stimulation of the brain— The physiological effects associated with electrical stimulation of the brain by these devices have not been studied systematically; therefore, adverse effects which may be caused by these electrical stimuli remain unknown." In thirty years of use and research, including the previous PMA, it is clear that "unknown adverse effects" are figments of FDA's imagination. Other "adverse effects" would have shown up after 30 years, but they haven't, because they don't exist.

Compare these "risks" to actual risks of certain FDA-approved psychiatric drugs used to treat anxiety, risks such as addiction, suicide, and homicide with SSRI's, and you see that CES is remarkably benign.

Currently, the biggest risk to the American public is that FDA will continue to block access to CES and legitimate information about its use in anxiety, depression, insomnia, and pain.

Thank you.

Sincerely,

William S Eidelman, M.D (e-signature)

William S Eidelman, M.D.

(1) Patterson, M, **Getting Off The Hook**, 1983, Harold Shaw Pub

(2) Eidelman, W, "Control of Cigarette Cravings with Cranial Electrotherapy Stimulation"
Townsend Letter: 311, 81-85, 2009

Edgar Rivera

October 14, 2001

Nancy K Stade
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**Re: The Federal Register, Vol. 76, No. 152. Pgs. 48062-48070. Proposed Rule:
“Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy
Stimulator.” [Docket No. FDA-2011-N-0504].**

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the Federal Register on August 8, 2011 (76 F.R. 152, p. 48062). As a Psychotherapist, practicing in Puerto Rico, who uses CES in my practice, I wanted to share with FDA my own findings on the efficacy and safety of CES as well as comment on the misleading and inadequate literature review of the research efficacy of CES which was outlined in the Federal Register.

As I mentioned, I practice psychotherapy in my own private office at the address mentioned in the face of this letter. I treat a variety of patients including children, adolescence, chronic pain patients, and adults with anxiety, trauma, and addictions. I have used the Alpha Stim SCS device for over 11 years with well over 500 patients. I have used this device to treat anxiety and adults recovering from addictions, coping with PTSD, or experiencing generalized anxiety disorder as well as major depression. I have also used it with a variety of chronic pain patients. I have also used this device with children and adolescents experiencing anxiety related to a variety of causal factors. More than 90% of the patients have had a good to excellent response to the Alpha Stim SCS . I have had chronic pain patients who were able to reduce their analgesic medications, and many patients who were able to much more successfully cope with cravings for drugs or alcohol by using the Alpha Stim. I always ask every patient about any possible adverse effects. In all the years of using this device, I have had no patients complaining of side effects or discomfort with the use of CES. That has been the extent of any adverse effects reported by my patients.

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If the FDA takes action which will reduce or eliminate patient's access to this device, many patients will suffer, needlessly, and will be forced to return to dependence on analgesics, anxiolytic and/or antidepressant medications. I was quite disturbed at reading your literature review in the Federal Register. Such literature seems to contradict all criteria for scientific review when it eliminates the majority of the studies from your review. The FDA's definition of "valid scientific evidence" does not ignore studies simply because they were conducted on a "specific population". I would urge you to employ a competent scientist to perform a more thorough and reasonable review of the available empirical support for CES.

Thank you for your attention to this matter.

Sincerely yours,

Edgar Rivera

PEI, TFT adv dx, Neurolinguistic Programmer, CFS .

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Nancy K. Stade

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Food and Drug Administration

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Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule:

□Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator. □[Docket No. FDA-2011-N-0504].

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the *Federal Register* on

August 8, 2011 (76 F.R. 152, p. 48062).

I am a Physical Therapist with a Doctoral degree and 38 years of clinical experience in treating people who have chronic pain. I am a Diplomate of the American Academy of Pain Management and the President of the Pain Management Special Interest Group of the Orthopaedic Section of the American Physical Therapy Association. I am also a guest lecturer in electrotherapy at Ithaca College, Utica College, and Broome Community College as well as an electrotherapy consultant for DJ Global. As a practitioner who uses CES in my practice, I wanted to share with FDA my own findings on the efficacy and safety of CES.

I have used the Alpha Stim CES device over the past 11 years with well over 700 patients. I have used this device with a variety of chronic pain patients and people who have had Central Sensitivity Syndrome. Well over 80% of the patients have had a good to excellent response to the Alpha Stim CES with many of these patients being able to reduce their narcotic and non steroidal analgesic medications.

I always ask every patient about any possible adverse effects. In the 11 years of using this device, I have had four patients complain of transient headache which resolved within 30 minutes of the cessation of treatment.

I was quite disturbed at reading your literature review in the Federal Register as you did not follow your own criteria for scientific review when you eliminated many of the

studies from your review. The FDA's definition of "valid scientific evidence" should not ignore studies simply because they were conducted on a "specific population".

I would urge you to perform a more thorough and reasonable review of the available empirical support for CES. Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down classified to a Class II device as it has proven itself to be safer and more effective than many OTC medications.

Sincerely,
John E. Garziona, PT, DPT, DAAPM