

## FDA misconduct not deemed newsworthy

August 7, 2012 – 5:20 PM | By [Mark McCarty](#) |

By Kelly Roman, Vice President of Fisher Wallace Labs

On February 10, 2012, the FDA convened an advisory panel hearing on whether to reclassify cranial electrotherapy stimulation (CES) devices. Despite being a low-risk device, CES has lingered in Class 3 (high risk) for more than 30 years as a result of being a grandfathered 510(k) medical device. The regulatory fate of CES, which is currently cleared to treat depression, anxiety and insomnia, will emerge at a time when antidepressants have been proven ineffective in treating soldiers with post-traumatic stress; CES has had great success treating this population. CES manufacturers such as my company will not survive the PMA process, and soldiers will lose access to CES should the FDA decide reclassification is unwarranted.

As the panelists took their seats, my business partner and I realized that Dr. Alvaro Pascual-Leone, professor of neurology at Harvard and director of the Berenson-Allen Center for Noninvasive Brain Stimulation, was missing from the panel. Our hearts sank – he was the only panel member with actual experience in non-invasive brain stimulation. He had even received a waiver from FDA to appear on the panel as a result of his irreplaceable expertise. Dr. Pascual-Leone was “unable to attend,” FDA’s Avena Russell [announced](#) to the crowded auditorium. Weeks later, we discovered this wasn’t true.

Without Dr. Pascual-Leone, the panel delivered a highly divided vote, which, by a slim margin, sided against reclassification. The dissenting panelists, while acknowledging that CES is safe, expressed discomfort with the fact that the vast majority of our effectiveness research was conducted between the 1960s and 1990s. There was little incentive to fund contemporary, large-scale studies

for a device that the FDA provided marketing clearance for in 1977, especially since no one had ever been injured by the device.

Five panelists believed we had proven CES safe and effective and deserving of reclassification, including Dr. Suresh Kotagal from Mayo Clinic and Dr. Richard Fessler from Northwestern. They were swayed by our well-controlled studies (albeit most pre-1995) and decades-long safety record. More than 600 board-certified psychiatrists currently prescribe our device.

Dr. Pascual-Leone may have voted in favor of CES reclassification (a fair assumption given his long-standing support of therapeutic non-invasive brain stimulation) and his expertise may have convinced one or more of the dissenting panel members that CES should be reclassified. His absence had an enormous negative impact on our bid for reclassification.

It was obvious from their presentation at the hearing that FDA's Malvina Eydelman and her team were determined to prevent CES from being reclassified. They went so far as to exclude 229 published studies on CES from consideration by applying biased exclusion criteria that did not reflect the regulatory definition of valid scientific evidence. For instance, they excluded all CES research that was not performed on humans. Since when are animal studies not accepted as valid scientific evidence?

"Let's contact Dr. Pascual-Leone and find out why he did not attend," I suggested to my business partner, Chip Fisher, after the hearing. Chip emailed Dr. Pascual-Leone who informed us that he was, in fact, able to attend the hearing but was instructed not to show up by the FDA a few days prior. My jaw hit the floor. The FDA had removed him and then lied about the reason for his absence.

Our Citizen Petition details this FDA misconduct but does not speculate on motive. I am reminded, however, every time I pick up a copy of *Psychiatric Times* that nearly all mental-health advertising is from Big Pharma. Last month, *Psychiatric Times* (aka *PT*) published an article titled "FDA Panel Votes to Curtail CES." The full-page article never mentioned Dr. Pascual-Leone or the controversy surrounding his removal from the panel. I

emailed *PT*'s editor-in-chief, Dr. James Knoll, and asked him why the article ignored the FDA misconduct. His emailed response to me ended with:

“Finally, for *PT* to delve into the issues surrounding Dr. Pasual-Leone would require an investigation and time investment that exceeds the depth and detail that we wished to communicate in this relatively brief news article.”

What does Dr. Knoll's staggering admission say about the integrity of *PT*'s other articles? What does the FDA's manipulation of our panel say about the integrity of other FDA hearings? CES is the only medical device on the market cleared to treat anxiety and insomnia – everything else is a drug. We manufacture our devices in New Jersey, not overseas, and our patients, more and more, are American soldiers in need of non-drug therapy. Unfortunately, we may be doomed if no one is watching the watchmen.

---

**The FDA works for the drug companies and they fear that the CES will become electronic drugs. CES has been shown better at helping depression addiction insomnia, anxiety and even psychosis than drugs. That would interfere with drug profits. So this is what made us make a change in the US CES on the SCIO for regulatory compliance.**



Fisher Wallace New Cranial electro stimulator using forehead electrodes

<http://cranialelectrotherapystimulation.com/?p=1>



# Cranial electrotherapy stimulation and fibromyalgia

Marshall F Gilula

## CONTENTS

Evidence for efficacy of CES in the treatment of FM

Role of the patient in FM treatment

Role of D-ribose in FM treatment

Stress reduction in FM treatment with the EPFX

Conclusion

Expert commentary

Five-year view

Information resources

Key Issues

References

Affiliation

*Life Energies Research Institute,  
2510 Inagua Avenue, Miami,  
FL 33133, USA  
Tel: +1 305 402 1475/  
+1 305 720 6501  
Fax: +1 305 854 8954  
mgilula@mindportag.com*

**KEYWORDS:**  
Alpha-Stim<sup>®</sup>, cranial electrotherapy stimulation, D-ribose, EPFX, fibromyalgia, mechanism of CES, neuroelectric modalities, rheumatology

Cranial electrotherapy stimulation (CES) is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients. CES is no panacea but, for some FM patients, the modality can be valuable. This article discusses aspects of both CES and FM and how they relate to the individual with the condition. FM frequently has many comorbidities such as anxiety, depression, insomnia and a great variety of different rheumatologic and neurological symptoms that often resemble multiple sclerosis, dysautonomias, chronic fatigue syndrome and others. However, despite long-standing criteria from the American College of Rheumatology for FM, some physicians believe there is probably no single homogeneous condition that can be labeled as FM. Whether it is a disease, a syndrome or something else, sufferers feel like they are living one disaster after another. Active self-involvement in care usually enhances the therapeutic results of various treatments and also improves the patient's sense of being in control of the condition. D-ribose supplementation may prove to significantly enhance energy, sleep, mental clarity, pain control and well-being in FM patients. A form of evoked potential biofeedback, the EPFX, is a powerful stress reduction technique which assesses the chief stressors and risk factors for illness that can impede the FM patient's built-in healing abilities. Future healthcare will likely expand the diagnostic criteria of FM and/or illuminate a group of related conditions and the ways in which the conditions relate to each other. Future medicine for FM and related conditions may increasingly involve multimodality treatment that features CES as one significant part of the therapeutic regimen. Future medicine may also include CES as an invaluable, cost-effective add-on to many facets of clinical pharmacology and medical therapeutics.

*Expert Rev. Med. Devices* 4(4), 489–495 (2007)

Cranial electrotherapy stimulation (CES) with Alpha-Stim<sup>®</sup> is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients (FIGURES 1 & 2). This article discusses aspects of both CES and FM and how they relate to the individual with the condition. CES is the US FDA- and EU-recognized generic category for medical devices using microcurrent levels of electrical stimulation applied across the head via transcutaneous electrodes for the treatment of anxiety, insomnia and depression. Microcurrent (<1000  $\mu$ A) stimulation usually means 1 mA or less, whereas transcutaneous electrical nerve stimulation (TENS) involves higher currents in the 60–100 mA range and with very different waveforms. CES treatment

of anxiety and depression began in the USA in the early 1960s, and is still being prescribed routinely by several hundreds of physicians today, but has yet to achieve ubiquitous acceptance in medical practice. That is possibly because sufficient information has not been made available to practitioners regarding the safety and efficacy of CES as a treatment for the approved indications of anxiety, insomnia and depression. Using an electromedical device requires more of an additional learning curve for both practitioners and patients who are accustomed to the pharmaceutical model of intervention. Ingesting a capsule or a tablet does not always require the attention to detail that correct application of ear clip electrodes, for example, demands. We have been conditioned

# A Study of the Effects of Cranial Electrical Stimulation on Attention and Concentration

SUSAN SOUTHWORTH, PSY.D.

*The Family Institute and Associates*

## Abstract

There have been several anecdotal accounts that cranial electrical stimulation (CES) enhances attention and the ability to learn new tasks in a normal population, but only one published investigation confirms that CES improves attention using the Alpha Stim CES (Madden and Kirsch, 1987). The purpose of this study to corroborate the findings of Madden and Kirsch, using more precise measures of attention, such as a Continuous Performance Test (CPT). A pretest and posttest CPT given two groups using the LISS CES device. The control group consisted of twenty-one subjects who received the placebo treatment. The experimental group of thirty-one subjects received twenty minutes of CES. Four measures of the CPT show significant gains in attention: Number of Hits, P Hit RT 151 Change,  $p = .016$ , Risk Taking,  $p = .055$ ; and Attentiveness,  $p = .054$ . Based on subjects who demonstrated improvement by one standard deviation on two different measures of the CPT, thirty-one percent of the experimental group improved versus four percent of the control group. The use of CES as a method of increasing is a promising area that requires further investigation.

Cranial Electrical Stimulation (CES) involves the application of small amounts of pulsed electric current using electrodes applied to the head. CES has been used in Europe and the United States for treatment of depression, anxiety, and insomnia for the past twenty years, and there have been several anecdotal accounts of how CES has been used to increase attention and concentration in normal subjects. These accounts include truck drivers using the device to increase concentration during times of long drives and students using the device to increase attention and concentration (Hutchinson, 1991).

## History of Electrostimulation

The application of electric current in the healing arts is not new practice. Long before William Gilbert defined electricity in 1600, the therapeutic value of naturally occurring electrostimulation was used by the ancient Egyptians and the Greeks. The use of Nile catfish (*Malopterus electricus*) is displayed on wall reliefs of Egyptian tombs dating back thousands of years. Aristotle and Plato reference the black torpedo, an electric ray fish, which the physician Scribonius Largus prescribed for relieving headaches and gout in 46 A.D. A similar application of electrical stimulation for relief of pain in the joints was described in 1747 using "an electrifying machine." The subject observed that the pain decreased prior to retiring for the night after the first treatment, and by the third day, the pain disappeared (Braverman et al., 1992).

The therapeutic use of electricity did not gain widespread acceptance due to the difficulty of providing a suitable source of electric current. The technology needed to manufacture CES devices is relatively recent. The earliest account of the use of small amounts of low voltage current for therapy appeared in 1953 by the Soviet researcher, Giljarowski, who used CES for relieving insomnia and in the