

FDA misconduct not deemed newsworthy

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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.