



March 25, 2016

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

Re: Electroconvulsive Therapy (ECT) Devices for Class II
Intended Uses: Draft Guidance for Industry, Clinicians
and FDA Staff; Availability; Docket ID: FDA-2014-D-
1318 & FDA-2014-N-1210.

Dear Food and Drug Administration:

This is the Public Submission (Comment) against the proposed order in the above referenced Docket to reclassify Electroconvulsive Therapy (Electroshock)¹ Devices into Class II for Major Depressive Episode associated with Major Depressive Disorder of Bipolar Disorder for use on patients 18 years or older who are "treatment-resistant" or who "require" a rapid response (Proposed Order) by the [Law Project for Psychiatric Rights \(PsychRights\)](#) and the [Committee for Truth In Psychiatry \(CTIP\)](#). PsychRights is a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock. CTIP is a national organization of over 500 former electroshock patients, none of whom were truthfully informed about the nature or consequences of electroshock before consenting to it.

My reading of the Proposed Order is that the "new information," it is based upon is in actuality a reevaluation of previously received data and this use of previous data is allowed only because of "newly available regulatory authority." My unpacking of this is that the Food and Drug Administration is using its "new regulatory authority" to overrule the March 18, 2011 recommendation of its own panel to not reclassify electroshock machines (except catatonia) because of the demonstrated harm and lack of proven efficacy. PsychRights submitted comments for the 2011 panel's consideration, a copy of which is appended hereto and incorporated herein. These comments cite the large body of evidence that demonstrates physical harm, cognitive harm, brain damage, high mortality, suicides, and lack of proven efficacy, especially for anything more than a few weeks.

The Proposed Order acknowledges the harm, but asserts that specified "special controls" address the problem. This is illusory. One of the special controls is cognitive status monitoring prior to beginning electroshock and during the course of treatment. However, the testing can only determine that harm has occurred, not prevent it. As the Washington Post reported on your 2011 panel's recommendations:

¹ Because of its harmful nature and lack of efficacy, PsychRights does not call the use of these devices therapy.

Panel member Christopher A. Ross, a psychiatrist and neuroscientist at Johns Hopkins University, asked if the published studies identified any risk factors that predisposed patients to memory loss and thinking impairment.

"Evidence-based data for that issue just doesn't exist," said Peter G. Como, a neuropsychologist at the FDA.²

Running electricity through people's brains is inherently brain damaging and the Proposed Order condones what could be described as Electroshock Roulette.

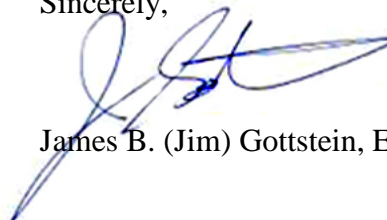
Theoretically, once such harm has been identified further electroshock would be halted, but that is not required in the Proposed Order, it is not the practice, and unlikely to occur, as well as being too late. The practice is for the people administering the Electroshock to ignore patients' reports of harm and to falsely state the harm will go away. There is absolutely no reason to believe that the cognitive monitoring special control will be implemented in any meaningful way even after harm has been inflicted. Even more concerning is the practice of courts to order patients to undergo electroshock over their wishes. This happens to thousands of people. There is simply no reason to believe that the hospitals obtaining such orders will bring this information to the judges. The United Nations Special Rapporteur on Torture has concluded that subjecting someone to electroshock against their will can constitute torture³ and has recently called for a complete ban on the non-consensual administration of electroshock.⁴ Thus, the effect of the Proposed Order will be to further enable torture as defined by International Law.

The other Special Control PsychRights & CTIP will address is the notion that mandating a warning that Electroshock may be associated with disorientation, confusion, and memory problems provides reasonable assurance of the safety and effectiveness of the device. The device is neither safe nor effective and giving a warning does not make it so.

Fundamentally, these Special Controls are an illusory protection and, at a minimum, it would be arbitrary and capricious to go forward with the reclassification. Additionally, in light of the facts, going forward with the reclassification would strongly suggest it is based on improper influence or other factors not based on the science.

Should the agency proceed with its Proposed Order, please give us notice, including the procedures to challenge/appeal the action.

Sincerely,



James B. (Jim) Gottstein, Esq.

² FDA Panel Advises more testing of "Shock-Therapy" Devices, by David Brown, *Washington Post*, January 28, 2011.

³ [Interim report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment](#), to United Nations General Assembly, July 28, 2008.

⁴ [Statement by Mr. Juan E Méndez, Special Rapporteur On Torture And Other Cruel, Inhuman Or Degrading Treatment Or Punishment](#), 22nd session of the Human Rights Council of the United Nations, March 4, 2013, Geneva.

PsychRights[®]
Law Project for
Psychiatric Rights, Inc.

January 24, 2011

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

Re: Docket No. FDA-2010-N-0585-0001,
Reclassification of Electroshock Machines

Dear Food and Drug Administration (FDA):

The Law Project for Psychiatric Rights (PsychRights[®]) is writing to oppose the reclassification of electroconvulsive therapy devices (Electroshock Machines) as a Class II or Class I device under the above referenced Docket. PsychRights is a public interest law firm whose mission is to mount a strategic legal campaign against forced psychiatric drugging and electroshock in the United States akin to what Thurgood Marshall and the NAACP mounted in the 40's and 50's on behalf of African American civil rights.

It is our understanding that under §513 of the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 USC §360c:

1. In order for reclassification of Electroshock Machines as a Class I device to be legal, there must be sufficient scientific information establishing that general controls are sufficient to provide reasonable assurance of their safety and effectiveness;
2. In order for reclassification of Electroshock Machines to a Class II device to be legal there must be sufficient scientific information establishing that special controls would provide reasonable assurance of their safety and effectiveness;
3. Absent meeting the criteria for reclassification as a Class I or Class II device, Electroshock Machines must go through the Pre-Market Approval process; and
4. In evaluating the safety and effectiveness of Electroshock Machines, the FDA must weigh any probable benefit to health from the use of Electroshock Machines against any probable risk of injury or illness from such use.

As set forth below, the criteria for reclassifying Electroshock Machines as a Class I or Class II device do not exist.

We are formally requesting notice of your final decision so that should your decision be to reclassify Electroshock Machines as either a Class II or Class I device, we may consider our legal options to prevent the harm that will be occasioned by such a decision, including seeking a stay from the FDA prior to seeking a court stay and review. In connection with such a decision, we are requesting under the Freedom of Information Act that you provide us with all of the information you received, reviewed, considered, or relied upon, or any combination thereof, in

making your decision and the grounds for such decision. This request is being made in advance of such a decision in order to allow timely filing.

Substantively, the legitimate scientific evidence¹ is overwhelming that Electroshock Machines are neither safe nor effective under the §513 criteria and any reclassification from a Class III device would be in violation of the Act. No studies show anything but short term benefit and there is overwhelming evidence Electroshock Machines cause brain damage, memory and cognitive losses in everyone. The brain damage, memory and cognitive losses, of course is to be completely expected from running electricity through people's brains. It is only through the dissembling of electroshock promoters and denigration of the first hand reports of harm, including catastrophic harm, by large numbers of electroshock recipients that this procedure is allowed at all.

In any event as set forth below, the scientific evidence does not allow the FDA to legally reclassify Electroshock Machines as a Class II or Class I device. Particularly interesting is *The Cognitive Effects of Electroconvulsive Therapy in Community Settings*, Sackeim HA, Prudic J, Fuller R, Keilp J, Lavori PW, and Olfson M, *Neuropsychopharmacology* (2007) 32, 244–254 because Sackeim is a long time proponent of electroshock as being safe and effective. The authors say their study is the first of its kind, but there is a long history of studies demonstrating the harm caused by electroshock. In any event, even these electroshock supporters, funded by the electroshock industry, found electroshock does indeed cause cognitive deficits: "This study provides the first evidence in a large, prospective sample that adverse cognitive effects can persist for an extended period, and that they characterize routine treatment with ECT in community settings."

A compilation of the other literature follows.

Amnesia, Other Memory & Cognitive Deficits Caused by Electroshock Machines

Rose D, Fleischmann P, Wykes T, Leese M, Bindman J: Patients' perspectives on electroconvulsive therapy: systematic review. *British Medical Journal*: 326 (7403), 1363-1367, 2003, June 21. This was the first-ever systematic review of *all* literature which included reports from patients, as well as studies designed and carried out by ex-patients. This study found that "At least one-third of patients reported persistent memory loss. Levels were between 29% and 79%." (persistent defined as lasting six months or more) The authors also note:

- "Routine neuropsychological tests to assess memory do not address the types of memory loss reported by patients."
- "Loss of memory is insufficiently systematically investigated."

¹ For an excellent analysis of the dissembling perpetrated by the electroshock industry, your attention is drawn to "Doctors of Deception: What They Don't Want You to Know About Shock Treatment, by Linda Andre, *Rutgers University Press*, New Brunswick, New Jersey and London, 2009, which Dr. Stefan Kruszewski described in his *International Journal of Risk & Safety in Medicine* review, as a "brilliant analysis," bringing to light, "distorted disclosure of faulty science" in the marketing of Electroshock Machines. Credit for assembling the scientific evidence against the safety and efficacy of Electroshock Machines also goes to Ms.Andre.

Johnstone L, Adverse psychological effects of electroshock. *Journal of Mental Health* 1999; 8(1):69-85. Johnstone asked patients to describe the sequelae of electroshock in their own words in semi-structured, qualitative interviews. Even though she did not ask about memory loss "nearly all spontaneously reported some degree of loss". They described the types of cognitive deficits and memory failures, such as failing to recognize formerly well-known persons, that have been consistently reported in the literature from since the 1940s. "If up to a third of people will suffer a serious adverse psychological reaction to electroshock, and if there is no way of identifying these individuals in advance, the ratio of costs to benefits may begin to seem unacceptably high. As always, more research is needed."

Squire LR, Slater PC, Electroconvulsive therapy and complaints of memory dysfunction: a prospective three-year follow-up study. *Br J Psychiatry* 1983;142: 1-8. In this study, Squire compared non-depressed former electroshock patients to depressed controls. Seven months post electroshock, the electroshock patients' reports of memory difficulty reflected amnesia, not depression. Three years after electroshock, the majority of electroshock patients (58%) reported their memory function was still impaired.

According to UK electroshock Review Group. Efficacy and safety of electroconvulsive therapy in depressive disorders: a systematic review and meta-analysis. *The Lancet* 2003 (March 8); 361: 799-808: "Several uncertainties about electroshock remain that merit further investigation. First, the current evidence does not provide a clear quantitative estimate of the degree of short-term cognitive impairment associated with present methods of electroshock and how much it may persist after symptomatic recovery. Indeed, very little randomized evidence exists on the possible long-term cognitive effects of electroshock."

In Rami-Gonzalez L, Salamero M, Boget T, Catalan R, et al., Pattern of cognitive dysfunction in depressive patients during maintenance electroconvulsive therapy. *Psychological Medicine* 2003; 33: 345-350, the investigators looked at patients who had had an average of 36 electroshocks, compared to matched controls who had no electroshock. Encoding of new information and performance on most tests of frontal lobe function were significantly impaired. Compared with controls, electroshock patients also showed alterations in verbal fluency, mental flexibility, working memory, and visuomotor speed.

In NICE (National Institute for Clinical Excellence, London, UK), *Guidance on the use of electroconvulsive therapy*, April 2003, it was found that: "There was evidence that the measurement scales used in RCTs do not adequately capture the nature and extent of cognitive impairment, and qualitative studies have indicated that the impairment may be prolonged or permanent."

In Calev A. Neuropsychology and electroshock: past and future research trends, *Psychopharmacology Bulletin* 1994; 30(3), 461-469:

- "It has been known for a long time that electroshock adversely affects memory and other cognitive functions."
- "Non-memory cognitive function is affected by electroshock, and therefore, needs to be addressed in future research. Patients should be informed of these effects of electroshock."

Philpot M, Collins C, Trivedi P, Treloar A, Gallacher S, Rose D: Eliciting users' views of electroshock in two mental health trusts with a user-designed questionnaire, *Journal of Mental Health* 13(4): 403-413, 2004, found, "The adverse effects profiles showed a high prevalence of adverse effects, with two thirds of respondents reporting memory disturbance or confusion at the time of treatment and nearly half permanently." This is the only study ever to ask patients about electroshock's effects on their intelligence; 35 to 42% said electroshock resulted in loss of intelligence.

Janis IL. Psychologic effects of electric convulsive treatments (I. Post-Treatment Amnesias). *Journal of Nervous and Mental Disease* 1950(a); 111: 359-381. Although this is a very old study, its methodology has been generally well accepted and there have been many calls over the years for its replication (which has never been done). It is one of the very few studies to employ matched controls. Janis interviewed nineteen electroshock patients about their lives before and after electroshock, and compared their performance to that of matched mental patient controls. At one month post-electroshock, all patients had "profound, extensive" amnesia for at least ten to twenty life experiences, while the controls, who had not received electroshock for purely administrative reasons, had no memory difficulties. A year after electroshock, the amnesias remained stable.

In Freeman CP, Weeks D, Kendell RE. electroshock II: Patients who complain. *Br J Psychiatry* 1980; 137:8-16, Freeman gave 26 patients, nine months to 30 years post-electroshock, one of the most extensive batteries of neuropsychological tests ever performed on a group of electroshock patients. Memory function was only one aspect of cognition addressed. No "subjective" memory tests were given, nor did these authors ever use the word "subjective". This study also employed a normal control group. Freeman found that the ex-patients were significantly impaired and that they accurately reported their impairments. Neither depression, nor drugs, nor other factors besides electroshock could account for all the neuropsychological deficits found in the patients. He concluded that "it may be that electroshock does cause some degree of permanent memory impairment."

In addition to the Sackeim study cited at the outset, severe permanent amnesia has also been found in the following two studies by financially conflicted researchers.

Weiner RD, Rogers HJ, Davidson JR, Squire LR. Effects of stimulus parameters on cognitive side effects. *Ann NY Acad Sci* 1986;462: 315-325. This study by Electroshock Machine manufacturer Mecta consultant Weiner is one of only a few to follow patients as long as six months, finding, "Provocative evidence for what amounts to objective personal memory losses lasting at least six months." After electroshock, patients could not remember 30 to 40% of the responses to personal questions they'd given on a questionnaire before electroshock. Though the authors did not state the percentages of patients with memory loss, it is possible to discern from the graphs that 94% of patients experienced memory loss lasting at least six months.

Coleman EZ, Sackeim HA, Prudic J, Devanand DP, McElhiney MC, Moody BJ. Subjective memory complaints prior to and following electroconvulsive therapy. *Biol Psychiatry* 1996; 39:346-356. In this study by Mecta consultant Sackeim and his team, electroshock patients all reported memory and cognitive impairment compared with controls. The study noted "ample objective documentation of anterograde and retrograde memory deficits" at one week. At two months post-electroshock, patients were still

impaired, and according to Sackeim, this can be considered to be permanent. The researchers "also observed significant associations between memory self-ratings and the extent of retrograde amnesia for autobiographical information." and "evidence of a relation between subjective self-assessment and objective neuropsychological findings in an electroshock sample." In other words, patients accurately reported their deficits.

Brain damage

In Templer DI, Veleber DM. Can electroshock permanently harm the brain? *Clinical Neuropsychology* 1982; 4(2): 62-66, the authors stated, "Our position remains that electroshock has caused and can cause permanent pathology."

Colon EJ, Notermans SLH. A long-term study of the effects of electro-convulsions on the structure of the cerebral cortex. *Acta Neuropathologica (Berlin)*1975; 32: 21-25. This was an animal study done two months after shock:

- "The results indicate a persistent change in the nuclear volume of the cerebral neurons in this area."
- "This constitutes a serious warning against the use of electroconvulsive therapy and a serious indication for the suppression of epileptic manifestations."

Weinberger DR, Torrey EF, Neophytides AN et al. Lateral cerebral ventricular enlargement in chronic schizophrenia. *Archives of General Psychiatry* 1979; 36: 735-739. This was not an electroshock study *per se*, but included patients who had had electroshock and concluded it was associated with ventricular enlargement. "Either electroshock enlarged the ventricles of the patients treated with it, or it was used with greater frequency in patients who tended to have larger ventricles." The latter, of course, is highly improbable.

Calloway SP, Dolan RJ, Jacoby RJ, Levy R. electroshock and cerebral atrophy. *Acta Psychiatrica Scandinavica* 1981; 64: 442-445, was a retrospective CAT-scan and case review study of 41 people. All patients were at least six months post-electroshock and the authors were so alarmed by their finding that they warned, "A significant relationship was demonstrated between frontal lobe atrophy and electroshock...In our opinion, this is a question of such importance that, in our opinion, the finding of a relationship between frontal atrophy and electroshock justifies this brief report. It emphasizes the need for a more detailed investigation, with larger number of patients in a younger age group."

In the Templer RI, Ruff CF, Armstrong G. Cognitive functioning and degree of psychosis in schizophrenics given many electroconvulsive treatments. *British Journal of Psychiatry* 1973; 123: 441-443, study, the performance of former electroshock patients---all of whom were at least seven years post-electroshock---on cognitive tests was significantly inferior to that of control mental patients matched for age, race and education. "The electroshock patients' inferior Bender-Gestalt performance does suggest that electroshock causes permanent brain damage."

Shah PJ, Glabus MF, Goodwin GM, Embeier KP. Chronic, treatment-resistant depression and right fronto-striatal atrophy. *British Journal of Psychiatry* 2002; 180: 434-440, was an MRI study of 20 patients with controls, but not an electroshock study as such, finding,

"Atrophy was confirmed on volumetric analysis, the degree correlating with the cumulative number of electroconvulsive therapy (electroshock) treatments received, suggesting an acquired deficit." The study concluded that "The possibility that the findings were electroshock-related cannot be discounted." In reality, it is a virtual certainty that the findings were electroshock related.

In Diehl DJ, Keshavan MS, Kanal E, et al Post-electroshock increases in T2 relaxation times and their relationship to cognitive side effects: a pilot study. *Psychiatry Res* 1994 (November); 54(2): 177-184, six patients were studied while undergoing unilateral electroshock. "The results demonstrate significant post-electroshock T2 increases in the right and left thalamus, and suggest a correlation between regional T2 increase and anterograde memory impairment. These findings are consistent with a post-electroshock increase in brain water content (perhaps secondary to a breakdown of the blood-brain barrier) and suggest that this process may be related to the memory impairment following electroshock."

Marcheselli et al. Sustained induction of prostaglandin endoperoxidase synthase-2 by seizures in hippocampus. *J Biol Chem* 1996; 271: 24794-24799 found that electroshock causes an increase in the production of inflammatory proteins in brain cells.

The Andreasen et al. MRI of the brain in schizophrenia. *Archives of General Psychiatry* 1990; 47: 35-41 MRI study demonstrated a strong correlation between the number of previous electroshock treatments and enlarged ventricles .

The Dolan et al. The cerebral appearance in depressed patients. *Psychological Medicine* 1986; 16: 775-779, study compared the brain scans of 101 depressed patients who had received electroshock with the scans of 52 normal volunteers and found a significant relationship between electroshock treatment and brain atrophy. The study also showed that the brain abnormalities correlated only with electroshock, and not with age, gender, severity of illness, or other variables.

In Figiel G, Coffey E, et al. Brain MRI findings in electroshock-induced delirium. *Journal of Neuropsych and Clin Sci* 1990; 2: 53-58, this study conducted by a well-known electroshock enthusiast found that 11% of elderly patients getting electroshock for depression remained delirious between electroshock sessions for no discernible medical reason other than the electroshock. 90% of these patients had lesions in the basal ganglia area of the brain, and 90% also had white matter lesions.

Teuber JL, Corkin S, Twitchell TE. A study of cingulotomy in man. Report to the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. 1976. The authors of this study stated, "We found that individuals whose prior treatments had included electroshock were inferior to normal control subjects and to patients [who had been subjected to psychosurgery] who had been spared electroshock, and this inferiority was apparent on the following measures: verbal and nonverbal fluency, delayed alternation performance, tactual maze learning, continuous recognition of verbal and nonverbal material, delayed recall of a complex drawing, recognition of faces and houses, and identification of famous public figures. In some cases, the degree of deficit was related to the number of electroshock received, patients

who had been given more than 50 being significantly worse than those who had sustained fewer than 50."

Permanent memory loss in rats

Unlike the literature on humans, which generally avoids the use of the word, "permanent," substituting "persistent," the rat study Luttges MW, McGaugh JL. Permanence of retrograde amnesia produced by electro-convulsive shock. *Science* 1967; 156: 408, concludes that shocked rats had permanent retrograde amnesia for a task they had known how to do before shock.

Efficacy

No study has ever found a beneficial effect of electroshock lasting more than four weeks. The following studies shows that efficacy of Electroshock Machines has not been established.

An independent review group (van der Wurff FB, Stek ML, Hoogendijk WL, Beekman ATF. Electroconvulsive Therapy for the Depressed Elderly, *Cochrane Database of Systematic Reviews*, The Cochrane Library, 2003; 3) set out to review the evidence of efficacy in elderly patients, but concluded: "None of the objectives of this review could be adequately tested because of the lack of firm, randomized evidence. It is of importance to conduct a well designed randomized trial in which the efficacy of electroshock is compared to one or more antidepressants."

NICE (National Institute for Clinical Excellence, London, UK), "Guidance on the use of electroconvulsive therapy", April 2003 discovered, "There was no conclusive evidence to support the effectiveness of electroshock beyond the short term or that it is more beneficial as a maintenance therapy in depressive illness than currently available pharmacological alternatives."

Lambourn L, Gill D. A controlled comparison of simulated and real electroshock. *British Journal of Psychiatry* 1978; 133: 514-519, found no advantage for real electroshock over simulated (anesthesia only) electroshock.

Sheppard GP, Ahmed SK. A critical review of the controlled real vs. sham electroshock studies in depressive illness. Paper presentation at the First European Symposium on electroshock, Graz, Austria, March 1992, reviewed every published controlled sham vs. real electroshock studies to date (there have been none since) and found, "Evidence does *not* in the opinion of the authors significantly indicate that real electroshock is more effective than sham electroshock in treating depressive illness."

High mortality, no effect on suicide

One of the presumed benefits of Electroshock is a reduction of suicide and therefore decreased mortality. Neither have been shown to be true and the evidence suggests the opposite:

Philpot et al, cited above, though not a mortality study, found 2 of 108 patients in the study group died within six weeks of electroshock.

The state of Texas, after reviewing the first five years of data on deaths occurring within 14 days of electroshock as required by the state law since 1993, changed the mandatory statewide consent requiring patients to be informed of the possibility of death due to electroshock---deleting the word "remote" in front of "possibility of death".

Barbigian HM, Guttmacher LB. Epidemiologic considerations in electroconvulsive therapy. *Archives of General Psychiatry* 1984; 41: 246-253, looked at all causes of death and stated, "electroshock patients died sooner after first hospitalization than patients not receiving electroshock."

In Milstein V, Small JG et al. Does electroconvulsive therapy prevent suicide? *Convulsive Therapy* 1986; 2: 3-6.1491, a study by doctors administering a lot of electroshock, patients were followed for 5-7 years, they could not produce any evidence that electroshock reduced the suicide rate. In fact, those who committed suicide were more likely to have received electroshock.

Black DW, Winokur GW et al. Does treatment influence mortality in depressives? was a follow-up of 1076 patients with major affective disorders. *Annals of Clinical Psychiatry* 1989; 1(3): 166-173 finding:

- "Neither general (all cause) mortality rates nor suicide rates varied significantly among treatment groups."
- "Mode of therapy received in the hospital has minimal influence on subsequent mortality, including suicide."

Avery DA, Winokur GW. Mortality in depressed patients treated with electroconvulsive therapy and antidepressants. *Archives of General Psychiatry* 1976; 33: 1029-1037, concluded: "In the current study treatment was not shown to affect the suicide rate."

Kroessler D, Fogel BS. Electroconvulsive therapy for major depression in the oldest old: effects of medical co-morbidity on post-treatment survival. *American Journal of Geriatric Psychiatry* 1993; 1(1): 30-37, found higher mortality in very elderly people treated with electroshock.

Karagulla S. Evaluation of electric convulsion therapy as compared with conservative methods of treatment in depressive states. *Journal of Mental Science* 1950; 96: 1060-1091, compared people treated in the pre-electroshock (pre-1939) era with those treated in later years. People who had had electroshock committed suicide at twice the rate of those who hadn't.

The foregoing makes clear that it would be improper for the FDA to reclassify Electroshock Machines as either a Class I or Class II device. In fact, the evidence is quite strong that they should not be allowed at all. Therefore, we are reiterating that we are formally requesting notice of your final decision when it is made so that should your decision be to reclassify Electroshock Machines as either a Class II or Class I device, we may consider and possibly pursue legal options and that at the same time you provide us with all of the information you received, reviewed, considered, or relied upon, or any combination thereof, in making your decision and the grounds for such decision.

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We appreciate your consideration and hope the FDA will make the proper decision to require the manufacturers of Electroshock Machines to comply with the Pre-market Approval process.

Yours truly,

A handwritten signature in blue ink, appearing to read "J. B. Gottstein", with a long horizontal flourish extending to the right.

James B. Gottstein, Esq.
President/CEO