MEMOMRANDUM

TO: Food and Drug Administration Ombudsman Office
Medical Devices Ombudsman

CC: The Public and All Elected, Appointed, or Otherwise Employed Government Officials and Workers

FROM: People who are Psychiatric Survivors, People who are Shock Treatment Survivors, Allies, and MindFreedom International Members

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SUBJECT: Official Public Complaint of FDA Processes Attempting to Down-Classify the Shock Device

RE: Docket No. 2014-N–1210 for ‘‘Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment-Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses”
and
Docket No. FDA-2014-D-1318 for “Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and FDA Staff”

This is a public official complaint concerning the processes the FDA is using in above referenced dockets. The dockets in question include one, proposing a rule to down-classify the shock device from a Class III device to a Class II device, which would place the shock device in the same category of devices such as eyeglasses or wheelchairs and two, draft guidance for the shock device as a Class II device.

Please see this complaint underscored by the fact that in 2008 the Special Rapporteur on Torture and Other Cruel, Inhuman and Degrading Treatment of the United Nations Human Rights Council reported that electroshock may constitute torture or ill treatment (Interim Report to the General Assembly, July 28, 2008[i]). He specified that "it is of vital importance that ECT be administered only with the free and informed consent of the person concerned, including on the basis of information on the secondary effects and related risks such as heart complications, confusion, loss of memory and even death."

In 2015, two United Nations Special Rapporteurs, the Rapporteur on the Rights of Persons with Disabilities and the Rapporteur on the Right to Health, issued a statement[ii] calling on all countries to "eradicate all forms of non-consensual psychiatric treatment" ("Dignity must prevail" - An appeal to do away with non-consensual psychiatric treatment World Mental Health Day – Saturday 10 October 2015).

Also in 2015, the United Nations Committee on the Rights of Persons with Disabilities, which monitors the Convention on the Rights of Persons with Disabilities that has been signed (although not yet ratified) by the United States, found that forced treatment is an act of torture or other cruel, inhuman or degrading treatment in its Guidelines on Article 14[iii], and has specifically expressed concern about forced electroshock in calling for abolition of forced treatment in two states parties to the Convention, Denmark[iv] and Sweden[v] (both in 2014).

As for our complaint, there are thirteen main issues (each with sub-issues) that we take with the process FDA has used for the proposed rule to down-classify the shock device and the draft guidance. Our issues are as follows:

First, the FDA announced the proposed rule and draft guidance on December 29, 2015, when the bulk of the world was otherwise involved with holiday. Due to the dedication of people who monitor the FDA and first noticed the proposal we are trying to respond to both dockets. It is a cruel reality that the deadline suggested by FDA, March 28, 2016, also falls over another holiday (although not a federal holiday).

We take issue with the way the proposals were released, in terms of their timing.

Additionally, it seems that weekends and federal holidays were not accounted for in the 90-day response time. If we have counted correctly, May 4, 2016 is 90 business days minus federal holidays and weekends from December 29, 2015. So the deadline to comment on the shock device ought to be May 4, 2016 not March 28, 2016, which is only 62 business days (not including federal holidays or weekends). . . The FDA proposed close date for the open docket (March 28, 2016) does not take into account federal holidays or weekends.

There are five other issues in relation to not having adequate access to comment to the FDA.

The first issue for people who do not have Internet access, even finding out that the FDA has these plans would be difficult to do without much effort and access to the Federal Register.

The second issue is that for people who have disabilities, accessing the online-information has posed issues. There is the situation of Judy from New Jersey, who has low vision. After learning about the proposed rule, Judy called the FDA for information that would be accessible to her. She left three messages with no responses. A week or so after her first call, she was contacted and told that a specialist would be in touch with her. After a week, when she was called back again, she specified the information that she needed in order to allow her to respond to the FDA. Judy was told the information would be sent to her. The information did not arrive. Finally, Judy, in complaint, on March 17, resorted to registered mail. At some point after that, Judy was contacted by someone from FDA. This person told Judy that information about the docket and how to respond to the docket would be sent to her. A package arrived for Judy on March 22, 2016 and

contained inadequate information, which did not include information on how to file. Judy is sending this information back to FDA. In attempt to respond to the FDA she has stretched limited funds to purchase a tablet so that she may respond, feeling it was her only option for submitting comment.

Judy's position is that those responsible for this proposed rule are so overloaded with work that the deadline ought to be extended.

Our position is that Judy's situation is probably not unique.

We believe the deadline for comments ought to be extended because there is simply not enough time to access information, process it, and respond to the FDA proposals in a meaningful way.

The third issue, for people most at risk for shock treatment, people languishing in institutions where they are not allowed to have access to their phones or computers, gaining access to the FDA's proposed rule is near impossible. If FDA really wanted feedback about what this proposed rule means to people potentially subjected to its orders, then there ought to be a nationwide effort to interview people in every institution in the United States.

The fourth issue is that there are many people who have been either severely damaged by shock treatment creating a situation that it would be difficult for them to comment on FDA proposal, or, people who are dead as a result of shock treatment who clearly cannot comment on the proposed rule.

The fifth issue is, in order to appropriately comment on the bulk of the guidelines about the device, one needs to understand electrical sciences. We have just found an expert in the field who is working through some of the technical meaning of the guidance with us. The level of technical understanding one needs to understand the material is specialized. Therefore, we must have more time to decipher what it is we are being asked to process.

Second, the FDA has made it as difficult as possible to participate in government processes in several ways. First, FDA has created two different dockets that people must respond to, which dilutes the responses on each, as many people are unaware of the existence of the other docket. Second, FDA has stated that:

> Agencies review all submissions, however some agencies may choose to redact, or withhold, certain submissions (or portions thereof) such as those containing private or proprietary information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign[vi].

This move to eliminate mass-mail in campaigns and duplicative or near-duplicative letters from the submission process both discourages people from participating in government and prevents those who, because of brain damage caused by shock treatment,

or other disabilities, may be able to participate in a petition, but are unable to draft their own statements.

Third, FDA has suggested that since it held hearings in 2011 on the shock device (where it was recommended by the panel to keep the shock device at a Class III level) that FDA does not need to hold hearings now—even though the current panel is made up of entirely different people from the 2011 panel. We find this new ability for the FDA to make an order and not have to go through rule-making processes particularly deleterious to the future lives of people who may be subjected to shock treatment because of this new rule.

Fourth, FDA is arguing that Section 513(e) of the Food Drug &Cosmetic Act allows that:

> FDA may, by administrative order, reclassify a device based upon 'new information.' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (p. 81224)

This is an issue beyond the shock device. This is of concern for anything that the FDA is doing.

However, concerning the shock device, the "new information" for which the proposed rule was created is debatable.

The "new information" that the FDA is citing includes both the industry guidance (and of course the industry has a vested interest in the continuation of the use of the shock device) and research where the bulk of information that reported the experiences of people who were subjected to shock treatment, was redacted. Through this investigative process of reviewing the materials, we were able to learn, through an author of the report that was redacted, that the overwhelming majority, if not all of the information that was redacted, was negative toward shock treatment.

There is an abundance of other information that FDA is not taking into account and in its attempts to include "new information" has not included any information about shock treatment that shows the damage that it does. There is a tremendous amount of work done by people trying to call attention to brain-damaging shock treatment. Some but not all resources FDA ought to thoroughly review include:

- the results of the Survivor Survey on www.ectjustice.com;
- Aftershock: Life After ECT https://aftershocklifeafterect.wordpress.com/2016/02/09/a-collection-of-ect-statistics

- The Law Project for Psychiatric Rights research collection page concerning shock treatment
  http://psychrights.org/research/Digest/Electroshock/electroshock.htm
- The Coalition for the Abolition of Electroshock in Texas
  www.endofshock.com
- From the Files of Leonard Roy Frank on Electroshock
  http://psychiatrized.org/LeonardRoyFrank/FromTheFilesOfLeonardRoyFrank.htm#Electroshock_
- Peter Breggin, M.D.'s The Dangers of Electroconvulsive Therapy
  http://www.breggin.com/index.php?option=com_content&task=view&id=40
- Peter Breggin M.D.'s ECT Resources Center
  http://www.ectresources.org/
- Mad in America's ECT Archives
  http://www.madinamerica.com/category/ect/
- MindFreedom International's Electroshock Page
  http://www.mindfreedom.org/kb/mental-health-abuse/electroshock/electroshock-info
- Linda Andre's (2009) Doctors of Deception: What They Don't Want You to Know About Shock Treatment
  http://rutgerspress.rutgers.edu/product/Doctors-of-Deception,4419.aspx
- Bonnie Burstow's *Psychiatry and the Business of Madness: An Ethical and Epistemological Accounting* (especially concerning debunking claims of reducing suicide).
  http://www.palgrave.com/fr/book/9781137503831
  Paula Joan Caplan's *The Say You're Crazy: How the Worlds Most Powerful Psychiatrists Decide Who Is Crazy* (especially for debunking the idea of a) psychiatric assignment and b) "treatment-resistance"
  https://books.google.com/books?id=X4CNx3EiGJUC&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false

Peter Breggin, M.D. supplied us with insight into the shock device and that shock treatment always causes brain damage and memory loss. Dr. Breggin stated:

> "The purpose of ECT is to cause an intense seizure or convulsion. Each time it knocks the patient into a coma, obliterates all normal electrical activity, and often results in temporary flat lining of the brain waves. The patient awakens minutes later in a concussive state of disorientation, confusion and memory loss, often in a delirium. Animal studies show widespread small hemorrhages and scattered cell death from routine doses of ECT. Without a doubt, the process always damages the brain and causes mental dysfunction, often leading to dementia. ECT is not a last resort because it does not work and can ruin recovery. ECT does not prevent suicide, but can cause it. Because ECT destroys the ability to protest by crushing the person with confusion, apathy and numbness, all ECT quickly becomes involuntary and thus it is inherently abusive and a human rights violation.

> Therefore, when ECT has already been started, concerned relatives or others should immediately intervene to stop it, if necessary with an attorney. ECT should be banned. For overwhelming scientific confirmation of these statements, see www.ECTresources.org."

As an additional note (de)VOICED: An Environmental Community-Based Participatory Action Research Project (Tenney, 2014) was not specifically about shock treatment, but offers new information and qualitative research as there were people who were shock survivors who participated in the research who were court ordered and coerced into shock treatment. These people revealed horror stories of both brain and body damage that they experienced because of shock treatment they were subjected to. Additionally, one person who had thought she gave 'informed consent' discussed the betrayal she felt by the doctor when she could not recall after shock, details of her life, including her significant other. Underscored in this research is how, the "informed consent" process was not "informed" at all, and actually deceptive (http://academicworks.cuny.edu/gc_etds/296/).

There exists a wealth of other information concerning brain-damaging and body-damaging shock treatment we have not seen accounted for by the FDA.

It is very important to understand that these studies that show various types of damage that shock treatment creates have largely been ignored and suppressed by FDA. FDA must address these studies especially since the entire argument for this proposed rule included a review of the 2010-2011 processes.

While FDA listed several studies that they saw as presenting new information, the materials above and other information obtained through 2010-2011 FDA processes attempting to down-classify the shock device must be addressed.

The following overview of these studies showing damage from shock treatment comes from James B. Gottstein, Esq.'s 2011 letter of opposition[vii] to the FDA's attempt to down-classify the shock device in 2011 and is still relevant today:

> **Amnesia, Other Memory & Cognitive Deficits Caused by Electroshock Machines**
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> 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:
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> · "Routine neuropsychological tests to assess memory do not address the types of memory loss reported by patients."

- "Loss of memory is insufficiently systematically investigated."

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 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 visiomotor 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."

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."

So our public complaint includes, that per section 513(e) of the FD&C Act, we want you to address all of the information that was given through the 2010-2011 comment/hearings processes as part of the "new information" in addition to the information contained in this complaint.

Per the Sunshine Laws, we want this information presented to the public, in order to have comment that the public gives adequately reflect the big picture of shock treatment, not a representation of what the industry clearly favors.

Fifth, The rule proposed, that we are opposing, is that for people who are 18 years of age and older, who experience a "depressive episode" as part of "major depressive disorder" or "bipolar disorder" and are "treatment-resistant" or "require rapid response" that the "probable benefit of ECT outweighs these risks" (Federal Register, 2015, p. 81228).

FDA explained that based on the review of the 2011 panel, "FDA concluded that ECT demonstrated effectiveness in the acute phase (less than 3 months after treatment)" (p. 81227). This is disputable when you search out the stories of shock survivors and pay less attention to the interests of the industry.

However, this supposed benefit that lasts for up to three months ***after*** treatment then turns into an argument that, "FDA conducted a systematic meta-analysis of these studies which supported a robust effect of ECT in the short-term (e.g. 3 months)" (pp. 81227 – 81228).

Then once more the 'new information' is turned around.

In the final proposed rule it is said that long-term treatment is "treatment in excess of 3 months" (p. 81233), implying that short-term treatment, which is being presented as 'safe enough' for people who experience "treatment-resistant" 'depression' or who "require rapid response", is three months long.

Therefore, what we contest is that even if there is some supposed acute benefit that lasts for up to 3 months after treatment (typically described in the DSM as a euphoria that can be confused with mania), what is proposed in the new rule is subjugation to short-term shock treatment for 3 months. So ultimately, here the issue is that the proposed rule does not even reflect what the supposed "new information" has shown.

We want FDA to be held accountable to have the rule meet the 'new information'.

Sixth, in the proposed rule, Section V lists the known devastating consequences of shock treatment on the brain and the body. These known consequences, as addressed below, include autobiographical memory loss caused by brain-damaging shock treatment and death.

Those who have had their autobiographical memory wiped clean argue that they their lives were taken away from them, deadened, even though their physical bodies persisted.

There is not one known benefit listed in the proposed rule, and in fact, an "unknown" benefit is alluded to as a potential reason of why the shock device should be allowed to remain Class III for those not targeted for Class II use. The proposed rule literally states:

> Because the benefits of these devices for such uses are unknown, it is impossible to estimate the direct effect of the devices on patient outcomes. However, based on claims made about the devices, the devices have the potential to benefit the public by providing additional treatment options for schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia (Federal Register, 2015, p. 81231)

The American public ought to be aware of the ways in which FDA is making rules based on claims of an industry that will lose a substantial source of funding if the shock device is not lowered to a Class II device.

As a reminder, if the device is unable to be put into Class I or Class II, it must be taken off of the market, banned under section 516 of the FD&C Act (21 U.S.C. 360f) (Federal Register, 2015, p. 81225). Concerning the 2011 attempts to down-classify the shock device, it is important to note that in the Federal Register (2015) it is specified:

> FDA received over 3,000 submissions to the docket, with the majority of respondents, approximately 80 percent, opposing reclassification of ECT. The majority of those opposing reclassification of ECT cited adverse events from ECT treatment as the basis for their opposition. The most common type of adverse event mentioned in the public docket were memory adverse events, followed by other cognitive complaints, brain damage, and death. (p. 81226)

We want to make sure that the shock device is not placed in a Class II device category, for any reason, and that the overwhelming opposition from previous hearings maintain the weight the opposition held when decisions were previously made to not down-classify the device.

Seventh, beyond the issue of the proposed rule and draft guidance published as two separate dockets causing confusion and preventing people from being able to participate in government processes with ease, we take issue about proposed guidance documents being compiled prior to the determination of the propose rule being ordered.

Further, despite the full section of known consequences and risks of shock treatment (printed below), the Draft Guidance simply requires “a prominently placed warning”: “Warning: ECT device use may be associated with: disorientation, confusion, and memory problems” (p. 13) and “Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT has not been demonstrated” (p. 13).

There is a long list of the known risks and consequences of shock treatment in the Proposed Rule (re-printed below) that have been written to share with those contemplating shock treatment. These known risks are barely addressed throughout the 28-page Draft Guidance document which FDA is receiving public comment, where the message is that risks “should” be conveyed to people potentially subjected to shock.

Part of what we object to is FDA's explanation of what FDA means when it indicates to the manufacturers what "should" be included in the warnings section of the operator's manual and patient information, at the outset of the guidance.

In the Draft Guidance, FDA is clear, "The use of the word *should* in any Agency guidances means that something is suggested or recommended, but not required" (p. 1).

In the Draft Guidance, there are specific requirements that must be included as a way of supposedly mitigating risk, such as conducting "pre-ECT medical and psychiatric assessment . . . ; patient monitoring during procedure . . . ; appropriate use of general anesthesia . . . ; pre-ECT dental assessment . . . ; EEG monitoring . . . ; instructions on electrode placement . . . ; monitoring cognitive status which includes cognitive function evaluation before beginning ECT and monitored throughout the course of treatment via formal neuropsychological assessment. . . . patient self report . .. by qualified, appropriately trained, mental health professionals licensed by the state; and that results should be reviewed and influence appropriate clinical decision making (e.g. holding or terminating treatment . . .)" (p. 15).

However, there is no way of accounting for, or knowing, whether psychiatrists who are shocking people are meeting these requirements. There is no way of holding physicians accountable to these processes. Additionally, there is no mechanism for consequences for straying from these processes—not that we in any way support the down-classification of the shock device, for any reason.

Further, in the section on "patient labeling" (pp. 16 – 19) there is no mention of any of these "requirements" (p. 15), so someone being subjected to shock may not even know that these processes are supposed to take place per the regulation of the shock device. This creates many issues, not least of which, whether someone is giving full informed consent, 'which is a process, not an event' as would say those who intensely work on human 'subject' protections.

It is incredibly important to understand that "voluntary" is not always truly voluntary, because of issues of not being given proper information about shock treatment. However, sometimes people did, knowingly consent to shock treatment, and experienced extreme damage. In creating this complaint, one person who is a shock survivor asked those in power to try to understand the experience she had:

> "If the shock was voluntary: for one to pull back from what one asks for—to come to terms that what one asked for is another to destroy one's brain—to face up to that one didn't say no, and so one couldn't say no, because of asking for it– one grieves. To turn back and say one was wrong – in some ways it is comparable to having it forced – when you know the response to any complaint will be, "Well you volunteered, didn't you?"

Therefore, there are three major issues with what the FDA's has suggested as the processes of labeling the shock device, operators' manual, and patient information pamphlet with warnings.

The first issue is that the theory that a simple label on a device, or in a patient information flyer will successfully mitigate the known debilitating consequences and risks of shock treatment is ludicrous and irresponsible. Because someone knows of the risk of death or autobiographical memory loss, brain damage, skin burns, body damages, etc., possessing knowledge of adverse events does not reduce the actual risk of shock treatment. This type of attitude is subversive protection from litigation based on assault, battery, attempted murder, and manslaughter, if not murder.

The second issue is that in the proposed Draft Guidance, the intent of the proposed rule, that informing 'operators' and 'patients' of the known consequences and risks of shock treatment, specifically Section V: Risks to Health, is relegated to several simple sentences required to be printed that in no way truly illustrates the long list of known consequences of shock.

To illustrate this, in the Proposed Rule, Section V. Risks to Health, reads as follows:

"After considering the available information from the reports and recommendations of the advisory committees (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of ECT devices and determined that the following risks to health are associated with its use:

- *Adverse reaction to anesthetic agents/neuromuscular blocking agents* .The muscle relaxing and sedating (or sleep inducing) drugs that are a part of the procedure may hamper the patient's ability to breathe spontaneously.
- *Adverse skin reactions.* The patient-contacting materials of the device may cause an adverse immunological or allergic reaction in a patient.
- *Cardiovascular complications.* The therapeutic convulsions may be accompanied by arrhythmias (irregular heartbeat) or ischemia/infarction (*i.e.,* heart attack). Hypertension (high blood pressure) as well as hypotension (low blood pressure) may be associated with ECT treatment. ECT treatment may also result in stroke (impairment of blood flow to the brain or bleeding in the brain).
- *Cognition and memory impairment.* ECT treatment may result in memory impairment, specifically immediate post-treatment disorientation, anterograde memory impairment and retrograde personal (autobiographical) memory impairment.
- *Death.* Death may result from various complications of ECT such as reactions to anesthesia, cardiovascular complications, pulmonary complications, or stroke.
- *Dental/oral trauma.* Dental fractures, dislocations, lacerations, and prosthetic damage may occur as a result of strong muscle contractions during treatment.

- *Device malfunction.* Faulty hardware, software or accessories (electrodes) or improper use may cause electrical hazards, such as the risk of excessive dose administration, prolonged seizures, and skin burns.
- *Manic symptoms.* ECT treatment may result in the development of hypomanic or manic symptoms.
- *Pain/discomfort.* The patient may experience mild to moderate pain following the motor seizure induced by ECT treatment.
- *Physical trauma.* Inadequate supportive drug treatment may allow the patient to be injured from unconscious violent movements during convulsions.
- *Prolonged or tardive seizures.* ECT treatment may result in prolonged or delayed seizures, and status epilepticus (continuous unremittent seizure) may ensue if prolonged seizures are not properly treated.
- *Pulmonary complications.* ECT treatment may result in prolonged apnea (no breathing) or inhalation of foreign material, such as regurgitated stomach contents.
- *Skin burns.* Excessive electrical current or improperly designed electrodes may cause the patient's skin under the electrodes to be burned.
- *Worsening of psychiatric symptoms.* ECT treatment may be ineffective and therefore may result in worsening psychiatric symptoms." (Federal Register, 2015)

Therefore, a warning required by the Draft Guidance, that reads that the shock device "may be associated with: disorientation, confusion, and memory problems" (p. 13), does not adequately reflect the known risks outlined in Section V of the proposed rule in which someone is subjected to if they are subjected to shock treatment.

It would seem if the intent of supposedly mitigating risk of shock treatment was genuinely possible via labeling the shock device, then creating written materials to be given to those using or subjected to the shock device must actually inform people of the known risks via the label and those labels must—not should—be accurate.

The third issue is that nowhere in the proposed warnings is any piece of information about the informed consent processes, which were a major issue of concern brought up in the 2011 hearings. The current processes and their deficits – and that there's no attempt to strengthen process remains an issue of concern.

Eighth, we want to see FDA hold the American Psychiatric Association and National Institute of Mental Health and other organizations promoting misinformation about the shock device held accountable. As an example, the American Psychiatric Association published an article, "Time is Now to Support the Reclassification Effort" (January 29, 2016). APA writes to its membership—and anyone who has access to the internet as it is newsletter is prominently placed on their website, "The FDA recently proposed a rule change that would reclassify electroconvulsive therapy (ECT) devices used for treating major depressive disorder from class III (high risk) to class II (low risk)[viii]." This is

blatantly untrue. A Class II device is not "low risk". It is a device that requires both general and special controls because of its known risks.

It is important to underscore that the shock device has never been tested for safety or efficacy, and while there are anecdotes of a short-lived "euphoric" result, often confused for mania, there is a tremendous amount of evidence of the damage that shock treatment inflicts on the body and the brain. Some of this record of damage, admittedly, is also anecdotal.

The American Psychiatric Association credits "testimony from former patients, who state that they suffered permanent memory loss and brain damage" for the 1976 failed attempts at down-classifying the shock device. APA also credits the 2010 (and 2011 hearings not mentioned) failures to down classify the shock device to "significant resistance from the anti psychiatry groups" and stresses " That is why it is so important for psychiatrists to take the lead in expressing their views in regard to the role that ECT plays in practice and in the treatment of major depressive disorder". Another point of misrepresentation –APA states, "The government does give importance to the number of letters or emails received, pro vs con, in its deliberations" and APA created form letters for psychiatrists to use, "supporting the reclassification effort".

The form letter espouses the idea that shock treatment is "safe and effective". This disinformation campaign ought to be punished. Even the FDA rule is clear that for some, a short-lived potential relief may outweigh the many known risks. To allow psychiatrists to reposition shock treatment as "safe and effective" without recourse is akin to allowing drug companies to not list the known adverse ramifications of their drugs.

Additionally, APA is not stopping with their blog, they have also taken to twitter with tweets such as: "Extensive body of evidence for safe, effective use of #ECT supports reclassification. Read our letter to the #FDA: http://apapsy.ch/fda-ect" and "We urge APA members to reach out to the FDA and support a class II designation for #ECT. Here's how you can help: http://apapsy.ch/ect-class"; and "#ECT is safe, effective, should be available to patients. We urge FDA to reclassify ECT. Show your support: http://apapsy.ch/ect-class."

It might be of interest to FDA that under a heading of "What APA is Doing for You", APA writes that the above mentioned "blog post is part of an occasional series highlighting how APA advocates on your behalf to support the profession of psychiatry and put our interests before key policymakers". Considering their knowledge of the contestations of people who have been subjected to shock treatment, one might argue, it is clear evidence that they are also putting the interests of psychiatrists before those that they might come in contact with and have power over in their practices.

Repeating a falsehood does not make it true.

Concerning the National Institute of Mental Health, the disinformation campaign on shock treatment must be stopped, immediately. On March 17, 2016 NIMH hosted a "Q

& A on Electroconvulsive Therapy". The government and psychiatric industries have been working together through a concentrated effort to repackage brain damage resulting from shock treatment as "brain stimulation". The profound lie-protection that psychiatric power has via state-power and government sanction and support of work is going to have negative consequences on the American population, and people across the world who will be more likely to be subjected to shock treatment because of the disinformation campaign. We have photo evidence of comments and questions asked of NIMH during the Q&A that were deleted and people were blocked from participating. One such comment was the list of known Risks to Health printed in Section V. of the FDA's (2015) Proposed Rule to down-classify the shock device.

It is amazing to see, for example, how Dr. Lisanby has risen through the ranks of government, from her 2011 role as Chair of the committee on shock treatment, to now, the director of "translational research" at NIMH, as a special guest on Facebook events. Lisanby, who in 2011 argued informed consent process could happen in 30 minutes, but take as long as 90 minutes (90 minutes!) is literally writing the rules for shock treatment in America.

The misinformation people are being given by these entities is of grave concern. The fact that there is no mechanism built in to measure whether consent is genuine, informed, and based on an array of choices, is an outstanding issue that must not be ignored. FDA, have you ever wondered why the psychiatrists and manufacturers 'care' so much, they are not demanding safety and efficacy themselves? FDA, you do see the conflicts of interest (if not financial, in terms of power and professional accolades), don't you? There are lobbyists pushing this through, pushing down the safety risks, covering up the death data, disregarding the animal studies—or any study that is in-depth. FDA cannot down-classify shock devices that have never been tested for safety or efficacy and the long known consequences and high risks of shock treatment.

Sham-ECT achieves no better outcomes than real shock treatment achieves no better outcomes than Sham-ECT. Sham ECT! Really – the whole idea that something called Sham-ECT even exists. Sham-ECT is basically where people are told they are being subjected to shock treatment and then, while s/he is under anesthesia, the electricity is actually withheld. Are the people who have been subjected to Sham-ECT ever told? FDA must hold researchers, trade organizations, and state-sponsored psychiatry accountable.

Ninth, we wonder if FDA realizes how absurd the proposed rule is and that is why there was specific comment sought on the terms "treatment-resistant" and "require rapid response" which are addressed more fully in our petition below (which has been signed by more than 1,200 people since it was published in February).

One of the people who participated in the process of creating this complaint, who is a shock survivor, urged that those in power to make decisions about the shock device understand the implications of fraudulent psychiatric assignments as well as misdiagnosing medical conditions as psychiatric in nature.

Concerning people being prescribed psychiatric drugs we were also reminded by one person who was subjected to shock that the drugs can be mistakenly given based on an incorrect diagnosis. The example offered was someone who was misdiagnosed with a psychiatric issue when the real issue was medical.

For this person, now assumed to have a "mental illness" being subjected to shock nearly cost one's life. When the person did not experience relief of what were actually medical symptoms, the 'doctor' overprescribed drugs, rapidly changed from one drug to another and eventually added benzos. This person described that she could not stand or walk a straight line. She was like a zombie. After all of this, it was declared by those in psychiatric power that she was "treatment-resistant". She was then subjected to electricity being shot through her brain to cause brain damage and they called it "treatment". She urges the FDA:

> *"Enough about this madness. This is not right. I literally crawled on floor for two years".*

The drugs were wrongly prescribed. The term "treatment-resistant" is a fraudulent concept. For those who are not attacked by psychiatry for political views and unpopular beliefs, or spiritual experiences, some people—so many people—are being misdiagnosed with a psychiatric label and undiagnosed or not-diagnosed with an actual medical condition.

I remind you here of the NASHMPD Morbidity/Mortality Report (2008) (and more recent studies), show that people with psychiatric histories die 25 – 30 years sooner than people who do not have psychiatric histories, when controlled for other factors.

The calls that made up the basis for this complaint were powerful. This person ,who is literally trying to survive post-shock, explained how the shock that she was subjected to because of being "treatment-resistant" had negative consequences on her overall health and qualify of life. Her heart; vision; balance; and work—now and for many years since having been subjected to shock treatment—all damaged. She is currently unable to do what she was able to do before the shock. The iatrogenic effects of shock are horrendous. These are the reasons people argue that shock treatment is a crime against humanity. She urges those in power:

"Shock needs to be eradicated. The FDA needs to understand there may also be underlying physical conditions that are assumed to be "mental illness".

In terms of the process of including information that is accurate, the FDA has not included important research that reveals problems with determining success of treatment on drugs that are known to routinely fail.

For example, a heavily referenced[ix] comment supplied by Eileen McGinn that ought to also become part of the 'new information' illustrates the ways that known information is obfuscated by the FDA becomes apparent:

> "It is well recognized now that antidepressant drugs do not work in what is called "major depressive disorder" as well as most Americans are led to believe by constant drug ads and biased media reviews. Randomized clinical trials for antidepressant drugs are set up to measure a 50% reduction in symptoms as "success": in addition, the success is in the eyes of the researcher, not the individual in the trial. For most people, a 50% reduction in some symptoms is not clinically meaningful, and the search for more, different and better drugs ensues. With such a low bar in clinical trials, it is not surprising that 'treatment resistance" is common.
>
> In fact, about two-thirds of people do not achieve remission (relief of symptoms) after initial treatment with a first-line antidepressant, and only about half experience response (Thase, 2012). The STAR*D research, conducted by the government rather than the drug industry, shows that common switching and augmentation strategies are not much more successful in achieving remission (National Institutes of Mental Health, 2006). The issue of non-response and non-remission, coupled with relapse and reoccurrence, is so widespread (Berlim, 2007; Davenport, 2016; deSousa, 2015; Rosenblat, 2015; Sheldon, 2010) that most people might at some time be classified as "treatment resistant". Since even the concept "treatment resistance" is not a standard one, people could be labeled "treatment resistant" very rapidly, depending on the treating clinician's views and values.
>
> In cases of so-called "treatment resistance" to antidepressant drugs, suggestions by psychiatrists and psychiatric organizations are conflicting and idiosyncratic: increase or decrease doses, change to another class of antidepressant drugs, add talk therapy, add exercise, add light, add thyroid hormones, add vitamins Ba and D, augment by adding lithium and antipsychotic drugs, use ketamine, or use stimulants (Rosenblat, 2015; Thase, 2013). These ideas are never actually studied to show to best course, and research is focused on drug interventions, even though they are not very effective according to psychiatry's own research. Even talk therapy is not always considered in "treatment resistance", although the evidence for improvement is substantial (Wiles, 2016).

> In addition, once drugs and devices are approved for any indication in psychiatry, they rapidly move to "off-label" use, resulting in overuse in the general population and inexplicable polypharmacy. Consider the campaigns by the Department of Health and Human Services against the overuse of opioid drugs (HHS, 2015) and antipsychotic drugs in nursing homes (Center for Medicare and Medicaid Services, 2012). Over 50% of antipsychotic drugs are used off-label in the U.S. ((Alexander, 2011; Olfson, 2015), even in children and even where there are black boxes for certain populations (older adults).
>
> In the case of the shock device, overuse via off-label use is to be expected, with extension to different populations for different indications than are being considered at this time. Especially concerning are the ideas of using shock for pregnant women, where multiple adverse events already known from the literature (Leikes, 2015).
>
> This attempt to reclassify this device is an example of more misplaced confidence on the parts of the medical and psychiatric community, based on choosing a technical and narrow review of unsubstantiated and/or subjective facts to fit a pre-ordained and biased model of "mental illness". Treatment is still understood in the older purely biological construct as consisting of only "drugs" and brain interventions, rather than the emerging nuanced understanding that people may need social and emotional support to be free of the condition commonly called "depression. These supports, based on human rights, consist of at a minimum: stable housing, healthy food, transportation, personal support, education and training, meaningful activities and goals, light, leisure, community of support, employment in some cases, etc. (World Health Organization, 2008).
>
> Since the last review of this device in 2011, the evidence has been in favor of social and economic and cultural responses to distress (Brooks,2016), not narrow and reductionistic biomedical aggressive interventions, where health is seen merely as a technical challenge (Birn, 2005).
>
> Many other objections could be raised here, some outlined in this petition: expected use on pregnant women and older adults (mainly women), very inadequate trials, conflicts of interest from device manufacturers/researchers, FDA violation of its own review guidelines, etc. The cognitive effects of frequent anesthesia and seizures need also to be considered.

Concerning off-label use of the shock device, and the push for what situations ought to be included in Class II use of shock, we turn for a moment to a disturbing response to the FDA docket from the American Academy of Child and Adolescent Psychiatry, who writes:

> Based on successful outcomes in adolescents treated with ECT, we propose that ECT should be classified as a Class II procedure for all major psychiatric disorders which have known positive response to ECT, (i.e. major depression,

> bipolar disorder, SSD, catatonia and neuroleptic malignant syndrome (NMS)) while imposing special precautions.

The industry will consistently work to protect the industry. In the AACAP's comment it is acknowledged that there are no comprehensive studies but there are dozens of footnotes on "case studies" or other research on shock treatment on minors.

The researchers who are experimenting on minors who have been psychiatrically assigned and minors who have developmental disabilities, or who are victims of psychiatric drugs and suffer Neuroleptic Malignant Syndrome, ought to be charged with Crimes of Humanity.

The field of psychiatry builds itself on its own claims. We want FDA to hold responsible psychiatrists who are using—or promoting the use—of shock treatment on minors—especially if that use is in the form of published experimentation.

Concerning the term "require rapid response" ,we are convinced that this is simply a euphemism for forced treatment. Concerns about people being subjected to shock treatment over objection were made clear at the 2011 hearings. There is no mention in the proposed rule or the draft guidance about prohibiting the use of shock treatment over objection. There is barely mention of consent. This phraseology of "require rapid response" will create an additional frightening avenue for forced shock treatment. Linda Andre (2009) wrote, "Legally, informed consent is the difference between treatment and assault and battery" (p. 68).

Tenth, we are concerned that there is no clear measure of how alternatives are offered to people, both in the consenting process, and as a matter of course. There are alternatives to the medical model of psychiatry. Section 4.9.2.3 of the Draft Guidance, "Alternative Treatments" states:

> "FDA is proposing a special control that would require patient labeling to describe currently-available alternative treatments, including medications, devices, and psychotherapy. FDA recommends that patients speak with their health care providers to determine if they are suitable alternatives for them" (p. 19)

This definition of alternatives is very limited and in no way addresses trauma-informed approaches or alternatives to psychiatry, in general, such as self-help, mutual support, and advocacy. There is no mention of alternatives, or dispelling of psychiatry and psychiatric assignment in this rule. There is no mention of those who work in alternatives to psychiatry fields, in this process, and that ought to be addressed.

One person who participated in the process of creating this complaint who is a shock survivor reminded us:

> "When someone is suicidal for a long time and experiences so much pain and suffering, one can feel one needs something to get out of the 'state'. The more drugs they give you, the more drugged and desperate people become. Psychiatry needs to not be seen as the profession to go to for assistance. Psychiatry just gives you drugs and shock. The powers make it tantalizing for one in that position to say, 'Zap my brain and this will all be over'. There need to be alternatives."

Eleventh, we are concerned about financial incentives that are built into the system that will result if the shock device is down-classified and broadly, these can be seen minimally in how shock treatment is paid for and advertising shock treatment. In the NIMH Facebook Q&A on March 17, 2016, NIMH responded to a question about how shock treatment is paid for this way: "Most major insurers cover ECT. For example, Medicare and Medicaid typically cover ECT".

In a letter to Lorretta Lynch, Debra Shcwartzkopff of www.ECTJustice.com who coordinated the above-mentioned survivor survey, details broad concerns of how shock is being applied in discriminatory fashion against women, people of color, the elderly, pregnant women, children, and those who are economically struggling. It is the opinion of some people who are shock survivors that doctors who say they have obtained consent from someone for a second time of having electricity directed into her or his brain, that they ought to be charged with malpractice. To these people who survived shock, they see consent void after the first shock.

In addition to the mandate to move all Class III devices into Class II or Class I, or be take off of the market, another part of the drive for down-classifying the shock device is to create a greater ability for private insurers to pay for shock treatment, which generally is not done with Class III experimental devices. The way this is set up, with tax-payer dollars paying for shock treatment with little to no question of the known risks and brain-damaging procedure, unfairly targets the most vulnerable of our society, elders, people who are poor, people who "require rapid response" because their insurance covers it. When some, who may be so despairing want to forget—they are urged by the psychiatric industry to "jump". Its greatest brain damaging consequences, one no longer remembering the details of ones' own life, determines the greatest 'success' of shock treatment.

We are opposed to advertising of shock treatment on any level, including these subtle disinformation campaigns of the American Psychiatric Association and National Institute of Mental Health, addressed earlier. However, there is also direct-to-consumer marketing of the shock device happening right now. This must be stopped. People who are shock survivors argue that this type of direct advertising is like egging someone on to play Russian roulette, with a gun, where every chamber is filled. Some people who are shock survivors say that it encourages "risk-taking behaviors".

As a note, one cannot help but wonder what the true motives are, with shock treatment being seen as less expensive as drugs for 'depression'. This supposed 'economic benefit' certainly was part of the 'new information' FDA is citing for those who are "treatment-

resistant" and "depressed". We ask how capitated managed care plays into the drive to have shock treatment portrayed to the public as a Class II, 'safe enough' procedure.

Psychiatry needs interventions that are effective from their point of view that they are cheap as dirt–not from the point of view of helping people truly heal. Only alternatives to psychiatry can bring about those changes.

Therefore, the real economic issues must be taken into account.

How and where people will be subjected to shock also is of concern. People who are shock survivors reported fears of being left to go home after shock, the potential of having a seizure, or suffering from the brain-damaging confusion that results from the shock when they are alone, and conversely, being required to be institutionalized to be subjected to the process for long periods of time.

Shock treatment is a violent assault on the brain and body—an induced electrical storm that causes the body to seize. A 'treatment' that 'works' by creating brain damage.

FDA continues to try to position the shock device as safe and effective but the FDA ought not be permitted to do this. This is not our government being truthful with the American people.

Shock has never been tested for safety and efficacy, and if new machines are so different from previous machines, they do not fit the definition of a device that can be brought on the market, because by definition, the device must meet the same criteria, essentially be the same as the predicate device. To disregard this information is irresponsible. Unconscionable. Arrogant. Current information and real informed consent must be part of the processes that FDA publishes and they simply are not.

FDA ought not be able to down-classify the shock device for any reason. FDA must hold public hearings about brain-damaging shock treatment. This must not be something that can be so ordered without going through proper rule-making procedures, where those in power can be held accountable to the truth.

Twelfth: No where in the draft guidance or proposed rule is information to operators of the shock device that they potentially could be harmed through electric shock during their passing the currents into the brains of people they are subjecting to shock treatment. Perhaps if operators knew of the risks, they, themselves faced, they would be less interested in operating the device.

Thirteenth: Our general concerns about the FDAs ties to the pharmaceutical industries cannot go without comment. The financial and personal interests that certain individuals have are now publicly discussed. We cannot help what the implications of the new leadership of FDA are and how it will affect fair and accurate processes of decisions that

FDA makes. Certainly, this is of concern beyond the shock device and is routinely being discussed in the general public.

The rationalization of action for peace of mind – accepting authority of a doctor – cannot deal with information sometimes. People cannot deal with what has actually happened – the denial makes them sick.

In Conclusion, we believe that we have offered you, the Ombuds Office and the Ombuds for Medical Devices, a wealth of information that must be considered as FDA attempts to down-classify the shock device. Be sure, that if the FDA is allowed to ignore and suppress this information and order the rule that is proposed with the draft guidance becoming the intent of the order, shock treatment in the United States will soar. People—with one of the most common and controversial psychiatric assignments—depressive episode—who are being given drugs that are known to be dangerous and routinely fail—will now be subjected to electrical assaults on a regular basis—three times a week. That is electricity shot through a someone's brain three times a week, general anesthesia three times a wake, muscle relaxers and pain killers continuously ingested for months, and food intake prohibited for large swaths of time, meaning food withheld in excess of 12 hours every 24 hours, for months on end. All this for a procedure that does not work, has never been tested for safety or efficacy and shows a wealth of known negative consequences with high risk of occurring.

To the people of the FDA Ombuds Offices and Ombudsperson for Medical Devices, we want you to respond to this public complaint with more than a "thank you for your concern".

We want you to respond to this public complaint with immediate and swift actions to put a moratorium on this proposed rule and draft guidance until proper and accessible hearings can be held.

We want you to put a moratorium on the use of shock treatment until these major issues of concern are adequately addressed.

We also want you to hold those who have been saying that shock treatment is "safe and effective" such as trade organizations such as the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry, and government, state-sponsored psychiatry, such as the National Institute of Mental Health, to be held publicly accountable by FDA for the disinformation they have been producing and promoting.

We want FDA to create a process for reparations for those who have been lied to about shock treatment and suffered its known consequences.

Shock treatment is a mechanism of injury. Having 600 volts of electricity—or any amount of electricity—shot through one's brain is a trauma.

To reiterate:

First, we do not want the shock device down-classified for any reason, but particularly the fraudulent reason that it is 'safe enough' for people who are 'depressed' 'bipolar', 'treatment-resistant' or 'require rapid response';

Second, we want FDA to hold public accessible hearings based on the balance of this new information prior to approving the proposed rule and draft guidance;

Third, we want a complete moratorium on all shock treatment until these issues are resolved; and

Fourth, we want all of the issues publicly asserted in this complaint addressed.

Ideally, we would appreciate an acknowledgement of receipt of this complaint with your response to this complaint prior to the close of the open dockets, March 28, 2016. If it is not possible to have a response included with acknowledgement by then, we ask for a full response by May 4, 2016 which ought to have been the close of the 90 day period if business days and holidays were taken into account.

In Anticipation of Your Response,

People Who Are Psychiatric Survivors, People who are Survivors of Shock Treatment, Allies, and MindFreedom International Members.

CONTACT: Lauren Tenney, PhD, MPhil, MPA, Psychiatric Survivor at (516) 319-4295 (718) 273-8708 or LaurenTenney@aol.com.

Below, is the petition that as of March 24, 2016 3:05 AM, was supported by 1,317 people.

This is a Letter of Opposition to FDA down-classifying the shock device from a Class III device to a Class II device for any reason.

There is a long history of the FDA attempting to remove the experimental status of the shock device. There is an even longer history of those who have been subjected to shock treatment and their allies working to expose the damage shock treatment causes. Shock treatment as robbed people of the memories of their lives, their education, skills, passions, relationships, children, significant others, and total sense of oneself. For decades, when proper rule-making processes were upheld, the voices of those whose lives were destroyed by shock treatment reached those in power and prevented the down-classification of the shock device from happening.

The video attached to this petition illustrates one recent example of shock survivors and allies feeling as if their voices were heard. This video was taken after the close of the FDA 2011 hearings on the shock device, where it was recommended that the shock device ought to remain a Class III device. It is unconscionable that the FDA would make such a grand reversal, potentially subjecting untold numbers of people to the known devastations of shock treatment.

FDA, you say you have "new information" that has caused you to put forward a proposed rule for the down-classification of the shock device. This information may include that shock for depression is "cost-effective". However, FDA it is important to note that you failed to mention that throughout the "new information" the perspectives of those who were subjected to shock treatment were redacted.

FDA you asked if the terms "treatment-resistant" and "require rapid response" provide sufficient clarity for what would be considered a Class II use of the shock device, if the proposed rule were to be approved for people who are accused of a "major depressive episode" experienced as part of "major depressive disorder" or "bipolar disorder".

My answer is no, there is no reason the FDA ought to down-classify the shock device from a Class III device to a Class II device.

I challenge the entire concept of someone being "treatment-resistant" and argue that there is no situation that would "require [a] rapid response" of shock treatment.

This petition is a result of five national teleconferences coordinated by MindFreedom International. Over 100 people who are survivors of psychiatry, including people who are shock survivors, their allies, and members of MindFreedom International participated in these processes. **I support the material generated in this letter of opposition.**

I oppose the FDA decision to not hold a public hearing about this proposed rule because a meeting was held in 2011. The information was presented to people on the Neurological and Medical Devices Panel of the FDA in 2011 produced a recommendation to keep the shock device a Class III device. Not one of the people on the 2011 panel is on the current panel. Therefore, the idea that the FDA does not need to hold a hearing because a hearing was held is not legitimate.

It is important for those making this decision concerning the potential down-classification of the shock device to be aware of the following information compiled through the National Teleconferences coordinated by MindFreedom International.

Briefly,

1. Psychiatric labels are not actual medical diagnoses; there are no biological tests to show evidence of any such 'disease'. Psychiatric labels do not reflect any actual chemical imbalances in the brain.

2. Most psychiatric drugs are ineffective and even for people who voluntarily take them, the drugs can and do cause physical and psychological harm and injury.
3. Relying on a psychiatric label and lack of response to drugs that are known to fail, as determinants for who gets shock treatment, is not a valid method for any treatment protocol. It is particularly not a viable method for a treatment where **the known risks outweigh potential unknown benefits**, as is the case with shock treatment. The fact that the FDA acknowledges "significant risks" (p. 81227) of shock treatment as palatable for this particular class of people shows how a psychiatric diagnosis also results in experiences of discrimination. People who are psychiatrically labeled are being put in harms way. The government through this proposed rule is justifying severe risk and known negative consequence of shock treatment because of a label with no diagnostic validity.
4. Many people who have psychiatric histories are put on multiple types of drugs simply because they have been given a psychiatric label. None of these drugs are always effective. Most of these drugs are usually ineffective. While there is no standard specified for the number of drug trials one must fail, and I do not believe there ought to be such a standard established, using the subjectivity of an individual psychiatrist to determine one as "treatment-resistant", or failure of some arbitrary number of drug experiment(s) as grounds for someone being “treatment-resistant” is punishing the person for the lack of effectiveness of the drug (and probably also, the lack of effectiveness of any psychiatric worker).
5. There is no situation that qualifies as an "emergency" to "require rapid response" of shock treatment. It is important for people to realize that the course of shock treatment the proposed rule suggests as outside of the bounds of Class II is "treatment in excess of 3 months" (FDA, 2015, p. 81233). This is particularly problematic because the "new evidence" cited for the establishment of the proposed rule was a supposed benefit seen in the "acute phase (less than 3 months after treatment)" (p. 81227). This is a gross misinterpretation of the findings, which already were questionable as "evidence". It is important to understand that the reality of shock treatment being haphazardly used on people is simply terrifying to those who may fall under the new definitions.
6. Emergencies do not last for three months. Justifying having electricity shot through your brain, general anesthesia, and a host of muscle relaxers and painkillers injected into your body, that create the need for a higher surge of electricity to induce the seizure to accomplish the desired brain damage because of an "emergency" is ludicrous and irresponsible. The fact that the findings showed a potential small and non-permanent benefit for no more than three months after treatment switched to promote treatment up to three months, again, slices at the idea of an emergency.
7. In the rule it specifies that after this "acute phase" of shock treatment it is expected that people will go back on drugs and back to therapy (p. 81227); what kind of "emergency" does this resolve?
8. Concerning the "medical condition" clause, if pregnancy is still considered a "medical condition", does shock treatment for a pregnant woman who has been on psychiatric drugs which have been ruled deleterious to a developing fetus constitute a need for shock treatment as a "first line treatment" for pregnant women? What "medical condition" meets the subjective call for requiring a rapid response of shock treatment?

9. Even if someone is on the verge of death--and that is the emergency--a thoughtful, researchable response--not a rapid response--is what is required.
10. "Require Rapid Response" is a euphemism for forced treatment.

No, FDA, the terms “treatment-resistant” and “require rapid response” do not provide sufficient clarity to the population for which the FDA is, in my estimation, falsely stating shock treatment benefits outweigh risks.

The risks of shock treatment consist of one whole section of the proposed rule. Yet, there is not one specific known benefit that the FDA lists in the proposed rule, just a consistent "unknown" benefit. Concerning risk, Section V (FDA, 2015, p. 81227) is as follows:

"After considering the available information from the reports and recommendations of the advisory committees (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of ECT devices and determined that the following risks to health are associated with its use:

- ***Adverse reaction to anesthetic agents/neuromuscular blocking agents.*** *The muscle relaxing and sedating (or sleep inducing) drugs that are a part of the procedure may hamper the patient’s ability to breathe spontaneously.*
- ***Adverse skin reactions.*** *The patient contacting materials of the device may cause an adverse immunological or allergic reaction in a patient.*
- ***Cardiovascular complications.*** *The therapeutic convulsions may be accompanied by arrhythmias (irregular heartbeat) or ischemia/infarction (i.e., heart attack). Hypertension (high blood pressure) as well as hypotension (low blood pressure) may be associated with ECT treatment. ECT treatment may also result in stroke (impairment of blood flow to the brain or bleeding in the brain).*
- ***Cognition and memory impairment.*** *ECT treatment may result in memory impairment, specifically immediate post-treatment disorientation, anterograde memory impairment and retrograde personal (autobiographical) memory impairment.*
- ***Death.*** *Death may result from various complications of ECT such as reactions to anesthesia, cardiovascular complications, pulmonary complications, or stroke.*
- ***Dental/oral trauma.*** *Dental fractures, dislocations, lacerations, and prosthetic damage may occur as a result of strong muscle contractions during treatment.*
- ***Device malfunction.*** *Faulty hardware, software or accessories (electrodes) or improper use may cause electrical hazards, such as the risk of excessive dose administration, prolonged seizures, and skin burns.*
- ***Manic symptoms.*** *ECT treatment may result in the development of hypomanic or manic symptoms.*
- ***Pain/discomfort.*** *The patient may experience mild to moderate pain following the motor seizure induced by ECT treatment.*
- ***Physical trauma****. Inadequate supportive drug treatment may allow the patient to be injured from unconscious violent movements during convulsions.*
- ***Prolonged or tardive seizures****. ECT treatment may result in prolonged or delayed seizures, and status epilepticus (continuous unremittent seizure) may ensue if prolonged seizures are not properly treated.*

- ***Pulmonary complications****. ECT treatment may result in prolonged apnea (no breathing) or inhalation of foreign material, such as regurgitated stomach contents.*
- ***Skin burns.*** *Excessive electrical current or improperly designed electrodes may cause the patient's skin under the electrodes to be burned.*
- ***Worsening of psychiatric symptoms.*** *ECT treatment may be ineffective and therefore may result in worsening psychiatric symptoms."*

Again, there is not one specific known benefit that the FDA lists in the proposed rule.

Moreover, when considering the use of shock treatment for other classes of people, FDA while acknowledging limited scientific evidence of benefits, instead of curtailing the use of the shock device makes way for device makers and psychiatric workers to create situations for potential expanded use of shock treatment. Specifically, creating opportunities for the use of the shock device where there is no known benefit, and plenty of known risk and damage. Specifically, FDA creates a bridge for shock treatment to be used on classes other than those targeted in the proposed rule, effectively covering all of the other major psychiatric diagnoses one could be assigned--not one of these diagnoses, again, as addressed above, a validated actual disease.

Why is it that the long list of known injuries and damage caused by the shock device are ignored while potential "unknown" benefits are privileged? Why is the FDA holding onto the shock device?

Perhaps the FDA is aware that the terms "treatment-resistant" and "require rapid response" are not sufficient determinants for people to be subjected to shock treatment and this is why the FDA is seeking public comment for an estimation that such subjective terminology is insufficient direction for such severe risk and known negative consequences.

The term "treatment-resistant" when used by psychiatric workers denotes a determination as to whether 'treatment' 'helped'. The rule by which this standard is measured is arbitrary – fail two drugs? Five drugs? Drugs that are known half of the time to fail?

Most importantly, the vast majority of people who are survivors of shock treatment say there is nothing therapeutic about shock treatment, that they are part of a class of people being targeted; and that it has nothing to do with the way they feel, but rather, how they make those around them feel.

I want the FDA to know that some people who even 'voluntarily' underwent shock treatment explained that their subjugation to shock had nothing to do with the way that they felt. Particularly for those who asked for shock treatment, having to admit that they were wrong and it had done them damage was incredibly difficult. Still others who thought that they had given informed consent, only later to learn that their consent was based on misinformation, also battled with the knowledge and feelings that they were duped by the doctors they trusted.

While there is no accepted standard for determining someone failing an attempted ‘treatment’ for a ‘disease’ for which there is no biological test to prove exists, there is a standard at which shock is sometimes ordered: at the level of a person becoming a nuisance or embarrassment to those in psychiatric power.

People who are shock survivors also felt that it is important for the FDA to understand the implications of the term “treatment-resistant” for people who may be enduring extenuating circumstances, that perhaps would take any person some time to recover. Lack of a positive response to a drug ought not determine one being a candidate for shock treatment, when one may be healing from loss or struggling to find a support system.

If the shock device is lowered to a Class II device—if people are told by a doctor that, now, based on the FDA's decision, the shock device is a significant risk but worth it, people will give even more trust to a doctor—especially if they are already in a place where they are desperate for a solution.

From the template letter, addressed to Steven Ostroff, M.D., Acting Commissioner of the FDA, that the American Psychiatric Association urged its members to send to FDA in support of the down-classification was this sentence illustrating the way this information is already getting twisted from "significant risk" to "safe, effective". APA urges its members to write to the FDA, "Your proposed reclassification will greatly improve access to safe, effective treatment for individuals with serious and persistent psychiatric disorders" (American Psychiatric Association Template-Letter-ECT-MS, 2016).

It is the position of MindFreedom International that the APA ought to be held accountable for this type of disinformation campaign by the FDA and I support this call for accountability.

Perhaps of most concern is the simultaneously released proposed document, "Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff" states: "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited" (FDA, 2015, p. 1)

There is a complete lack of accountability that will occur in the guidance if the shock device is down-classified to a Class II device. This is demonstrated by the fact that a) the guidelines for shock devices have been simultaneously put out with the proposed rule, reflecting the proposed rule, before the proposed rule has been past, and b) with little exception, as stated by FDA, these guidelines are by and large, suggestions, not requirements.

The exceptions of special controls from the proposed rule make it so shock devices must have labels with the following warnings:

"**Warning: ECT device use may be associated with: disorientation, confusion, and memory problems**" (p. 13).

"**Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated**" (p. 13).

One can see the disingenuous nature of "special controls" when one compares the two "must"-have warnings with the multiple pages of recommended "should"-have guidance. This recommended information will never get to the average person. The information is not guaranteed to even get to those working in the psychiatric industry. Most importantly, this information is not guaranteed to get to those who will be subjected to shock treatment.

I say this with some sense of assurances that the pages of precautions, contraindications, potential risks, and known consequences of shock treatment will not be shared, because it is not mandated to be shared.

FDA (2015) specified, "The use of the word should in Agency guidances means that something is suggested or recommended, but not required" (p. 1).

The most concerning example of "should" as opposed to "must" in the draft guidance is that, "Each patient should have access to clear information in plain language to assist with forming realistic expectations of the treatment and its potential complications (p. 16). Should have access to clear information, not must have access to clear information.

I object to FDA plans to simply put a general label on the shock device as a legitimate means to mitigate the many known risks and negative consequences of shock, including destruction of autobiographical memory, death, and a host of other physical, psychological, and cognitive injuries.

FDA reminded us that in 2009, among other strategies, in order to mitigate risk, "The manufacturers stated that safety and effectiveness of these devices may be assured by reducing the frequency of treatments, temporary or permanent interruption of treatments" (p. 81226).

As illustrated, the person subjected to shock treatment is not guaranteed to be informed of all of the risks of the shock device. As a matter of fact, the term "consent" does not appear anywhere in the FDA proposed rule.

It is offensive that the FDA, supposedly existing to protect people from potential and known damage caused by medical devices and other inventions of industries, does not see it as imperative to inform people about the many known body-damaging, brain-damaging, and spirit-damaging risks of the shock device. **Someone drugged and restrained on a shock table is not going to see the shock device or read its label.**

There is a tremendous amount of work done by people trying to call attention to brain-damaging shock treatment. Some but not all resources you ought to thoroughly review include: ECT Justice;Aftershock; PsychRights; End of Shock; From the Files of Leonard Roy Frank; Linda Andre's (2009) *Doctors of Deception*; Peter Breggin's Dangers; ECT Resources Center; Mad in America ECT Archives; and MindFreedom International's Electroshock Page.

So, FDA, by signing this petition, I affirm that my short answer is no.

I oppose FDA down-classifying the shock device from a Class III device to a Class II device for any reason.

I oppose FDA making this rule without public hearings.

I support MindFreedom International's call for the FDA to hold public hearings prior to making any decisions about the future of shock treatment in the United States.

This concludes this petition. This petition was signed by the following 1,317 people as of March 24, 2016, at 3:05 AM.

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Christa Turnell	Christie Peden	Henrik Bentzen
Timothy Holmes	Lisa Forestell	Deirdre oliver
Christine Lanier	Ian Deitchler	Alain Lipowicz
Darby Penney	Lillian Taylor	Jennifer Padron
Michele Koppinger	Salima Hitchcock	glynn lannon
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Sera Davidow	Mette Ellingsdalen	Samantha Butz
DOROTHY DUNDAS	Laura Li	Maribel Galindo Rico
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Barbara Fralish	Marcia Benjamin, CID	Kendra Achtymichuk
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Marit Pettersen	Ute Maria Kraemer	Judy Wood
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Ellen Le Brun
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Maxine Hayden
Giovanni Rodriguez
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Babs Beebe
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Martin McLean
Marianne Briggs
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Sarah Mouser
Rosalyn Newhouse
Florence Rongo
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Robin Smith
Barbara Perz
Art Leibowitz
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Cassandra Auerbach
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Ann Nash
Nicole Crellin
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Wendy Slutsky
Amy Blomquist
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Tauna moody
Thomas Behrendt

tony bouchahine
Colette Ni Dhuinneacha
Cindy Olejar
Clodagh Burke
Dorothy Winston
Jobe Toole
Eleanor Howe
joan casey
barbara sims
Coreen Kendrick
Rev. L. William Yolton
Frances Muzio
Mary Kelly
Herb Cohen
Louisa Livingstone
jim maddock
Maria Alindato
Barbara Cantrella
Kelly Mooney
Bruno Zacke
Deborah Fickling
Patricia Stacke-kelly
Darren Treacy
Deborah Bratcher
Olli Mustonen
sheila simpson
Hannah Blakeman
Kelly Richardson
Wendy Dann
amal bouchentouf
Clint Taylor
Aaron Edens
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CHI HOI LEE
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Erika Dr. Czelenk
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Sebastian Stehle
josseline Rundgren Stehle
Danny Sheridan
Johanna Ryan
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[i] http://www.un.org/disabilities/images/A.63.175.doc

[ii] http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=16583&LangID=E

[iii] Guidelines on Article 14 can be found at http://www.ohchr.org/Documents/HRBodies/CRPD/GC/GuidelinesArticle14.doc See also Committee on the Rights of Persons with Disabilities, General Comment No. 1 on Article 12, Equal recognition before the law, UN Doc. No. CRPC/C/GC/1, 19 May 2014, para 42 ("States parties must abolish policies and legislative provisions that allow or perpetrate forced treatment, as it is an ongoing violation found in mental health laws across the globe, despite empirical evidence indicating its lack of effectiveness and the

views of people using mental health systems who have experienced deep pain and trauma as a result of forced treatment.")
http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRPD/C/GC/1

[iv] UN Doc. No. CRPD/C/DNK/CO/1, 30 Oct 2014
http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRPD%2fC%2fDNK%2fCO%2f1&Lang=en

[v] UN Doc. No. CRPD/C/SWE/CO/1, 12 May 2014.
http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRPD%2fC%2fSWE%2fCO%2f1&Lang=en

[vi] http://www.un.org/disabilities/images/A.63.175.doc
http://www.regulations.gov/#!docketDetail;rpp=100;so=DESC;sb=docId;po=0;D=FDA-2014-N-1210

[vii]
http://psychrights.org/Issues/Electroshock/110124FDAElectroshockNoReclassLtr.pdf

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