LAW OFFICE OF KENDRICK L. MOXON, P.C.

KENDRICK L. MOXON

ADMITTED IN

CALIFORNIA AND
THE DISTRICT OF COLUMBIA

3500 WEST OLIVE AVE SUITE 300 BURBANK, CALIFORNIA 91505

TELEPHONE (818) 827 7104 TELECOPIER (818) 827-7114 kmoxon@kmoxonlaw.com

July 29, 2017

SUPPLEMENT TO CITIZEN PETITION

Docket No. FDA-2016-P-2559

This memorandum briefly supplements the Citizen's Petition submitted on August 24, 2016, by Petitioners Atze Akkerman, Evelyn Scogin, Dianna Loper Posthauer, Kenneth Fleischman and Tony Buonfiglio, and filed in Docket No. FDA-2016-P-2559, opposing FDA's proposed administrative order reclassifying ECT devices. *See* 80 Fed. Reg. 81223, et seq.

We submit this Supplement to address several central justifications in the Proposed Order which ignore, avoid, or misrepresent harms caused to patients by ECT, and which misapprehensions are central to why the proposed rule manifests a failure to consider important aspects of the problem addressed. The Proposed Order constitutes arbitrary and capricious action due to, *inter alia*, its failure to appropriately address the issue of death, cognitive impairment and memory loss arising out of ECT. (See, 80 F.R. p. 81228.)

As set forth in detail in our Petition, and as addressed in other submissions to the FDA in related dockets protesting a lowered classification of ECT devices, it has been acknowledged by the FDA that for over 50 years ECT is a potentially dangerous treatment, the full harms of which and the efficacy of which is dramatically disputed. No other treatment in medicine is so subject to objection and protest by patients – so much so that when the reclassification was proposed, thousands of patients, deeming themselves to be victims of the treatment and patient's rights advocates objected.

Studies, reports from states, extensive testimony, independent government reports and testimonials of thousands of persons refute the cursory conclusions set forth in the Proposed Order respecting death, cognitive impairment, inability of recipients to learn (anterograde memory), brain damage and long term memory loss.

Death From ECT

The Proposed Order, with only two sentences and with no attempt to utilize existing evidence, brushes aside the important issue of mortality from ECT. It states, at p. 81225:

While medical/physical risks may occur with ECT, they vary in frequency, with the most severe risks being quite rare. Death associated with ECT appears to occur at a very low rate comparable to that of minor surgical procedures. Recent *estimates* of the mortality rate associated with ECT treatment are 1 per 10,000 patients or 1 per 80,000 treatments (Refs. 1, 10). (emphasis added)

The references supporting this guess are a 2001 text from the American Psychiatric Association (Reference 1), which text asserts merely that these figures are estimated. The second reference is to a non peer-reviewed Indian psychiatric journal comparing ECT with risperidone, and has no remote reference to the frequency of mortality from ECT treatments (Reference 10).

Yet the FDA fails to note, or apparently consider, that despite the existence of over 1,200 studies of ECT, none specifically studied ECT mortality rates. Thus, for the important issue of whether ECT kills patients immediately or if it damages body structure to the extent that it accelerates death, and after more than 40 years of opportunity to provide evidence to the contrary, neither the manufacturers or ECT advocates have done so.

Futhermore, Texas is one of the few states that mandates reporting of deaths while undergoing ECT or within 14 days of undergoing ECT. Otherwise, the FDA must rely upon Maude reports. The FDA has stated that 100,000 Americans undergo ECT a year, yet this is a guess only as that figure relates to estimates from 1995. There is no national database on the number of people receiving ECT and states are not required to keep statistics. In producing its Executive Summary on ECT in 2010, the FDA did not indicate that it had diligently tried to collect state, Medicaid and Medicare figures relating to ECT usage, and is therefore, unaware of how many Americans are electroshocked and what deaths, if any, have occurred or the percentage of deaths. Indeed, it has fallen to advocacy groups to collect this information.

In lieu of evidence, FDA accepted a mere estimate from the APA, a group with a special interest to continue the practice of ECT.

Moreover, the FDA ignored the statistical evidence from one of the two states that actually maintain records regarding the issue. Texas requires practitioners of ECT to provide information to the state regarding "reportable events" arising out of ECT,

which includes memory loss and death.¹ In 2008 alone, five patients died soon after receipt of ECT out of the several hundred that received ECT.² The machines utilized at each of the facilities where patients died after receiving ECT, were manufactured by MECTA and Somaticsthat failed to report the deaths to MAUDE.³ Such devices were permitted to be manufactured and sold through the 150k process, and despite earlier orders from the FDA to manufacturers to provide PMA data. In 2006, there were 3 additional deaths in Texas reported following treatment.⁴ In the first three years of mandated reporting in the early 1990's, 21 patients were reported as having died soon after receiving ECT.⁵ From June 1993, through August 1994, eight deaths were reported among less than 1,700 ECT patients.⁶

Thus, the sole actual *evidence* relating to death rates establishes a rate approximately 49 times *higher* than the "estimate" the FDA accepted from a conflicted third party (the APA) to justify the supposed absence of factual information.

That ECT drastically shortens the lifespan of recipients has been well known for decades. For example, in a large retrospective study of 3,288 patients receiving ECT in Monroe County, NY, recipients were found to have a substantially increased death rate from all causes. ⁷ FDA chose to exclude this peer-reviewed study among those considered.

In another study by researchers at Brown University of 65 elderly patients hospitalized and treated for depression, the 37 patients who had received ECT had survival rates of 73.0% at one year, 54.1% at two years, and 51.4% at three years. In contrast, depressed patients who *did not* receive ECT had survival rates of 96.4%, 90.5% and 75.0% at 1, 2 and 3 years respectively. ⁸ Again, FDA declined to include this peer-reviewed study in what it deemed appropriate for its analysis.

In another study, the death rate was doubled in depressed patients who received ECT in a seven-year follow up study of 188 patients. ⁹ Thus, besides the immediate impact of the electrical shock to the brain, ECT has a debilitating effect on the body's systems, the

¹ Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *Exhibit C: Report of ECT and Other Therapies* (page 2). http://www.dshs.texas.gov/mhsa/bhmd/ect/

² Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. FY08 Annual ECT Facility Summary. http://www.dshs.texas.gov/mhsa/bhmd/ect/

³ Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. ECT Equipment Registration History. http://www.dshs.texas.gov/mhsa/bhmd/ect/

⁴ Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. FY 2006 ECT Data.

⁵ Don Gilbert, Commissioner, Texas Department of Mental Health and Mental Retardation, 1996.

⁶ Gary Null, citing Peter R. Breggin M.D., (1998) "Electroshock: scientific, ethical, and political issues," *International Journal of Risk & Safety in Medicine* 11 5-40 IOS Press. http://www.garynull.com/documents/ECT/SideEffects2.htm.

⁷ Babigian, H., et al., "Epidemiologic Considerations in ECT." Arch Gen Psych 1984;4:246-253.

⁸ Kroessler, D. and Fogel, B., "Electroconvulsive Therapy for Major Depression in the Oldest Old." Am J Geriatr Psych 1993;1:1:30-37.

⁹ O'Leary, D. and Lee, A. "Seven Year Prognosis in Depression - Mortality and Readmission Rates in the Nottingham ECT Cohort." *British J of Psychiatry* 1996;169: 423-429.

brain evidently losing its ability to control delicate systems. Yet again, this peer-reviewed journal study was excluded from those deemed appropriate for the FDA's analysis.

The FDA should have had such information from Texas before it prepared the Executive Summary in 2010, and such information was specifically provided during the January 2011 hearings in submissions made on FDA-2010-N-0585 as well as in FDA-2014-N-1210 prior to the 2011 re-classification hearings. Indeed, even the FDA's Executive Summary admitted that it received a number of reports of deaths – none of which were investigated or followed up by the FDA; none of which were queried to the manufacturers.

This all demonstrates that the FDA failed to diligently consider important factual information on the issue of deaths arising out ECT.

Cognitive Impairment and Memory Loss

Worse, is that virtually all patients receiving ECT experience a deleterious side effect that is completely ignored by the FDA. The Proposed Rule confoundingly ignores extensive information and evidence demonstrating that persistent, permanent cognitive impairment is a typical and expected outcome of ECT. The Proposed Rule states:

The risks of greatest concern to clinicians and patients remain cognitive and memory impairment. Both the FDA review of literature and the meta-analyses of the randomized controlled studies indicate that while post-procedure disorientation occurs frequently, it is transient, typically resolving within minutes after the procedure is complete. The systematic meta-analyses of the randomized controlled clinical trials data by FDA revealed that there is no evidence that disorientation following ECT is long term or persistent. The primary areas of concern for persistent changes are anterograde and retrograde autobiographical memory. While rates of occurrence are difficult to estimate, it appears that both types of memory impairment are not uncommon. The literature review suggests that anterograde memory declines immediately post-ECT and then returns to baseline within 3 months post-ECT. Retrograde autobiographical memory declines immediately post-ECT and then appears to improve over time. It is important to note that while improvement is seen, impairment may persist past 6 months post-ECT. Data on persistent retrograde autobiographical memory deficits beyond 6 months is lacking in the scientific literature. Therefore, it cannot be concluded that retrograde autobiographical memory returns to baseline over time. (See tables 6 and 7 and Figures 2–24 from FDA's Executive Summary, Ref. 11.)

The assertion that some literature "suggests" that anterograde memory loss returns to baseline within 3 months, is an example of FDA selecting some conclusions

of pro-ECT studies and ignoring contrary evidence. Literally thousands of patients of ECT have asserted the contrary through the submissions in the FDA docket and evidence supplied as exhibits to the dockets. FDA has thus eschewed testimonial statements of the actual victims of ECT, for reasons which cannot logically by justified.

These statements, the lawsuits filed against the manufacturers, the testimony of individuals, and many peer-reviewed studies rejected by the FDA for consideration, demonstrate that "anterograde" memory – i.e., ability to learn and ability to retain recent events – is dramatically damaged by ECT. Patient after patient has asserted before the Advisory Committee and in the Dockets referenced above, that their IQ was lowered generally by ECT, that they were debilitated and remain so many years after receipt after ECT, that their abilities to perform normal functions of life have been dramatically reduced. This represents general cognitive impairment and permanent anterograde memory loss. That anterograde "memory" loss is an extremely persistent or permanent result of ECT, has been ignored by the FDA's Proposed Order – though it may be the single most important harmful effect of ECT.

FDA could reach such a conclusion only by limiting its analysis to less than 70 studies, ignoring over 1,100 other studies, and ignoring what it deemed to be "anecdotal evidence" by way of the numerous statements of patients who believed they were victims of ECT. The rejection of patient testimony is contrary to federal law and the regulations of the FDA, and respectfully, demonstrates an arbitrary and capricious conclusion by the agency. (See 21 CFR 860.7(c)(2), recognizing that "reports of significant human experience with a marketed device" is to be considered to determine safety and efficacy of the device.)

Such evidence includes the multi-year survey of ECT patients from the advocacy website www.ect.org conducted to determine their attitudes and damages caused to them by ECT. The vast majority of these persons gave chilling, conclusions regarding the damages they received from ECT. Receipt of this evidence legally warranted consideration by the FDA respecting the issue of lack of efficacy, and the danger and harm resulting from this treatment.

Indeed, an NIH Consensus Statement on ECT in 1985 noted:

It is, however, well established that ECT produces memory deficits. Deficits in memory function, which have been demonstrated objectively and repeatedly, persist after the termination of a normal course of ECT. Severity of the deficit is related to the number treatments, type of electrode placement, and nature of the electric stimulus. ... research conducted as long as three years after treatment has found that many patients report that their memory was not as good as it was prior to the treatment.

As another example, the National Council of Disability, a federal agency created by President Clinton, conducted its own survey of ECT patients, and came to the identical conclusion: ECT causes grave disabilities. As stated in the federal publication, "From Privileges to Rights: People With Psychiatric Disabilities Speak for Themselves", January 20, 2000, (page 39):

Even proponents of electroconvulsive therapy (ECT or shock treatment) admit that it is a highly controversial procedure. Many of those who have been subjected to it consider it to have been extremely physically and emotionally damaging, and many believe that it has had long-lasting adverse effects, particularly on memory. The stories of those who testified as to the harmfulness of ECT in their own lives were heart-rending, especially since many witnesses were given the procedure without full informed consent, including information about the risks of long-term memory loss.

See also the Petitioner's descriptions of their own disabilities arising out of ECT, which are decidedly *not* limited to long term memory loss or short term confusion after the treatment. They are damages, decades later, have lowered IQs, lowered abilities to reason, inability to learn new things because they cannot remember or retain new information easily or fully. The Petitioner's experiences are mirrored by those of persons who testified at the Advisory Committee hearings, who posted comments for the Dockets, and from victim's organizations which posted comments to the Dockets.

Brain Damage

The Citizen's Petition erroneously stated that brain damage was one of the significant risks of ECT articulated in the Proposed Order. We wish to correct this error.

The Proposed Order ignores completely the issue of brain damage.

In fact, it is the FDA's Executive Summary that *repeatedly* made reference to evidence and assertions of brain damage. The Proposed Order ignores completely the subject of brain damage. The FDA's Executive Summary prepared for the January 27-28, 2011 meeting of the Neurological Devices Panel respecting classification of ECT devices, notes that the were 289 reports of brain damage in the public docket. (See, p. 12.) Issues relating to brain damage are located throughout the Executive Summary.

Indeed, the Executive Summary notes that the manufacturers conceded brain damage was a risk of their devices, "including structural injury, brain cell injury, hippocampal damage). Thus, the unusual situation exists here, in which the manufacturers admit that brain injury is a risk of use of their devices, but the Proposed Order flatly and fully ignores the issue.

During the 2011 FDA Advisory Panel hearing, there were lengthy discussions regarding how and whether ECT causes brain-damage. The transcript of those hearings reflects the following:

- Dr. Allison Komiyama, neurobiologist at the FDA in the Center for Devices and Radiological Health told the 2011 hearing that even MECTA and Somatics report brain damage: "...regarding neuropathological changes, the manufacturer and public dockets both indicated brain damage as a potential risk associated with ECT." 10
- Further she said: "Brain injury by indirect means from ECT-induced seizures is an obvious safety concern, and recent research is aimed to understand both the gross and microscopic changes that occur in the brain due to ECT." 11
- Lieutenant Commander Bradley Cunningham, Center for Devices and Radiological Health (CDRH) FDA, Office of Device Evaluation, Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices also indicated that "the manufacturer and public dockets both indicated 'brain damage' as a potential risk associated with ECT. 12
- Dr. Anna Georgiopoulos, Psychiatric Medical Officer at the Center for Devices and Radiological Health, Office of Device Evaluation, Division of Ophthalmic, Neurological and ENT Devices, reviewed the manufacturers' summary of identified risks, which included brain damage. ¹³
- Dr. David Good, professor and Chair of Neurology at Penn State University, commented: "It seems a little amazing that systematic MR imaging hasn't been performed on people who have had the ECT." 14
- Dr. Thomas Brott, Chair of the FDA Advisory Panel, stated: "...as a neurologist...as Chair, [I] take the prerogative to challenge psychiatry, as a specialty, with 100,000 of these procedures being done every year, to do

¹⁰ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 27 Jan. 2011, p. 171.

¹¹ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 27 Jan. 2011, p. 166.

¹² FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, pp. 412-413, ttps://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm247595.pdf.

¹³ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 27 Jan. 2011, p. 143,

¹⁴ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p. 223, https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm247595.pdf

more to answer the questions that have been raised in the public docket, in the literature review, and by this Panel with regard to structural and electrical changes in the brain. We don't have good biomarkers, but we do have good structural measures of the living brain." ¹⁵

- Dr. Kevin Duff, Ph.D. a neuropsychologist and Associate Professor in the Department of Neurology at the University of Utah stated: "....the changes in cognition have to represent something. I don't know that we can identify it the same way that we would a stroke or a head injury, but-- and maybe it's that we don't have the technology yet or we don't have the studies, but there's something...." ¹⁶
- Dr. Glenn T. Stebbins, Professor of Neurological Sciences at Rush University Medical Center in Chicago told the hearing, "there are some troubling little studies here....the increased white matter, there's some PET studies and some spec studies showing hypo-metabolism in the frontal lobes long-term. I don't think there's definitive answers out there as to whether or not there's brain damage, but it looks like there are some changes that occur in the brain following ECT that have not been explained. ¹⁷ [Emphasis added]

Those at the 2011 Hearing that refuted that ECT causes brain damage also admitted a paucity of research "using the latest, greatest techniques" to back up their claims.

• For example, Dr. Jane S. Paulsen, Professor of Neurology and Psychiatry at the University of Iowa and neuropsychologist, said: "I don't agree that there's any clinical data to support that brain damage occurs as a result of ECT" but adds "I think we don't know if there may be evidence of this using more cutting-edge techniques...." Dr. Thomas Brott on one hand claimed there's very little evidence to indicate brain change but then admits that "the studies that have been

¹⁵ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p416, https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm247595.pdf

¹⁶ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p416, https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm247595.pdf

¹⁷ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p. 414, https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-adcom/documents/document/ucm247595.pdf

¹⁸ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p. 414

done to date have not answered the question as to whether or not there may be instances of brain damage which have gone undetected." ¹⁹

As such, even those proponents that assert there is no brain damage, have no evidence upon which to base this decision and ignore patient evidence to the contrary. This only serves the fact that a PMA is needed for the manufacturers to assure FDA that the ECT device does not cause brain damage and other significant injuries to satisfy the FDA's primary mission to "protect the public health by ensuring the safety, efficacy, and security of...medical devices." ²⁰

The fact of ubiquitous memory loss and cognitive impairment from the practice of ECT certainly does, as noted above by Dr. Kevin Duff, "have to represent something." It is illogical to assume that notwithstanding these cognitive effects that no injury occurs. Humans do not simply begin having memory loss, lose their historical memories, lose their abilities to think, for no reason. That it occurred immediately and always following ECT must "represent something."

Respectfully, that reason has always been known and it is known to the FDA. The American Psychiatric Association conducted a survey of its members who were ECT practitioners in its 1978 Task Force Report: Electroconvulsive Therapy. The APA's publication revealed that 16% of ECT practitioners conceded that ECT should be discontinued or at least curtailed. Such a high proportion of practitioners making a comparable suggestion about any other treatment would warrant summary termination of the treatment until it was proven to be safe. The APA's 1978 Task Force Report also reported that 41% of its member practitioners acknowledged that ECT caused at least "slight or subtle brain damage," and only 26% of those practitioners disagreed with the conclusion. ²¹

Notwithstanding the manifest conclusion that the FDA has not determined the extent of brain damage from ECT (not having required the manufacturers provide PMAs over the last 40 years), this should not be subject to reasonable dispute unless the manufacturers *admissions* regarding brain damage of their devices continue to be ignored. Indeed, the most that can be stated regarding the Proposed Order is that notwithstanding the evidence of brain injury and concessions from the manufacturers, FDA is willing to ignore that evidence and proceed without having definitive studies upon which to base the finding.

Again, and respectfully, doesn't that "represent something?"

¹⁹ FDA Hearing on ECT, "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE, NEUROLOGICAL DEVICES PANEL," 28 Jan. 2011, p.419. ²⁰ "FDA Mission," https://www.fda.gov/AboutFDA/WhatWeDo/

²¹ Electroconvulsive Therapy. Report of the Task Force on Electroconvulsive Therapy of the American Psychiatric Association. (1978), p. 3.

Unfortunately the FDA's impotent labeling response as a solution for the patients who receive ECT, will not enable them be informed that brain damage is likely and that it is understood as an effect of ECT each will, to a greater or lesser degree, suffer.

MDE and MDD justification

The proposed rule states, in part:

Despite the occurrence and uncertainty of duration of memory impairment, FDA believes that the potential benefits of ECT outweigh the risks in patients 18 years of age or older for MDE associated with MDD or BPD in patients who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition.

But what the FDA purports to "believe" in the face of contrary evidence, thousands of testimonials and objections from victims and the acknowledged harm to patients, cannot justify such violent and permanent treatment. It would appear that the FDA is simply determined to permit this treatment to go forward despite the harms and in violation of its responsibility to protect the public's health. The requirement of a PMA for other purposes and MDD and MDE is a logical ruse, since the agency recognizes that no PMA will be forthcoming once a Class II designation is permitted for any other use.

It should also not be overlooked that the FDA's Advisory Panel did *not* recommend its use for these stated but amorphous conditions. FDA never asked the panel about these specific conditions, but it voted to decline to relive the manufacturers of the Class II designation and necessity for a PMA for the use of ECT for depression – which would encompass the newly minted MDD and MBE of the Proposed Order.

FDA can assert that it did not ask the Panel to vote, and seek to ignore that vote – but vote it did and the vote was contrary to the position taken in the Proposed Order. This suggests a pre-determined conclusion to the classification debate, since contrary studies were ignored, science was ignored, statistics from actual ECT deaths was ignored, and the pleas of thousands of victims were ignored.

FDA's Proposed Rule for ECT is arbitrary and without reasonable grounds or adequate consideration of all relevant evidence, leading to the conclusion that a clear error of judgment has been made and an abuse of patient protections.

In sum, the FDA's proposed labeling ignores the ubiquitous long term effects effect regarding ECT. Provision of a label or information to the patients cannot prevent these deleterious effects. At best, it *may* prevent some patients from being injured. But those that receive the treatment will be injured, irrespective of the label. The supposed

need to assist those with serious depression or having a supposed major depressive incident, cannot medically, logically or ethically justify damaging them for the rest of their shorten lives after ECT.

Sincerely,

Jonathan Emord

EMORD & ASSOCIATES

Kendrick Moxon

Law Office of Kendrick L. Moxon, PC