

# Citizen Petition

Submitted August 24, 2016

Petitioners Atze Akkerman, Evelyn Scogin, Dianna Loper Posthauer, Kenneth Fleischman and Tony Buonfiglio, hereby submit this Citizen Petition under 21 U.S.C. §§ 360e(b) and 360f(a) and 21 C.F.R. § 10.30, to request that the Commissioner of the Food and Drug Administration (“Commissioner”) either promulgate a final regulation making electroconvulsive therapy (“ECT”) devices banned devices or maintain the Class III classification of the devices and issue a final order establishing the effective date for premarket approval (PMA) for all ECT devices.

Petitioner Atze Akkerman was given a round of 10 shock therapy treatments in 2003. He experienced dramatic memory loss and amnesia for his historical memory, including all memories of his children, his parents and his wife. Although he was a professional musician and toured with the Navy Band, he lost his ability to play music. He continues to suffer substantial long term memory loss and short term memory loss making learning new matters difficult. He remains on full disability following his ECT. The details of his injuries were submitted to the FDA through detailed Comment and submission of his attorney in FDA-2010-N-0585 and FDA 2014-N-1210. Mr. Akkerman also submitted a report to the MAUDE database. Mr. Akkerman is resident of California.

Petitioner Evelyn Scogin is a resident of Texas who has suffered personal injury by way of persistent and continuing memory loss and cognitive damages from the receipt of ECT in 2005. She experienced dramatic memory loss, wiping out, for example, knowledge of friends and family. She has lost years of memory of her youth, as well as most of the two years of memory prior to the shock treatment. The shock damaged her ability to walk, resulting in the necessity of using a wheelchair for a considerable time. She lost several teeth broken during the procedure and suffered massive pain throughout her body. She has advocated for the abolition of ECT on children and adults, and has publicly spoken on the issue of harms arising from ECT. Ms. Scogin submitted a written statement which was read on the record to the FDA Advisory Committee in January 2011, opposing reclassification of ECT to Class II.

Petitioner Dianna Loper Posthauer suffered considerable damage from the involuntary receipt of ECT over 35 years ago following post-partum depression. She thereafter didn’t know her child, didn’t remember being married, or even bearing her child. The ECT lowered her IQ and she has suffered permanent cognitive impairment, long term memory loss and new memory disability. Such damages are a continuing problem and injury. She views shock treatment as a crime against an individual’s spirit and a rape of the soul. Ms. Posthauer has advocated before government bodies and the press that ECT should be banned or sharply restricted. She submitted Comments to dockets FDA-2010-N-0585 and FDA 2014-N-1210. Ms. Posthauer is a resident of Texas, and the Founder of Christians United for the Ban of Electroshock.

Petitioner Kenneth (Kenny) Fleischman is a 28-year-old young man who was given 30 rounds of ECT in 2009 and 2010 at age 21. Previously a high school honor student, Kenny had to

relearn to tie his shoes following treatment. Kenny grew up in a difficult family situation and had normal life struggles and feelings of depression. At age 14 he was diagnosed with hypothyroidism. One of the symptoms of hypothyroidism is feelings of depression. The doctor put him on a thyroid medication and an antidepressant to “boost” the effects of the thyroid med. The antidepressant caused a worsening of his symptoms. The psychiatrist then added another drug which gave him new and worse symptoms. This pattern of adding and changing drugs continued until, at one point, he was on a cocktail of six different psychiatric drugs. He was thereafter told he was “treatment resistant” and required electroshock therapy. The risks were downplayed. Kenny was told he might have a slight memory problem, but it would come back after a few months. However, Kenny lost all memories of childhood and all memories of high school. He reports that he has lost memories of his life and who he was. Neurocognitive testing by a neurologist, done six months after the shocks, showed a loss of 50 IQ points compared to his high school IQ. Kenny suffered severe headaches for a year and a half after the shocks and was under the treatment of a cardiologist because ECT left him with heart arrhythmia. Kenny also suffered eye injury, with his eyes not tracking correctly since the shocks (Nystagmus). Kenny is on disability and unable to work. He is a resident of Michigan.

Petitioner Tony Buonfiglio received a series of ECT treatments at the age of 16, several decades ago. Afterwards he was put into a special education class because his memory and cognitive abilities were so diminished. He experienced extensive and permanent memory loss, losing the memories of most of his childhood and high school. These memories have never returned. His working memory, or short term memory is very poor, making work a challenge, and is easily thrown off a train of thought. Mr. Buonfiglio is a resident of Florida.

### **ACTION REQUESTED**

Petitioners respectfully request that the Food and Drug Administration (“FDA”) either:

- Promulgate a final regulation banning ECT devices; or
- Issue a final administrative order: (1) maintaining Class III designation, and requiring a premarket approval application (“PMA”) for any ECT device that is a preamendment device or any ECT device that has been found to be substantially equivalent to such a device; and (2) specifying that all other ECT devices have an approved PMA in effect before being placed in commercial distribution for any purpose.

### **STATEMENT OF GROUNDS**

#### **I. FACTUAL BACKGROUND AND REGULATORY HISTORY OF ECT DEVICES**

##### **A. The FDA Initially Proposed Classifying ECT Devices into Class II**

The Medical Device Amendments of 1976 (“Amendments”), enacted on May 28, 1976, established three classes of medical devices: Class I (General Controls), Class II (Performance Standards), and Class III (Premarket Approval). Whether a device is Class I, II, or III depends

upon its intended use, indications for use, and risk to the user.

An ECT device is “a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.” 21 C.F.R. § 882.5940(a). Some ECT devices were marketed in the U.S. before enactment of the Amendments (hereinafter referred to as “preamendments devices”). Thus, following the Amendments, the FDA needed to classify them. Pursuant to the Amendments, in 1978, the FDA issued a proposed rule classifying ECT devices into Class II. *See* 43 Fed. Reg. 55729 (Nov. 28, 1978).

### **B. The FDA Ultimately Classified ECT Devices into Class III**

Although the FDA initially proposed classifying ECT devices into Class II, it ultimately promulgated a final rule classifying them as Class III in response to comments it received on the 1978 proposed rule. *See* 44 Fed. Reg. 51776 (Sept. 4, 1979); 21 C.F.R. § 882.5940. Such comments included, *inter alia*, those from patients who suffered memory loss after receiving ECT treatment and wanted strict controls over the application of ECT as a result. *Id.* A separate comment said that the information necessary to develop a performance standard was insufficient. *See id.* One comment noted that ECT is inherently brain damaging and stated that the FDA could not assure effectiveness because there was no consensus regarding the effectiveness of ECT. *See id.*

The FDA considered comments on the proposed rule at a meeting of its Neurological Section of the Respiratory and Nervous System Devices Panel.<sup>1</sup> A representative of the American Psychiatric Association (“APA”) told the panel that, at the request of the FDA, it formed a committee to develop standards for ECT devices and was in the process of reviewing the literature and gathering information, and that it expected to have sufficient information to write the standard in six months. Because such information did not yet exist to develop a performance standard, the panel recommended classifying ECT devices into Class III.

The FDA followed the section’s recommendation. When classifying ECT devices as Class III, it stated:

FDA has carefully considered the classification of electroconvulsive therapy devices and has decided to classify the devices in class III rather than class II as proposed. FDA is aware of and encourages the work of the APA committee in developing a performance standard. The agency is persuaded, however, based on the comments received on the proposal and on the recommendation of the Panel, that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device.

*Id.*

### **C. The FDA Did Not Require Premarket Approval for Class III ECT Devices**

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<sup>1</sup> The panel used to be called the Neurological Device Classification Panel.

Manufacturers of Class III devices are ordinarily required to submit a premarket approval application (“PMA”) to the FDA that contains safety and effectiveness information, including information from clinical trials.

ECT devices legally marketed in the U.S. before the enactment date of the Amendments (hereinafter referred to as “preamendments devices”) or marketed after May 28, 1976, but deemed substantially equivalent to a preamendments device, do not require a PMA. The latter require a notification to the FDA under section 510(k) of the FDCA, however. Specifically, the FDA’s regulations provide:

Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval... Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device.

21 C.F.R. § 882.3(a).

A PMA ordinarily requires data from human clinical trials to assure that a device is safe and effective for its intended use, whereas a 510(k) notification generally does not require such data. Rather, non-clinical performance or other data is usually sufficient to demonstrate that a device is substantially equivalent to a predicate device. *See* 21 U.S.C. §§ 360(c), 360e (premarket approval). To date, no human clinical trials have been required for a new ECT device to receive marketing clearance from the FDA under section 510(k) of the FDCA.

As to ECT devices, the FDA published an Order in the Federal Register on September 4, 1979, which it represented was a “final ruling” placing ECT devices into Class III. The ruling stated, in part:

The Food and Drug Administration (FDA) is issuing a final ruling classifying electroconvulsive therapy devices into Class III (premarket approval). The effect of classifying a device into Class III is to require each manufacturer of the device to submit to FDA a premarket approval application [“PMA”] that includes information concerning safety and effectiveness tests for the device.”<sup>2</sup>

The FDA effectively gave manufacturers 30 months to perform clinical trials and submit their PMAs – by April 1982. However, an April 1981 notice in the *American Journal of*

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<sup>2</sup> See 44 FR 172, September 4, 1979, page 51776-51777, reporting 21 CFR Part 882 [Docket No. 78N-1103].

*Psychiatry*<sup>3</sup> explained that it was unlikely manufacturers would conduct clinical trials:

This ruling places the burden on manufacturers to prove that their respective devices are safe and effective... There does not appear to be any move on the part of the manufacturers to accomplish this.... [T]he APA task force is currently working in conjunction with the Division of Government Relations to petition to FDA for a reclassification of ECT devices back into Class II.

The FDA eventually allowed the April 1982 deadline to pass and failed to enforce its Order that manufacturers provide PMAs.

#### **D. The APA Petitioned the FDA to Reclassify ECT Devices into Class II**

Thereafter, on August 13, 1982, the APA petitioned the FDA to reclassify ECT devices from Class III to Class II based on alleged “new information.” *See* 48 Fed. Reg. 14758 (April 5, 1983).

Having ignored its pending Order that manufacturers submit PMAs, the FDA issued a public notice on April 5, 1983 that it intended to reclassify ECT devices to Class II. However, the FDA took no action on reclassification for many years, and it continued to decline to enforce its Order that manufacturers provide proof of safety and efficacy through a PMA.

Notwithstanding this history, FDA permitted manufacturers to submit 510(k) applications, beginning in 1984 and continuing through 1997,<sup>4</sup> which necessarily asserted that the devices were substantially equivalent to pre-amendment devices. And, as noted herein, FDA declined to require manufacturers ever to provide PMA information demonstrating either safety or efficacy of these devices.

#### **E. The FDA Proposed a Rule Reclassifying ECT Devices Intended for Severe Depression into Class II**

After seven more years of administrative silence, in 1990 the FDA published a further proposed rule reclassifying ECT devices into Class II when intended solely for the treatment of severe depression. *See id.* at 36579.

FDA based the proposed rule on its belief that supposed “valid scientific evidence” established that the benefits of ECT for severe depression outweighed the risks. FDA questioned the extent to which ECT caused memory deficits, noting, for instance, that depression impairs memory functions, asserting that patients’ anecdotal reports of memory loss were difficult to evaluate given their nature, and that clinical studies “attempt[ing] to quantify memory deficits, or even to identify persistent memory changes, are beset with numerous sources of error . . .” *Id.*

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<sup>3</sup> Am J. Psychiatry 138:4, April 1981, p. 572

<sup>4</sup> See Exhibit 1, FDA Executive Summary Prepared for the January 27-18, 2011 Meeting of the Neurological Devices Panel, Meeting to Discuss the Classification of Electroconvulsive Therapy Devices (ECT), at page 66.

In sum, FDA rationalized that the risks of self-injury and suicide with untreated severe depression (and the risks associated with severe depression treated with therapy less effective than ECT) were greater than the documented risks associated with ECT. *See id.*

The FDA also asserted that because the risks of ECT were primarily related to techniques and the duration and nature of the patient's exposure to it, a performance standard (Class II) that addressed those issues could assure the safe and effective use of ECT for severe depression, thus eliminating the need for a product-by-product review of ECT devices under PMAs. *See id.* According to the FDA, the standard would address the labeling (e.g., priority order of treatment, treatment protocols, and indications and contraindications) and design and environmental features of ECT devices (such as requirements that would control energy output, duration, electrical wave lengths and duration of thousands of electrical shocks, and assure accurate device performance over expected environmental ranges of temperature, humidity, supply voltage, etc.). *See id.*

Although the FDA proposed reclassifying ECT devices into Class II that were intended solely for use in the treatment of severe depression, it acknowledged that reclassification meant that such devices were now deemed safer. *Id.* at 36579. The FDA also explained that it intended to initiate proceedings to require PMA's for ECT devices that were intended for use in conditions other than severe depression. *See id.*, at 36579-80. Moreover, it said it would consider requiring PMA's for ECT devices indicated for use in the treatment of severe depression if an acceptable performance standard was "not forthcoming within a reasonable period of time . . ." *Id.* at 36580.

#### **F. The Safe Medical Devices Act of 1990 Mandated that FDA Require PMAs for ECT Devices or Reclassify Them**

By the late 1980's, FDA failed to establish a performance standard for Class II ECT devices. It also had not promulgated final rules reclassifying ECT devices intended for severe depression into Class II and requiring PMAs for all other ECT devices. As a result, the less stringent 510(k) process remained the pathway to market approval for ECT devices although they remained in Class III for all indications. *See* 21 U.S.C. § 351(f).

Congress intervened through the Safe Medical Devices Act of 1990 ("SMDA"), which required FDA to take action regarding preamendments devices for which PMAs were not yet mandated, including ECT devices. Specifically, the SMDA required FDA to: (1) before December 1, 1995, order industry to submit safety and effectiveness data for preamendments devices that were not yet required to undergo PMA approval; (2) use that safety and effectiveness data to publish regulations reclassifying each such device into Class I or II or requiring it to remain in Class III<sup>5</sup>; and (3) no later than 12 months after the effective date of a regulation requiring a device to remain in Class III, establish a schedule for the promulgation of regulations requiring the submission of PMAs for such devices. *See* 21 U.S.C. § 360e.

The SMDA also changed the definition of Class II devices from those that required a

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<sup>5</sup> As discussed above, the FDA had undertaken rulemaking proceedings to reclassify ECT devices intended solely for the treatment of severe depression into Class II and requiring PMAs for all other ECT devices.

performance standard to provide a reasonable assurance of safety and effectiveness to those for which sufficient information exists to establish special controls to provide that assurance. *See* 21 U.S.C. § 360c(a)(1)(B). Special controls include “performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions . . .), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance.” *Id.*

Thus, following the enactment of the SMDA, FDA issued an order requiring the manufacturers of ECT devices to “submit to the FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the [FDCA].” 60 Fed. Reg. 41986, 41987 (Aug. 14, 1995). The Order called for ECT device manufacturers to submit the safety and efficacy information by the following year – by August 14, 1996.<sup>6</sup> FDA intended to use such information to determine whether reclassification was appropriate. *See id.*

After FDA issued the order, however, it did not take any steps to finalize its proposed rule reclassifying ECT. The manufacturers failed to comply by providing safety and efficacy information – and again FDA failed to enforce its order. Rather, FDA procrastinated again, this time issuing a Notice in the Federal Register on November 26, 2004, “announcing the withdrawal of certain advance notice of rulemakings... to reduce its regulatory backlog and focus its resources on current public health issues.” As to ECT devices, FDA stated that it “intend[ed] to start a new proceeding on this matter” and would “retain the data and information contained in [the] docket and consider it at that time.” *Id.* at 68833.

### **G. FDA Issued a Renewed Order for Safety and Effectiveness Information for ECT Devices**

Five years after its withdrawal of the proposed rule, the FDA, for the second time, issued an order requiring ECT device manufacturers to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices. *See* 74 Fed. Reg. 16214 (April 9, 2009). The two U.S. ECT device manufacturers responded to that order. *See* 80 Fed. Reg. 81223, 81226 (Dec. 29, 2015). According to their submissions, ECT devices allegedly could be reclassified into Class II because their safety and effectiveness “may be assured by reducing the frequency of treatments, temporary or permanent interruption of treatments, reduction of stimulus dose, electrode placement, dosage or type of anesthetic (or other) medications, including minimizing psychotropic medications, brief pulse or ultra-brief pulse waveform stimulus, EEG monitoring, proper preparation (including conductive gel) and contact of the electrodes to the skin, changing anesthetic medications or doses, and changing concurrent medications.” *Id.* None of the information provided directly addressed the issues of permanent memory loss and cognitive impairment, or the likelihood of brain damage arising out of ECT.

Also in 2009, the FDA opened a public docket for information and comments on the reclassification of ECT devices. *See* 74 Fed. Reg. 46607 (Sept. 10, 2009). According to the FDA

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<sup>6</sup> Federal Register , August 14, 1995, Vol. 60, No. 156, p. 41986-41987.

Executive Summary of the Docket and its own research and analysis, the FDA received more than 3,000 comments, most of which (79%) opposed reclassifying ECT devices to Class II. *See* Exhibit 1, and 80 Fed. Reg. at 81226. The comments related hundreds of stories of permanent memory loss, deaths of loved ones and the debilitating effects of ECT. In addition, there were 92 group submissions representing 6,462 individuals against reclassification and only 462 in favor. The comments that opposed reclassification largely based their opposition on the adverse events associated with ECT treatment, such as memory loss, other cognitive complaints, brain damage, and death. *See id.* The FDA summarized harms caused by ECT as reported by commenters to the Public Docket: “A majority of respondents identified an adverse event they felt was associated with ECT treatment. The most common type of adverse event reported in the public docket was memory adverse event (529 reports). This was followed by other cognitive complaint (413 reports), brain damage (298 reports) and death (103 reports).”

In 2011, the FDA’s Neurological Device Panel held a meeting on the reclassification of ECT devices. It performed a safety and effectiveness review of ECT devices for multiple indications. To that end, the panel reviewed, *inter alia*, manufacture docket submissions in FDA-2010-N-0585; public docket submissions; adverse events and other reported concerns in the Manufacturer and User Facility Device Experience (“MAUDE”) Database; published studies, and the FDA’s own review and meta-analyses of published studies; and practice guidelines. Ultimately, the panel voted to recommend that ECT devices intended for schizophrenia, bipolar manic states, schizoaffective, and schizophreniform disorder and depression remain in Class III. *See id.* The panel did not reach consensus on the classification of ECT devices intended for the treatment of catatonia, but a majority voted to reclassify to Class II for this single, extremely rare condition. *See id.*

#### **H. The FDA Issued a Proposed Administrative Order in December 2015 Reclassifying ECT Devices**

For four more years, FDA failed to take any action, evidently stultified by the Advisory Panel’s determination that ECT remain in Class III for essentially all conditions for which it was used. Contrary to its Advisory Panel’s determination, in December 2015, FDA published a proposed administrative order to reclassify certain ECT devices into Class II for use in treating major depressive episode (“MDE”) associated with major depressive disorder (“MDD”) or bipolar disorder (“BPD”) in patients 18 years of age and older who are treatment-resistant or require a rapid response due to the severity of their psychiatric or medical condition. *See id.* at 81223. Such uses were not among those even *proposed* by FDA to its Advisory Committee. Under the proposed rule, such devices would not be exempt from premarket (510(k)) notification requirements. *See* 80 Fed. Reg. at 81226. The agency also proposed to require the filing of a PMA or a notice of completion for of a product development protocol (“PDP”) for ECT devices intended for other uses, but invited interested persons to request that it change the classification of such devices. *See id.* at 81223.

According to FDA, reclassification was appropriate for ECT devices intended for severe major depressive disorder associated with MDD and BPD in patients 18 years of age and older who are treatment resistant or who require a rapid response due to the severity of their psychiatric or medical condition because there was alleged “new information” about their effectiveness and special controls, in addition to general controls, can be established to provide reasonable assurance of their safety and effectiveness. *See id.* at 81277. FDA explained:



FDA believes that in the specified patient population, and with the application of general and special controls as described in this document, the probable benefit to health from use of the device outweighs the probable injury or illness from such use. FDA acknowledges significant risks associated with ECT but believes that for the specified population . . . the probable benefit of ECT outweighs these risks.<sup>7</sup>

Concerning the alleged “new information,” FDA said that sufficient evidence had been developed since ECT devices were originally classified into Class III to support the proposed reclassification. *See id.* FDA stated that it reviewed the clinical literature and the largest body of scientific evidence for ECT effectiveness exists for MDE associated with MDD and BPD in patients 18 years of age or older, albeit only in the acute phase (less than 3 months after treatment). FDA’s clinical literature review allegedly included “examining the results of over 60 randomized controlled clinical trials comparing ECT with either placebo (sham) or antidepressant therapy in which ECT was superior for patients with MDD and BPD in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition.” *Id.* It did not identify these alleged “randomized controlled clinical trials.” FDA asserted that it also performed a systematic meta-analysis of the studies and concluded that they showed a “robust effect of ECT in the short-term” for those conditions. *See id.* at 81227-28. Again, its findings were contrary to those of its Advisory Committee, and certainly contrary to approximately 2,400 comments by the public decrying and protesting reclassification of what was universally considered to be a dangerous and destructive practice in the objecting comments. On the other hand, FDA asserted scientific evidence was lacking regarding the effectiveness of ECT for other conditions (e.g., schizophrenia), other ages (i.e., children and adolescents), or patients that did not receive benefit from prior treatments. *See id.* at 81228.

Regarding the proposed special controls, below is a table that shows how the FDA believes that the risks of ECT can be mitigated by special controls:

Risk	Special Control	Details
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<sup>7</sup> The risks the FDA identified include the following: adverse reaction to anesthetic agents/neuromuscular blocking agents; adverse skin reactions; cardiovascular complications; cognition and memory impairment; death; dental/oral trauma; device malfunction; manic symptoms; pain/discomfort; physical trauma; prolonged or tardive seizures; pulmonary complications; skin burns; and worsening of psychiatric symptoms if ineffective. 80 Fed. Reg. at 81227. Regarding the risk of death, the FDA said it was rare, estimated to occur in 1 per 10,000 patients or 1 in 80,000 treatments, and that it was comparable to the death rate of minor surgical procedures. *See id.* at 81228. This estimated number is refuted below. Concerning cognitive and memory impairment, which the FDA recognized was not uncommon and might, in some instances, persist, the FDA continued to assert that the benefits outweighed such a risk. *See id.*

<p>Adverse reaction to anesthetic agents/neuromuscular blocking agents; cardiovascular complications; death; and pulmonary complications</p>	<p>Labeling</p>	<p>Both physician and patient labeling would include information regarding contraindications, precautions, warnings, and potential adverse effects to inform users and patients of when ECT should not be used. Labeling for users would also include specific device use instructions (e.g., information on conduct of pre-ECT patient assessments and appropriate patient monitoring during ECT) to minimize potential procedural complications.</p>
<p>Adverse skin reaction</p>	<p>Biocompatibility and labeling</p>	<p>Biocompatibility testing would be used to ensure that the patient-contacting materials are safe for skin contact, and labeling would provide information on validated methods for reprocessing any reusable components between uses.</p>
<p>Cognitive and memory impairment</p>	<p>Technical parameters, non-clinical test data, and labeling</p>	<p>The technical parameters for the device and non-clinical testing data would be used to confirm the electrical characteristics of the output waveform to ensure that the device performance characteristics are consistent with existing clinical performance data that supports a reasonable assurance of safety and effectiveness. Labeling would be used to help users and patients make informed decisions about how and when to use ECT. It would include information on potential adverse effects, alternative treatments, and a prominent warning that it may be associated with disorientation, confusion, and memory problems and limited in its long-term effectiveness (greater than 3 months). The labeling would also provide instructions for users on cognitive status monitoring before beginning ECT and during the course of treatment.</p>

Risk	Special Control	Details
Dental/oral trauma; physical trauma; prolonged or tardive seizures; and pain/discomfort	Labeling	The physician and patient labeling would include information on contraindications, precautions, warnings, and adverse effects to advise them of conditions under which ECT should not be used and to make sure they know about adverse effects. Additionally, specific device use instructions (e.g., conduct of pre-ECT assessments, use of mouth protection during the procedure, use of general anesthetic agents and neuromuscular blocking agents, and appropriate patient monitoring) would be used to help users minimize potential post-ECT complications.
Device malfunction	Performance data, electromagnetic compatibility, and software verification, validation, and hazard analysis	The performance data would be used to demonstrate the electrical and mechanical safety and the functioning of all safety features. Electromagnetic compatibility testing would be used to show that electromagnetic interference would not cause device malfunction. Software verification, validation, and hazard analysis would be used to ensure that device software has been adequately designed.
Manic symptoms or worsening of psychiatric conditions	Labeling	The labeling would: (1) explain the clinical training users need to ensure appropriate use of ECT and the patient's ongoing medical management; and (2) provide information on the intended patient population (e.g., clinical testing, adverse effects, and typical course of treatment) to enable users and patients to make informed decisions about ECT use.
Skin burns	Performance data and labeling	Performance testing would be used to demonstrate safe electrical performance, adhesive integrity, and physical and chemical stability of the stimulation electrodes. Labeling would include specific user instructions regarding proper electrode placement, (e.g., instructions for adequate skin preparation and use of conductivity gel in placing the electrodes).

*See id.* at 8828-29.

If FDA issues a final order to implement its proposed rule, the final order will be effective 90 days after publication in the Federal Register. *See id.* at 81231. If an ECT device manufacturer would want to continue to lawfully market its device for intended uses other than the treatment of MDE associated with MDD or BPD in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, the manufacturer will need to file a PMA within 90 days after the issuance of the final order. *See id.* at 8129-30. Failure to timely file the PMA will cause the device to be adulterated. *See id.* at 81230. Similarly, an amended 510(k) demonstrating compliance with the above special controls will be required for: ECT devices already on the market and which, in future, will only be intended for use in treating severe MDE associated with MDD and BPD in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. *See id.* The manufacturer's failure to file the amended 510(k) within 60 days after the final order's effective date would cause the device to be adulterated. *See id.*

## II. ARGUMENT

As explained below, due to the absence of competent evidence establishing safety and efficacy, rather than pursue the reclassification of certain ECT devices into Class II, the FDA should either ban all ECT devices under 21 U.S.C. § 360f or, at the very least, issue an administrative order under 21 U.S.C. § 360e requiring all ECT devices to have an approved PMA regardless of which psychiatric or medical conditions they are intended to treat.

### **A. Failure to Require an Approved PMA for ECT Devices (when Special Controls Are Insufficient to Provide a Reasonable Assurance of Safety and Effectiveness) Is Arbitrary and Capricious Agency Action and an Abuse of Discretion in Violation of the APA**

Under the Administrative Procedure Act ("APA"), a court will set aside agency action that is, *inter alia*, "arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law . . ." 5 U.S.C.A. § 706(2)(A). A well-established tenet of administrative law is that the reviewing court will assess whether the agency decision at issue was based on consideration of the relevant facts. *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983) (explaining that the arbitrary and capricious standard under section 706(2)(a) is met when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise"). "If the agency's reasons and policy choices conform to minimal standards of rationality, then its actions are reasonable and must be upheld." *Tex. Oil & Gas Ass'n v. U.S. E.P.A.*, 161 F.3d 923, 934 (5th Cir.1998). Nonetheless, the reviewing court "may not supply a reasoned basis for the agency's action that the agency itself has not given." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43, 103 S. Ct. 2856.

As addressed below, the FDA's actions are manifestly arbitrary, capricious, and not in conformance with law.

**1. The FDA based its order on an insignificant amount and inadequate quality of information. It excluded evidence, studies, publications, and comments, contrary to its proposed order**

The FDA's proposed Rule dated December 29, 2015, provides a cursory list of items as references supporting the order. Section XIX lists the references relied upon, consisting of only 10 published articles, and the FDA Executive Summary Prepared for the January 27-28, 2011 meeting of the Neurological Devices Panel to Discuss the Classification of Electrotherapy Devices.

Yet the FDA's 2010 Executive Summary prepared for the Advisory Committee on this issue, Exhibit 1, acknowledged that the FDA located more than 1,200 studies relating to ECT. However, in choosing what published studies to consider, FDA rejected more than 94% of all studies relating to ECT, because the studies allegedly were unreliable. It thus included for serious evaluation only 68 studies published in the past 70 years regarding ECT and excluded 1163 other studies, giving them no consideration. (*Id.*, Executive Summary, p. 12.) Many of the excluded studies concluded that ECT lacked efficacy and unquestionably created severe and permanent injury, including the death of some patients. See below, and, i.e. the attached Analysis of Dr. Moira Dolan. (Exhibit 2)

Primary information, studies and information necessary to an appropriate determination of the correct classification of ECT devices was thus excluded by FDA, not because the studies failed to supply credible evidence, but rather, because the standard arbitrarily set for exclusion of probative evidence resulted in a mass reduction of the quantum of science reviewed to just 68 studies, leaving 1163 not examined at all. FDA did not conclude that there was no scientific merit in the 1163 studies excluded, only that the studies failed to satisfy arbitrarily selected exclusion criteria. Thus, FDA did not review all publicly available scientific evidence germane to safety and efficacy, only an extreme subset of that evidence, which skewed its assessment, biasing it in favor of its ultimate conclusion. In short, exclusion of those materials was an abuse of agency discretion and constituted arbitrary and capricious agency action, contrary to FDA's obligations and the safety and well-being of the public.

FDA also excluded from substantive consideration the extensive comments and submissions made for the 2011 Advisory Committee hearing, purportedly because thousands of comments explaining actual harm caused to patients, was merely "anecdotal." FDA thus excluded direct evidence of injury caused by ECT from the very persons harmed by ECT devices, which is highly probative, particularly given FDA's routine reliance on adverse event reports in assessing drug and medical device safety. See, "MAUDE – Manufacturer and User Facility Device Experience", [www.accessdata.fda.gov/scripts/cdhr/cfdocs/cfmaude/search.cfm](http://www.accessdata.fda.gov/scripts/cdhr/cfdocs/cfmaude/search.cfm).<sup>8</sup> As noted in the Executive Summary respecting Comments received on the public docket in No. FDA-2010-N-0585:

A majority of respondents, 79%, expressed an opinion against reclassification (i.e., maintain Class III designation) while 14% supported reclassification (i.e., reclassify to Class II). In addition, there were 92 group submissions, representing a total of 6462

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<sup>8</sup> See also, Exhibit 3, Complaint of Misconduct, Center for Medical Devices and Radiological Health, Food and Drug Administration, February 8, 2012.

individuals, against reclassification and 462 individuals in favor of reclassification. A majority of respondents identified an adverse event they felt was associated with ECT treatment. The most common type of adverse event reported in the public docket was memory adverse event (529 reports). This was followed by other cognitive complaint (413 reports), brain damage (298 reports) and death (103 reports).

(Executive Summary, p. 14.)

In contradictory fashion, FDA listed each adverse event submitted to its MAUDE database, and evidently considered such information. Yet the sole difference between the adverse events listed in MAUDE and the comments of adverse events in Dockets No. FDA-2010-N-0585 and FDA 2014-N-1210 vilifying ECT, was solely the location and the FDA database in which the reports were submitted. Thus, a small number of unauthenticated and even anonymous MAUDE reports were considered, and about 2,400 adverse comments were excluded from consideration by the FDA – including 103 reports of deaths, 529 reports of memory impairments, 413 reports of cognitive impairments and 298 reports of brain damage. Moreover, the Former Commissioner of the FDA has conceded that “about 1 % of serious adverse events are reported to FDA...”<sup>9</sup>

The FDA’s failure to consider the comments posted in Docket No. FDA-2010-N-0585, as well as the numerous, as yet uncounted comments posted on Docket No. FDA-2014-N-1210, constitutes arbitrary and capricious action by the agency warranting rejection of the Proposed Order.

Moreover, FDA has not justified its continuing failure for nearly 4 decades to require manufacturers to conform to the standard practice of submitting PMAs for Class III devices, which include clinical trials to prove of safety and efficacy. However, the FDA has allowed the companies to sell such devices without restraint for almost 40 years. Many thousands of people were subjected to shock treatment against their will or without informed consent and thousands reported significant long-term memory loss, cognitive damage and death. There are no reporting requirements in any but two states for ECT, and therefore the extent of the damage is neither known nor recorded.

## **2. The Proposed Special Controls Will not Provide a Reasonable Assurance of Safety and Effectiveness of ECT Devices**

As explained above, FDA found that ECT therapy is associated with “significant risks,” including, but not limited to, the following: skin burns; brain damage; cognition and memory impairment; dental/oral trauma; other physical trauma; prolonged or tardive seizures; pain/discomfort; cardiovascular complications; and death. *See* 80 Fed. Reg. at 81226-27. Despite the severity and permanency of those injuries, FDA nonetheless determined that special controls were satisfactory forms of mitigation, warranting, in its view, elimination of a PMA

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<sup>9</sup> Kessler, D.A. (June 2, 1993) Introducing MEDWatch. A New Approach to Reporting Medication and Device Adverse Effects and Product Problems by David A. Kessler, M.D., for the Working Group. *JAMA*, Vol. 269, No. 21 pages 2765-2768. [www.fda.gov/downloads/Safety/MedWatch/UCM201419.pdf](http://www.fda.gov/downloads/Safety/MedWatch/UCM201419.pdf)

requirement for all uses.

The agency acted in an arbitrary and capricious manner when it eliminated the PMA requirement, however. FDA has failed to prove that the proposed special controls have any material effect in reducing the injuries which it admits ECT creates. Further, any purported immediate benefits of ECT are ephemeral in nature, while the injuries caused are often permanent and some irreversible, as explained below.

**(a) The FDA’s Proposed “Cognitive and Memory Impairment” Controls Avoid and Ignore The Magnitude of the Damages Caused By ECT, for Which the Proposed Controls Would be Ineffectual**

**(i) Apparent Brain Damage, Memory Loss and Cognitive Impairment**

The one ubiquitous result of ECT is memory loss and cognitive impairment, as has long been conceded by the FDA, the manufacturers and numerous scientific studies. The apparent reason for this memory loss and cognitive impairment is the effect of as much as 450 volts of electricity being forced randomly through the brain, with electrodes being placed at two parts of the head and allowing the electricity to flow through the brain where it may, without control, overwhelming delicate brain circuitry and function. None of the purported “controls” have any effect whatsoever on this reality. Indeed, both of the US manufacturers of ECT devices so admit – though in an indirect fashion.

The manufacturers, in their submissions to the FDA in 2010, asserted to the FDA that requiring ECT to be performed with unilateral electrode placement (electrodes both on one side of the head) rather than bilateral (electrodes placed on each temple) would allegedly reduce the universal memory loss experienced by patients. Somatics however noted that a substantially greater amount of electricity is needed with unilateral treatments “to maximize efficacy.” (Somatics Submission, p. 15.) One psychiatrist who publicly argued for the effectiveness of electroshock treatment, in a letter published in *Electroconvulsive Therapy*, conceded,

Improvement in effective disorders follows the induction of transient mental confusion which appears after treatment ... This confusion coincides with recent memory impairment.<sup>10</sup>

The 1978 American Psychiatric Association Task Force Report on ECT reported that 41% of its member ECT practitioners acknowledged that ECT caused at least “slight or subtle brain damage,” and only 26% of those practitioners disagreed with that conclusion.<sup>11</sup> Coming from this source, the fact of brain damage from ECT should be deemed conceded. This publication was not cited in the FDA’s proposed Order, even though it was brought to the FDA’s attention. Of course, utilizing the 510(k) process, the manufacturers represented to the FDA (which representations were relied upon by the FDA in granting the 510(k) applications) that the

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<sup>10</sup> Bennett, A.E., MD, letter published in *Electroconvulsive Therapy*, Correspondence, Vol. 14, No. 2.

<sup>11</sup> *Electroconvulsive Therapy. Report of the Task Force on Electroconvulsive Therapy of the American Psychiatric Association.* (September 1978), Library of Congress Catalogue No. 78-69521

devices in use today are substantially equivalent to pre-amendment devices.<sup>12</sup> And indeed they are: the same amount of electricity is used, the devices still apply electricity to the brain through electrodes placed bilaterally on the temples or unilaterally at two spots on one side of the head. The sole significant difference in the pre-amendment and “modern” devices is that the electricity is now often delivered in a “brief pulse” format, in which the electrical wave is broken up into staccato bursts of energy many times per second rather than a normal wave. As addressed below, staccato bursts are even more damaging to the brain’s delicate circuitry. In any event, the manufacturers represented in their 510(k) submissions there is substantial equivalence between the pre-amendment and new devices.

Dr. Peter Sterling, a neuroscientist and professor at the University of Pennsylvania and ECT researcher, testified before the New York State Assembly on July 18, 2001 regarding the effects of ECT on the brain, which was also provided to the FDA in Docket No. FDA-2010-N-0585, but ignored by the FDA in its Executive Summary and its present proposed Order. He stated:

ECT unquestionably damages the brain, and there are a variety of mechanisms that lead to this damage. In the first place, the electroshock delivered to the skull is basically similar to what you would get out of an electrical wall outlet, except that there is a transformer in the ECT machine that steps up the voltage ... when this is done two or three times a week for weeks, it's just completely obvious that this is going to eventually cause some kind of brain damage...

The second point, source of brain damage for ECT is that it causes... grand mal epileptic seizures ... and this causes an acute rise in blood pressure, well into the hypertensive range... And it frequently causes small ... hemorrhages in the brain.

And wherever a hemorrhage occurs in the brain, nerve cells die, and they are not replaced. And so one can accumulate these hemorrhages over a period of treatments leading to brain damage.

A third thing that ECT does is to rupture the blood brain barrier. This barrier normally protects the brain from potentially damaging substances in the blood... breaching this barrier exposes nerve cells in the brain to chemical insults that can kill them ... also leads ... to swelling of the brain ... swelling leads to local arrest of blood supply to loss of oxygen ... and to death of neurons. The fourth thing ... is that ECT ... causes neurons to release large quantities of ... glutamate. Glutamate excites further neuronal activity...and this becomes a vicious cycle ... Neurons literally kill themselves from over activity...the key manifestation of this brain damage is retrograde memory loss.<sup>13</sup>

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<sup>12</sup> See Exhibit 1, Executive Summary, page 66.

<sup>13</sup> Report to the New York Assembly reviewing the safety of ECT, 2001.  
<http://www.survivorlink.org/electroshock/nyassemblyreport/AR-safety.html>



There are many studies relating to brain damage caused by ECT, which were eschewed in the FDA's list of references relied upon in its proposed Order. For example, a study in *Archives of General Psychiatry* documented that cerebral atrophy (brain shrinkage) was significantly more common in those patients who had *ever* received electroshock therapy.<sup>14</sup> Another brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.<sup>15</sup> A study relating MRI scans of patients demonstrated a strong correlation between the numbers of previous ECT treatments to loss of brain tissue.<sup>16</sup> Another study found that ECT recipients were twice as likely to have a measurable loss of brain tissue in the front area of the brain and a tripling of the incidence of a loss of brain tissue in the back of the brain:

Most significantly, the brain abnormalities correlated only with ECT, and not with the age, alcohol use, gender, family history of mental illness, age at the time of psychiatric diagnosis, or severity of mental illness.<sup>17</sup>

FDA excluded from its consideration numerous references to brain damage in its bibliography of sources upon which the 2016 proposed order was based and ignored information provided to it in Docket No. FDA-2010-N-0585 regarding brain damage and the severity of memory loss indicative of brain injury. For example, the FDA ignored a particularly graphic study of brain damage caused by current ECT devices demonstrated inter-cranial bleeding arising from the treatment.<sup>18</sup>

According to the manufacturers, electricity causing injury to the brain is the “therapeutic agent,” but they concede that resulting convulsions *do not cause* the appropriate purported therapeutic result. Rather, the manufacturers recommend that practitioners give patients substantially more electricity than is necessary to produce a convulsion – called “supra-threshold or multiples of electricity above convulsion threshold.” (See Exhibit 5, MECTA Submission to FDA, p. 6, 10, 23; Exhibit 6, Somatics, Inc. Submission to FDA, p. 9, 10, 16, 17.)

Moreover, the MECTA Manual appended to its 2010 Submission to the FDA, asserted that “when an ultrabrief stimulus is used, the traditional bilateral placement has reduced efficacy even when dosage is set at 2.5 *times* the initial seizure threshold.” (MECTA Manual, p. 33.) And, it then recommended that patients be given 6 times the amount of electricity needed to cause a seizure:

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<sup>14</sup> Weinberger, et al. (1979) Structural abnormalities in the cerebral cortex of chronic schizophrenic patients. *Archives of General Psychiatry*, 36:935-939.

<sup>15</sup> Calloway, et al., (1981) ECT and cerebral atrophy: a CT study. *Acta Psych Scand*, 64:442-445.

<sup>16</sup> Andreasen, et al., (1990) MRI of the Brain in Schizophrenia. *Arch Gen Psych*, 47:35-41.

<sup>17</sup> Dolan, R.J.; et al., (1986) The cerebral appearance in depressed subjects. *Psychol Med*, 16:775-779.

<sup>18</sup> Kulkarni and Melkundi (2012) Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review. *Case Reports in Psychiatry*. While other articles are merely referenced, the instant article, containing graphic scans, is attached hereto as Exhibit 4.

At a traditional pulse width of 1.0 ms or more, right unilateral ECT has been shown to match the efficacy of unilateral ECT, when dosage is 6.0 times the initial threshold. Similarly, the initial evidence indicates that with an ultrabrief stimulus (i.e., 0.3 ms) right unilateral ECT retains strong efficacy when dosage is 6.0 times initial threshold.

(MECTA Manual, p. 33.)

The manifest conclusion to be drawn from the manufacturers' recommendations regarding the amount of electricity necessary to produce the desired effect, is that:

- The manufacturers know that seizures are not the basis for the alleged benefit from ECT.
- The manufacturers recommend unilateral ECT, but assert that to get the same efficacy, practitioners need to double the electricity;
- Doubling the electricity translates to up to 6 *times* the amount of electricity needed to cause a grand mal seizure (which elsewhere in medicine is recommended to be assiduously avoided).

### **(ii) Memory Loss Is Universal for ECT Procedures**

An anomaly of the FDA's proposed order permitting ECT into Class II for some uses is that it is predicated upon the need for a rapid form or treatment, but avoids the fact that every recipient of the treatment is damaged – usually permanently and often severely. Memory loss for the past and impairment of learning for the present in a greater or lesser degree is a uniform result of ECT.

The references cited by the manufacturers and relied upon by the FDA respecting the purported reduction of the memory loss by modern ECT methods, and transience of memory loss, are articles from ECT researcher Harold Sackeim from 2004 and earlier and an APA article from 2001 that also heavily relies on Sackeim. Sackeim is the most published author of ECT studies over the past 35 years, and the most oft-cited researcher in the FDA's materials supporting the proposed Order.

MECTA failed to inform the FDA of a direct conflict of interest: that it paid a great deal of money to Sackeim as a "consultant" and lecturer during the time periods when he was uttering his conclusions respecting the purportedly transient nature of memory loss — over \$100,000. (Exhibit 7, Sackeim Deposition, p. 64-68.)

Moreover, as a UK Department of Health study (not listed in the FDA's bibliography) found, Sackeim's use of the Autobiographical Memory Interview as of 2004 relied upon by the FDA, did not sufficiently measure the level of amnesia patients' experience:

...[T]he Autobiographical Memory Interview assumes that amnesia is limited to events that took place within the 12 months prior to ECT and does not attempt to assess amnesia that is not limited to that time period. However, only about 20% of the questions ask specifically about that year; the rest ask about over-learned personal

information (What are your parents' names? What are the rooms in your house?) or about events that have 'ever' happened to patients or their families. Thus, it is remarkable that even as insensitive an instrument as this has shown extensive permanent retrograde amnesia measured at 2 months (Coleman *et al*, 1996) and 6 months (Weiner *et al*, 1986) after ECT. Thus, patients can be told that permanent amnesia is one of the 'common' (Sackeim, 2000) or 'serious/frequently occurring' (Royal College of Psychiatrists, 2005: p. 207) effects of ECT and that it affects at least one-third of patients (Service User Research Institute, 2002; Rose *et al*, 2003). Such amnesia may be presented as having multiple dimensions: the amount of life lost the temporal gradient, the nature of what is lost, and the effect of the memory erasure on the individual's life.<sup>19</sup>

Moreover, FDA ignored that Sackeim backed off of his prior conclusions regarding the permanence of ECT memory loss which the Manufacturers and FDA cite. Sackeim published an article in 2007, "The Cognitive Effects of Electroconvulsive Therapy in Community Settings," *Neuropsychopharmacology* (2007) 32, 244–254, Sackeim, et al., which *refuted* the conclusions in his prior work and contradicted the assertions upon which the FDA's Order is predicated. The 2007 Sackeim study purports to be the *very first study* conducted of long-term memory loss; i.e., 6 months after treatment. This is important, as the Manufacturers and the FDA assert that the long-term effects of memory loss are essentially nil, or not understood.<sup>20</sup> That is clearly not what over 2,400 adverse comments in the public docket revealed. And the Sackeim study demonstrates that studies upon which the FDA relies are not accurate. He admitted in 2007:

- "Shortly following the ECT course, most patients manifest deficits in retaining newly learned information (anterograde amnesia) and recalling events that occurred in the weeks or months preceding the ECT course (retrograde amnesia)"
- "Empirical information about ECT's long-term effects derives mainly from small sample studies conducted in research settings, with follow-up intervals frequently limited to 2 months or less. By excluding individuals with significant medical and psychiatric co-morbidities, use of optimized forms of ECT, and limited statistical power, these studies could not adequately assess the severity and persistence of long-term deficits."
- His 2007 study was "the first large-scale, prospective long-term study of cognitive outcomes following ECT."
- A substantial percentage of the patients in the study had "marked and persistent retrograde amnesia" even after 6 months.
- The memory loss and inability to learn new matters was directly related to the number of ECT treatments received.

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<sup>19</sup> Robertson, H., Pryor, R. (2006) Memory and cognitive effects of ECT: informing and assessing patients, *Advances in Psychiatric Treatment Vol. 12*, pages 228–238.  
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>

<sup>20</sup> The recognition that universal memory loss for ECT is not understood, obviously necessitates clinical trials, and, after 40 years, that the FDA actually deign to require an understanding of what ECT treatments do to the brain. This alone warrants reversal of the proposed order shows that the proposed order constitutes arbitrary and capricious action by the FDA.

The purported analysis of memory loss and cognitive impairment by FDA researchers set forth in the Executive Summary, utilizes either 2, 4 or 5 articles from studies deemed acceptable from the hundreds available, and *two* of them are written by Sackeim, one from 1993 and one from 2000. (See Exhibit 1, Executive Summary, pages 92-103.) Thus, the FDA found useful, to support an otherwise unsupported postulated damage from ECT, Sackeim's earlier (and discredited) prognostications, and determined his later, 2007 article backing off of his results, not worthy of consideration.

One of the most concise analyses of memory loss and cognitive damage caused by ECT (but ignored by the FDA) is that published in *Advances in Psychiatric Treatment* (2006), and reported online by UK's Royal College of Psychiatrists. In January 2002, as part of a review of ECT undertaken by the UK's Department of Health, the Service User Research Enterprise (SURE) undertook the first-ever systematic review of patients' views on ECT (Service User Research Institute, 2002). The review encompassed several large-scale surveys by or of people who had received ECT in the UK.<sup>21</sup> Their conclusions, which FDA ignored, are a further refutation of the FDA's position that these devices can be safely down-classified:

At least one-third of patients experience permanent amnesia.

It is evident from a close reading of patient reports such as those documented by SURE that 'memory' is too simple a term to encompass the range of ECT's permanent adverse effects, yet there has been almost no work done on improving terminology.

A comprehensive battery of neuropsychological tests carried out on individuals who had had ECT between 9 months and 30 years previously revealed impairment on a range of measures, even after controlling for the effects of illness and medication (Freeman *et al*, 1980).

In the groups whose findings were incorporated into the SURE systematic review, one found that 65% of people who had had ECT reported impaired organizational skills (ECT Anonymous, 1999). Another found that one-third had difficulty concentrating, and 15% reported loss of reasoning ability (Pedler, 2001). A third asked people whether they had experienced a loss of intelligence 'soon after the treatment', and about 40% answered affirmatively (they were not asked whether the loss persisted) (Philpot *et al*, 2004).

... [F]ormer patients have publicly testified that ECT can result in a very significant (>30 point) permanent decrement in IQ score (Food and Drug Administration, 1982; Andre, 2001; Cott, 2005: p. 5) and have documented the claims by extensive neuropsychological evaluation. Although surveys and case reports are not rigorous

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<sup>21</sup> Robertson, H., Pryor, R. (2006) Memory and cognitive effects of ECT: informing and assessing patients, *Advances in Psychiatric Treatment Vol. 12*, pages 228–238.  
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>

controlled trials, in the absence of such trials conducted months or years after ECT, *they provide a basis for inferences as to the treatment's permanent adverse effects and possible mechanisms of action.* [emphasis added]

More recent work using the SMQ [Standardized MedDRA Query] suggests that, in the short term as well, *patient ratings of memory function are negative and are correlated with the results of objective tests, even when controlling for the level of depression. These researchers say that patient reports of memory impairment 'must not be dismissed as being depressive complaints only'* (Schulze-Rauschenbach *et al*, 2005). [emphasis added]

Numerous controlled studies show that individuals who are depressed but have not had ECT do not suffer amnesia (Janis, 1950); *People who have experienced the effects of both depression and ECT rarely mistake one for the other* (Food and Drug Administration, 1982; Donahue, 2000): *ECT's effects are different and worse, they occur only after ECT and they persist in the absence of depression and drugs.* [emphasis added]

*Since ECT affects both temporal and frontal lobes, it is logical that its effects would not be limited to amnesia, but would involve both memory and non-memory neuropsychological functions* (Calev *et al*, 1995). Sackeim (2000) hypothesizes that the traditional view that amnesia results from damage to medial temporal lobe structures alone may be wrong, since it is known both that frontal lobe damage can result in amnesia as extensive as that seen after ECT and that ECT exerts its most profound effects on the prefrontal cortex. If this hypothesis holds, then frontal functions must be affected as well as memory. Simply because there has been very little investigation of ECT's effects on these functions, *doctors should not be sanguine as to lack of permanent effects.* Absence of evidence is not evidence of absence... Three trials, two controlled and one small and uncontrolled, support the theory of frontal lobe involvement in functional impairment, although assessments were carried out only during or immediately after ECT (Neylan *et al*, 2001; Rami-Gonzalez *et al*, 2003; Schulze-Rauschenbach *et al*, 2005). [emphasis added]

*The current APA consent forms not only contain no warnings about adverse effects on cognition, but advise that 'Most patients report that memory is actually improved by ECT'* (American Psychiatric Association, 2001). *This statement is contradicted by all service-user research as well as the findings of SURE (2002) and NICE (2003); indeed, Scott (2005) remarked that NICE took 'special note of the evidence from users that cognitive impairment after ECT often outweighed their perception of any benefit from it'.*[emphasis added]

There are many reasons why hospitalized patients who have received ECT might overestimate their abilities. After each treatment they experience acute organic brain syndrome (Sackeim, 1986). In hospital, they are not exposed to even minimally taxing actions such as shopping and driving. There are no environmental cues as to what they are expected to know and remember in their roles outside the hospital. In a few days or even weeks, patients cannot gain enough experience of using their minds and memories to accurately assess their altered capacities (Weiner *et al*, 1986; Coleman *et al*, 1996; Donahue, 2000). In the longer term, i.e. 2–6 months, patients who initially rated their memory and cognition as improved, experience and accurately report impairment (Weiner *et al*, 1986; Coleman *et al*, 1996).

The ECT psychiatrist and treatment team may not be trained in neuropsychological evaluation, since outside of research settings it is not routinely performed on people who have had ECT. When it is, it is usually initiated by the patient, not the doctor. Because of this, *the treating psychiatrist may fear personal liability and thus be unwilling to attribute deficits to ECT.* [emphasis added]

In contrast to the minimalist labeling and “controls” proposed by the FDA, the Royal College of Psychiatrists (2005: p. 19) and NICE (2003) also “advise that the potential for cognitive impairment be highlighted during the consent process. Patients should be clearly told that ECT might have serious and permanent effects on both memory ability and non-memory cognition. These are best described in everyday terms: ‘the ability to plan and organize and get things done’ rather than ‘executive function’.”<sup>22</sup>

**(iii) ECT Provides No Clear Immediate Benefit and Certainly Provides No Long Term Benefit to Patients Offsetting the Infliction of Universal Harm**

FDA’s proposed order concludes that ECT’s benefits outweigh its risks for at least some patients. However, FDA bases its conclusion on a selective culling from the probative evidence that which tends to support its chosen outcome. In “The Sham ECT Literature: A Review,” *Ethical Human Psychology and Psychiatry*, 2006 Spring; 8(1):17-28, Colin Ross, the author concludes that ECT is no more effective than placebo, except during the period of time that ECT is being administered. There is not a single study showing a difference in depression scores between patients receiving real and sham ECT at one month post-treatment. The cost-benefit of ECT may therefore be negative. The negative side of the ECT cost-benefit analysis includes injuries of the most dire magnitude: deaths, cardiovascular complications, and memory loss and cognitive impairment.

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<sup>22</sup> *Id.*, pages 228–238. <http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>

Similarly, researchers John Read and Richard Bentall in their literature review on “The effectiveness of electroconvulsive therapy” reviewed the substantial sham studies on the subject. They systematically revealed that even the early studies by proponents of ECT largely resulted in demonstrations of complete ineffectiveness, and that any purported benefits were transitory and short-lived. Their study concluded, in part: “There is no evidence at all that the treatment has any benefit for anyone lasting beyond a few days. ECT does not prevent suicide. The short-term benefit that is gained by some simply does not warrant the risks involved.” It also stated, “Given the strong evidence . . . of persistent and, for some, permanent brain dysfunction, primarily evidenced in the form of retrograde and anterograde amnesia, and the evidence of a slight but significant increased risk of death, the cost-benefit analysis for ECT is so poor that its use cannot be scientifically justified.”<sup>23</sup> As with the Ross study, the Read and Bentall study was selectively eliminated from the FDA’s literature review for the 2010 Executive Summary provided to its Advisory Panel, and omitted from its bibliography in support of the present proposed Order.

Indeed, Manufacturer Somatics, Inc.’s 2010 Submission to the FDA conceded that absent continuing treatments, “evaluations performed weeks or months after completion of the acute ECT treatment course usually fail to show a significant advantage of ECT.” (Exhibit 6, p. 15.) Thus, it also concedes, it is necessary to continue *other* forms of psychiatric treatment for patients after the ECT, or to continue “maintenance” ECT if any improvement is to be expected. (*Id.*) In short, even the Manufacturer admits that once the patient “comes around” from the overwhelming shock to the brain, and begins to recover some sensibility, the “effectiveness” of ECT is absent.

To cite again the UK Department of Health 2006 analysis, the treatment can ruin intelligence, memory and, in turn, quality of life:

Intact memory and intelligence are highly prized in our culture. The more valuable a possession, the more important it is to know about even a small chance that it might be permanently lost. Even if the answer to how often IQ is permanently lowered is ‘We don’t know’, that is a material fact to be weighed by the patient. As individuals, patients vary greatly in the demands placed on their intellect and the potential consequences of permanent impairment.

In light of alarming findings that 50% of patients report receiving inadequate warnings of the potential side effects of ECT, informed consent practices need to be revised. In particular, *prospective patients should be warned of the significant risk of permanent amnesia and the possibility of permanent memory and cognitive disability.*” [emphasis added]

The FDA’s failure to evaluate substantively studies contrary to the conclusions in its proposed order is an abuse of discretion and results in arbitrary and capricious agency action whereby ECT devices for which injuries, including severe and permanent injuries, are likely are

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<sup>23</sup> Read, J. and Bentall, R. (2010) The Effectiveness of Electroconvulsive therapy: A literature review, *Epidemiologia e Psichiatria Sociale*, 19, 4,. See also, <http://behaviorismandmentalhealth.com/2013/03/27/shock-treatment-is-not-safe-and-provides-little-if-any-benefit/>

nevertheless deemed to possess requisite safety and efficacy despite no proof of any benefit beyond the transitory (and even that is debatable).

The FDA's "special control" to address memory loss and cognitive impairment does nothing to mitigate the impairment. It states:

Labeling would be used to help users and patients make informed decisions about how and when to use ECT. It would include information on potential adverse effects, alternative treatments, and a prominent warning that it may be associated with disorientation, confusion, and memory problems and limited in its long-term effectiveness (greater than 3 months). The labeling would also provide instructions for users on cognitive status monitoring before beginning ECT and during the course of treatment.

A mere alleged "label" explaining that memory loss and cognitive impairment *may result* from the treatment is a cruel parody of informed consent to a patient, given the evidence addressed above. Many recipients of ECT decry the practice and the damage incurred by them, as evidenced by more than 2,400 comments to Docket No. FDA-2010-N-0585, reflecting human suffering arising out of the treatment. As noted by the United States National Council of Disability, a federal agency, which conducted its own survey of ECT patients, concluded that ECT causes grave disabilities. The federal publication, "From Privileges to Rights: People With Psychiatric Disabilities Speak for Themselves, January 20, 2000, stated:

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.

(*Id.*, p. 39.)

Application of the minimal labeling and controls would similarly ratify the failure of informed consent to patients, and result in the harms patients receiving this treatment almost uniformly report and from which few claim benefit.

(iv) **Injury, Harm to Bodily Systems and Death, Particularly to the Vulnerable Class of Elderly Persons**

In its brief listing of special controls as to the category of "Adverse reaction to anesthetic agents/neuromuscular blocking agents; *cardiovascular complications; death; and pulmonary complications*" [emphasis added], the FDA provides an inadequate "control" which would have no practical effect:



Both physician and patient labeling would purportedly include information regarding contraindications, precautions, warnings, and potential adverse effects to inform users and patients of when ECT should not be used. Labeling for users would also include specific device use instructions (e.g., information on conduct of pre-ECT patient assessments and appropriate patient monitoring during ECT) to minimize potential procedural complications. Such “controls” would be useless.

No labeling can appropriately address the likelihood of death, as no studies have been undertaken in this regard by the Manufacturers or the FDA, and the largest manufacturer, MECTA, has even declined to provide information to the FDA required by law regarding the deaths for which they have been sued. *Infra*

ECT is much more frequently used on the elderly, as two articles highlighted on MECTA’s website concedes. On the MECTA website, it promotes an article entitled, *ECT in Geriatric Neuropsychiatric Practice*,<sup>24</sup> which it makes available for download. The article notes:

For years after its introduction in 1938, ECT was used primarily in younger adults because of concerns about its safety in older patients and in Kramer (1985) reviewed patterns of ECT use in California from 1977 to 1983 and found that the probability of receiving ECT increased with age of the patient. Patients ages 65 years and older were given ECT at a rate of 3.86/10,000 population, compared with 0.85/10,000 in those ages 25–44 years. In an analysis of the data on ECT use in California from 1984 to 1994, Kramer (1999) found similar patterns. ...Thompson et al. (1994) analyzed data from the National Institute of Mental Health Sample Survey program for 1980 and 1986, which included representative samples of psychiatric inpatients in the United States. They found that approximately one-third of ECT recipients were ages 65 years and older, a figure far out of proportion to the representation of that age group in the sample (8.2%). Rosenbach et al.(1997) studied a sample (~4,000 people) of Medicare Part B claims from 1987 to 1992 and found an ECT rate of 5.1/10,000 population. In an analysis of inpatient data from the 1993 Healthcare Cost and Utilization Project of the Agency for Healthcare Policy and Research, Olsson et al. (1998) found ... [i]ncreasing age was one of several patient variables associated with higher ECT use; persons ages 65 years and older were seven times more likely to receive ECT than were persons ages 18–34 years.

It would appear that Medicare aged patients are among those at highest risk of injury from ECT, presumably because of their uniform health insurance coverage and because of a lessened age-related ability to withstand their physician’s suggestions for treatment. Those

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<sup>24</sup> Coffey CE, Cummings JL (eds): *The American Psychiatric Publishing Textbook of Geriatric Neuropsychiatry*, Third Edition. 2011 American Psychiatric Association. <http://www.mectacorp.com/clinician.html>

issues were not examined or considered by the FDA – though it’s proposed order obviously sought to minimize use of ECT for children. This failure too warrants rejection of the proposed order, as Max Fink conceded in *Electroshock – Restoring the Mind*, the ECT device is “riskier” and “inadequate for effective treatment” in the elderly population.<sup>25</sup> Another study excluded from consideration by FDA was conducted 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.<sup>26</sup> FDA ignored this information.

Not only does ECT adversely impact the elderly, besides the immediate impact of the electrical shock to the brain, ECT has a debilitating effect on the body’s systems generally and drastically shortens the lifespan of recipients. 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.<sup>27</sup> Another study reported the death rate was doubled in depressed patients who received ECT in a seven-year follow up study of 188 patients.<sup>28</sup> FDA ignored these studies.

Yet, as evidenced by the 103 adverse comments in Docket No. FDA-2010-N-0585 asserting deaths from ECT, it is a serious issue.

Although the FDA’s adverse event reporting system is famous for inadequately capturing adverse events<sup>29</sup>, the FDA has also failed to evaluate data collection on ECT use from two states that have mandatory ECT reporting systems, which include deaths and other adverse events.

Texas is one of only two states that require practitioners of ECT to provide information to the state regarding “reportable events” arising out of ECT, which includes memory loss and death.<sup>30 31</sup> In 2008 alone, five patients died soon after receipt of ECT out of the several hundred

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<sup>25</sup> Fink, Max. (1999) *Electroshock – Restoring the Mind*. New York, NY: Oxford University Press. page 108 “*The devices now sold in the United States are inadequate for effective treatment of some patients.*”<sup>14</sup> Citation #14 “*For some elderly patients, psychiatrists must now use cumbersome and riskier techniques, such as the administration of caffeine or theophylline (Nobler and Sackeim, 1993) or double stimulation (Swartz and Mehta, 1986; Andrade, 1991)...*”

<sup>26</sup> Kroessler, D. and Fogel, B., (1993) Electroconvulsive Therapy for Major Depression in the Oldest Old. *Am J Geriatr Psych*;1:1: pages 30-37.

<sup>27</sup> Babigian, H., et al., (1984) Epidemiologic Considerations in ECT. *Arch Gen Psych*;4:246-253.

<sup>28</sup> O’Leary, D. and Lee, A. (1996) Seven Year Prognosis in Depression - Mortality and Readmission Rates in the Nottingham ECT Cohort. *British J of Psychiatry*. 169: 423-429.

<sup>29</sup> By Spencer, J., Carlson, J. and Webster, MJ (April 10, 2016) Question of risk: Medtronic’s lost Infuse device study - StarTribune.com <http://www.startribune.com/question-of-risk-medtronic-s-lost-infuse-study/372957441/> See also, Goldschmidt, D., LaMotte, S. (March 1, 2016) FDA mandates new warnings, new data for Essure contraceptive device. <http://www.cnn.com/2016/02/29/health/fda-essure-birth-control-device/>

<sup>30</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *Report of ECT and Other Therapies* (page 2). <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

<sup>31</sup> Kessler, D.A. (June 2, 1993) Introducing MEDWatch. A New Approach to Reporting Medication and Device Adverse Effects and Product Problems by David A. Kessler, M.D., for the Working Group. *JAMA*, Vol. 269, No. 21 pages 2765-2768. See

that received the treatment.<sup>32</sup> The machines utilized at each of the facilities where patients died after receiving ECT, were manufactured by MECTA and Somatics, and apparently not reported to MAUDE.<sup>33</sup> In 2006, there were 3 additional deaths in Texas reported following treatment,<sup>34</sup> and again, the machines utilized were from Somatics and MECTA. In the first three years of mandated reporting in the early 1990's, 21 patients were reported as having died soon after receiving ECT.<sup>35</sup> From June 1993, through August 1994, eight deaths were reported among less than 1,700 ECT patients.<sup>36</sup>

Reports from Texas for state fiscal year 2014 are even worse in that a significant number of the deaths immediately following ECT were suicides. In the 2014 ECT Annual Report, 6 deaths were reported shortly after ECT administration, “which was double the average number for the prior five years.”<sup>37</sup> Thus, as noted *infra*, the modification of the electrical delivery to “brief-pulse” wave lengths resulted in no benefit, and statistically significant indications that the newer forms of electrical delivery is more, rather than less, deleterious. The *2014 Individual Facility Summary* identifies the hospitals where those deaths occurred. Zale Lipshy University Hospital in Dallas had 2 deaths out of 62 of their patients in Q2.<sup>38</sup> Per the *Texas 2013 Equipment Registration History – Detail*, Zale used solely MECTA devices.<sup>39</sup>

Coupled with the FDA's assertion that the devices are now allegedly safe with controls, its failure to investigate the serious damages caused by ECT, including the 2,400 adverse comments, is an abuse of agency discretion that results in an arbitrary and capricious outcome, uninformed by the totality of publicly available evidence.

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<http://www.fda.gov/downloads/Safety/MedWatch/UCM201419.pdf> Dr. Kessler clarified that “Physicians should report when there is a *suspicion* that the drug or device may be related to a serious adverse effect; they are not expected to establish the connection or even to wait until evidence seems compelling... This new system encourages health care professionals to regard reporting as a fundamental professional and public health responsibility. It was developed with the enthusiastic support of the medical community, and its success will depend on close cooperation among the FDA, the medical community, and industry to identify and report adverse events and problems with medications and devices.” [emphasis *bold/italics* is only in italics in the original text]

<sup>32</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. FY08 Annual ECT Facility Summary. <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

<sup>33</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. ECT Equipment Registration History. <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

<sup>34</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. FY 2006 ECT Data.

<sup>35</sup> Don Gilbert, Commissioner, Texas Department of Mental Health and Mental Retardation, 1996.

<sup>36</sup> 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>,

<sup>37</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *FY 2014 ECT Annual Report*, page 1. <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

<sup>38</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *FY 2014 Individual Facility Summary*, page 41. <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

<sup>39</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *FY 2013 Equipment Registration History – Detail*, page 10 <http://www.dshs.texas.gov/mhsa/bhmd/ect/>

Calculating standard mortality rates (deaths/100,000 population) associated with Texas ECT use is problematic. Each quarter there is an ECT report submitted for each patient receiving ECT. Thus quarterly figures show the exact number of patients who received ECT. Because a patient may receive ECT in more than one quarter, the annual number of ECT reports (which simply totals the number of reports per quarter) may reflect more than the total number of patients who actually received ECT. However, using the given number of ECT reports as an approximate figure for numbers of patients who died, the 6 deaths in 2014, when calculated by the standard of deaths per 100,000 persons, equate to an astonishing death rate of 243 deaths per 100,000 persons receiving ECT.

Suicide deaths immediately following ECT (4 of 6 deaths reported in Texas 2014), reveals a suicide rate of 162 per 100,000 persons. The overall Texas suicide rate according to the American Foundation for Suicide Prevention was 12.18 per 100,000.<sup>40</sup> Thus, the suicide rate for Texas patients shortly following ECT was 13 times greater than the state suicide rate for the year. As noted above, since the Texas reporting system captures the annual number of reports (the overall number of ECT treatments) rather than the total number of patients treated. Hence, the suicide rate post ECT is likely to be much higher than what is here presented.<sup>41</sup>

Proponents of ECT calculate a mortality rate based upon the number of sessions rather than the number of patients who received the treatment. Some calculations in ECT proponent's publications will reference number of suicides or deaths by the total number of treatments delivered. Such a methodology is comparable to calculating the suicide rate for persons taking antidepressants by the number of pills (doses), or deaths of heroin addicts by the number of heroin fixes divided by number of deaths. Since a single patient may take hundreds or even thousands of doses over time, mortality rates would be reduced exponentially. Thus, like the hypothetical antidepressant users above, calculating mortality rate based on dose or treatment instead of number of people treated with ECT minimizes death as a rare event. For example, a recent paper published in the July 2016 *Journal of ECT*, by Somatics and MECTA consultant. Richard Weiner et al, calculates mortality rates based on Texas data on deaths vs. number of treatments rather than deaths vs. number of people. And even with that minimization of data, they were still able to find that "*Death rate increased significantly with increasing patient age (P = 0.001)...*"<sup>42</sup> Moreover, it is clear from the FDA's Executive Summary for the 2011 FDA Advisory Committee Hearings that the FDA improperly accepted such skewed data as accurate.<sup>43</sup>

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<sup>40</sup> American Foundation for Suicide Prevention. State Fact Sheets. Suicide: Texas 2016 Facts & Figures. <https://afsp.org/about-suicide/state-fact-sheets/#Texas>

<sup>41</sup> Texas Department of State Health Services. Electroconvulsive Therapy (ECT) Reports. *FY 2014 All Facilities Summary*. <http://www.dshs.texas.gov/mhsa/bhmd/ect/> "*Number of patients, reported quarterly, to have received ECT: 2466\**" "*\*This number may reflect patients who have received ECT in more than one quarter this year.*"

<sup>42</sup> Dennis NM, Dennis PA, Shafer A, Weiner RD, Husain MM. (July 16, 2016) Electroconvulsive Therapy and All-Cause Mortality in Texas, 1998-2013. *J ECT*. DOI: 10.1097/YCT.0000000000000340 <http://www.ncbi.nlm.nih.gov/pubmed/27428480>

<sup>43</sup> FDA Executive Summary. Prepared for the January 27-28, 2011 meeting of the Neurological Devices Panel Meeting to Discuss the Classification of Electroconvulsive Therapy Devices (ECT). FDA, 515(i) Executive Summary, beginning on page 35.

## **B. FDA’s Purported Special Controls and Unprecedented Split Classification for this Dangerous Class III Device Would Guarantee the Device Will Be Misused and Patients Harmed**

The information above demonstrates that the FDA’s belief that special controls can sufficiently mitigate all of the risks of ECT therapy is therefore unfounded and disingenuous. For instance, the special controls that concern the labeling of ECT devices are insufficient to reduce the risks of ECT therapy because the FDA does not regulate the practice of medicine. *See* 21 U.S.C. § 396 (“Noting in [the federal Food, Drug, and Cosmetic Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”). Accordingly, health care practitioners may disregard “labeling” as numerous lawsuits and prosecutions against pharmaceutical companies have shown.<sup>44</sup>

Specifically, health care practitioners could refuse to follow the instructions for use, or use it for whatever purpose any individual physician saw fit. Health care practitioners could also ignore labeling recommendations regarding the clinical training needed by users of the device, and use ECT therapy regardless of whether they have such clinical training. Moreover, even if the labeling provided information to health care practitioners regarding the patient population in which the ECT device is intended to be used i.e., patients 18 years and older who have severe major depressive episodes (associated with MDD or BPD) and who are either treatment resistant or require a rapid response due to the severity of their psychiatric or medical condition, health care practitioners may use ECT devices off-label. In other words, a health care practitioner could use a Class II ECT device on children or adolescents or for schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, catatonia, or literally anything else, even though the FDA concluded that the benefits for such patients do not outweigh the risks because there is insufficient valid scientific evidence establishing the effectiveness of ECT therapy for such patients or psychiatric conditions. In light of this, the FDA cannot guarantee that Class II ECT devices will be used in a safe and effective manner and decline to take any responsibility whatsoever for the predictable deleterious consequences of the split-classification.

Similarly, the proposed patient labeling likely will not mitigate the risks associated with ECT because, due to their psychiatric or medical conditions, patients may not be capable of making informed decisions regarding the use of ECT. Thus, even if patient labeling includes information regarding contraindications, warnings, precautions, potential benefits, alternative treatments, known risks, how the device operates, and clinical testing of the device, there is no guarantee that patients will be able to use such information, especially with respect to patients who receive ECT therapy without their consent, e.g., involuntarily committed patients.

This concern is not merely hypothetical. In the *Akkerman* litigation cited above, the court entered an injunction against Santa Barbara Cottage Hospital under the California consumer protection law, California Business and Professions Code §§ 17200 and 17500. The Court enjoined the use of ECT at the hospital until such time as the hospital could submit proof of its correction of flawed of informed consent protocol. (Exhibit 8, Statement of Decision on Submitted Issues, January 5, 2005.) Part of the evidence upon which the injunction was based

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<sup>44</sup> See, e.g., 31 settlements addressed in “List of off-label promotion pharmaceutical settlements”. [https://en.wikipedia.org/wiki/List\\_of\\_off\\_label\\_promotion\\_pharmaceutical\\_settlements](https://en.wikipedia.org/wiki/List_of_off_label_promotion_pharmaceutical_settlements).

was a survey of California psychiatric patients, which underscored the lack of control and unlikelihood that patients will receive true informed consent merely through “labeling” by the manufacturer to hospitals. The Court found:

The survey’s purpose was to determine what it is that people understand about the information provided by way of written consent forms (informed consent) as well as verbal information given by the physician in conjunction with the written information he or she provides relative to proposed psychiatric treatments. The results were instructive and not surprising. 49% of those polled wished, first and foremost, to be advised of the potential risks and possible side effects of the treatment. 42% were concerned about the specifics of the treatment and its effectiveness. A whopping 78% said they accept as accurate the representations of their psychiatrist concerning the effectiveness of treatment options; 76% accepted the doctor’s representations of the safety of the procedure. 70% of the respondents said that their decision to receive the treatment would be affected by the second opinion of the chief psychiatrist of the hospital regarding whether to have ECT. These results underscore the high regard patients extend to doctors and the compelling need for full disclosure of all known risks by the doctor to the patient, *regardless of the doctor’s personal opinion on the subject.*

Exhibit 8, Order, p. 5.)(emphasis in original)

Unless and until the FDA can demonstrate that ECT patients are actually provided full informed consent, and are generally capable of exercising informed consent with respect to the use of ECT, the proposed patient labeling cannot be expected to reduce the known risks associated with ECT. Indeed, FDA admits in the proposed rule that those considered for ECT treatment are oftentimes incapable of making an informed or rational decision, thus making the special controls superfluous in those cases. See, 80 F.R. 81223, Docket No. FDA-2014-N-1210. The adoption of special controls that depend on informed and rational decision-making thus constitute arbitrary and capricious agency action in light of the FDA’s own admission concerning the ability of many, if not most, patients to exercise informed consent.

Special controls regarding the design features of ECT devices are also incapable of significantly reducing the risks associated with ECT therapy. As noted above, Robin Nicol, the President and CEO of MECTA Corporation, testified that although ECT therapy was intended to cause a grand mal seizure, the mechanism of how ECT therapy actually works is entirely theoretical. *See* Exhibit 9 at 147-149 (Deposition of Ms. Nicol). How ECT “works” and even *if* it works is highly disputed. Without understanding how ECT therapy works, how can the FDA develop special controls regarding, for instance, energy output, duration, and frequency? Moreover, applying an electrical current to the brain can result in heat damage, especially if short-duration (“brief”) pulses are used. *See* Exhibit\_10,, Expert Memorandum Kenneth Castleman. regarding ECT brain damage. Further, if brief pulses are used instead, higher voltage levels are required, and this can damage brain cell membranes. *See id.* Unless that damage is small enough that it can be quickly repaired by the cells, it will lead to the death of the effected brain cells. *See id.* Thus, brain damage is likely to occur regardless of whether special controls

address, for instance, pulse duration or voltage and current.

Moreover, the split-classification mechanism devised by the FDA for ECT devices, requiring no PMA for several uses and purportedly requiring PMAs for all other applications, is disingenuous and irresponsible, because it manifests a knowing result that no PMAs will ever need to be submitted – given that the FDA does not regulate the practice of medicine, and that the practitioners of ECT will accordingly use the device for whatever uses they deem appropriate.

Indeed, ECT is administered off label for many purposes. It is currently used to “treat” autism and mood disorders in children (i.e., keeping children quiet by stultifying their ability to createem problems). A study undertaken by Charles Kellner et al., examined pediatric ECT use in treating the symptoms exhibited by an autistic 11-year-old boy said to have “bipolar affective disorder.”<sup>45</sup> Quite apart from ECT being administered for autism, it is also to a child younger than 18—yet 18 is the recommended age under the current FDA Proposal for bipolar.

*The Autism Key*, an online information and support network, states that ECT is being recommended and used on autistic children who self-harm and warns about more 'widespread autism applications,' noting a lack of evidence that electroshock is safe for children.<sup>46</sup>

Yet, there is a prohibition of pediatric ECT in some U.S. states and a recent ban under the Western Australian Mental Health Act and by the Australian Capital Territory.<sup>47</sup> In October 2014, the Western Australian Mental Health Act banned the use of ECT on those younger than 14 and poses a \$15,000 fine and 2 years imprisonment on anyone performing the procedure on this age group. Even an adolescent aged between 14 and 18 who is a voluntary patient cannot have the treatment without informed consent and approval by a Mental Health Tribunal.<sup>48</sup>

This is supported by a 2014 study by Cheryl van Daalen-Smith et al. who stated: “The ongoing and growing interest within psychiatry in prescribing electroshock or shock-like procedures for treating certain behaviors or conditions deemed psychoneurologic in children is of grave concern, given that the plethora of evidence that electroshock has at its very core an intent to damage and incapacitate the brain appears to be ignored.”<sup>49</sup> The authors concluded that “given the volume of evidence demonstrating its substantive brain-damaging outcomes, we call for an immediate global ban on the use of electroshock on all children.”<sup>50</sup>

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<sup>45</sup> <http://brainblogger.com/2011/05/30/electroconvulsive-therapy-in-pediatric-psychiatry/>

<sup>46</sup> Cheryl van Daalen-Smith, et al., “The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock,” CHILDREN and SOCIETY, Vol. 28, 205-217 (2014) , [http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014\\_ECTchildren.pdf](http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf)

<sup>47</sup> Australian Capital Territory Mental Health Bill 2015,

<sup>48</sup> “Electroshock therapy on under-14s banned in WA after law passes Parliament,” *ABC News*, 17 Oct. 2014, <http://www.abc.net.au/news/2014-10-17/mental-health-bill-passes-wa-parliament/5822874>

<sup>49</sup> Cheryl van Daalen-Smith, et al., “The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock,” CHILDREN and SOCIETY, Vol. 28, 205-217 (2014), [http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014\\_ECTchildren.pdf](http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf)

<sup>50</sup> Cheryl van Daalen-Smith, et al., “The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock,” CHILDREN and SOCIETY, Vol. 28, 205-217 (2014) , [http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014\\_ECTchildren.pdf](http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf)

The World Health Organization's Resource Book on Mental Health, Human Rights and Legislation 2005, also states: "If ECT is used, it should only be administered after obtaining informed consent." Further, "There are no indications for the use of ECT on minors, and hence this should be prohibited through legislation."<sup>51</sup>

Yet, MECTA's website, under the tab "Clinician" and "Standard of Care" are publications from Sackeim and Dr. C.E. Coffey targeting ECT for the elderly.<sup>52</sup> And, linked to the Clinician section of the site are numerous publications suggesting clearly unapproved uses, such as the publication, "Electroconvulsive Therapy in Children and Adolescents, Neera Ghaziuddin and Garry Walter, Editors." That article summary states:

A few years ago, such a volume would have been inconceivable. Electroconvulsive therapy for this age group has been done all along of course, but infrequently, sometimes surreptitiously, and almost apologetically. Such is no longer the case. The publication of this volume finally brings ECT for the pediatric population out of the shadows.

The summary continues:

The remaining 8 chapters are clinical in nature, devoted to a technical overview of ECT and to the specific clinical indications for ECT in the pediatric population (mood disorders, schizophrenia spectrum disorders, catatonia, and self-injurious behavior in autism).

Indeed, manufacturer MECTA promotes a wide range of uses for its devices on its website and through links on its website. MECTA similarly promotes other off-label uses through publications for sale through the MECTA website,<sup>53</sup> including the APA's Practice of Electroconvulsive Therapy: Recommendations for Treatment, *Training, and Privileging. Second Edition* (2001), written with MECTA's advisors Richard Weiner and Harold Sackeim.<sup>54</sup> On the website is also the book *Clinical Manual of Electroconvulsive Therapy* (2010), written by Dr. Richard Weiner,<sup>55 56</sup> in which recommends ECT for the indications of mania, schizophrenia, and schizoaffective disorder, purported disorders which the FDA noted will require a PMA due to

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<sup>51</sup> Benedetto Saraceno, MD, "WHO RESOURCE BOOK ON MENTAL HEALTH, HUMAN RIGHTS AND LEGISLATION WHO 2005," p. 64.

<sup>52</sup> <https://www.mectacorp.com/clinician.html> Sackeim, H.A. *Electroconvulsive Therapy in Late-Life Depression* and Coffey, C.E. *Electroconvulsive Therapy and Related Treatments*.

<sup>53</sup> <http://www.mectacorp.com/clinician-educational-material.html> "Clinical Publications" section, as well as "Patient and Family Books, Videotapes and DVDs."

<sup>54</sup> Douglas G. Cameron, "ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation," *The Journal of Mind and Behavior*; Winter and Spring 1994, Vol. 15, Nos. 1 and 2; pages 177-198, [http://www.stopshrinks.org/reading\\_room/ecb/docs/sham.htm](http://www.stopshrinks.org/reading_room/ecb/docs/sham.htm).

<sup>55</sup> Andre, L. (2009) *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*. Piscataway, NJ. Rutgers University Press. page 162

<sup>56</sup> [http://www.mectacorp.com/pdf/156888%20DOM\\_Ed%20Publications.pdf](http://www.mectacorp.com/pdf/156888%20DOM_Ed%20Publications.pdf)



insufficient evidence of effectiveness.

Since 1990's,<sup>57</sup> the FDA held there was insufficient evidence of effectiveness for schizophrenia, yet doctors were never warned about this.<sup>58</sup> Manufacturers did not have the need to warn about any indication in which they may have known ECT was not effective, but instead promoted material in the form of publications and books to the contrary, in their websites.

The device industry and its practitioners have translated an “on-label” practice to mean that the device only needs to be legally put on the market for any indication to then assume safety and efficacy for all other diagnosis without the proof of a PMA. This has led to ineffective treatments given to vulnerable patients at the expense of the patient and government health funds, reinforcing the need for a PMA for all indications.<sup>59</sup>

And, if a PMA—with clinical trials — is required for other indications— schizophrenia, Parkinson's disease, extreme upset over acne, obesity, drug addiction, fear of snakes, etc., how does the FDA enforce that? It cannot because the FDA argues it cannot regulate the practice of medicine. Thus, off-label use will undoubtedly, certainly, occur, and the FDA will take no more action than it has these past 40 years to prevent harm to patients.

### **1. The FDA's Unprecedented Split-Classification Is Dangerous, Arbitrary and Capricious and Illogical**

The FDA's proposed order is unprecedented in establishing different classifications for different diagnoses of vague mental illnesses.

Diagnoses of actual illnesses in medicine are based upon physical examination, blood tests, tissue tests and laboratory tests. The practice of psychiatric diagnoses is, however, notoriously unreliable and vague, as admitted by the American Psychiatric Association and its leaders. In the APA publication, *A Research Agenda for DSM-V*,<sup>60</sup> addressing the fact that the efforts of organized psychiatry through the various iterations of the DSM over 40 years, diagnostic criteria have been haphazard, contradictory and unreliable and lacked any scientific validity. It stated:

In the more than 30 years since the introduction of the Feighner criteria by Robins and Guze, which eventually led to DSM-III, the

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<sup>57</sup> Federal Register 55 FR 36578-01 Neurological Devices; Proposed Rule to Reclassify the Electroconvulsive Therapy Device Intended for Use in Treating Severe Depression. September 5, 1990. “...FDA has tentatively concluded that evidence regarding the effectiveness of ECT in the treatment of schizophrenia is inconclusive. Accordingly, this document proposes to limit reclassification to those ECT devices intended to be used solely for the treatment of severe depression.”

<sup>58</sup> Frankel, F et al. Electroconvulsive Therapy Task Force Report 14 (1978). American Psychiatric Association. Washington, D.C. “It can only be concluded that the data are not adequate when considering the question of ECT and schizophrenia.” page 26.

<sup>59</sup> <http://www.nytimes.com/1989/12/26/science/electroshock-therapy-is-defended.html> Electroshock Therapy Is Defended. AP December 26, 1989. “Despite its renewed use, Dr. Weiner said electroshock will continue to be used rarely. He also said that psychiatrists are hopeful that more effective drugs will be found and that there will no longer be any need for electroshock.”

<sup>60</sup> American Psychiatric Association, 2002

goal of validating these syndromes and discovering common etiologies has remained elusive. Despite many proposed candidates, not one laboratory marker has been found to be specific in identifying any of the DSM-defined syndromes. Epidemiologic and clinical studies have shown extremely high rates of comorbidities among the disorders, undermining the hypothesis that the syndromes represent distinct etiologies. Furthermore, epidemiologic studies have shown a high degree of short-term diagnostic instability for many disorders.<sup>61</sup>

Quoting this same source and bemoaning the continuing problem with agreement on alleged psychiatric diagnoses between psychiatrists, an article published in *Psychiatric Times* noted in 2013, “In the ensuing years, advances in neuroscience and genetics were still not validating the DSM-IV categories. The perfectly reasonable directives for the [DSM-V] Work Groups outlined in the Guidelines mentioned above could not accomplish much without clear support from basic science.”<sup>62</sup>

The British Psychological Society in May 2013 similarly acknowledged the inability of the existing diagnostic criteria to have scientific value and reliability, and therefore published a formal position statement challenging the same DSM-V criteria upon which the FDA’s ECT proposal is predicated. It stated:

[I]t should be noted that functional psychiatric diagnoses such as schizophrenia, bipolar disorder, personality disorder, attention deficit hyperactivity disorder, conduct disorders and so on, due to their limited reliability and questionable validity, provide a flawed basis for evidence-based practice, research, intervention guidelines and the various administrative and non-clinical uses of diagnosis. This has been a matter of cross-professional concern for many years.<sup>63</sup>

For many years members of the profession and its own professional societies have acknowledged that its criteria lack validity, science or duplicability. Many commentators, victims and others have equally challenged psychiatric diagnoses as unreliable and lacking in any physical proof. There are literally hundreds of books, articles and scientific studies addressing this very issue, regarding the confusion caused by the amorphous psychiatric diagnoses and categories.<sup>64</sup> The current version of the APA’s Diagnostic and Statistical Manual of Mental

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<sup>61</sup> *Id.*, Introduction, p. xviii.

<sup>62</sup> *Psychiatric Times*, DSM-5 Field Trials: What was Learned, <http://www.psychiatrictimes.com/dsm-5/dsm-5-field-trials-what-was-learned>

<sup>63</sup> Classification of Behaviour and Experience In Relation To Functional Psychiatric Diagnoses: Time For A Paradigm Shift. May 2013, British Psychological Society, April 2013, <http://www.bps.org.uk/system/files/Public%20files/cat-1325.pdf>

<sup>64</sup> See, eg, Hyman, S.E., M.D., “Psychiatric Drug Development: Diagnosis a Crisis,” former director of NIMH, says DSM’s “underlying science remains immature,” psychiatric diagnoses seem arbitrary and lack objective tests, and no validated biomarkers with which to judge the success of clinical trials, Dana Foundation, Apr. 2, 2013; Insel, T. “Director’s Blog: Transforming Diagnosis,” then director of NIMH, said DSM’s weakness is its lack of validity,” its diagnoses are “based on a consensus about clusters of clinical symptoms, not any objective laboratory measure.” NIMH, Apr. 29, 2013; Knoll, J.L. IV, M.D., says DSM-III, IV and 5 *do not* approximate science; most of DSM has been based on opinion, and “If you

Disorders V, lists hundreds of supposed mental illnesses. None is denominated with a blood test, physical examination or any other reliable criteria.

Thus, the FDA's assertion that psychiatrists can readily distinguish between (1) supposed major depressive episode ("MDE") associated with major depressive disorder ("MDD") or bipolar disorder ("BPD") in patients 18 years of age and older who are treatment-resistant or require a rapid response due to the severity of their psychiatric or medical condition and (2) patients who purportedly suffer from such alleged named ailments who are *not* treatment resistive or who do *not* require a "rapid response" in the opinion of a single psychiatrist (or husband, wife, trustee, etc.) is unreliable, unsupported, and speculative. The FDA's proposed order asserts by inference that the alleged disorders identified may be clearly demonstrated. Yet that assumption is based on no proof at all, and has been denied even by the American Psychiatric Association.

Further, the extraordinary use of a split-classification for the device manifests an arbitrary and capricious procedure, unsupported by logic or science. If use of ECT for, say "bipolar disorder" is not safe, how is the precisely identical treatment "safe" for the use in treating supposed "major depressive episode?" This is particularly true, since neither MDE or bipolar or any other alleged psychiatric illness is subject to any medical test. The illnesses are all and each hypothetical without scientific, actual medical validation.

Split classification is extraordinarily rare. The FDA has sought to justify such a procedure by asserting to the Neurological Devices Advisory Committee in January 2011 that split-classification was not *entirely* unprecedented, it also being used for PTCA catheters, spinal cages and contact lenses.<sup>65</sup>

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have opinion, and nothing else, it's not science. If you refuse to change your opinions, it's not science." He is Editor in Chief Emeritus of *Psychiatric Times*, Professor of Psychiatry at the SUNY Upstate Medical Center in Syracuse, Director of Forensic Psychiatry, and Director of the Forensic Psychiatry Fellowship at Central New York Psychiatric Center, *Psychiatric Times* (Oct. 14, 2013); Frances, A.J., M.D., Psychiatric diagnosis is facing a renewed crisis of confidence caused by diagnostic inflation, and "new psychiatric diagnoses are now potentially more dangerous than new psychiatric drugs," Prof. Allen Frances, DSM-IV Task Force Chairman, Former Chair of the department of psychiatry at Duke University School of Medicine, Durham, NC; *Medscape* (May 17, 2013); International Coalition for DSM-5 Reform, DSM-5 Response Committee, "Statement of Concerns over the DSM-5," that it is "clinically risky because of many new and untested diagnoses and lowered diagnostic thresholds;" it "will result in the mislabeling of mental illness.;" American Psychiatric Association: "There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention Deficit/Hyperactivity Disorder," DSM-IV (APA, Washington DC, 1994); Council for Evidence-Based Psychiatry, comprising psychiatrists, academics and others, notes that the DSM is not a work of "objective science," as it has "largely been developed through clinical consensus and voting." Therefore, the "validity and clinical utility is therefore highly questionable."(2014, UK).

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<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247595.pdf.%20Accessed%20December%203>, pp. 427-28, 431

But a dual classification for a device known to cause ubiquitous damage and for which clinical trials have been eschewed for 40 years -- cannot be compared to those devices or procedures. But for each of the other so-called examples of split-classification, the Class II vs. Class III devices were entirely different or the uses thereof were quite different. For example, the PTCA catheter used merely to expand an artery was re-classified to Class II, while the type that also has a cutting tool appended remained, logically in Class III. The split classification for some contact lenses was differentiated by length of use (for extended wear, overnight, they're Class III; for daily wear, Class II). Moreover, these are wholly medical issues with crystal clear reasons for the split classification. No such logic pertains to ECT devices. A person can't be involuntarily committed to a hospital and forced to use extended care contact lenses. That isn't the case for someone diagnosed with an amorphous mental illness, the existence of which cannot be proven and is subject to great variation in diagnosis. For ECT, a patient can be denominated as mentally ill, involuntarily committed and deemed they are so depressed that a rapid response is needed, warranting applying 450 volts to their brain, and potentially destroying their future life, welfare and ability to think and reason.

Why, for example, would the need for a "rapid response" justify the use of a treatment with no lasting benefit, that is known to cause universal memory loss and cognitive impairment, and that the evidence suggests causes brain damage? For the sake of argument: a patient whose loved one dies and the patient is (understandably) despondent – does that justify the need for a "rapid response" that will cause permanent injury and disability to the patient? Indeed, when a patient is in deep despondence over a devastating life event, that is hardly the time when true informed consent could ever possibly be acquired.

The split-classification proposal appears to be a mechanism created by the FDA to continue avoiding requiring the manufacturers to submit PMAs. The 4 decades of FDA's refusal to enforce getting PMAs represents arbitrary, capricious agency action and an incorrigible refusal to carry out its duties to citizens.

## **2. The FDA's Proposal That a Special Control "Characterizing" the "Output Waveform" and "Technical Parameters" Of ECT Would Provide Safety Measures, Is Arbitrary, Capricious and Erroneous**

As noted *infra*, the universal harm caused by ECT is memory loss and cognitive impairment. That means a person may lose some or all of vast portions of the life memory, intelligence, and ability to remember new data (i.e., their learning capacity is often greatly reduced). But the proposed special control with respect to this ubiquitous damage from ECT is ineffective.

FDA's proposed order asserts that "The risk of cognitive and memory impairment can be mitigated by establishing the technical parameters for the device along with non-clinical testing data to confirm the electrical characteristics of the output waveform to ensure that the device performance characteristics are consistent with existing clinical performance data that supports a reasonable assurance of safety and effectiveness." This states the erroneous assumption that if an ECT device is working properly (meets its electrical specifications), then the patients will not suffer cognitive or memory impairment. FDA proposes revising § 882.5940 to state:

(i) The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, and the type of impedance monitoring system must be fully characterized.

(ii) Non-clinical testing data must confirm the electrical characteristics of the output waveform.

However, “characterizing” waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, is not any form of a control. It is comparable to “characterizing” the caliber of the bullet. This is particularly so, because with no studies, clinical trials or evidence, ECT proponents have asserted that the “waveform” and “output mode” of ECT devices is different and safer and less damaging than the older, pre-amendment devices.

To differentiate and remove themselves from the decades of studies and reports indicating the severe brain damaging effects of ECT, the Manufacturers and proponents of ECT have asserted that the devices are now more safe, in light of the ultra-brief pulse waveforms and wavelengths utilized, falsely asserting that less electricity is now needed to induce the seizure.

But the assertion that “brief pulse” devices bring less energy to bear upon the brain (and therefore cause less damage), are an oft-repeated falsehood, based on no science other than the ECT proponents’ *ipse dixit*. Further, it contradicts basic principles of physics.

Further, in 2001, the New York State Assembly investigated the safety and use of ECT, holding hearings where it heard expert and patient testimony and issued its findings in a 2002 report.<sup>66</sup> It reported:

It has now become fashionable to declare brain damage from ECT a thing of the past because of ‘new refinements’ in the procedure and in the machines ... The implication that the sine wave device of old has been replaced by the brief pulse device of present lurks behind much of the continued use of ECT... Modern day BP devices are not ‘lower current’ machines, as most proponents claim. Through electrical compensation, they equal SW devices in every respect, and emit far greater energy...Most experts agree that current, not convulsion ... is responsible for long-term memory loss and severe cognitive dysfunction.... Manufacturers may have parted from the convulsion theory exemplified by just above seizure threshold devices of the past, to what might be just above damage threshold devices of the present, *and if not forced to stop and prove the safety of their devices* (allowing for even more powerful machines), might be embarking upon just above agnosognosic [unawareness or denial of a neurological deficit] threshold appliances of the future.

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<sup>66</sup> “Report on Electroconvulsive Therapy (ECT),” Committee on Mental Health (March 2002), New York State Assembly Standing Committee On Mental Health, Mental Retardation and Developmental Disabilities. <http://www.survivorlink.org/electroshock/nyassemblyreport/AR-safety.html>

In summary, modern electric shock machine companies are attempting to redefine safety from the original convulsion concept of ‘just above seizure threshold’ to ‘safer wave form.’”<sup>67</sup>

A report by the UK’s Department of Health, Service User Research Enterprise (SURE), published in *Advances in Psychiatric Treatment* (2006), and reported online by UK’s Royal College of Psychiatrists, determined:

Newer methods of ECT *have not* resulted in an appreciable decrease in adverse effects (UK ECT Review Group, 2003)” and “suggest that changes are overdue in both practice and policy.” [emphasis added]<sup>68</sup>

Indeed, the manufacturers could not avoid conceding the existence of memory loss caused to all ECT patients, but misrepresented that the harm could be managed by some controls – controls which provide no diminution of harm. Under a heading, “c) Cognitive Side Effects,” MECTA admitted “some degree of memory loss is universal,” but contradicted its admission by thereafter claiming, “The scientific data clearly shows that cognitive side effects are nearly eliminated by following [several] guidelines.” Those guidelines include the use of unilateral ECT, using a “brief pulse” waveform of the shock, allegedly minimizing the amount of electricity used and increasing the time between treatments. (MECTA Submission, p. 6.) Each of these proposals implicitly concedes the damage that the *electricity* does to the brain. And, the Manufacturers have also asserted that it is necessary to dramatically increase the electricity to the brain to achieve its intended effect, as addressed in Section \_\_\_ below. Further, the assertion that less memory loss would be effectuated by reducing the number of ECT treatments logically means that the treatments cause memory loss and, thus, fewer treatments means less (but does not eliminate) memory loss.

The FDA’s proposed “special control” provides: “The technical parameters for the device and non-clinical testing data would be used to confirm the electrical characteristics of the output waveform to ensure that the device performance characteristics are consistent with existing clinical performance data that supports a reasonable assurance of safety and effectiveness.” That control is, in fact, not a control at all. It does nothing to mitigate the foreseeable risks. It is comparable to having knowledge that a bullet fired into flesh does substantial damage, and asserting a “special control” of perceiving the “technical parameter” of the muzzle velocity of the bullet to see that the gun is performing as per specifications, “consistent with clinical performance data” to assure reasonable safety. Monitoring the muzzle velocity of a bullet would be no more effective a control than monitoring the wave form of the electricity pulsing through a patient’s brain.

Moreover, the Manufacturers and proponents of ECT all concede that their view of the benefit of ECT requires substantially more energy than is necessary to cause a seizure. Indeed,

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<sup>67</sup> Report to the New York Assembly reviewing the safety of ECT, 2001.  
<http://www.survivorlink.org/electroshock/nyassemblyreport/AR-safety.html>

<sup>68</sup> Robertson, H., Pryor, R. (2006) Memory and cognitive effects of ECT: informing and assessing patients, *Advances in Psychiatric Treatment Vol. 12*, pages 228–238.  
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>

MECTAS's website promotes that its devices can now automatically determine and be set for multiples of the seizure threshold for a patient, from 1.5 to 6 times *over* a patient's seizure threshold. See Exhibit 11, "OPTIMIZED AND FULL spECTrum© DOSING PARAMETERS", promoting, "Dosing is provided at 1.5, 2.0, 2.5 and 6x seizure threshold, and is separately provided at 0.3, 0.5 and 1.0 [millisecond] pulse widths." <sup>69</sup>

And, contributing to the FDA's position, the manufacturers have asserted that their devices are substantially equivalent to the pre-amendment devices. The FDA accepted this representation in permitting the 510(k) application to be approved to market the device. Both the application and its acceptance demonstrate that the assertion the new, "improved" waveforms are vastly different and safer, warrant banning the device altogether, and manifest abuse of agency discretion resulting in arbitrary and capricious agency action in violation of the APA.

MECTA's website also proves the inconsistency of its position and grievous arbitrary and irresponsible acceptance of the "new and improved" version that supposedly reduces cognitive impairment by reducing electricity to the brain through the utilization of brief "pulses" of electricity. As MECTA website admits,

PULSE WIDTH likely has the greatest impact on the efficiency of stimulation. For example, the overall dosage (i.e., the charge) needed to elicit seizures is approximately 3-4 times lower when a 0.3 ms pulse width is used than when a 1.5 ms pulse width is used. Thus, selecting a pulse width is a key clinical determination, and MECTA spectrum device users now have the option to choose from three pre-selected ranges of optimized pulse widths that begin with 0.3 ms ultrabrief stimulation, or 0.5 ms or 1.0 ms brief pulse stimulation. These pulse widths correspond to the administration of an ultrabrief stimulus (0.3 ms), a stimulus (0.5 ms) on the border between ultrabrief pulse (0.3-0.49 ms), and brief pulse (0.5-2.0 ms) stimulation which is now limited to a maximally wide brief pulse (1.0 ms). Since the inefficiency of wider pulses is firmly established, the upper-limit for all spectrum devices is now 1.0 ms.

#### DURATION

There is evidence that increasing the duration of the pulse train is more efficient than increasing pulse frequency. Overall, the evidence suggests that increases in train duration may be the next most critical parameter in terms of impact on the efficiency of seizure elicitation. Consequently, on the single dial 5000M<sup>TM</sup> /4000M<sup>TM</sup> models, before any other parameter is altered, increases in dose first involve an increase in train duration, until the maximum of 8 seconds is reached. On all four MECTA models and in all OPTIMIZED and FULL SPECTRUM DOSING Parameter Sets, the range of train duration is now from less than 0.5 to 8 seconds.

In other words, MECTA has now developed machines that cause literally thousands of

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<sup>69</sup> [http://www.mectacorp.com/pdf/155247%20DOM\\_Dosing%20Parameters.pdf](http://www.mectacorp.com/pdf/155247%20DOM_Dosing%20Parameters.pdf)

“pulses” of electricity to flow through the brain, for as long as 8 seconds, far beyond the brain’s seizure threshold.

And the claim that the waveform in new devices which the controls will allegedly carefully “characterize” will ameliorate damage is simply false *ab initio*, as explained in the Statement of Expert Dr. Kenneth Castleman appended hereto as Exhibit 10. Dr. Castleman, an expert in biomedical engineering, states:

This memorandum concerns the safety of “Brief pulse” and “Ultra-brief pulse” devices used for electroconvulsive therapy (ECT). Advocates of these modern devices assert that they are safer than the sine-wave and square-wave ECT devices that have been used in the past. ... In fact, the newer devices actually elevate the risk of brain damage from ECT, as addressed below.

The differences between these methods of delivering electricity are as follows: The electrodes of the ECT device apply a voltage (measured in volts) to the patient’s head. This voltage applies a force to electrons in the patient’s head, causing them to flow through the brain. This flow of electrons is the current, measured in milliamperes. The voltage applied to the patient’s head is not constant, but is supplied in pulses. That is to say, the voltage is “on” for a time during one pulse, and then off for a time between pulses. ...

The older ECT devices left no gaps between pulses. Each positive pulse was followed immediately by a negative pulse, with no delay, and vice versa. The modern “Brief-Pulse” devices, however, introduce a delay between pulses. In any one cycle, the voltage is “on” in the positive direction for a while, then “off” for a time, then “on” in the negative direction for a while, and finally “off” for a time. Since each pulse is “on” for only a portion of its time, the pulses are called “brief.”

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ECT advocates argue that the shorter pulses used by modern ECT devices deliver “less electricity” to the brain. This is simply not true. The ECT dose delivered to the patient’s brain is not significantly reduced when shorter pulses are used. The same number of electrons are forced through the patient’s head with any ECT device, whether it is a sine wave, square wave, brief pulse or ultra-brief pulse unit.

But the current flows for a shorter period of time with the brief pulse devices. Thus more pulses are required in order to deliver the same electrical dose. This usually entails a longer treatment duration. The ECT dose delivered to the patient’s brain is measured in joules or, more recently, in millicoulombs. ... A typical ECT dose (“stimulus charge”) is 300 millicoulombs, but it can go as high as 1,000. Stimulus voltage is typically limited to 450 volts and current is set at 800 or 900 milliamperes. The ECT operator sets the dose level (in millicoulombs) at from 1.5 to six times the amount of electricity that is required to induce a seizure in the patient. ... The operator then chooses a pulse duration between 0.3 and 1.5 milliseconds. The device determines how many pulses are required and selects a combination of pulse frequency (in cycles per second) and treatment duration (in seconds) that will deliver the specified stimulus charge.



When activated, the device applies whatever voltage is required to produce the specified current. As the duration of each pulse is reduced, the number of pulses must increase by the same factor to achieve the specified ECT dosage. Thus, at 50 Hz, a brief-pulse device set for 1.5 msec pulses would have to use 6.5 times as many pulses to deliver the same dose as a sine-wave device using 10 msec pulses. An ultra-brief pulse device set for 0.3 msec pulses would have to use 33 times as many pulses (since the voltage is “on” for only  $0.3/10 = 3\%$  of the time). This typically requires a longer duration of treatment, lasting as long as eight seconds, as indicated in the technical parameters of electrical “dosing” with MECTA devices, attached.

With brief and ultra-brief pulses, the patient is subjected to many more pulses over a longer treatment period than was the case with sine-wave devices. These very brief pulses have to turn on and off very quickly, and this rapidly changing electric field can put considerable additional stress on the brain cells.

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ECT-induced brain damage can result from two phenomena. One is heating. Using briefer pulses necessarily increases the treatment duration and the total number of pulses, in order to deliver the same electrical dose. The heating effect of the electric current thus lasts longer with the longer treatment duration. A large enough increase in temperature can damage or kill brain cells. In addition, the voltage applied to the ECT electrodes creates an electric field inside the skull. If it is strong enough, electrical forces will create holes (“pores”) in the walls of the cells. This process, called “electroporation,” is a commonly used technique in biomedical research. Figure 1 below is a conceptual drawing of the electroporation process. Figure 2 is an electron micrograph showing the effects of electroporation caused by brief pulses of electricity. While the cell can repair a few small holes, stronger electric fields create more and larger holes that cannot be repaired. When this happens the cell dies. Due to their size, brain cells are many times more susceptible to electroporation than smaller cells. Further, brief pulses are much more effective at producing pores in cells than longer pulses.

In summary, it is clear, just from basic principles of biology and physics, that the modern brief-pulse and ultra-brief pulse ECT devices inherently subject the patient to more pulses, with faster switching times, and to longer durations of treatment than the older devices. As a result, the risk of brain cell damage and cell death is not reduced, but is actually increased.

Thus, brain damage is likely (or certain) to occur regardless of whether special controls address, for instance, pulse duration or voltage. The control is a “control” of nothing, since the electrical waveforms are fixed, and the device amplitude is set. All that changes is the automatic variation of voltage, depending upon the resistance of the skull and brain to which the device is attached – up to 450 volts if necessary to punch the required amount of current through the patient’s head from one side to the other.

Because the proposed special controls will not reduce the known risks associated with

ECT therapy, which are both serious and life-threatening, the FDA should either ban ECT devices on the grounds that they present an unreasonable and substantial risk of illness or injury or, at the very least, require premarket approval for all ECT devices for all purposes.

### **C. The FDA Unreasonably Delayed the PMA Requirement for ECT Devices in Violation of the APA**

Under the APA, administrative agencies, including the FDA, must act within a “reasonable time.” *See* 5 U.S.C. § 555(b). Although the Medical Device Amendments of 1976 did not explicitly compel the FDA to require PMAs for Class III preamendments devices by a certain date, Congress intended that the FDA would take such action within a reasonable time, as evidenced by Congress’ subsequent enactment of the SMDA and the GAO report entitled, “FDA should Take Steps to Ensure that High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process,” both of which followed the FDA’s failure to do so.

Here, it has been nearly 40 years since the FDA first classified ECT devices as Class III. The FDA has yet to establish an effective date for premarket approval and as noted above, the Proposed Rule, if implemented, would reasonably assure that no PMAs will ever be submitted. Thus, during that time, ECT devices that qualify as preamendments devices have been allowed to remain on the market, and devices that have been found to be substantially equivalent to them have been allowed to enter the marketplace through the less stringent 510(k) process. Given the serious risks associated with ECT therapy and the inability of special controls to mitigate such risks, this is unacceptable. A product-by-product review of ECT devices is long overdue. ECT devices manufacturers, such as MECTA Corporation, should no longer be able to market their devices without establishing their devices’ safety and effectiveness through, *inter alia*, clinical trials. If the FDA is unwilling to ban ECT devices, it must, at the very least, require an approved PMA to prevent unnecessary ECT injuries in the future.

### **D. The FDA Failed to Enforce Manufacturer Reporting Requirements, and Failed To Investigate or Acknowledge Third Party Reports of Adverse Events From Manufacturers’ Devices**

For more than five years, FDA has been aware that the manufacturers of ECT devices withheld vital information regarding the dangers of treatments given by their devices. Despite such knowledge, in the 5 years after the Advisory Committee Panel hearings on classification of ECT devices, the FDA failed to demand compliance with federal regulations and failed to collect information reasonably necessary to make a responsible determination regarding classification of ECT devices.

### **E. Evidence that Manufacturer MECTA Withheld Information From the FDA and that the FDA failed to exercise any reasonable regulatory or investigative authority to acquire complete information from the manufacturer, or sanction its misconduct**

In 2005, the sworn deposition was taken of Robin Nicol, the President and CEO of

MECTA Corporation, in *Akkerman v. MECTA Corp.*, No. 01-10362, U.S.D.C., CD Cal. Excerpts of the deposition are attached as Exhibit 9. Ms. Nicol admitted that she was aware of articles written in the 1940's and 1950's indicating that the purpose of shock treatment was to *cause* memory loss, i.e., that the therapeutic effect of shock treatment was memory loss. MECTA refused to consider or investigate the issue, (Exhibit 9, p. 41-42), because, "MECTA does not do research." (*Id.*, p. 42.) MECTA has never done any study or investigation regarding the safety and efficacy of ECT provided by its devices. (*Id.*, p. 84-85.) Rather, MECTA made a decision to "disregard" what it characterized as the "minority view of ECT, the minority view being that it causes brain damage and causes memory loss." (*Id.*, p. 44-45) MECTA's President admitted that if she "had information that [its] devices weren't safe, it would not be considered unless the information came from double-blind studies." (*Id.*, p. 105-06.) Thus, MECTA's President's view was that if patients claim to have brain damage or to have lost large chapters of the memories of their lives, they must be lying. (*Id.*, p. 121-122.)

Ms. Nichols said she would be "compassionate," but not curious to know why victims were complaining about injuries from her devices. (*Id.*, p. 110.) She explained, "We are not responsible for individual patients.... That is not our responsibility from the FDA perspective or from our perspective as medical-device manufacturers." (*Id.*, p. 109-111.) MECTA's president also admitted the company has made no "effort to solicit information from persons who have received ECT to see whether or not they have been harmed," because that would not be part of her company's responsibilities. (*Id.*, p. 113.)

MECTA's President could offer no evidence of how ECT allegedly works, except that its machines are designed to cause a grand mal seizure, and beyond that, the mechanism is entirely theoretical. (*Id.*, p. 147-49.) Yet, she also admitted that more electricity is used by ECT than is necessary to cause the grand mal seizure, because, "The patients were not getting better." (*Id.*, p. 183-84.) She was asked, "Do you know what the point is of sending electricity through a brain if it's not just to cause a convulsion?" Her simple answer was, "No." (*Id.*, p. 184.)

MECTA has also hidden and obscured reports of serious adverse events from the FDA, revealed in the following briefly described lawsuits.

In 2001, Atze Akkerman filed suit against MECTA Corporation, arising out of serious and permanent damages he alleged were caused by the receipt of ECT by a MECTA device. (Complaint, Exhibit 12). Mr. Akkerman lost his memory for most of the events of his life. He no longer recognized or knew his wife, his two children or his parents. His abilities lost included playing and writing music (he played professionally for years and toured with the U.S. Navy Band.) He was unable to remember know-how to perform the duties of his job, and no longer knew the people he formerly worked with. In the suit, witnesses testified to Mr. Akkerman's injuries, including expert neurologists, psychiatrists and psychologists who swore that his injuries were caused by MECTA's device. MECTA declined to provide the allegations of the suit to the FDA as a report of obvious adverse events despite the above, and that Mr. Akkerman submitted an Adverse Event Report to the MAUDE Database. (Exhibit 12A)

Additional lawsuits made serious allegations of harm arising out of MECTA's ECT devices, and which it also failed to report to the FDA:

- In 1996, plaintiff Terri Adamchick sued MECTA and health care providers, alleging that

the ECT treatments caused memory loss, seizures, pain and anguish, among other monetary damages. (Exhibit 13)

- Also in 1996, plaintiff Imogene Rohovit sued MECTA and health care providers, alleging that the ECT treatments caused substantial impairment of memory and inability to concentrate caused by brain damage from the ECT. (Exhibit 14.) The complaint alleged permanent brain damage.
- In 1998, the heirs of Jesus Torres sued MECTA and health care providers. The suit alleged that the ECT caused him to have a ruptured bowel, caused substantial weight loss, spontaneous seizures, and ultimately, killed him. (Exhibit 15.)
- MECTA's president also acknowledge a further lawsuit filed against the company by a Mr. or Ms. Tuch.
- A further lawsuit was filed against MECTA by Ms. Linda Andre in New York, also alleging substantial memory loss, and other damages.

According to Ms. Nichol, these six lawsuits alleged that MECTA's devices caused brain damage to the patients. (Exhibit 9, Nichols Deposition, p. 333-342.) Yet, despite the requirements of section 519, she was not even curious why 6 people sued MECTA for causing them brain damage, because claims of harm arising out of ECT conflicted with her view opinions regarding ECT, and therefore the lawsuits were viewed by MECTA as "frivolous." (*Id.*, 344-45.)

On April 2, 2009, in the context of consideration of potential reclassification of ECT devices from Class III to Class II, the FDA issued orders to ECT manufacturers, ("Medical Devices; Order for Certain Class III Devices; Submission of Safety and Effectiveness Information") requiring them to:

... summarize *all adverse safety and effectiveness information* that has not been submitted under section 519 of the act, particularly the most significant information. The mechanisms or procedures that will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided. [emphasis added]

It should be noted that no MDRs from MECTA appear on the FDA's MAUDE data base. None of the cases above were reported by MECTA. (Exhibit 16.) In MECTA's submission to the FDA dated August 7, 2010 (Exhibit 5), it continued to withhold this material information regarding the lack of safety and efficacy of ECT devices which it had acquired over prior decades, but had failed to provide it to the FDA in compliance with Section 519. However, MECTA's avoidance of its section 519 responsibilities and its submission of deceptive and incomplete information in response to the April 2, 2009 Order, was revealed to the FDA in submissions made by members of the public in 2010 in Docket No. FDA-2010-N-0585. (Exhibit 5.)

Recent Freedom of Information Act Requests to the FDA reveal that MECTA has never provided any MDR reports of injuries or deaths as required by reports, (Exhibit 16), and thus, no

reports from MECTA are present in the MAUDE database regarding adverse events arising from ECT from its devices. Such reports are mandatory as matter of law. However, the FDA has given at least the larger of the two manufacturers a pass, failed to enforce the law, and failed to protect citizens

Despite possessing clear evidence that MECTA materially misrepresented adverse effects of ECT from its own devices, FDA took no action, made no communication to MECTA seeking explanation or further detail, and generally provide MECTA air-cover to continue marketing ECT devices without oversight, and without censure. (Exhibit 16.) Rather, the FDA's examination of devices has been limited to manufacturing practices and parameters, with no regard to the effect of the treatment on patients.<sup>70</sup>

And, despite these failures, the FDA seeks to reward this largest manufacturer of ECT devices by down classifying its devices to Class II for allegedly limited uses, and declining therefore to require a PMA demonstrating safety or efficacy. The FDA accordingly relied upon knowingly incomplete and misleading information in proposing reclassification.

## **F. Incorporation of Other Comments on ECT**

To further support the actions requested in this Citizen Petition, we hereby incorporate the arguments and information contained in the attached comments from CCHR (Exhibit 18), attorney Kendrick Moxon (Exhibits 19 and 20), and medical doctor and ECT researcher, Moira Dolan (Exhibit 21), all of which concern the proposed order reclassifying certain ECT devices into Class II. Such comments, *inter alia*, explain how the risks of ECT therapy are greater than the FDA has characterized, and that the effectiveness of ECT, for any psychiatric or medical condition is not supported by valid scientific evidence, at least not to the extent that it outweighs the known risks.

## **III. SUMMARY OF VIOLATIONS**

### **A. FDA's Actions Constitute an Abuse of Discretion and Arbitrary and Capricious Agency Action**

FDA's conduct described *supra* is in violation of the Administrative Procedures Act. The APA instructs that a court should "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. An agency's decision is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983). "The APA requires meaningful review; and its enactment meant stricter judicial review of agency factfinding than Congress believed some courts had previously conducted." *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999).

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<sup>70</sup> See records of FDA inspections of MECTA plant in 2012 and 2014 released pursuant to FOIA Requests, Exhibit 17 hereto.

1. FDA failed to consider whether its “Special Controls” would actually protect the patient population

FDA violated the APA when it failed to consider whether, in practice, its proposed special controls would actually reduce patient risk. As explained *supra*, FDA’s “Special Controls” related to labeling will not protect the patient population whatsoever. The labeling requirements will have absolutely no practical impact on whether individuals receive ECT treatment, whether ECT treatment is provided with informed consent, and most importantly, whether the well documented and life-altering negative effects of ECT treatment will be experienced by patients. Furthermore, the “Special Controls” related to design features ignore the overwhelming body of evidence establishing that sending large amounts of electricity through the brain without the ability to direct or control where that electricity goes will invariably cause damage. FDA has also ignored that no reliable evidence exists that establishes which, if any, design features are safer than others. FDA failed to consider that the mechanism of action for ECT is wholly theoretical. The FDA cannot reasonably create effective design controls when neither it, nor anyone else, knows whether certain energy outputs, durations or frequencies are more or less dangerous or effective than others. *Florida Wildlife Fed’n, Inc. v. Jackson*, 853 F. Supp. 2d 1138, 1169 (N.D. Fla. 2012) (where a scientific disconnect exists between the Agency’s regulatory objective and the means by which it seeks to achieve that objective, the agency has violated the APA). Thus, FDA has violated the APA by first announcing that special controls can adequately protect the patient population before it has determined what, if any, designs are capable of actually doing so. *See Rahman v. Napolitano*, 814 F. Supp. 2d 1098, 1107 (W.D. Wash. 2011) (citing *The Button Depot, Inc. v. DHS*, 386 F.Supp.2d 1140, 1149 (C.D.Cal.2005) (basing an agency decision on a conclusory statement without any support is an abuse of discretion).

2. FDA’s decision runs counter to the available evidence

FDA violated the APA by failing to consider the vast majority of available safety and efficacy evidence. *See N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1075 (9th Cir. 2011) (Where agency’s basis for including or excluding evidence is clearly erroneous or arbitrary and capricious, the agency has violated the APA). FDA’s principle conclusion, that ECT’s benefits outweigh its risks for at least some patients, runs counter to the available evidence, ignoring the factual record and considering only those few studies and anecdotal evidence that supports FDA’s arbitrary conclusion. In fact, there is not a single study showing a difference in depression scores between patients receiving real and sham ECT at one month post treatment. FDA only considered 10 published articles in drafting its proposed rule despite the admitted availability of more than 1,200 studies on ECT. FDA’s basis for rejecting 1163 studies and considering only 10 is based on arbitrary inclusion/exclusion criteria. For instance, FDA repeatedly cites to Sackeim’s publications and studies regarding ECT safety and efficacy, specifically his conclusions that ECT does not cause long term cognitive or memory problems. Yet, FDA, inexplicably and arbitrarily rejected consideration of his 2007 article which called into question his own research cited by FDA. *Id.* (where the record clearly demonstrates that the agency made a clear error in judgment, the agency has violated the APA).

FDA failed to consider thousands of submissions and comments made for the 2011 Advisory Committee hearing because those records, from actual ECT patients, of actual harm caused by ECT was “anecdotal.” Yet, for no rational reason, FDA chose to consider the adverse

event submissions to its MAUDE database. Those submissions are no less anecdotal than the thousands of comments that FDA excluded. This arbitrary rejection of viable, relevant evidence that establishes the extreme safety risk posed by ECT (e.g., death, memory and cognitive impairment) resulted in a decision that runs counter to the evidence before the agency. See *Sierra Club v. U.S. E.P.A.*, 671 F.3d 955, 965 (9th Cir. 2012) (Agency's failure to consider substantial new data without reasoned explanation was arbitrary and capricious). This decision is also so wholly irrational and arbitrary in violation of the APA.

Significant literature exists which demonstrates that ECT provides no long term benefits, and none of the studies purporting to show long term benefits are actually valid. This literature was inexplicably rejected by FDA. Even ECT manufacturers admit in *written submissions to FDA* that ECT fails to provide benefits that outlast the treatment course. In contrast, ECT can cause death, cardiovascular complications, memory loss and cognitive impairment. FDA's conclusion therefore runs counter to the available evidence and constitutes arbitrary and capricious agency action in violation of the APA.

FDA's position that "Special Controls" related to "waveform" and "output mode" will limit the risks of cognitive and memory impairment is unsupported by the factual record and violates the APA. There are no studies, clinical trials, or evidence that supports the conclusion that certain "waveform" and "output modes" are safer or less damaging than those of older devices. The contention that newer "brief pulse" devices cause less damage has never been substantiated; it has merely been repeated by ECT proponents for the purpose of distancing modern devices from the alarming harmful effects of predecessor devices. FDA ignored the substantial evidence that demonstrates that these brief pulse devices actually bring more energy to bear on the brain, not less. Thus, the factual record indicates that this special control will not reduce brain damage but may, in fact, *increase* it. This agency action therefore runs counter to the body of scientific evidence in violation of the APA. *Sierra Club*, 671 F.3d at 963 (An agency action is arbitrary and capricious if there is no rational connection between the available facts and the agency's decision).

### 3. FDA has taken positions that are wholly irrational and implausible

FDA's decision not to impose a PMA requirement for Class III ECT devices conflicts with its longstanding position that Class III devices must submit PMA's. See *Tapis Int'l v. INS*, 94 F.Supp.2d 172, 174 (D. Mass. 2000) (citing *Shanti, Inc. v. Reno*, 36 F.Supp.2d 1151, 1162 (D.Minn.1999)) (noting that an agency abuses its discretion if its "decision is inconsistent with the agency's own precedent."). FDA provides no explanation for why a device that can cause death and brain damage would not be required to submit a PMA, or establish efficacy and safety through a submission of clinical trial data. *Judulang v. Holder*, 132 S. Ct. 476, 484 (2011) (agency action that lacks reasoned explanation violates the APA). FDA requires such submissions for any other comparably dangerous device, and this departure is wholly irrational, constituting arbitrary and capricious agency action. *Montana Wilderness Ass'n v. McAllister*, 666 F.3d 549, 557 (9th Cir.), *aff'd*, 460 F. App'x 667 (9th Cir. 2011) (Agency action that conflicted with longstanding policy and Congressional intent violated the APA); *Republic Airline Inc. v. U.S. Dep't of Transp.*, 669 F.3d 296, 300 (D.C. Cir. 2012) (Upon significant showing that analogous cases have been decided differently, the agency must provide a detailed and reasoned explanation for the departure).

FDA's split classification system is wholly irrational and constitutes arbitrary and capricious agency action. The split classification plainly creates a Class II path to market for devices that are frequently used for Class III purposes. By lowering the classification of ECT devices used to treat specified populations, FDA has essentially declassified the entire ECT market. Any Class II ECT device that has an off-label, Class III use, can be and will be used for Class III purposes. This includes ECT treatment of children. Therefore, the split classification guarantees that PMAs will never be submitted for ECT devices. However, this outcome directly conflicts with FDA's apparent intent which was to limit declassification to a narrow subset of devices purportedly because the remaining devices cannot be sufficiently regulated with "special controls." Thus, FDA's action guarantees an outcome adverse to the agencies' own stated intent.

### **B. FDA's Conduct Conflicts with its Prior Actions**

As explained *supra*, FDA's decisions related to the declassification of ECT devices and FDA's refusal to require submission of PMA's or clinical trials by ECT manufacturers conflicts with prior agency actions and policies. Under binding precedent, the general rule of agency deference is inapplicable when an agency acts in conflict with a consistently held agency view. *Provena Hosps. v. Sebelius*, 662 F. Supp. 2d 140, 150 (D.D.C. 2009) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994)). Thus, FDA should immediately conform its conduct to its prevailing agency view, specifically, that manufactures of dangerous devices, especially those that can cause death or brain damage, submit robust clinical evidence in a PMA to support safety and efficacy or be prohibited from selling their product in the United States.

## **IV. CONCLUSION**

Because ECT therapy is associated with potentially dangerous and life threatening risks that cannot be mitigated with special controls, and the effectiveness of such treatment is not sufficiently established, the petitioners respectfully request that the FDA promulgate a final rule banning ECT devices or, in the alternative, require approved PMAs for all ECT devices regardless of which psychiatric or medical conditions they are intended to treat.

## **ENVIRONMENTAL IMPACT**

The actions requested in this petition are not within any of the categories for which an environmental assessment or environmental impact statement is required pursuant to 21 C.F.R. § 25.22. *See, e.g.*, 80 Fed. Reg. at 81231 (proposing to, *inter alia*, require PMA approval for certain ECT devices, and stating that the FDA "determined under 21 CCFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment" and "[t]herefore, neither an environmental assessment nor an environmental impact statement is required").

## **ECONOMIC IMPACT**

Information on the economic impact of this proposal will be submitted if requested by the Commissioner.



## CERTIFICATION

I certify that, to my best knowledge and belief, this petition includes: (1) all information and views upon which the petition relies, and (2) representative data and/or information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

/s/ Jonathan W. Emord

Jonathan W. Emord  
Bethany R. Kennedy  
Joshua S. Furman  
Emord and Associates, P.C.  
11808 Wolf Run Ln.  
Clifton, VA 20124  
(202) 466-6937

Kendrick Moxon  
Law Office of Kendrick Moxon, P.C.  
3500 West Olive Ave., Suite 300  
Burbank, CA 91505  
(818) 827-7104

*Counsel for Petitioners*