

EXHIBIT 6

CONFIDENTIAL

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Food & Drug Administration
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The following information is submitted in response to the FDA order for submission of safety and effectiveness information for certain class III medical devices [Docket No. FDA-2009-M-0101], and specifically in this instance the electroconvulsive therapy (ECT) device.

1. Identification.

Electroconvulsive therapy (ECT), previously known as "shock therapy" or "electroshock therapy" is the oldest of the presently used biological treatments in psychiatry, having been first introduced into U.S. psychiatric practice almost 70 years ago. It is administered via an electroconvulsive therapy device that delivers a controlled dose of electricity to the head of an anesthetized and fully oxygenated patient to induce a generalized discharge of brain neurons lasting about a minute. This "seizure" or "convulsion" is similar to an epileptic seizure except that the muscle contractions are reduced or eliminated by muscle-relaxing medications, the risks of hypoxia and hypercarbia are eliminated by supported respiration, and the occurrence and duration of the seizure are medically controlled

During the early years of ECT before anesthesia and muscle-relaxants were introduced, dislocations, fractures, and dental injury sometimes occurred, and the experience of receiving the treatment without anesthesia caused some patients to become fearful of it. Since the introduction of modern anesthesia techniques for ECT in the late 1950s the procedure is much like any other carried out under brief anesthesia. In fact, most patients queried in one carefully done study said they preferred having ECT to a visit to the dentist (Freeman and Kendell, 1980).

The first ECT devices introduced in the U.S. in the 1940s delivered a sine-wave stimulus based on the alternating current found at wall outlets. Beginning in the late 1960s the more efficient brief pulse square wave stimulus began to replace the sine wave stimulus because it produced the same therapeutic effect with an improved safety profile, particularly with regard to memory and cognitive functioning.

FDA-2009-M-0101-DRAFT-0025

INFO

Somatics' Thymatron ECT device is intended to be used in the ECT procedure by a physician to treat patients suffering from severe major depressive disorder. The Thymatron device is a free-standing, table-top medical electronic device. It includes transformers, electronic displays, a printer, and modular circuit boards with microprocessors, memory chips, optical isolators and other electronic components, in a case. On powering up it automatically performs tests of its own integrity. It delivers a brief pulse square wave stimulus of 0.9A constant current, of maximum charge 504 mC (99.4 Joules at 220 ohms impedance) and minimum charge 5.0 mC. The Thymatron device prints the patient's electroencephalogram (EEG), electrocardiogram (ECG), pulse rate, and electromyogram (EMG, for muscle movements) during treatment on a paper strip chart that emerges from the front panel of the device.

Current: 0.9 A constant, isolated from line current

Frequency: 10 to 70 Hz in 10 Hz increments (to 140 Hz for 0.25 ms pulse)

Pulsewidth: 0.25 to 1.5 ms in 0.25 ms increments

Duration: 0.14 to 8.0 s in increments of equal charge

Maximum: 504 mC (99.4 J @ 220 ohm)

The exceptionally careful and detailed meta-analysis of the efficacy and safety of ECT in depressive disorders performed by The UK ECT Group (2003) provides an excellent general overview and introduction to the present submission. A meta-analysis combines the results of multiple scientifically-valid studies on a subject into a single study, using a widely-accepted statistical technique. In this way it is often possible to detect effects that are hard or impossible to discern in the original studies because of too small a sample size.

The conclusions of the UK ECT Group were that real ECT was significantly more effective than simulated ECT; ECT was significantly more effective than pharmacotherapy; overall mortality was lower in patients who received ECT than those who did not; and previous ECT or total lifetime ECTs were not associated with structural brain changes.

Each of these points, as well as other related points, will be further considered below in an analysis of individual scientifically-valid studies.

2. Risks to Health

As for all medical treatments, the decision to administer ECT is reached through a risk-benefit analysis in which the risks of treatment are balanced against the risks of alternate treatments or of no treatment at all.

The typical patient referred for ECT in the present era is a geriatric person with melancholia—an individual in his 60s or 70s who suffers from major depressive disorder with melancholic features (e.g., anorexia, weight loss, insomnia, motor agitation or retardation, ruminations of hopelessness, guilt or worthlessness, and serious suicidal

tendencies). One or more medical problems (e.g., hypertension, cardiac arrhythmia) are usually present in such patients, together with the inanition and dehydration that accompany melancholic depression in this age group.

Offering no treatment at all is not a viable option in such patients. Most have already failed 2 or more courses of antidepressant drugs, often administered together with an antipsychotic agent if agitation or ruminations of guilt, worthlessness, or hopelessness are prominent. In view of recent FDA black box warnings about using antipsychotic drugs in patients of this age range and the cardiovascular risks of these drugs, this alternative treatment has become relatively undesirable. These melancholic patients have been admitted to hospital as a last resort because of inability to function at home, often compounded by weight loss and the adverse anticholinergic symptoms caused by the antidepressant and antipsychotic medications they have been taking, including dehydration, confusion and agitation. Inanition, dehydration, confusion, agitation, or suicidal behavior urgently require mitigation. Further treatment with different antidepressant or antipsychotic drugs does not reliably provide this mitigation and the resultant lack of relief most often leads to a worsening of the patient's condition.

Because the risks of ECT as outlined below are few and minimal compared with existing drug therapies or no therapy at all, ECT will often be prescribed as the conservative treatment of choice for the geriatric melancholic patient.

i) The Thymatron ECT Device

Somatics' safety experience with the Thymatron ECT device

Since September 27, 1984, when FDA cleared the Somatics Thymatron ECT device for marketing, more than (b) (4) Thymatron devices have been sold worldwide. During that time Somatics has maintained complete safety files on the Thymatron device, including those required by the FDA's Good Manufacturing Practice regulation, the Canadian Standards Association, the German TÜV testing agency, and KEMA Registered Quality. The latter three agencies regularly make on-site inspection visits to review manufacturing practices, documentation, and established quality control procedures for compliance with applicable published standards. In the ensuing 25 years there has been no occurrence of a reported adverse event (death or serious injury) related to the use of a Thymatron ECT device, no reported occurrence of catastrophic ECT component failure, and no product recall issued.

A review of FDA's Manufacturer and User Facility Device Experience (MAUDE) database (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM) from 1983 to the present reveals 20 non-duplicated events that were filed. These comprise 12 reported problems with stimulus electrodes, 2 problems involving operation of the Thymatron ECT device, and 6 of alleged death or permanent disability.

Stimulus electrode problems: Eleven of the 12 reported stimulus electrode events involved Somatics' single-use, adherent Thymapads, designed as an integral part of the

Thymatron System IV. To put these 11 events in perspective, they represent (b) (4) of (b) (4) Thymapads sold. Most involved superficial (1st or 2^d degree) skin burns under the electrode application site, sometimes associated with an electrical flash or arc, and occasionally with a burning smell or smoke. In one instance, too-vigorous removal of the Thymapad caused the skin to bleed. In another instance, single-use Thymapads were being re-used multiple times in the same patient. In each instance where the end-user had retained the Thymapad in question it was returned to the original equipment manufacturer for examination; no manufacturing faults were found. Telephone interviews conducted by Somatics with the end-user or his representative invariably revealed one or another lapse of technique or failure to precisely follow Somatics' printed instructions for use accompanying each box of Thymapads. Where indicated, these instructions were revised to improve clarity.

One of the reported stimulus electrode events involved metal disk electrodes; the individual filing the report unequivocally stated "MD did not apply enough gel".

Thymatron ECT device problems: No injuries or deaths were stated in the reports concerning operation of the Thymatron ECT device.

One of the 2 reports alleged that the device delivered a stimulus on power-up, without the doctor pressing the treatment button. No injury occurred. The complaint offered a convoluted explanation involving the claim that the treatment button might have stuck in the ON position because it had been installed upside down. The device in question was examined and put through a complete test cycle by the original equipment manufacturer (OEM), Elekrika, and found to be operating normally. It had a properly-functioning treatment switch that had been correctly installed. The OEM noted that it was impossible for the device to deliver a stimulus on power-up even if the treatment button was deliberately pressed and held down before and throughout power-up. The device was returned without modification to the end-user, who reported no further problems. The best explanation is that the shock had nothing to do with the Thymatron device but was static electricity.

The second report alleged that the device continued to generate current after the physician stopped the treatment because a nurse received a shock when trying to remove the treatment electrodes after the treatment had ended. No injury occurred. The unit was sent to the OEM for examination and found to be operating properly and without fault. The hospital Biomed Manager met with the nurse in question and determined that the nurse had experienced a static electricity shock, and that the report should not have been filed.

Reports of death and permanent disability: The 6 reports alleging death or permanent disability share the following characteristics:

- a) They contain similar wording of an idiosyncratic nature not used by ECT doctors or nurses. Four of the 6 reports contain the phrase "psychiatric electroshock", a term appearing only once in the entire medical literature and not in any of the other MAUDE reports summarized above. However, this

phrase is commonly found on anti-ECT websites (e.g., www.endofshock.com, www.wittenbergces.com). Moreover, 5 of the 14 MAUDE reports concerning the only other U.S.-made ECT device (Mecta) contain claims of permanent disability that include the phrase “psychiatric electroshock”; some also contain additional phrasing identical to that in some of the Thymatron reports.

- b) None of the reports was filed by a physician or hospital employee involved in giving ECT.
- c) None of the claims of death or permanent disability were confirmed by the hospital from which the report was filed.

For these reasons these reports appear to be spurious.

Risk reduction with the Thymatron ECT Device

a) Risk of prolonged seizures and cardiac arrhythmias

The two most frequent complications during an ECT treatment session are excessively long seizures and irregular heart rhythms (Nuttall et al, 2004), both of which can be detected by routine monitoring during the treatment. A brain-wave monitor (electroencephalogram, EEG) enhances the safety of ECT by allowing the treating doctor to detect a prolonged seizure as it occurs so that it can be terminated with intravenous medication. Likewise, a heart monitor (electrocardiogram, ECG) allows the treating doctor to detect irregular heartbeat patterns as they occur so that they can be managed with intravenous medication. The Somatics Thymatron device includes integral EEG and ECG monitors that start recording automatically as soon as the ECT stimulus is delivered and continue until they are turned off by the doctor.

In addition to the paper EEG record the Somatics Thymatron device has an auditory EEG monitor that allows the user to tell without looking at the patient or the paper EEG whether or not the seizure has stopped. In a study of 82 consecutive ECTs the auditory EEG of the Thymatron device allowed the investigators to determine the occurrence and the duration of the induced EEG seizure with a high degree of accuracy when tested against the paper EEG standard (Swartz and Abrams, 1986).

b) Risk of excessive dose due to component failure

In the extremely rare event of catastrophic failure of an ECT device component there exists the remote possibility for an ECT device to deliver an electrical stimulus dose substantially in excess of that set by the operator, potentially causing excessive memory disturbance. To prevent such an occurrence the Somatics Thymatron device includes an independent separate redundant safety circuit that automatically measures the electrical charge at the output terminals each time the stimulus button is pressed and prevents delivery of any stimulus charge that exceeds by more than 5% that set by the operator.

To test the integrity of the electrical connection to the patient, the Somatics Thymatron device includes a static impedance test initiated by a button press. The test current is too

small to be felt by a fully awake person. This test helps assure good electrode contact and thereby prevent excessive heat release onto the skin.

Published risk assessments of the Thymatron ECT device

a) Risk of hippocampal damage

Ende et al (2000) used proton magnetic resonance spectroscopic imaging to study hippocampal effects of the Thymatron ECT device as reflected in N-acetylaspartate signals. In 17 patients receiving either unilateral or bilateral ECT (all of whom improved with treatment), no differences were found from 30 control subjects in hippocampal N-acetylaspartate signals, and thus providing no evidence for ECT-induced hippocampal atrophy or cell death.

b) Risks to everyday memory and semantic memory

The most commonly investigated potential risk of ECT concerns its possible impact on memory and cognitive functioning. Research on this risk with respect to ECT devices in general is reviewed in Section 2.ii. below. The following study reviews this risk specifically with respect to the Thymatron ECT device.

Schat et al (2007) used a Thymatron ECT device to treat 83 DSM-IV medication-free patients with unipolar depression who had been evaluated at baseline on tests of behavioral (everyday) memory and semantic memory (word fluency). One year after a course of bilateral or unilateral ECT neither everyday memory scores nor semantic memory scores were reduced from baseline—in fact, bilateral ECT was associated with significantly improved semantic (but not everyday) memory scores.

It should be noted that the risk of adverse memory effects is controlled through a variety of mechanisms. It is standard clinical practice that the physician administering ECT assess the patient's mental status, including memory and cognitive functioning, before the start of the first ECT treatment and each day while the patient is undergoing treatment. If a significant adverse change in cognitive functioning is observed, the physician has several choices available to ameliorate or reduce this change, including reducing the number of treatments per week, temporarily interrupting treatment for a number of days, reducing the stimulus dose, changing the treatment electrode placement or stimulus parameter settings, changing anesthetic medications or doses, changing concurrent medications, and decreasing the total number of ECT treatments given.

ii) The generic ECT device

Risk of Death or Serious Injury

ECT is a safe treatment. The most recent hospital-based statistics are from the Mayo Clinic (Nuttall et al, 2004). This report described no permanent injuries and no deaths in 17,394 consecutively administered ECTs to 2,279 patients over a 14-year period.

The most recent state-based statistics are from Texas for the 5 years ending 1998 (Shiwach, Reid, and Carmody, 2001). These statistics show two deaths per 49,048 treatments. A report from California (Kramer, 1999) for the decade ending 1994, noted three deaths per

160,847 treatments. Both figures reflect the fact that receiving ECT is substantially safer than giving birth, as reflected in the most recently reported U.S. statistic of 12.1 deaths per 100,000 live births for the year 2003 (Hoyert, 2007).

Risk to the Brain

Because the brain is the intended recipient of the electrical stimulus of ECT it is necessary to consider whether ECT might conceivably cause brain injury, either directly via the electrical stimulus itself, or indirectly, via the induced seizure.

Direct brain injury from ECT could only occur through temperature elevation from heat liberated by the electrical stimulation or from cerebral anoxia occurring during the induced seizure. During the passage of the electrical stimulus for ECT the high impedance of the skull relative to the skin and subcutaneous tissues causes most of the stimulus current to be shunted through the scalp (Weaver, Williams and Rush, 1976). Considering the worst-case (i.e., smallest volume) calculation that regards the heat generated in the brain to be evenly distributed through a cylinder of end area 20 cm² (the standard stimulus electrode surface area in use in the U.S.) and length of 13 cm (the typical trans-cranial distance between bitemporal stimulus electrodes), the maximum FDA-allowed output of modern brief-pulse ECT devices (100 Joules at 220 ohms impedance) would elevate deep tissue temperature by less than 0.092°C (Swartz, 1989).

Moreover, the actual brain temperature increase from an ECT stimulus is only a fraction of 0.092°C because the tissue volume through which the stimulus current passes is greatly increased by dispersion of the voltage along the scalp, and the stimulus charge greatly reduced by the aforementioned shunting through the scalp.

And, because ECT has for more than 50 years been administered concurrent with full oxygenation of the patient to consistently yield a partial oxygen pressure of at least 100 mm Hg (Posner, Plum and Van Poznak, 1969), cerebral anoxia is eliminated as a possible cause of brain injury during ECT.

Risk of brain cell injury

When brain cells are injured there are detectable increases in blood levels of a variety of proteins and protein enzymes; these can be measured before and after ECT in an attempt to determine whether ECT causes such damage.

Giltay et al (2008) measured serum levels of C-reactive protein (CRP) and several intracellular enzymes, including alkaline phosphatase (ALP), lactate dehydrogenase (LDH), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and creatine kinase (CK), before and 5 min, 30 min, 4 h, 1 day, 2 days, and 3 days after ECT in 15 consecutive patients. All concentrations remained within the normal range in every patient, except for five samples with elevated CK levels. However, because CK-MB and CK-BB fractions remained low in those samples, skeletal muscle was the presumed source of the CK elevation. These data provide no support for the possibility that ECT causes either direct brain cell leakage or a brain inflammatory response.

Zachrisson et al (2000) determined the concentrations in the cerebrospinal fluid (CSF) of three established markers of neuronal/gliai degeneration: tau protein (tau), neurofilament (NFL), and S-100 beta protein, in 9 depressed patients who received therapeutic courses of ECT. Also measured was the CSF/serum albumin ratio, a reflection of potential blood-brain barrier (BBB) dysfunction. Neither levels of CSF-tau, CSF-NFL and CSF-S-100 beta protein, nor the CSF/S albumin ratio, were significantly changed by ECT, providing no biochemical evidence of neuronal/gliai damage or BBB dysfunction following a therapeutic course of ECT.

Berrouschoot et al (1997) measured serum neuron-specific enolase (NSE), a sensitive marker of neuronal damage, in 7 patients with major depressive disorder who were treated with ECT for the first time. ECT was administered every 2 days, three times a week under standard conditions and blood samples were drawn at the following times. For the first ECT: 15 and 1 min before ECT, and 1, 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 105, 120 min, and 8, 12, 24 h after ECT. For all subsequent ECTs: 1 min before and 4 h after every ECT. After an average of 10 ECTs per patient, there was no difference in serum NSE levels before and at all times following the first ECT, nor were any differences found in serum NSE levels before and after each subsequent ECT, indicating that ECT does not cause neuronal damage.

Myelin basic protein is an antigen that constitutes 30% of the myelin sheath, and its immunoreactivity in serum and cerebrospinal fluid correlates with the degree of central nervous system damage that occurs with stroke and cerebral trauma. Hoyle, Pratt, and Thomas (1984) found no difference in serially sampled serum myelin basic protein immunoreactivity between a sample of 13 patients undergoing ECT and a sample of 14 normal controls, nor was any pre- to post-ECT increase in mean reactivity observed in the patient sample.

Risk of brain structural damage

Magnetic Resonance Imaging (MRI) provides a clear opportunity for non-invasive high-resolution viewing of brain structure in patients receiving ECT.

Coffey et al (1991) blindly-analyzed serial MRIs obtained before and after treatment and at 6-month follow-up in 35 depressed patients receiving courses of brief-pulse bilateral ECT. No acute or delayed change in brain structure were found, as measured by alterations of the total volumes of the lateral ventricles, the third ventricle, the frontal lobes, the temporal lobes, or the amygdala-hippocampal complex. In five subjects, pairwise global comparisons revealed an apparent increase in subcortical hyperintensity, which the authors interpreted as most likely reflecting progression of ongoing cerebrovascular disease during follow-up.

Risk of creating an epileptic focus in the brain

It has been suggested on hypothetical grounds that the repeated seizure inductions of ECT might create ("kindle") a permanent epileptic focus in the brain of some patients receiving this treatment. Ethical considerations prohibit the study of human brain kindling, so the relevant data must come from animal studies.

Kragh et al (1993) implanted electrodes in the amygdalae of 32 rats that were then randomly allocated to receive 12 weekly genuine or sham electroconvulsive shocks (ECS). Three months after the last ECS, kindling was initiated artificially in all the rats by daily stimulation via the implanted electrodes: rats pretreated with genuine ECS did not kindle faster than sham ECS-treated rats—in fact, rather than a facilitated development of kindling following ECS, a statistically significant inhibition of kindling was found in the genuine ECS group.

Post et al (1984) demonstrated a marked protective effect against kindling lasting up to 5 days after a 7-day course of once-daily ECS in rats. Moreover, when ECS was administered before the stimulation given to induce kindling, this phenomenon was completely blocked.

Considering the potent antikindling properties of ECS in rodents, it is highly unlikely that ECT causes kindling in man.

Risk of persistent or permanent memory loss

All forms of ECT are capable of causing immediate adverse effects on memory shortly after each individual treatment and after a course of treatments, and some of the clinical approaches to ameliorating such adverse effects are outline in the last paragraph of section 2.i above. The question is whether any of these short-term memory effects are detectable as long as 6 months after the final treatment, which is the generally-accepted interval for classifying such memory changes as "persistent" rather than "temporary".

Memory (amnesic) effects of ECT consist of two main types: anterograde, for events occurring after a treatment or course of treatments, and retrograde, for events occurring just before the first treatment, or for personal (autobiographical) and public events occurring during the weeks, months, or years before the first treatment. The studies reviewed below are limited to the stimulus wave-form of ECT now exclusively used in virtually all U.S. hospitals—the brief pulse, square-wave stimulus. Further, it should be noted that this review only considers the effects of bilateral (i.e., bitemporal or bifronto-temporal) treatment electrode placement, the method that invariably produces the more pronounced immediate anterograde and retrograde memory effects in every published comparison. If persistent amnesic effects are not detectable after bilateral ECT, they will not be detectable after any other form of ECT either.

Lisanby et al (2000) randomly assigned 55 patients with major depressive disorder to low- or high-dose right unilateral or bilateral ECT and tested them at baseline on memory batteries containing both autobiographical and public events. Two months after ECT these investigators did not find statistically significant ($p < .05$) worsening of either autobiographical or public event memory for either form of ECT at either dosage level.

Calev, Nigal, and Shapira (1991) administered a comprehensive test battery of memory and other cognitive functions to 27 medication-free patients with major depression before and shortly after a mean course of 9 bilateral, brief-pulse ECTs administered according to a dosage titration procedure. They reexamined 14 patients 1 month and 6 months after the conclusion of the treatment course. Anterograde memory was significantly impaired immediately following the course of ECT, but at 1 month follow-up, performance had improved to pre-ECT levels and exceeded them at the 6 month follow-up.

Calev, Nigal, and Shapira (1991) also included retrograde memory tests for autobiographical and public events using a test battery that covered the period of several years prior to ECT. Although significant impairment for autobiographical (but not public) events was recorded immediately following a course of ECT, this impairment had disappeared 1 month later, followed by improvement over baseline shown at the 6 month test interval.

Sackeim et al (1986, 1987b) employed a variety of recall and recognition tests for words, shapes, and faces that had to be learned 15 minutes prior to brief-pulse, just-above-threshold unilateral or bitemporal ECT. Patients were retested immediately after orientation had returned, at which time no retrograde amnesic effects were detected and improvement over baseline was recorded on one of the retrograde memory tasks. Of course, if retrograde amnesia was not detected immediately after ECT, it could not persist afterwards. This fact was confirmed by Sackeim et al (1993) in a follow-up study in which autobiographical memory assessments prior to

ECT showed no decrements 2 months after a course of either just-above-threshold or 2.5 times threshold bitemporal ECT.

Thus, follow-up studies up to 6 months after a course of bilateral brief-pulse square-wave ECT find no evidence for persistent anterograde or retrograde amnesia.

3. Recommendation.

Somatics believes the ECT device should be reclassified into class II because special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness. There presently exists sufficient information to recommend the following specifications based on almost 70 years' safe and effective use of ECT devices in the U.S.

brief pulse, square wave stimulus

All published studies report the brief pulse, square wave stimulus to be more efficient at seizure induction than the sine wave stimulus, achieving the same therapeutic effect with significantly less memory and cognitive disturbance. Typical parameter settings are in the ranges of pulsewidth 0 to 1.5 ms, frequency 0 to 140 Hz, and total stimulus duration 0 to 8 sec.

constant current stimulus output

A constant current ensures delivery of a specified charge (in millicoulombs, mC) at each stimulation, whereas with constant voltage the charge delivered varies with the skin impedance of the patient, which can change from day to day.

maximum energy dose 100J @ 220 ohm impedance

This is the present electrical energy dosage limitation of U.S.-made ECT devices, based on recommendations made to FDA in 1982 by the American Psychiatric Association in its failed *Petition to Reclassify ECT Devices to Class II*. However, it should be considered that several U.S.-based ECT investigators (Sackeim, 1991; Krystal, Dean, and Weiner, 2000; Abrams, 2001) have recommended a higher maximum electrical dose in order to be able to treat the large and increasing number of older patients with major depression, who have much higher than average seizure thresholds. Moreover, other English speaking countries (e.g., U.K., Australia) have allowed ECT devices to be marketed with double the output of U.S. devices: 200J @ 220 ohms impedance. In fact, the U.K. has made that particular higher maximum dose mandatory for all ECT devices sold there.

pretreatment stimulus electrode impedance test

A test of impedance of the electrode-to-skin interface employing a current too small to be felt by a fully awake person helps assure good contact and prevent skin burns. Typical clinical measures routinely used to lower skin impedance and thus also reduce the risk of skin burn include increasing pressure on the stimulus electrode(s), cleaning the skin and applying a conductive gel or solution, repositioning the electrode(s), and gently abrading the skin under the electrode(s) as with an emery board.

treatment electrode surface area no less than 20 cm²

In order to prevent excessive heat liberation at the electrode-to-skin interface and possible resultant skin burns, the temperature at the electrode-to-skin interface should not exceed 50 deg. C. This constraint is reliably achieved if the stimulus electrode surface area is no smaller than 20 cm², and an acceptably low pretreatment impedance result is obtained from testing as noted in the preceding paragraph.

independent dosage output monitoring and controlling circuit

As described in 2i(b) above, this circuit repeatedly tests the dose at the output terminals and aborts stimulus delivery if the output exceeds the user-set dose by more than 5%.

two channel EEG monitor

Being able to assess for continuing cerebral seizure is important for preventing the memory and cognitive risks of prolonged seizures. Because paroxysmal seizure activity can persist in the brain after all visible muscle movements have ceased, the EEG is necessary for monitoring for continuing seizure activity and for assessing the efficacy of any intravenous anticonvulsant medications administered to terminate a prolonged seizure. Moreover, because a generalized brain seizure involving both hemispheres is considered necessary for the full therapeutic effect of ECT, two channels of EEG monitoring are needed to ensure that the induced seizure is not limited to one hemisphere.

stimulus charge display

To avoid delivery of a stimulus charge different from the one intended, the stimulus charge selected by the user should be on display when stimulus delivery is initiated.

labeling

WARNING: HAZARDOUS ELECTRICAL OUTPUT, READ USER'S MANUAL BEFORE OPERATING. FOR USE ONLY BY A LICENSED PHYSICIAN PRIVILEGED TO ADMINISTER ECT. A COPY OF THE USER'S MANUAL SHOULD BE IMMEDIATELY AVAILABLE WHEN THIS DEVICE IS IN USE.

INFORMED CONSENT: It is incumbent on the treating physician to obtain the patient's written informed consent for ECT in full compliance with the laws of the state in which treatment is to be administered. Such informed consent routinely requires language suitable for patients to understand, assurance that the patient is capable of understanding the information about treatment, and a full and free explanation by the treating physician or his agent of the potential risks and benefits to be expected from ECT, the availability and risks of alternate treatments for the condition, and the risks of receiving no treatment at all. Patients receive a copy of the signed consent document and are advised that they may withdraw their consent at any time, verbally or in writing.

In addition to the explanations presented by the physician or his agent, the informed consent process is often augmented by educational materials. This includes presenting the patient with a printed information pamphlet on ECT and offering him and interested family the opportunity to view an informational video presentation about ECT.

4. Summary of Reasons for Recommendation.

The Somatics Thymatron ECT device has already been in functional class II during its entire lifetime of 25 years, during which its safety and effectiveness have been demonstrated as outlined above and in paragraph 5 below.

For the last 20 years the Thymatron device was certified by the German testing agency TÜV to IEC 60601.2.14, the internationally-accepted mandatory performance standard for the ECT device. That particular performance standard was withdrawn several years ago; following is a list of all FDA-recognized standards as published on www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm that the Thymatron meets (the first line of each entry is the recognition number of the standard, followed by its category, title, description, reference number, effective date, and issuing organization):

5-4

General

Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

60601-1 10/31/2005 IEC

5-32

General

Graphical Symbols for Use in the Labeling of Medical Devices

EN 980:1996+A1:1999+A2:2001 05/21/2007 CEN

5-35

General

Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004)

(AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 60601-1-2 09/09/2008 AAMI ANSI IEC

5-40

General

Medical devices - Application of risk management to medical devices

14971:2007 09/12/2007 ISO

5-44

General

Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems, sec

60601-1-8:2006 09/09/2008 IEC

3-30

Card

Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs

60601-2-25 Amendment 1 (1999) 07/25/2000 IEC

3-61

Card

Medical electrical equipment -- Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

Since 1998 the Somatics Thymatron ECT device has been subject to the special controls of post-market surveillance and vigilance as monitored and certified by KEMA Registered Quality, to the International Organization for Standardization (ISO) 9002 consensus standard. KEMA has included in its survey all Thymatron devices sold in the U.S., and FDA has historically incorporated international ISO consensus standards into special controls guidance documents for the purpose of reclassifying certain class III devices (e.g., the kneejoint patellofemoral prosthesis) to class II (Federal Register, 2003). KEMA is also one of the organizations accredited by FDA to conduct inspections of class II and class III manufacturing establishments.

5. Summary of valid scientific evidence on which the recommendation is based.

Efficacy of the Thymatron ECT Device

Scientifically-valid investigations across 4 countries in well over 600 patients found patients with major depression who were treated with a Thymatron ECT device enjoyed substantial, objectively-measured improvement in the relatively narrow range of 67% to 95%.

Williams et al (2008) used a Thymatron ECT device to administer 1.5 times threshold bitemporal ECT to 515 patients with DSM-IV unipolar major depression, obtaining a 68% reduction in Hamilton Depression scale scores at the end of their course of treatment.

Ranjesh, Barekatin, and Akuchakian (2005) randomly assigned 39 DSM-IV patients with major depression to receive courses of 8 bifrontal, bitemporal, or right unilateral ECT administered with a Thymatron ECT device. Blindly-obtained Hamilton Depression scale ratings at baseline and after the 8th ECT revealed 73% improvement for the entire sample, with no significant difference among the treatment groups.

Kho et al (2004) conducted a retrospective chart review study of the response of 57 patients with DSM-IV unipolar major depression to treatment with a Thymatron ECT device using age-based dosing. Hamilton Depression Scale scores obtained before and after a mean course of 7.2 ECTs showed 70.4% improvement, with a 67% remission rate achieved across the entire sample.

Heikman et al (2002) used a Thymatron ECT device to treat 24 DSM-IV patients with major depression who were randomly assigned to high-dose right unilateral ECT, moderate-dose right unilateral ECT, or low-dose bifrontal ECT. Blindly-obtained Hamilton Depression scale scores at baseline and after the ECT course showed an overall 66% improvement, with the best improvement (73%) recorded for the high-dose right unilateral group.

In the multi-hospital NIH-funded CORE study Petrides et al (2001) used Thymatron ECT devices to treat 253 patients with unipolar major depression with bilateral ECT at 50% above threshold. The overall remission rate for the sample as determined by blindly-obtained Hamilton Depression Scale ratings was 87%, with patients with psychotic depression enjoying a remarkable 95% remission rate, compared with 83% for patients with non-psychotic depression.

Abrams, Swartz, and Vedak (1991) conducted a random-assignment, double-blind, controlled comparison of the antidepressant potencies of fixed-high-dose (378 mC) right and left unilateral ECT using a Thymatron ECT device in 30 patients who satisfied criteria for major depression with melancholia, of whom 19 received right-sided and 11, left-sided, ECT. Depression ratings were blindly obtained at baseline and immediately following the 3rd and 6th ECTs. Patients receiving left unilateral ECT showed an 85% improvement after 6 treatments, compared with only 70% for right unilateral ECT; left unilateral ECT worked faster later in the course.

Efficacy of ECT in general

Data from scientifically valid studies using the form of ECT (bitemporal) generally associated with the highest response rates demonstrate it to be a highly effective treatment for depression. The following table shows the results for bitemporal ECT only of the 6 large studies published in the modern era using structured diagnostic evaluation, systematic blind outcome assessment on a reliable observer-administered depression rating scale, and brief-pulse, square wave stimuli with specified dosage. The response rates achieved vary in a narrow range from 70% to 87.8% with a mean of 83.7% and demonstrate the reliably high efficacy of ECT in the treatment of depression.

RESPONSE RATES WITH BITEMPORAL ELECTROCONVULSIVE THERAPY

Study	Sample size	No. of responders	Response rate (%)
Kellner et al., 2006	394	346	87.8
McCall et al., 2002	37	27	73
Abrams et al., 1991	18	14	77.8
Sackeim et al., 1987a	27	19	70.4
Sackeim et al., 1993	50	35	70
Sackeim et al., 2000	50	16	80
<i>Total</i>	<i>546</i>	<i>457</i>	<i>83.7</i>

Since none of the studies included a sham- or drug-treated control group, however, the question arises whether this apparent efficacy might be merely a placebo effect. To clarify this point it is necessary to review several types of studies: Genuine vs. sham ECT in depression; ECT versus other FDA-approved treatments for depression (antidepressant drugs and transcranial magnetic stimulation); and comparisons of different forms of ECT in depression

1. Genuine vs. Sham ECT in Depression

The following sham ECT studies all satisfy strict methodological requirements, including random assignment to treatment groups and double-blind, objective, outcome assessments.

Freeman, Basson, and Crighton (1978) treated 10 patients with primary depression with either 2 genuine (bilateral, partial sine-wave) or 2 simulated ECTs during their first week of treatment, after which all patients received genuine bitemporal ECT for the remainder of the course. Mean scores on the Hamilton, the Wakefield, and the Visual Analogue depression scales after the first 2 treatments were significantly lower after genuine than after sham ECT, and patients in the sham ECT group ultimately received significantly more treatments prescribed by clinicians who were blind to group assignment.

Lambourn and Gill (1978) assigned 32 patients with psychotic depression to receive either 6 brief-pulse, ultra low-dose (only 10 joules) unilateral ECTs or an equal number of identical anesthesia inductions without the passage of electricity. Mean Hamilton rating-scale scores obtained 24 hours after the sixth treatment did not differ significantly for the 2 groups.

In the Northwick Park ECT trial Johnstone et al (1980) gave 70 patients with endogenous depression a 4-week course of 8 sine-wave bitemporal ECTs or 8 anesthesia inductions without electrical stimulation. Mean Hamilton depression scale scores after 4 weeks were significantly lower in the genuine ECT group by about 26 points. The advantage of genuine over sham ECT in this study was

most marked in the subgroup of patients with delusional depression (Clinical Research Centre, 1984), the most severely ill of all patients with depression.

West (1981) treated 22 patients with primary depression with courses of 6 genuine or 6 sham ECTs. The patients were blindly rated on both doctors' and nurses' rating scales, and were then switched to the alternate treatment if indicated. There was a highly statistically significant and clinically important improvement in the genuine compared with the sham ECT group, and 10 out of 11 sham ECT patients (but no genuine ECT patients) were switched to the alternate method, from which they derived the expected degree of improvement.

In the Leicestershire trial. Brandon et al. 1984 studied 95 patients with major depression who were allocated to up to 8 genuine bitemporal sine wave ECTs or 8 sham ECTs. A significantly greater improvement in Hamilton depression scale scores was seen in the genuine compared with the sham ECT group at 2 and 4 weeks. As in the Northwick Park trial above, the largest genuine ECT advantage occurred in the most severely ill patients—the subgroup of patients with delusional depression.

In the Nottingham ECT study, Gregory, Shawcross and Gill (1985) randomly assigned 60 patients with depression to sine-wave ECT with bitemporal or unilateral placement or to sham ECT. Both genuine methods were superior to sham ECT after 2, 4, and 6 treatments, as measured by the blindly-administered Hamilton and Montgomery-Asberg depression scales.

Thus, 5 out of 6 scientifically valid studies of simulated compared with real ECT in the treatment of depressive illness show both a statistically significant and clinically substantial advantage for genuine ECT in reducing depression scale scores during and immediately following the treatment course.

It is not surprising that the single study (Lambourn and Gill, 1978) that failed to show an advantage for real compared with sham ECT differs from all the others in having used brief-pulse, ultra low-dose (10 J) unilateral ECT as the "active" treatment. A similar low-dose technique using an even higher stimulus energy (mean = 18 J) was shown by Sackeim et al. (1987a) to be clinically ineffective for right unilateral ECT, the same application used by Lambourn and Gill (1978). Subsequent studies (e.g., Abrams, Swartz, and Vedak, 1991) amply demonstrated that unilateral ECT must be administered with high stimulus dosing to maximize efficacy.

Following a successful course of ECT it is standard practice to prescribe maintenance antidepressant medication to prevent relapse, for example with nortriptyline, lithium, or both. If this fails, continuation ECT may be tried, in which patients continue to receive an outpatient ECT treatment every 1 to 4 weeks. A problem with most of the efficacy studies reviewed above is that patients typically receive either no post-ECT maintenance therapy, or receive a variety of "doctor's choice" treatments, including both ECT and drugs, administered non-systematically. So it is also not surprising that evaluations performed weeks or months after completion of the acute ECT treatment course usually fail to show a significant advantage for ECT.

2. ECT vs. Other FDA-Approved Treatments for Depression

ECT versus Antidepressant Drugs

Folkerts et al (1997) randomly assigned 39 patients with major depression to receive either 2.5 times threshold unilateral ECT (N=21) or treatment with the FDA-approved antidepressant paroxetine (N=18). After 4 weeks there was a substantial and highly significant advantage for ECT over paroxetine: a 59% reduction in blindly-obtained Hamilton Depression Scale score for the ECT group, compared with only 29% for the paroxetine group.

Gangadhar, Kapur, and Kalyanasundaram (1982) studied 24 patients with primary endogenous depression who were randomly assigned to receive a course of genuine bilateral or sham ECT in conjunction with either placebo capsules or imipramine, 150 mg/day. The first 6 treatments were given over 2 weeks, after which genuine ECT plus placebo was found to be significantly superior to sham ECT plus imipramine in lowering blindly-obtained Hamilton depression scale scores. This neatly demonstrated the efficacy of genuine versus sham ECT as well as the superior efficacy of ECT over imipramine.

In a retrospective chart-review study Gagne et al (2000) identified 29 patients who received continuation ECT + antidepressant medication and compared them with 29 carefully-matched control patients who received only continuation antidepressants after initially responding to a course of ECT. Over a 4-year follow-up period the outcome was significantly better in the ECT + antidepressants group (93% likelihood of continuing without relapse or recurrence) than in those who received antidepressants alone (52% likelihood of continuing without relapse or recurrence).

ECT vs. Transcranial Magnetic Stimulation (TMS)

TMS, in which a magnetic field is applied to the head, is an FDA-approved treatment for major depression.

Eranti et al (2007) randomly assigned 46 patients with DSM-IV major depression to receive either a 15-day course of TMS to the left dorsolateral prefrontal cortex (n = 24) or a doctor's choice course of ECT delivered at 1.5 times seizure threshold (n = 22). Blindly-obtained Hamilton Rating Scale Depression scores at baseline and at the end of the treatment course showed significantly greater improvement in the ECT group, with 13 (59%) achieving remission compared with only four (17%) in the TMS group.

3. Comparison of different Forms of ECT in Depression

Proof of the efficacy of a given treatment is not limited to studies comparing that treatment with placebo or alternative approved active treatment. So long as scientifically valid methods are employed, efficacy can be demonstrated by studies that compare two different forms of a particular active treatment and find one form superior to the other.

One standard procedure for determining the stimulus dose for ECT requires preliminary testing of the patient's threshold for developing a seizure and then administering a stimulus dose at a particular multiple of that threshold. An alternate method administers a fixed stimulus dose, set high enough to ensure a well-developed seizure on the first application.

Moderately Suprathreshold vs. Fixed High-dose Unilateral ECT in Depression

McCall et al (2000) randomly assigned 72 patients with major depressive disorder to receive right unilateral ECT at either a moderately suprathreshold dose (mean = 136 millicoulombs, mC) or a fixed high dose of 403 mC. After an average course of 5.7 ECTs 67% of the patients receiving fixed high dose ECT responded, compared with 39% of those who received moderately suprathreshold dosing (p=.02), thus demonstrating the efficacy of fixed, high-dose ECT in the treatment of major depression.

In bilateral (bitemporal) ECT, one treatment electrode is placed on each temple, whereas in unilateral ECT both treatment electrodes are placed over the same side of the head, almost invariably the right hemisphere. Although it is abundantly clear that unilateral ECT is associated with fewer adverse memory effects than bilateral ECT, it remains to be determined whether unilateral ECT is clinically as effective.

Bitemporal vs. Right Unilateral ECT in Depression

Sackeim et al (1987) conducted a double-blind, random-assignment study comparing the relative efficacy of bitemporal and right unilateral ECT, both administered with just-above-threshold dosing. The two conditions did not differ in the duration of generalized seizures or in the number of treatments administered to achieve clinical response. In 52 patients with primary major depressive disorder, bilateral ECT was markedly and significantly superior to right unilateral ECT in reducing blindly-obtained Hamilton Rating Scale scores for depression, thus demonstrating the efficacy of just-above-threshold bitemporal ECT as a treatment for major depression.

4. Comparison of ECT in Different Forms of Depression

Proof of the efficacy of ECT can also come from scientifically-valid studies that demonstrate a differential response rate to ECT of different forms of the same illness. Demonstrating that one form of an illness responds significantly better to ECT than another confirms the efficacy of ECT in the responsive form.

In the study of Petrides et al (2001) cited above, patients with psychotic depression (i.e., uniformly severe major depression) exhibited a significantly greater remission rate with bilateral ECT than patients with non-psychotic depression, thus demonstrating that bilateral ECT is an effective treatment for major depression that is so severe it is psychotic.

Thus, numerous and varied scientifically valid studies in patients with major depression provide a definitive answer to the question raised in the opening paragraph of this section as to whether the reported great efficacy of ECT might be only a placebo effect: ECT clearly is more effective than placebo. The data summarized above further demonstrate that ECT is a reliable and substantially efficacious treatment for major depression, and that its results in treating this disorder compare very favorably with other FDA-approved treatments for major depression, especially when severe.

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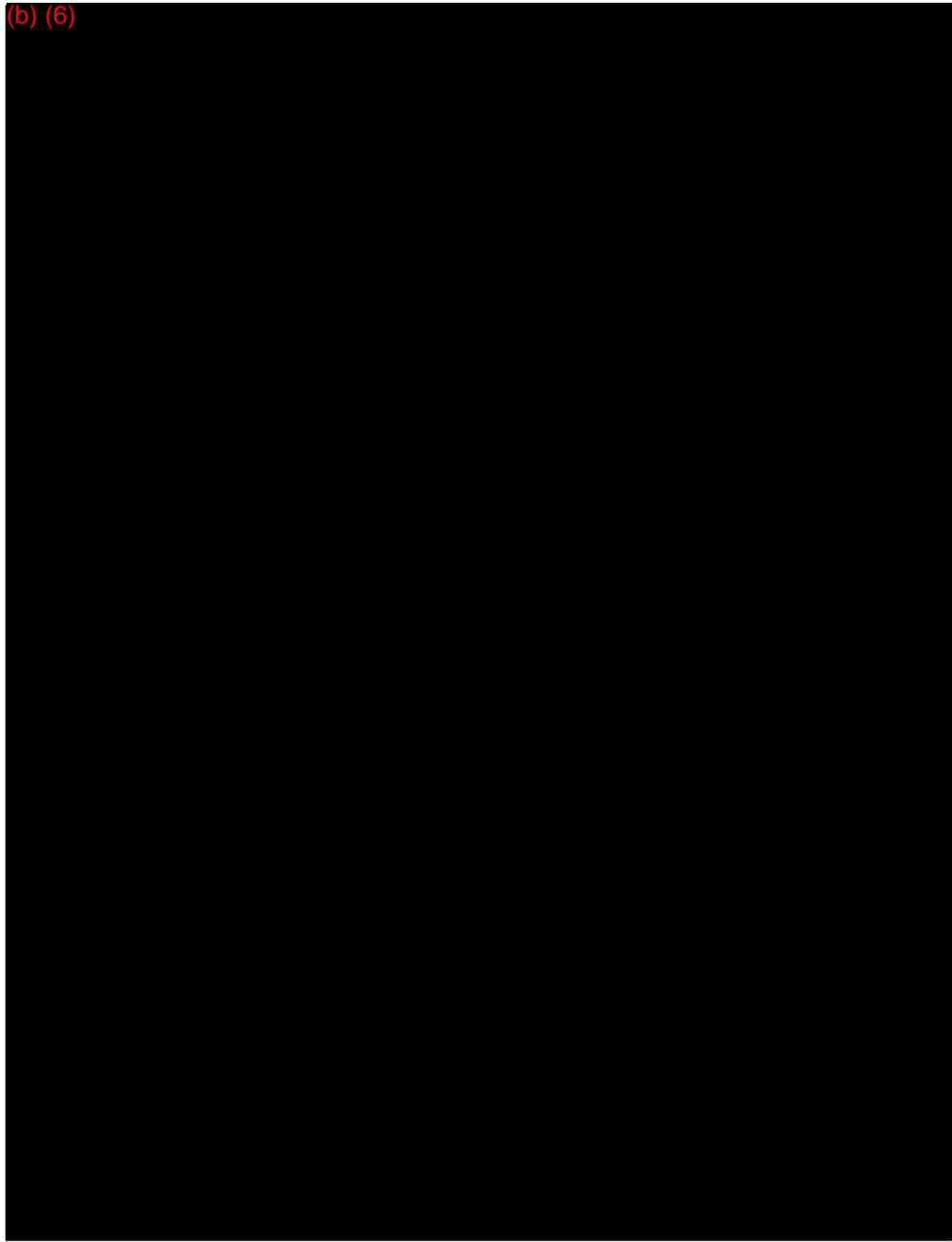


EXHIBIT 7

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COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SANTA BARBARA
ANACAPA DIVISION

ATZE AKKERMAN and ELIZABETH AKKERMAN,

Plaintiffs,

vs. CASE NO. 01069713

JOSEPH JOHNSON, SANTA BARBARA
COTTAGE HOSPITAL and DOES 1-20,

Defendants.

VIDEOTAPE DEPOSITION OF
HAROLD SACKeim, PH.D.
JAMAICA, NEW YORK
MARCH 14, 2004
10:00 A.M.

ATKINSON-BAKER, INC. COURT REPORTERS
330 North Brand Boulevard, Suite 250
Glendale, California 91203
(818) 551-7300

Nancy Anne Flynn, RPR
FILE No.: 9E021D0

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SANTA BARBARA
ANACAPA DIVISION

ATZE AKKERMAN and ELIZABETH AKKERMAN,

Plaintiffs,

vs. CASE NO. 01069713

JOSEPH JOHNSON, SANTA BARBARA
COTTAGE HOSPITAL and DOES 1-20,

Defendants.

VIDEOTAPE DEPOSITION of HAROLD SACKEIM, Ph.D.,
taken at Holiday Inn at JFK, 144-02 135th Avenue,
Jamaica, New York 11436, commencing at 10:00 A.M. on
Sunday, March 14, 2004, before Nancy Anne Flynn, RPR.

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I N D E X

WITNESS: HAROLD SACKEIM, Ph.D. PAGE
EXAMINATION BY MR. MOXON 6

E X H I B I T S

#	DESCRIPTION	PAGE
1	Document Request and Deposition Notice.	13
2	Correspondence file.	21
3	Invoice from Dr. Sackeim to Ms. Ramsey.	21
4	Folder of e-mails and attachments.	22
5	Objections of Defendant Johnson.	46
6	Group of e-mails.	52
7	Partial transcript of hearings before NYS Assembly, May 18, 2001.	59
8	Progress records January 14th, 2000, and January 17th, 2000. (Exhibits attached)	138

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0005

1 JAMAICA, NEW YORK; SUNDAY, MARCH 14, 2004, 10:15 A.M.
2 10:14:18 THE VIDEOGRAPHER: We are now on the
3 record, this is the video operator speaking,
4 Robert Calvert, and I represent Atkinson
5 Baker, Incorporated of Glendale, California.
6 I am a Notary Public, I am not financially
7 interested in this action, nor am I a
8 relative nor employee of any attorney of any
9 of the parties.
10 10:14:46 Today's date is March 14, 2004, the
11 time on the video monitor is 10:15 A.M.
12 This deposition is taking place at the
13 Holiday Inn at JFK, located at 144-02 135
14 Avenue, Jamaica, New York.
15 10:15:04 This case number is 01069713, entitled
16 Atze Akkerman and Elizabeth Akkerman versus
17 Joseph Johnson, Santa Barbara Cottage
18 Hospital and Does 1-20. The deponent is Dr.
19 Harold Sackeim. This deposition is taking
20 place on behalf of the Plaintiff. Our court
21 reporter today is Nancy Flynn with Atkinson
22 Baker.
23 10:15:33 Counsel please voice introduce
24 themselves and state whom they represent.
25 10:15:36 MR. MOXON: Kendrick Moxon for the

0006

1 Plaintiffs.
2 10:15:38 MS. RAMSEY: Patricia Ramsey on behalf
3 of Dr. Joseph Johnson.
4 10:15:44 MR. MCANDREWS: Tom McAndrews for
5 Santa Barbara Cottage Hospital.
6 10:15:47 MR. SKOGSBERG: Duncan Skogsberg on
7 behalf of Dr. Clinton LaGrange.
8 10:15:50 MR. LANGELAND: Eric Langeland with
9 Mr. Moxon.
10 10:15:52 MS. ANDRE: I am an ECT consultant for
11 Mr. Moxon, Linda Andre.
12 10:16:06 THE VIDEOGRAPHER: Will the court
13 reporter please swear in the witness.
14 10:16:14 HAROLD SACKEIM, Ph.D.
15 10:16:14 having been duly sworn by a Notary
16 10:16:14 Public of the State of New York,
17 10:16:14 testified as follows:
18 EXAMINATION
19 10:16:15 BY MR. MOXON:
20 10:16:15 Q Please state and spell your name.
21 10:16:17 A My name is Harold Sackeim,
22 S-a-c-k-e-i-m.
23 10:16:22 Q You've provided many depositions in
24 the past, right?
25 10:16:25 A Not many.

0064

1 11:29:16 Q Do you have any such documents?
2 11:29:19 A No.
3 11:29:19 Q Have you ever --
4 11:29:24 MR. MOXON: Why is it burdensome?
5 11:29:27 MS. RAMSEY: He answered -- those were
6 our objections. He answered he doesn't have
7 the documents, so go ahead.
8 11:29:35 Q Did you ever have any financial
9 interest in any manufacturer of ECT devices?
10 11:29:43 A Again, what do you mean by "financial
11 interest"? Do I own stock?
12 11:29:48 Q We'll start with that, investment
13 or --
14 11:29:52 A No.
15 11:29:52 Q -- stock?
16 11:29:52 A No, never.
17 11:29:53 Q Have you ever received any money from
18 any manufacturer of ECT devices?
19 11:29:58 MS. RAMSEY: What do you mean by
20 received -- well, objection, vague and
21 ambiguous.
22 11:30:02 Q Has a manufacturer of ECT devices ever
23 given you money?
24 11:30:07 MS. RAMSEY: Personally.
25 11:30:08 A I've received reimbursements and

0065

1 honoraria.

2 11:30:12 Q From whom?

3 11:30:13 A From who? From both manufacturers in
4 the United States.

5 11:30:17 Q MECTA and Somatics, Inc.?

6 11:30:21 A MECTA and Somatics, Inc., as well as
7 the new companies.

8 11:30:26 Q What is that?

9 11:30:27 A People like Neuronetics, Magstim.

10 11:30:32 Q You receive money from all of those
11 companies, all four of them, MECTA, Neuronetics,
12 Magsta?

13 11:30:41 A Magstim.

14 11:30:42 Q And Somatics?

15 11:30:45 A Yes, and a number of pharmaceutical
16 companies.

17 11:30:49 MS. RAMSEY: He's just asking you --

18 11:30:51 Q What's the total amount of funds that
19 you've received from the MECTA corporation in
20 reimbursements?

21 11:30:59 MS. RAMSEY: Objection, privacy,
22 financial privacy rights. If you want to
23 ask him percentage, just like --

24 11:31:07 MR. MOXON: Well, he's received money
25 from the manufacturer of the machine at

0066

1 issue in this case. That's quite relevant
2 and you can't say the money received from
3 them is private. Goes directly to his bias.
4 11:31:19 MR. MCANDREWS: May call for
5 speculation, though.
6 11:31:22 A The --
7 11:31:24 Q The question is, how much did you
8 receive in reimbursements from MECTA?
9 11:31:28 A In the -- again, you're not giving me
10 a time frame so I can't --
11 11:31:38 Q I know I'm not. Ever.
12 11:31:40 A Ever?
13 11:31:40 MR. MCANDREWS: Excuse me.
14 11:31:40 A Then I can't answer it.
15 11:31:42 MR. MCANDREWS: Excuse me. Then it
16 would be overbroad. Within a ten-year time
17 frame is a general question --
18 11:31:48 MR. MOXON: Ever is my question.
19 11:31:49 MR. MCANDREWS: Then I object as to
20 relevance.
21 11:31:51 MS. RAMSEY: He can't answer.
22 11:31:54 Q Can I have an answer, please?
23 11:31:57 A All I can tell you is that the total
24 amount for reimbursement, honoraria, whatever,
25 probably would come to less than 1 percent of my

0067

1 income.

2 11:32:10 Q I'll give my question again. How much
3 money have you received from MECTA for
4 reimbursements?

5 11:32:21 A Over my lifetime? I don't know, maybe
6 \$15,000.

7 11:32:26 Q How much in honoraria over your
8 lifetime have you received from MECTA Corporation.

9 11:32:32 A 20, 25,000.

10 11:32:33 Q What's that for, the honoraria?

11 11:32:38 A Honoraria are what academics get when
12 they make a speech, give a presentation, do a
13 training course.

14 11:32:49 Q So you've assisted MECTA to give
15 courses on their behalf and gotten honoraria --

16 11:32:56 A The other way around.

17 11:32:58 Q -- and gotten up to \$25,000.

18 11:33:00 A No, the honoraria has not been up to,
19 total lifetime. And I never agreed to do something
20 on their behalf or anybody else's behalf. It's
21 always on the condition that there's -- unrestricted
22 in terms of what can be done in teaching when I'm
23 teaching, lecturing when I lecture. So it's just
24 like Pfizer --

25 11:33:27 Q Okay, I understand. So MECTA has

0068

1 given you \$25,000 for giving speeches and seminars
2 about ECT?

3 11:33:37 A Oh, yes.

4 11:33:39 Q That's over what time period?

5 11:33:42 A Twenty-five years.

6 11:33:49 Q Have you received any money from MECTA
7 other than the \$40,000 for reimbursements and
8 honoraria?

9 11:33:58 A Yes.

10 11:33:58 Q For what?

11 11:33:59 A For consulting.

12 11:34:00 Q How much have you received for
13 consulting?

14 11:34:03 A Lifetime?

15 11:34:05 Q From MECTA, yes.

16 11:34:06 A I don't know, maybe 70,000.

17 11:34:12 Q Maybe more?

18 11:34:20 A Doubt it.

19 11:34:21 Q Have you reported this income to any
20 state or federal entity?

21 11:34:25 MR. MCANDREWS: Objection, relevance.

22 11:34:28 A It wasn't income, most of it. It was
23 given to the university, not to me. Recently, partly
24 because of my medical bills, I have accepted it as
25 income. And that is reported to the New York State

EXHIBIT 8

COPY

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FILED
SUPERIOR COURT OF CALIFORNIA
COUNTY OF SANTA BARBARA
JAN 05 2005
GARY H. BLAIR, EXCL. OFFICER
BY *Liane Campos*
LIANE CAMPOS Deputy Clerk

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SANTA BARBARA**

**ATZE AKKERMAN and ELIZABETH
AKKERMAN**

Plaintiffs,

vs.

**JOSEPH JOHNSON, SANTA BARBARA
COTTAGE HOSPITAL, et. al.**

Defendants

Case No.: 1069713
**STATEMENT OF DECISION ON
SUBMITTED ISSUES**

A twenty-five day jury trial in the above-entitled action concluded with a special verdict that contained findings that both defendant Joseph Johnson, M.D., and Santa Barbara Cottage Hospital had been negligent, respectively, in obtaining informed consent and performing the informed consent review of plaintiff, Atze Akkerman, before he underwent electro-convulsive therapy (ECT), but that neither defendant's negligence was a substantial factor in causing plaintiffs' harm. A court trial was then conducted on plaintiff's remaining claims for violations of California Business and Professions Code Sections 17200 and 17500. The matter was submitted and then re-submitted at the trial court's request following Judge de Bellefeuille's lengthy illness in the fall of 2004. The court now renders its decision as follows.

///

1 The Court finds in favor of plaintiffs on both remaining claims. An injunction shall issue
2 forthwith prohibiting the further conduct of ECT at Santa Barbara Cottage Hospital until the
3 defendant submits proof of correction in its protocol for the informed consent process and
4 informed consent review consistent with the Court's decision herein. Plaintiffs' request for
5 restitution is denied, for failure to show that plaintiffs suffered any out of pocket loss as a result
6 of defendant's wrongdoing, and failure to establish that any other ECT patient treated during the
7 same time period suffered an out of pocket loss. Damages are not available for such claims.
8 Plaintiffs shall recover their costs as prevailing parties.

9 10 FACTS

11 Beginning in 1999, plaintiff Atze Akkerman underwent a series of electro-convulsive
12 treatments for severe depression at Santa Barbara Cottage Hospital under the supervision of his
13 treating physician, Dr. Joseph Johnson. The evidence revealed that at the time of Mr.
14 Akkerman's treatment, both Dr. Johnson and Cottage Hospital were utilizing an out-dated and
15 incomplete informed consent form not authorized under the governing provisions of Welfare and
16 Institutions Code, sections 5326.2 through 5326.75. Though the California State Department of
17 Mental Health promulgated and disseminated a new informed consent form in 1998, and sent it
18 to the hospital, Darcy Keep, the hospital employee in charge of tracking such information,
19 testified that the hospital never received it. It was not perhaps until as late as May 2004, long
20 after Mr. Akkerman filed this suit, that the hospital began to use the 1998 form, and only as a
21 result of this suit. The hospital was not diligent in pursuing updated information from the
22 Department of Mental Health and, to this day, does not have in place any meaningful and
23 trustworthy procedure for doing so.

24 The form used by Dr. Johnson did not contain within it the facts (included in the 1998
25 model form that he should have used) that ECT could cause irreversible, permanent memory
26 loss, or that unilateral shocks cause less memory loss than the bilateral shocks plaintiff would
27 receive, or that there is a division of opinion as to the efficacy of ECT or how it works.
28

1 The Welfare and Institutions Code also requires that a patient contemplating ECT must
2 undergo an informed consent review process with a board certified or board eligible psychiatrist
3 or neurologist *before* receiving ECT. The uncontroverted evidence at trial revealed that the
4 hospital's designated doctor for this process was neither board eligible or certified during his
5 entire tenure at the hospital. Dr. Carlos Sluzki admitted in his testimony that he had conducted
6 hundreds of these informed consent reviews, signing a document *under penalty of perjury* on
7 each and every occasion that he was certified or eligible, *which is false*. Dr. Sluzki purported to
8 conduct the informed consent review for Mr. Akkerman prior to his first ECT treatment, but had
9 no independent recollection of the event.

10
11 Indeed, there was considerable confusion and uncertainty about how and when Mr.
12 Akkerman received the informed consent review from Dr. Sluzki prior to the administration of
13 the therapy. It may have happened when Mr. Akkerman was being wheeled into the operating
14 theatre. It may have happened *after* the treatment was administered. It may not have happened
15 at all. One thing alone is clear: the chaos and disorganization surrounding this procedure does not
16 meet the minimal standards contemplated by the Welfare and Institutions Code to protect the
17 rights of mental health patients who must decide whether to have ECT.

18 The hospital argues that it cannot be held responsible for its failure to provide the right
19 consent form, for the language of the statute speaks of the treating physician's duty to do so.
20 This argument is disingenuous, for the physician and the hospital act in concert to provide the
21 service to the patient. The hospital provides the forum and equipment. Its own policy manual
22 includes instruction on stocking consent forms and providing them to the doctors with privileges
23 at the hospital. Here the hospital undertook a duty and cannot pass the buck.

24 California's unfair competition law is a broad statute that prohibits any unlawful, unfair, or
25 fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. The
26 courts of California have narrowly construed advertising to include one-on-one representations.
27
28

1 The Court finds that the written representations in the informed consent review form signed
2 by Dr. Sluzki constitute an advertisement within the meaning of B & P Code Section 17500.
3 The Court further finds that the defendant Cottage Hospital knew the representations of Dr.
4 Sluzki were false, and yet allowed him to engage in the deceptions at hand. The Court does not
5 agree with the Hospital that this was "merely a technicality", as Dr. Sluzki is an accomplished
6 physician who happened to receive his medical training abroad in Argentina, a country that does
7 not share reciprocity of benefits with American doctors. The fact remains that under California
8 law, Dr. Sluzki was not qualified to determine Mr. Akkerman's capacity to intelligently and
9 comprehensively consent to ECT. It is not up to Cottage Hospital to determine that the law does
10 not apply to its employees.

11 The Court also finds that Dr. Johnson's use of an incomplete and erroneous consent form
12 likewise fell within the purview of 17200's sweeping consumer protections. His failure to
13 follow the dictates of the Welfare and Institutions Code constituted an unfair business practice.
14 It is not necessary for plaintiff to prove that he was harmed by the practice. To show that he was
15 deceived is sufficient for an adverse finding.

16 The defendant also disputes one of plaintiffs' major contentions- that ECT is a dangerous
17 modality that merits the close scrutiny of the law. Defense witnesses described it as "safe and
18 effective". Dr. Erickson, Dr. Sluzki's successor at the Hospital, denied knowing that there was
19 any considerable controversy in the medical community about ECT's value in treating mental
20 illness. Yet Dr. Johnson himself admitted in his testimony that no one understands how ECT
21 works to combat mental illness. It remains a mystery to the medical profession.

22 ECT has been utilized for many years, and some things are understood about it- the
23 potential side effects, which are enumerated in the Welfare and Institutions Code. Section
24 5326.2 mandates that the information required for a true informed consent shall include, in a
25 clear and explicit manner, a discussion with the patient of memory loss (including its
26 irreversibility) and that there exists a division of opinion as to the efficacy of the proposed
27
28

1 treatment, why and how it works and its commonly known risks and side effects. The
2 Akkermans did not receive this vital information from either Dr. Johnson or Dr. Sluzki.

3
4 In the second phase of the trial the plaintiffs introduced a survey conducted under the
5 auspices of Moore v. California State Board of Accountancy (1992) 2 Cal 4th 999, which the
6 court admitted over defense objection. The survey's purpose was to determine what it is that
7 people understand about the information provided by way of written consent forms (informed
8 consent) as well as verbal information given by the physician in conjunction with the written
9 information he or she provides relative to proposed psychiatric health treatments. The results
10 were instructive and not surprising. 49% of those polled wished, first and foremost, to be
11 advised of the potential risks and possible side effects of a treatment. 42% were concerned about
12 the specifics of the treatment and its effectiveness. A whopping 78% said they accept as
13 accurate the representations of their psychiatrist concerning the effectiveness of treatment
14 options; 76 % accepted the doctor's representations of the safety of the procedure. 70% of the
15 respondents said that their decision to receive the treatment would be affected by the second
16 opinion of the chief psychiatrist of the hospital regarding whether to have ECT. These results
17 underscore the high regard patients extend to doctors and the compelling need for full disclosure
18 of all known risks by the doctor to the patient, *regardless of the doctor's personal opinion on the*
19 *subject.*

20 The survey went on to ask respondents to interpret key phrases taken from the actual
21 consent form utilized by Dr. Johnson in his initial informed consent process with Mr. Akkerman.
22 In regards to the critical issue of memory loss the following statement from the form was
23 analyzed:

24 *"This treatment could have the following side effects and risks: memory loss lasting from an*
25 *hour or so after each treatment to spotty losses lasting for several months or years following a*
26 *series of treatments"*

1 56% of respondents agreed that the statement definitely or very likely included the possibility of
2 memory loss, but 62% believed it to be temporary rather than permanent. Only 22% read it as
3 suggesting permanent memory loss. The consent form used by Dr. Johnson was decidedly
4 misleading in this critical regard.

5
6 The Court finds further that the hospital has not cured the defects in its system sufficient to
7 avoid the imposition of the injunctive relief requested by plaintiffs. Darcy Keep states in her
8 declaration that the hospital is now using the correct consent form, and has in place a system for
9 communicating with the mental health rights advocate and the Department of Mental Health to
10 make sure that the hospital is in compliance with the law. Curiously, the consent form currently
11 in use by the hospital was not appended to her declaration. Further, the system she describes is
12 exactly the same one that failed in 1998. She claims to be the gatekeeper of information for the
13 hospital, but cannot explain why, for the last six years her employer has not kept abreast of
14 critical changes in the mandates of the law governing the use of ECT.

15 Furthermore, the Court is not convinced that Dr. Erickson has put in place an informed
16 consent review procedure that thoroughly complies with the dictates of the Welfare and
17 Institutions Code, particularly in light of his lack of experience in administering ECT and his
18 lack of knowledge of the law's requirements. He admitted in his testimony that he had never
19 read the Code until called upon to participate in this case as a witness. The Court lacks
20 confidence in the hospital's ability to self-police. There appears to be a strong likelihood that the
21 harmful practices at the heart of this suit will continue unless the Court issues the injunction as
22 requested.

23 THEREFORE the Court declares that Santa Barbara Cottage Hospital violated Business
24 and Professions Code Sections 17200 and 17500 from 1998 to May 2004. An injunction is an
25 appropriate remedy, for the harm complained of has not ceased and there is a significant risk that
26 it shall continue without on-going court supervision and intervention.
27
28

1 Santa Barbara Cottage Hospital is enjoined from engaging in the dissemination of inaccurate,
2 unlawful and/or deceptive information to its mental health patients who are considering ECT.
3 The hospital shall not permit an unauthorized person to perform the required inform consent
4 review, and must be in compliance with Welfare and Institutions Code Sections 5326.2 and
5 5326.75 in properly verifying that patients have received all of the information under the law
6 constituting true informed consent prior to receiving ECT.

7
8 Santa Barbara Cottage Hospital shall immediately cease providing ECT to patients, and
9 advise its attending physicians that the hospital has lost the right to perform such treatment.

10 Should the hospital wish to re-institute the practice of providing ECT, it must provide to
11 this Court the following items:

- 12 1. A copy of the current consent form proposed for use by treating physicians who wish to
13 utilize the hospital to perform ECT.
14
15 2. A written plan for on-going communications with the Department of Mental Health and
16 the patients' rights' advocates office in regards to on-going changes in the law
17
18 3. A written protocol on informed consent reviews for ECT to be utilized by the board certified
19 or eligible psychiatrist or neurologist who conducts said reviews. This protocol must include the
20 same information on risk factors as the model consent form and also contain a checklist
21 regarding the factors to be included in the doctor's determination of a patient's capacity to give
22 consent.

23 January 2, 2005

24 

25 Judge of the Superior Court
26
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EXHIBIT 9

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CERTIFIED COPY

ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
Plaintiffs,)
vs.)
MECTA CORPORATION, and DOES)
1-20,)
Defendants.)

Case No. 01-10362 RSWL (RZx)

VIDEOTAPED DEPOSITION OF ROBIN NICOL

AND

30 (b) (6) EXAMINATION OF MECTA CORPORATION

VOLUME I

PORTLAND, OREGON

NOVEMBER 18, 2004

ATKINSON-BAKER, INC.
CERTIFIED COURT REPORTERS
500 North Brand Boulevard, Third Floor
Glendale, California 91203
(818) 551-7300

REPORTED BY: HEATHER A. SUMMERS, CSR NO. 92-0246

FILE NO.: 9E09AFE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)

Plaintiffs,)

vs.)

Case No. 01-10362 RSWL (RZx)

MECTA CORPORATION, and DOES)
1-20,)

Defendants.)

Deposition of ROBIN NICOL and 30(b)(6) Examination of
MECTA Corporation, taken on behalf of the Plaintiffs, at Allen
Sheridan & McClanahan, 190 Southwest Harrison Street,
Portland, Oregon, commencing at 9:13 a.m. on Thursday,
November 18, 2004, before Heather A. Summers, CSR No. 92-0246.

A P P E A R A N C E S

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FOR THE PLAINTIFFS:

MOXON & KOBRIN
KENDRICK L. MOXON, ESQUIRE
3055 Wilshire Boulevard, Suite 900
Los Angeles, California 90010
(213) 487-4468

FOR THE DEFENDANTS:

LEWIS BRISBOIS BISGAARD & SMITH LLP
JOSEPH C. OWENS, ESQUIRE
221 North Figueroa Street, Suite 1200
Los Angeles, California 90012
(213) 250-1800

ALSO PRESENT: Gaabriel Becket, paralegal
Jay Webster, videographer

1 for identification.)

2 MR. MOXON: Swear the witness, please.

3 THE COURT REPORTER: I did.

4

5

EXAMINATION

6

BY MR. MOXON:

7

Q. Could you please state and spell your name for
8 the record?

9

A. Robin Nicol, R-O-B-I-N, Nicol, N-I-C-O-L.

10

Q. Ms. Nicol, you have given depositions before?

11

A. One.

12

Q. It was in the Rohovit case?

13

A. Yes.

14

Q. Have you had an opportunity to speak with your
15 counsel concerning the scope of the deposition?

16

A. Which deposition?

17

Q. This deposition.

18

A. Can you clarify "scope," what you mean by
19 "scope"?

20

Q. Did you talk to your attorney about the fact that
21 you're having a deposition and he told you what it
22 encompassed?

23

A. Yes.

24

Q. If there is any question, such as the one I just
25 asked you that you don't fully understand, please do have me

1 clarify it. I want to make sure we're on the same page. I
2 will assume that you've understood every question I've asked
3 you if you have answered it. Okay?

4 A. Fine.

5 Q. And we will need an oral response to every
6 question since we're making an verbatim transcript by an
7 authorized court reporter sitting to your left.

8 A. Fine.

9 Q. What is your position in the MECTA Corporation?

10 A. I'm the president.

11 Q. How long have you been the president?

12 A. Since 1987.

13 Q. Did you have a position prior to that?

14 A. I was the sales manager.

15 Q. From when to when?

16 A. From 1980 until 1987.

17 Q. Did you have a position before that?

18 A. No. We purchased the company in 1980.

19 Q. What are the scope of your duties as the
20 president?

21 A. I'm primarily administrative in terms of the
22 company. I manage all of the departments within the company.
23 I'm responsible specifically for 12 areas that I manage.

24 Q. Do you have any formal education?

25 A. I do.

1 Q. After high school?

2 A. I do.

3 Q. Please tell me what it is.

4 A. I have two college degrees. I have a Bachelor of
5 Arts in English and a Master of Arts in English.

6 Q. Do you have any electrical training or
7 electronics training?

8 A. No, I don't.

9 Q. Do you have any training in the health-care
10 field?

11 A. Other than the 26 years I have been the president
12 of the company, no, I don't.

13 Q. No formal training in any health-care field,
14 correct?

15 A. Correct.

16 Q. Do you have any training in any research fields?

17 A. Can you be more specific? Researching --

18 Q. Well, you don't have any formal training beyond
19 high school except in English, correct?

20 A. Educational training, correct.

21 Q. Yes. Thank you. Can you tell me -- well, let me
22 ask you first, are you testifying now solely on your own
23 behalf or also on behalf of MECTA Corporation?

24 MR. OWENS: Well, that's a legal question. I'm going
25 to object on that basis. She has no foundation to answer

1 MR. MOXON: Could you read the question back to the
2 witness?

3 (The record was read as follows:

4 Q. After you read the complaint, were you
5 surprised by the allegations in the complaint
6 indicating that a number of writers and
7 practitioners of shock treatment in the
8 '40s and '50s stated the purpose of it in part
9 is to cause brain damage and to cause memory loss?)

10 Q. (By Mr. Moxon) Could you answer, please?

11 A. It is a ludicrous complaint. One would not
12 create a medical -- it would not happen in responsible medical
13 -- with a responsible medical community --

14 Q. I couldn't agree with you more.

15 A. -- under the auspices of the AMA.

16 Q. I couldn't agree with you more.

17 A. It is a very --

18 MR. OWENS: Just a minute. Ms. Nicol, you have
19 answered the question.

20 THE WITNESS: Right.

21 MR. OWENS: You are engaging in conversation with
22 counsel. That's not what this is.

23 THE WITNESS: Right.

24 Q. (By Mr. Moxon) So when you saw allegations in
25 the pleading that articles had been written indicating that

1 the purpose of ECT was to cause brain damage, you consider
2 that too ludicrous to consider?

3 A. As I said earlier, I don't accept that premise.

4 Q. I know.

5 A. I don't accept that premise.

6 Q. I know. But you consider it too ludicrous to
7 even consider that that might have been true?

8 MR. OWENS: The question is vague as to time.

9 Q. (By Mr. Moxon) Answer?

10 A. In an environment with medical -- M.D.s, I would
11 find that impossible to believe.

12 Q. I take it you didn't read any of the shock
13 literature written in the 1940s and 1950s; is that right?

14 MR. OWENS: At what point in time?

15 Q. (By Mr. Moxon) Ever.

16 A. I'm aware of it, as I said earlier. I'm aware of
17 excerpts from it. I have never read it. I have never read
18 it. I'm aware, very aware of it, but I have never read it.

19 Q. During the 1980s were you aware that there was
20 literature in the 1940s and 1950s indicating that the purpose
21 of ECT was to cause brain damage?

22 A. I would have been aware of that, again, but it's
23 a very fringe perspective.

24 Q. You rejected that, correct?

25 A. I was aware of it.

1 Q. You rejected it?

2 A. In terms of what? Rejected it?

3 Q. Rejected it in terms of finding out if there was
4 any truth to it?

5 A. Based on the work that was done by the clinicians
6 in the field and the research that was done that I mentioned
7 earlier, it was rejected in terms of science, in terms of the
8 work that's been done from 1980 to the present. So we had to
9 accept that research as it was the majority.

10 Q. In the 1980s were you aware of the articles
11 written in the 1940s and 1950s indicating that the purpose of
12 shock treatment was also to cause memory loss, i.e., that the
13 quote, "therapeutic effect," end quote, of shock treatment was
14 memory loss?

15 A. Once again, I wouldn't accept the premise.

16 Q. I didn't ask you if you accepted it, Ms. Nicol.
17 I simply wanted to know if you were aware of it?

18 A. Again, I was aware of it, but I would never have
19 read the articles.

20 Q. Did you conduct any investigation or research to
21 determine if the representations that the purpose of shock
22 treatment was to cause memory loss was accurate?

23 A. MECTA does not do research.

24 Q. The answer is no?

25 A. The answer is no.

1 Q. Now, neither John Friedberg, Peter Breggin or
2 Peter Sterling were physicians in the 1940s and 1950s. These
3 were articles written by other practitioners -- did you know
4 that -- not those three?

5 A. These are your questions. I wouldn't know.
6 These are your articles. I wouldn't know. You would have to
7 identify the articles. That's the only way I would know.

8 Q. Okay. I take it you never examined the
9 bibliographies in Dr. Friedberg's book or Peter Breggin's book
10 indicating that scientific tests demonstrated that ECT caused
11 brain damage, correct?

12 A. I didn't read their books.

13 Q. Let me just modify my initial kind of
14 instructions and admonitions to you that I gave you at the
15 beginning. I'm asking you a number of questions because I
16 seek answers specific to my questions, of course. If you
17 could specifically answer my questions, I have no problem with
18 you making further comments or conclusions thereafter. But
19 it's going to take quite a long time if I need to repeat the
20 questions to get direct answers. And I'm not even asserting
21 that you're doing it intentionally, but I'm just asking you to
22 please listen carefully to my questions, and if you could
23 please directly answer my questions. Then if you want to give
24 further justification, I have no problem with that.

25 MR. OWENS: Well, Mr. Moxon, she is answering your

1 questions specifically. If you don't like her answers, that's
2 another issue. If anybody is being repetitive in this
3 deposition, it's you.

4 MR. MOXON: That is because she's not answering the
5 questions.

6 MR. OWENS: That is your opinion.

7 MR. MOXON: That's right. That is my opinion.

8 MR. OWENS: I'm not going to have you instruct my
9 witness to the effect that you're not answering the question
10 the way I want you to; please do so. That's not going to
11 happen.

12 MR. MOXON: Could you please read the last question
13 back to the witness, and when you do that, can you retype it
14 into the record at that point?

15 (The record was read as follow:

16 Q. I take it you never examined the
17 bibliographies in Dr. Friedberg's book or
18 Peter Breggin's book indicating that
19 scientific tests demonstrated that ECT caused
20 brain damage, correct?)

21 MR. OWENS: Assumes facts not in evidence.

22 THE WITNESS: My response is the same. I did not
23 read the books; therefore, I did not see the bibliographies.

24 Q. (By Mr. Moxon) Did anyone tell you that you
25 should disregard what you have characterized as the minority

1 view of ECT, the minority view being that it causes brain
2 damage and causes memory loss?

3 A. No.

4 Q. So it was a decision made by MECTA?

5 A. Correct.

6 Q. Did you see the list of articles that I provided
7 to your counsel in response to some of the discovery requests
8 in this case?

9 A. Yes.

10 Q. Do you know if you have copies of any of the
11 articles that were listed in those discovery requests?

12 A. Not with me. The articles that we produced I
13 would have at work.

14 MR. OWENS: That was not the question that he asked,
15 Ms. Nicol. He asked you about articles that he has identified
16 in discovery; not that we've identified in discovery.

17 Q. (By Mr. Moxon) Let me give it to you again. I
18 provided responses to some discovery that was issued by
19 Mr. Owens.

20 A. Okay.

21 Q. And I listed a number of articles which had
22 reference to, in my view, brain damage and memory loss, about
23 some 40 articles that were in medical journals. Did you see
24 that list?

25 MR. OWENS: I'm going to object to the question. It

1 that, and that percentage was debated.

2 Q. I'm sorry. I didn't understand your answer.

3 A. In the literature, that percentage varied widely.

4 So, yes, we noted that. We noted that.

5 Q. I just want to understand your question (sic) so
6 let me see if I can clarify this. You noted that there was a
7 wide variance in the percentage of the number of psychiatrists
8 who believed that ECT caused permanent memory loss?

9 A. Yes. Correct. Based on the research that we did
10 and the literature.

11 Q. What were the highs and lows or the variance in
12 what you read of the number of psychiatrists that believed ECT
13 caused permanent memory loss?

14 A. I can't tell you that. That was in 1979. I
15 would have to go back and look at that literature from 1979
16 because the percentages have changed markedly in the 26 years,
17 and I have focused on research as it becomes available, and
18 the numbers have decreased markedly, of course, as you know.
19 So there is very little impairment and cognitive effect now
20 compared to what was perceived as being memory impairment. So
21 I have been very cognizant of that.

22 Q. Really? How many people have you spoken to who
23 have personally had ECT?

24 A. I have spoken to patients.

25 Q. How many?

1 A. Five or six.

2 Q. Over the last 30 years?

3 A. Over the last 25 years. And I have spoken to
4 their families also.

5 Q. Did any of the patients who had received ECT tell
6 you whether or not they had memory problems?

7 A. In cases -- where I spoke with patients, they
8 were thanking us for saving their lives. So I have spoken
9 with patients who are very grateful.

10 Q. Let me ask you the question I asked you again.
11 Did you talk to any of those five or six people over the last
12 25 years who indicated to you whether or not they had memory
13 problems arising out of their ACT?

14 A. And my answer would be they did not mention
15 memory problems.

16 Q. Did you ask them?

17 A. No, I did not.

18 Q. Have you ever received any letters of complaint
19 from any ECT practitioner that ECT harmed a patient?

20 A. Can you be more specific?

21 Q. Yes. Have you ever received any letter of
22 complaint from any practitioner of shock treatment that the
23 treatment harmed a patient?

24 A. In what way? Can you define "harm" in your
25 vernacular?

1 Q. Just a minute. You don't consider broken bones
2 from ECT to be an adverse effect from ECT?

3 A. I believe they're considered to be adverse
4 effects because they're not -- this doesn't happen with the
5 modified ECT that we have been giving for 26 years with muscle
6 relaxants, anesthetic, and the patient being oxygenated by an
7 anesthesiologist with a muscle relaxant that can occur.

8 Q. Is a broken bone an adverse effect? Would that
9 be an adverse effect or not?

10 MR. OWENS: The question is vague and ambiguous.

11 THE WITNESS: It would be, but it's not listed in any
12 of the professional textbooks on adverse effects by the
13 medical community.

14 Q. (By Mr. Moxon) How about broken teeth? Would
15 you consider that an adverse effect of ECT?

16 A. Yes, I would.

17 Q. That happens, doesn't it?

18 A. It's not listed, but I would consider it.

19 Q. That happens, doesn't it, from ECT? You're aware
20 that ECT causes --

21 A. It could happen.

22 Q. Let me finish my question. You're aware that ECT
23 and the convulsions caused by your machines causes people
24 sometimes to have broken teeth, correct?

25 MR. OWENS: When? The question is vague and

1 ambiguous as to time.

2 THE WITNESS: That would be a clinical occurrence
3 based on how the clinician was treating, but that could be an
4 adverse effect.

5 Q. (By Mr. Moxon) I'm not asking for a
6 justification. I'm just asking for yes or no. Are you
7 aware --

8 A. I believe I said yes two questions ago. I did.

9 Q. Let's just have the question clear. You're aware
10 that your machines sometimes cause people to have broken
11 teeth, right?

12 A. Yes.

13 Q. And you're aware that your machines cause people
14 sometimes to have permanent memory loss, right?

15 A. In what time frame? In the literature?

16 MR. OWENS: No. He's asking --

17 MR. MOXON: I'm asking --

18 MR. OWENS: Excuse me. If I may clarify.

19 THE WITNESS: As an adverse effect, correct?

20 MR. OWENS: No. He's not asking what adverse effects
21 are. He's asking if you are aware if these machines have
22 caused these various problems. Do you understand the
23 question?

24 THE WITNESS: I do understand the question.

25 Q. (By Mr. Moxon) Let me give you the question

1 again on the record. Are you aware that your machines cause
2 patients to have permanent memory loss?

3 MR. OWENS: Excuse me.

4 THE WITNESS: That can be a complication.

5 MR. OWENS: I have to get my objections in. I don't
6 know whether he's asking if your machines have caused these or
7 potentially can cause, and I don't know whether you
8 understand --

9 THE WITNESS: I don't.

10 MR. OWENS: -- the assumption. So the objection is
11 that it is vague and ambiguous.

12 Q. (By Mr. Moxon) It would actually help both
13 Mr. Owens and I out if you just listen to my question
14 carefully. I will try to make it as clear as possible. If
15 it's not clear I will clarify it. And then after you've
16 duplicated the question, then go ahead and give your answer.
17 Okay?

18 A. Right.

19 Q. Are you aware that your machines have caused
20 patients to experience permanent memory loss?

21 A. Yes.

22 Q. Do you consider that to be an adverse effect --

23 A. Yes.

24 Q. -- of shock treatment?

25 A. Yes.

1 Q. Do you have copies of any of them?

2 A. I don't.

3 Q. Have you read any of them?

4 A. At times I have seen them, yes, but I have not
5 kept the copies.

6 Q. Are you aware that this survivors group takes the
7 position that ECT is very harmful to patients?

8 A. Yes.

9 Q. Have you ever spoken to David Oaks?

10 A. No, I haven't.

11 Q. Have you ever made any effort to communicate with
12 the people that publish *Mind Freedom* --

13 A. No, I haven't.

14 Q. -- to see why they so vehemently assert that
15 their members have been gravely harmed by shock treatment?

16 A. I have not.

17 Q. Why not?

18 A. Again, we're very focused on what we do in terms
19 of the research and the literature that supports our products,
20 that it is a safe and effective treatment. We are very
21 convinced it is a safe and effective treatment given the work
22 that I have already produced to you in the form of five
23 textbooks, a substantial amount of manuals and articles. And
24 all of this indicates to us that it is a safe and effective
25 treatment. So I felt no need to go further other than relying

1 on science.

2 Q. And the stories and the reports of the actual
3 patients of ECT who say they have been severely harmed is not
4 in your view science?

5 A. It is not science in that regard.

6 Q. So it is disregarded by the company?

7 A. It is not disregarded, but that's not our role.

8 Q. Are you familiar with a group called ECT.org?

9 A. I have heard of them, yes.

10 Q. What have you heard about them?

11 A. That they are an antipsychiatry group.

12 Q. And they are an anti-ECT group, right?

13 A. Primarily I have just heard antipsychiatry.

14 Q. Have you ever looked on the ECT.org Web page?

15 A. No, I haven't.

16 Q. Have you communicated with any of the persons
17 that run ECT.org?

18 A. No, I have not.

19 Q. Why not?

20 A. Once again, I'm very focused on what we're doing.

21 And as this is considered a fringe organization by the
22 psychiatric community, there is -- there's nothing to be
23 gained. We're very focused on healing people and saving lives
24 and providing the psychiatric community with the safest
25 devices we can, and that's where our focus and energies lie.

1 Q. So if you had information that your devices
2 weren't as safe as they could be or that they weren't safe at
3 all, would that change your business?

4 A. It would have to be scientific evidence. It
5 would have to be proven. It would have to be controlled in
6 double-blind studies. Then, yes, I would be absolutely
7 interested.

8 Q. So 50 or a hundred individual patients said it
9 destroyed their memory; that wouldn't fit within the category
10 of the information that you would consider to change your
11 devices, correct?

12 MR. OWENS: The question is vague and ambiguous. It
13 is an incomplete hypothetical.

14 Q. (By Mr. Moxon) He's right. In the ECT.org
15 there's perhaps 200 people, 200 shock patients, who have
16 written in their personal stories about the results of their
17 shock treatment. Have you ever heard of that?

18 MR. OWENS: The question assumes facts not in
19 evidence. It lacks foundation.

20 Q. (By Mr. Moxon) It kind of does. I'm asking if
21 you have heard that.

22 MR. OWENS: Same objections. Go ahead.

23 THE WITNESS: No, I have not.

24 Q. (By Mr. Moxon) If you received credible reports
25 from 200 patients that weren't examined by any blind or

1 double-blind studies or not examined by any psychiatrist or
2 not examined by anybody but just reports from 200 former
3 patients saying that they were severely harmed by ECT, would
4 that have any effect on how you do business?

5 MR. OWENS: It is vague and ambiguous. It is an
6 incomplete hypothetical.

7 THE WITNESS: Certainly we would be very
8 compassionate. We know that in any medical environment there
9 is a risk/benefit, and when you make a choice to have a
10 therapy, any therapeutic -- any medical procedure, there is a
11 risk and there is a benefit.

12 Q. (By Mr. Moxon) So you balance --

13 A. There is a balance, and I'm sure with any medical
14 procedure there are what we would call failures and successes,
15 good experiences and bad experiences. And that's how I would
16 regard it. And I would regard it with compassion.

17 Q. But not enough compassion to actually acquire the
18 information to see what the balance should be?

19 MR. OWENS: The question is argumentative. It's
20 vague and ambiguous. Unintelligible.

21 THE WITNESS: Again, the science being done addresses
22 those issues. The goal, of course, is to eliminate any side
23 effect in terms of our devices, and that would be true in any
24 therapeutic -- any therapy for any medical procedure. That is
25 the goal.

1 Q. (By Mr. Moxon) What changes have you made in
2 your machines to eliminate permanent memory loss caused by the
3 machines?

4 A. We have made changes. There have been changes
5 over the last 20 years that have all decreased memory
6 deficits.

7 Q. So you have intentionally made changes in your
8 machines for the purpose of reducing memory loss caused by
9 ECT?

10 A. They have decreased memory deficits, yes,
11 features that we have introduced.

12 Q. What features have you introduced for the purpose
13 of lessening the memory loss that you know is caused by ECT?

14 A. In the last year we introduced a new parameter
15 set called Ultra-Brief, and I believe we produced a
16 document -- excuse me. Can I have a glass of water since I am
17 doing all of the talking -- an Ultra-Brief parameter set.
18 It's an Ultra-Brief ECT is what we call it, which uses much
19 lower pulse widths and in concert with titration it -- the
20 side effects are far less; the memory deficits are far less.

21 We have also developed a machine -- it is a pulse
22 waveform machine -- in 1980. The memory loss, the deficits,
23 are a third of the sinusoidal waveform. So you can bracket
24 from '80 to 2003 that we have worked very hard and diligently
25 on achieving this.

1 Q. We will get to these waveforms a little bit
2 later. Thank you for identifying them. Have you ever heard
3 of an Institute for Treatment in Psychiatry?

4 A. No, I haven't.

5 Q. Center for the Treatment - Psychiatry?

6 A. Perhaps. I'm not sure.

7 Q. It is a group that's organized by Linda Andre in
8 New York. Does that sound familiar?

9 A. Yes.

10 Q. And it is also an anti-ECT group?

11 A. Correct.

12 Q. Are you aware of any other treatments anywhere in
13 medicine that has at least three survivor groups adamantly
14 opposed to the form of the treatment?

15 A. I've not done --

16 MR. OWENS: The question assumes facts not in
17 evidence.

18 Q. (By Mr. Moxon) Answer?

19 A. I haven't done that kind of research.

20 Q. Well, do you know of any practice in medicine
21 other than ECT where there are survivor groups that seek to
22 oppose and legislate against the treatment?

23 A. I wouldn't know without researching it.

24 Q. So the answer is no?

25 A. The answer is no. Without researching it, yes.

1 Q. There are only two shock manufacturers in the
2 United States, correct?

3 A. Correct.

4 Q. You're one of them?

5 A. Yes.

6 Q. Aren't you curious to find out as one of the two
7 manufacturers in the country why there are victim groups
8 established to legislate against your machines?

9 MR. OWENS: Assumes facts not in evidence. It's
10 argumentative.

11 THE WITNESS: I'm not curious. I would be very
12 compassionate. But I also know, again, that in the
13 risk/benefit selections that people have to make there are
14 going to be some side effects over a 40- or 50-year period of
15 ECT being given and that certainly not all of it would be
16 given with our devices.

17 Q. (By Mr. Moxon) So you would be very
18 compassionate, you say?

19 A. Yes.

20 Q. What have you done in the exercise of this
21 compassion to communicate with any of the victims of your
22 machines?

23 MR. OWENS: That misstates the testimony. Assumes
24 facts not in evidence.

25 THE WITNESS: That is not our responsibility as a

1 medical-device manufacturer. We are responsible for our
2 medical devices. The physicians who treated those patients
3 would work with those patients. We are not responsible for
4 individual patients.

5 Q. (By Mr. Moxon) That's not your problem? That's
6 the psychiatrists' problem?

7 A. That is not our responsibility from the FDA
8 perspective or from our perspective as medical-device
9 manufacturers.

10 Q. Not your responsibility?

11 MR. OWENS: Wait a minute. She has answered the
12 question. You are being argumentative. Go on to the next
13 question.

14 Q. (By Mr. Moxon) Do you know why these victims
15 groups were established against ECT?

16 A. No, I don't.

17 Q. Have you had any curiosity over the past 25 years
18 to learn why some victims of ECT established groups to attempt
19 to legislate or control the practice?

20 MR. OWENS: Assumes facts not in evidence.

21 THE WITNESS: Of course it would be of interest, but
22 I haven't done that. I haven't researched it.

23 Q. (By Mr. Moxon) And why is that?

24 MR. OWENS: Same objection.

25 THE WITNESS: Objection?

1 MR. OWENS: I said same objection.

2 Q. (By Mr. Moxon) Why is that?

3 A. Because it's not in the purview of my ownership
4 of a medical-device electronics company. I'm very focused on
5 the device, making it the safest and most effective device I
6 can as an owner.

7 Q. You are more interested in the business end of
8 ECT, correct?

9 MR. OWENS: Object.

10 Q. (By Mr. Moxon) That is your focus?

11 MR. OWENS: Argumentative and vague.

12 THE WITNESS: I'm interested in providing a safe and
13 effective device for psychiatrists to use to heal people.

14 Q. (By Mr. Moxon) Do you know why in the state of
15 California there is only one medical treatment that has a
16 legislated form of standardized informed consent?

17 MR. OWENS: Assumes facts not in evidence.

18 THE WITNESS: No, I don't.

19 Q. (By Mr. Moxon) Did you know that you can't have
20 ECT in California without signing a very specific consent
21 form?

22 A. Yes, I was aware of that.

23 Q. Do you have any idea why?

24 A. No, I don't.

25 Q. Do you have any curiosity why the state would

1 require a specific consent form to be signed by a person
2 before they have this treatment?

3 MR. OWENS: It's argumentative.

4 THE WITNESS: No, I don't.

5 Q. (By Mr. Moxon) Did you ever hear that the city
6 of Berkeley banned ECT at one point in the '70s?

7 A. I remember that.

8 Q. Did you look into that at all?

9 A. Yes, that is one of the things that we researched
10 when we purchased the company.

11 Q. Did that give you any cause for concern?

12 A. No, it didn't. Again, it was a very tiny fringe
13 minority opinion at that time, in the 1970s in Berkeley.

14 Q. Did you see any of the anti-ECT demonstrations of
15 hundreds of people demonstrating against it in Berkeley?

16 MR. OWENS: Assumes facts not in evidence.

17 THE WITNESS: No, I wasn't there in the '70s. We
18 didn't own the company then.

19 Q. (By Mr. Moxon) Were you aware that that
20 happened?

21 MR. OWENS: Assumes facts not in evidence.

22 THE WITNESS: When did that happen? I'm not aware of
23 that.

24 Q. (By Mr. Moxon) In the 70s.

25 A. I wasn't aware of that.

1 Q. When the city of Berkeley banned ECT within the
2 city limits, is it your understanding that that was a minority
3 of persons that were interested in doing that?

4 A. It was a minority, assumed to be in the
5 psychiatric community and in the rest of the United States.
6 It was a minority opinion, if you will.

7 Q. But you did not --

8 A. It was not mainstream.

9 Q. Has you or your company made any effort to
10 solicit information from persons who have received ECT to see
11 whether or not they have been harmed?

12 A. No.

13 Q. Why not?

14 A. Again, that is not in the purview of our
15 company's responsibilities.

16 Q. That is a responsibility of the practitioners who
17 use your machines?

18 A. Correct.

19 Q. Now, you've paid money to Harold Sackeim as a
20 consultant, correct?

21 A. Correct.

22 Q. What did you pay him for?

23 A. As a consultant in some cases. In some case,
24 very few cases, he would travel, as would other physicians, to
25 speak in scientific meetings only. And because the community

1 damage, so no. The answer is no.

2 Q. (By Mr. Moxon) You're aware that many people who
3 have received ECT think that they have been caused brain
4 damage by ECT, correct?

5 MR. OWENS: Assumes facts not in evidence.

6 THE WITNESS: I'm aware there is a fringe minority
7 that believes that, a small group.

8 Q. (By Mr. Moxon) Do you think there is a fringe
9 minority of patients?

10 A. When you say "people," you need to be specific.

11 Q. Patients. I'm talking about patients, people who
12 have received ECT. Do you think that's --

13 A. I think it is a small.

14 MR. OWENS: Just a minute. You're not going to argue
15 with Mr. Moxon. Mr. Maxon is not going to argue with you.
16 It's not going to happen in this deposition.

17 Q. (By Mr. Moxon) I agree. Let me finish the
18 question. You used the term "fringe minority." Are you
19 referring to a fringe minority of commentators or fringe
20 minority of patients?

21 A. I will restate that. I would say small minority
22 of patients.

23 Q. Do you think the persons that have indicated they
24 received brain damage from ECT are lying?

25 MR. OWENS: Assumes facts not in evidence.

1 Speculation.

2 Q. (By Mr. Moxon) Is that your assumption?

3 A. Again, as we do not believe ECT causes brain
4 damage, the answer would be no.

5 Q. You don't think they're lying? You think they
6 are lying?

7 MR. OWENS: Same objections.

8 THE WITNESS: I do, because we don't believe brain
9 damage exists from ECT.

10 Q. (By Mr. Moxon) And if ECT patients have
11 indicated that immediately after the ECT they lost huge
12 chapters of their life, of the memory of their lives, do you
13 think that they're misrepresenting the truth?

14 MR. OWENS: Assumes facts not in evidence. It's
15 irrelevant.

16 Q. (By Mr. Moxon) Answer?

17 A. Yes.

18 Q. And have you talked to some of these people to
19 find out why they're saying these bad things about your
20 product that are untrue?

21 A. No, I have not.

22 MR. OWENS: Just a minute. It's argumentative.
23 We're going to take a break.

24 MR. MOXON: Let's take a lunch break. It is.

25 (Lunch recess taken at 12:20 p.m. to 1:31 p.m.)

1 Q. (By Mr. Moxon) Why is there a maximum amount of
2 voltage utilized by your machine?

3 A. Why would it be limited?

4 Q. Yes.

5 A. Because primarily we are a preamendment device.
6 We are -- the FDA has limited our maximum energy, limited our
7 maximums in all regards for safety and efficacy or safety and
8 effectiveness. So there would be a maximum number, of course.

9 Q. If the FDA didn't limit the amount of energy you
10 could use, would you use more in your machine?

11 A. No, we would not.

12 Q. So notwithstanding with the FDA does, you would
13 set a limit on the amount of voltage?

14 A. We would always set a limit, based again on the
15 literature and the research in the field.

16 Q. Would that be to prevent injury by the machines?

17 A. It would be for safety and effectiveness, yes; to
18 maximize that safety and effectiveness.

19 Q. Well, I don't understand your answer with respect
20 to effectiveness. Is there a voltage rate that is considered
21 more effective to a patient than another voltage rate?

22 MR. OWENS: Lacks foundation.

23 THE WITNESS: With any parameter, the decision would
24 be made based on the grandfathered, if you will, 1973 device,
25 the substantially equivalent designs of the four designs

1 following that, and the research that was current that we
2 would be constantly accessing.

3 Q. (By Mr. Moxon) So you can't really change the
4 electrical parameters, can you, because it has to be
5 substantially similar to a prior machine?

6 A. Correct.

7 Q. Well, as I understand it then the changes that
8 were made in the machine don't go to the electrical
9 parameters, correct?

10 A. Any changes that are made in the machine would be
11 consistent with the preamendment device.

12 Q. In terms of the electrical parameters?

13 A. Correct.

14 Q. And the purpose of the device, of course, is to
15 cause a grand mal seizure?

16 A. Correct.

17 Q. The position of your company is that there is a
18 therapeutic effect from shock treatment, right?

19 A. Correct.

20 Q. It has a therapeutic effect?

21 A. Yes.

22 Q. Is that therapeutic effect caused by the
23 convulsion?

24 A. The mechanisms of ECT.

25 Q. Is that alleged therapeutic effect caused by the

1 convulsion?

2 MR. OWENS: Lacks foundation.

3 THE WITNESS: It's caused by the mechanisms of ECT
4 that are caused by the convulsion, if you will.

5 Q. (By Mr. Moxon) Well, what are the mechanisms of
6 ECT that cause a therapeutic effect by virtue of a convulsion?

7 A. The convulsion causes many different things to
8 occur, and those are the theoretic mechanisms, if you will.

9 Q. So the therapeutic effect is not known?

10 A. There are numerous theories. They're well
11 understood in the world of neuropsychiatry, the
12 neuropsychiatric community. I just can't articulate them to
13 you.

14 Q. But they're theoretical?

15 A. They're very well-supported theories, yes.

16 Q. But they are still theories?

17 A. As with any medical procedure, yes.

18 Q. Well, I'm not going to argue that point with you.
19 You don't know then what the therapeutic -- what has an
20 alleged therapeutic effect by virtue of ECT, do you?

21 MR. OWENS: The question is vague, ambiguous, and
22 unintelligible.

23 THE WITNESS: Is that a question?

24 MR. MOXON: Yes.

25 MR. OWENS: Do you understand the question?

1 THE WITNESS: I do understand the question. And the
2 therapeutic effect is well understood.

3 Q. (By Mr. Moxon) Well, I asked you --

4 A. It is well understood in the clinical community
5 and we understand it, but we are not able to articulate it as
6 the clinicians would articulate those mechanisms to you
7 because they would be articulated by neuropsychiatrists, not
8 medical manufacturers of ECT devices. That wouldn't be our
9 role.

10 Q. So you're not able to articulate what the
11 therapeutic effect is of ECT, correct?

12 A. There are excellent articles and books on the
13 mechanisms of ECT --

14 Q. Ms. Nicol, I'm sorry but --

15 A. But they're in the clinical arena.

16 Q. I am just asking you --

17 MR. OWENS: Are you asking her by therapeutic effect
18 whether the ECT alleviates depression?

19 Q. (By Mr. Moxon) I will give you an example. You
20 have a broken bone and you set a bone and you put it back in
21 place and you know that when you put it back in place the bone
22 mends through a well-known mechanism. You know exactly how a
23 bone mends and heals. Okay?

24 Do you know what the purported therapeutic effect
25 is, the cause of a therapeutic effect, arising out of ECT?

1 to cause a convulsion?

2 MR. OWENS: Lacks foundation. It is an incomplete
3 hypothetical.

4 THE WITNESS: I can't agree with that question
5 because this doesn't send energy through the brain, as you
6 just expressed. It causes a convulsion.

7 Q. (By Mr. Moxon) Of course it does. The only way
8 a convulsion -- I don't want to argue with you. My question
9 to you is the convulsion is caused by electricity passing
10 through the brain, right?

11 A. Partially, yes.

12 Q. Partially? What else causes --

13 A. A small amount, correct.

14 Q. What else causes a convulsion other than the
15 electricity passing through the brain?

16 A. Nothing else.

17 Q. Okay. Is there any reason then to send more
18 electricity through the brain than is necessary to cause a
19 convulsion?

20 A. Yes.

21 Q. What's that?

22 A. In this case we had a preponderance of APA,
23 American Psychiatric Association, members, including task
24 force members, ask us to please increase the parameters on our
25 devices.

1 Q. Why?

2 A. The patients were not getting better. So we --
3 again, this was all based on research coming from numerous
4 centers in the U.S. And as we have always done, we used that
5 double-blind, peer-reviewed research to make that decision,
6 and we made it over five years.

7 Q. Correct me if I am wrong. As I understand your
8 testimony then a certain amount of energy is required for a
9 convulsion but a number of practitioners told you in their
10 view more energy was needed to cause a benefit?

11 A. Therapeutic response.

12 Q. Therapeutic response than just what causes the
13 convulsion?

14 A. Correct.

15 Q. Okay. Do you know what the point is of sending
16 electricity through a brain if it's not just to cause a
17 convulsion? Why? Why would you send electricity through a
18 brain beyond what's necessary to cause a convulsion? Do you
19 understand why?

20 MR. OWENS: The question is argumentative. It is
21 vague and ambiguous. Lacks foundation.

22 THE WITNESS: No.

23 Q. (By Mr. Moxon) Who made the decision to increase
24 the amount of energy the machine puts out? Who made that
25 final decision?

1 going to instruct her not to answer in an effort to expedite
2 the deposition. She can go ahead. Do you have the question
3 in mind?

4 Q. (By Mr. Moxon) I don't even have the question in
5 mind anymore.

6 MR. OWENS: Shoot away.

7 THE WITNESS: I don't. You will have to repeat it.
8 There has been too much discussion.

9 MR. OWENS: Fair enough.

10 Q. (By Mr. Moxon) When you heard that ECT had a bad
11 reputation, were you curious as to why?

12 A. Yes.

13 Q. What did you determine?

14 MR. OWENS: Asked and answered.

15 THE WITNESS: I determined that it was a fringe group
16 of people that felt that way and that it didn't represent the
17 mainstream medical community and the clinicians in ECT and
18 researchers that were the large, large majority of the
19 psychiatric community who believed in ECT.

20 Q. (By Mr. Moxon) Who told you that it was a fringe
21 group?

22 A. When?

23 Q. Or how did you come to believe that it was a
24 fringe group that had this bad impression of ECT?

25 A. It is just an assumption I have made based on

1 reading -- based on reading, based on literature, based on
2 impressions in the psychiatric community.

3 Q. As one of the two manufacturers of these devices
4 in the United States, were you curious to communicate with any
5 of the people of these which you concluded to be a fringe
6 group to see why they held this bad opinion of your business?

7 MR. OWENS: The question is vague and ambiguous.

8 THE WITNESS: I think we answered this this morning
9 also.

10 Q. (By Mr. Moxon) Humor me. I don't think I asked
11 it like that.

12 A. I think I said this morning -- and I will say it
13 again -- my focus was very specific in terms of running a
14 company and being very concerned about developing products
15 that were safe and effective. So I wasn't -- and I had also a
16 huge burden to work with the research and the developers that
17 are mainstream. So I didn't take the time to understand
18 because it wasn't in my purview. It wasn't within the job
19 description that I would have within my company as a
20 president.

21 Q. To talk to --

22 A. It just wouldn't be part of our focus.

23 Q. To talk to the detractors of ECT?

24 A. Correct.

25 Q. Do you know where Rex Hiatt lives?

1 THE WITNESS: Right. It doesn't address the claim.

2 Q. (By Mr. Moxon) Are there any governmental or
3 nongovernmental entities to whom you are required to send
4 reports concerning your machines, the manufacturer of your
5 machines, the effects of your machines, complaints, anything
6 relating to ECT or ECT machines?

7 A. Of course the FDA we would.

8 Q. What reports --

9 A. And --

10 Q. I'm sorry. Go ahead.

11 A. Requirements to file reports regarding the
12 machines, that would be the only organization in the United
13 States.

14 Q. What about the rest of the world?

15 A. To file reports, the European Union.

16 Q. Any others?

17 A. There are no others.

18 Q. What reports are required to be filed with the
19 FDA?

20 A. The only reports that would be required by the
21 FDA is if there were an adverse event. We would have to file
22 one form, an MDR, and that's it.

23 Q. Have you produced to me every single adverse
24 event report that you've filed with the FDA?

25 MR. OWENS: An MDR, in other words?

1 THE WITNESS: An adverse event.

2 Q. (By Mr. Moxon) If MDRs are the only one.

3 A. There haven't been any other than the one we
4 produced.

5 Q. So since 1980 there has only been one adverse
6 event that you reported to the FDA?

7 A. That was reported to us, correct.

8 Q. Are you required or were you ever required to
9 make any submissions to any state in the United States
10 concerning the sale of your machines?

11 A. No.

12 Q. Do you know if MECTA has ever had any
13 communication with the California Department of Mental Health?

14 A. No.

15 Q. How about the Oregon Department of Mental Health?

16 A. No.

17 MR. OWENS: No, you don't know or --

18 THE WITNESS: I don't know. I don't know. I would
19 have to go back and look at records in order to determine if
20 we had any contact over 26 years.

21 Q. (By Mr. Moxon) Do you sell machines in Asia
22 also?

23 A. Yes.

24 Q. Japan?

25 A. No.

1 placement, correct.

2 Q. Is it your understanding that your machine can
3 cure some ailment?

4 A. No.

5 Q. Do you represent that your machine can cure
6 anything?

7 A. No.

8 Q. Do you believe it can cure anything?

9 A. No.

10 Q. Then why do you market it?

11 A. Because endogenous depression can be alleviated.
12 There is no cure for it at this time.

13 Q. I guess it is not a disease then?

14 MR. OWENS: Well, wait a minute.

15 Q. (By Mr. Moxon) Is it a disease?

16 MR. OWENS: Lacks foundation.

17 Q. (By Mr. Moxon) Is depression a disease?

18 MR. OWENS: Lacks foundation.

19 THE WITNESS: It is considered a DSM criteria. It's
20 a category in the DMS.

21 Q. (By Mr. Moxon) Is it a disease?

22 A. I think the APA categorizes it as such.

23 Q. As a disease?

24 A. In the DSM the APA -- you would have to -- I
25 would have to resource that to give you that answer. And,

REPORTER'S CERTIFICATE

I, HEATHER A. SUMMERS, CSR. NO. 92-0246, Certified Shorthand Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

I further certify that I am not a relative or employee of any attorney or of any of the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of Oregon that the foregoing is true and correct.

Dated this 29th day of November 2004.



Heather Summers

HEATHER A. SUMMERS, C.S.R. No. 92-0246

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CERTIFIED COPY

ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
)
Plaintiffs,)
)
vs.)
)
MECTA CORPORATION, and DOES)
1-20,)
)
Defendants.)

Case No. 01-10362 RSWL(RZx)

VIDEOTAPED DEPOSITION OF ROBIN NICOL

AND

30(b)(6) EXAMINATION OF MECTA CORPORATION

VOLUME II

PORTLAND, OREGON

NOVEMBER 19, 2004

ATKINSON-BAKER, INC.
CERTIFIED COURT REPORTERS
500 North Brand Boulevard, Third Floor
Glendale, California 91203
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REPORTED BY: HEATHER A. SUMMERS, CSR NO. 92-0246

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

- - -

ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
Plaintiffs,)
vs.)
MECTA CORPORATION, and DOES)
1-20,)
Defendants.)

Case No. 01-10362 RSWL(RZx)

Deposition of ROBIN NICOL and 30(b)(6) Examination of
MECTA Corporation taken on behalf of the Plaintiffs, at Allen
Sheridan & McClanahan, 190 S.W. Harrison Street, Portland,
Oregon, commencing at 9:13 a.m. on Friday, November 19, 2004,
before Heather A. Summers, CSR No. 92-0246.

A P P E A R A N C E S

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11 ALSO PRESENT: Gorham Nicol
Jay Webster, videographer
12
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1 A. As I'm not a medical doctor --

2 Q. I'm asking you what you're referring to. Are you
3 referring to any other cognitive -- severe cognitive side
4 effects arising out of ECT other than memory loss and
5 confusion?

6 A. No.

7 Q. Are you aware of any other cognitive deficits
8 caused by ECT beyond memory loss and confusion?

9 A. No.

10 Q. If you're aware of potential serious cognitive
11 side effects caused by ECT, why didn't you endeavor to make
12 sure that every single patient who received ECT from one of
13 your machines was warned of its potential harms?

14 MR. OWENS: Asked and answered.

15 THE WITNESS: We warn regarding potential side
16 effects and memory impairment in our instruction manuals that
17 we provide. We also warn in our videotapes. The clinician
18 who counsels the patient prior to ECT uses these materials,
19 this instruction manual and our videotape, to counsel the
20 patient. In addition, that could mean making copies of those
21 sections, verbally working, teaching, counseling his patient.
22 In addition he has the opportunity to purchase the patients
23 and family materials from the University of Michigan or
24 Dartmouth and send them home.

25 Q. (By Mr. Moxon) I take it from your answer then

1 that you don't endeavor to provide it to the patient because
2 you rely entirely upon the physician or hospital to provide
3 any warning information to the patient; is that right?

4 A. That is because our device is sold, and we are
5 under the auspices of the FDA, and we cannot counsel the
6 patient or treat the patient.

7 Q. Is your answer yes?

8 A. My answer is yes.

9 Q. Now, you have mentioned this FDA again. Is there
10 some FDA regulation that prohibits you from providing
11 warnings, written warnings to patients?

12 A. We don't directly treat. The warnings are very
13 specific in the Federal Register regarding that. We are
14 medical-device manufacturers.

15 Q. Let me give you that question again. Is there
16 some FDA regulation that prohibits you from providing written
17 warnings to patients?

18 A. I would have to look at the Federal Register
19 again to determine if there is a prohibition.

20 Q. You're not aware of any, are you?

21 MR. OWENS: That is not what she said. That
22 misstates the testimony.

23 THE WITNESS: I would have to look at it. It is a
24 very extensive section.

25 Q. (By Mr. Moxon) You have been the president of

1 this company for 25 years. I'm asking you your personal
2 knowledge.

3 A. Right.

4 Q. Are you aware, without telling me if there is a
5 number -- I'm not asking you for a number. I'm asking if you
6 are aware of some federal regulation that prohibits you from
7 providing written warnings to patients?

8 A. I think it would be more likely in the domain of
9 the AMA and The American Psychiatric Association that -- where
10 the warnings may be. Psychiatrists would in their medical
11 practices treat their patients and want to provide that
12 material to their patients. That would be where the warnings
13 would be, in the domain of the medical community.

14 Q. Ms. Nicol, are you aware of any FDA regulation
15 that prohibits you from providing written warnings to
16 patients?

17 A. I believe I said I would have to review the
18 Federal Register again to determine if there is a warning.

19 Q. So the answer is no?

20 A. The answer is I'd have to review it. I can't
21 answer yes or no.

22 Q. Because you don't know?

23 A. I don't have it memorized. It is a very large
24 portion of the Federal Register.

25 Q. Let me ask you this question. Are you as you sit

1 here now, after having been the president of MECTA for 25
2 years, aware of any federal regulation which prohibits MECTA
3 from providing written warnings to patients?

4 MR. OWENS: Okay. Rick, this is the third, perhaps
5 fourth time you have asked this same question.

6 MR. MOXON: I agree. I have yet to receive an
7 answer.

8 MR. OWENS: She's told you she understands the FDA
9 prohibits it.

10 MR. MOXON: No, she didn't.

11 Q. (By Mr. Moxon) Are you adopting Mr. Owens'
12 testimony; you believe the FDA prohibits you? That's exactly
13 what I'm asking you. Is it your understanding that the FDA
14 prohibits you from providing warnings to patients?

15 A. Yes, it is. I just haven't been able to resource
16 that section --

17 Q. Okay.

18 A. -- in this.

19 Q. But you have read it in the past? You have read
20 somewhere where the FDA says you MECTA or you device
21 manufacturer, you're prohibited from providing written
22 warnings to patients?

23 A. Again, the answer is yes with the caveat that I
24 would need to resource that material.

25 Q. How long have you held that view, that the FDA

1 prohibited you from providing written warnings to patients?

2 MR. OWENS: Rick, this is so fundamental. Why are
3 you spending 30 minutes on it? MECTA can't practice medicine.
4 They can't contact patients.

5 MR. MOXON: Joe, please. This is completely --

6 MR. OWENS: This is a matter of law.

7 MR. MOXON: This is an improper objection. Now
8 you're just going to spin her off and she just repeats your
9 objections.

10 MR. OWENS: No. She has already said that, Rick.

11 Q. (By Mr. Moxon) I'm trying to get an answer to
12 the question. How long have you held the view that the FDA
13 prohibits you from providing written warnings to patients?

14 A. Since 1980 when we purchased the company.

15 Q. Is memory loss a side effect or direct effect of
16 ECT?

17 A. It's a side effect.

18 Q. What makes it a side effect?

19 A. It's an effect from the therapeutic effect of the
20 treatment. After the therapy is finished, completed there are
21 side effects. And it is the only side effect.

22 Q. How about brain damage?

23 A. Brain damage is not an effect from ECT. ECT does
24 not cause brain damage.

25 Q. It's your view that the articles that were

1 written in the 1940s and '50s and '60s indicating the ECT
2 causes brain damage were written by fringe psychiatrists?

3 A. It's my view that it is a small, very small
4 community of psychiatrists that are fringe.

5 Q. And the ones that wrote about brain damage in the
6 '40s and '50s were part of the fringe community also?

7 A. I would have to see those articles in the '40s
8 and '50s. I don't know what articles you're referring to.

9 Q. So you don't know whether or not those articles
10 were written by fringe psychiatrists or not?

11 A. That's correct.

12 MR. OWENS: She doesn't even know the articles were
13 written, Rick, other than your statement to her. You haven't
14 shown her the articles. The question lacks foundation.

15 MR. MOXON: She has answered it.

16 MR. OWENS: Well, yes, she has answered it, but the
17 judge still gets to rule on the question.

18 Q. (By Mr. Moxon) If you look at page 316 of the
19 instruction manual in front of you, M 00316, which is page 31
20 of the manual. The second paragraph, could you please read
21 that to yourself?

22 The bottom sentence -- actually, I will read the
23 whole thing. "In selecting a stimulus intensity some facts
24 should be kept in mind. The available evidence indicates that
25 a stimulus intensity that is barely above the seizure

1 necessary to cause a seizure or slightly above a seizure, it
2 could cause more serious cognitive deficits?

3 MR. OWENS: Well, it's now all those objections, plus
4 it's argumentative.

5 Q. (By Mr. Moxon) Answer?

6 A. 100 joules is a very responsible and low maximum
7 energy. The FDA has approved it.

8 Q. That is not responsive. Was it your intention
9 that the machine not necessarily be cranked up all the way
10 with each patient in order to lessen the cognitive deficits
11 that would be caused by too much electricity?

12 MR. OWENS: Same objections.

13 THE WITNESS: As I mentioned earlier, these are
14 parameter sets that will be selected by the clinician. It is
15 in their domain and their determination as to the energy that
16 they choose with each patient and what parameter selections
17 they choose. They would be the appropriate trained personnel
18 to determine what the cognitive effects are of their decision.

19 Q. (By Mr. Moxon) Did you understand my question?

20 A. Yes, I did.

21 MR. MOXON: Could you read the question back to the
22 witness?

23 Q. (By Mr. Moxon) Since you have understood it,
24 could you please answer it?

25 MR. OWENS: You have answered the question. It has

1 been asked and answered. Ask the next question.

2 MR. MOXON: Please read the question back to the
3 witness.

4 MR. OWENS: She has answered the question.

5 (The record was read as follows:

6 Q. Was it your intention that the machine
7 not necessarily be cranked up all the way
8 with each patient in order to lessen the
9 cognitive deficits that would be caused by
10 too much electricity?)

11 MR. OWENS: She has answered the question. Next
12 question.

13 MR. MOXON: She has not. She told me about what --
14 some clinicians make the decision. That had nothing to do
15 with my question. My question sought the intention of the
16 company, not what she thinks clinicians think. Can you please
17 repeat the question back to the witness. I would like a
18 direct answer, please.

19 MR. OWENS: This is the last time.

20 MR. MOXON: I hope.

21 (The record was read as follow:

22 Q. Was it your intention that the machine
23 not necessarily be cranked up all the way
24 with each patient in order to lessen the
25 cognitive deficits that would be caused by

1 too much electricity?)

2 MR. OWENS: It has been asked and answered.

3 Q. (By Mr. Moxon) Answer, please.

4 A. The clinician has to make that determination.

5 The FDA has designed the devices to be safe and effective with
6 the 100-joule limit. They make that decision. I cannot
7 evaluate nor can I dispense medicine as a medical-device
8 manufacturer.

9 Q. That is completely unresponsive. My question --

10 MR. OWENS: It is not going to be asked again, Rick.
11 If you have a problem, take it to the judge.

12 MR. MOXON: Read back the question to the witness.

13 MR. OWENS: No.

14 MR. MOXON: Please listen very carefully to the
15 question. If you're going to instruct her not to answer, I
16 will read it back one more time.

17 MR. OWENS: Well, if you want to use your seven hours
18 having the court reporter read back questions three or four or
19 five times, that's your prerogative.

20 MR. MOXON: She's not answering the question.

21 MR. OWENS: We are getting very close to that seven
22 hour time period.

23 MR. MOXON: Please read the question back to the
24 witness.

25 MR. OWENS: You can go ahead, but she's not going to

1 answer it again, Rick. I'm instructing her not to answer.

2 Q. (By Mr. Moxon) Ms. Nicol, you understand that
3 I'm asking what your intention was. And I don't care what the
4 FDA said. I don't care what you think a clinician thinks. I
5 don't care whose responsibility it is. I'm asking for the
6 intention of you and your company, nothing else with this
7 question.

8 MR. MOXON: Please read the question back to the
9 witness.

10 MR. OWENS: Did you understand that in responding to
11 the question?

12 THE WITNESS: That it was the intention of the
13 company?

14 MR. OWENS: He is asking you about the intention of
15 the company. When you responded to the question, were you
16 responding to that?

17 THE WITNESS: No, I was not.

18 MR. MOXON: Please read the question back to the
19 witness.

20 THE WITNESS: Joe, can we take a break?

21 MR. OWENS: We can.

22 (Recess taken at 10:20 a.m. to 10:37 a.m.)

23 Q. (By Mr. Moxon) Could you read back the
24 question, please.

25 (The record was read as follows:

1 Q. Was it your intention that the machine
2 not necessarily be cranked up all the way
3 with each patient in order to lessen the
4 cognitive deficits that would be caused by
5 too much electricity?)

6 THE WITNESS: As I would repeat again, it is not
7 in -- MECTA Corporation cannot make decisions for the
8 clinician. The clinician will make the decisions regarding
9 his or her choices of stimulus parameters and access the
10 cognitive effects. We are not licensed medical practitioners.

11 Q. (By Mr. Moxon) So you're still not answering
12 my question, but let me try to phrase it this way -- and I
13 will seek to move to compel an answer. After seven times I
14 give up.

15 Do you have any intention whatsoever -- do you
16 care, not to be pejorative, but do you care whether or not
17 practitioners use the full amount of electricity in their
18 machine with every patient?

19 A. We provide a range of parameters for the
20 clinician. It is -- all ranges are applicable and appropriate
21 determinations, and those determinations will be made by the
22 clinicians. So we provide them, they're appropriate, their
23 use can be determined by the clinical population or the
24 medical doctors.

25 Q. So basically it's not your concern whether or not

1 the physician uses more electricity than is necessary?

2 MR. OWENS: It is argumentative.

3 THE WITNESS: These are safe and effective limits
4 from one to 100 joules. They have been determined safe and
5 effective by the FDA for the last 25 years for four
6 generations of devices.

7 Q. (By Mr. Moxon) Ms. Nicol, I didn't ask you that.

8 A. So we feel very comfortable --

9 Q. I understand you have positions and you're fully
10 capable of articulating your view on things --

11 A. Right.

12 Q. -- but the only reason I'm here is to ask you the
13 questions I need answered.

14 A. Right.

15 Q. Is it of no concern to you what amount of
16 electricity the clinicians use with their patients?

17 MR. OWENS: It is asked and answered. It is
18 argumentative.

19 THE WITNESS: It is a concern, and we are -- we
20 provide our clinicians with these parameters because they are
21 appropriate parameters.

22 Q. (By Mr. Moxon) Why is it a concern? Is it
23 because if too much electricity is used or more electricity
24 than is necessary the patient can be harmed?

25 A. It is a concern that we have addressed by

1 submitting our devices to be tested and approved by the FDA,
2 and that concern was answered by their approvals.

3 Q. I didn't ask you anything about the FDA. I asked
4 you absolutely nothing about the FDA.

5 MR. OWENS: Rick, you really have to --

6 MR. MOXON: Please read the question back?

7 MR. OWENS: Rick, you have to cut back on the
8 argument.

9 MR. MOXON: You took her out to instruct her, I
10 thought, to answer the questions, but she's still refusing to
11 answer them.

12 MR. OWENS: Rick, don't argue with me; don't argue
13 with the witness. It's not getting us anywhere. It is not
14 appropriate to make statements like that on the record.

15 MR. MOXON: I will just keep repeating the question
16 until I get an answer. Please read the question back?

17 MR. OWENS: Well, you're not going to do that. She's
18 answering the question. You disagreed with the answer.
19 Badgering is not an appropriate approach. This is a fact
20 deposition. You are here to ask for factual information, not
21 for her to agree with your concepts and your statements.

22 MR. MOXON: That is exactly right. That is exactly
23 what we are here for. I'm here to get the intentions,
24 viewpoints, and facts of the company. I didn't ask her any
25 question about the FDA whatsoever. Completely unresponsive.

1 promote your product?

2 A. No.

3 Q. What was the purpose of sending the videos?

4 A. The purpose was to clinically teach. Much as the
5 instruction manual, to give our clinicians as much clinical
6 education as we can, and the basis for that would be to have
7 clinicians who understood the treatment, to teach the
8 treatment and to share that, either in videotape format or an
9 instruction format or in a textbook format.

10 Q. Did you want the clinicians to take the
11 representations as accurate?

12 A. Yes, I did. Yes, we did as a corporation.

13 Q. Yesterday we mentioned a lawsuit, Rohovit, a suit
14 in Iowa. Do you remember that?

15 A. Yes, I do.

16 Q. Is there any other litigation that has been filed
17 against MECTA other than the Rohovit suit and the instant
18 suit?

19 A. Yes.

20 Q. Tell me what that is.

21 A. I could give you the names of the plaintiffs. I
22 can't give you the dates exactly.

23 MR. OWENS: That is fine. Just give him the names.

24 THE WITNESS: I think you mentioned one yesterday,
25 which was Andre.

1 Q. (By Mr. Moxon) Linda Andre?

2 A. I believe you mentioned that yesterday. And, of
3 course, I mentioned Rohovit. And Torres.

4 Q. Spell it.

5 A. T-O-R-R-E-S. And Adam Chick, A-D-A-M, C-H-I-C-K.
6 And Tuch, T-U-C-H. And of course this.

7 Q. When was the Torres suit filed?

8 A. I can't tell you. I really would have to go back
9 and look. I don't have them memorized.

10 Q. Approximately.

11 A. Sometime in the '90s.

12 Q. Where was it filed?

13 A. I can't tell you that either.

14 Q. Do you have any papers at all --

15 MR. OWENS: We have produced that to you.

16 Q. (By Mr. Moxon) -- relating to that suit?

17 MR. OWENS: It has been produced.

18 Q. (By Mr. Moxon) Do you have any papers relating
19 to that suit?

20 MR. OWENS: It has been produced.

21 Q. (By Mr. Moxon) So I guess the answer is yes?

22 A. Yes.

23 MR. MOXON: Do you have a Bates number for it?

24 MR. OWENS: I can get it. Do you want me to?

25 Q. (By Mr. Moxon) What records do you have

1 concerning the Torres suit?

2 A. Very few records. Most of the records are in the
3 possession of my attorney.

4 Q. Who is that?

5 A. Bill Sheridan.

6 Q. What was that suit about?

7 A. I believe the claim was brain damage. Again, I
8 would have to look at the complaint.

9 Q. So it was filed up here in Oregon?

10 A. I can't tell you where it was filed. I can't
11 remember them. I haven't memorized them prior to this
12 deposition. I'm sorry.

13 Q. What happened to the case?

14 A. It was -- it did not go to trial. I think for
15 some -- there were reasons that it was settled. It -- there
16 was a legal issue. I'm not sure what the legal issue was.
17 I'm not an attorney.

18 Q. You settled the case?

19 A. No, we did not settle the case.

20 Q. Was it dismissed?

21 A. It was dismissed.

22 Q. Did you settle the Rohovit case?

23 A. Yes, we did.

24 Q. What was the amount of the settlement?

25 MR. OWENS: Well, I don't know whether that

1 settlement -- I haven't seen the agreement, and I don't know
2 whether it is confidential.

3 THE WITNESS: I think it is.

4 MR. OWENS: Do you know whether it is confidential?

5 THE WITNESS: I don't know, and I think we need to
6 know.

7 MR. OWENS: We don't know whether it is confidential,
8 Rick.

9 MR. MOXON: Okay. Well --

10 MR. OWENS: I'm not going to have her testify and
11 violate --

12 MR. MOXON: Are you instructing her not to answer?

13 MR. OWENS: -- violate the terms of an agreement
14 without knowing if it is confidential or not. Do you have any
15 information on that? Do you have a document, perhaps copy of
16 the settlement agreement?

17 MR. MOXON: I haven't seen it.

18 MR. OWENS: Well, she can't answer that question
19 without knowing more.

20 MR. MOXON: Are you instructing her not to answer?

21 MR. OWENS: Yes, without any proof by you that it is
22 not confidential.

23 Q. (By Mr. Moxon) When was the Adam Chick case
24 filed?

25 A. It also was in the '90s, I believe.

1 Q. Where was it?

2 A. Again, I can't tell you the location.

3 Q. Was it in Oregon?

4 A. No, I'm sure it wasn't, but I can't tell you
5 where it was, again.

6 Q. What was the nature of the suit?

7 A. I believe it was brain damage also.

8 Q. What happened to the suit?

9 A. It was dismissed.

10 Q. Was it settled?

11 A. No.

12 Q. And you identified -- do you have any documents
13 concerning the Adam Chick case?

14 A. I think they were produced.

15 Q. So you gave them to your attorney?

16 A. Yes, I did.

17 MR. MOXON: I haven't seen those, Mr. Owens.

18 THE WITNESS: I think --

19 MR. OWENS: There is no question. Okay?

20 Q. (By Mr. Moxon) What documents did you have
21 concerning the Adam Chick case?

22 A. I believe I produced those.

23 MR. OWENS: Well, the question is what documents do
24 you have relating to the Adam Chick case.

25 THE WITNESS: Again, my attorney would have those.

1 MR. OWENS: The question is not what your attorney
2 has, Robin.

3 THE WITNESS: Right.

4 MR. OWENS: The question is what documents do you
5 have?

6 THE WITNESS: I believe I produced everything that I
7 have.

8 Q. (By Mr. Moxon) What documents did you have?

9 A. I believe it was the complaint.

10 Q. Nothing else?

11 A. Nothing else.

12 Q. T-U-C-H?

13 A. Correct.

14 Q. Who was that?

15 A. That's the plaintiff, again. And I can't tell
16 you where that was filed. That was also in the 1990s.

17 MR. OWENS: You have answered the question.

18 Q. (By Mr. Moxon) What was the nature of the case?

19 A. What was the claim? I believe it was brain
20 damage. I would have to look at that again. I'm not sure. I
21 haven't looked at that.

22 Q. Is the case over?

23 A. It was dismissed.

24 Q. Not settled?

25 A. It was not settled.

1 Q. Who was your attorney on that case?

2 A. Bill Sheridan.

3 MR. OWENS: He represented MECTA in that case?

4 THE WITNESS: In each case --

5 MR. OWENS: No, no. The question is on Tuch.

6 THE WITNESS: Right. I can't tell you because the
7 insurance company would select an attorney to represent them.

8 MR. OWENS: Was that Bill Sheridan?

9 THE WITNESS: In each case the insurance company
10 would make that decision, and it would never be Bill Sheridan.
11 Bill Sheridan is our corporate attorney.

12 MR. OWENS: So Bill Sheridan did not represent the
13 company in the Tuch case?

14 THE WITNESS: That's correct. I misunderstood. That
15 is correct. Right.

16 Q. (By Mr. Moxon) Do you have any documents
17 concerning the Tuch case?

18 A. I don't, and I wasn't able to provide them to
19 Mr. Owens.

20 Q. Did you ask Mr. Sheridan to give you any of the
21 documents?

22 MR. OWENS: Hold on. It is attorney-client
23 privileged. Do you know whether Mr. Sheridan has any
24 documents regarding the Tuch case?

25 THE WITNESS: I don't. I don't know.

1 Q. (By Mr. Moxon) He represented you in that case
2 in some manner, correct, Ms. Nicol?

3 MR. OWENS: Well, that's vague.

4 Q. (By Mr. Moxon) Did Mr. Sheridan advise you with
5 respect to the Tuch case?

6 A. He is our corporate attorney. I would have to go
7 back and look at the records during that time, but I don't
8 have any records.

9 Q. Did Mr. Sheridan advise you with respect to the
10 Tuch case?

11 A. Our attorney at the time would have advised me --

12 Q. Who is that?

13 A. -- who the insurance company would have selected.
14 And since I don't have records, I can't tell you who that was.

15 Q. You don't know who the attorney was in the Tuch
16 case?

17 A. I do not.

18 Q. Have you made any effort to find out?

19 A. No, I haven't, because I don't have any records.

20 Q. Who was your insurance company?

21 MR. OWENS: Currently?

22 THE WITNESS: I'd have to look back.

23 MR. OWENS: Wait a minute.

24 Q. (By Mr. Moxon) Who was your insurance company in
25 the Tuch case that hired the attorney to represent you?

1 A. I don't have that memorized. I would have to go
2 look at that information.

3 Q. Have you changed insurance since the 1990s?

4 A. Yes, I have.

5 Q. So you do have records that would tell you who
6 the insurance company was?

7 A. That's correct.

8 MR. OWENS: In the 1990s?

9 THE WITNESS: In the 1990s.

10 Q. (By Mr. Moxon) Do you have records concerning
11 the case filed by Linda Andre against you?

12 A. I believe I produced -- well, I didn't produce
13 those. That's right. I think I have something.

14 MR. OWENS: The question, Robin, is not whether you
15 produced documents. The question is whether you have
16 documents with respect to the Linda Andre case.

17 THE WITNESS: I looked for a complaint and couldn't
18 find one.

19 Q. (By Mr. Moxon) Do you have any other documents?

20 A. I would have to look.

21 Q. You haven't looked yet?

22 A. I have looked and haven't found anything, but I
23 can look again because I do need to look further. I wasn't
24 able to locate a complaint.

25 Q. You have other places you can look?

1 A. I do.

2 Q. Do you have a copy of the complaint in the Torres
3 case?

4 MR. OWENS: We have produced it, Counsel, if that's
5 what you're curious about.

6 THE WITNESS: We have produced that, correct.

7 MR. MOXON: I may be wrong, Joe. I don't recall
8 seeing that, but I'm happy to be corrected.

9 MR. OWENS: We have produced it. If you go back to
10 your office and you don't find them, I am happy to provide
11 copies again.

12 MR. MOXON: Thank you.

13 Q. (By Mr. Moxon) Are there any arbitrations or
14 mediations that were filed with respect to alleged harm by
15 patients other than these suits that you have identified?

16 A. No.

17 Q. Have there been any claims which have been filed
18 against you or letters of complaint asking for compensation
19 which didn't go to litigation?

20 A. No.

21 Q. Was it your view that in each of the five cases,
22 the Andre case, Rohovit, Torres, Chick, and Tuch, that the
23 allegations of the complaints were false that the plaintiffs
24 received brain damage arising out of ECT from your machines?

25 MR. OWENS: Well, I'm going to object to the question

1 to the extent it assumes facts not in evidence. Go ahead.

2 You can answer.

3 THE WITNESS: Yes. My assumption was that the claim
4 was false as I don't accept the premise that ECT causes brain
5 damage.

6 Q. (By Mr. Moxon) That is your belief?

7 A. That's the belief of mainstream researchers of
8 ECT worldwide.

9 Q. Did you talk to any of these five people that
10 filed lawsuits against you to see why they felt that they had
11 been brain damaged by your machines?

12 A. No, I did not.

13 Q. Why not?

14 A. In most cases I was not available. I was not
15 even in the same state. They didn't go to trial. We had no
16 communication --

17 Q. Are you curious why --

18 A. In four of the six cases --

19 Q. Aren't you curious why at least six people now
20 have sued your company alleging serious harm and brain damage
21 arising out of your machines --

22 MR. OWENS: The question is argumentative. It is
23 vague and ambiguous. It is irrelevant.

24 Q. (By Mr. Moxon) Well, I didn't finish the
25 question. Aren't you curious as to why these people claim

1 they have been brain damaged by your machines enough to find
2 out what it is they're talking about?

3 MR. OWENS: It's argumentative.

4 THE WITNESS: Since it is not mainstream, not
5 accepted by the medical community, it is not a mainstream
6 philosophy, it's not proven in science by a very large
7 majority of the medical community, I would say that I'm not
8 curious because I would regard them as frivolous lawsuits.

9 Q. (By Mr. Moxon) You are a true believer?

10 MR. OWENS: Don't answer the question. It is
11 argumentative.

12 Q. (By Mr. Moxon) Do you have a philosophical
13 belief that ECT doesn't cause brain damage?

14 MR. OWENS: The question is vague and ambiguous.

15 THE WITNESS: No. I accept the research and the work
16 that is done by mainstream medicine in the United States and
17 around the world in all the major teaching hospitals and
18 leading university centers that ECT does not cause brain
19 damage.

20 Q. (By Mr. Moxon) So it's -- no point in arguing
21 with you or even commenting on it, I suppose. But it's your
22 position then that all the major universities all over the
23 world have found that ECT does not cause brain damage, flatly
24 does not?

25 MR. OWENS: Lacks foundation.

1 Q. (By Mr. Moxon) Correct?

2 A. I said mainstream community of researchers and
3 the majority, a very large majority.

4 Q. Have you seen any publication which flatly says
5 ECT does not cannot cause brain damage, any publication of any
6 type?

7 A. Yes, I have.

8 Q. Tell me what that is.

9 A. I'd have to go back, get you the reprints, the
10 articles.

11 Q. Tell me any one of the ones you claim that are
12 all over the world.

13 A. I don't have the articles memorized, but I can
14 provide them to you.

15 Q. Can you think of a single publication or author
16 who has flatly said unquestionably that ECT doesn't cause
17 brain damage?

18 A. Yes.

19 Q. Who?

20 A. But I can't give you the title of the article. I
21 can give you the author. Dr. Harold Sackeim is one.

22 Q. Okay.

23 A. I can get that information to Mr. Owens and he
24 can --

25 MR. OWENS: No. It is not your obligation to get

EXHIBIT 10

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To: Whom it may Concern:

My name is Kenneth Castleman. I have a PhD in Biomedical Engineering, which includes education in biology and medicine as well as engineering. I have served on the faculty at Caltech and The University of Texas at Austin and on the research staff at USC and UCLA. I was a senior scientist at the NASA Jet Propulsion Laboratory for fifteen years. I have served as a consultant to the National Institutes of Health, NASA, the USPTO, and the FBI. I am a fellow of the American Institute for Medical and Biological Engineering and a member of the Space Technology Hall of Fame.

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. However, basic principles of biology and physics demonstrate that this is not the case. 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. Further, the pulses alternate in polarity. That is, the right side electrode will be positive for one pulse and negative for the next pulse. A pair of pulses (one positive followed by one negative) make up one “cycle.”

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.”

Consider an example where the ECT pulse frequency is 50 Hz (i.e., 50 pairs of pulses in every second) and the treatment lasts for two seconds. One hundred pairs of pulses (one positive and one negative pulse in each pair) will be delivered, one pulse every 10 milliseconds. The “duty cycle” is the percentage of the time that the voltage is “on.” With the older sine-wave and square-wave devices, the duty cycle was 100% because the voltage was on all the time. With brief-pulse devices the duty cycle can be as low as 15% (1.5 msec pulses). With ultra-brief pulse devices the duty cycle can go as low as 3% (0.3 msec pulses).

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 joule is the amount of energy expended when one watt of power is consumed in one second. For example, a 100-watt light bulb will consume 100 joules of energy every second. One hundred joules is a common ECT dose level. If the treatment duration is one second, the patient is being treated like a 100-watt bulb. ECT dose can go as high as 200 joules. [1]

It is now more common to specify ECT dose level in millicoulombs. A millicoulomb is a specific number of electrons (approximately a six with fifteen zeros behind it). 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. [1, 2]

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 exact value is set according to the patient's age, with older patients receiving a larger dose because of the greater resistance of the skull to electrical flow. 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. [1, 2]

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. Further, electric circuits that switch on and off quickly are subject to "overshoot," where the voltage briefly goes beyond its correct value at the moment of switching.

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. [3]

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. [4, 5]

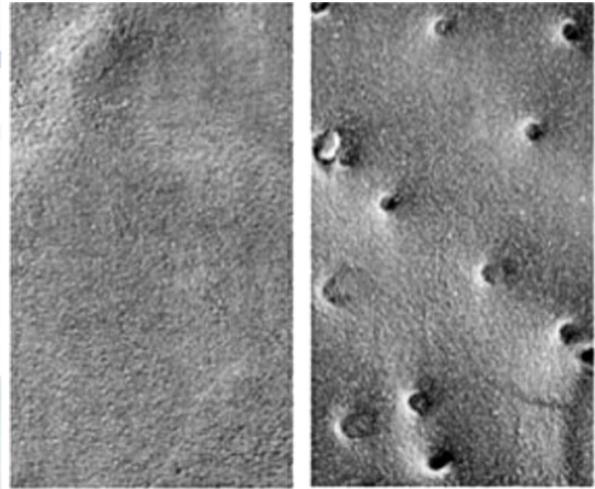
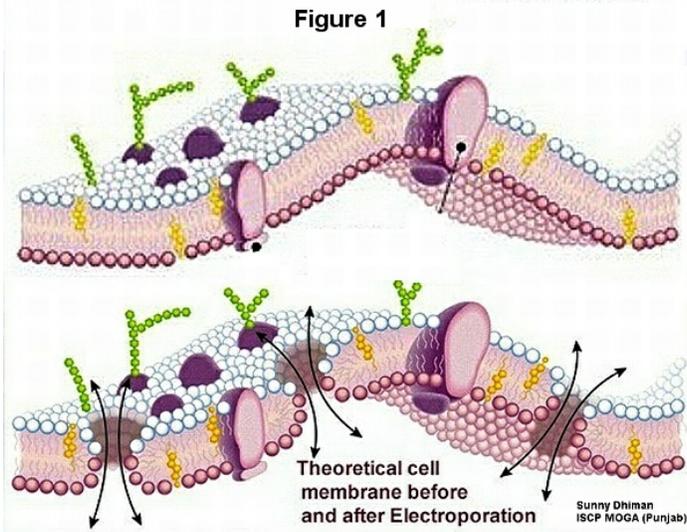
In summary, it is clear, just from basic principles of biology and physics, that the modern brief-pulse and ultra-brief pulse ECT devices inherently subject the patient to more pulses, with faster switching times, and to longer durations of treatment than the older devices. As a result, the risk of brain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

If seizure production is the therapeutic mechanism of ECT, then those seizures should be produced at minimum risk of brain damage to the patient. That is, with long duration (not brief) pulses and the accompanying fewer pulses and shorter treatment durations. Given the increased risk of electroporation, the newer ECT devices are potentially more dangerous than their predecessors. Note also, that the manufacturer's electrical parameters and adjustments call for dosages of 1.5 to 6 times that necessary to cause seizure, also increasing the risk of brain cell damage.

In short, it is my opinion that the "modern" ECT devices utilized from the 1980's to present, provide little or no reduction of total electricity delivered to the brain, but deliver it in a fashion that is potentially more harmful to brain tissue than the older devices.

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2. *Evidence Based ECT Technology* (Brochure, 2011), MECTA Corporation, 19799 SW 95th Avenue, Suite B, Tualatin, OR 97062 <www.mectacorp.com>.
3. John A. Pearce, "Comparative analysis of mathematical models of cell death and thermal damage processes," *International Journal of Hyperthermia*, **29**(4): 262-280, 2013.
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Electroporation



Cell Membrane Before Pulse

Cell Membrane During Pulse

Figure 2

Kenneth R Castleman

Kenneth R. Castleman, PhD

OPTIMIZED AND FULL SPECTRUM[®] DOSING PARAMETERS

NEW STANDARD OF CARE

NEW DOSING PARAMETER SETS OFFERING GREATER EFFICIENCIES AND WIDER TREATMENT RANGES

Pulse width, pulse frequency, train duration, and current (pulse amplitude) are the ECT stimulus parameters that radically determine the efficiency of stimulation.^{1,2} Now MECTA's newest, more efficient and flexible treatment options allow clinicians and ECT researchers a more extensive and optimized range of treatment parameters. Here's how:

OPTIMIZED DOSING Parameter Sets – 0.3, 0.5, 1.0 ms **NEW!** Evidence for Optimization

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.³ 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,³ 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.^{2,4} 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[™]/4000M[™] 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.

FREQUENCY In the 5000M[™]/4000M[™], pulse frequency is the parameter that is changed after train duration to increase dosage. It is firmly established that increases in stimulus frequency contribute to seizure induction since stimulus dose titration has often been conducted with stimulus frequency as the primary variable manipulated when incrementing dosing.^{5,6,7} The maximum frequency in the ultrabrief 0.3 ms parameter set is 120 Hz. At longer pulse widths (0.5 and 1.0 ms), maximum device output (576 mC U.S. devices) is achieved at lower pulse frequencies, resulting in a pulse frequency cutoff specific to each parameter set.

CURRENT Current or pulse amplitude is fixed at 800 mA in the OPTIMIZED 5000Q[®]/4000Q[™] parameter sets and all of the 5000M[™]/4000M[™] parameter sets. There is little published information on optimal pulse amplitude in ECT. The vast body of clinical research with MECTA devices has exclusively used the 800 mA setting, although there has been speculation that titration in the current domain* may ultimately prove superior in refining stimulus properties.^{2,8} MECTA provides the only device with flexibility and choice of pulse amplitudes. Indeed, the 5000Q[®]/4000Q[™] devices have an expanded range of pulse amplitudes in the new FULL SPECTRUM DOSING Parameter Sets. This range is from 500 to 900 mA. **NEW!**



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FULL SPECTRUM® DOSING Parameter Sets NEW!

The SPECTRUM 5000Q®/4000Q™ models now include a fourth parameter set that allows the experienced clinician or researcher to vary pulse width, train duration, pulse frequency and current independently throughout the full range of device parameters. Only with the SPECTRUM 5000Q®/4000Q™, FULL SPECTRUM DOSING Parameter Sets can be individualized and historical doses be selected and set, using the knob and visual interface without accessing menus. This enhances the efficiency of operation and allows the clinician and the researcher the greatest freedom in their choice of parameters.

TITRATION AND PRE-SELECTED DOSING TABLES

With these changes in optimized parameter sets, MECTA

has developed new Titration and Pre-Selected Dosing Tables. These are the most accurate and up to date tables, taking into account gender, age, and electrode placement.⁹

NEW! 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 pulse widths. Empirical titration remains the most accurate way to determine seizure threshold. MECTA provides extensive new and Historical Titration and Pre-Selected Dosing Tables for the OPTIMIZED and FULL SPECTRUM DOSING Parameter Sets. **NEW!**

Contact MECTA for pricing and upgrade information and also to order Pre-Selected and Titration Dosing Tables and/or a new MECTA Instruction Manual containing the instructions for using these new stimulus dosing parameters.

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ECT PARAMETERS / 100 JOULE SYSTEMS

Q Models

	OPTIMIZED DOSING Parameter Sets			FULL SPECTRUM DOSING Parameter Set
	0.3	0.5	1.0**	Set 4** NEW!
Four Parameter Sets:				
Pulse Width	0.3-0.37 ms	0.5 ms	1.0 ms	0.3-1.0 ms
Stimulus Duration	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec NEW!
Frequency	20-120 Hz	20-90 Hz	20-45 Hz	20-120 Hz
Stimulus Current	800 mA	800 mA	800 mA	500-900 mA NEW!
Charge	4.0-568 mC	8.0-576 mC	16-576 mC	3.0-576 mC
Energy @ 220 ohm patient impedance	0.8-100 joules	1.4-101.4 joules	2.8-101.4 joules	0.3-101.4 joules

M Models

	OPTIMIZED DOSING Parameter Sets			
	0.3	0.5	1.0**	NEW!
Three Parameter Sets:				
Pulse Width	0.3-0.38 ms	0.5 ms	1.0 ms	
Stimulus Duration	0.59-7.9 sec	0.35-8.0 sec	0.18-8.0 sec	NEW!
Frequency	20-120 Hz	20-90 Hz	20-45 Hz	
Stimulus Current	800 mA	800 mA	800 mA	NEW!
Charge	5-576 mC	5-576 mC	5-576 mC	
Energy @ 220 ohm patient impedance	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules	

*Patent Pending

**EEG Data Analysis enabled for use with 1.0 OPTIMIZED DOSING Parameter Sets and Historical Parameters in the FULL SPECTRUM DOSING Parameter Set.



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EXHIBIT 11

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OPTIMIZED DOSING Parameter Sets – 0.3, 0.5, 1.0 ms **NEW!** Evidence for Optimization

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.³ 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,³ 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.^{2,4} 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[™]/4000M[™] 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.

FREQUENCY In the 5000M[™]/4000M[™], pulse frequency is the parameter that is changed after train duration to increase dosage. It is firmly established that increases in stimulus frequency contribute to seizure induction since stimulus dose titration has often been conducted with stimulus frequency as the primary variable manipulated when incrementing dosing.^{5,6,7} The maximum frequency in the ultrabrief 0.3 ms parameter set is 120 Hz. At longer pulse widths (0.5 and 1.0 ms), maximum device output (576 mC U.S. devices) is achieved at lower pulse frequencies, resulting in a pulse frequency cutoff specific to each parameter set.

CURRENT Current or pulse amplitude is fixed at 800 mA in the OPTIMIZED 5000Q[®]/4000Q[™] parameter sets and all of the 5000M[™]/4000M[™] parameter sets. There is little published information on optimal pulse amplitude in ECT. The vast body of clinical research with MECTA devices has exclusively used the 800 mA setting, although there has been speculation that titration in the current domain* may ultimately prove superior in refining stimulus properties.^{2,8} MECTA provides the only device with flexibility and choice of pulse amplitudes. Indeed, the 5000Q[®]/4000Q[™] devices have an expanded range of pulse amplitudes in the new FULL SPECTRUM DOSING Parameter Sets. This range is from 500 to 900 mA. **NEW!**



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FULL SPECTRUM® DOSING Parameter Sets NEW!

The SPECTRUM 5000Q®/4000Q™ models now include a fourth parameter set that allows the experienced clinician or researcher to vary pulse width, train duration, pulse frequency and current independently throughout the full range of device parameters. Only with the SPECTRUM 5000Q®/4000Q™, FULL SPECTRUM DOSING Parameter Sets can be individualized and historical doses be selected and set, using the knob and visual interface without accessing menus. This enhances the efficiency of operation and allows the clinician and the researcher the greatest freedom in their choice of parameters.

TITRATION AND PRE-SELECTED DOSING TABLES

With these changes in optimized parameter sets, MECTA

has developed new Titration and Pre-Selected Dosing Tables. These are the most accurate and up to date tables, taking into account gender, age, and electrode placement.
NEW! 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 pulse widths. Empirical titration remains the most accurate way to determine seizure threshold. MECTA provides extensive new and Historical Titration and Pre-Selected Dosing Tables for the OPTIMIZED and FULL SPECTRUM DOSING Parameter Sets. **NEW!**

Contact MECTA for pricing and upgrade information and also to order Pre-Selected and Titration Dosing Tables and/or a new MECTA Instruction Manual containing the instructions for using these new stimulus dosing parameters.

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ECT PARAMETERS / 100 JOULE SYSTEMS

Q Models

	OPTIMIZED DOSING Parameter Sets			FULL SPECTRUM DOSING Parameter Set
	0.3	0.5	1.0**	Set 4**
Four Parameter Sets:				NEW!
Pulse Width	0.3-0.37 ms	0.5 ms	1.0 ms	0.3-1.0 ms
Stimulus Duration	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec NEW!
Frequency	20-120 Hz	20-90 Hz	20-45 Hz	20-120 Hz
Stimulus Current	800 mA	800 mA	800 mA	500-900 mA NEW!
Charge	4.0-568 mC	8.0-576 mC	16-576 mC	3.0-576 mC
Energy @ 220 ohm patient impedance	0.8-100 joules	1.4-101.4 joules	2.8-101.4 joules	0.3-101.4 joules

M Models

	OPTIMIZED DOSING Parameter Sets			
	0.3	0.5	1.0**	
Three Parameter Sets:				NEW!
Pulse Width	0.3-0.38 ms	0.5 ms	1.0 ms	
Stimulus Duration	0.59-7.9 sec	0.35-8.0 sec	0.18-8.0 sec	NEW!
Frequency	20-120 Hz	20-90 Hz	20-45 Hz	
Stimulus Current	800 mA	800 mA	800 mA	NEW!
Charge	5-576 mC	5-576 mC	5-576 mC	
Energy @ 220 ohm patient impedance	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules	

*Patent Pending

**EEG Data Analysis enabled for use with 1.0 OPTIMIZED DOSING Parameter Sets and Historical Parameters in the FULL SPECTRUM DOSING Parameter Set.



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EXHIBIT 12

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6 ELIZABETH AKKERMAN

7
8 UNITED STATES DISTRICT COURT
9 CENTRAL DISTRICT OF CALIFORNIA

10 ATZE AKKERMAN and
11 ELIZABETH AKKERMAN; each
12 suing individually and on behalf of
the general public,
13 Plaintiffs,
14 v.
15 MECTA CORPORATION, and
DOES 1-20.
16 Defendants.
17

Case No. 01-10362 RSWL(RZx)
**SECOND AMENDED COMPLAINT
FOR DAMAGES FOR PRODUCTS
LIABILITY; NEGLIGENCE; LOSS
OF CONSORTIUM; BREACH OF
WARRANTY, AND FOR
INJUNCTIVE RELIEF AND
RESTITUTION FOR CONSUMER
FRAUD AND FALSE AND
DECEPTIVE ADVERTISING
PURSUANT TO BUSINESS AND
PROFESSIONS CODE §§17200 &
17500 AND WEL.& INST. CODE**

JURY TRIAL DEMANDED

18
19
20 1. This is an action for damages against defendant MECTA Corporation
21 (“MECTA”), for grievous harm inflicted upon plaintiff Atze Akkerman, both to
22 his body and his mind, by electro-convulsive therapy (“ECT”), better known as
23 “shock treatment.” The shock treatment caused Mr. Akkerman to experience
24 substantial amnesia, including the loss of his knowledge and memories of his wife
25 and their 17-year marriage, knowledge and memories of his parents, loss of
26 knowledge and abilities including musical composition and most of his ability to

1 play music, loss of his job, and the loss of all memories of his teenage children and
2 their entire family life together. In short, his past memories of those things which
3 make life most important and skills he learned to make a living and survive, have
4 been taken from him, through fraud, lies and negligence; through the manufacture,
5 sale, distribution, and propagation by the defendants and their co-conspirators of a
6 device that is extremely dangerous to human beings. This action is brought by
7 plaintiffs individually for monetary damages, and also seeks to enjoin defendants
8 from defrauding and deceiving the public in violation of California Business and
9 Professions Codes Sections 17200 & 17500. As to the injunctive and declaratory
10 relief sought, the action is brought on behalf of the general public for false,
11 misleading and deceptive advertising and deceptive business practices relating to
12 the promotion, sale and use of electro-shock therapy devices; and equally false,
13 misleading and deceptive advertising which minimizes or ignores the permanent
14 injuries and often deadly results caused by "shock therapy."

15 **PARTIES**

16 2. Plaintiff Atze Akkerman is a resident of Ventura, California.

17 3. Plaintiff Elizabeth Akkerman is a resident of Camarillo, California.

18 4. MECTA Corporation is, on information and belief, an Oregon
19 corporation, engaged in the business of manufacturing and distributing shock
20 treatment devices in California. MECTA engages in advertising and sale of its
21 goods in Ventura County, and elsewhere within this federal judicial district.

22 **JURISDICTION AND VENUE**

23 5. This action was filed in Ventura County where plaintiffs live, however
24 was removed to federal court by defendant. Defendant MECTA advertises and
25 does business in this county, state and federal district.

26 //

1 knew his wife. He no longer recognized or knew his two teenage children. He no
2 longer knew or recognized his parents. His brother, who was a close companion
3 and best friend in his childhood years, is a stranger. Mr. Akkerman has essentially
4 no memory of past events with any of his family; they are all wiped out and
5 destroyed by the force of the shock treatment.

6 10. Mr. Akkerman was taken back to his home by persons he conceived
7 to be strangers, although in the case of his wife, she had lived with him and shared
8 his life for 17 years; and as to his children, they had shared their entire lives with
9 him. He has never recovered these memories. He has never recovered these
10 intimate relationships in the months following his shock treatment.

11 11. Mr. Akkerman was formerly engaged as a musician in the Navy,
12 playing keyboards and horns. He played French horn in a local philharmonic
13 orchestra. He played professionally for various events and performances on
14 keyboard, piano, synthesizer, and various horns and wind instruments. While over
15 the following months, Mr. Akkerman recovered parts of his once immense
16 abilities to play music, for the most part the ability and knowledge was lost and
17 destroyed by the shock treatment. He has disposed of most of his musical
18 equipment as it has become useless to him.

19 12. Prior to the shock treatment, Mr. Akkerman was employed in a
20 supervisory position with the Turning Point Foundation. After the shock
21 treatment, he was unable to remember what he did in his job, did not know how to
22 perform the duties of his job and no longer knew the people he formerly worked
23 with.

24 13. Although Mr. Akkerman had no recollection of the conversation
25 with Dr. Johnson prior to his shock treatment, he was informed by his wife that
26 Dr. Johnson told them both that any memory temporarily reduced would quickly

1 return. When after nearly two months Mr. Akkerman's memory did not return as
2 promised, Mr. Akkerman contacted Dr. Johnson and sought from him a letter for
3 his employer as to the reason he was unable to perform his work. On February 28,
4 2000, Dr. Johnson represented in writing that Mr. Akkerman's memory, "will
5 improve completely soon." Relying upon both the original representations of Dr.
6 Johnson told to him by his wife, and the February 28, 2000 representations, Mr.
7 Akkerman reasonably believed that his memory would return. He patiently waited
8 for his memory to return in accordance with the representations made to him.

9 14. Over the following months, Mr. Akkerman's position with his job
10 became more and more untenable. Unable to remember what his work entailed,
11 unable to contribute, finally he was fired in February 2001 as incompetent to
12 handle a position he competently performed prior to the shock treatment.

13 15. Mr. Akkerman's prior loving and intimate relationship with his wife
14 was also destroyed by the shock treatment. While he was informed that Liz
15 Akkerman was his wife, and he attempted for months to learn what he was
16 supposed to do, feel and think as a husband, he has been unable to do so.
17 Eventually, Mr. Akkerman developed psychosomatic ailments in proximity to his
18 wife, becoming physically ill and even vomiting when he spent more than a short
19 time with her.

20 16. In May of 2000, Mr. Akkerman finally realized that if he had not
21 regained his memory as of then, over a year after his shock treatments, that he had
22 been lied to and defrauded and that his memory would not likely return. The brain
23 damage and injuries to Mr. Akkerman caused by the shock treatment exacerbated
24 his inability to recognize his injuries – as often occurs with victims of shock
25 treatment.

26 17. Mr. Akkerman has attempted to re-unite with his family and re-

1 establish what he was told was a formerly loving relationship. However, he has
2 been unable to establish a viable relationship and remains separated from them,
3 but for short visits.

4 18. Unable to work, Mr. Akkerman has been unemployed for nearly 3
5 years and lives in a recreational vehicle in his parents' backyard.

6 19. Mrs. Akkerman has lost the support, love, affection and consortium
7 she previously enjoyed with her husband, arising out of the damage caused to him
8 by the shock treatments.

9 20. Defendant MECTA knew when it sold the ECT machine to Santa
10 Barbara Cottage Hospital and promoted the use of its machines in California and
11 elsewhere, that the history and literature regarding the use of ECT is littered with
12 stories of disabling injury, death, memory loss, extensive memory loss of long
13 duration, loss of substantial memory of events prior to ECT, loss of cognitive
14 abilities and loss of ability to experience normal emotional response to life and
15 relationships, a small part of which is addressed below.

16 **FACTUAL ALLEGATIONS REGARDING THE NATURE OF**
17 **SHOCK TREATMENT AND DEFENDANTS' FRAUD**

18 21. While the psychiatrist and hospital who inflicted shock treatment on
19 plaintiff Atze Akkerman, on information and belief, did so intentionally or with
20 gross negligence and with knowledge that he would be or would be expected to be
21 severely harmed, even the psychiatrists were not provided the full scope of the
22 harm expected to be caused by the machines to living subjects, which information
23 was fully known by MECTA. Practitioners of ECT, their patients, and the public
24 at large are also the subjects of fraudulent, misleading and deceptive advertising
25 and unfair and fraudulent business conduct by defendant MECTA Corporation,
26 which distributes false consumer information and misleading testimonial

1 information regarding the dangers and effects of shock treatment, which produces
2 an inherently dangerous machine for the purpose of causing brain damage and
3 memory loss. Ignoring the official patient surveys of the states which conduct
4 such surveys – including California – defendant publicly promotes that shock
5 treatment does not cause brain damage, and falsely promotes that shock treatment
6 causes little or no long term memory loss. In fact, shock treatment “works” by
7 damaging the brain, and permanent memory loss is experienced by virtually all
8 victims of this activity.

9 22. Shock treatment was developed in the early part of this century in
10 European slaughterhouses for the purpose of incapacitating animals without
11 killing them, so that their throats could be slit and the animals more easily bled
12 while alive. Personally observing such treatment, Italian psychiatrist Dr. Ugo
13 Cerletti experimented with the practice. Cerletti and his staff bribed authorities to
14 provide stray dogs that were experimented on with shock devices and many, in the
15 process, died. Cerletti persevered however, experimenting until he found an
16 appropriate voltage and duration of shock which did not kill many of the animals.
17 Cerletti decided to try the same practice on humans, for reasons that defy rational
18 explanation. The first human victim was a derelict found in the streets of Rome.
19 Cerletti shocked the “patient” and found that since he was not killed by the
20 treatment, and was substantially quieter than he had been before meeting Cerletti
21 and his staff, that the treatment was “effective” in relieving mental illness.

22 23. The most commonly manifested “side effect” of shock treatment was
23 that of broken bones, particularly of the spine. The patient would be strapped to a
24 table, with a rubber mouthpiece inserted to prevent the patient from biting off his
25 tongue or breaking teeth when his teeth involuntarily clenched during the
26 treatment. Electrodes would be placed on the temple of the patient, and varying

1 amounts and various durations of electricity would be forced through the brain
2 from temple to temple, causing immediate and violent convulsions, typically
3 resulting in compression fractures of the spine, broken teeth and dislocated joints.
4 Eventually, the dramatic and damaging results of shock treatment caused its
5 practitioners to apply muscle “relaxants” which made muscle contractions
6 impossible. While substantially lessening the number of bone fractures, such
7 medication, however, did not save the brain.

8 24. Early proponents of electro-shock therapy acknowledged as obvious,
9 what the current purveyors of this practice today hide: that a “change” in the
10 patient is brought about by damage to the brain and loss of memory. Such
11 concession was prevalent in the 1940s, as published by psychiatrist Walter
12 Freeman, M.D., in discussing “brain damage and the ‘therapeutic’ benefit resulting
13 from various psychiatric procedures, including ... shock therapy...” Freeman
14 admitted that the *intention* of these practices was to cause brain damage:

15 The apparent paradox develops, however, that the greater the damage,
16 the more likely the remission of psychotic symptoms ... It has been
17 said that if we don't think correctly, it is because we haven't 'brains
18 enough.' Maybe it will be shown that a mentally ill patient can think
19 more clearly and more constructively with less brain in actual
20 operation.

21 25. Medical reports and journals during the 1940s frequently repeated the
22 known physical damages caused by shock treatment, including “profound changes
23 in general circulation,” “coronary complications,” heart attacks, deaths, coma,
24 lung abscesses, and “Reversible or irreversible central nervous system changes
25 [which] must accompany the amnesia characteristic of the usual shock-induced
26 organic syndrome.” Such a result was acknowledged through the 1940's and
1950's as the source of the “effectiveness” of the treatment. As noted in one study
on “experimental neurosis,” caused by giving shock treatment to animals, “All in

1 all, these experiments support the growing conviction among psychiatrists that
2 electroshock and other drastic procedures, though possibly useful in certain
3 relatively recent and acute psychoses, produce cerebral damage which charges the
4 indiscriminate use of such 'therapies' with potential tragedy."

5 26. These "tragedies" were the intended result of this practice, as
6 reported by leading shock doctors in 1948 who reported the "treatment" of a
7 number of patients to reduce them to a state where they acted like small children
8 because they had shown no improvement from other psychiatric procedures:

9 We started by inducing two to four grand mal convulsions daily until
10 the desired degree of regression was reached. After about 10 days to
11 two weeks without treatment, regressed patients returned to their
12 previous levels, but usually without their symptoms. A number of
13 these patients were well enough to go home and carry on as they had
14 before the psychosis developed. We considered a patient had
15 regressed sufficiently when he wet and soiled, or acted and talked like
16 a child of four . . . Sometimes the confusion passes rapidly and
17 patients act as if they had awakened from dreaming; their minds seem
18 like clean slates upon which we can write. They are usually
19 cooperative and very suggestible, and thus amenable to
20 psychotherapy. . . This technique is a valuable asset to psychiatric
21 therapy, where less drastic measures have failed.

22 27. Damage to most patients was obvious, as during this period, a vast
23 number of victims of the treatment suffered compression fractures of the spine and
24 other broken bones. A publication from the National Institutes of Health
25 Consensus Development Conference Statement in 1985 placed the figure of spinal
26 fractures at approximately 20% of those receiving shock treatment. The NIH
27 Consensus report stated that some 40% of persons receiving ECT suffered what
28 has been referred to as "complications" from the treatment, which it noted "the
29 most common being vertebral compression fractures."

30 28. A psychiatrist who publicly argued for the effectiveness of
31 electroshock treatment claimed: "Improvement in effective disorders, follows the
32 induction of transient mental confusion which appears after treatment ... This

1 confusion coincides with recent memory impairment. This transient, induced,
2 organic, psychotic reaction makes the patient forget his worries, breaks up
3 introspection and obsessive thinking and reverses the effect, frequently changing
4 depression into mental elation.” In other words, the purpose of the “treatment” is
5 to cause memory failure and mental confusion.

6 29. Shock treatment thus came to have a well deserved reputation for
7 death, mayhem, destruction of memory and thought. Shock treatment developed
8 such a frightening notoriety thereby, that shock doctors and manufacturers such as
9 MECTA, changed the name of the treatment to avoid association with the past.
10 Thus, the treatment became known as Electroconvulsive Therapy, or “ECT,”
11 pretending that it was brain and body convulsions that caused the alleged
12 therapeutic effect, and not the electricity.

13 30. In the 1970’s, even after the use of extremely strong drugs or “muscle
14 relaxants” such as succinylcholine to paralyze the muscles to stop bones fractures
15 during convulsions, most doctors still recognized that the treatment was causing
16 brain damage and permanent deleterious effects on patients. For example, in a
17 1972 survey of psychiatrists who gave shock treatment, a large percentage
18 conceded that “treatments leave irrecoverable gaps in memory and that a large
19 number of treatments cause intellectual deterioration, seizures, or personality
20 blunting akin to the effects of lobotomy.” The NIH Consensus Statement in 1985
21 thus noted:

22 During the few minutes following stimulus, profound and potentially
23 dangerous systemic changes occur.

24 * * *

24 Depressive disorders are characterized by cognitive deficits that may
25 be difficult to differentiate from those due to ECT. It is, however,
26 well established that ECT produces memory deficits. Deficits in
 memory function, which have been demonstrated objectively and
 repeatedly, persist after the termination of a normal course of ECT.

1 Severity of the deficit is related to the number of treatments, type of
2 electrode placement, and nature of the electric stimulus. ... research
3 conducted as long as three years after treatment has found that many
4 patients report that their memory was not as good as it was prior to
5 the treatment.

6 31. Psychiatrists and hospitals are able to make a great deal of money
7 through the application of ECT. The purchase of a shock machine from MECTA
8 or one its rivals for approximately \$25,000 permits the application of more than a
9 dozen treatments per day billed at over \$1,000 each – often paid by the state and
10 federal health care or by insurance.

11 32. In the face of the historical evidence of the grave danger of ECT,
12 manufacturers of shock machines such as MECTA Corporation utilized false,
13 misleading and deceptive advertising to sell this dangerous product.

14 **DISTRIBUTION OF FALSE, MISLEADING AND DECEPTIVE**
15 **STATEMENTS BY DEFENDANTS REGARDING CLAIMS OF**
16 **KNOWLEDGE AS TO THE CAUSE OF MENTAL ILLNESS**
17 **AND CURATIVE EFFECTS OF SHOCK TREATMENT**

18 33. Statistics from California surveys by the California Department of
19 Mental Health indicate that over 95% of all ECT patients reporting adverse effects
20 at all, reported long term memory loss.

21 34. Plaintiff Atze Akkerman is an example of the sort of memory loss
22 damage that can be caused by shock treatment. Mr. Akkerman has no memory of
23 the assertions made to him to induce him to consent to ECT, however, the
24 minimalistic information provided to him in writing by Dr. Johnson and the Santa
25 Barbara Cottage Hospital could not remotely provide him with consent which
26 could be considered “informed” consent, as required under California law.
27 However, plaintiff Elizabeth Akkerman was present during the discussion of the
28 effects of ECT, and knows that Mr. Akkerman was told only that he would
29 experience *temporary* memory loss, and even then, primarily of alleged depressive

1 thoughts. The entirety of the worthwhile events of Mr. Akkerman's past, his
2 childhood memories, his loving relationship with his wife of 17 years, the entirety
3 of the birth, growth and nurturing of his own children, is lost to him. His former
4 love of music is gone. His life with his parents and brother is lost and forgotten,
5 forced from his memory by a dangerous electric shock.

6 35. As MECTA knows, ECT does not "work" at all – it simply causes
7 brain damage, loss of memory and loss of will to live. Some patients would not
8 complain regarding a lack of efficacy, for fear of more "treatments" and greater
9 damage. Thus, the advertising and claims regarding how ECT "works" are
10 deceptive, manipulative and fraudulent.

11 36. MECTA disseminates a pamphlet to the public and to health care
12 providers in California and elsewhere, entitled, "Electroconvulsive Therapy
13 (ECT), The Treatment, the questions and the answers," regarding the efficacy and
14 safety of shock treatment. Numerous false statements and deceptive statements
15 are made in the pamphlet, intended to encourage doctors to give patients ECT, to
16 refer patients to practitioners who give ECT, and to convince individuals that ECT
17 is safe and effective. Among the false and deceptive statements in the pamphlet
18 are the following:

- 19 • "Many people have heard that ECT can be uncomfortable or damaging, and
20 they react with fear when it is suggested as a treatment. However, the way
21 ECT is administered has greatly improved. ECT, as performed today, is a
22 safe and effective treatment for severe depression.
- 23 • "During ECT, a small amount of electrical current is sent to the brain. This
24 current produces a seizure which affects the entire brain, including centers
25 which control thinking, mood, appetite, and sleep. Repeated treatments
26 normalize the messengers in these centers. Consequently, patients return to

1 a higher level of functioning and begin to recover from their illness.

- 2 • “We know that ECT works – over 80 percent of depressed patients who
3 receive it respond favorably, making ECT the most affective treatment for
4 severe depression. People who have responded to ECT report it made them
5 feel “like themselves again” and as if “life was worth living again.”
- 6 • “ECT is a very safe procedure. The rates of significant injury or mortality
7 with ECT are very low even though ECT is very commonly performed on
8 elderly patients ...”
- 9 • “When people are seriously depressed they have a difficult time
10 concentrating and learning new material. When patients recover with ECT,
11 there is often marked improvement in concentration and many other aspects
12 of thinking. However during and shortly following treatment with ECT,
13 patients will usually experience specific difficulties with memory. Many
14 patients experience problems in remembering some events from the recent
15 past. These memory problems typically subside within a few weeks
16 following the ECT course.”
- 17 • “Regardless of the form of ECT you receive, within a few weeks after
18 receipt of ECT, your ability to learn and remember new information should
19 return to normal. Patients with bilateral ECT may occasionally complain
20 that their memory is not as sharp as before the ECT treatments. The only
21 lasting effect you may experience is a gap in memory for events that
22 occurred in the weeks surrounding the ECT treatment. Some of this loss is
23 likely due to the ECT treatment, and some of it is likely due to the
24 difficulties in learning that arise when people are depressed.”

25 37. The pamphlet distributed by MECTA makes no mention of memory
26 loss under the sections “Are there any risks involved with ECT” or the section,

1 “Side effects and what to do about them.” Brain damage is not mentioned
2 anywhere in the pamphlet. Although MECTA is aware of the vast dangers of
3 ECT, and although it had the opportunity to provide adequate warnings of the
4 danger of shock treatment and MECTA’s product through such pamphlet, it failed
5 to do so, and intentionally not done so – choosing to leave consumers of this
6 “product” in ignorance of the true nature of the dangers thereof. Worse, through
7 the pamphlet MECTA has chosen to distribute, it has grossly misrepresented the
8 known dangers of the machine it manufacturers and sells, such as misrepresenting
9 that patients will experience an enhanced ability to think, when in fact virtually all
10 persons who receive ECT are impaired in their thinking and their memory. The
11 assertion, “The only lasting effect you may experience is a gap in memory for
12 events that occurred in the weeks surrounding the ECT treatment,” is also false,
13 fraudulent and deceptive, as virtually all persons who receive ECT experience
14 permanent memory loss for substantial amounts of memory and abilities they
15 possessed prior to the ECT. The assertion, “Many patients experience problems in
16 remembering some events from the recent past. These memory problems typically
17 subside within a few weeks following the ECT course,” is also a knowingly false
18 and deceptive statement, as MECTA knows that while some patients certainly
19 recover a large amount of their lost memory in few weeks, nearly all persons
20 receiving ECT experience massive and long lasting memory loss for years and for
21 the rest of their lives. The statement, “Some of this loss is likely due to the ECT
22 treatment, and some of it is likely due to the difficulties in learning that arise when
23 people are depressed” is also quite deceptive, by diverting the cause of the
24 memory loss to the alleged depression, and using this as a ready justification for
25 the nearly universal memory loss experienced by patients.

26

1 **FIRST CAUSE OF ACTION**

2 (Products Liability - Strict Liability)

3 38. Plaintiffs hereby incorporate by reference as though fully set forth
4 herein, paragraphs 1 to 37, above.

5 39. The Electro-Convulsive Therapy device manufactured and sold by
6 MECTA was known by MECTA to be extremely dangerous, causing memory loss
7 and brain damage to patients against whom it was used. On information and
8 belief, MECTA has known for as long as it has manufactured machines about the
9 dangers of its machines to cause brain convulsions in humans. MECTA knows
10 that the basis for the machines' effect in seeming to temporarily "relieve" some
11 mental conditions is by causing brain damage and by causing memory to be
12 eradicated.

13 40. Defendant MECTA provided no warning to Mr. Akkerman or doctors
14 or hospitals purchasing or utilizing its machines that the alleged "benefits" of its
15 machines are the direct result and sole result of brain damage and loss of memory.
16 Defendant MECTA provided no warning to Mr. Akkerman or other patients who
17 were the recipients of electric shocks from its machines, or the practitioner who
18 might use the machines, that the alleged "benefits" of its machines are the direct
19 result and sole result of brain damage and loss of memory. Defendant MECTA
20 provided no warning to Mr. Akkerman or patients who were the recipients of
21 electric shocks from its machines, or the practitioners who might use the
22 machines, that most patients never recover major portions of their memories, and
23 all patients lose some portion of their memories after "treatment" with its
24 machines. MECTA provided no warning to the purchasers and users of the
25 machines, nor to the end user patients, including Mr. Akkerman, who would
26 receive shock treatment with the machines, that bilateral shock treatment would

1 substantially increase the memory loss and brain damage.

2 41. Defendant MECTA provided no warning to the doctors and hospitals
3 purchasing the machine, or to plaintiff Atze Akkerman, that the machine which
4 would be used on him would cause him brain damage and permanent memory loss.
5 The defects in the machines sold by MECTA were both design defects and
6 inadequate or entirely absent warnings regarding its product. Plaintiffs allege the
7 machine also has a manufacturing defect, in that its machines are made in a
8 manner which is likely to cause additional harm through faulty manufacture –
9 even beyond the intended harm of ECT machines. There is no benefit to
10 consumers that remotely outweighs the damages caused to consumers arising out
11 of use of the machines against them. The danger to Mr. Akkerman and to other
12 consumers by MECTA's product is unreasonable and unfair, and cannot be
13 justified by insulating the company and the consumer with doctors or hospitals
14 who are also not provided specific facts relating to the inherent danger of the
15 product.

16 42. MECTA knew that the machine it was placing on the market would be
17 used by doctors and hospitals on patients, without inspection for defect and
18 knowing that the machine was certain to cause brain damage and loss of memory.
19 Mr. and Mrs. Akkerman, reasonably believing the representations of Dr. Johnson
20 that shock treatments would help Mr. Akkerman, and that any minimal memory
21 loss would be quickly restored, were injured thereby. MECTA knew of the defect
22 in its machines as described herein: that its design ensures brain damage and harm
23 to recipients of the shock, causing memory loss and other cognitive disabilities.

24 43. After the series of shock treatments, plaintiff Atze Akkerman was
25 unable to function at his former place of work, no longer remembering how to do
26 his job, the persons in his place of work or any of the functions of his former

1 work. Although he sought reasonable accommodation at his work for the
2 disabilities he now possesses arising from the shock treatment, he was eventually
3 found to be unemployable as a result of the shock treatments and incapable of
4 functioning in any position at his former employment, and was thus terminated.

5 44. MECTA acted with fraud, oppression and malice for the reasons set
6 forth herein, and that it knew and intended that its product would both
7 temporarily and permanently harm patients, including Mr. Akkerman, but acted
8 with a conscious disregard of the rights and safety of others out of a pecuniary
9 motive to defraud and trick patients, doctors and hospitals in order to sell its
10 product. MECTA's conduct was despicable, subjecting Atze Akkerman (and
11 many other patients in this State) to cruel and unjust hardship in disregard of their
12 rights. Defendant, MECTA, is strictly liable for failing properly to prepare and/or
13 warn of the dangerous propensities of ECT. Defendant MECTA knew that electric
14 shock treatment was defective and that those who were prescribed and
15 administered ECT would experience, and did experience, severe physical, mental,
16 and emotional damages/injuries and yet, notwithstanding this knowledge,
17 MECTA, despicably, and in willful and conscious disregard of the safety of those
18 who were prescribed electric shock treatments and of the plaintiff herein, without
19 giving any notice of the defect to the purchasers of electric shock treatment, placed
20 and persisted in placing electronic shock treatment machines in the stream of
21 commerce. Plaintiffs are entitled to compensation in the amount of no less than
22 \$2,000,000 in compensatory damages and punitive damages in an amount to be
23 determined by the jury, under this cause of action.

24 **SECOND CAUSE OF ACTION**

25 (Negligence)

26 45. Plaintiffs hereby incorporate by reference as though fully set forth

1 herein, paragraphs 1 to 44, above.

2 46. Any reasonably prudent manufacturer of a device intended to be
3 applied to humans which directs a potentially lethal and dangerous electrical shock
4 through the brains of the patients to receive the treatment offered, would have
5 warned plaintiffs of the dangers inherent in the machine: that the machine would
6 cause brain damage; that the machine would cause some level of memory loss; and
7 the machine would cause amnesia for events prior to the application of the shock
8 treatment. The risks inherent in shock machines are known and knowable to
9 MECTA, but, by failing to provide reasonable warning either to the purchasers
10 and users of its machines (doctors and hospitals), or to the patients victimized by
11 its machines; and by minimizing the dangers, MECTA acted in a grossly negligent
12 fashion without regard to the health, safety or lives of persons who were likely to
13 be harmed by its machines.

14 47. Plaintiffs are entitled to compensation in the amount of no less than
15 \$2,000,000 in compensatory damages, and punitive damages in an amount to be
16 determined by the jury, under this cause of action.

17 **THIRD CAUSE OF ACTION**

18 (Breach of Warranty)

19 48. Plaintiffs hereby incorporate by reference as though fully set forth
20 herein, paragraphs 1 to 47, above.

21 49. Defendant MECTA, expressly and impliedly warranted to the
22 physicians and their health-care patients, including Mr. Akkerman, that electric
23 shock treatments was a treatment fit for the use for which it was intended and was
24 of merchantable quality despite the fact that the product was unfit and unsafe for
25 use by health-care patients in light of its known propensity to cause serious side-
26 effects, including, but not limited to physical, mental and emotional injuries to

1 her husband was permanently injured and that he would be lost to her. It was not
2 until after May of 2001 that Mrs. Akkerman realized or could have been
3 reasonably expected to know that she was injured, and could reasonably know the
4 cause and source of her injuries.

5 54. Plaintiff Liz Akkerman is entitled to compensation in the amount of
6 no less than \$2,000,000 in compensatory damages and punitive damages in an
7 amount to be determined by the jury, under this cause of action.

8 **FIFTH CAUSE OF ACTION**

9 (Violation of Business and Professions Code 17200)

10 55. Plaintiffs hereby incorporate by reference as though fully set forth
11 herein, paragraphs 1 to 56 above.

12 57. Plaintiffs are suing on their own behalf and on behalf of all members
13 of the
14 public who have received shock treatment over the past four years.

15 58. The acts and practices described above violate Business and
16 Professions Code 17200 in at least the following respects:

17 a) Defendant, by its conduct described above, engaged in false
18 advertising in violation of Cal. Business and Professions Code Section 17200,
19 which prohibits “any unlawful, unfair or fraudulent business act or practice and
20 unfair, deceptive, untrue or misleading advertising and any act prohibited by
21 Section 17500 of the California Business and Professions Code.”

22 b) Defendant sells and distributes booklets in California which
23 contain false and deceptive advertising regarding shock treatment, and instruction
24 manuals that contain false and deceptive information. It also distributes
25 information on its machines to psychiatrists and agents of hospitals and clinics.
26 MECTA realizes that shock treatment is very cheap to deliver and that

1 psychiatrists can charge a substantial fee for each shock delivered – up to \$2,000 –
2 making the practice financially attractive, notwithstanding the permanent harm
3 caused to patients receiving the treatment. MECTA capitalizes upon this financial
4 incentive by promoting to psychiatrists and hospitals the low cost of the shock
5 machine compared to the high income potential of the treatment.

6 c) The fraudulent, misleading and deceptive publications distributed
7 by MECTA are given or sold to doctors, hospitals, associations, and sold or given
8 to the public and other doctors and health care professionals.

9 d) Patients are caused the harms described above by these acts by
10 suffering physical and mental damages, including brain damage, loss of memory,
11 loss of livelihood, and loss of quality of life. Defendant's practices constitute an
12 unfair business act or practice within the meaning of Business and Professionals
13 Code section 17200.

14 e) The harm to plaintiffs and to members of the general public
15 outweighs the utility of this experimental and inherently dangerous practice upon
16 the brains of members of the public.

17 f) Defendant's practices and conduct has and is likely to continue to
18 mislead the general public and consequently constitutes a fraudulent business act
19 or practice within the meaning of Business and Professionals Code section 17200.

20 g) Defendant's acts of untrue, misleading and deceptive advertising
21 and promotion of the alleged benefits of shock treatment are, by definition,
22 violations of Business and Professionals Code section 17200.

23 59. The unlawful, unfair and fraudulent business practices and false and
24 misleading advertising of the defendants present a continuing threat to members of
25 the public in that members of the public are likely to believe defendants'
26 assertions and claims and thereby permit themselves to be subjected to shock

1 treatment without realizing the dangers and certainly the permanent damages
2 inherent in such treatment.

3 60. As a direct and proximate result of the aforementioned acts, defendant
4 MECTA received and continues to hold funds received from the sale of its shock
5 treatment machines, and funds from the sale of the pamphlets described above,
6 from doctors and hospitals who paid for the machines.

7 61. As a direct and proximate result of the aforementioned acts, MECTA
8 has received ill gotten gains. MECTA is an indirect recipient of funds provided by
9 Mr. Akkerman and other patients to doctors and hospitals and insurance
10 companies because of the false, misleading and deceptive statements by each of
11 the defendants respectively. In good conscience, defendant should make
12 restitution to the patients who have received ECT, to the state which has paid for
13 shock treatment through public welfare funds, and to insurance companies which
14 have paid for shock treatments.

15 62. Unless enjoined, defendant will continue to engage in the practices set
16 forth above in the future, as they continue in the present to disseminate the false,
17 misleading and deceptive advertising and fraudulent business practices described
18 herein.

19 63. Plaintiff prays for the relief set forth below.

20 **SIXTH CAUSE OF ACTION**

21 (Violation of Business and Professions Code Section 17500)

22 64. Plaintiffs hereby incorporate by reference as though fully set forth
23 herein, paragraphs 1 to 63 above.

24 65. Plaintiffs are suing on their own behalf and on behalf of all members
25 of the public who have received shock treatment over the past four years.

26 66. As set forth above, beginning at an exact date unknown to plaintiffs,

1 MECTA engaged in acts of false and misleading advertising as defined by
2 Business and Professions Code section 17500, with the intent to induce members
3 of the public to receive shock treatment, to their extreme and permanent detriment
4 and harm. As set forth above, beginning at an exact date unknown to plaintiffs,
5 MECTA has also engaged in acts of false and misleading advertising as defined by
6 Business and Professions Code section 17500, with the intent to induce health care
7 providers to administer shock treatment to patients in this State, to their extreme
8 and permanent detriment and harm. As set forth above, beginning at an exact date
9 unknown to plaintiffs, defendants have also engaged in acts of false and
10 misleading advertising as defined by Business and Professions Code section
11 17500, with the intent to induce insurance companies and state welfare agencies
12 administering health care assistance and funding, to pay for the administration of
13 shock treatment to patients in this State, to their extreme and permanent detriment
14 and harm.

15 67. The acts of untrue and misleading advertising by defendants
16 described above present a continuing threat to the safety, health and welfare of Mr.
17 Akkerman and to members of the public and a continuing threat to the financial
18 resources of insurance companies and state health care and welfare agencies.
19 Unless enjoined, MECTA will continue to engage in the practices set forth above
20 in the future, as they continue in the present to disseminate the false, misleading
21 and deceptive advertising and fraudulent business practices described herein.

22 Wherefore, plaintiff prays for relief as set forth hereinafter.

23 //
24 //
25 //
26 //

1 **PRAYER FOR RELIEF**

2 Wherefore, plaintiffs pray for judgment as follows:

3 1. For compensatory damages against MECTA Corporation in an amount
4 no less than \$10,000,000.

5 2. For punitive damages against MECTA Corporation in an amount to be
6 determined by the jury.

7 3. For injunctive relief to prohibit MECTA from engaging in false
8 advertising of the efficacy of ECT; engaging in false advertising by failing to
9 inform doctors and consumers that ECT causes brain damage, and that ECT causes
10 both temporary and permanent loss of memory in all or virtually all persons who
11 receive the treatment.

12 4. For equitable relief of requiring defendants to inform hospitals, doctors
13 and clinics utilizing ECT that the information provided to them regarding the
14 safety and efficacy of ECT was inaccurate, that ECT causes brain damage, and that
15 ECT causes permanent memory loss.

16 5. For equitable relief of requiring defendants to inform the known
17 victims of electro shock therapy that the information set forth in the pamphlet
18 distributed by MECTA is inaccurate.

19 6. For restitution by defendant to all shock treatment victims experiencing
20 brain damage and/or memory loss within the appropriate statutory period, state
21 agencies and insurance companies in California bearing the costs of shock
22 treatment. The expenses of determining the identity of all such victims to be borne
23 by defendants.

24 7. Costs and expenses of suit.

25 8. For reasonable attorneys' fees incurred in prosecuting this action as
26 provided by law.

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9. For such other relief as the Court may deem just and proper.

Dated: November 15, 2004

Respectfully submitted,

MOXON & KOBRIN

(S)

Kendrick L. Moxon
Ava M. Paquette

Attorneys for Plaintiffs
ATZE AKKERMAN and

ELIZABETH AKKERMAN

MEDWATCH

For VOLUNTARY reporting of adverse events, product problems and product use errors

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	

A. PATIENT INFORMATION

1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lb or _____ kg
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B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: _____ (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 _____
#2 _____

2. Dose or Amount	Frequency	Route
#1 _____	_____	_____
#2 _____	_____	_____

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 _____
#2 _____

4. Diagnosis or Reason for Use (Indication)

#1 _____
#2 _____

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Lot # 7. Expiration Date

#1 _____ #1 _____
#2 _____ #2 _____

8. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other: _____
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone # E-mail

2. Health Professional? 3. Occupation 4. Also Reported to:

Yes No Manufacturer
 User Facility
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 3

B6. Relevant tests/laboratory data, including dates continued

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 4

B7. Other relevant history, including preexisting medical conditions continued

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5

F. Other (Concomitant) medical products

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

EXHIBIT 13

COPY

CAUSE NO. 96-15067

TERRI ADAMCHICK,
Plaintiff,

vs.

DR. DAVID G. JOSEPH, DR. JAMES
E. KREISLE, JR., DR. ROBERT
ZAPALAC, ST. DAVID'S HOSPITAL
and MECTA CORPORATION,
Defendant.

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IN THE DISTRICT COURT OF

TRAVIS COUNTY, TEXAS

201 JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE DISTRICT JUDGE:

NOW COMES, Terri Adamchick, Plaintiff herein, complaining of Defendants herein, and for cause of action, would respectfully show unto the Court and Jury the following:

I.
PARTIES

Plaintiff, Terri Adamchick is a resident of Round Rock, Williamson County, Texas.

Defendant, Dr. David G. Joseph is a resident of Austin, Travis County, Texas and may be served with process in this case in person at his residence address which is located at 4208 Farhills Drive, Austin, Texas 78731, or by sending a copy of the citation and petition by registered or certified mail, return receipt requested, WITH DELIVERY RESTRICTED TO THE ADDRESSEE ONLY pursuant to Tex. R. Civ. P. 106(a)(2).

Defendant, Dr. James E. Kreisle, Jr. is a resident of Austin, Travis County, Texas and may be served with process in this case in person at his business address which is located at 720 West 34th Street, Austin, Texas 78705, or by sending a copy of the citation

II.
VENUE

Venue of this case is proper in Travis County, Texas in accordance with Section 15.002 of the Texas Civil Practice and Remedies Code because the incident made the basis of this suit occurred in Austin, Travis County, Texas.

III.
FACTS

The evidence will show upon trial of this case that Plaintiff was caused to undergo Electroconvulsive Shock Therapy (ECT) prescribed for her by Defendant Physicians and administered by Defendant St. David's. The manufacturer of the machine involved in the shocking was Defendant MECTA Corporation. The evidence in this case will further show that Defendants did not perform a sufficient history and physical of Plaintiff to determine the appropriateness of this treatment for Plaintiff and, together with incorrect administration of this treatment and a defective product, Plaintiff was caused to incur damages and injuries as more particularly set out below.

IV.
CAUSE OF ACTION

As a direct and proximate result of the conduct of the Defendants, Plaintiff has sustained personal injuries and damages. Defendants are negligent, as that term is known and understood in the law, with such negligence constituting a proximate cause of the injuries and damages made the basis of this suit.

M 00828

V.
DAMAGES

As a result of the conduct of the Defendants, Plaintiff has suffered pain, anguish, memory loss, seizures, loss of income, medical expenses and other damages, general and special, such damages exceeding the minimum jurisdictional limits of this Court.

VI.
JURY DEMAND

Plaintiff makes application and demand for jury trial of this cause, and concurrently with the filing of this Petition tenders her jury fee.

WHEREFORE PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear herein and answer and that on final hearing, Plaintiff have judgment against Defendants for her damages, plus pre-judgment and post-judgment interest at the legal rate, for costs of suit, and for such other and further relief, both general and special, at law and in equity, to which Plaintiff may show herself justly entitled under the attending facts and circumstances.

Respectfully submitted,

TERRI ADAMCHICK
510 Quail Creek
Round Rock, Texas 78664
(512) 310-7844

By: 
TERRI ADAMCHICK
Pro Se

Dated: 12/13/96

M 00829

EXHIBIT 14

7.5.00 path

File

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

IMOGENE LORETTA ROHOVIT, an Individual;
JULIE LYNN ROHOVIT, an individual;
and LORI JANELLE ROHOVIT, an individual;

Plaintiffs,

vs.

MECTA CORPORATION, a corporation;
STATE OF IOWA;
EDWARD SATHOFF, M.D., an individual;
KEITH ROGERS, M.D., an individual;
BRUCE PFOHL, M.D., an individual;
D. W. BLACK, M.D., an individual;
MARK FULTON, M.D., an individual;
and J. LIESVELD, M.D., an individual;

Defendants.

LAW NO: CL 56175

PETITION AT LAW

M

COME NOW the Plaintiffs, above named, and in support of all their causes of action against the above-named Defendants, state as follows:

JURISDICTIONAL FACTS

1. That Plaintiff, Imogene Loretta Rohovit, is an individual who at all material times hereto lived and continues to live in Iowa City, Johnson County, Iowa.
2. That Plaintiff, Julie Lynn Rohovit, is an individual who at all material times hereto also lived in Iowa City, Johnson County, Iowa. She is the natural daughter of Plaintiff, Imogene Loretta Rohovit.
3. That Plaintiff, Lori Janelle Rohovit, is an individual who at all material times hereto also lived in Iowa City, Johnson County, Iowa. She too is the natural daughter of Plaintiff, Imogene Loretta Rohovit.
4. Defendant, MECTA Corporation, is a duly organized Oregon corporation with its principal place of business located at 56 S.W. Kelly Street, Portland, Oregon. Defendant, MECTA Corporation, is the manufacturer of an electrical shock therapy machine, Model No. "D"; Serial No. 7039BB.

M 00830

X

Said machine was owned and used by the physicians within the Psychiatry Department at the University of Iowa Hospitals and Clinics in Iowa City, Iowa, during the calendar years 1987, 1988 and 1989.

5. Defendant, the State of Iowa, is a duly organized governmental entity. Suit against the State of Iowa is authorized under Chapter 25A of the *Iowa Code* and it is pursuant to said Chapter that this litigation is commenced. That the University of Iowa Hospitals and Clinics in Iowa City, Johnson County, Iowa, is a duly authorized agency of the Defendant, State of Iowa; it is by reason of the negligent acts or omissions of various employees, agents or representatives of said agency, including those specifically named as Defendants herein, that this action is commenced against Defendant, State of Iowa.

6. Jurisdiction for this suit against the State of Iowa is conferred upon this Court by reason of the fact that Plaintiffs have exhausted their administrative remedies by filing a claim before the State Appeal Board on January 7, 1991; said claim was formally denied on October 15, 1991, by Craig Kellinson, Special Assistant to the Attorney General. Specifically, jurisdiction is conferred upon this Court by reason of *Iowa Code*, Sections 25A.4 and 25A.13.

7. That Defendant, Edward Sathoff, is an individual who at all material times hereto was a duly licensed Iowa physician. Defendant, Sathoff, was a staff physician at the University of Iowa Hospitals and Clinics in the Department of Psychiatry. He was one of the treating staff physicians of Plaintiff, Imogene Loretta Rohovit, during her hospitalization at the University of Iowa Hospitals and Clinics during the calendar years 1988 and 1989.

8. That Defendant, Keith Rogers, at all material times hereto was a duly licensed Iowa physician. He too was a staff physician at the University of Iowa Hospitals and Clinics within the Psychiatry Department. He also was one of treating staff physicians of Plaintiff, Imogene Loretta Rohovit, during her hospitalization at the University of Iowa Hospitals and Clinics during the calendar years of 1988 and 1989.

9. That Defendant, Bruce Pfohl, at all material times hereto was a duly licensed Iowa physician. He too was a staff physician at the University of Iowa Hospitals and Clinics within the Department of Psychiatry. He too was one of the treating staff physicians of Plaintiff.

Imogene Loretta Rohovit, in connection with the care that she received at the University of Iowa Hospitals and Clinics during the calendar years 1988 and 1989.

10. That Defendant, D. W. Black, at all material times hereto was a duly licensed Iowa physician. He was a staff physician at the University of Iowa Hospitals and Clinics within the Psychiatry Department during the calendar year of 1987. He was one of the treating staff physicians for Plaintiff, Imogene Loretta Rohovit, in connection with care that she received at the University of Iowa Hospitals and Clinics during the calendar year 1987.

11. That Defendant, Mark Fulton, at all times material hereto was a duly licensed Iowa physician. He was a resident within the Department of Psychiatry at the University of Iowa Hospitals and Clinics during the calendar year 1987. He was one of the resident physicians who provided care to Plaintiff, Imogene Loretta Rohovit, during the calendar year of 1987.

12. That Defendant, J. Liesveld, at all material times hereto was a duly licensed Iowa physician. He too was a resident within the Department of Psychiatry at the University of Iowa Hospitals and Clinics during the calendar year 1987. He was another resident who provided care to Plaintiff, Imogene Loretta Rohovit, at the University of Iowa Hospitals and Clinics during the calendar year of 1987.

THE FACTS

13. That on August 21, 1987, Plaintiff, Imogene Loretta Rohovit, was hospitalized at the University of Iowa Hospitals and Clinics because of depression.

14. That upon being admitted at the University of Iowa Hospitals and Clinics, Plaintiff, Imogene Loretta Rohovit, was diagnosed as suffering from a "major depressive disorder with mood congruent and incongruent psychotic features".

15. That even though the initial plan was to treat Plaintiff, Imogene Loretta Rohovit's depression "with a combination of tricyclic antidepressants and neuroleptics", such medication treatment was not pursued; instead, Plaintiff, Imogene Loretta Rohovit, was given a series of six treatments of electroconvulsive therapy (ECT) which began on August 28, 1987, and continued on August 31, September 2, September 4, September 9 and September 11, 1987.

M 00832

16. That following the series of six ECT treatments in August and September of 1987, Plaintiff, Imogene Loretta Rohovit, was discharged from the University of Iowa Hospitals and Clinics on September 18, 1987; her discharge diagnosis was that of "major depressive disorder with psychotic features in remission" and "hypothyroidism".

17. That following her discharge in September of 1987, Plaintiff, Imogene Loretta Rohovit, experienced memory difficulties and an inability to concentrate which deterred her from returning to work as a registered nurse within the Obstetrical Department of the University of Iowa Hospitals and Clinics.

18. That on June 17, 1988, by reason of her continued problems with memory and forgetfulness, she returned to the University of Iowa Hospitals and Clinics for a neurobehavioral evaluation. By reason of that evaluation, she was told that there was no indication of "cognitive impairment suggestive of brain dysfunction". She was reassured and told that the electrical shock therapy had nothing to do with her perceived memory and concentration problems.

19. That on December 14, 1988, Plaintiff, Imogene Loretta Rohovit, returned to the University of Iowa Hospitals and Clinics, again for depression. She was diagnosed as having a "bipolar affective disorder, not otherwise specified".

20. That in connection with the December 14, 1988, admission, Plaintiff, Imogene Loretta Rohovit, had recommended to her a second series of electroconvulsive therapy (ECT).

21. That without being given any options, Plaintiff, Imogene Loretta Rohovit, received a series of seven more ECT treatments on December 19, 1988, December 21, 1988, December 23, 1988, December 28, 1988, December 30, 1988, January 4, 1989, and January 6, 1989.

22. That following the series of seven additional ECT treatments, Plaintiff, Imogene Loretta Rohovit, continued to follow up at the University of Iowa Hospitals and Clinics where she primarily saw Defendants, Edward Sathoff and Keith Rogers. She consistently voiced concern to them over her impaired memory following ECT treatments but was consistently reassured that she had no such problems or that the shock therapy was not an explanation.

23. That Plaintiff, Imogene Loretta Rohovit, continued to voice concerns and complaints about memory problems and lack of concentration but continued to get no direction, advice, explanation or treatment for those problems at the University of Iowa Hospitals and Clinics.

24. That as a result, Plaintiff, Imogene Loretta Rohovit, referred herself to the Veterans Hospital in Iowa City for care and treatment.

25. That on March 29, 1990, Plaintiff, Imogene Loretta Rohovit, received a complete neuropsychological evaluation at which time it was determined that she demonstrated symptoms consistent with a marked frontal lobe syndrome and that she had a clearly impaired memory retention in the context of superior intelligence and concentration (i.e., a partial amnesic syndrome).

26. That on November 30, 1990, Plaintiff, Imogene Loretta Rohovit, saw a television show which addressed the issue of brain damage resulting from electrical shock therapy; it was on that date that she first reasonably knew or had reason to know that her ongoing problems with memory, lack of concentration and cognitive deficits were related to the electrical shock therapies that she had received in August and September of 1987 and in December of 1988 and January of 1989.

27. That the representatives, agents or employees of the university of Iowa Hospitals and Clinics, including the specific physicians named as Defendants herein, concealed any relationship between her ongoing memory and lack of concentration problems and the ECT treatments from Plaintiff, Imogene Loretta Rohovit; it was not until she saw the television show on November 30, 1990, that the relationship became apparent to her.

28. That Plaintiff, Imogene Loretta Rohovit, now suffers from permanent brain damage, producing diminished cognitive capabilities, decreased memory, an inability to concentrate and learn, and other related problems; said brain damage is permanent.

COUNT I

Strict Products Liability--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count I of their Petition at Law against Defendant, MECTA Corporation, states as follows:

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1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That at the time Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987 and in December of 1988 and January of 1989, the electrical shock therapy machine identified in the preceding two paragraphs, manufactured by Defendant, MECTA Corporation, was in a defective condition.
6. That when said electrical shock therapy machine was used to zap the brain of Plaintiff, Imogene Loretta Rohovit, in both August and September of 1987 and in December of 1988 and January of 1989, said machine was used in a reasonably foreseeable manner.
7. That the defective condition of the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in both August and September of 1987 and then again in December of 1988 and January of 1989, rendered said machine unreasonably dangerous to Plaintiff, Imogene Loretta Rohovit.
8. That Defendant, MECTA Corporation, was in the business of manufacturing the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and in December of 1988 and January of 1989.

9. That the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, Model No. "D", Serial No. 7039BB, was expected to and did reach the University of Iowa Hospitals and Clinics without substantial change in condition from the time of manufacture; in other words, the defect in said machine which rendered it unreasonably dangerous to Plaintiff, Imogene Loretta Rohovit, existed at the time of manufacture and sale.

10. That the defect in the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and then again in December of 1988 and January of 1989 was a proximate cause of the permanent brain injury sustained by Plaintiff, Imogene Loretta Rohovit, including her permanent memory deficit, her permanent inability to concentrate and her permanent diminished ability to learn.

11. That more specifically, as a proximate result of the defective and unreasonably dangerous condition of the electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB, Plaintiff, Imogene Loretta Rohovit, has sustained damage and seeks compensation for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

12. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain

injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

13. That the conduct of Defendant, MECTA Corporation, demonstrates an intentional, reckless and conscious disregard for the safety of the patients undergoing electrical shock therapy; as a result, Plaintiffs do hereby make claim for punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT II

Negligence--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count II of their cause of action against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That as the manufacturer of the electrical shock therapy machine utilized to zap the brain of Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and again in December of

1988 and January of 1989, Defendant, MECTA Corporation, had a duty to use reasonable care in the research, design, manufacture, inspection and testing of the final product, installation, maintenance and in the labeling, advertising, instructing and warning with regard to said product.

6. That Defendant, MECTA Corporation, breached one or more of said duties of reasonable care.

7. That said breach of one or more of the above-referenced duties of reasonable care by Defendant, MECTA Corporation, with regard to the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and again in December of 1988 and January of 1989, constituted negligence.

8. That the negligence of Defendant, MECTA Corporation, was a proximate cause of the resulting injuries and damage sustained by Plaintiff, Imogene Loretta Rohovit.

9. That more specifically, as a proximate result of the negligence of Defendant, MECTA Corporation, Plaintiff, Imogene Loretta Rohovit, seeks recovery for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

10. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain

injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

11. That the conduct of Defendant, MECTA Corporation, demonstrates an intentional, reckless and conscious disregard for the safety of the patients undergoing electrical shock therapy; as a result, Plaintiffs do hereby make claim for punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT III

Negligent Misrepresentation--Fraud--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count III against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovlt, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovlt, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.

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5. That in connection with the manufacture and sale of the electrical shock therapy machine, specifically Model No. "D", Serial No. 7039BB, Defendant, MECTA Corporation, provided and made available a MECTA Instruction Manual concerning said machine.

5a. That in addition to the MECTA Instruction Manual concerning the electrical shock therapy machine in question, Defendant, MECTA Corporation, also made available and aggressively marketed other written and video presentations concerning electrical shock therapy and the safety of its machines.

6. That the MECTA Instruction Manual as well as the other written and video information distributed by Defendant, MECTA Corporation, is written and/or produced so as to minimize any concern on the part of the health care practitioner contemplating the use of electrical shock therapy with regard to the potential for permanent brain injuries resulting therefrom. Specifically, the risk of permanent brain injury and permanent cognitive deficits, including memory, concentration and an inability to learn are substantially minimized. The procedure was represented within the Manual as being "easy and safe to use"; it further represented that the practitioners utilizing the device could not "conduct safe, effective procedures" and that "the design of said machine incorporates many fail safe features, which assure maximum patient safety".

7. That the MECTA Instruction Manual and the other written or video materials, when read or viewed as a whole, constitute a representation or representations concerning the safety of the electrical shock therapy machine in question, Model No. "D", Serial No. 7039BB.

8. That said representation/representations were false and misleading.

9. That Plaintiff, Imogene Loretta Rohovlt, reasonably and indirectly relied on said false representations by Defendant, MECTA Corporation, in that she was advised by her physicians at the University of Iowa Hospitals and Clinics that the electrical shock procedure being contemplated was totally safe. The information upon which those representations were made by the staff at the University of Iowa Hospitals and Clinics to Plaintiff, Imogene Loretta Rohovlt, included in part the information submitted in the

MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation.

10. That the false representations by Defendant, MECTA Corporation, as contained in the MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation, contributed to the persistence of the use of damaging electrical shock treatments and specifically contributed to the recommendation and implementation of electrical shock therapy as part of the treatment received by Plaintiff, Imogene Loretta Rohovit, for her depression.

11. That as a result of the justifiable reliance on the part of her physicians at the University of Iowa Hospitals and Clinics, which advice was based in part upon the false representations contained in the MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation, Plaintiff, Imogene Loretta Rohovit, went ahead and consented to the electrical shock therapy treatments which were done in August and September of 1987 and then again in December of 1988 and January of 1989.

12. That as a proximate cause of Plaintiff, Imogene Loretta Rohovit's justifiable reliance on the false representations of Defendant, MECTA Corporation, she has been permanently and seriously damaged; she seeks recovery for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

13. That at the time Defendant, MECTA Corporation, wrote, published and began distributing the information contained in the MECTA Instruction Manual and the other written and/or video

information distributed, it knew or should have known that the information contained therein was false; it knew or should have known that the information contained in its instruction manual did not accurately set forth the controversial nature of electrical shock therapy, the damaging effects of the therapy; the fact that said therapy was the most controversial treatment in psychiatry; the fact that many doctors and many institutions refuse to use electrical shock therapy; the fact that many doctors believe that shock therapy causes permanent brain damage; the fact that electrical shock therapy causes permanent memory loss spanning a period of time before and after the treatment that impairs recollection for many months and even years of time; that shock therapy can impair the ability of a person to learn new material and to use one's mental abilities; and the fact that there are no controlled studies showing beneficial impact beyond one month after treatment.

14. That in marketing said instruction manual and the other written and/or video information, defendant, MECTA Corporation, did so in reckless and conscious disregard for the safety of patients who would likely consent to electrical shock therapy in part by reason of the false representations contained in said instruction manual.

15. That as the natural daughters of plaintiff, Imogene Loretta Rohovit, plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

16. That by reason of the reckless and conscious disregard for the safety of patients undergoing electrical shock therapy, plaintiffs do hereby seek recovery for exemplary and/or punitive damages.

WHEREFORE, plaintiffs do hereby seek judgment against defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT IVRestatement (Second) of Torts, Section 402B—MECTA Corporation

COME NOW the Plaintiffs, and in support of Count IV of their claim against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 5, 5a and 6 of Count III of this Petition and incorporate the same by reference herein.
6. That Defendant, MECTA Corporation, through its advertising, labels, instruction manuals, other written materials distributed, and/or video presentations, has made to the public a misrepresentation of a material fact concerning the character and quality of its electrical shock therapy machine, Model No. "D", Serial No. 7039BB.
7. That Defendant, MECTA Corporation, is, therefore, subject to liability for the permanent and irreversible brain injury sustained by Plaintiff, Imogene Loretta Rohovit, by reason of her reasonable, indirect and justifiable reliance upon the misrepresentation of Defendant, MECTA Corporation. Her reasonable, indirect and justifiable reliance occurred by reason of the fact that she was advised by her

physicians at the University of Iowa Hospitals and Clinics that the electrical shock procedure being contemplated was totally safe. The information upon which those representations were made by the staff of the University of Iowa Hospitals and Clinics to Plaintiff, Imogene Loretta Rohovit, included in whole or in part the advertising, instruction manual, labels, other written materials, and/or video tape presentations distributed by Defendant, MECTA Corporation.

8. That pursuant to this Count, Plaintiff, Imogene Loretta Rohovit, is relying on the *Restatement (Second) of Torts*, Section 402B.

9. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 10 through 16 of Count III of this Petition and incorporate the same by reference herein.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT V

Negligence--1987 Shock Therapy--As Against Defendants, State of Iowa, Black, Fulton and Liesveld

COME NOW the Plaintiffs, and in support of their cause of action against Defendants, State of Iowa, Black, Fulton and Liesveld, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 3, paragraphs 5 and 6, and paragraphs 10 through 12 of the "Jurisdictional Facts" and incorporate the same by reference herein.

2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.

3. That when Plaintiff, Imogene Loretta Rohovit, came to the University of Iowa Hospitals and Clinics in August of 1987 in a depressed condition, the Defendant, State of Iowa, through its agents, representatives and/or employees, and Defendants, Black, Fulton and Liesveld, had a duty to exercise reasonable care under the circumstances in connection with the medical evaluation, diagnosis, care, treatment and advice rendered to Plaintiff, Imogene Loretta Rohovit.

4. That Defendant, State of Iowa, by and through one or more of its duly authorized agents, representatives or employees, and Defendants, Black, Fulton and Liesveld, breached one or more of the duties set forth in the preceding paragraph and were, therefore, negligent. More specifically, said Defendants were negligent in one or more of the following particulars:

- a. In failing to properly inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with electroconvulsive therapy (ECT);
- b. In failing to inform Plaintiff, Imogene Loretta Rohovit, of alternative methods of treatment other than electroconvulsive therapy (ECT) for her depression;
- c. In failing to pursue alternative forms of treatment for the depression of Plaintiff, Imogene Loretta Rohovit, other than electroconvulsive therapy (ECT);
- d. In recommending electroconvulsive therapy (ECT) when they knew or should have known that the documented beneficial impact of such therapy was far outweighed by the risk of permanent brain dysfunction and lessened cognitive abilities;
- e. In failing to survey and review the medical literature concerning electroconvulsive therapy (ECT) so as to be in a position to inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with said therapy, the minimal documented beneficial impact of said therapy, and the alternative forms of treatment other than electroconvulsive therapy (ECT); and
- f. In failing to exercise that degree of skill, care and learning required under the circumstances for the diagnosis and treatment of Plaintiff, Imogene Loretta Rohovit's condition of depression.

5. That the negligence of Defendants, State of Iowa, Black, Fulton and Liesveld, was a proximate cause of the resulting injuries and damages sustained by Plaintiff, Imogene Loretta Rohovit.

6. That more specifically, Plaintiff, Imogene Loretta Rohovit, has been injured in that she has sustained a permanent brain injury resulting in diminished cognitive functioning and abilities, including decreased memory, decreased ability to concentrate, and decreased ability to learn and retain new information, all of which entitles her to recover for the following elements of loss:

- a. Past medical expense;
- b. Future medical expense;

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- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

7. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

8. That the conduct of Defendants, State of Iowa, Black, Fulton and Liesveld, demonstrates an willful, wanton and/or reckless disregard for the safety of Plaintiff, Imogene Loretta Rohovit, and thereby entitles her to punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendants, State of Iowa, Black, Fulton and Liesveld, in an amount which would reasonably compensate them for their injuries and loss; they also seek punitive damages in an amount which would reasonably deter such future conduct; in addition, Plaintiffs seek interest on said judgment at the maximum legal rate plus the costs of this action.

COUNT VI

Negligence--December of 1988 and January of 1989 Shock Therapy--Defendants, State of Iowa, Sathoff, Rogers and Pfohl

COME NOW the Plaintiffs, and in support of Count V of their Petition against Defendants, State of Iowa, Sathoff, Rogers and Pfohl, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 3, and paragraphs 5 through 9 of the "Jurisdictional Facts" and incorporate the same by reference herein.

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2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.

3. That when Plaintiff, Imogene Loretta Rohovit, came to the University of Iowa Hospitals and Clinics in December of 1988 and January of 1989 in a depressed condition, the Defendant, State of Iowa, through its agents, representatives and/or employees, and Defendants, Sathoff, Rogers and Pfohl, had a duty to exercise reasonable care under the circumstances in connection with the medical evaluation, diagnosis, care, treatment and advice rendered to Plaintiff, Imogene Loretta Rohovit.

4. That Defendant, State of Iowa, by and through one or more of its duly authorized agents, representatives or employees, and Defendants, Sathoff, Rogers and Pfohl, breached one or more of the duties set forth in the preceding paragraph and were, therefore, negligent. More specifically, said Defendants were negligent in one or more of the following particulars:

- a. In failing to properly inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with electroconvulsive therapy (ECT);
- b. In failing to inform Plaintiff, Imogene Loretta Rohovit, of alternative methods of treatment other than electroconvulsive therapy (ECT) for her depression;
- c. In failing to pursue alternative forms of treatment for the depression of Plaintiff, Imogene Loretta Rohovit, other than electroconvulsive therapy (ECT);
- d. In recommending electroconvulsive therapy (ECT) when they knew or should have known that the documented beneficial impact of such therapy was far outweighed by the risk of permanent brain dysfunction and lessened cognitive abilities;
- e. In failing to survey and review the medical literature concerning electroconvulsive therapy (ECT) so as to be in a position to inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with said therapy, the minimal documented beneficial impact of said therapy, and the alternative forms of treatment other than electroconvulsive therapy (ECT);
- f. In failing to exercise that degree of skill, care and learning required under the circumstances for the diagnosis and treatment of Plaintiff, Imogene Loretta Rohovit's condition of depression; and

g. In using bilateral electroconvulsive therapy (ECT) when they know or should have known that the bilateral electroconvulsive therapy increased the risk of permanent brain injury to Plaintiff, Imogene Loretta Rohovit.

5. That the negligence of Defendants, State of Iowa, Sathoff, Rogers and Pfohl, was a proximate cause of the resulting injuries and damages sustained by Plaintiff, Imogene Loretta Rohovit.

6. That more specifically, Plaintiff, Imogene Loretta Rohovit, has been injured in that she has sustained a permanent brain injury resulting in diminished cognitive functioning and abilities, including decreased memory, decreased ability to concentrate, and decreased ability to learn and retain new information, all of which entitles her to recover for the following elements of loss:

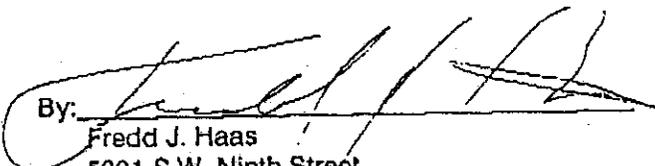
- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

7. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

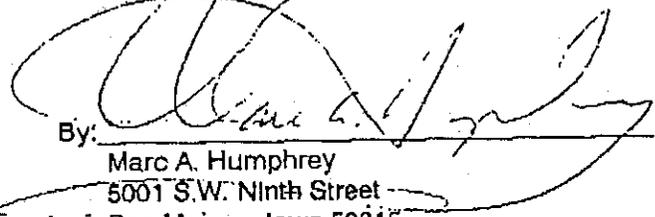
8. That the conduct of Defendants, State of Iowa, Sathoff, Rogers and Pfohl, demonstrates an willful, wanton and/or reckless disregard for the safety of Plaintiff, Imogene Loretta Rohovit, and thereby entitles her to punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendants, State of Iowa, Sathoff, Rogers and Pfohl, in an amount which would reasonably compensate them for their Injuries and loss,, they also seek punitive damages in an amount which would reasonably deter such future conduct; in addition, Plaintiffs seek interest on said judgment at the maximum legal rate plus the costs of this action.

HUMPHREY AND HAAS, P.C.

By: 

Fredd J. Haas
5001 S.W. Ninth Street
Des Moines, Iowa 50315
Telephone: (515) 287-4490

By: 

Marc A. Humphrey
5001 S.W. Ninth Street
Des Moines, Iowa 50315
Telephone: (515) 287-4490
AIN: PK1000044

ATTORNEYS FOR PLAINTIFFS

EXHIBIT 15

capacity as heirs of his estate, collectively hereinafter referred to as "Plaintiffs, complain of the above-referenced persons and entities, known hereinafter collectively referred to as "Defendants" and for cause of action would show:

I. BENEFICIARIES

1. The deceased, Jesus G. Torres, never completed a will and thus his legal beneficiaries under

Texas law, in said action are:

Ben Torres (Brother)
409 East Poplar
Sonora, Texas 76950

Ninfa DeLeon (Sister)
1214 Oak Street
Grand Prairie, Texas 75211

Elfida Martinez (Sister)
605 Orient
Sonora, Texas 76950

Damasio Torres (Brother)
501 South Church
Winters, Texas 79567

Frances Reyna (Sister)
315 South Church
Winters, Texas 79567

Guadalupe Torres (Brother)
2926 Reforma Street
Grand Prairie, Texas 75052

Erma Torres (Sister)
2944 Gladstone Street
Dallas, Texas 75211

STATEMENT OF CLAIM

2. Plaintiffs file this civil action seeking monetary relief for the deprivation of the rights guaranteed to Jesus G. Torres under the Texas Mental Health Code and for tortious acts under other Texas statutory, regulatory and common law.

II. JURISDICTION

3. This Court has jurisdiction over the subject matter of Plaintiffs' claims under Tex. Health & Safety Code Ann. § 321.003 and Texas tort law.

III. VENUE

4. Venue is proper in Travis County under Tex. Health & Safety Code Ann. § 321.003 (e)(2), because the Kerrville State Hospital and the Terrell State Hospital are inpatient mental health facilities operated by Defendant Texas Department of Mental Health and Mental Retardation ("TDMHMR"). Defendant TDMHMR conducts business in Travis County.

IV. PARTIES

5. Jesus G. Torres, hereinafter also referred as to "the deceased" had been involuntarily committed to the Kerrville State Hospital, in Kerrville, Texas and was transferred to the Terrell State Hospital in Terrell, Texas in and around October 1, 1996. He was receiving treatment at that mental health facility when he died on October 8, 1996. His natural brothers and sisters, known collectively as Plaintiffs, and as representatives of the deceased estate, bring this action to recover for the injuries the deceased suffered while alive as a result of Defendants negligence and violations of statutory and regulatory law, and the injuries and damages they too have received because of such actions by Defendants.
6. Defendant TDMHMR administers and enforces rules and regulations relating to the management of state mental health facilities, the duties of officers and employees of those hospitals, and the provision of care and treatment to persons in state mental health facilities,

as adopted by the Texas Board of Mental Health and Mental Retardation. Defendant TDMHMR may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested, to Karen Hale, Acting Commissioner, TDMHMR, P.O. Box 12668, Capitol Station, Austin, Texas 78711-2668.

7. Defendant Terrell State Hospital ("TSH") is a state mental health facility operated by Defendant TDMHMR in Terrell, Kaufman County, Texas. TSH employs Defendant Beatrice Butler as its superintendent and Defendant Monte Goen, M.D., as physician. TSH may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested to Beatrice Butler, Superintendent, TSH, 1200 East Brin Street, Terrell, Texas 75160.
8. Defendant Kerrville State Hospital ("KSH") is a state mental health facility operated by Defendant TDMHMR in Kerrville, Kerr County, Texas. KSH employs Defendant Gloria P. Olsen as its superintendent and Defendant Vernon Groves, M.D., as physician. KSH may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested to Gloria P. Olsen, Superintendent, KSH, 721 Thompson Drive, Kerrville, Texas 78028.
9. Defendant Don Gilbert was the duly appointed Commissioner of TDMHMR at the time the deceased was treated at KSH and TSH. In that capacity, he served as the chief executive and administrative officer of TDMHMR. His duties included observing, executing, and enforcing the mandates and regulations established pursuant to state and federal law. Among the legal mandates and regulations with which he and his agency must comply were the Texas Health and Safety Code and the rules and regulations promulgated pursuant to the Texas Health and Safety Code. As the Commissioner of TDMHMR, Defendant Gilbert was also responsible

for ensuring compliance by TDMHMR and its employees and facilities with these laws and regulations. Defendant Gilbert is sued in his official capacity as Commissioner of TDMHMR. Defendant Gilbert may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, at the Texas Health and Human Services Commission, 4900 North Lamar, 4th Floor, Austin, Texas 78751.

10. Defendant Karen Hale is the Acting Commissioner of TDMHMR. In that capacity, she serves as the chief executive and administrative officer of TDMHMR. Her duties include observing, executing, and enforcing the mandates and regulations established pursuant to state and federal law. Among the legal mandates and regulations with which she and her agency must comply are the Texas Health and Safety Code and the rules and regulations promulgated pursuant to the Texas Health and Safety Code. As the Acting Commissioner of TDMHMR, Defendant Hale is also responsible for ensuring compliance by TDMHMR and its employees and facilities with these laws and regulations. Defendant Hale is sued in her official capacity as Acting Commissioner of TDMHMR. Defendant Hale may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, at TDMHMR, P. O. Box 12668, Capitol Station, Austin, Texas 78711-2668.
11. Defendant Gloria P. Olsen is the Superintendent of KSH. As such, she is the supervisor of all KSH staff. She is responsible for ensuring that KSH is in compliance with Texas law and TDMHMR regulations. At all relevant times, Defendant Olsen was acting as the agent, servant, and employee of Defendants KSH and TDMHMR. Defendant Olsen is sued in her official and individual capacities and may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, at the KSH, 721 Thompson Drive, Kerrville, Texas 78028.

12. Defendant Vernon E. Grove, Jr. M.D. was one of the attending physicians of the deceased Jesus Torres, at KSH. As such, Defendant Groves was responsible for assessing the deceased's mental condition and ordering psychiatric care and medical treatment for him. At all relevant times, Defendant Groves was acting as the agent, servant, and employee of Defendants KSH and TDMHMR. Defendant Groves is sued in his official and individual capacities and may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, at the KSH, 721 Thompson Drive, Kerrville, Texas 78028.
13. Defendant Beatrice Butler is the Superintendent of TSH. As such, she is the supervisor of all TSH staff. She is responsible for ensuring that TSH is in compliance with Texas law and TDMHMR regulations. At all relevant times, Defendant Butler was acting as the agent, servant, and employee of Defendants TSH and TDMHMR. Defendant Butler is sued in her official and individual capacities and may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, to the Terrell State Hospital, 1200 East Brin Street, Terrell, Texas 75160.
14. Defendant Monte Goen, M.D. was one of the attending physicians of the deceased while he was at TSH. As such, Defendant Goen was responsible for assessing the deceased's mental condition and ordering psychiatric care and medical treatment for him. At all relevant times, he was acting as the agent, servant, and employee of Defendants TSH and TDMHMR. Defendant Goen is sued in his official and individual capacities and may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, to 4630 Parkwood Drive, Rockwall, Texas 75087.

15. Defendant MECTA, is a foreign corporation and not incorporated under the laws of the State of Texas. At all times material to this action, MECTA has been engaged in business in Texas, as more particularly described below. Defendant does not appear to have a regular place of business in Texas, nor has any known designated agent on whom service may be made in this cause. The causes of action asserted arose from or are connected with purposeful acts committed by this Defendant in Texas, as MECTA manufactures and provides electro convulsive shock therapy machinery to Defendants TDMHMR, KSH and TSH. Accordingly, Defendant may be cited by serving the Secretary of the State of Texas provided that citation and petition are forwarded to Defendant home address, by certified mail, return receipt requested at MECTA Corporation, 7015 McEwan Road, Lake Oswego, Oregon, 97035-7830.
16. Whenever Plaintiffs use the word "Defendants" in this petition, they mean defendants, their agents, employees, successors, and all persons acting in concert with them or at their direction.

V. FACTUAL ALLEGATIONS

17. On and around September of 1993, Jesus Torres (deceased) was admitted to the KSH. In 1993 Mr. Torres weighed over 133 pounds and was about 66.5" tall. Upon admission he was in emotional distress but nevertheless had all his faculties, was capable of self-care, but treated with substantial amounts of neuroleptics. These caused neuroleptic malignant syndrome (NMS) from which he never fully recovered.
18. On or about August 1995, Jesus Torres was again in involuntarily commitment status at the Kerrville State Hospital. He was in very poor physical health due to a long history of deteriorated health due to the NMS which occurred as a result of the psychiatric treatment

at KSH. Mr. Torres had genuinely drug induced brain damage and was increasingly withdrawn. He was treated with amphetamines and amphetamine like drugs that caused increased agitation, appetite suppression and significant weight loss. Defendant physicians and other professionals and agents of KSH and TDMHMR, recommended Mr. Torres receive electroconvulsive treatment (ECT) and initiated transfer to TSH. Mr. Torres was transferred to TSH on or about December 19, 1995, where he was under the care of Dr. Monte Goen, M.D.

19. Defendant MECTA corporation provided to TSH the machinery used for the provision of ECT therapy. MECTA is responsible to assure such machinery meets and exceeds standards of care for such equipment.
20. Despite abundant documentation that Mr. Torres was not competent, his "mark" was finally coerced from him, and put on a consent form. Within his first course of ECT he was reduced to being tied up in a "geri-chair" and wearing a diaper until he began more and more and more vocal about refusing the ECT treatment. Nevertheless, up to and through February of 1996, Jesus Torres underwent several sessions of ECT under Goen's care and supervision. He was soon transferred back to KSH.
21. Months later, after more and more amphetamines and even further weight loss while at KSH, he was again transferred by Defendants KSH and Grove, to TSH where he was provided ECT. Again there is ample evidence Mr. Torres was not competent so as to provide the requisite informed consent for such treatments. The nursing assessment of 10/2/96 notes reads "I am not sure he understands medication instructions." The psychological assessment of 10/4/96 states that "... insight and judgement are both seriously impaired and essentially nil." Yet Defendant Goen states that Jesus Torres gave him informed consent for ECT treatment.

22. Further, Jesus Torres was not medically stable at the time he received the ECT treatment. For instance, upon transfer from KSH and admission to TSH he weighed about 85 pounds. Yet unbelievably Defendant physicians at both KSH and TSH state that "he was not in need of nasal gastric or any sort of replenishment of volume or nutrition ..."
23. Further and addition to the above, Jesus Torres' received treatment at KSH for seizures. Yet upon admission to TSH this fact is unaddressed by TSH medical personnel, including Defendant Goen. None of his seizure medications, including Ativan, were provided to him upon transfer from KSH to TSH. On 10/4/96 he does have a seizure, ostensibly due to the fact Ativan therapy was prematurely stopped.
24. On October 7, 1996 the deceased was again provided ECT against his will and without informed consent and in violation of state law. On October 8, 1996 Jesus Torres was found in a chair in the group room, unresponsive and later pronounced dead. He was found while already in a state of rigor mortis. The autopsy revealed that Mr. Torres was in severe malnutrition and had a ruptured bowel. The deceased had burns marks on his head due to and among other things, the malfunctioning of the ECT machinery provided by Defendant MECTA.

VI. STANDARDS OF CARE

25. All Defendants have an obligation to comply with the provisions of, or any rules adopted under, the Texas Mental Health Code, Tex. Health & Safety Code Ann. § 571.001 *et seq.* In accordance with Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108, a person receiving care and treatment in a state mental health facility is prohibited from receiving ECT unless he or she has provided informed consent to ECT.

26. Defendants Gilbert and TDMHMR have general supervision and control over Defendants KSH and TSH. As such, Defendants Gilbert and TDMHMR have a duty to see that persons who are receiving medical and psychiatric care and treatment at KSH, and medical and psychiatric care, including ECT at TSH, are not administered ECT unless those persons provide informed consent.
27. Defendant Olsen, as superintendent of KSH, and Defendant KSH owed Mr. Torres a duty to see that he was provided the highest standards of medical care so that his physical health did not deteriorate. Further, Defendant Olsen owed Mr. Torres a duty of care to assure he was not transferred when he was in a medically unstable state. Further, this Defendant owed Mr. Torres a duty to assure all his patient rights were fully provided, including but not limited to the administration of ECT unless Torres was able to provide informed consent. Defendant Olsen was aware of the fact that Mr. Torres lacked the capacity to consent to his transfer or provision of ECT. Upon information and belief, Defendant Olsen was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.
28. Defendant Groves, as the attending physician for Mr. Torres at KSH, owed him a duty to see that he was provided the highest standards of medical care. Further, Defendant Groves owed Mr. Torres a duty of care to assure he was not transferred when he was in a medically unstable state. Further, this Defendant owed Mr. Torres a duty to assure all his patient rights were fully provided, including but not limited to the administration of ECT unless Torres was able to provide informed consent. Defendant Groves was aware of the fact that Mr. Torres lacked the capacity to consent to his transfer or provision of ECT. Upon information and

belief, Defendant Groves was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.

29. Defendant Butler, as superintendent of TSH, and Defendant TSH owed Mr. Torres a duty to see that he was not administered ECT unless he was able to provide informed consent. Defendant Butler was aware of the fact that Mr. Torres lacked the capacity to consent to ECT. Upon information and belief, Defendant Butler was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.
30. Defendant Goen, as the attending physician for Mr. Torres, owed him a duty to see that he was not administered ECT unless he was able to provide informed consent. Defendants completely failed to fulfill this duty owed to Plaintiff and provided him with ECT in direct violation of Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108.
31. As a result of the Defendants' failure to ensure that Mr. Torres was not administered ECT unless he was able to provide informed consent to such treatment, Jesus Torres did reasonably suffer mental, psychological and emotional anguish, discomfort, worry, distress, and anxiety. Additionally, Mr. Torres suffered bodily discomfort and pain as a result of receiving ECT. He also suffered headaches, muscle soreness and confusion from the ECT treatment that ultimately was the proximate cause of his untimely decease.

VII. CAUSES OF ACTION

32. All the factual and legal allegations addressed in the above and below numbered paragraphs are thereby incorporated into the remainder of this petition.

A: NEGLIGENCE PER SE-TEXAS HEALTH AND SAFETY CODE

33. Under Tex. Health & Safety Code Ann. § 321.003, Defendants are liable for the actual damages caused by their violations of any provisions of, or any rules adopted under, the Texas Mental Health Code at the Tex. Health & Safety Code Ann. § 571.001 *et seq.* Further, and in addition to the above, Defendants' administration of ECT without obtaining informed consent from Jesus Torres violated Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108 and proximately caused him to suffer mental anguish, fear, bodily discomfort, headaches, pain, muscle soreness, confusion, permanent and temporary memory loss and memory dysfunction and ultimately death.

B: TORT CLAIMS ACT

34. Under the Texas Tort Claims Act (TEX. CIV. PRAC. & REM. CODE ANN. § 101.021), Defendants are liable for the personal injuries proximately caused by the Defendants' improper use of tangible personal property. Defendants' misuse of the ECT stimulus apparatus that was used to administer ECT to Jesus Torres proximately caused him to have mental anguish, fear, bodily discomfort, headaches, pain, muscle soreness, confusion, permanent and temporary memory loss and memory dysfunction and ultimately death. Plaintiffs have previously provided notice to Defendants and complied with all prerequisites contemplated by this act.

C: INTENTIONAL TORT

35. Defendant Goen intentionally committed battery upon Mr. Torres person in violation of Texas law by causing ECT to be administered to him without his informed consent.

D. SURVIVAL CAUSE OF ACTION

36. Under the "Survival of Cause of Action" statute, at Texas Civil Practices and Remedies Code § 71.021, Defendants are liable for the personal injuries, pain and suffering, medical expenses, funeral expenses, and other costs related to the probate of the deceased's estate. Further, Defendants are liable to the heirs for the mental anguish and loss of companionship they have suffered because of their beloved brother's untimely demise.

D. MEDICAL NEGLIGENCE

37. Under the Texas Medical Liability and Insurance Act, Texas Revised Civil Statutes Annotated, Article 4590i, Defendants are liable to Jesus Torres' heirs for the medical negligence that was the proximate cause of his untimely demise. Plaintiff's have given notice of their claims to Defendants, as contemplated by this statute.

E. GROSS NEGLIGENCE

38. The negligence of the Defendants described herein was of such character as to make the Defendants guilty of gross negligence. The conduct of Defendants, viewed objectively from the standpoint of the Defendants at the time of its occurrence, involved an extreme degree of harm, considering the medical history of the deceased, Jesus Torres. Moreover, Defendants engaged in the conduct with the conscious indifference to the rights, safety and welfare of the deceased, despite the Defendants actual, subjective awareness of the risks involved. Plaintiffs are thereby entitled to recover exemplary damages in such an amount as may be found to be proper under the facts and circumstances.

XIII. FEES AND DAMAGES

39. By reason of all the above Jesus Torres has been damaged, as had his estate, and all within the jurisdictional limits of the Court.

IX. JURY DEMAND

40. Plaintiffs demand a trial by jury on all issues so triable.

X. PRAYER FOR RELIEF

41. WHEREFORE, Plaintiffs request and pray that Defendants be cited to appear and answer, and on the final trial Plaintiffs have:

- a. Judgement against Defendants, jointly and severally for damages within the jurisdictional limits of the Court;
- b. Attorney fees as permitted, *inter alia*, by the Tex. Health & Safety Code § 321.003 and the Tex. Civ. Prac. & Rem. Code § 37.009;
- c. Prejudgement and postjudgement interest as permitted by Tex. Civ. Prac & Rem. Code § 71.021;
- d. Exemplary damages as permitted by, *inter alia*, the Tex. Health & Safety Code § 321.003(d), the Tex. Civ. Prac & Rem. Code at § 71.021 for Defendants gross negligence, and also under the Tex. Const. Art. 16 § 26 and the Tex. Civ. Prac & Rem. Code § 41.003(a)(3); all with such amounts to be determined by the trier of fact;
- e. Costs of suit including expert fees;
- f. Such other and further relief to which Plaintiffs may be entitled in this action, at law or in equity.

Dated: October 7, 1998.

Respectfully submitted,

MARTIN J. CIRKIEL
State Bar No. 00783829

Cirkiel & Associates, P.C.
1901 Palm Valley Boulevard
Round Rock, Texas 78664
(512) 244-6658
(512) 244-4355 (Fax)

ATTORNEYS FOR PLAINTIFFS

EXHIBIT 16

From: Lawrence, Lisa D [<mailto:Lisa.Lawrence@fda.hhs.gov>]
Sent: Thursday, July 21, 2016 9:50 AM
To: Kendrick Moxon <knoxon@knoxonlaw.com>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: RE: FDA Freedom of Information Request 2016-4067

Yes, that is correct.

Should you have any questions or concerns, please feel free to contact me.

CDR Lisa D. Lawrence, RN, MSHS
Senior Program Management Officer
Division of Information Disclosure
Office of Communication & Education, Center for Devices and Radiological Health
Food and Drug Administration
Direct phone: 301-796-5945 | Fax: 301-847-8526 | Email: Lisa.Lawrence@fda.hhs.gov
[FDA FOIA Webpage](#)

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From: Kendrick Moxon [<mailto:knoxon@knoxonlaw.com>]
Sent: Thursday, July 21, 2016 12:48 PM
To: Lawrence, Lisa D
Cc: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Lawrence,

Thank you. And to confirm: there are no communications from FDA to MECTA requesting clarification or explanation regarding adverse events or reports or injury submitted by third parties?

Kendrick Moxon
LAW OFFICE OF KENDRICK MOXON, PC
3500 West Olive Avenue, Suite 300
Burbank, CA 91505
(818) 827-7104
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From: Lawrence, Lisa D [<mailto:Lisa.Lawrence@fda.hhs.gov>]
Sent: Thursday, July 21, 2016 9:44 AM
To: Kendrick Moxon <kmoxon@kmoxonlaw.com>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: RE: FDA Freedom of Information Request 2016-4067

Hello Mr. Moxon,

The component office that process these reports stated that the MAUDE reports sent in response to your FOIA request 2016-4067 includes all reports which includes voluntary, user facility and manufacturer reports. In this instance, the manufacturer, Mecta, did not submit any reports to FDA.

Thank you,

Should you have any questions or concerns, please feel free to contact me.

CDR Lisa D. Lawrence, RN, MSHS
Senior Program Management Officer
Division of Information Disclosure
Office of Communication & Education, Center for Devices and Radiological Health
Food and Drug Administration
Direct phone: 301-796-5945 | Fax: 301-847-8526 | Email: Lisa.Lawrence@fda.hhs.gov
[FDA FOIA Webpage](#)

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From: Kendrick Moxon [<mailto:kmoxon@kmoxonlaw.com>]
Sent: Tuesday, July 19, 2016 12:08 PM
To: Lawrence, Lisa D
Cc: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Lawrence,

One final point of clarification: the responses to my FOIA Requests turned up no MDRs from MECTA. Please confirm that MECTA has not provided MDRs regarding any alleged deaths or injury. Thank you.

Kendrick Moxon
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From: Kendrick Moxon
Sent: Monday, July 18, 2016 2:25 PM
To: 'Lawrence, Lisa D' <Lisa.Lawrence@fda.hhs.gov>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Lawrence,

Thanks very much. Yes I would like to have copies of these documents. Electronic would be easiest for me if possible. Is there a charge?

I note there was an August 2, 2010 submission from MECTA to the FDA in docket FDA -2010-N-0585 which made repeated references to the issues of safety and efficacy of its devices for giving ECT. If there was no follow-up by the FDA or MECTA or communication between them that may have related to the safety and efficacy of ECT and/or their devices after that time, please let me know.

And if that's the case, then other than these 1985 501k submissions, and the August 2, 2010 submission to the FDA in docket FDA -2010-N-0585, there have been no communications between FDA and MECTA respecting adverse events, and therefore no records exist? If you can confirm that, this request will be concluded.

Thanks again.

Kendrick Moxon
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From: Lawrence, Lisa D [<mailto:Lisa.Lawrence@fda.hhs.gov>]
Sent: Monday, July 18, 2016 1:17 PM
To: Kendrick Moxon <kmuxon@kmuxonlaw.com>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: FDA Freedom of Information Request 2016-4067

Hello Mr. Moxon,

After completing my search I found 3-510(k)s for Mecta Corporation, they are:

- [K965070](#)
- [K960754](#)
- [K852069](#)

Do want the 510(k) applications listed above?

The previous response I sent to you are the only adverse events that came up in our database for this company. I will need to contact another component office to ask if they have records addressing any issues with this company's device.

Thank you again for your patience.

Kind regards,
Lisa

Should you have any questions or concerns, please feel free to contact me.

CDR Lisa D. Lawrence, RN, MSHS
Senior Program Management Officer
Division of Information Disclosure
Office of Communication & Education, Center for Devices and Radiological Health
Food and Drug Administration
Direct phone: 301-796-5945 | Fax: 301-847-8526 | Email: Lisa.Lawrence@fda.hhs.gov

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From: Kendrick Moxon [<mailto:knoxon@knoxonlaw.com>]
Sent: Thursday, July 14, 2016 5:23 PM
To: Lawrence, Lisa D
Cc: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Thanks very much. If you can send me a letter indicating that in the categories searched [what you searched] there were no responsive records, that would suffice. I appreciate your efforts.

Kendrick Moxon
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From: Lawrence, Lisa D [<mailto:Lisa.Lawrence@fda.hhs.gov>]
Sent: Thursday, July 14, 2016 2:18 PM
To: Kendrick Moxon <knoxon@knoxonlaw.com>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: FW: FDA Freedom of Information Request 2016-4067

Dear Mr. Moxon,

I apologize for not getting back to you sooner. I am still researching your request and so far I have not found any matches. We will have your request re-opened and we can make the final determination.

Kind regards,

Lisa

Should you have any questions or concerns, please feel free to contact me.

CDR Lisa D. Lawrence, RN, MSHS
Senior Program Management Officer
Division of Information Disclosure
Office of Communication & Education, Center for Devices and Radiological Health
Food and Drug Administration
Direct phone: 301-796-5945 | Fax: 301-847-8526 | Email: Lisa.Lawrence@fda.hhs.gov
[FDA FOIA Webpage](#)

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From: Lawrence, Lisa D
Sent: Thursday, July 07, 2016 2:32 PM
To: Kendrick Moxon
Cc: Howard, Jasmine M. (Jasmine.Howard@fda.hhs.gov)
Subject: RE: FDA Freedom of Information Request 2016-4067

Hello Mr. Moxon,

I will research the below mentioned item and follow up with you by closed of business on Monday.

Thank you,
Lisa Lawrence

Should you have any questions or concerns, please feel free to contact me.

CDR Lisa D. Lawrence, RN, MSHS
Senior Program Management Officer
Division of Information Disclosure
Office of Communication & Education, Center for Devices and Radiological Health
Food and Drug Administration
Direct phone: 301-796-5945 | Fax: 301-847-8526 | Email: Lisa.Lawrence@fda.hhs.gov
[FDA FOIA Webpage](#)

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From: Howard, Jasmine M.
Sent: Thursday, July 07, 2016 2:23 PM
To: Kendrick Moxon
Cc: Lawrence, Lisa D
Subject: RE: FDA Freedom of Information Request 2016-4067

Good Afternoon Mr. Moxon,

I have asked Lisa Lawrence to research your request further. She will be able to assist you from here. I will be out of the office tomorrow however Lisa will keep me informed.

Lisa is copied on this email and will reach out to you for further information if she needs it.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at: [Customer Service Survey](#)

Best Regards,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
FDA/CDRH/Office of Communication Education
Phone: 301-796-5950 • Email: jasmine.howard@fda.hhs.gov



From: Kendrick Moxon [<mailto:kmoxon@kmoxonlaw.com>]
Sent: Friday, July 01, 2016 6:43 PM
To: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Howard,

Thanks for your response. If there were no communications between MECTA and FDA regarding adverse incidents and the potential harmful effects arising from ECT, then I'm satisfied. If the 510ks or other communications address adverse reports or justify the harmful effects of ECT, then yes, I would request those as well.

In 2010, MECTA made a submission to FDA in support of reclassification of ECT devices from Class III to Class II, and made representations therein regarding its position on adverse events. Other submissions to FDA refuted the claims of MECTA, which should have given rise to questions from the FDA to MECTA. If there were any further communications between FDA and MDECTA regarding the effects of its devices in relation to the adverse effects of ECT, those should have been located and produced.

I much appreciate your effort and courtesy.

Kendrick Moxon
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3500 West Olive Avenue, Suite 300
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From: Howard, Jasmine M. [<mailto:Jasmine.Howard@fda.hhs.gov>]
Sent: Friday, July 01, 2016 3:14 PM
To: Kendrick Moxon <knoxon@knoxonlaw.com>
Subject: Re: FDA Freedom of Information Request 2016-4067

Hi Mr. Moxon,

The interpretation of your request was that you wanted the regulatory submissions or correspondence addressing the adverse events, this would be in the adverse events that were sent. In your email below, it seems like you are requesting to the 510k submission in hopes that the FDA and the sponsor addressed the adverse events in there. Am I understanding you correctly?

Sent from my BlackBerry 10 smartphone.

From: Kendrick Moxon
Sent: Friday, July 1, 2016 5:18 PM
To: Howard, Jasmine M.
Cc: Lawrence, Lisa D
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Howard,

Thank you for your response records. Since nothing was received other than documents from the MAUDE database, am I correct that there are no other responsive records? I.e., there are no other records

- 1) Regarding submission to the FDA by MECTA Corporation to the FDA respecting any Medical Device Adverse Event caused by an Electroconvulsive Therapy device manufactured by MECTA.

And

- 2) Any and every report by MECTA Corporation in any regulatory submission or correspondence, addressing any actual or alleged adverse event of any nature caused by an Electroconvulsive Therapy device manufactured by MECTA

I question the adequacy of the response, in that MECTA made a lengthy submission to the FDA in 2010 in consideration of potential re-classification of ECT devices – which is not here provided. That submission most definitely concerned adverse effects of ECT. There were many questions raised in the context of MECTA’s submission and this issue, and one would assume there was further communication between MECTA and the FDA in that regard.

If there has been no such communication between FDA and MECTA regarding the effects of ECT, so be it. But that would be hard to believe.

Moreover, MECTA submitted 510k submissions and updates which certainly would be responsive as “regulatory submissions” which necessarily address adverse events. Were regulatory submissions searched?

I therefore seek confirmation that a thorough search was conducted, and not merely someone looking at the MAUDE database. Thank you.

Kendrick Moxon
LAW OFFICE OF KENDRICK MOXON, PC
3500 West Olive Avenue, Suite 300
Burbank, CA 91505
(818) 827-7104
(818) 827-7114 (fax)
kmoxon@kmoxonlaw.com

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From: Howard, Jasmine M. [<mailto:Jasmine.Howard@fda.hhs.gov>]
Sent: Friday, July 01, 2016 1:29 PM
To: Kendrick Moxon <knoxon@knoxonlaw.com>
Subject: RE: FDA Freedom of Information Request 2016-4067

Hi Mr. Moxon,

Please see attached MAUDE records and response letter. Please let me know you received your information.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at: [Customer Service Survey](#)

Best Regards,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
FDA/CDRH/Office of Communication Education
Phone: 301-796-5950 • Email: jasmine.howard@fda.hhs.gov



From: Kendrick Moxon [<mailto:knoxon@knoxonlaw.com>]
Sent: Friday, July 01, 2016 2:58 PM
To: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Howard,

Could you please send me this information this afternoon before leaving? Thanks very much.

Kendrick Moxon
LAW OFFICE OF KENDRICK MOXON, PC
3500 West Olive Avenue, Suite 300
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(818) 827-7104

(818) 827-7114 (fax)
kmuxon@kmuxonlaw.com

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From: Howard, Jasmine M. [<mailto:Jasmine.Howard@fda.hhs.gov>]
Sent: Tuesday, June 28, 2016 10:17 AM
To: Kendrick Moxon <kmuxon@kmuxonlaw.com>
Subject: RE: FDA Freedom of Information Request 2016-4067

Hi Mr. Moxon,

The component office reached out to me today. They plan to get it to me today or tomorrow. I should take about 24 hours for us to review for possible redactions. If the records are able to be sent by email, would you like us to send it to you via email?

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at: [Customer Service Survey](#)

Best Regards,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
FDA/CDRH/Office of Communication Education
Phone: 301-796-5950 • Email: jasmine.howard@fda.hhs.gov

From: Kendrick Moxon [<mailto:kmuxon@kmuxonlaw.com>]
Sent: Tuesday, June 28, 2016 12:41 PM
To: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Howard,

Thank you. Hopefully you'll receive this information today. If you can nudge it I would appreciate it.

Kendrick Moxon
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From: Howard, Jasmine M. [<mailto:Jasmine.Howard@fda.hhs.gov>]
Sent: Tuesday, June 28, 2016 6:06 AM
To: Kendrick Moxon <kmoxon@kmoxonlaw.com>
Subject: RE: FDA Freedom of Information Request 2016-4067

Good Morning Mr. Moxon,

I also wanted to clarify my email to you on June 21st. In my email, I indicated “we should receive the information in about 4 days” meaning “we” as in our office, should receive the information so we can perform the appropriate redactions and then send to you by the end of the June month. I apologize for the misunderstanding. Once I receive a status from the component office, I will email you.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at: [Customer Service Survey](#)

Best Regards,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
FDA/CDRH/Office of Communication Education
Phone: 301-796-5950 • Email: jasmine.howard@fda.hhs.gov

From: Kendrick Moxon [<mailto:kmoxon@kmoxonlaw.com>]
Sent: Monday, June 27, 2016 9:10 PM
To: Howard, Jasmine M.
Subject: RE: FDA Freedom of Information Request 2016-4067

Ms. Howard,

Thank you for taking the time to speak with me last week, and the courtesy of your email.

I note that your, sent on June 21st, indicates that a response to my FOIA Request would be sent “in about 4 days.” I filed no formal administrative

appeal based on this assurance. It has been 5 days since then but I have received no response.

Can you please look into this matter? Thank you.

Kendrick Moxon
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(818) 827-7104
(818) 827-7114 (fax)
knoxon@knoxonlaw.com

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From: Howard, Jasmine M. [<mailto:Jasmine.Howard@fda.hhs.gov>]
Sent: Tuesday, June 21, 2016 1:51 PM
To: Kendrick Moxon <knoxon@knoxonlaw.com>
Cc: Howard, Jasmine M. <Jasmine.Howard@fda.hhs.gov>
Subject: FDA Freedom of Information Request 2016-4067

Good Afternoon Mr. Moxon,

Thank you for contacting the FDA's Center for Devices and Radiological Health's, Division of Information Disclosure. This email is in regards to your status call today for FOIA request control number 2016-4067. The status is as follows: We have contacted the component office for the records. We should receive this information in about 4 days. We strongly believe that your request will be closed by end of June 2016. If at any time we feel that we will not complete your request by the end of June, we will contact you.

During our call today, you also asked for the appeal address. Below is the address where you can submit an appeal.

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services,
5600 Fishers Lane Room 19-01
Rockville, MD 20857

Please feel free to contact me directly for any other questions or concerns.

Have a great day.

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received at: [Customer Service Survey](#)

Have a great day,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
FDA/CDRH/Office of Communication Education
Phone: 301-796-5950 • Email: jasmine.howard@fda.hhs.gov

EXHIBIT 17

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO. 22215 26 th AVE STE 210 BOTHELL, WA 98021 425-302-0340
---	--

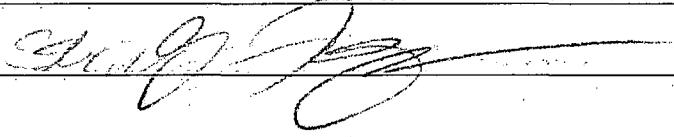
TO	2. NAME AND TITLE OF INDIVIDUAL GORHAM D. NICOL, CHIEF EXECUTIVE OFFICER	3. DATE 6/23/15
	4. FIRM NAME MELTA CORPORATION	5. HOUR 0925 a.m. — p.m.
	6. NUMBER AND STREET 19799 SW 95 th AVE BLDG D STE B	
	7. CITY AND STATE & ZIP CODE TUALATIN, OR 97062	8. PHONE NO. & AREA CODE (503) 612-6780

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s)) 	10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s)) STANLEY B. EUGENE, INVESTIGATOR

<p>¹ Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:</p> <p>Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information</p>	<p>described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this</p> <p style="text-align: right;"><i>(Continued on Reverse)</i></p>
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EF

Establishment Inspection Report

MECTA Corporation

Tualatin, OR 97062-7525

FEI: 3020533

EI Start: 06/23/2015

EI End: 06/30/2015

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SUMMARY

This Level 2, comprehensive, Quality System Inspection Technique (QSIT) inspection of a manufacturer of electro-convulsive therapy (ECT) devices and accessories, used for the treatment of severe depression, was assigned as part of the Seattle District FY 2015 work plan (FACTS assignment number 11538535). This inspection was conducted in accordance with CP 7382.845, Inspection of Medical Device Manufacturers, under Program Assignment Codes (PACs) 82845B, 81845R (Corrections and Removals), and 81011 (MDR practices). MECTA Corporation (MECTA) is currently registered with FDA.

The previous inspection, a Level 1 inspection conducted from 3/12/13 through 3/15/13, covered the: Management Controls, Corrective and Preventive Action (CAPA) Controls, and Production and Process Controls subsystems; and was classified No Action Indicated (NAI).

MECTA develops the specifications; assembles; performs Quality Assurance (QA) and functional testing; packages; and ships its ECT devices and accessories from its facility. MECTA currently develops the specifications and manufactures Class 3 electro-convulsive therapy devices; distributed under the spECTrum name; and cleared under premarket notification clearance number **K965070**. The firm's devices do not require tracking. Profile classes COS, ELE, and MTL were covered. This Level 2, comprehensive, QSIT inspection covered the Management Controls, Design Controls,

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Corrective and Preventive Action (CAPA) Controls, Production and Process Controls (P&PC) subsystems; and focused on MECTA's only domestically distributed medical devices: the spECTrum 5000M and 5000Q models of ECT devices. During the inspection, I observed manufacturing operations; and reviewed MECTA's: Quality procedures and instructions; design controls procedures and activities; CAPA activities and documentation; calibration records; and production activities and documentation; to assess MECTA's compliance with current Good Manufacturing Practices (cGMPs) and Medical Device Reporting (MDR) regulations.

At the conclusion of this inspection, a Form FDA 483, Inspectional Observations, was issued to the Chief Executive Officer for failure: to adequately establish procedures for Design Input; of design verification to confirm design outputs meet design input requirements; and to adequately establish procedures to ensure equipment is routinely calibrated. Issues discussed with management include: performing CAPA effectiveness checks whenever possible; record retention requirements; and the ISO 13485: 2003 Voluntary Audit Report Submission Pilot Program. Management promised to correct the inspectional observations at the close-out meeting.

There were no complaints on file with FDA for follow up. There were no refusals. No samples were collected during the inspection.

ADMINISTRATIVE DATA

Inspected firm: MECTA Corporation
Location: 19799 SW 95th Ave Bldg D Ste B
Tualatin, OR 97062-7525
Phone: 503-612-6780
FAX: 503-612-6542
Mailing address: 19799 SW 95th Ave Bldg D Ste B
Tualatin, OR 97062-7525
Website address: www.mectacorp.com
Dates of inspection: 6/23/2015, 6/24/2015, 6/25/2015, 6/26/2015, 6/30/2015
Days in the facility: 5
Participants: Stanley B. Eugene, Investigator

On 6/2/15, I preannounced the inspection, via phone call, to Mrs. Robin H. Nicol, President, for an attempted start date of 6/8/15. Due to the unavailability of the firm's Quality Manager, and subsequent Investigator schedule conflicts, a start date of 6/23/15 was finalized. Prior to the inspection I requested and was provided electronic copies of the firm's: Quality Systems Manual; Complaint Processing Procedure; and CAPA System Overview procedures.

At the start of the inspection, on 6/23/15, I presented my credentials to Mrs. Robin H. Nicol. I also presented my credentials and issued Form FDA 482, Notice of Inspection, to Mr. Gorham D. Nicol, Chief Executive Officer (CEO), who was identified as the most responsible person at MECTA Corporation (MECTA).

Establishment Inspection Report

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At the conclusion of the inspection, on 6/30/15, I issued Form FDA 483, Inspectional Observations, to Mr. Nicol, CEO.

HISTORY

At the start of the inspection, Mr. and Mrs. Nicol provided a brief description of MECTA Corporation's history and current operations. They explained MECTA was founded in Oregon in 1980; and started distributing electro-convulsive therapy (ECT) devices in 1983. They explained the precursor to the firm's ECT devices was originally developed by an Oregon Health Sciences University (OHSU) physician in 1973; and distributed solely to academic institutions. Mrs. Nicol provided the firm currently distributes four (4) models of ECT devices: spECTrum 4000M; spECTrum 4000Q; spECTrum 5000M; and spECTrum 5000Q. She added only the spECTrum 5000 models are distributed in the United States (U.S.). She further added MECTA's earlier generations of ECT devices, the C, D, SR, and JR models are all obsolete; and no longer serviced.

MECTA Corporation is an Oregon corporation and has been at the current facility located at 19799 SW 95th Ave, Building D, Ste B, Tualatin, OR 97062-7525 since 2000. Mrs. Nicol explained the Chief Executive Officer, President, Vice President, and functional Managers (i.e. Quality, Engineering, Production, International Sales, Domestic Sales, and Purchasing) all operate out the current facility. Mrs. Nicol provided a copy of MECTA's organizational chart as **Exhibit 1**. There are no other associated facilities.

MECTA conducts: specifications development; functional and Quality Assurance testing; packaging; component and accessories storage; and shipping operations in roughly (b) (4) square feet of the approximately (b) (4)-square foot facility. Mrs. Nicol explained MECTA Corporation continues to share the current facility with Beverage Management Services; a beverage dispensing management systems and barroom fixtures company, also owned by Mr. Nicol, which occupies the remaining space.

The previous inspection, a Level 1 inspection conducted from 3/12/13 through 3/15/13, covered the: Management Controls, Corrective and Preventive Action (CAPA) Controls, and Production and Process Controls subsystems; and was classified No Action Indicated (NAI).

MECTA Corporation (MECTA) is currently registered with the FDA for 2015 as a manufacturer, and U.S. Manufacturer of Export Only. The firm has no history of regulatory actions. MECTA is certified ISO 13485 through TUV.

Mrs. Nicol explained MECTA's office hours continue to be from 7:00am to 4:00pm Monday through Friday. The firm currently employs (b) (4) workers including Top Management.

Post-inspectional correspondence and the **FMD-145** copy of this report should be addressed to:

Mr. Gorham D. Nicol, Chief Executive Officer (CEO)
MECTA Corporation
19799 SW 95th Ave, Building D, Ste B

Establishment Inspection Report

MECTA Corporation

Tualatin, OR 97062-7525

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Tualatin, OR 97062-7525

INTERSTATE COMMERCE

According to Mrs. Nicol MECTA's operations have not changed significantly since the last inspection. The firm receives some components for the manufacture of its ECT devices in Interstate commerce. For example the firm receives (b) (4)

(b) (4). In addition, Mrs. Nicol explained the firm currently conducts about (b) (4) of sales in Oregon; with the remainder outside Oregon including overseas in countries and regions such as (b) (4)

(b) (4). She further explained the firm distributes about (b) (4) % of its products domestically; about (b) (4) % in (b) (4); and approximately (b) (4) % of outside North America. Mrs. Nicol provided, as **Exhibit 2**, an example of the documents and records maintained by MECTA for the shipment of a spECTrum 5000 device. The documentation for the shipment of a spECTrum 5000Q device to a hospital in (b) (4) included a Purchase Order, shipping list, Packing List, Invoice, (b) (4) shipment receipt, and Device History Record (DHR) cover sheet.

Mrs. Nicol explained MECTA ships devices to customers from its facility exclusively via (b) (4)

(b) (4). She added MECTA ships devices directly to customers in the U.S; and uses distributors overseas. She explained the firm's customers are qualified: psychiatric and mental health hospitals, clinics and physicians. She also explained the firm distributes (b) (4)

(b) (4)

I asked Mrs. Nicol about MECTA's promotional activities. She explained the firm generates interest and awareness of its products by attending symposia, and annual meetings of the American Psychiatric Association and the Canadian Psychiatric Association; by setting up promotional booths at trade shows; and by generating promotional brochures and data sheets for its devices. Mrs. Nicol also explained MECTA's distributors also participate in trade shows. The firm also maintains a website located at: www.mectacorp.com; which provides product information. Mrs. Nicol explained there are no direct internet sales. She also explained the firm conducts U.S. Federal Government sales to the Department of Veterans Affairs (VA); and to individual branches of the military (e.g. Navy, Army, and Air Force).

JURISDICTION

MECTA develops the specifications; assembles; performs Quality Assurance (QA) and functional testing; packages; and ships its ECT devices and accessories from its facility. MECTA currently develops the specifications and manufactures Class 3 electro-convulsive therapy devices; distributed under the spECTrum name; and cleared under premarket notification clearance number **K965070**. The firm's devices are indicated for the treatment of severe depression with no age restrictions. Mrs. Nicol provided the FDA "substantially equivalent" determination letter for **K965070** as **Exhibit 3**.

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Tualatin, OR 97062-7525

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The firm currently distributes four (4) models of ECT devices: spECTrum 4000M; spECTrum 4000Q; spECTrum 5000M; and spECTrum 5000Q. The 5000 models are 4000 models with the added electrocardiograph (ECG) and electroencephalograph (EEG) monitoring capability. The 4000M and 5000M models have one stimulus control knob while the 4000Q and 5000Q models have four (4) stimulus control knobs that offer more flexibility in adjusting four (4) stimulus parameters: pulse width, frequency, duration, and current to control energy and charge. MECTA distributes only the spECTrum 5000M and 5000Q models in the U.S. Additionally, the U.S. devices have a nominal energy output range up to 100 Joules; while a majority of overseas devices have a nominal energy output range up to 200 Joules.

The firm has implemented the Unique Device Identifier (UDI) for domestic units. Mrs. Nicol provided representative labeling for the spECTrum ECT instruments in the form of a product brochure, an accessories list, the domestic spECTrum specifications, and a device UDI label as Exhibits 4a – 4d.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

At the start of the inspection, on 6/23/15, I presented my credentials and issued Form FDA 482, Notice of Inspection, to **Mr. Gorham D. Nicol, CEO**, who was identified as the most responsible person at MECTA Corporation. At the conclusion of the inspection, on 6/30/15, I issued Form FDA 483, Inspectional Observations, to Mr. Nicol. He sits atop MECTA's organizational chart. He explained he purchased the business in 1980. According to the Quality System Manual reviewed, and observations during the inspection, his day to day duties and responsibilities include but are not limited to: supervision of the executive team; formulation of policies; and setting strategic direction with the President. He receives regular updates from the President on the day to day operations of the firm. He is, along with the President, the Quality Manager, the Research & Development Manager, the Engineering Manager, the Production Manager and the General Manager, a member of the Quality Council which meets (b) (4) to review quality activities and the performance of the Quality System. Mr. Nicol and the President in conjunction with the functional Managers determine resource needs and provide the resources necessary for all activities including the maintenance of the Quality System. Mr. Nicol provided information regarding the firm's history at the opening meeting and attended the close-out meeting on 6/30/15. He provided the firm's annotation decision on the Form FDA 483. During the close-out meeting, I observed he set the deadline for the corrective actions to be implemented by responsible Managers.

During the inspection, I also met **Mrs. Robin H. Nicol, President**. She was present every day of the inspection; and was along with (b)(6),(b)(7)(C),(b)(4) Quality Manager, the points of contact for the inspection. According to the Quality System Manual reviewed, and observations during the inspection, her day to day duties and responsibilities include but are not limited to: maintaining the Quality System including providing program oversight, authorizing corrective actions, overseeing and authorizing audits, stopping processes until they comply with Quality requirements, overseeing written policies, authorizing manual revisions, authorizing releases of new product versions or prototypes, and serving as the Management Representative. She provides regular updates on the day to day operations of the firm to Mr. Nicol and is member of the Quality Council. She accompanied

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during my tours of the facility on 6/23/15 and 6/26/15; and provided documentation and information, regarding the firm's products, operations, and procedures, used in this report. She reports to Mr. Nicol, CEO, and attended the close-out meeting on 6/30/15.

During the inspection, I also met **Ms. Adrian N. Kettering, Vice President**. She was present for the inspection on 6/23/15 and 6/24/15; and accompanied me on my tour of the facility on 6/23/15. She explained she has worked for MECTA since (b) (4) and became Vice President on 6/17/15. She further explained, as Vice President, she will eventually oversee (b) (4) (b) (4). She added she is currently assisting Mrs. Nicol; learning from her; and is getting exposure to the duties and responsibilities of the other functional Managers. She reports to Mrs. Nicol, President.

At the start of the inspection, I met (b)(6),(b)(7)(C),(b)(4) **Quality Manager**. He was present throughout the inspection and accompanied me on my tours of the facility on 6/23/15 and 6/26/15. (b)(6),(b)(7)(C),(b)(4) explained he is currently a consultant for MECTA and is typically present at the firm for (b)(6),(b)(7)(C),(b)(4). He further explained he has been a consultant for MECTA since (b)(6),(b)(7)(C); and his duties and responsibilities include reviewing: all complaints; reviewing or providing inputs to Quality procedures; tracking new regulatory requirements such as the UDI; reviewing, preparing Quality data, and chairing the (b) (4) Quality Council meetings; developing software for the firm's devices and accessories as the Software Manager; and providing input to device specifications for New Product Development and Research and Development (R&D) projects as the R&D Manager. He provided information and documentation used in this report including those relating to the firm's procedures, software changes, design control activities, complaints, CAPAs, quality data analyzed by the firm, and the operation of the firm's devices. He reports Mrs. Nicol, President, and attended the close-out meeting on 6/30/15.

At the start of the inspection I also met (b)(6),(b)(7)(C),(b)(4), **Engineering Manager**. He was present throughout the inspection and accompanied me on my tours of the facility on 6/23/15 and 6/26/15. (b)(6),(b)(7)(C),(b)(4) explained he is currently a consultant for MECTA and typically works (b)(6),(b)(7)(C). He added he has worked for MECTA on and off since (b)(6),(b)(7)(C); and his duties and responsibilities include conducting hardware, Printed Circuit Board (PCB), and mechanical engineering design; managing Engineering Change Orders (ECOs); providing technical support to customers; performing repairs; and obtaining certification from external bodies such as TUV. He provided information and documentation used in this report including those dealing with finished device testing; equipment calibration; design verification testing; and the production flow of spECTrum devices. He reports to Mrs. Nicol, President, and attended the close-out meeting on 6/30/15.

During the inspection I met the following individuals who provided subject matter expertise:

(b)(6),(b)(7)(C) Purchasing Manager, was present on my tour of the facility on 6/23/15 and provided information regarding incoming inspection, vendor qualification, and purchasing control activities. He reports to Mrs. Nicol, President.

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MECTA Corporation
Tualatin, OR 97062-7525

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(b)(6),(b)(7)(C) Production Manager, was present during my tours on 6/23/15 and 6/30/15 and provided information regarding the assembly process for a spECTrum device. He reports to Mrs. Nicol, President.

(b)(6),(b)(7)(C) Technician, was present during my tours on 6/23/15 and 6/30/15 and provided information regarding the assembly and testing of spECTrum devices. He reports to Mrs. Nicol, President.

(b)(6),(b)(7)(C) International Sales / Service Manager and General Manager, provided information regarding customer communication. She accompanied me during portions of my tour of the facility on 6/23/15. She reports to Mrs. Nicol, President.

FIRM'S TRAINING PROGRAM

During the inspection, I reviewed the firm's *Training Procedure, Document P-TR-#0001, Rev D, Effective Date 11/8/11*. Mrs. Nicol explained New Hires receive training on the firm's Quality System Manual; and the procedures relevant to the performance of their job activities. Mrs. Nicol explained most of MECTA's employees are seasoned and experienced at their task. She further explained training consists of: reading procedures; and hands-on application. I also reviewed: the training record for the most recent hire, (b)(6),(b)(7)(C) to verify the training supports his assigned tasks; and the training log document (**Exhibit 5**) for international distributors to verify they are trained on the firm's complaint procedure. I did not note any deficiencies with the training program.

MANUFACTURING/DESIGN OPERATIONS

MECTA develops the specifications and manufactures Class 3 electro-convulsive therapy devices; and accessories. MECTA conducts: specifications development; functional and Quality Assurance testing; packaging; component and accessories storage; and shipping operations in roughly (b) (4) square feet of the approximately (b) (4)-square foot facility. The facility consists of office and administrative space; and a production area where component storage, device assembly, manufacturing, testing, packaging, and shipment occur. Major pieces of equipment observed during the inspection include: (b) (4)

(b) (4)

MECTA currently utilizes commercial-off-the-shelf software “ (b) (4) ” for its Enterprise Resource Planning (ERP) operations.

This Level 2, comprehensive, QSIT inspection covered the Management Controls, Design Controls, Corrective and Preventive Action (CAPA) Controls, Production and Process Controls (P&PC) subsystems; and focused on MECTA's only domestically distributed medical devices: the spECTrum 5000M and 5000Q models of ECT devices. During the inspection, the firm's

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manufacturing operations were observed; and procedures, records, and activities were reviewed to assess the firm's compliance with the Quality System Regulations.

I observed and (b)(6),(b)(7)(C) and (b)(6),(b)(7)(C) explained the spECTrum device manufacturing process as follows.

MECTA's Domestic Sales Managers receive an order from a qualified hospital → (b) (4)

(b) (4)

(b) (4) → product release → packaging and shipment to customer via (b) (4)

Mrs. Nicol provided production flow procedures and documents for the manufacture of spECTrum devices in the form of: production flow procedure; test procedure; production flow chart; (b) (4) (b) (4) QA Form; Safety Tests Form; Manual Checkout Form; and Finished Goods / Shipping Release Form as **Exhibits 6a – 6g**.

Mrs. Nicol explained the firm builds on order exclusively because each unit is customized to the customer's requirements; such as the number of monitoring channels. She estimates MECTA manufactures approximately (b) (4) spECTrum devices per year; and about (b) (4) per month. She estimates MECTA manufactures approximately (b) (4) spECTrum 4000 models per year out of the (b) (4) total devices produced yearly. She added it takes (b) (4) days from the time the Purchase Order is finalized to the shipment of the finished spECTrum device. Mrs. Nicol indicated the spECTrum devices have a one (1) year standard warranty; and customers have the option to purchase a five (5)-year extended warranty. The firm also assembles accessories such as the handheld electrodes onsite.

MANAGEMENT CONTROLS

I reviewed MECTA's procedures and instructions for the management of its quality system including but not limited to those governing management reviews, training, document controls, purchasing and supplier controls, acceptance activities, control of nonconforming product, corrective and preventive actions, and complaints. During the inspection, I reviewed MECTA's: *Quality System Manual, Document D-QS-#0007, Rev V, Effective Date 10/24/14*; procedure *Quality Council Meetings, Document P-QS-0003, Rev I, Effective Date 11/08/11*; procedure *Management SOP, Document D-MG-#0001, Rev G, Effective Date 11/29/12*; and procedure *Document Control SOP, Document D-DC-#0001, Rev G, Effective Date 10/10/14*. I also covered the management reviews conducted through the Quality Council meetings on (b) (4) (b) (4) for the individuals in attendance and the topics covered. I observed management reviews through the Quality Council meetings are conducted (b) (4) .

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During my review of the Quality System Manual and the Document Control SOP I observed the following document retention requirements. Records are retained for one of two time periods:

1. (b) (4)
2. (b) (4)

I explained to Mrs. Nicol, (b)(6),(b)(7)(C),(b)(4), and Ms. Kettering, there can be a conflict between the two requirements since there is no qualifier that the longer retention requirement must be followed. Please see the **Discussion with Management** section **issue 2** for a discussion regarding Quality System record retention requirements.

I also reviewed the firm's *Quality System Audit Procedure, Document P-QS-#0002, Rev L, Effective Date 10/10/14* and the internal audit schedule contained in the procedure. I also reviewed documentation of the performance of audits of the Quality System conducted from 8/6/14 to 11/10/14 for 2014; and from 9/6/13 to 10/11/13 for 2013. I observed the entire Quality System is audited annually by in-house auditors. (b)(6),(b)(7)(C),(b)(4) conducts the internal audits of the Quality System; except for the Quality and Engineering Department areas which are audited by Mrs. Nicol.

DESIGN CONTROLS

I reviewed MECTA's: design controls procedures contained in the Quality System Manual; *Engineering Change Procedure, Document P-EE-#0001, Rev D, Effective Date 1/31/03; New Software Package Procedure, Document P-SW-#0020, Rev D, Effective Date 11/10/10; All Software Changes Procedure, Document P-SW-#0009, Rev G, Effective Date 10/10/14;* and documentation for the firm's software change for its **spECTrum Optimized New Parameter Sets** project to (b) (4)

(b) (4)
(b) (4) Please refer to the **Objectionable Conditions and Management's Response** section of this report, **Observations 1 -2** for failure: to adequately establish procedures for Design Input; and of design verification to confirm design outputs meet design input requirements.

CORRECTIVE AND PREVENTIVE ACTION CONTROLS (CAPA)

I reviewed MECTA's: *CAPA System Overview, Document D-MG-#0002, Rev F, Effective Date 11/12/13 (Exhibit 7); and Complaint Processing Procedure, Document P-QS-#0001, Rev I, Effective Date 10/4/11 (Exhibit 8).*

I also reviewed: the firm's twenty (20) customer contact / complaint forms covering a period of 1/23/14 to present; and fourteen (14) CAPA records from 10/18/13 to present. Please see the **Discussion with Management** section **issue 1** for a discussion on performing CAPA effectiveness checks whenever possible.

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MDR and Corrections and Removals

I reviewed MECTA's written *Complaint Processing Procedure* which covers the firm's complaint handling, adverse event reporting, and recall activities. (b)(6),(b)(7)(C),(b)(4) stated he reviews all complaints for MDR reportability. Mrs. Nicol explained a recommendation for recall would be made by (b)(6),(b)(7)(C),(b)(4) and her if the situation arose. She stated the firm has not submitted any MDRs since the previous inspection and has never conducted a recall. A review of FDA's Manufacturer and User-Facility Device Experience (MAUDE) database revealed no MDRs related to MECTA Corporation's products since the previous inspection. I observed complaints are investigated and evaluated for adverse event reportability. I also observed the firm maintains an MDR binder.

Tracking

MECTA does not handle devices requiring tracking.

PRODUCTION AND PROCESS CONTROLS (P&PC)

During the inspection, I observed the firm's manufacturing operations; and reviewed MECTA's: Device History Record (DHR) documentation for ten (10) spECTrum 5000 model devices; and the calibration records for four (4) pieces of equipment used during production for the testing of spECTrum devices.

Sterilization

MECTA's devices are not intended to be sterile.

Purchasing Controls

I reviewed MECTA's: *Purchasing SOP, Document D-PU-#0002, Rev D, Effective Date 10/24/14; Choosing New or Substitute Vendors / Parts Procedure, Document P-PU-#0003, Rev D, Effective Date 10/24/14; Vendor Review Procedure, Document P-PU-#0012, Effective Date 1/31/03;* and documentation for the most recent qualification of vendor (b) (4) which supplies the firm with (b) (4). I did not note any deficiencies.

Acceptance Activities

MECTA's acceptance activities include: visual inspection, QC testing, and (b) (4) (b) (4) final testing of the spECTrum devices. I did not note any deficiencies.

Non-Conforming Product

I reviewed the firm's Control of Nonconforming Material activities. I observed nonconforming material data is analyzed as part of the CAPA system and reviewed during (b) (4) Quality Council meetings. I also observed the firm provides for the segregation of nonconforming materials; and

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documentation through various logs such as the Rejected Parts log for incoming materials; Production Rework Bin log; and Final Test Nonconformance log. I did note any deficiencies.

Calibration of Test and Measuring Equipment

I reviewed MECTA's: *Test Equipment Maintenance Procedure, Document P-TE-#0003, Rev C, Effective Date 9/31/03*; *Test Equipment Out-of-Calibration Procedure, Document P-TE-#0004, Rev A, Effective Date 10/9/02*. I also reviewed calibration records for: a Safety Analyzer from 2014 and 2013; a Hi-Pot tester for 2014 and 2013; a ground tester for 2015, 2014, and 2013; and the automated Final Test Fixture from 2015 and 2014. Please refer to the **Objectionable Conditions and Management's Response** section of this report, **Observation 3** for a failure to adequately establish procedures to ensure equipment is routinely calibrated.

MANUFACTURING CODES

MECTA utilizes manufacturing codes for the spECTrum devices; which includes a unique five-digit serial number; a reference number indicating the model number and whether the device is a domestic unit; and the manufacturing date in the format **YYYY-MM-DD**. For example, during the inspection, I observed the manufacturing of spECTrum devices with code: **SN 12663 REF 5000DQ 2015-06-26**. The "D" in the reference number indicates the device is a 100 Joule domestic device.

COMPLAINTS

Details of complaints, MDRs, and corrections and removals are documented under the heading **Corrective and Preventive Action Controls**.

RECALL PROCEDURES

Please refer to the **Corrective and Preventive Action Controls** heading for the discussion on any applicable MECTA recall activity.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Procedures for design input have not been adequately established.

Specifically,

Your firm's **spECTrum Optimized New Parameter Sets** design project was reviewed and the following deficiency was noted. Your firm's document *New Parameter Sets - Project ^{(b) (4)} Software Maintenance Plan*, dated 3/1/11 and form *F-SW-#0011, Rev A, Software Verification Report* for processing Software spECTrum ^{(b) (4)} version ^{(b) (4)} with test dates 4/19/11 to 4/22/11 which cover the spECTrum Optimized New Parameter Sets design project contain conflicting requirements.

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- The Software Maintenance Plan, dated 3/1/11 specifies that processing Software spECTrum (b) (4) version (b) (4) will compute the maximum possible delivery power (Watts) and requested energy (Joules) for given parameter settings; compare them to the limiting values of (b) (4) watts (Joules/second) and 101 Joules (domestic units) or 202 Joules (international units); and cause a DOSAGE EXCEEDED message to display on screen if the power or energy limit is exceeded.
- The Software Verification Report with test dates 4/19/11 to 4/22/11, documenting the testing conducted for processing Software spECTrum (b) (4) version (b) (4) used (b) (4) Watt (Joules/second) power limit.

Annotation: Promised to correct within 15 days.

Reference: 21 CFR 820.30(c)

Supporting Evidence and Relevance:

Exhibit 9 is New Parameter Sets - Project (b) (4) Software Maintenance Plan, dated 3/1/11.

Exhibit 10a is form F-SW-#0011, Rev A, Software Verification Report for processing Software spECTrum (b) (4) version (b) (4) with test dates 4/19/11 to 4/22/11.

Exhibit 10b is processing Software spECTrum (b) (4) version (b) (4) data sheets for test dates 4/19/11 to 4/22/11.

During my coverage of the firm's design controls activities, I reviewed the firm's **spECTrum Optimized New Parameter Sets** project to (b) (4)

(b) (4) During my review I observed the Software Maintenance Plan and the Software Verification Report data sheets documented conflicting requirements. During the inspection and the close-out meeting, I explained to Mr. Nicol, Mrs. Nicol, (b) (6), (b) (7) (C), (b) (4), and Mr. (b) (6), (b) (7) (C), (b) (4) the requirement to have clearly defined and unambiguous specifications that can be objectively verified. (b) (6), (b) (7) (C), (b) (4) and (b) (6), (b) (7) (C), (b) (4) explained the specification for power is not a requirement from any Standard and does not have any safety impact. They explained the use of (b) (4) Watt (Joules/second) power limit is appropriate because a 1 Joule/second power difference is almost indiscernible. I explained to them, while there might not be a safety concern, if the firm defines a design input the requirement must be unambiguous and must be met. They stated they understood. I also stressed the importance of conducting thorough design reviews to identify incomplete or ambiguous design inputs.

Discussion with Management:

At the close-out meeting I referred management to the applicable section of the Code of Federal Regulations (CFRs); and asked management if they had any questions about the observation or the deficiency. Management stated no. I asked the firm about the corrective actions it anticipates implementing to address the observation. (b) (6), (b) (7) (C), (b) (4) explained the firm will initiate CAPA 484, dated 6/30/15, that will include a justification for the appropriateness of using the (b) (4) watt power limit. I explained to management the written response provides an opportunity for MECTA to update FDA on made corrections and to advise FDA action plans and implementation time frames for achieving

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Exhibit 10b is processing Software spECTrum (b) (4) version (b) (4) data sheets for test dates 4/19/11 to 4/22/11.

Exhibit 11 is Production Software Version History for processing Software spECTrum (b) (4) showing approval of version (b) (4) on 6/7/11.

During my coverage of the firm's design controls activities, I reviewed the firm's **spECTrum Optimized New Parameter Sets** project. During my review I observed the Software Maintenance Plan and the Software Verification Report data sheets documented conflicting requirements; and results on the data sheets did not confirm the requirements for power and energy limits were met. During the inspection and the close-out meeting, I explained to Mr. Nicol, Mrs. Nicol, (b) (6), (b) (7) (C), (b) (4) and (b) (6), (b) (7) (C), (b) (4) the requirement for design verification to provide objective evidence design outputs meet design inputs. As discussed in **Observation 1**, above, (b) (6), (b) (7) (C), (b) (4) and (b) (6), (b) (7) (C), (b) (4) explained the specification for power is not a requirement from any Standard and does not have any safety impact. They added the use of (b) (4) Watt (Joules/second) power limit (versus (b) (4) Watt) is appropriate because a 1 Joule/second power difference is almost indiscernible. I explained to them, while there might not be a safety concern, the firm self-imposed the (b) (4) Watt power specification which must be met. I also explained the issue with the discrepancy in power limit would be lessened if the data showed the more stringent (b) (4) Watt requirement was met; which is not the case.

I asked (b) (6), (b) (7) (C), (b) (4) about the discrepant data for the 202-Joule energy limit for international spECTrum models that were not met according to the data sheets. He explained the 202-Joule limit is a nominal limit and the actual specification is really (b) (4) Watts. I reiterated to management at the close-out meeting the requirement to have clear and unambiguous specifications that can be objectively verified. (b) (6), (b) (7) (C), (b) (4) added there is not a safety concern because energy differences in the tenths of Joule are practically indiscernible. I explained to management since MECTA defined the requirements in the *Software Maintenance Plan* it must ensure the requirements are unambiguous through their normal design controls processes including design reviews.

Discussion with Management:

At the close-out meeting I referred management to the applicable section of the CFRs; and asked management if they had any questions about the observation or the deficiency. Management stated no. I asked the firm about the corrective actions it anticipates implementing to address the observation. (b) (6), (b) (7) (C), (b) (4) explained the firm will initiate CAPA 485, dated 6/30/15, that will include a justification for why the results on spECTrum (b) (4) version (b) (4) provide evidence of the verification of the design inputs. (b) (6), (b) (7) (C), (b) (4) also explained the firm will revise the **spECTrum Optimized New Parameter Sets** design project documentation to remove any conflict and ambiguities. Mrs. Nicol explained the firm will submit documentation of its implemented corrective actions with its response.

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OBSERVATION 3

Procedures to ensure equipment is routinely calibrated have not been adequately established.

Specifically,

Your firm's automated Final Test Fixture is used in production to perform a final checkout verification of the proper operation and calibration of your spECTrum Electro-Convulsive Therapy (ECT) devices. The most recent in-house verification of the automated Final Test Fixture, performed 1/30/15, yielded out-of-tolerance results which were not detected.

The Final Test - (b) (4) Fixture Verification procedure includes the following requirements for accuracy:

- Low Frequency Knee (analog and digital) = +/- (b) (4) % of measured value
- High Frequency Knee (analog and digital) = +/- (b) (4) % of measured value

The Final Test Fixture Verification report, dated 1/30/15, indicates fixture out-of-tolerance results for the unit under test; including for the analog and the digital low frequency knees on channels EEG1, EEG2, EEG3, EEG4, ECG1, and OMS (Optical Motion Sensor); and for the analog high frequency knee on channel ECG1. The Final Test Fixture Verification report, dated 1/30/15, indicates "Pass" on all channels for: Low Frequency Knee (analog and digital); and High Frequency Knee (analog and digital) in the "Analysis of the results" section.

Annotation: Promised to correct within 15 days.

Reference: 21 CFR 820.72(a)

Supporting Evidence and Relevance:

Exhibit 12 is Final Test - (b) (4) Fixture Verification procedure with Final Test Fixture Verification report, dated 1/30/15.

During my review of the firm's Test Equipment maintenance and calibration program I reviewed the 2015 and 2014 calibration records for the automated Final Test Fixture used in production to perform a final checkout verification of the proper operation and calibration of the spECTrum devices. I observed the most recent in-house verification of the automated Final Test Fixture, performed 1/30/15, yielded out-of-tolerance results which were not detected. The following table highlights out-of-tolerance results from the data contained in the Final Test Fixture Verification report, dated 1/30/15.

Channel	Band Pass Amplitude normalized fixture	Band Pass tolerance	Low Freq. Knee fixture analog	Low Freq. Knee fixture digital	Lo. Freq. Knee toler.	High Freq. Knee fixture analog	High Freq. Knee fixture digital	Hi Freq. Knee toler.	Recorded Results
EEG 1	(b) (4)	(4)	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed
EEG 2			Hz	Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed
EEG 3			Hz	Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed
EEG 4			Hz	Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed
ECG1			Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed
OMS			(b) (4) Hz	Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	(b) (4) Hz	Passed

Figure 1. Out-of-tolerance results (in bold) from Final Test Fixture Verification Report, dated 1/30/15.

During the inspection and the close-out meeting I discussed the issue with the firm. (b)(6),(b)(7)(C),(b)(4) explained the issue is mitigated because the spECTrum devices undergo (b) (4) checkout to verify their proper operation. I explained to (b)(6),(b)(7)(C),(b)(4), (b)(6),(b)(7)(C),(b)(4), and Mrs. Nicol, the automated Test Fixture is used as a final checkout of the spECTrum devices which is required for the shipment release of the devices; and must be capable of yielding valid results. I explained the results of the 1/30/15 do not provide evidence the automated Test Fixture can provide valid results. (b)(6),(b)(7)(C),(b)(4) and (b)(6),(b)(7)(C),(b)(4) explained it appears there were some transcription errors in transferring the results from the computer screen to the form. I explained, since the firm does not keep a print-out of the automated results, I do not have access to the source data and cannot determine if transcription errors were made. They agreed. They also added the firm's tolerances used in the calibration procedure are tighter than those required by the International Electro-technical Commission (IEC) standard. I explained MECTA is required to meet self-imposed specifications. They stated they understood.

Discussion with Management:

At the close-out meeting I referred management to the applicable section of the CFRs; and asked management if they had any questions about the observation or the deficiency. Management stated no. I asked the firm about the corrective actions it anticipates implementing to address the observation. (b)(6),(b)(7)(C),(b)(4) stated the firm will re-perform the calibration of the automated Test Fixture on 6/30/15 and conduct an evaluation of the effect of the calibration failure on distributed devices. He added, in the long term, the test procedure and associated data fields will be reformatted to make it easier for the tester to detect out-of-tolerances. Mrs. Nicol explained the firm will submit documentation of its implemented corrective actions with its response.

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REFUSALS

There were no refusals during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the close of the inspection on 6/30/15 I issued a Form FDA 483, Inspectional Observations, to Mr. Gorham D. Nicol, CEO. Mrs. Nicol, President, (b)(6),(b)(7)(C),(b)(4), Quality Manager, and (b)(6),(b)(7)(C),(b)(4) Engineering Manager, also attended the close-out meeting.

I explained to management the top two (2) statements on Form FDA 483. I further explained the conditions I observed during this inspection may, after further review by the Agency, be considered violations of the Federal Food, Drug and Cosmetic Act; and legal sanctions, including seizure, injunction, and prosecution are available to the FDA if a firm does not comply with the medical device regulations. I informed management other actions, including letters, Warning Letters, regulatory meetings, civil money penalties, and future FDA inspections, are also available to the FDA. I also informed management of the option to submit a written response to the U.S. FDA's Seattle District within 15 working days of the close of the inspection. I also explained the voluntary options the firm has to annotate the Form FDA 483. Mr. Nicol stated the firm will submit a written response to Seattle District.

I also discussed the following issues with Management during the inspection and at the close-out meeting.

(1) Performing CAPA effectiveness checks whenever possible

During my review of the firm's CAPA documentation, I observed CAPAs whose corrective actions resulted only in changes to procedures did not require effectiveness checks. Please see, for example, CAPA 472, dated 10/15/14 (**Exhibit 13a**); and CAPA 482, dated 11/17/14 (**Exhibit 13b**). During the inspection I explained to (b)(6),(b)(7)(C),(b)(4); and to management at the close-out meeting it is always useful to conduct effectiveness checks whenever possible. I explained it would be important, for example, to verify whether the new procedures were being followed over a defined period after implementation; and whether there was any recurrence of the original issue in order to provide objective evidence the corrective actions were effective. (b)(6),(b)(7)(C),(b)(4) stated he understood.

(2) Retention requirements for Quality records

During my review of the Quality System Manual and the Document Control SOP I observed the following document retention requirements Records are retained for one of two time periods:

1. (b) (4)
2. (b) (4)

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I asked Mrs. Nicol to describe how she would determine the record retention requirement for a line of product MECTA chose to retire. She explained once the firm made the decision to retire a product the retention requirement would be (b) (4). I explained to Mrs. Nicol, (b)(6),(b)(7)(C),(b)(4) and Ms. Kettering, there can be a conflict between the two requirements if the (b) (4) is greater than (b) (4) since there is no qualifier that the longer retention requirement must be followed. I also referred them to the applicable section of the regulations, 21 CFR §820.180. (b)(6),(b)(7)(C),(b)(4) stated the retention requirement can be clarified.

(3) ISO 13485: 2003 Voluntary Audit Report Submission Pilot Program

During the inspection, Mrs. Nicol inquired about the FDA using or recognizing third party audits in conjunction with FDA inspections. I explained to Mrs. Nicol the FDA started a pilot program that allowed qualifying firms to submit audit reports from qualifying bodies. I provided her with a copy of the Guidance Document, Medical Device ISO 13485: 2003 Voluntary Audit Report Submission Pilot Program.

SAMPLES COLLECTED

No samples were collected during the inspection.

EXHIBITS COLLECTED

1. MECTA's organizational chart
2. Example of documentation for a shipment spECTrum to (b) (4) 7 pp
 - Pg 1: Purchase Order Number (b) (4)
 - Pg 2: Shipment list for June 2015 showing shipment of SN (b) (4) under P.O. (b) (4)
 - Pg 3-4: Invoice Number 043918 for SN (b) (4) referencing P.O. (b) (4)
 - Pg 5: Packing List SN (b) (4) referencing P.O. (b) (4)
 - Pg 6: (b) (4) shipment receipt for delivery of SN (b) (4) to (b) (4) and referencing P.O. (b) (4)
 - Pg 7: DHR coversheet for SN (b) (4)
3. FDA "substantially equivalent" determination letter for **K965070** 3 pp
4. spECTrum device labeling
 - a. Product brochure
 - b. Accessories list
 - c. Domestic spECTrum specifications 8 pp
 - d. Domestic spECTrum UDI label
5. Distributor Training Log
6. spECTrum device manufacturing flow documentation
 - a. Production Flow procedure 6pp
 - b. Test procedure
 - c. Production Flow Chart 4 pp
 - d. (b) (4) QA Form 5 pp
 - e. Safety Tests Form 4 pp
 - f. Manual Checkout Form 4 pp

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- g. Finished Goods / Shipping Release Form
7. *CAPA System Overview, D-MG-#0002, Rev F* 3 pp
 8. *Complaint Processing Procedure, P-QS-#0001, Rev I* 8 pp
 9. *New Parameter Sets - Project (b) (4) Software Maintenance Plan, dated 3/1/11* 3 pp
 10. Software spECTrum (b) (4) version (b) (4) verification documentation
 - a. *F-SW-#0011, Rev A, Software Verification Report* with test dates 4/19/11 to 4/22/11
 - b. spECTrum (b) (4) version (b) (4) data sheets for test dates 4/19/11 to 4/22/11 5 pp
 11. Production Software Version History for processing Software spECTrum (b) (4)
 12. *Final Test - (b) (4) Fixture Verification* procedure with Verification report dated 1/30/15 6 pp
 13. Examples of MECTA CAPA forms without verification of effectiveness
 - a. CAPA 472, dated 10/15/14
 - b. CAPA 482, dated 11/17/14

ATTACHMENTS

1. Form FDA 482, Notice of Inspection, issued to Mr. Gorham D. Nicol, Chief Executive Officer, dated 6/23/15. 3 pp
2. Form FDA 483, Inspectional Observations, issued to Mr. Gorham D. Nicol, Chief Executive Officer, dated 6/30/15. 4 pp


Stanley B. Eugene, Investigator

EXHIBIT 18



CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL

Established in 1969 by the Church of Scientology to investigate and expose psychiatric violations of human rights

INTERNATIONAL PRESIDENT

Jan Eastgate

NATIONAL U.S. PRESIDENT

Bruce Wiseman

BOARD MEMBER

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The late Thomas Szasz,
Professor of Psychiatry
Emeritus, State University of
New York Health Science
Center

Science, Medicine & Health

Rohit Adi, M.D.

Prof. Garland Allen

Giorgio Antonucci, M.D.

Lisa Bazler, B.A., M.A.

Ryan Bazler, B.S.

Shelley Beckmann, Ph.D.

Lisa Benest, M.D.

John Breeding, Ph.D.

Lisa Cain, Ph.D.

Anthony Castiglia, M.D.

James Chappel, D.C., N.D.,
Ph.D.

Beth Clay

Ann Y. Coxon, M.B., B.S.

Moira Dolan, M.D.

David Enger, Ph.D.

Seth Farber, Ph.D.

Brett Hartman, Psy.D.

Georgia Janisch, R.D.

Jonathan Kalman, N.D.

Prof. Oleg Khilkevich

Eric Lambert, R.Ph.

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Craig Newnes, M.D.

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9 February 2016

<http://www.regulations.gov>

**Re: Comments in Response to "Proposed Rule" dated 29
December 2015, Docket ID: FDA-2014-N-1210-0001**

**FDA's "Neurological Devices; Reclassification of
Electroconvulsive Therapy Devices Intended for Use in
Treating, it is recommended the ECT device be rated Class
II for:**

- Severe 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 who require a rapid response due to the severity of their psychiatric or medical condition, which is a pre-amendments class III device, into class II (special controls) based on new information.¹

The following submission and comments are in support of the ECT device being rate remaining as Class III for all indications.

INTRODUCTION

Citizens Commission on Human Rights International is a mental health rights group established in 1969 to investigate psychiatric abuses and violations of human rights. CCHR has been and remains a voice for many thousands of individuals who report abuse, damage and injury that they have suffered in the mental health system. CCHR's response to the Proposed Rule with regard

to rating the ECT machine as class 2 is based upon 46 years of research and investigation, including from the very patients who have actually experienced and to whom psychiatrists have administered shock treatments.

In the forty years that the ECT device manufacturers have had the device on the market they have never conducted a clinical trial to support its safety and efficacy from which they have profited. Add to this the psychiatric community's outcry against feedback from patients to whom they have administered electro-shock. Who better to report what occurred, than the very person upon whom the treatment is being rendered?

Contrary to the psychiatric community's position, the FDA is supposed to recognize "reports of significant human experience with a marketed device" as a form of valid scientific evidence." (21 CFR Ch 1 860.7 (c)(2)²

The need to respect the patients' perspective and not dismiss their experiences of harm as "anecdotal" was raised by psychiatrist, Dr. Colin Ross, in his submission to the FDA in 2011. He stated: "In general, the effectiveness of ECT is greatly exaggerated in the ECT literature and its toxicities and side effects are greatly minimized, discredited as 'anecdotal, attributed to the depression rather than the treatment, or dismissed as 'anti-psychiatry.'"³

In May 2006 Harold Robertson, Robin Pryor addressed the patients' perspective in *BJPsych*. They said that ECT has come under scrutiny, "with the first systematic review of patients' experiences and new national guidelines" in the UK. As part of a review of electroconvulsive therapy (ECT) undertaken by the UK's Department of Health, the Service User Research Enterprise (SURE) published 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 (United Kingdom Advocacy Network, 1996; ECT Anonymous, 1999; Pedler, 2000).⁴

The authors report some of the conclusions to come out of the new work. In particular, at least one-third of patients experience *permanent* amnesia (Service User Research Institute, 2002; Rose et al, 2003; Scott, 2005), half of patients had not received an adequate explanation prior to treatment (Rose et al, 2003, 2005; Philpot et al, 2004) and that newer methods of ECT have not resulted in an *appreciable decrease in adverse effects* (UK ECT Review Group, 2003).⁵
[Emphasis added]

In contradiction to this, psychiatrists that appeared before Neurological Devices Panel of the Medical Devices Advisory Committee hearings in January 2011 dispute patients' experience as anecdotal: For example, Dr. Charles Kellner appeared before the January 27 2011 meeting. He was a consultant for the two ECT device manufacturers, MECTA and SOMATICS, Inc. and wants the ECT device rated Class II.⁶ Dr. Charles Kellner (cited in the MECTA submission to the FDA about 5 times) was a member of the APA ECT Task Force in 2001 and 2010. The

MECTA submission to the FDA cites the APA ECT Task Force of 2001 at least a dozen times. Dr. Kellner claims that “almost all of the controversy about ECT is anecdotal opinion, unsupported by evidence.”⁷

Dr. Kellner provided his opinion against a patient who filed a lawsuit over ECT damage in 2003. He asserted that the patient, Ms. Peggy Salters’ suicidality justified the administration of ECT; however, the court found that this could not be substantiated by the medical records. In 2005, the court awarded Ms. Salters more than \$635,000 for the long-term memory loss the ECT caused her.⁸

CCHR was one of the groups instrumental in obtaining the first informed consent provisions in U.S. law for ECT and psychosurgery in California in 1976.

CCHR has worked since then to strengthen restrictions on these procedures, including the prohibition of their use in some U.S. and Australian states in the treatment of children, and recently in Sicily, Italy the prohibition of ECT entirely.⁹

CCHR’s work aligns with the UN Universal Declaration of Human Rights, in particular:

Article 3: “Everyone has the right to life, liberty and security of person,” and Article 5: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.”

FDA must put patient protection above the financial interests of companies that have failed to conduct clinical trials and provide a PMA for 40 years. Because there are state laws that allow for electroshock to be administered to patients without their consent, even greater protections are needed. Under some circumstances, this constitutes assault and torture. Any class II rating could increase this risk and would potentially endanger people’s lives.

Given that every indication from APA members, NIMH’s Dr. Matthew Rudorfer and the manufacturers that the manufacturers either cannot financially undertake a clinical trial or “don’t do research” anyway, the FDA Proposal is disingenuous and misleading.

Accordingly and based upon the information contained herein, CCHR opposes the FDA’s Proposed Order. CCHR strongly recommends that the ECT device remain Class III for all indications and Pre-Market Application (PMA) be required to prove safety and efficacy or be removed from the market entirely—the latter, in fact, being a safer option.

In lieu of removing the device from the market, it must remain as Class III so that FDA can ensure the health and safety of patients are protected and placed above the economic concerns of the ECT device manufacturers.

Sincerely

Jan Eastgate
President
Citizens Commission on Human Rights
International

ECT PRODUCES BRAIN DAMAGE

FDA undermines the scores of studies and patient testimonies that indicate ECT causes brain damage. Dr. Lawrence Park, the FDA Medical Officer who wrote the Executive Summary on ECT for the FDA is a psychiatrist who has co-authored numerous studies on ECT.¹⁰ Before he joined the FDA, he served as the Director of Research and Attending Psychiatrist for the Somatic Therapies Unit at Massachusetts General Hospital, where ECT is administered.¹¹ Its website states ECT does not cause brain damage and is a safe and relatively comfortable experience—contrary to thousands of ECT “consumers” who presented comments to the FDA stating the opposite.¹² He has participated in research for Cyberonics (maker of Vagus Nerve Stimulator) and Medtronic (manufactures Deep Brain Stimulation device).¹³

The Neurological Devices Panel of the Medical Devices Advisory Committee Chairman Dr. Matthew Brott, a neurologist, commented on the lack of any valid study using modern methodology/technology that substantiates one way or the other the brain damage ECT causes. Of the biological markers cited as evidence that brain damage didn’t exist, he said, “None of them have been shown to be reliable. All of them have been shown to be unreliable. That’s why they’re not used in the hospital down the block or anywhere in the country to measure brain injury.

“We also have MRI scans that we use...we also have the EEG that’s going in the device, and with 100,000 people a year, as a neurologist, I’m asking, how many people have had MRIs to look at the structure of the brain? How many people have had serial EEGs to look at potential changes in the EEG? And how many people have had neuropathological examinations, which would be appropriate to judge whether or not this device impacts the structure of the brain? And I tried to look and I saw very little, and I concluded that the evidence is not there to really address the question either way....” [pp. 221-22 28 Jan 2011 hearing]

How then can the FDA conclusively *believe* that ECT does not cause brain damage?

The panel couldn’t even agree on what, today, constituted brain damage. Again, the chairman stated, “I think the Panel has expressed that the term brain damage is not particularly precise and is open to different interpretations...the studies that have been done, to date, have not answered the question as to whether or not there may be instances of brain damage which have gone undetected.” [p. 417, 28 January 2011.]

FDA relies in part upon the APA Task Force report “Practice of Electroconvulsive Therapy,” 2001, which recommends “brain damage should not be included in the ECT consent form as a potential risk of treatment.”¹⁴ The APA ECT Task Force was headed by Dr. Richard Weiner (the MECTA consultant, who developed ECT devices for the company) and members included Harold Sackeim,

Ph.D. (consultant to MECTA/SOMATICS) and Charles Kellner who has organized a training course on ECT that was sponsored in part by SOMATICS Inc. and MECTA.¹⁵

In 2004, under deposition from attorney Rick Moxon, MECTA owner and president, Robin Nicol provided revelatory information and exemplifies why the FDA should not rely upon evidence from psychiatrists with conflicts of interest with MECTA. According to Nicol:

- She 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.”
- When asked about whether MECTA had spoken with patient groups whose members had been gravely harmed by ECT, Ms. Nicol said she relied on “literature that supports our products, that it is a safe and effective treatment,” so “there’s nothing to be gained.”
- She admitted that if she had “information that [MECTA’s] devices were not safe, it would not be considered unless the information came from double-blind studies.”
- “We are not responsible for individual patients....They are not our responsibility from the FDA perspective or from our perspective as medical-device manufacturers.”
- MECTA could not provide evidence of how ECT works, except that their machines are designed to cause a grand mal seizure and, beyond that, the mechanism is entirely theoretical.
- More electricity is used by MECTA machines than is necessary to cause a grand mal seizure, because, “The patients were not getting better.”
- When asked, “Do you know what the point is of sending electricity through the brain if it’s not just to cause a convulsion?” she answered, “No.”
- Although the company was well aware of its responsibility to provide the FDA of all adverse events, the company had only done so ONCE in the 25 years she had run the company.

ECT CAUSES HARM

The FDA evaluated the risks of the devices but doesn’t consider the serious adverse effects outweigh the benefit—despite no clinical trial proving safety. It undermines the severity of the adverse effects patients complain of to justify classifying the device being rated as Class II.

Dr. Anna Georgiopoulos, Psychiatric Medical Officer at the Center for Devices and Radiological Health, Office of Device Evaluation, Division of Ophthalmic, Neurological and ENT Devices reported the FDA's MAUDE database reports:

- "As of December 7, 2010, the FDA has received 151 original adverse event reports, including 135 voluntary reports and 16 user facility reports associated with ECT devices.¹⁶ ...the most commonly cited adverse event type in the MAUDE database was memory loss. Some type of memory loss was reported in 117 cases or 77 percent of all reports. After memory loss, general emotional or psychiatric events were reported most commonly. General motor symptoms, general functional disability, headache, cognitive side effects, seizure, and pain followed in order of frequency."¹⁷
- "Other events reported in the MAUDE database included burns, neurological complications, ineffective treatment, brain damage, sleep disturbance, visual change, reports of forced treatment, nausea, personality change, mechanical malfunction, cardiac problems, stroke, improper consent, death, one instance of which occurred within two months of ECT, auditory complaints, dental or oral trauma, hypertension, hypotension, suicide with one completed suicide and one attempt, urinary complaints, incontinence, anesthesia-related complications, coma, miscarriage, and a pulmonary complication."¹⁸
- From the list of all reported adverse events, a review team "made a determination regarding which of the reported adverse events should be considered potentially significant adverse events. Significant adverse events were identified as being substantiated by a comprehensive review of all sources of data demonstrating sufficient evidence of significant frequency and severity and demonstrating evidence of being associated with ECT device use."¹⁹

From this review of side effects, it was determined that the following were the most significant potential risks of ECT:

- Cognitive and memory dysfunction,
- Neuropathological changes or *brain damage*, and death. The basis of this determination was made with the following criteria: the frequency of reports from all sources of information, the estimated frequency of occurrence from literature reports, and the potential severity.²⁰ [Emphasis added]

However, despite the risks and in the reasoning for reclassifying the device, the FDA Proposal relies on a lot of "belief" that there's "probable" safety, not irrefutable clinical data and irrefutable fact. For example:

- "FDA *believes* that ECT devices ...should be reclassified from class III to class II because, in light of new information about the effectiveness of these devices, special controls, in addition to general controls, can be established

to provide *reasonable* assurance of safety and effectiveness of the device, and because general controls themselves are insufficient to provide *reasonable* assurance of its safety and effectiveness.”

- “FDA *believes* that in the specified patient population, *and with the application of general and special controls...* the *probable* benefit to health...outweighs the *probable* injury or illness from such use.”
- FDA *acknowledges significant risks associated with ECT* but *believes* that ...the *probable* benefit of ECT outweighs these risks.²¹

FDA underplays the risks, claiming, “Death associated with ECT *appears* to occur at a very low rate,” “cognitive and memory impairment” is “transient” and “there is no evidence that disorientation following ECT is long-term or persistent.” Further, “The literature review *suggests* that anterograde memory declines immediately post-ECT and then returns to baseline within 3 months post-ECT.”²² [Emphasis added]

DEEP SLEEP TREATMENT WITH ECT BANNED

Between 1988 and 1990, a New South Wales, Australia Royal Commission Inquiry into Deep Sleep Therapy—the highest form of government inquiry—provided a unique insight into patients who recalled the ECT procedure. The treatment involved heavy doses of psychotropic drugs to the point of a drug-induced coma, while ECT was administered daily. Because of the heavily sedated state, psychiatrists omitted the use of anesthetic or muscle relaxant. But experts testified that the sedated condition was similar to being in a state of anesthesia.²³ It was a graphic description of how painful ECT is: The court relied upon four sources of evidence: the psychiatrist administering the ECT, nursing records, nurses’ statements and the patients’ themselves.²⁴

Justice John Slattery overseeing the inquiry determined, “...the similarity of the patients’ stories combined with what would be expected if a conscious person had an electric current passed through their head, seems to establish that many of the experiences described were associated with ECT.”²⁵ He described the sensations they experienced as “callous and perhaps brutal.”²⁶ He accepted their recollections and evidence “as correct.”²⁷

Evidence included:

- Medical Record entry: “Very weepy and restless stating he wants to stop treatment with ECT, is very painful. So—jumped through window! Superficial abrasions to forehead, right hand and lower back.”²⁸
- Patient testimony: “...all of a sudden it felt like I’d been lifted up and branded with a red hot sort of Jew’s harp. That’s what was the vivid picture. It went zzz on my brain.”²⁹

- Another patient: "...it felt like all the telegraph wires came down on the top of my head and a big blue flash all around me."³⁰
- Patient R.D., "I have memories of shock treatment being administered...it was like someone trying to twist my head off...I remember screaming out at one stage about the cruelty I was receiving...."³¹
- Patient A.F. "The feeling was one of pain from the top of your head to the tip of your toes...It was like someone hit you with a sledge hammer, wham, and you exploded. It was so bad that [I] thought, 'These bastards are trying to kill me.'"³²

Justice Slattery determined that administering ECT without a patient's consent or after obtaining consent by use of fraud and deceit "committed a trespass to the person of each of these patients and were responsible for an assault on them."³³ Deep Sleep Therapy was banned under the New South Wales Mental Health Act, 1983, and carries criminal penalties if administered.

Whether you mask ECT with anesthetic and muscle relaxants or add controls in an attempt mitigate the risks, it doesn't change the fact that it is not a proven safe and effective treatment and that for the majority undergoing it, workability has not been established.

ECT DEVICE WREAKS OF CONFLICTS OF INTEREST

The FDA Proposal is of enormous concern because of potential conflicts of interest of those it is relying upon.

As stated above, the FDA is relying, in part, on the neurological device advisory committee panel hearing held in January 2011.³⁴ Yet many of the panel members voiced concerns about the lack of data about long-term effects of ECT, particularly with regard to memory loss and cognitive function. The FDA has included bipolar mania as one of the indications for the ECT Device to be Class II, yet the majority of the panel members were against this (12 vs 5).³⁵

A majority of those psychiatrists wanting the device rated as Class II had conflicts of interest with brain stimulation devices or ECT device companies. Several of these and representatives of the APA argued that it would be too expensive for ECT device manufacturers to conduct clinical trials.

The following comments show that the decision to make the device Class II was likely made before the 2011 Hearing because the major indications for which ECT is to be administered as Class II could not sustain a clinical trial and, as such, APA psychiatrists claim the financial burden shouldn't be placed on the manufacturers to do so. This is arguably to protect their practices and not in the interest of patients.

Consider attorney Rick Moxon's submission to the FDA who stated that in a deposition, the President of MECTA stated the company "does not do research."³⁶

Ms. Robin Nicol, a salesperson at MECTA, bought MECTA with her husband, Gorham Nicol, and became CEO in 1980. Mr. Nicol said: "The doctors in research centers provide the medical requirements and information we need to build the equipment because our function is strictly as a manufacturer."³⁷

On January 23, 2011, psychiatrist Conrad M. Swartz, co-owner of SOMATICS was reported in *The New York Times* as saying that the company could not afford an in-depth study that the FDA could require if it left the devices in the high-risk category. "There is not nearly enough money in this industry to begin to pay for clinical trials that would be substantially larger than those already in the medical scientific literature," Dr. Swartz said.³⁸

The APA conceded this as far back as 1981, when in April that year, the chairman of the APA's Council on Research wrote in *The American Journal of Psychiatry*: "Unless a successful reclassification petition [for Class II] is filed, the manufacturers have until April 4, 1982, to prove safety and efficacy or discontinue production of their devices. There does not appear to be any great move on the part of the manufacturers to accomplish this. *Thus, unless ECT devices are reclassified, the FDA ruling could potentially wipe out ECT as a viable treatment modality.*"³⁹ [Emphasis added]

Furthermore, in 2011, immediately prior to the FDA panel hearings. Dr. Matthew Rudorfer, a psychiatrist who administers and oversees grant money for NIMH and is its associate director for treatment research and head of ECT Research, told *The New York Times* that clinical trials would be "too expensive" for "mom and pop" operations such as the manufacturers of ECT devices.⁴⁰

- Dr. Rudorfer co-wrote an ECT textbook published in 2003 with Dr. Harold Sackeim, Ph.D, who has received at least \$8 million over 20 years from NIMH while having financial ties to and is a consultant to MECTA and SOMATICS.⁴¹ In the book *Shock Therapy: A History of Electroconvulsive Treatment in Mental Illness*, a 1994 photo of an "ECT Victory Party" thrown by Sackeim celebrating the founding of the journal *Convulsive Therapy*, included Matthew Rudorfer, Max Fink, Charles Kellner (above) and psychiatrist Richard Weiner, a MECTA consultant, who developed ECT devices for the company.⁴²
- Dr. Sackeim was a member of the APA ECT Task Force 2001 and, as stated above, he is a consultant to and has received funding from SOMATICS, Inc. and MECTA.⁴³ MECTA has also funded his ECT studies.⁴⁴ In 1981, NIMH began giving Dr. Sackeim grants to study the "affective and cognitive consequences of ECT."⁴⁵ In testimony given to the New York State Assembly investigating ECT on May 18, 2001, it was stated: "Because Sackeim had a lock on this [NIMH] money for 20 years, because his money is renewed automatically for as long as he wants it without his proposals having to compete with other grants, and because he sits on the panel which decides who gets funded, other researchers aren't able to get grants to do research in this area. Dr. Sackeim is on the American Psychiatric Association's Task Force on ECT, and he's the spokesman for industry...While

- he's been getting millions of NIMH dollars, he's also been a consultant for, and received grant money from, the companies that make most of the shock machines in America....⁴⁶
- Dr. Richard D. Weiner has a long-standing relationship with MECTA and consulted for SOMATICS, Inc.⁴⁷ In the 1978 APA ECT Task Force Report it acknowledges Weiner for his research, while not disclosing that as an engineer he had developed ECT machines for MECTA, wrote their instruction manuals and did a video for them.⁴⁸ Circa 1985, he was in charge of the APA's lobbying campaign at the FDA, while he had conflicts of interest with MECTA and consulted for SOMATICS.⁴⁹ In 1995, he filed a patent for an "electroconvulsive therapy method using ictal EEG data as an indicator of ECT seizure adequacy."⁵⁰ He was Chairman of the APA ECT Task Force 1990. In 2005, he was on the Speaker's Bureau of MECTA.⁵¹ He is a co-inventor on a Duke University-patent licensed to MECTA but says he receives no royalties for the patent.⁵²
- Max Fink was part of the first APA ECT Task Force in 1978 and was an author of its report. He served on the APA's 1990 ECT task force, which drafted guidelines for the treatment. He has made videos about ECT for SOMATICS, Inc. which paid him \$18,000 for the rights to the videotapes.⁵³ In 1997, he was a principal investigator in a multicenter collaborative study group known as CORE (Consortium for Research in ECT) under grants from NIMH, along with Charles Kellner.⁵⁴

In 1994, Douglas G. Cameron addressed conflicts of interest in the *Journal of Mind and Behavior*, stating: "An insidious source of misinformation about ECT's effects on memory are videotapes marketed by some of the ECT device manufacturers (SOMATICS, MECTA) and made available to patients, family members, and shock facility professionals in the United States and Canada. There are no disclosures in these videos identifying either SOMATICS or MECTA as manufacturers of ECT devices (Find, 1986; Grunhaus, 1988)...."⁵⁵

It is clear FDA and APA members know that the ECT device manufacturers are not going to conduct research while at the same time, don't want the device taken off the market. Therefore, any discussion of it remaining as Class III is a moot point. FDA was and is only looking for "mitigating" circumstances to keep the shock device on the market without a PMA and clinical trials supporting the device's safety—and is doing this, despite the ongoing risk to patients.

In 1982, APA filed a petition to the FDA for reclassification of the ECT device to Class II. NIMH supported the petition.⁵⁶ APA cited studies done as far back as 1940; in the bibliography they referenced only a handful of studies conducted since 1979. The APA and the device manufacturers failed to conduct any safety tests to prove their claims.⁵⁷ This incestuous relationship continues today.

Ms. Malvina Eydelman, Director of the Division of Ophthalmic, Neurological and ENT Devices, said at the 2011 hearings that “in order to try to delineate potential mitigating factors, whether it goes into Class II or Class III, we need to figure out what is the safety profile of a particular device.” (p. 280, 28 January 2011). However, FDA has known since its inception that a PMA was needed and should have worked this out long before 2011—and in the five years since—the necessary safety profile were patient safety a priority for it.

- Ms. Eydelman further stated: “What we're trying to say, is there sufficient information about all ECT devices such that we can write special controls that will be able to control each ECT device that's going to come on the market from now on? As opposed to PMA, its assurance of safety and effectiveness of each device on its own.” p. 427, 28 January 2011 Hearing
- Dr. Wayne Goodman, a consultant to Medtronic, Inc. (Deep Brain Stimulator trainer)⁵⁸ and 2011 Panel member asked: “So if the Panel says, recommends, that for major depression, ECT should remain a Class III device, that means that we do not feel that there's sufficient evidence for its efficacy or effectiveness or safety and that special controls are insufficient to ensure, particularly, safety? ...that they are not convinced that existing data support efficacy or effectiveness....” p. 426, 28 January 2011 Hearing
- Dr. Goodman added: “So let's assume we leave ECT Class III for unipolar depression, PMAs are called for and those require, based on your question to me, a large-scale study, say, involving 150 patients... And assuming that that led to a design of a trial that required 150 patients per group and a sham design, *it is conceivable, then, that no manufacturer would be able to afford that and at some point after the period of, say, 30 months expired, existing ECT devices could be taken off the market?*” Emphasis added. Pp. 429-430
- Panel Member Dr. Christopher Ross: “I think, *based on the existing knowledge, it would be hard to design a trial in which you would give sham ECT.*” Emphasis added. pp. 431-432
- Dr. Eydelman: “I'm just throwing this out—for the current manufacturers, we do want their assessment, *but we'll believe that perhaps going back and trying to see if we can find historical information with that particular device, that that would—for us to consider that for assessment of safety and efficacy.*” Emphasis added. p. 432
- Panel Member Dr. William McDonald: “...If we have a 33-month waiting period for people to conduct the clinical trial is nothing. *There's no way you're going to get a clinical trial with an ECT group.*” Emphasis added. P. 434. Dr. McDonald was a member of the APA ECT Task in 2010. He has received research support from and been a consultant for Neuronetics [brain stimulation].⁵⁹

- Panel Member Dr. Jane S. Paulsen, Ph.D. stated: "We aren't going to be shutting down ECT. *We're not going to be taking a device off the market... p. 435...* The primary difference, in my mind, that's left, *since we all agree with the effectiveness data, is whether we can mitigate the risks. And if we cannot mitigate the risks, it needs to remain a Class III. If we can mitigate the risks, it goes to a Class II... I have not heard any way we can mitigate the 77 to 80 percent cognitive risk.*" p. 436
- Dr. Sarah Lisanby, a consultant to the Neurological Devices Panel of the Medical Devices Advisory Committee and Chair of the APA ECT Task Force in 2010, testified in 2011 on behalf of the APA that if ECT were to disappear, "it's not the economy that would suffer. *The two companies that make ECT devices are small and not publicly traded.*" [Emphasis added; p. 35, 27 Jan 2011 Hearing]⁶⁰ Later quoted in media, she said it was unlikely ECT manufacturers could "*finance the studies required to get it approved....*"⁶¹ Yet Dr. Lisanby knows of the potential damage, stating previously in the media that "in terms of persistent retrograde memory loss [the ability to form new memories], that has been, according to the evidence, found to be most marked for the events that occurred close in time to the treatment."⁶² Dr. Lisanby is on the Editorial Board of the *Journal of ECT*, along with Harold Sackeim and Max Fink (who have financial conflicts with ECT device makers) and Dr. Richard Abrams, co-owner of SOMATICS, Inc.⁶³ In March 2015, Dr. Lisanby was chosen to be the director for NIMH's Division of Translational Research.⁶⁴
- Dr. Charles Kellner, who appeared before the January 27 2011 hearing, was a member of an APA ECT Task Force. In July 2011, he wrote in *Psychiatric Times*: "The crux of the matter is that premarket approval [for ECT] usually requires controlled clinical trials be carried out prospectively; such trials cost many millions of dollars and, in the case of drugs, are typically supported by the pharmaceutical industry. *For ECT devices, there may not be a funding source for such trials. FDA officials suggested that the existing scientific evidence base for the efficacy and safety of ECT might be sufficient for a determination of device classification. Such an option is referred to as a 'paper' premarket approval. That means no new trials would be required.*"⁶⁵
- Ms. Eydelman suggested the PMA could be based on existing research, stating: "It is up to the Panel to recommend whether a retrospective analysis should be entertained by FDA, in other words, whether it's something from historical data, something 'paper PMA,' in other words, gathering—if there's a way to pull together information known in the literature about ECT devices in a scientific manner to assess its safety and effectiveness...." p. 425, 28 January 2011 Hearing

While in 2011, the FDA said that special controls may not mitigate the risks of ECT, in the December 31, 2015 Proposal it said that based on new information (the Executive Summary on ECT, the 2011 Hearings etc., APA Task ECT TaskForce/Guidelines etc.): "FDA *believes* that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified" and that these "special controls, together with general controls, will provide a *reasonable assurance* of safety and effectiveness for ECT devices intended for 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." [Emphasis added.]

"Believes" implies a supposition or assumption of truth, not a proven fact.

STUDY CASTS DOUBT ON BASES FOR FDA PROPOSAL

The findings from the FDA's review, it says, are consistent with:

- The American Psychiatric Association (APA) recommendations/guidelines
- the Third report of the Royal College of Psychiatrists' Special Committee on ECT (2004)
- the United Kingdom National Institute for Health and Clinical Excellence (NICE 2003; NICE 2009)
- The Surgeon General's report on mental health

Aside from the conflicts of interest cited above, the following data casts doubt upon the above opinions that the FDA relies upon, including APA and NICE guidelines etc., with emphasis added. The APA consent form on ECT is refuted and contrary to FDA assertions that memory loss and cognitive problems are short lived (up to 6 months), this is not the case. The below study states that while "In the longer term, i.e. 2-6 months, patients who initially rated their memory and cognition as improved," they more accurately report "impairment."

In May 2006, Harold Robertson, Robin Pryor writing in *BJPsych*, "Memory and cognitive effects of ECT: informing and assessing patients," determined:

- "Data do not exist at this time to confirm the mechanisms *by which ECT exerts its adverse effects.*" Emphasis added. As such the ECT device inflicts "adverse effects" but it's not known why. So, "clinicians should fully inform patients of the *possible permanent* adverse effects of the treatment, which include amnesia, memory disability and cognitive disability, and should provide follow-up testing using relevant instruments."⁶⁶
- "Some of the conclusions to come out of the new work – in particular, that at least one-third of patients experience *permanent amnesia*" and "*newer*

*methods of ECT have not resulted in an appreciable decrease in adverse effects."*⁶⁷

- "...the most common effect of ECT ... is variously called amnesia, retrograde amnesia or memory loss. By these terms is generally understood *the obliteration of a specific time period in a person's life*...It has long been known that ECT can produce deficits in non-memory-related cognitive function."⁶⁸
- "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)."⁶⁹
- "Despite recommendations that psychiatrists inform patients of non-memory cognitive after-effects (Calev, 1994) and warn them that 'they are not going to function well on more tasks than they anticipate' (Calev et al, 1995), patients are still routinely not informed about these effects; *there is no mention of them in the recommended consent forms of the American Psychiatric Association (APA; 2001), the Royal College of Psychiatrists (2005: Appendix IV) or the manufacturers of ECT equipment. This may contribute to the consistent findings (Rose et al, 2003, 2005; Philpot et al, 2004) that half of people given ECT say they did not receive an adequate explanation of the treatment.*"⁷⁰
- "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'."⁷¹
- "Although terms such as memory loss are often used interchangeably by clinicians to describe the temporary effects of depression on cognition (especially attention) and the long-lasting effects of ECT on a range of cognitive functions, this confusion is unnecessary and could be avoided. The effects of ECT are quantitatively and qualitatively different from those of depression (Squire et al, 1979) and researchers have consistently distinguished between them (Cronholm & Ottoson, 1963; Squire et al, 1979; Squire & Slater, 1983; Pettinati & Rosenberg, 1984; Squire & Zouzounis, 1988). For example, "numerous controlled studies show that individuals who are depressed but have not had ECT do not suffer amnesia. ... 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.*"⁷²

- "Other theories focus on ECT's effects on brain metabolism and neurochemistry: breach of the blood-brain barrier and increased cerebral blood pressure (Bolwig et al, 1977; Taylor et al, 1985); regional increases in T2 relaxation times (Diehl et al, 1994); disturbance of the long-term potentiation mechanism (Sackeim, 2000; Rami-Gonzalez et al, 2001); excessive release of excitatory amino acids and activation of their receptors (Chamberlin & Tsai, 1998; Rami-Gonzalez et al, 2001), and decreased cholinergic transmission (Khan et al, 1993; Rami-Gonzalez et al, 2001). *Even temporary alterations in any of these may have permanent effects on the brain.*"⁷³
- "The Royal College of Psychiatrists (2005: p. 19) and NICE (2003) advise that the potential for cognitive impairment be highlighted during the consent process. *Patients should be clearly told that ECT may have serious and permanent effects on both memory ability and non-memory cognition.*"⁷⁴
- Because of "evaluation and re-evaluation of ECT's risks and benefits by SURE, NICE and the Royal College of Psychiatrists, and the growing recognition of the extent and importance of research by and involving people who have experienced ECT, as well as increased interest in qualitative data...In particular, prospective patients should be warned of the significant risk of permanent amnesia and the possibility of permanent memory and cognitive disability."⁷⁵

In addition:

- A 2003 BMJ study, *Patients' perspectives on electroconvulsive therapy: systematic review*, pointed out that patients refute the Royal College of Psychiatrists' fact sheet on ECT. This states that 'in most cases this memory loss goes away within a few days or weeks although some patients continue to experience memory problems for several months. As far as we know, electroconvulsive therapy does not have any long term effects on your memory or intelligence.' However, the BMJ study says, "Some patients, however, report severe and long-lasting memory losses after electroconvulsive therapy."⁷⁶
- Of 35 studies on ECT, 20 considered memory loss as a consequence of electroconvulsive therapy. "The rate of reported persistent memory loss varied between 29% and 55%, but, unlike levels of perceived benefit, the rate did not seem to depend on whether studies were clinical or patient based, with relatively high levels being reported by both types of study."⁷⁷
- "Routine neuropsychological tests have been used in studies of electroconvulsive therapy to establish objective measures of memory loss and concluded that there was no evidence of persistent memory loss. It would seem that these are the studies on which the Royal College of Psychiatrists based its findings. *The studies, however, typically measure the ability to form new memories after treatment (antero-grade memory).*

Reports by patients of memory loss are of the erasing of autobiographical memories or retrograde amnesia. Thus the risks reported by patients do not appear in clinical assessments.”⁷⁸

- “At least one third of patients report significant memory loss after treatment.”
- “Routine neuropsychological tests to assess memory do not address the types of memory loss reported by patients.”
- “Reported patient satisfaction with electroconvulsive therapy depends on the methods used to elicit a response.”⁷⁹
- MIND mental health charity, UK, 2001 conducted a survey on ECT: Of 418 recipients to their survey, 84% said that they had experienced unwanted side effects; 40.5% reported permanent loss of past memories and 36% permanent difficulty in concentrating.⁸⁰

A sample of ECT survivors’ accounts is **Attachment 1**, including those that sued.

As for the Surgeon General’s report being relied upon, NIMH’s Dr. Matthew Rudorfer edited the chapter on “Adults and Mental Health,” for the 1999 Surgeon General’s Report.⁸¹ The report stated that “ECT may be the safest treatment option for severe depression.” The reference for this was the textbook chapter written by Doctors Sackeim and Rudorfer.⁸²

- The Surgeon General draft-report also called ECT “safe and effective.” Mostly, the report referenced MECTA’s Dr. Richard Weiner’s review article and the textbook chapter written by Sackeim and Rudorfer.⁸³ The most frequently cited sources in the Surgeon General’s report regarding ECT were Dr. Weiner and Andrew D. Krystal M.D. The latter received \$150,036 in funding from the NIMH in fiscal year 1998 to conduct research on improving ECT’s effectiveness.⁸⁴ Krystal and Weiner are the inventors listed on a U.S. patent that Duke University has licensed to MECTA Corporation.⁸⁵ Krystal was a member of the APA’s 2010 ECT Task Force under the chair of Sarah Lisanby.⁸⁶
- In the preamble to an earlier proposed rule (43 FR 55729, November 28, 1978), FDA described the recommendation of the Neurological Device Classification Panel (the Panel) that ECT be classified into class II because: “Although the use of this device involves a *substantial risk to the patient*, the Panel *believes* that the benefit of the treatment outweighs the risks involved if the patients are selected carefully and the devices are designed and used properly.” Despite this, “the Panel voted to recommend that ECT be classified into class III. FDA agreed with the Panel stating that FDA did not *believe* that the characteristics of ECT devices had been identified precisely

enough such that special controls could be established that would provide reasonable assurance of the safety and effectiveness of the device.”

- The Consensus Development Conference on Electroconvulsive Therapy organized by the National Institutes of Health (1985) found that patients reported memory impairments as long as 3 years after treatment, according to a 2014 study. The authors stated: “Following years of criticism over the failure to acknowledge interminable memory loss as an outcome of ECT... Sackeim and others (2007) followed up 347 adult patients given ECT in routine out-patient practice, evaluating them with neuropsychological testing up to 6 months later. For all types of ECT, they found lasting serious effects on mental function, including three tests for memory retention, one test for attention and one for the all-important autobiographical memory test, which was severe. Most patients showed unresolved deficits on the modified Mini-Mental Status examination: a test for dementia, which by definition reflects underlying brain damage.”⁸⁷
- In 2008, Miriam Felui from the Department of Psychiatry & Behavior Science, Duke University, et al, published a study in *Neuropsychiatric Disease and Treatment*. Researchers cognitively tested 46 people before and after receiving ECT. The results of the study supported the findings of previous research indicating that “ECT results in decreased memory functioning” and also “relatively immediate and significant decreases in multiple areas of memory following ECT compared with pre-ECT levels of functioning....”⁸⁸
- *Psychological Medicine* published a study in 2010 by D.W. Falconer, Dept of Mental Health, Clinical Research Centre, Royal Cornhill Hospital, University of Aberdeen, UK, et al. Researchers conducted a battery of cognitive tests specifically on visual and visuospatial memory tests on 24 patients “with severe depression” receiving ECT. Researchers found that patients showed significant impairments in visual memory and visuospatial memory both during and within the week after ECT. After a one-month follow-up, significant impairment in spatial recognition memory remained.⁸⁹
- Sydney Samant, M.D. was quoted in *Clinical Psychiatry News* in March 1983, stating: “As a neurologist and electroencephalographer, I have seen many patients after ECT, and I have no doubt that ECT produces effects identical to those of a head injury. After multiple sessions of ECT, a patient has symptoms identical to those of a retired, punch-drunk boxer...After a few sessions of ECT the symptoms are those of moderate cerebral contusion, and further enthusiastic use of ECT may result in the patient functioning at a subhuman level. Electroconvulsive therapy in effect may be defined as a controlled type of brain damage produced by electrical means.”⁹⁰

ELECTROSHOCK RISK NOT THE SAME LEVEL AS CONTACT LENSES, ESPECIALLY WHERE PATIENTS CAN BE FORCED TO UNDERGO ECT.

The panel of FDA's Neurological Devices Panel of the Medical Devices Advisory Committee hearing in January 2011 had a consensus recommending class III for Schizophrenia, Bipolar manic states, Schizoaffective, and Schizophreniform disorder. The Panel did not reach consensus on the classification of ECT for catatonia.⁹¹

While for depression, the panel was divided for and against the device being Class II (9 were in favor of keeping it at Class III and 8 were in favor of Class II), the Chairman, Dr. Thomas Brott, a neurologist, and Director of Research at Mayo Clinic in Florida, favored it remaining Class III, stating:

"I'm confident that were these procedures to go through the PMA process that they will meet the conditions of the PMA process, and I'm very confident. So I don't see that the reclassification would decrease the access of psychiatric patients to this procedure. And for that reason, the degree of risk, the level of the evidence, and the long-term, I would like to put confidence in the FDA in a Class III in seeing these processes go forward."⁹²

A dual classification of the ECT device cannot be compared to those examples FDA provided during the FDA Neurological Devices Panel of the Medical Devices Advisory Committee hearings in January 2011. These included PTCA catheters, spinal cages and contact lenses (for extended wear, overnight, they're Class III; for daily wear, Class II).⁹³

PTCA catheters and spinal cages have risks⁹⁴ but the procedures can't be forced onto an individual without their consent, as ECT can. A person can't be involuntarily committed to a hospital to enforce them to undergo an operation using a catheter or spinal cage. And individuals have a choice as to whether or not they use extended wear contact lenses.

That isn't the case for someone diagnosed mentally ill who can be involuntary committed.

ECT CREATES TORTURE: UN CALLS FOR BAN ON NON-CONSENSUAL MEDICAL INTERVENTIONS

In considering a Class II classification for MDE associated with MDD, this population could be at a higher risk of involuntary commitment and ECT treatment being forced on them.

In 2013, Kathleen Lynch, Minister of State for Disability, Equality, Mental Health and Older People in Ireland stated that Ireland's law "will be changed so that unwilling patients will no longer be forced to receive ECT."⁹⁵

This aligns with the February 16, 2013, United Nations Special Rapporteur on Torture and Other Cruel Inhuman or Degrading Treatment or Punishment report that defined procedures such as electroshock without the consent of the patient as a form of torture.

The Rapporteur called upon states to “Impose an absolute ban on all forced and non-consensual medical interventions against persons with disabilities, including the non-consensual administration of psychosurgery, electroshock and mind-altering drugs such as neuroleptics...”⁹⁶

The UN committee’s mandate “held that the discriminatory character of forced psychiatric interventions, when committed against persons with psychosocial disabilities, satisfies both intent and purpose required under the article 1 of the Convention against Torture, notwithstanding claims of ‘good intentions’ by medical professionals....The doctrine of medical necessity continues to be an obstacle to protection from arbitrary abuses in health-care settings. It is therefore important to clarify that treatment provided in violation of the terms of the Convention on the Rights of Persons with Disabilities – either through coercion or discrimination – cannot be legitimate or justified under the medical necessity doctrine.”⁹⁷

Statistics on the rate of involuntary committed patients receiving ECT in the U.S. against their wishes or without their consent were not available. In fact, the dearth of statistics on ECT’s usage in the United States is egregious given its risks. Even the FDA deferred to a 1995 study—more than 20 years old—that reported 100,000 Americans are given ECT every year.

FDA claimed: “In clinical practice, ECT is generally considered after failure of one or more antidepressant medication trials, or when there is need for a rapid and definitive response.”⁹⁸ However, FDA has no statistical data to support this is valid or how ECT is used as a first option treatment or off-label.

In 2013, it was reported that in Scotland, the use of ECT without consent was 33% and in New Zealand, 26% were involuntarily given ECT.⁹⁹

In 2006 *J Am Acad Psychiatry Law* reported that what government regulatory involvement in ECT exists is due to several factors, including patient advocate groups and prior abuse by psychiatrists. Including the District of Columbia and Puerto Rico, the report said there are 33 geographical jurisdictions where the state laws and administrative codes do not comment on the use of ECT.¹⁰⁰ In other words, there are insufficient protections to ensure that the ECT is never administered without consent, especially to an involuntary patient.

One study in the United States reported the use of the informed consent form for ECT was *never* in 26% of the time and only 37% listed it as “always” used.¹⁰¹ As covered above, an Australian judge determined that administering ECT without a patient’s consent or after obtaining consent by use of fraud and deceit

“committed a trespass to the person of each of these patients and were responsible for an assault on them.”¹⁰²

In a UK review, approximately one third of patients did not feel they had freely consented to ECT, even when they had signed a consent form.¹⁰³

This population also has the added disadvantage that none of the diagnoses given them can be substantiated with any physical medical test, including for major depressive or bipolar disorders. That’s likely to be the case for many years to come, and arguable forever. Essentially, a physically damaging procedure such as ECT is administered to treat a condition that is not physical—akin to prescribing chemotherapy to someone who doesn’t have evidence of cancer.

In 2013, Thomas Insel, Director of the NIMH said the “weakness” in the APA’s *Diagnostic and Statistical Manual for Mental Disorders* (DSM) “is its lack of validity. Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever.”¹⁰⁴

DSM5 Chairman, David Kupfer, said the promise of finding a biological basis for mental disorders has been just that—a “promise, which we have anticipated since the 1970s [and] remains disappointingly *distant*.”¹⁰⁵ [Emphasis added]

It is incumbent upon the FDA, then, to increase the safeguards for the use of medical devices on mental health patients, not reduce them, and thus the ECT device should remain Class III.

CLASS II & DUAL CLASSIFICATION RUINS PROTECTIONS: “OFF-LABEL” USE

Given that the ECT Proposal is for a dual classification (Class II and Class III)—and given every indication from APA members, NIMH’s Dr. Rudorfer and the manufacturers that the manufacturers either cannot financially undertake a clinical trial or “don’t do research” anyway, the FDA Proposal is disingenuous and misleading.

FDA plans to have the device stay on the market as Class II only for an MDE for MDD and Bipolar disorder, but as the FDA does not control medical or psychiatric practices, the device will most likely be used “off label.”

If a PMA—with clinical trial—were required for other indications—catatonia, schizophrenia etc.—and MECTA and SOMATICS default yet again (as they have done for decades), and FDA is forced to remove the device from the market, how does the FDA plan to do this? How do the devices get removed for one set of conditions but not the others? How does FDA enforce that?

The FDA says it does not regulate a doctor's practice and should the ECT device be lowered to Class II, FDA is failing to take any responsibility for the off-label use that will, undoubtedly, happen.

Already, ECT is administered off label to treat autism and mood disorders in children. 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."¹⁰⁶ 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.¹⁰⁷

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.¹⁰⁸ 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.¹⁰⁹

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."¹¹⁰

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."¹¹¹

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."¹¹²

The same protections do not exist in each U.S. state. Classifying the ECT device as Class II for specified disorders opens the door to a massive potential for off label use and enforced treatment in the case of involuntarily detained patients and children.

FDA needs to take greater precautions with the ECT device. It's already been accused of failing to protect consumers from the adverse effects of certain prescription drugs. A 2007 Consumer Reports poll revealed: More than 60% of Americans agreed that the FDA had failed to adequately protect consumers from harmful prescription drugs. Six in 10 disapproved of allowing doctors and scientists with a conflicting financial interest to participate on advisory boards. Jim Guest, CEO of Consumers Union, stated: "Americans are fed up with being kept in the dark about critical health and safety information, and they overwhelmingly want change."¹¹³

"SPECIAL CONTROLS" CREATE DAMAGE

FDA consistently asserts that it does not regulate the practice of medicine or doctors, although FDA says it monitors the ongoing safety and efficacy of all regulated marketed devices.¹¹⁴

Whatever "special controls" it plans on imposing it cannot ensure their compliance and the mitigation of risks. The controls are largely limited to labeling provisions, instructions, pre-ECT assessments and "appropriate patient monitoring during an ECT procedure."¹¹⁵

The two manufacturers claim risks can be mitigated by reducing the frequency of treatments, reduction of the stimulant process, electrode replacement, dosage and type of anesthetic, EEG monitoring etc. FDA commented that the manufacturers did not provide specific details regarding treatment parameters (e.g., specific stimulus dose, length of brief pulse, energy level, specific medications and dosages, etc.) pp 142-143 27 January 2011.¹¹⁶

However, per MECTA's President, "MECTA does not do research"¹¹⁷ and no effort was made to acquire adverse information caused by its devices.¹¹⁸ So, it's also disingenuous—and self-serving—that the manufacturers claim the risks can be mitigated.

FDA also "believes" that "disclosure of contraindications, precautions, warnings, and adverse effects/complications in both physician and patient labeling will mitigate risks."¹¹⁹ CCHR rejects this.

TREATMENT-RESISTANT COVERS UP TREATMENT FAILURE

FDA is inviting comments on whether the term "treatment resistant" and the phrase "require rapid response" provide sufficient clarity to the population for which ECT benefits outweigh risks. And, "Most of the published literature FDA is aware of and reviewed focused on subject populations that did not receive benefit from prior treatments; therefore, the recommended reclassification is limited to treatment resistant populations as well as those patients who require a rapid response due to the severity of their psychiatric or medical condition." [FDA Proposal]

The term "treatment-resistant" depression is misleading, implying fault on the part of the patient or his "disease" rather than the treatment being ineffective and/or causing an iatrogenic worsening of the depression.

With a 29% to 46% antidepressant failure rate¹²⁰ according to some studies, the pharmaceutical industry and many psychiatrists funded by the industry redefine this as "therapy resistant." This is merely a means of boosting drug sales, especially with the approval of "adjunct" therapy like AstraZeneca's antipsychotic Seroquel, Bristol Myers Squibb/Otsuka's Abilify or Eli Lilly's Symbyax, (Prozac and Zyprexa).

Already DSM includes medication-induced disorders (neuroleptic malignant syndrome, acute akathisia, acute dystonia).

Harvard's Joseph Glenmullen reported that when drug companies became concerned about the withdrawal effects of SSRIs, Eli Lilly & Co. funded a closed-door conference with experts who decided to call this effect "antidepressant discontinuation syndrome" to avoid the negative connotations of drug withdrawal (addictive) effects.¹²¹

The APA Committee developing depression treatment guidelines recommends ECT as an effective form of treatment for patients with treatment-resistant depression. The Committee has its own conflicts of interest and any definition of "treatment-resistant" is arbitrary, not scientific.

SUMMARY

The simplicity is that the evidence does not support the FDA's "belief" that ECT is safe and effective for severe 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 who require a rapid response due to the severity of their psychiatric or medical condition, which is a pre-amendments class III device, into class II (special controls) based on new information.

The committees and industry guidelines, as well as the 2011 hearings upon which FDA is largely relying, are rife with conflicts of interest which, if relied upon, could cause serious injury and irreparable harm to thousands, if not hundreds of thousands. Classifying the device as Class II opens the door to potential massive off-label usage of ECT, including children.

THE CITIZENS COMMISSION ON HUMAN RIGHTS (CCHR)

CCHR was established in 1969 by the Church of Scientology and the late Dr. Thomas Szasz, professor of psychiatry, to investigate and expose psychiatric violations of human rights, and to clean up the field of mental healing. Today, it has more than 250 chapters in over 30 countries. Its board of advisors, called Commissioners, includes doctors, psychiatrists, psychologists, lawyers, educators, artists, businessmen, and civil and human rights representatives.

While it doesn't provide medical or legal advice, it works closely with and supports medical doctors and medical practice.

CCHR has inspired and helped obtain many hundreds of reforms by testifying before legislative hearings and conducting public hearings into psychiatric abuse, as well as working with media, law enforcement and public officials the world over.

MISSION STATEMENT

The Citizens Commission on Human Rights investigates and exposes psychiatric violations of human rights. It works shoulder-to-shoulder with like-minded groups and individuals who share a common purpose to clean up the field of mental health. It shall continue to do so until psychiatry's abusive and coercive practices cease and human rights and dignity are returned to all.

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ATTACHMENT 1: SAMPLE ECT ABUSE CASES

Salters v. Palmetto Health Alliance, Inc.

- In 2005—five years after ECT had been administered—a jury in Columbia, SC, awarded Peggy S. Salters, 60, \$635,177 in compensation finding that her loss of 30 years of memory and cognitive impairment was due to ECT. In 2000, Peggy S. Salters, 60, received an intensive course of ECT following the death of several close family members, including her husband. Her treating psychiatrist, Dr. Eric Lewkowiez, M.D. prescribed antidepressants, she worsened and he recommended ECT. This was administered 16 times by Dr. Robert Schnackenberg. During the course of the treatment, she began having memory difficulties and was unable to function at home, which she reported to Dr. Lewkowiez. Dr. Lewkowiez did not convey this to the doctor administering the ECT. Dr. Schnackenberg's medical records show Dr. Lewkowiez encouraged Salters to continue with the treatments. Later, Dr. Lewkowiez observed Salters continued "to be confused and disoriented." At this point, Salters decided to stop the ECT because she was "completely unable to function." Eventually, Dr. Lewkowiez recommended Salters see psychologist Dr. Mary Elizabeth Shea for memory loss secondary to ECT. In Dr. Shea's opinion, Salters suffered memory loss as a result of the ECT. Ms. Salters held a Masters of Science in nursing and had a long career as a psychiatric nurse, but lost her knowledge of nursing skills and was unable to return to work after ECT. She lost all memories of the past, including memories of her husband of three decades and the births of her three children.¹²² In 2007, Dr. Lewkowiez, lost an appeal with the court reaffirming that Dr. Lewkowiez's breach of the standard of care proximately caused Salters' injuries.
- A Scottish family won an \$82,600 settlement from the Greater Glasgow Health Board (GGHS) over the death of 30-year-old Joseph Doherty, who committed suicide while undergoing ECT. Doherty's medical records show that before being electroshocked he had repeatedly refused to consent to ECT.¹²³
- An Australian case in the 1980s settled for an undisclosed amount. The patient, "Jill," was voluntarily incarcerated but given ECT without her consent. She was studying science at the University of Melbourne, intending to major in psychology. While hospitalized she was heavily drugged and tried to leave but was held against her will. She was told she was to undergo ECT. "We had studied it at uni in the same unit as we studied lobotomies. I thought it might affect my brain or memory. I kept saying I did not want it." She was given the treatment regardless. "They say you feel nothing, but you certainly feel a lot afterwards. When you wake up it is as if your head has been hit by a sledgehammer. You feel like jelly, it is the most tremendous thud to your body." "I had three units of my degree and thesis to do. I was on huge doses of drugs and could not concentrate. The shock treatment

- made me feel so vague and out of it. I would read a page and not understand what I had read."¹²⁴
- In 2007, a Leeds UK man, Richard Green, was awarded half a million pounds in an out-of-court settlement with Leeds Eastern Health Authority over ECT he'd undergone. Mr. Green was undergoing ECT at St James' Hospital, Leeds when his airways became blocked. Despite over 40 'tipping trolleys' being in use in the hospital (designed to minimize such blockages) none were used in the ECT suite. The subsequent brain damage left him paralyzed from the chest down, and with speech difficulties.¹²⁵
- Dolphin Reeves wrote to the *Los Angeles Times* in 2003, calling for a full investigation into ECT use on elderly citizens: "My father had a series of three hospitalizations in New York where he underwent numerous ECTs....He was 90 years old when he received the last of at least 11 ECTs. I voiced my opposition, but he was nevertheless subjected to the jolts to his brain....[He was] unable to remember where he lived, his memory was so impaired that the administering doctor decided he could not return to his home. I had expressed concern to this doctor about the possible danger of administering the shocks to my father's brain at his age. The doctor assured me that there was no danger. He failed to mention the deleterious effects the electroshock would have on my father's memory. Medicare pays for shock treatments for the elderly. I believe it is an abuse not only of the patient but of the Medicare system."¹²⁶

In the study by Harold Robertson, Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* in May 2006, they include a sample of patient reports of permanent amnesia and disability:

- 'I've got 13 GCEs, top grade, but no professional qualifications since ECT.'
- 'I've sat only one exam, and despite its being 70% project work and continual assessment, I've struggled to just pass, well bottom - my memory and impaired concentration can't cope.'
- 'After ECT I could no longer play my guitar. I could not remember chord sequences/ patterns, words or songs that I had performed hundreds of times before ECT. The ability to play or learn new music has never returned.'
- 'In addition to destruction of entire blocks of pre-ECT memories, I have continued to have considerable difficulty in memory recall with regard to academic pursuits. I have been forced to tape-record all education materials that require memorization. I was forced to "re-take" accounting. Now I am again forced to "re-take" a basic one semester course in computerized word processing.'

- 'I can't remember new information with the ease that I could before ECT. Distractions and interruptions seriously interfere with information retention, and any new bit of information may "cancel out" the bit that preceded it.'
- 'I have trouble with my memory today. My IQ was 120 before the treatments and it is not anywhere near that now. I have trouble just trying to cook a meal. I do not work. I make lists so that I can try to recall what I need to do.'
- 'I had to drop out of school when I realized I could not remember what I had studied before entering the hospital, and I was totally unable to absorb new material. I continue to have difficulty concentrating for extended periods of time.'
- 'Before ECT, I studied math up through calculus. After ECT, I can just barely make change in a store. ECT gives a person a different brain from the one a person had.' (Food and Drug Administration, 1982; Pedler, 2001; Service User Research Enterprise, 2002)¹²⁷
- "The clinician who tells her patients that there is a lack of research on the permanent adverse effects of ECT will certainly be on solid ground...."¹²⁸
- When amnesia is permanent it has profound, rarely positive, effects on all aspects of the patient's subsequent life. For many people the effects of permanent amnesia and/or memory and cognitive disability negate any benefit sustained from ECT (National Institute for Clinical Excellence, 2003).
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¹²⁹ Harold Robertson, Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* May 2006, 12 (3) 228-237; DOI: 10.1192/apt.12.3.228, <http://apt.rcpsych.org/content/12/3/228.full>

EXHIBIT 19

KENDRICK I. MOXON*
HELENA K. KOBRIN#
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* ALSO ADMITTED IN
THE DISTRICT OF COLUMBIA

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JEANNE M. GAVIGAN

January 6, 2010

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

Docket No. FDA-2009-N-0392

**Medical Devices: Neurological Devices; Electroconvulsive Therapy
Device; Establishing a Public Docket**

I write to formally object to any re-classification of electroconvulsive therapy devices other than Class III, and to further urge that manufacturers be required to submit Premarket Approval Applications before any further lawful use is permitted.

Summary:

I am an attorney, and have been involved in extensive litigation with MECTA corporation regarding their devices. In such litigation, I learned that substantial memory loss from the use of shock treatment remains ubiquitous. Often the memory loss is massive and thoroughly debilitating. Sometimes it is less pronounced, but it is *always* present. Some patients seek oblivion thereby, or otherwise represent they have been benefitted. But the majority of patients rue the treatments they have been given. Most, too damaged even to further cogently communicate, are silent.

Memory loss and brain damage were previously widely acknowledged as the “therapeutic action” of shock treatment. Subsequently, manufacturers and advocates of the therapy have retreated from that admission, claiming now that they do not know what the supposed therapeutic action is, which remains to them a mystery.

MECTA has plainly lied to the FDA, to practitioners and to the public regarding the lack of safety and lack of efficacy of the treatment provided through their devices. MECTA’s principals have admitted, under oath, that it has conducted no research in the

practice for the more than 30 years it has profited from making and selling ECT devices. MECTA's principals have admitted that they ignore all complaints made to their company which are derogatory because, since they "feel" the practice is safe and effective, any assertions to the contrary are perforce, not credible.

By this deceptive and irresponsible reasoning, and by placing both responsibility and blame for the alleged "approval" and "design" of ECT devices upon the FDA, MECTA has declined to fulfill its obligations under federal law to provide instances of adverse affects arising out of its devices. And, although MECTA has been repeatedly sued for causing harm to patients, it has failed to report the allegations of such adverse events to the FDA. Because of this misconduct, MECTA's devices should be withdrawn from the market and MECTA prosecuted.

ECT remains at best, an experimental or theoretical "therapy." It is the FDA's solemn responsibility and duty to demand painstakingly thorough PMA information and require manufacturers to *prove* the safety and efficacy of any ECT devices before more patients are subjected to this damaging treatment.

Pertinent History of Shock Treatment/ECT

Shock treatment was developed in the early part of this century in European slaughterhouses, for the purpose of incapacitating animals so that their throats could be slit and the animals more easily bled while alive. Observing such treatment, Italian psychiatrist Dr. Ugo Cerletti, experimented with the practice on dogs, and many, in the process, died. Cerletti continued until he found an appropriate voltage and duration of shock which did not kill many of the animals. Cerletti tried the practice on patients, for reasons that defy explanation. Cerletti shocked the man and found that since he was not killed by the treatment, and was substantially quieter than he had been before, the treatment was "effective" in relieving mental illness.

German psychiatrists during World War II utilized the new-found procedure in experiments and executions in concentration camps.¹ Shock treatment was also frequently utilized against German soldiers displaying cowardice, essentially so that the fear and penalty of the shock would overwhelm the fear of battle.² A similar use was employed by the American Army to assist with the "management of insane soldiers, who would become quite meek and manageable after a session with the 'thing.'"³

Early proponents of shock therapy acknowledged what current purveyors of this practice deny: that a change in the patient is brought about by damage to the brain and loss of memory.⁴ Such concession was prevalent in the 1940's, as published by psychiatrist Walter Freeman, M.D., in discussing "brain damage and the 'therapeutic'

benefit resulting from ... shock therapy.” Freeman admitted the *intention* of these practices was to cause brain damage:

The apparent paradox develops, however, that the greater the damage, the more likely the remission of psychotic symptoms ... It has been said that if we don't think correctly, it is because we haven't 'brains enough.' Maybe it will be shown that a mentally ill patient can think more clearly and more constructively with less brain in actual operation.”⁵

Medical reports and journals during the 1940's frequently repeated the known physical damages caused by shock treatment, including “profound changes in general circulation,” “coronary complications,” heart attacks, deaths, coma, lung abscesses,” and “Reversible or irreversible central nervous system changes [which] must accompany the amnesia characteristic of the usual shock-induced organic syndrome.”⁶

While it became politically incorrect in the 1960's and 1970's to refer to shock treatment in terms of brain damage, such a result was acknowledged through the 1940's and 1950's as the source of the “effectiveness” of the treatment.⁷ As noted in one study on “experimental neurosis,” caused by giving shock treatment to animals, “All in all, these experiments support the growing conviction among psychiatrists that electroshock and other drastic procedures, though possibly useful in certain relatively recent and acute psychoses, produce cerebral damage which charges the indiscriminate use of such ‘therapies’ with potential tragedy.”⁸

Such “tragedies” were not only not a concern, they were the admitted intended result of this practice, as reported by two leading doctors in 1948 who published results of the “treatment” of a number of patients to reduce them to a state where they acted like small children because, perhaps unremarkably, they had shown no improvement from other psychiatric procedures:

We started by inducing two to four grand mal convulsions daily until the desired degree of regression was reached. After about 10 days to two weeks without treatment, regressed patients returned to their previous levels, but usually without their symptoms. A number of these patients were well enough to go home and carry on as they had before the psychosis developed. We considered a patient had regressed sufficiently when he wet and soiled, or acted and talked like a child of four. . . Sometimes the confusion passes rapidly and patients act as if they had awakened from

dreaming; their minds seem like clean slates upon which we can write. They are usually cooperative and very suggestible, and thus amenable to psychotherapy. . . This technique is a valuable asset to psychiatric therapy, where less drastic measures have failed. ⁹

One psychiatrist who substantially profits through sales by Somatics, Inc., Max Fink, also admitted in the 1950's that it was brain damage which caused what he and other psychiatrists viewed as the "therapeutic" aspect of electro shock therapy. However, this effect was hardly "therapeutic." Another psychiatrist who publicly argued for the effectiveness of electroshock treatment, claimed, "Improvement in effective disorders, follows the induction of transient mental confusion which appears after treatment ... This confusion coincides with recent memory impairment. This transient, induced, organic, psychotic reaction makes the patient forget his worries, breaks up introspection and obsessive thinking and reverses the effect, frequently changing depression into mental elation." ¹⁰

Another psychiatrist who utilized shock treatment in 1966 conceded, "In summary, even one or two ECT treatments risk limbic damage in the brain leading to retarded speech, coordination, handwriting, concentration, attention span, memory, response, flexibility, retention and re-education. On the psychological side, fear of ECT and resistance to re-educative or psychological therapy. The research thus indicated that ECT was a slower-acting lobotomy with the added complications of shock-induced terror." ¹¹ Another psychiatric practitioner stated, "I'd much rather have a small lobotomy than a series of electroconvulsive shocks ... I just know what the brain looks like after a series of shocks -- and its not very pleasant to look at." ¹²

Several other books, articles, and exposes in the 1960's revealed that shock treatment was frequently used in psychiatric institutions for the purpose of controlling and punishing patients. As noted in a published "Electroconvulsive Therapy, National Institutes of Health, Consensus Development Conference Statement, June 10-12, 1985:

"In the United States in the 1940's and 1950's, the treatment was often administered to the most severely disabled patients residing in large mental institutions. As often occurs with new therapies, ECT was used for a variety of disorders, frequently in high doses and for long periods. Many of these efforts proved ineffective, and some even harmful. Moreover, its use as a means of managing unruly patients, for whom other treatments were not then available, contributed to the perception of ECT as an abusive instrument of

behavioral control ...”¹³

Physical damage to most patients was more obvious than it is today, as during this period, a vast number of victims of the treatment suffered compression fractures of the spine and other broken bones. One government study placed the figure of spinal fractures at approximately 20% of those receiving shock treatment.¹⁴ A 1985 NIH Consensus report on ECT stated that some 40% of persons receiving ECT suffered what has been euphemistically referred to as “complications” from the treatment, which it noted, “the most common being vertebral compression fractures.”¹⁵

Shock treatment thus came to have a well deserved reputation for death, mayhem, and destruction of memory and thought. It became synonymous with punishment and control of unruly patients in mental hospitals in the United States as graphically portrayed in the books *One Flew Over The Cuckoo's Nest* and *The Bell Jar*. Shock treatment developed such a frightening notoriety, that practitioners endeavored to simply change the name of the treatment to avoid association with the past. Thus, the treatment became known as Electroconvulsive Therapy, or “ECT” pretending that it was brain and body convulsions that caused the purported therapeutic effect and not electricity.

In the 1970's, even after the use of extremely strong drugs or “muscle relaxants” such as succinylcholine to inhibit the use of all voluntary muscles to reduce bone fractures and spinal compressions during convulsions, most doctors still recognized that the treatment was causing brain damage and permanent deleterious effects on patients. For example, in a 1972 survey of psychiatrists who gave shock treatment, a large percentage conceded that “treatments leave irrecoverable gaps in memory and that a large number of treatments cause intellectual deterioration, seizures, or personality blunting akin to the effects of lobotomy.”¹⁶

The American Psychiatric Association conducted a survey of its own members who were ECT practitioners in its 1978 *Task Force Report: Electroconvulsive Therapy*. The APA's publication revealed that even among those practitioners – and obviously proponents of the practice – 38% percent agreed that ECT should be used “only when all else has failed.”¹⁷ Obviously the acknowledgment that a practice should be utilized only as a last resort or “only when all else has failed” manifests a recognition that it is too dangerous to be used except in desperation.

The APA's 1978 *Task Force Report* similarly reported that 16% of ECT practitioners conceded in the same survey that ECT should be discontinued or at least curtailed.¹⁸ Such a high proportion of practitioners making a comparable suggestion about any other treatment would warrant summary termination of the treatment until it was *proven* to be safe.

Finally, the APA's 1978 *Task Force Report* also reported that 41% of its member practitioners acknowledged that ECT caused at least "slight or subtle brain damage," and only 26% of those practitioners disagreed with the conclusion.¹⁹ Coming from this source – before the time of vast public relations assaults by manufacturers and other vested interests -- the acknowledgment of brain damage from ECT should be deemed conceded.

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

During the few minutes following stimulus, profound and potentially dangerous systemic changes occur.

* * *

Depressive disorders are characterized by cognitive deficits that may be difficult to differentiate from those due to ECT. It is, however, well established that ECT produces memory deficits. Deficits in memory function, which have been demonstrated objectively and repeatedly, persist after the termination of a normal course of ECT. Severity of the deficit is related to the number treatments, type of electrode placement, and nature of the electric stimulus. ... research conducted as long as three years after treatment has found that many patients report that their memory was not as good as it was prior to the treatment.²⁰

Current practitioners and manufacturers point to the "advances" in the treatment procedure which, they say, eliminate much of the physically manifested damages of ECT. The machines however, are essentially identical to those utilized in the 1940's and 1950's in terms of the amount of electricity passing through the patients brain. Indeed, unless the devices are substantially similar to the earlier devices grandfathered into legality in 1976, they are by definition illegal. In fact, while now computerized, the machines are essentially no different. The only practical difference is the use of paralyzing drugs to prevent fractures, which have no role whatsoever in reduction of the force of damaging electricity thrust through the patient's brain – the cause of memory loss, the cause of terror, and the cause of injury.

MECTA's Refusal to Consider the Dangers of its Devices, and Further Withholding of Information from the FDA, the Public and Practitioners

I represented a man in a lawsuit who had received a series of ECT treatments, Mr. Atze Akkerman. Defendant in the case was META Corporation, as the damage was

caused by a MECTA device. During the Akkerman lawsuit, the deposition was taken of Robin Nicol, the President and CEO of MECTA Corporation. (Excerpts of the deposition are attached as Exhibit A.) Among the damaging admissions made by Ms. Nichol, evidencing criminal misfeasance, violation of law and irresponsibility for those injured, are as follows:

Ms. Nichol and her husband purchased MECTA in 1980. She was sales manager until 1980 and President from 1987 to the present. (Deposition, p. 10-11.) Although informed in the litigation that articles had been written indicating that the purpose of ECT was to *cause* brain damage, she refused to “accept that premise,” finding it “impossible to believe.” (*Id.*, p. 40-41)

Yet Ms. Nicol admitted that she was aware of the articles written in the 1940's and 1950's indicating that the purpose of shock treatment was also to *cause* memory loss, i.e., that the therapeutic effect, of shock treatment was memory loss. But MECTA refused to consider or investigate the issue, (*Id.*, page 41-42), because, as she said, “MECTA does not do research.” (*Id.*, page 42.) MECTA has never has done any research, studies or investigation regarding the safety and efficacy of ECT. (*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 recognizes that one of the “complications” of ECT is broken teeth, (*id.*, p. 97-99), and that memory loss can also be a “complication.” (*Id.*)

MECTA is aware of groups opposing ECT and which feel that their members have been gravely harmed by shock treatment, but has never communicated with them, because, as Ms. Nichols testified, “we’re very focused on what we do in terms of the research and the literature that supports our products, that it is a safe and effective treatment,” so “there’s nothing to be gained.” (*Id.*, p. 104.) Thus, MECTA’s President testified 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.)

Asked if she would be curious to find out why ECT victim groups sought to establish legislation against MECTA machines, Miss Nichols said she would not. She claimed 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 cannot even offer an opinion, much less evidence, of how ECT allegedly works, except that their machines are designed to cause a grand mal seizure, and beyond that, the mechanism is entirely theoretical. (*Id.*, p. 147-49.) Yet, Ms. Nichol also admitted that more electricity is used by MECTA machines than is necessary to cause the grand mal seizure, because, she said, “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.)

It is MECTA’s President’s opinion that if patients claim to have brain damage or to have lost large chapters of the memories of their lives, they must be lying. Of course, she has never asked them why they feel that way. (*Id.*, p. 121-122.)) Indeed, Ms. Nichol admitted that over a period of 25 years, she has spoken to only 5 or 6 persons who have received ECT, but she didn’t even ask them if they had received memory loss. (*Id.*, p. 90-91)

In one incredible admission, Ms. Nichol exemplified the level of irresponsibility the company has respecting the harms caused to patients who receive the treatment:

Q. As one of the two manufacturers of these devices in the United States, were you curious to communicate with any of the people of these which you concluded to be a fringe group to see why they held this bad opinion of your business?

A. I think I said this morning -- and I will say it again -- my focus was very specific in terms of running a company and being very concerned about developing products that were safe and effective. So I wasn’t -- and I had also a huge burden to work with the research and the developers that are mainstream. So I didn't take the time to understand because it wasn’t in my purview. It wasn’t within the job description that I would have within my company as a president....It just wouldn’t be part of our focus.

Q. To talk to the detractors of ECT?

A. Correct.

(*Id.*, p. 191.)

Ms. Nichol also confessed that although she and the company were well aware of their responsibility to provide reports to the FDA of all adverse events, the company had only done so *once* in the 25 years she has run the company. (*Id.*, p. 207-208.) In truth,

MECTA has merely hidden and obscured reports of extremely serious adverse events from the FDA, preventing the FDA from exercising any oversight concerning shock treatment, revealed in the following briefly described lawsuits.

MECTA's president also admitted that, with respect to efficacy, ECT machines and the practice of electroconvulsive therapy can cure nothing, absolutely nothing. (*Id.*, p. 211.)

Litigation Against MECTA Not Reported to the FDA

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 MECTA device. (Complaint, Exhibit B).

It was represented to Mr. Akkerman and his wife, Elizabeth Akkerman, that he would benefit from a course of ECT to treat his depression. The psychiatrist who made these representations, asserted that shock treatment was not harmful, and although it might cause some limited memory loss, it only eliminated unhappy or depressing memories, and that Mr. Akkerman's full memory would be restored in a short time but that he would no longer feel depressed. In January of 2000, Mr. Akkerman received a series of 8 treatments from a MECTA shock machine.

Following the treatment, Mr. Akkerman had lost his memory for most of the events of his life. He no longer recognized or knew his wife. He no longer recognized or knew his two teenage children. He no longer knew or recognized his parents. His brother, who was a close companion and best friend in his childhood years, was a stranger. Mr. Akkerman not recovered these memories.

Mr. Akkerman's abilities lost included playing and writing music (he played professionally for years) and toured with the U.S. Navy Band. Prior to the shock treatment, Mr. Akkerman was employed in a supervisory position with a non-profit foundation. After the shock treatment, he was unable to remember what he did in his job, did not know how to perform the duties of his job, and no longer knew the people he formerly worked with.

In the suit, numerous 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 adverse events. But the Akkerman lawsuit is not the only lawsuit

making serious allegations of harm arising out of MECTA's ECT devices, and which it 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. (Ex. C)

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 D.) 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 E.)

MECTA's president also acknowledge a further lawsuit filed against the company by a Mr. or Ms. Tuch. And, a further lawsuit was filed against MECTA by Ms. Linda Andre, also alleging substantial memory loss, and other damages.

According to Ms. Nichol, these five separate lawsuits were which filed prior to the Akkerman action, alleged that MECTA's devices caused brain damage to the patients. (Ex. A, Nichols Deposition, p. 333-342.) Ms. Nichols testified that she was not even curious why 6 different people had sued her company for causing them brain damage, because claims of harm arising out of ECT conflict with her view of the "mainstream" of the medical community, and therefore, ipso facto, the lawsuits are "frivolous." (*Id.*, 344-45.)

None of these lawsuits or the allegations of adverse events caused by ECT from MECTA's devices were reported by it to the FDA.

MECTA Blaming the FDA

Repeatedly throughout the deposition, Ms. Nichols asserted that it was unnecessary to warn patients of the dangers of ECT because, the FDA prohibited them from doing so! (*Id.*, p. 274-278.)

Incredibly, MECTA also justified its use of ECT, asserting, falsely, that the devices "have been determined safe and effective by the FDA for the last 25 years for four generations of devices." (*Id.*, p. 288-89.) She also misrepresented in sworn

testimony that the FDA “designed the devices to be safe and effective with a 100 joules limit.” (*Id.*, p. 285-86.)

Patients’ Views of the Damages Caused

For several years, a website named www.ect.org has conducted a survey of ECT patients to determine their attitudes and damages caused to them by ECT. Many of the patients identified themselves and some remained relatively anonymous. However, the vast majority of these persons gave chilling, horrifying conclusions regarding the damages they received from receipt of ECT. A sampling of these stories, these surveys are appended hereto, and warrant consideration by the FDA respecting the issue of lack of efficacy, and the extreme level of danger from this treatment. This sample is appended as Exhibit F.)

The National Council of Disability, a federal agency created by President Clinton, conducted its own survey of ECT patients, and came to the identical conclusion: ECT Causes grave disabilities. As stated in the federal publication, “From Privileges to Rights: People With Psychiatric Disabilities Speak for Themselves, January 20, 2000, stated, in part:

Even proponents of electroconvulsive therapy (ECT or shock treatment) admit that it is a high 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.)

Electro-convulsive therapy is a treatment which cannot be made safe, regardless of the controls system implemented. As the President of MECTA explained, it is not merely the grand mal seizure which is sought in this treatment, as this alone does not create the so-called “therapeutic effect” the practitioner seeks from ECT. Rather, the treatment seeks the effect of dumbfounded, damaged person who makes little trouble and are unable to think, reason and perform well in society. This requires even more electricity than is necessary to cause the grand mal seizure.

Thus, the treatment requires destruction of parts of the brain. The use of muscle paralyzing agents obscures the seizure, but it does not eliminate the damages caused by the treatment.

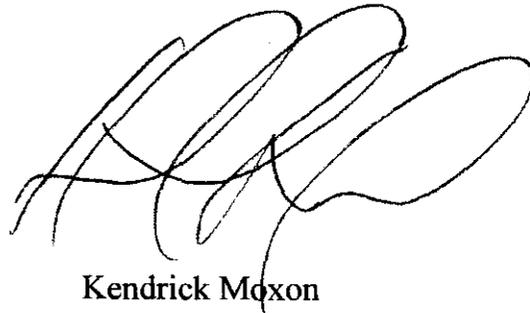
CONCLUSION

Given the historical damages known to be caused by ECT, given the ubiquitous memory loss of recipients of the treatment; given the lack of efficacy of the treatment' given the dishonesty of manufacturers in failing to inform the FDA of the adverse effects of the treatment and even falsely justifying the treatment because it has been "approved" by the FDA, the use of ECT should be suspended.

Only if and when a full PMA submission is made and approved should this practice and these devices be permitted.

No such showing of reasonable safety and efficacy can be made by the manufacturers, and accordingly the manufacturers will certainly argue that a PMA is unnecessary. I urge the FDA to take seriously its own responsibilities to protect the public and to reject the opinions of the manufacturers and ECT advocates who seek to continue the use of this treatment without meeting the most basic requirements all other device manufacturers must pass.

Thank you.

A handwritten signature in black ink, appearing to read 'Kendrick Moxon', with a stylized, cursive script.

Kendrick Moxon

Endnotes

1. Leo Alexander, "Public Mental Health Practices in Germany: Sterilization and Execution of Patients Suffering from Nervous or Mental Disease," CIOS Item 24 Medical, 19 August 1945, combined intelligence Objectives Subcommittee, G-2 Division SHAEF (Rear) APO 413, page 33-34
2. Leo Alexander, "Neuropathology and Neurophysiology, Including Electro-Encephalography in Wartime Germany," CIOS Item 24 Medical, 19 August 1945, combined intelligence Objectives Subcommittee, G-2 Division SHAEF (Rear) APO 413, page 42.
3. W.H. Kaye, *We Can't All Be Sane!*, (Los Angeles: Collectors Publications, 1965), pp. 117-19.
4. "Fatalities Following Electric Convulsive Therapy: A report of two cases with autopsy findings" *Trans. American Neurological Assoc.* 68 (June 1942).
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6. Kalinowsky, L.B., "Organic psychotic syndromes occurring during electric convulsive therapy." *Archeology, Neurology & Psychiatry*, 53:269-273 (April) 1945, quoted in, Lowinger, Louis, B.S.S., and Huddleson, James H., M.D., "Complications in electric shock therapy." *American Journal of Psychiatry*, 102:495-497 (March) 1946.
7. Cameron, Douglas, "ECT: Sham Statistics, the Nyth of Comnvulsive Therapy and the Case for Consumer Misinformation", *The Journal of Mind and Behavior*, Winter/Spring 1994, Vol. 15, p. 177-198
8. Masserman, Jules., M.D., [American Psychiatric Assoc. President, 1978-79]. "Experimental Neurosis," *Scientific America*, Mar. 1950, p. 249.
9. Kennedy, C.J.C., and Anchel, D., "Regressive electric-shock in schizophrenia refractory to other shock therapies," *Psychiatric Quarterly*, Vol. 22, No. 2, 1948, pp. 317-320.
10. Dr. A.E. Bennett, letter published in *Electroconvulsive Therapy*, Correspondence, Vol. 14, No. 2.
11. Morgan, Robert, Dr., "The isolation, description and treatment of the pathological behavior of ECT - damaged patients," unpublished research proposal, February 1966. p. 5-6.
12. "From lobotomy to physics to Freud ... and interview with Karl Pribam, *APA Monitor*, American Psychological Association, Sept-Oct 1974, p. 9.

13. *Electroconvulsive Therapy. NIH Consensus Statement Online*. 1985 June 10-12, 1985; 5(11): 11-23, quoting Introduction.
14. "Complications and Electric Shock Therapy," *American Journal of Psychiatry* 102 (1946)
15. *Electroconvulsive Therapy. NIH Consensus Statement Online*. 1985 June 10-12, 1985; 5(11): 11-23, from section, "What Are the Risks and Adverse Effects of ECT?"
16. Frankel, Fred H., M.D., "Electro-convulsive therapy in Massachusetts, a task force report." *Massachusetts Journal of Mental Health*, 3:3-29 (Winter), 1973.
17. *Electroconvulsive Therapy. Report of the Task Force on Electroconvulsive Therapy of the American Psychiatric Association*. (1978), p. 3.
18. *Id.*
19. *Id.*, p. 4.
20. *Id.*, contained in section, "What Are The Risks And Adverse Effects of ECT?"

1 UNITED STATES DISTRICT COURT
2 CENTRAL DISTRICT OF CALIFORNIA

3 - - - -
4 **CERTIFIED COPY**

4 ATZE AKKERMAN and)
5 ELIZABETH AKKERMAN; each)
6 suing individually and on)
7 behalf of the general public,)

6 Plaintiffs,)

7 vs.)

Case No. 01-10362 RSWL (RZx)

8 MECTA CORPORATION, and DOES)
9 1-20,)

10 Defendants.)

11
12
13 VIDEOTAPED DEPOSITION OF ROBIN NICOL

14 AND

15 30 (b) (6) EXAMINATION OF MECTA CORPORATION

16 VOLUME I

17 PORTLAND, OREGON

18 NOVEMBER 18, 2004

19
20
21 ATKINSON-BAKER, INC.
22 CERTIFIED COURT REPORTERS
23 500 North Brand Boulevard, Third Floor
24 Glendale, California 91203
25 (818) 551-7300

REPORTED BY: HEATHER A. SUMMERS, CSR NO. 92-0246

FILE NO.: 9E09AFE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
)
Plaintiffs,)
)
vs.)
)
MECTA CORPORATION, and DOES)
1-20,)
)
Defendants.)

Case No. 01-10362 RSWL (RZx)

Deposition of ROBIN NICOL and 30(b)(6) Examination of
MECTA Corporation, taken on behalf of the Plaintiffs, at Allen
Sheridan & McClanahan, 190 Southwest Harrison Street,
Portland, Oregon, commencing at 9:13 a.m. on Thursday,
November 18, 2004, before Heather A. Summers, CSR No. 92-0246.

A P P E A R A N C E S

1
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13 (213) 250-1800

14 ALSO PRESENT: Gaabriel Becket, paralegal
15 Jay Webster, videographer
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1 for identification.)

2 MR. MOXON: Swear the witness, please.

3 THE COURT REPORTER: I did.

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5

EXAMINATION

6

BY MR. MOXON:

7

Q. Could you please state and spell your name for
8 the record?

9

A. Robin Nicol, R-O-B-I-N, Nicol, N-I-C-O-L.

10

Q. Ms. Nicol, you have given depositions before?

11

A. One.

12

Q. It was in the Rohovit case?

13

A. Yes.

14

Q. Have you had an opportunity to speak with your
15 counsel concerning the scope of the deposition?

16

A. Which deposition?

17

Q. This deposition.

18

A. Can you clarify "scope," what you mean by
19 "scope"?

20

Q. Did you talk to your attorney about the fact that
21 you're having a deposition and he told you what it
22 encompassed?

23

A. Yes.

24

Q. If there is any question, such as the one I just
25 asked you that you don't fully understand, please do have me

1 clarify it. I want to make sure we're on the same page. I
2 will assume that you've understood every question I've asked
3 you if you have answered it. Okay?

4 A. Fine.

5 Q. And we will need an oral response to every
6 question since we're making an verbatim transcript by an
7 authorized court reporter sitting to your left.

8 A. Fine.

9 Q. What is your position in the MECTA Corporation?

10 A. I'm the president.

11 Q. How long have you been the president?

12 A. Since 1987.

13 Q. Did you have a position prior to that?

14 A. I was the sales manager.

15 Q. From when to when?

16 A. From 1980 until 1987.

17 Q. Did you have a position before that?

18 A. No. We purchased the company in 1980.

19 Q. What are the scope of your duties as the
20 president?

21 A. I'm primarily administrative in terms of the
22 company. I manage all of the departments within the company.
23 I'm responsible specifically for 12 areas that I manage.

24 Q. Do you have any formal education?

25 A. I do.

1 Q. After high school?

2 A. I do.

3 Q. Please tell me what it is.

4 A. I have two college degrees. I have a Bachelor of
5 Arts in English and a Master of Arts in English.

6 Q. Do you have any electrical training or
7 electronics training?

8 A. No, I don't.

9 Q. Do you have any training in the health-care
10 field?

11 A. Other than the 26 years I have been the president
12 of the company, no, I don't.

13 Q. No formal training in any health-care field,
14 correct?

15 A. Correct.

16 Q. Do you have any training in any research fields?

17 A. Can you be more specific? Researching --

18 Q. Well, you don't have any formal training beyond
19 high school except in English, correct?

20 A. Educational training, correct.

21 Q. Yes. Thank you. Can you tell me -- well, let me
22 ask you first, are you testifying now solely on your own
23 behalf or also on behalf of MECTA Corporation?

24 MR. OWENS: Well, that's a legal question. I'm going
25 to object on that basis. She has no foundation to answer

1 MR. MOXON: Could you read the question back to the
2 witness?

3 (The record was read as follows:

4 Q. After you read the complaint, were you
5 surprised by the allegations in the complaint
6 indicating that a number of writers and
7 practitioners of shock treatment in the
8 '40s and '50s stated the purpose of it in part
9 is to cause brain damage and to cause memory loss?)

10 Q. (By Mr. Moxon) Could you answer, please?

11 A. It is a ludicrous complaint. One would not
12 create a medical -- it would not happen in responsible medical
13 -- with a responsible medical community --

14 Q. I couldn't agree with you more.

15 A. -- under the auspices of the AMA.

16 Q. I couldn't agree with you more.

17 A. It is a very --

18 MR. OWENS: Just a minute. Ms. Nicol, you have
19 answered the question.

20 THE WITNESS: Right.

21 MR. OWENS: You are engaging in conversation with
22 counsel. That's not what this is.

23 THE WITNESS: Right.

24 Q. (By Mr. Moxon) So when you saw allegations in
25 the pleading that articles had been written indicating that

1 the purpose of ECT was to cause brain damage, you consider
2 that too ludicrous to consider?

3 A. As I said earlier, I don't accept that premise.

4 Q. I know.

5 A. I don't accept that premise.

6 Q. I know. But you consider it too ludicrous to
7 even consider that that might have been true?

8 MR. OWENS: The question is vague as to time.

9 Q. (By Mr. Moxon) Answer?

10 A. In an environment with medical -- M.D.s, I would
11 find that impossible to believe.

12 Q. I take it you didn't read any of the shock
13 literature written in the 1940s and 1950s; is that right?

14 MR. OWENS: At what point in time?

15 Q. (By Mr. Moxon) Ever.

16 A. I'm aware of it, as I said earlier. I'm aware of
17 excerpts from it. I have never read it. I have never read
18 it. I'm aware, very aware of it, but I have never read it.

19 Q. During the 1980s were you aware that there was
20 literature in the 1940s and 1950s indicating that the purpose
21 of ECT was to cause brain damage?

22 A. I would have been aware of that, again, but it's
23 a very fringe perspective.

24 Q. You rejected that, correct?

25 A. I was aware of it.

1 Q. You rejected it?

2 A. In terms of what? Rejected it?

3 Q. Rejected it in terms of finding out if there was
4 any truth to it?

5 A. Based on the work that was done by the clinicians
6 in the field and the research that was done that I mentioned
7 earlier, it was rejected in terms of science, in terms of the
8 work that's been done from 1980 to the present. So we had to
9 accept that research as it was the majority.

10 Q. In the 1980s were you aware of the articles
11 written in the 1940s and 1950s indicating that the purpose of
12 shock treatment was also to cause memory loss, i.e., that the
13 quote, "therapeutic effect," end quote, of shock treatment was
14 memory loss?

15 A. Once again, I wouldn't accept the premise.

16 Q. I didn't ask you if you accepted it, Ms. Nicol.
17 I simply wanted to know if you were aware of it?

18 A. Again, I was aware of it, but I would never have
19 read the articles.

20 Q. Did you conduct any investigation or research to
21 determine if the representations that the purpose of shock
22 treatment was to cause memory loss was accurate?

23 A. MECTA does not do research.

24 Q. The answer is no?

25 A. The answer is no.

1 Q. Now, neither John Friedberg, Peter Breggin or
2 Peter Sterling were physicians in the 1940s and 1950s. These
3 were articles written by other practitioners -- did you know
4 that -- not those three?

5 A. These are your questions. I wouldn't know.
6 These are your articles. I wouldn't know. You would have to
7 identify the articles. That's the only way I would know.

8 Q. Okay. I take it you never examined the
9 bibliographies in Dr. Friedberg's book or Peter Breggin's book
10 indicating that scientific tests demonstrated that ECT caused
11 brain damage, correct?

12 A. I didn't read their books.

13 Q. Let me just modify my initial kind of
14 instructions and admonitions to you that I gave you at the
15 beginning. I'm asking you a number of questions because I
16 seek answers specific to my questions, of course. If you
17 could specifically answer my questions, I have no problem with
18 you making further comments or conclusions thereafter. But
19 it's going to take quite a long time if I need to repeat the
20 questions to get direct answers. And I'm not even asserting
21 that you're doing it intentionally, but I'm just asking you to
22 please listen carefully to my questions, and if you could
23 please directly answer my questions. Then if you want to give
24 further justification, I have no problem with that.

25 MR. OWENS: Well, Mr. Moxon, she is answering your

1 questions specifically. If you don't like her answers, that's
2 another issue. If anybody is being repetitive in this
3 deposition, it's you.

4 MR. MOXON: That is because she's not answering the
5 questions.

6 MR. OWENS: That is your opinion.

7 MR. MOXON: That's right. That is my opinion.

8 MR. OWENS: I'm not going to have you instruct my
9 witness to the effect that you're not answering the question
10 the way I want you to; please do so. That's not going to
11 happen.

12 MR. MOXON: Could you please read the last question
13 back to the witness, and when you do that, can you retype it
14 into the record at that point?

15 (The record was read as follow:

16 Q. I take it you never examined the
17 bibliographies in Dr. Friedberg's book or
18 Peter Breggin's book indicating that
19 scientific tests demonstrated that ECT caused
20 brain damage, correct?)

21 MR. OWENS: Assumes facts not in evidence.

22 THE WITNESS: My response is the same. I did not
23 read the books; therefore, I did not see the bibliographies.

24 Q. (By Mr. Moxon) Did anyone tell you that you
25 should disregard what you have characterized as the minority

1 view of ECT, the minority view being that it causes brain
2 damage and causes memory loss?

3 A. No.

4 Q. So it was a decision made by MECTA?

5 A. Correct.

6 Q. Did you see the list of articles that I provided
7 to your counsel in response to some of the discovery requests
8 in this case?

9 A. Yes.

10 Q. Do you know if you have copies of any of the
11 articles that were listed in those discovery requests?

12 A. Not with me. The articles that we produced I
13 would have at work.

14 MR. OWENS: That was not the question that he asked,
15 Ms. Nicol. He asked you about articles that he has identified
16 in discovery; not that we've identified in discovery.

17 Q. (By Mr. Moxon) Let me give it to you again. I
18 provided responses to some discovery that was issued by
19 Mr. Owens.

20 A. Okay.

21 Q. And I listed a number of articles which had
22 reference to, in my view, brain damage and memory loss, about
23 some 40 articles that were in medical journals. Did you see
24 that list?

25 MR. OWENS: I'm going to object to the question. It

1 that, and that percentage was debated.

2 Q. I'm sorry. I didn't understand your answer.

3 A. In the literature, that percentage varied widely.

4 So, yes, we noted that. We noted that.

5 Q. I just want to understand your question (sic) so
6 let me see if I can clarify this. You noted that there was a
7 wide variance in the percentage of the number of psychiatrists
8 who believed that ECT caused permanent memory loss?

9 A. Yes. Correct. Based on the research that we did
10 and the literature.

11 Q. What were the highs and lows or the variance in
12 what you read of the number of psychiatrists that believed ECT
13 caused permanent memory loss?

14 A. I can't tell you that. That was in 1979. I
15 would have to go back and look at that literature from 1979
16 because the percentages have changed markedly in the 26 years,
17 and I have focused on research as it becomes available, and
18 the numbers have decreased markedly, of course, as you know.
19 So there is very little impairment and cognitive effect now
20 compared to what was perceived as being memory impairment. So
21 I have been very cognizant of that.

22 Q. Really? How many people have you spoken to who
23 have personally had ECT?

24 A. I have spoken to patients.

25 Q. How many?

1 A. Five or six.

2 Q. Over the last 30 years?

3 A. Over the last 25 years. And I have spoken to
4 their families also.

5 Q. Did any of the patients who had received ECT tell
6 you whether or not they had memory problems?

7 A. In cases -- where I spoke with patients, they
8 were thanking us for saving their lives. So I have spoken
9 with patients who are very grateful.

10 Q. Let me ask you the question I asked you again.
11 Did you talk to any of those five or six people over the last
12 25 years who indicated to you whether or not they had memory
13 problems arising out of their ACT?

14 A. And my answer would be they did not mention
15 memory problems.

16 Q. Did you ask them?

17 A. No, I did not.

18 Q. Have you ever received any letters of complaint
19 from any ECT practitioner that ECT harmed a patient?

20 A. Can you be more specific?

21 Q. Yes. Have you ever received any letter of
22 complaint from any practitioner of shock treatment that the
23 treatment harmed a patient?

24 A. In what way? Can you define "harm" in your
25 vernacular?

1 Q. Just a minute. You don't consider broken bones
2 from ECT to be an adverse effect from ECT?

3 A. I believe they're considered to be adverse
4 effects because they're not -- this doesn't happen with the
5 modified ECT that we have been giving for 26 years with muscle
6 relaxants, anesthetic, and the patient being oxygenated by an
7 anesthesiologist with a muscle relaxant that can occur.

8 Q. Is a broken bone an adverse effect? Would that
9 be an adverse effect or not?

10 MR. OWENS: The question is vague and ambiguous.

11 THE WITNESS: It would be, but it's not listed in any
12 of the professional textbooks on adverse effects by the
13 medical community.

14 Q. (By Mr. Moxon) How about broken teeth? Would
15 you consider that an adverse effect of ECT?

16 A. Yes, I would.

17 Q. That happens, doesn't it?

18 A. It's not listed, but I would consider it.

19 Q. That happens, doesn't it, from ECT? You're aware
20 that ECT causes --

21 A. It could happen.

22 Q. Let me finish my question. You're aware that ECT
23 and the convulsions caused by your machines causes people
24 sometimes to have broken teeth, correct?

25 MR. OWENS: When? The question is vague and

1 ambiguous as to time.

2 THE WITNESS: That would be a clinical occurrence
3 based on how the clinician was treating, but that could be an
4 adverse effect.

5 Q. (By Mr. Moxon) I'm not asking for a
6 justification. I'm just asking for yes or no. Are you
7 aware --

8 A. I believe I said yes two questions ago. I did.

9 Q. Let's just have the question clear. You're aware
10 that your machines sometimes cause people to have broken
11 teeth, right?

12 A. Yes.

13 Q. And you're aware that your machines cause people
14 sometimes to have permanent memory loss, right?

15 A. In what time frame? In the literature?

16 MR. OWENS: No. He's asking --

17 MR. MOXON: I'm asking --

18 MR. OWENS: Excuse me. If I may clarify.

19 THE WITNESS: As an adverse effect, correct?

20 MR. OWENS: No. He's not asking what adverse effects
21 are. He's asking if you are aware if these machines have
22 caused these various problems. Do you understand the
23 question?

24 THE WITNESS: I do understand the question.

25 Q. (By Mr. Moxon) Let me give you the question

1 again on the record. Are you aware that your machines cause
2 patients to have permanent memory loss?

3 MR. OWENS: Excuse me.

4 THE WITNESS: That can be a complication.

5 MR. OWENS: I have to get my objections in. I don't
6 know whether he's asking if your machines have caused these or
7 potentially can cause, and I don't know whether you
8 understand --

9 THE WITNESS: I don't.

10 MR. OWENS: -- the assumption. So the objection is
11 that it is vague and ambiguous.

12 Q. (By Mr. Moxon) It would actually help both
13 Mr. Owens and I out if you just listen to my question
14 carefully. I will try to make it as clear as possible. If
15 it's not clear I will clarify it. And then after you've
16 duplicated the question, then go ahead and give your answer.
17 Okay?

18 A. Right.

19 Q. Are you aware that your machines have caused
20 patients to experience permanent memory loss?

21 A. Yes.

22 Q. Do you consider that to be an adverse effect --

23 A. Yes.

24 Q. -- of shock treatment?

25 A. Yes.

1 Q. Do you have copies of any of them?

2 A. I don't.

3 Q. Have you read any of them?

4 A. At times I have seen them, yes, but I have not
5 kept the copies.

6 Q. Are you aware that this survivors group takes the
7 position that ECT is very harmful to patients?

8 A. Yes.

9 Q. Have you ever spoken to David Oaks?

10 A. No, I haven't.

11 Q. Have you ever made any effort to communicate with
12 the people that publish *Mind Freedom* --

13 A. No, I haven't.

14 Q. -- to see why they so vehemently assert that
15 their members have been gravely harmed by shock treatment?

16 A. I have not.

17 Q. Why not?

18 A. Again, we're very focused on what we do in terms
19 of the research and the literature that supports our products,
20 that it is a safe and effective treatment. We are very
21 convinced it is a safe and effective treatment given the work
22 that I have already produced to you in the form of five
23 textbooks, a substantial amount of manuals and articles. And
24 all of this indicates to us that it is a safe and effective
25 treatment. So I felt no need to go further other than relying

1 on science.

2 Q. And the stories and the reports of the actual
3 patients of ECT who say they have been severely harmed is not
4 in your view science?

5 A. It is not science in that regard.

6 Q. So it is disregarded by the company?

7 A. It is not disregarded, but that's not our role.

8 Q. Are you familiar with a group called ECT.org?

9 A. I have heard of them, yes.

10 Q. What have you heard about them?

11 A. That they are an antipsychiatry group.

12 Q. And they are an anti-ECT group, right?

13 A. Primarily I have just heard antipsychiatry.

14 Q. Have you ever looked on the ECT.org Web page?

15 A. No, I haven't.

16 Q. Have you communicated with any of the persons
17 that run ECT.org?

18 A. No, I have not.

19 Q. Why not?

20 A. Once again, I'm very focused on what we're doing.

21 And as this is considered a fringe organization by the
22 psychiatric community, there is -- there's nothing to be
23 gained. We're very focused on healing people and saving lives
24 and providing the psychiatric community with the safest
25 devices we can, and that's where our focus and energies lie.

1 Q. So if you had information that your devices
2 weren't as safe as they could be or that they weren't safe at
3 all, would that change your business?

4 A. It would have to be scientific evidence. It
5 would have to be proven. It would have to be controlled in
6 double-blind studies. Then, yes, I would be absolutely
7 interested.

8 Q. So 50 or a hundred individual patients said it
9 destroyed their memory; that wouldn't fit within the category
10 of the information that you would consider to change your
11 devices, correct?

12 MR. OWENS: The question is vague and ambiguous. It
13 is an incomplete hypothetical.

14 Q. (By Mr. Moxon) He's right. In the ECT.org
15 there's perhaps 200 people, 200 shock patients, who have
16 written in their personal stories about the results of their
17 shock treatment. Have you ever heard of that?

18 MR. OWENS: The question assumes facts not in
19 evidence. It lacks foundation.

20 Q. (By Mr. Moxon) It kind of does. I'm asking if
21 you have heard that.

22 MR. OWENS: Same objections. Go ahead.

23 THE WITNESS: No, I have not.

24 Q. (By Mr. Moxon) If you received credible reports
25 from 200 patients that weren't examined by any blind or

1 double-blind studies or not examined by any psychiatrist or
2 not examined by anybody but just reports from 200 former
3 patients saying that they were severely harmed by ECT, would
4 that have any effect on how you do business?

5 MR. OWENS: It is vague and ambiguous. It is an
6 incomplete hypothetical.

7 THE WITNESS: Certainly we would be very
8 compassionate. We know that in any medical environment there
9 is a risk/benefit, and when you make a choice to have a
10 therapy, any therapeutic -- any medical procedure, there is a
11 risk and there is a benefit.

12 Q. (By Mr. Moxon) So you balance --

13 A. There is a balance, and I'm sure with any medical
14 procedure there are what we would call failures and successes,
15 good experiences and bad experiences. And that's how I would
16 regard it. And I would regard it with compassion.

17 Q. But not enough compassion to actually acquire the
18 information to see what the balance should be?

19 MR. OWENS: The question is argumentative. It's
20 vague and ambiguous. Unintelligible.

21 THE WITNESS: Again, the science being done addresses
22 those issues. The goal, of course, is to eliminate any side
23 effect in terms of our devices, and that would be true in any
24 therapeutic -- any therapy for any medical procedure. That is
25 the goal.

1 Q. (By Mr. Moxon) What changes have you made in
2 your machines to eliminate permanent memory loss caused by the
3 machines?

4 A. We have made changes. There have been changes
5 over the last 20 years that have all decreased memory
6 deficits.

7 Q. So you have intentionally made changes in your
8 machines for the purpose of reducing memory loss caused by
9 ECT?

10 A. They have decreased memory deficits, yes,
11 features that we have introduced.

12 Q. What features have you introduced for the purpose
13 of lessening the memory loss that you know is caused by ECT?

14 A. In the last year we introduced a new parameter
15 set called Ultra-Brief, and I believe we produced a
16 document -- excuse me. Can I have a glass of water since I am
17 doing all of the talking -- an Ultra-Brief parameter set.
18 It's an Ultra-Brief ECT is what we call it, which uses much
19 lower pulse widths and in concert with titration it -- the
20 side effects are far less; the memory deficits are far less.

21 We have also developed a machine -- it is a pulse
22 waveform machine -- in 1980. The memory loss, the deficits,
23 are a third of the sinusoidal waveform. So you can bracket
24 from '80 to 2003 that we have worked very hard and diligently
25 on achieving this.

1 Q. We will get to these waveforms a little bit
2 later. Thank you for identifying them. Have you ever heard
3 of an Institute for Treatment in Psychiatry?

4 A. No, I haven't.

5 Q. Center for the Treatment - Psychiatry?

6 A. Perhaps. I'm not sure.

7 Q. It is a group that's organized by Linda Andre in
8 New York. Does that sound familiar?

9 A. Yes.

10 Q. And it is also an anti-ECT group?

11 A. Correct.

12 Q. Are you aware of any other treatments anywhere in
13 medicine that has at least three survivor groups adamantly
14 opposed to the form of the treatment?

15 A. I've not done --

16 MR. OWENS: The question assumes facts not in
17 evidence.

18 Q. (By Mr. Moxon) Answer?

19 A. I haven't done that kind of research.

20 Q. Well, do you know of any practice in medicine
21 other than ECT where there are survivor groups that seek to
22 oppose and legislate against the treatment?

23 A. I wouldn't know without researching it.

24 Q. So the answer is no?

25 A. The answer is no. Without researching it, yes.

1 Q. There are only two shock manufacturers in the
2 United States, correct?

3 A. Correct.

4 Q. You're one of them?

5 A. Yes.

6 Q. Aren't you curious to find out as one of the two
7 manufacturers in the country why there are victim groups
8 established to legislate against your machines?

9 MR. OWENS: Assumes facts not in evidence. It's
10 argumentative.

11 THE WITNESS: I'm not curious. I would be very
12 compassionate. But I also know, again, that in the
13 risk/benefit selections that people have to make there are
14 going to be some side effects over a 40- or 50-year period of
15 ECT being given and that certainly not all of it would be
16 given with our devices.

17 Q. (By Mr. Moxon) So you would be very
18 compassionate, you say?

19 A. Yes.

20 Q. What have you done in the exercise of this
21 compassion to communicate with any of the victims of your
22 machines?

23 MR. OWENS: That misstates the testimony. Assumes
24 facts not in evidence.

25 THE WITNESS: That is not our responsibility as a

1 medical-device manufacturer. We are responsible for our
2 medical devices. The physicians who treated those patients
3 would work with those patients. We are not responsible for
4 individual patients.

5 Q. (By Mr. Moxon) That's not your problem? That's
6 the psychiatrists' problem?

7 A. That is not our responsibility from the FDA
8 perspective or from our perspective as medical-device
9 manufacturers.

10 Q. Not your responsibility?

11 MR. OWENS: Wait a minute. She has answered the
12 question. You are being argumentative. Go on to the next
13 question.

14 Q. (By Mr. Moxon) Do you know why these victims
15 groups were established against ECT?

16 A. No, I don't.

17 Q. Have you had any curiosity over the past 25 years
18 to learn why some victims of ECT established groups to attempt
19 to legislate or control the practice?

20 MR. OWENS: Assumes facts not in evidence.

21 THE WITNESS: Of course it would be of interest, but
22 I haven't done that. I haven't researched it.

23 Q. (By Mr. Moxon) And why is that?

24 MR. OWENS: Same objection.

25 THE WITNESS: Objection?

1 MR. OWENS: I said same objection.

2 Q. (By Mr. Moxon) Why is that?

3 A. Because it's not in the purview of my ownership
4 of a medical-device electronics company. I'm very focused on
5 the device, making it the safest and most effective device I
6 can as an owner.

7 Q. You are more interested in the business end of
8 ECT, correct?

9 MR. OWENS: Object.

10 Q. (By Mr. Moxon) That is your focus?

11 MR. OWENS: Argumentative and vague.

12 THE WITNESS: I'm interested in providing a safe and
13 effective device for psychiatrists to use to heal people.

14 Q. (By Mr. Moxon) Do you know why in the state of
15 California there is only one medical treatment that has a
16 legislated form of standardized informed consent?

17 MR. OWENS: Assumes facts not in evidence.

18 THE WITNESS: No, I don't.

19 Q. (By Mr. Moxon) Did you know that you can't have
20 ECT in California without signing a very specific consent
21 form?

22 A. Yes, I was aware of that.

23 Q. Do you have any idea why?

24 A. No, I don't.

25 Q. Do you have any curiosity why the state would

1 require a specific consent form to be signed by a person
2 before they have this treatment?

3 MR. OWENS: It's argumentative.

4 THE WITNESS: No, I don't.

5 Q. (By Mr. Moxon) Did you ever hear that the city
6 of Berkeley banned ECT at one point in the '70s?

7 A. I remember that.

8 Q. Did you look into that at all?

9 A. Yes, that is one of the things that we researched
10 when we purchased the company.

11 Q. Did that give you any cause for concern?

12 A. No, it didn't. Again, it was a very tiny fringe
13 minority opinion at that time, in the 1970s in Berkeley.

14 Q. Did you see any of the anti-ECT demonstrations of
15 hundreds of people demonstrating against it in Berkeley?

16 MR. OWENS: Assumes facts not in evidence.

17 THE WITNESS: No, I wasn't there in the '70s. We
18 didn't own the company then.

19 Q. (By Mr. Moxon) Were you aware that that
20 happened?

21 MR. OWENS: Assumes facts not in evidence.

22 THE WITNESS: When did that happen? I'm not aware of
23 that.

24 Q. (By Mr. Moxon) In the 70s.

25 A. I wasn't aware of that.

1 Q. When the city of Berkeley banned ECT within the
2 city limits, is it your understanding that that was a minority
3 of persons that were interested in doing that?

4 A. It was a minority, assumed to be in the
5 psychiatric community and in the rest of the United States.
6 It was a minority opinion, if you will.

7 Q. But you did not --

8 A. It was not mainstream.

9 Q. Has you or your company made any effort to
10 solicit information from persons who have received ECT to see
11 whether or not they have been harmed?

12 A. No.

13 Q. Why not?

14 A. Again, that is not in the purview of our
15 company's responsibilities.

16 Q. That is a responsibility of the practitioners who
17 use your machines?

18 A. Correct.

19 Q. Now, you've paid money to Harold Sackeim as a
20 consultant, correct?

21 A. Correct.

22 Q. What did you pay him for?

23 A. As a consultant in some cases. In some case,
24 very few cases, he would travel, as would other physicians, to
25 speak in scientific meetings only. And because the community

1 damage, so no. The answer is no.

2 Q. (By Mr. Moxon) You're aware that many people who
3 have received ECT think that they have been caused brain
4 damage by ECT, correct?

5 MR. OWENS: Assumes facts not in evidence.

6 THE WITNESS: I'm aware there is a fringe minority
7 that believes that, a small group.

8 Q. (By Mr. Moxon) Do you think there is a fringe
9 minority of patients?

10 A. When you say "people," you need to be specific.

11 Q. Patients. I'm talking about patients, people who
12 have received ECT. Do you think that's --

13 A. I think it is a small.

14 MR. OWENS: Just a minute. You're not going to argue
15 with Mr. Moxon. Mr. Maxon is not going to argue with you.
16 It's not going to happen in this deposition.

17 Q. (By Mr. Moxon) I agree. Let me finish the
18 question. You used the term "fringe minority." Are you
19 referring to a fringe minority of commentators or fringe
20 minority of patients?

21 A. I will restate that. I would say small minority
22 of patients.

23 Q. Do you think the persons that have indicated they
24 received brain damage from ECT are lying?

25 MR. OWENS: Assumes facts not in evidence.

1 Speculation.

2 Q. (By Mr. Moxon) Is that your assumption?

3 A. Again, as we do not believe ECT causes brain
4 damage, the answer would be no.

5 Q. You don't think they're lying? You think they
6 are lying?

7 MR. OWENS: Same objections.

8 THE WITNESS: I do, because we don't believe brain
9 damage exists from ECT.

10 Q. (By Mr. Moxon) And if ECT patients have
11 indicated that immediately after the ECT they lost huge
12 chapters of their life, of the memory of their lives, do you
13 think that they're misrepresenting the truth?

14 MR. OWENS: Assumes facts not in evidence. It's
15 irrelevant.

16 Q. (By Mr. Moxon) Answer?

17 A. Yes.

18 Q. And have you talked to some of these people to
19 find out why they're saying these bad things about your
20 product that are untrue?

21 A. No, I have not.

22 MR. OWENS: Just a minute. It's argumentative.
23 We're going to take a break.

24 MR. MOXON: Let's take a lunch break. It is.

25 (Lunch recess taken at 12:20 p.m. to 1:31 p.m.)

1 Q. (By Mr. Moxon) Why is there a maximum amount of
2 voltage utilized by your machine?

3 A. Why would it be limited?

4 Q. Yes.

5 A. Because primarily we are a preamendment device.
6 We are -- the FDA has limited our maximum energy, limited our
7 maximums in all regards for safety and efficacy or safety and
8 effectiveness. So there would be a maximum number, of course.

9 Q. If the FDA didn't limit the amount of energy you
10 could use, would you use more in your machine?

11 A. No, we would not.

12 Q. So notwithstanding with the FDA does, you would
13 set a limit on the amount of voltage?

14 A. We would always set a limit, based again on the
15 literature and the research in the field.

16 Q. Would that be to prevent injury by the machines?

17 A. It would be for safety and effectiveness, yes; to
18 maximize that safety and effectiveness.

19 Q. Well, I don't understand your answer with respect
20 to effectiveness. Is there a voltage rate that is considered
21 more effective to a patient than another voltage rate?

22 MR. OWENS: Lacks foundation.

23 THE WITNESS: With any parameter, the decision would
24 be made based on the grandfathered, if you will, 1973 device,
25 the substantially equivalent designs of the four designs

1 following that, and the research that was current that we
2 would be constantly accessing.

3 Q. (By Mr. Moxon) So you can't really change the
4 electrical parameters, can you, because it has to be
5 substantially similar to a prior machine?

6 A. Correct.

7 Q. Well, as I understand it then the changes that
8 were made in the machine don't go to the electrical
9 parameters, correct?

10 A. Any changes that are made in the machine would be
11 consistent with the preamendment device.

12 Q. In terms of the electrical parameters?

13 A. Correct.

14 Q. And the purpose of the device, of course, is to
15 cause a grand mal seizure?

16 A. Correct.

17 Q. The position of your company is that there is a
18 therapeutic effect from shock treatment, right?

19 A. Correct.

20 Q. It has a therapeutic effect?

21 A. Yes.

22 Q. Is that therapeutic effect caused by the
23 convulsion?

24 A. The mechanisms of ECT.

25 Q. Is that alleged therapeutic effect caused by the

1 convulsion?

2 MR. OWENS: Lacks foundation.

3 THE WITNESS: It's caused by the mechanisms of ECT
4 that are caused by the convulsion, if you will.

5 Q. (By Mr. Moxon) Well, what are the mechanisms of
6 ECT that cause a therapeutic effect by virtue of a convulsion?

7 A. The convulsion causes many different things to
8 occur, and those are the theoretic mechanisms, if you will.

9 Q. So the therapeutic effect is not known?

10 A. There are numerous theories. They're well
11 understood in the world of neuropsychiatry, the
12 neuropsychiatric community. I just can't articulate them to
13 you.

14 Q. But they're theoretical?

15 A. They're very well-supported theories, yes.

16 Q. But they are still theories?

17 A. As with any medical procedure, yes.

18 Q. Well, I'm not going to argue that point with you.
19 You don't know then what the therapeutic -- what has an
20 alleged therapeutic effect by virtue of ECT, do you?

21 MR. OWENS: The question is vague, ambiguous, and
22 unintelligible.

23 THE WITNESS: Is that a question?

24 MR. MOXON: Yes.

25 MR. OWENS: Do you understand the question?

1 THE WITNESS: I do understand the question. And the
2 therapeutic effect is well understood.

3 Q. (By Mr. Moxon) Well, I asked you --

4 A. It is well understood in the clinical community
5 and we understand it, but we are not able to articulate it as
6 the clinicians would articulate those mechanisms to you
7 because they would be articulated by neuropsychiatrists, not
8 medical manufacturers of ECT devices. That wouldn't be our
9 role.

10 Q. So you're not able to articulate what the
11 therapeutic effect is of ECT, correct?

12 A. There are excellent articles and books on the
13 mechanisms of ECT --

14 Q. Ms. Nicol, I'm sorry but --

15 A. But they're in the clinical arena.

16 Q. I am just asking you --

17 MR. OWENS: Are you asking her by therapeutic effect
18 whether the ECT alleviates depression?

19 Q. (By Mr. Moxon) I will give you an example. You
20 have a broken bone and you set a bone and you put it back in
21 place and you know that when you put it back in place the bone
22 mends through a well-known mechanism. You know exactly how a
23 bone mends and heals. Okay?

24 Do you know what the purported therapeutic effect
25 is, the cause of a therapeutic effect, arising out of ECT?

1 to cause a convulsion?

2 MR. OWENS: Lacks foundation. It is an incomplete
3 hypothetical.

4 THE WITNESS: I can't agree with that question
5 because this doesn't send energy through the brain, as you
6 just expressed. It causes a convulsion.

7 Q. (By Mr. Moxon) Of course it does. The only way
8 a convulsion -- I don't want to argue with you. My question
9 to you is the convulsion is caused by electricity passing
10 through the brain, right?

11 A. Partially, yes.

12 Q. Partially? What else causes --

13 A. A small amount, correct.

14 Q. What else causes a convulsion other than the
15 electricity passing through the brain?

16 A. Nothing else.

17 Q. Okay. Is there any reason then to send more
18 electricity through the brain than is necessary to cause a
19 convulsion?

20 A. Yes.

21 Q. What's that?

22 A. In this case we had a preponderance of APA,
23 American Psychiatric Association, members, including task
24 force members, ask us to please increase the parameters on our
25 devices.

1 Q. Why?

2 A. The patients were not getting better. So we --
3 again, this was all based on research coming from numerous
4 centers in the U.S. And as we have always done, we used that
5 double-blind, peer-reviewed research to make that decision,
6 and we made it over five years.

7 Q. Correct me if I am wrong. As I understand your
8 testimony then a certain amount of energy is required for a
9 convulsion but a number of practitioners told you in their
10 view more energy was needed to cause a benefit?

11 A. Therapeutic response.

12 Q. Therapeutic response than just what causes the
13 convulsion?

14 A. Correct.

15 Q. Okay. Do you know what the point is of sending
16 electricity through a brain if it's not just to cause a
17 convulsion? Why? Why would you send electricity through a
18 brain beyond what's necessary to cause a convulsion? Do you
19 understand why?

20 MR. OWENS: The question is argumentative. It is
21 vague and ambiguous. Lacks foundation.

22 THE WITNESS: No.

23 Q. (By Mr. Moxon) Who made the decision to increase
24 the amount of energy the machine puts out? Who made that
25 final decision?

1 going to instruct her not to answer in an effort to expedite
2 the deposition. She can go ahead. Do you have the question
3 in mind?

4 Q. (By Mr. Moxon) I don't even have the question in
5 mind anymore.

6 MR. OWENS: Shoot away.

7 THE WITNESS: I don't. You will have to repeat it.
8 There has been too much discussion.

9 MR. OWENS: Fair enough.

10 Q. (By Mr. Moxon) When you heard that ECT had a bad
11 reputation, were you curious as to why?

12 A. Yes.

13 Q. What did you determine?

14 MR. OWENS: Asked and answered.

15 THE WITNESS: I determined that it was a fringe group
16 of people that felt that way and that it didn't represent the
17 mainstream medical community and the clinicians in ECT and
18 researchers that were the large, large majority of the
19 psychiatric community who believed in ECT.

20 Q. (By Mr. Moxon) Who told you that it was a fringe
21 group?

22 A. When?

23 Q. Or how did you come to believe that it was a
24 fringe group that had this bad impression of ECT?

25 A. It is just an assumption I have made based on

1 reading -- based on reading, based on literature, based on
2 impressions in the psychiatric community.

3 Q. As one of the two manufacturers of these devices
4 in the United States, were you curious to communicate with any
5 of the people of these which you concluded to be a fringe
6 group to see why they held this bad opinion of your business?

7 MR. OWENS: The question is vague and ambiguous.

8 THE WITNESS: I think we answered this this morning
9 also.

10 Q. (By Mr. Moxon) Humor me. I don't think I asked
11 it like that.

12 A. I think I said this morning -- and I will say it
13 again -- my focus was very specific in terms of running a
14 company and being very concerned about developing products
15 that were safe and effective. So I wasn't -- and I had also a
16 huge burden to work with the research and the developers that
17 are mainstream. So I didn't take the time to understand
18 because it wasn't in my purview. It wasn't within the job
19 description that I would have within my company as a
20 president.

21 Q. To talk to --

22 A. It just wouldn't be part of our focus.

23 Q. To talk to the detractors of ECT?

24 A. Correct.

25 Q. Do you know where Rex Hiatt lives?

1 THE WITNESS: Right. It doesn't address the claim.

2 Q. (By Mr. Moxon) Are there any governmental or
3 nongovernmental entities to whom you are required to send
4 reports concerning your machines, the manufacturer of your
5 machines, the effects of your machines, complaints, anything
6 relating to ECT or ECT machines?

7 A. Of course the FDA we would.

8 Q. What reports --

9 A. And --

10 Q. I'm sorry. Go ahead.

11 A. Requirements to file reports regarding the
12 machines, that would be the only organization in the United
13 States.

14 Q. What about the rest of the world?

15 A. To file reports, the European Union.

16 Q. Any others?

17 A. There are no others.

18 Q. What reports are required to be filed with the
19 FDA?

20 A. The only reports that would be required by the
21 FDA is if there were an adverse event. We would have to file
22 one form, an MDR, and that's it.

23 Q. Have you produced to me every single adverse
24 event report that you've filed with the FDA?

25 MR. OWENS: An MDR, in other words?

1 THE WITNESS: An adverse event.

2 Q. (By Mr. Moxon) If MDRs are the only one.

3 A. There haven't been any other than the one we
4 produced.

5 Q. So since 1980 there has only been one adverse
6 event that you reported to the FDA?

7 A. That was reported to us, correct.

8 Q. Are you required or were you ever required to
9 make any submissions to any state in the United States
10 concerning the sale of your machines?

11 A. No.

12 Q. Do you know if MECTA has ever had any
13 communication with the California Department of Mental Health?

14 A. No.

15 Q. How about the Oregon Department of Mental Health?

16 A. No.

17 MR. OWENS: No, you don't know or --

18 THE WITNESS: I don't know. I don't know. I would
19 have to go back and look at records in order to determine if
20 we had any contact over 26 years.

21 Q. (By Mr. Moxon) Do you sell machines in Asia
22 also?

23 A. Yes.

24 Q. Japan?

25 A. No.

1 placement, correct.

2 Q. Is it your understanding that your machine can
3 cure some ailment?

4 A. No.

5 Q. Do you represent that your machine can cure
6 anything?

7 A. No.

8 Q. Do you believe it can cure anything?

9 A. No.

10 Q. Then why do you market it?

11 A. Because endogenous depression can be alleviated.
12 There is no cure for it at this time.

13 Q. I guess it is not a disease then?

14 MR. OWENS: Well, wait a minute.

15 Q. (By Mr. Moxon) Is it a disease?

16 MR. OWENS: Lacks foundation.

17 Q. (By Mr. Moxon) Is depression a disease?

18 MR. OWENS: Lacks foundation.

19 THE WITNESS: It is considered a DSM criteria. It's
20 a category in the DMS.

21 Q. (By Mr. Moxon) Is it a disease?

22 A. I think the APA categorizes it as such.

23 Q. As a disease?

24 A. In the DSM the APA -- you would have to -- I
25 would have to resource that to give you that answer. And,

REPORTER'S CERTIFICATE

I, HEATHER A. SUMMERS, CSR. NO. 92-0246, Certified Shorthand Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

I further certify that I am not a relative or employee of any attorney or of any of the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of Oregon that the foregoing is true and correct.

Dated this 29th day of November 2004.



Heather Summers

HEATHER A. SUMMERS, C.S.R. No. 92-0246

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CERTIFIED COPY

ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
)
Plaintiffs,)
)
vs.)
)
MECTA CORPORATION, and DOES)
1-20,)
)
Defendants.)

Case No. 01-10362 RSWL(RZx)

VIDEOTAPED DEPOSITION OF ROBIN NICOL

AND

30(b)(6) EXAMINATION OF MECTA CORPORATION

VOLUME II

PORTLAND, OREGON

NOVEMBER 19, 2004

ATKINSON-BAKER, INC.
CERTIFIED COURT REPORTERS
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REPORTED BY: HEATHER A. SUMMERS, CSR NO. 92-0246

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

- - -

ATZE AKKERMAN and)
ELIZABETH AKKERMAN; each)
suing individually and on)
behalf of the general public,)
Plaintiffs,)
vs.)
MECTA CORPORATION, and DOES)
1-20,)
Defendants.)

Case No. 01-10362 RSWL(RZx)

Deposition of ROBIN NICOL and 30(b)(6) Examination of
MECTA Corporation taken on behalf of the Plaintiffs, at Allen
Sheridan & McClanahan, 190 S.W. Harrison Street, Portland,
Oregon, commencing at 9:13 a.m. on Friday, November 19, 2004,
before Heather A. Summers, CSR No. 92-0246.

A P P E A R A N C E S

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11 ALSO PRESENT: Gorham Nicol
Jay Webster, videographer
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1 A. As I'm not a medical doctor --

2 Q. I'm asking you what you're referring to. Are you
3 referring to any other cognitive -- severe cognitive side
4 effects arising out of ECT other than memory loss and
5 confusion?

6 A. No.

7 Q. Are you aware of any other cognitive deficits
8 caused by ECT beyond memory loss and confusion?

9 A. No.

10 Q. If you're aware of potential serious cognitive
11 side effects caused by ECT, why didn't you endeavor to make
12 sure that every single patient who received ECT from one of
13 your machines was warned of its potential harms?

14 MR. OWENS: Asked and answered.

15 THE WITNESS: We warn regarding potential side
16 effects and memory impairment in our instruction manuals that
17 we provide. We also warn in our videotapes. The clinician
18 who counsels the patient prior to ECT uses these materials,
19 this instruction manual and our videotape, to counsel the
20 patient. In addition, that could mean making copies of those
21 sections, verbally working, teaching, counseling his patient.
22 In addition he has the opportunity to purchase the patients
23 and family materials from the University of Michigan or
24 Dartmouth and send them home.

25 Q. (By Mr. Moxon) I take it from your answer then

1 that you don't endeavor to provide it to the patient because
2 you rely entirely upon the physician or hospital to provide
3 any warning information to the patient; is that right?

4 A. That is because our device is sold, and we are
5 under the auspices of the FDA, and we cannot counsel the
6 patient or treat the patient.

7 Q. Is your answer yes?

8 A. My answer is yes.

9 Q. Now, you have mentioned this FDA again. Is there
10 some FDA regulation that prohibits you from providing
11 warnings, written warnings to patients?

12 A. We don't directly treat. The warnings are very
13 specific in the Federal Register regarding that. We are
14 medical-device manufacturers.

15 Q. Let me give you that question again. Is there
16 some FDA regulation that prohibits you from providing written
17 warnings to patients?

18 A. I would have to look at the Federal Register
19 again to determine if there is a prohibition.

20 Q. You're not aware of any, are you?

21 MR. OWENS: That is not what she said. That
22 misstates the testimony.

23 THE WITNESS: I would have to look at it. It is a
24 very extensive section.

25 Q. (By Mr. Moxon) You have been the president of

1 this company for 25 years. I'm asking you your personal
2 knowledge.

3 A. Right.

4 Q. Are you aware, without telling me if there is a
5 number -- I'm not asking you for a number. I'm asking if you
6 are aware of some federal regulation that prohibits you from
7 providing written warnings to patients?

8 A. I think it would be more likely in the domain of
9 the AMA and The American Psychiatric Association that -- where
10 the warnings may be. Psychiatrists would in their medical
11 practices treat their patients and want to provide that
12 material to their patients. That would be where the warnings
13 would be, in the domain of the medical community.

14 Q. Ms. Nicol, are you aware of any FDA regulation
15 that prohibits you from providing written warnings to
16 patients?

17 A. I believe I said I would have to review the
18 Federal Register again to determine if there is a warning.

19 Q. So the answer is no?

20 A. The answer is I'd have to review it. I can't
21 answer yes or no.

22 Q. Because you don't know?

23 A. I don't have it memorized. It is a very large
24 portion of the Federal Register.

25 Q. Let me ask you this question. Are you as you sit

1 here now, after having been the president of MECTA for 25
2 years, aware of any federal regulation which prohibits MECTA
3 from providing written warnings to patients?

4 MR. OWENS: Okay. Rick, this is the third, perhaps
5 fourth time you have asked this same question.

6 MR. MOXON: I agree. I have yet to receive an
7 answer.

8 MR. OWENS: She's told you she understands the FDA
9 prohibits it.

10 MR. MOXON: No, she didn't.

11 Q. (By Mr. Moxon) Are you adopting Mr. Owens'
12 testimony; you believe the FDA prohibits you? That's exactly
13 what I'm asking you. Is it your understanding that the FDA
14 prohibits you from providing warnings to patients?

15 A. Yes, it is. I just haven't been able to resource
16 that section --

17 Q. Okay.

18 A. -- in this.

19 Q. But you have read it in the past? You have read
20 somewhere where the FDA says you MECTA or you device
21 manufacturer, you're prohibited from providing written
22 warnings to patients?

23 A. Again, the answer is yes with the caveat that I
24 would need to resource that material.

25 Q. How long have you held that view, that the FDA

1 prohibited you from providing written warnings to patients?

2 MR. OWENS: Rick, this is so fundamental. Why are
3 you spending 30 minutes on it? MECTA can't practice medicine.
4 They can't contact patients.

5 MR. MOXON: Joe, please. This is completely --

6 MR. OWENS: This is a matter of law.

7 MR. MOXON: This is an improper objection. Now
8 you're just going to spin her off and she just repeats your
9 objections.

10 MR. OWENS: No. She has already said that, Rick.

11 Q. (By Mr. Moxon) I'm trying to get an answer to
12 the question. How long have you held the view that the FDA
13 prohibits you from providing written warnings to patients?

14 A. Since 1980 when we purchased the company.

15 Q. Is memory loss a side effect or direct effect of
16 ECT?

17 A. It's a side effect.

18 Q. What makes it a side effect?

19 A. It's an effect from the therapeutic effect of the
20 treatment. After the therapy is finished, completed there are
21 side effects. And it is the only side effect.

22 Q. How about brain damage?

23 A. Brain damage is not an effect from ECT. ECT does
24 not cause brain damage.

25 Q. It's your view that the articles that were

1 written in the 1940s and '50s and '60s indicating the ECT
2 causes brain damage were written by fringe psychiatrists?

3 A. It's my view that it is a small, very small
4 community of psychiatrists that are fringe.

5 Q. And the ones that wrote about brain damage in the
6 '40s and '50s were part of the fringe community also?

7 A. I would have to see those articles in the '40s
8 and '50s. I don't know what articles you're referring to.

9 Q. So you don't know whether or not those articles
10 were written by fringe psychiatrists or not?

11 A. That's correct.

12 MR. OWENS: She doesn't even know the articles were
13 written, Rick, other than your statement to her. You haven't
14 shown her the articles. The question lacks foundation.

15 MR. MOXON: She has answered it.

16 MR. OWENS: Well, yes, she has answered it, but the
17 judge still gets to rule on the question.

18 Q. (By Mr. Moxon) If you look at page 316 of the
19 instruction manual in front of you, M 00316, which is page 31
20 of the manual. The second paragraph, could you please read
21 that to yourself?

22 The bottom sentence -- actually, I will read the
23 whole thing. "In selecting a stimulus intensity some facts
24 should be kept in mind. The available evidence indicates that
25 a stimulus intensity that is barely above the seizure

1 necessary to cause a seizure or slightly above a seizure, it
2 could cause more serious cognitive deficits?

3 MR. OWENS: Well, it's now all those objections, plus
4 it's argumentative.

5 Q. (By Mr. Moxon) Answer?

6 A. 100 joules is a very responsible and low maximum
7 energy. The FDA has approved it.

8 Q. That is not responsive. Was it your intention
9 that the machine not necessarily be cranked up all the way
10 with each patient in order to lessen the cognitive deficits
11 that would be caused by too much electricity?

12 MR. OWENS: Same objections.

13 THE WITNESS: As I mentioned earlier, these are
14 parameter sets that will be selected by the clinician. It is
15 in their domain and their determination as to the energy that
16 they choose with each patient and what parameter selections
17 they choose. They would be the appropriate trained personnel
18 to determine what the cognitive effects are of their decision.

19 Q. (By Mr. Moxon) Did you understand my question?

20 A. Yes, I did.

21 MR. MOXON: Could you read the question back to the
22 witness?

23 Q. (By Mr. Moxon) Since you have understood it,
24 could you please answer it?

25 MR. OWENS: You have answered the question. It has

1 been asked and answered. Ask the next question.

2 MR. MOXON: Please read the question back to the
3 witness.

4 MR. OWENS: She has answered the question.

5 (The record was read as follows:

6 Q. Was it your intention that the machine
7 not necessarily be cranked up all the way
8 with each patient in order to lessen the
9 cognitive deficits that would be caused by
10 too much electricity?)

11 MR. OWENS: She has answered the question. Next
12 question.

13 MR. MOXON: She has not. She told me about what --
14 some clinicians make the decision. That had nothing to do
15 with my question. My question sought the intention of the
16 company, not what she thinks clinicians think. Can you please
17 repeat the question back to the witness. I would like a
18 direct answer, please.

19 MR. OWENS: This is the last time.

20 MR. MOXON: I hope.

21 (The record was read as follow:

22 Q. Was it your intention that the machine
23 not necessarily be cranked up all the way
24 with each patient in order to lessen the
25 cognitive deficits that would be caused by

1 too much electricity?)

2 MR. OWENS: It has been asked and answered.

3 Q. (By Mr. Moxon) Answer, please.

4 A. The clinician has to make that determination.

5 The FDA has designed the devices to be safe and effective with
6 the 100-joule limit. They make that decision. I cannot
7 evaluate nor can I dispense medicine as a medical-device
8 manufacturer.

9 Q. That is completely unresponsive. My question --

10 MR. OWENS: It is not going to be asked again, Rick.
11 If you have a problem, take it to the judge.

12 MR. MOXON: Read back the question to the witness.

13 MR. OWENS: No.

14 MR. MOXON: Please listen very carefully to the
15 question. If you're going to instruct her not to answer, I
16 will read it back one more time.

17 MR. OWENS: Well, if you want to use your seven hours
18 having the court reporter read back questions three or four or
19 five times, that's your prerogative.

20 MR. MOXON: She's not answering the question.

21 MR. OWENS: We are getting very close to that seven
22 hour time period.

23 MR. MOXON: Please read the question back to the
24 witness.

25 MR. OWENS: You can go ahead, but she's not going to

1 answer it again, Rick. I'm instructing her not to answer.

2 Q. (By Mr. Moxon) Ms. Nicol, you understand that
3 I'm asking what your intention was. And I don't care what the
4 FDA said. I don't care what you think a clinician thinks. I
5 don't care whose responsibility it is. I'm asking for the
6 intention of you and your company, nothing else with this
7 question.

8 MR. MOXON: Please read the question back to the
9 witness.

10 MR. OWENS: Did you understand that in responding to
11 the question?

12 THE WITNESS: That it was the intention of the
13 company?

14 MR. OWENS: He is asking you about the intention of
15 the company. When you responded to the question, were you
16 responding to that?

17 THE WITNESS: No, I was not.

18 MR. MOXON: Please read the question back to the
19 witness.

20 THE WITNESS: Joe, can we take a break?

21 MR. OWENS: We can.

22 (Recess taken at 10:20 a.m. to 10:37 a.m.)

23 Q. (By Mr. Moxon) Could you read back the
24 question, please.

25 (The record was read as follows:

1 Q. Was it your intention that the machine
2 not necessarily be cranked up all the way
3 with each patient in order to lessen the
4 cognitive deficits that would be caused by
5 too much electricity?)

6 THE WITNESS: As I would repeat again, it is not
7 in -- MECTA Corporation cannot make decisions for the
8 clinician. The clinician will make the decisions regarding
9 his or her choices of stimulus parameters and access the
10 cognitive effects. We are not licensed medical practitioners.

11 Q. (By Mr. Moxon) So you're still not answering
12 my question, but let me try to phrase it this way -- and I
13 will seek to move to compel an answer. After seven times I
14 give up.

15 Do you have any intention whatsoever -- do you
16 care, not to be pejorative, but do you care whether or not
17 practitioners use the full amount of electricity in their
18 machine with every patient?

19 A. We provide a range of parameters for the
20 clinician. It is -- all ranges are applicable and appropriate
21 determinations, and those determinations will be made by the
22 clinicians. So we provide them, they're appropriate, their
23 use can be determined by the clinical population or the
24 medical doctors.

25 Q. So basically it's not your concern whether or not

1 the physician uses more electricity than is necessary?

2 MR. OWENS: It is argumentative.

3 THE WITNESS: These are safe and effective limits
4 from one to 100 joules. They have been determined safe and
5 effective by the FDA for the last 25 years for four
6 generations of devices.

7 Q. (By Mr. Moxon) Ms. Nicol, I didn't ask you that.

8 A. So we feel very comfortable --

9 Q. I understand you have positions and you're fully
10 capable of articulating your view on things --

11 A. Right.

12 Q. -- but the only reason I'm here is to ask you the
13 questions I need answered.

14 A. Right.

15 Q. Is it of no concern to you what amount of
16 electricity the clinicians use with their patients?

17 MR. OWENS: It is asked and answered. It is
18 argumentative.

19 THE WITNESS: It is a concern, and we are -- we
20 provide our clinicians with these parameters because they are
21 appropriate parameters.

22 Q. (By Mr. Moxon) Why is it a concern? Is it
23 because if too much electricity is used or more electricity
24 than is necessary the patient can be harmed?

25 A. It is a concern that we have addressed by

1 submitting our devices to be tested and approved by the FDA,
2 and that concern was answered by their approvals.

3 Q. I didn't ask you anything about the FDA. I asked
4 you absolutely nothing about the FDA.

5 MR. OWENS: Rick, you really have to --

6 MR. MOXON: Please read the question back?

7 MR. OWENS: Rick, you have to cut back on the
8 argument.

9 MR. MOXON: You took her out to instruct her, I
10 thought, to answer the questions, but she's still refusing to
11 answer them.

12 MR. OWENS: Rick, don't argue with me; don't argue
13 with the witness. It's not getting us anywhere. It is not
14 appropriate to make statements like that on the record.

15 MR. MOXON: I will just keep repeating the question
16 until I get an answer. Please read the question back?

17 MR. OWENS: Well, you're not going to do that. She's
18 answering the question. You disagreed with the answer.
19 Badgering is not an appropriate approach. This is a fact
20 deposition. You are here to ask for factual information, not
21 for her to agree with your concepts and your statements.

22 MR. MOXON: That is exactly right. That is exactly
23 what we are here for. I'm here to get the intentions,
24 viewpoints, and facts of the company. I didn't ask her any
25 question about the FDA whatsoever. Completely unresponsive.

1 promote your product?

2 A. No.

3 Q. What was the purpose of sending the videos?

4 A. The purpose was to clinically teach. Much as the
5 instruction manual, to give our clinicians as much clinical
6 education as we can, and the basis for that would be to have
7 clinicians who understood the treatment, to teach the
8 treatment and to share that, either in videotape format or an
9 instruction format or in a textbook format.

10 Q. Did you want the clinicians to take the
11 representations as accurate?

12 A. Yes, I did. Yes, we did as a corporation.

13 Q. Yesterday we mentioned a lawsuit, Rohovit, a suit
14 in Iowa. Do you remember that?

15 A. Yes, I do.

16 Q. Is there any other litigation that has been filed
17 against MECTA other than the Rohovit suit and the instant
18 suit?

19 A. Yes.

20 Q. Tell me what that is.

21 A. I could give you the names of the plaintiffs. I
22 can't give you the dates exactly.

23 MR. OWENS: That is fine. Just give him the names.

24 THE WITNESS: I think you mentioned one yesterday,
25 which was Andre.

1 Q. (By Mr. Moxon) Linda Andre?

2 A. I believe you mentioned that yesterday. And, of
3 course, I mentioned Rohovit. And Torres.

4 Q. Spell it.

5 A. T-O-R-R-E-S. And Adam Chick, A-D-A-M, C-H-I-C-K.
6 And Tuch, T-U-C-H. And of course this.

7 Q. When was the Torres suit filed?

8 A. I can't tell you. I really would have to go back
9 and look. I don't have them memorized.

10 Q. Approximately.

11 A. Sometime in the '90s.

12 Q. Where was it filed?

13 A. I can't tell you that either.

14 Q. Do you have any papers at all --

15 MR. OWENS: We have produced that to you.

16 Q. (By Mr. Moxon) -- relating to that suit?

17 MR. OWENS: It has been produced.

18 Q. (By Mr. Moxon) Do you have any papers relating
19 to that suit?

20 MR. OWENS: It has been produced.

21 Q. (By Mr. Moxon) So I guess the answer is yes?

22 A. Yes.

23 MR. MOXON: Do you have a Bates number for it?

24 MR. OWENS: I can get it. Do you want me to?

25 Q. (By Mr. Moxon) What records do you have

1 concerning the Torres suit?

2 A. Very few records. Most of the records are in the
3 possession of my attorney.

4 Q. Who is that?

5 A. Bill Sheridan.

6 Q. What was that suit about?

7 A. I believe the claim was brain damage. Again, I
8 would have to look at the complaint.

9 Q. So it was filed up here in Oregon?

10 A. I can't tell you where it was filed. I can't
11 remember them. I haven't memorized them prior to this
12 deposition. I'm sorry.

13 Q. What happened to the case?

14 A. It was -- it did not go to trial. I think for
15 some -- there were reasons that it was settled. It -- there
16 was a legal issue. I'm not sure what the legal issue was.
17 I'm not an attorney.

18 Q. You settled the case?

19 A. No, we did not settle the case.

20 Q. Was it dismissed?

21 A. It was dismissed.

22 Q. Did you settle the Rohovit case?

23 A. Yes, we did.

24 Q. What was the amount of the settlement?

25 MR. OWENS: Well, I don't know whether that

1 settlement -- I haven't seen the agreement, and I don't know
2 whether it is confidential.

3 THE WITNESS: I think it is.

4 MR. OWENS: Do you know whether it is confidential?

5 THE WITNESS: I don't know, and I think we need to
6 know.

7 MR. OWENS: We don't know whether it is confidential,
8 Rick.

9 MR. MOXON: Okay. Well --

10 MR. OWENS: I'm not going to have her testify and
11 violate --

12 MR. MOXON: Are you instructing her not to answer?

13 MR. OWENS: -- violate the terms of an agreement
14 without knowing if it is confidential or not. Do you have any
15 information on that? Do you have a document, perhaps copy of
16 the settlement agreement?

17 MR. MOXON: I haven't seen it.

18 MR. OWENS: Well, she can't answer that question
19 without knowing more.

20 MR. MOXON: Are you instructing her not to answer?

21 MR. OWENS: Yes, without any proof by you that it is
22 not confidential.

23 Q. (By Mr. Moxon) When was the Adam Chick case
24 filed?

25 A. It also was in the '90s, I believe.

1 Q. Where was it?

2 A. Again, I can't tell you the location.

3 Q. Was it in Oregon?

4 A. No, I'm sure it wasn't, but I can't tell you
5 where it was, again.

6 Q. What was the nature of the suit?

7 A. I believe it was brain damage also.

8 Q. What happened to the suit?

9 A. It was dismissed.

10 Q. Was it settled?

11 A. No.

12 Q. And you identified -- do you have any documents
13 concerning the Adam Chick case?

14 A. I think they were produced.

15 Q. So you gave them to your attorney?

16 A. Yes, I did.

17 MR. MOXON: I haven't seen those, Mr. Owens.

18 THE WITNESS: I think --

19 MR. OWENS: There is no question. Okay?

20 Q. (By Mr. Moxon) What documents did you have
21 concerning the Adam Chick case?

22 A. I believe I produced those.

23 MR. OWENS: Well, the question is what documents do
24 you have relating to the Adam Chick case.

25 THE WITNESS: Again, my attorney would have those.

1 MR. OWENS: The question is not what your attorney
2 has, Robin.

3 THE WITNESS: Right.

4 MR. OWENS: The question is what documents do you
5 have?

6 THE WITNESS: I believe I produced everything that I
7 have.

8 Q. (By Mr. Moxon) What documents did you have?

9 A. I believe it was the complaint.

10 Q. Nothing else?

11 A. Nothing else.

12 Q. T-U-C-H?

13 A. Correct.

14 Q. Who was that?

15 A. That's the plaintiff, again. And I can't tell
16 you where that was filed. That was also in the 1990s.

17 MR. OWENS: You have answered the question.

18 Q. (By Mr. Moxon) What was the nature of the case?

19 A. What was the claim? I believe it was brain
20 damage. I would have to look at that again. I'm not sure. I
21 haven't looked at that.

22 Q. Is the case over?

23 A. It was dismissed.

24 Q. Not settled?

25 A. It was not settled.

1 Q. Who was your attorney on that case?

2 A. Bill Sheridan.

3 MR. OWENS: He represented MECTA in that case?

4 THE WITNESS: In each case --

5 MR. OWENS: No, no. The question is on Tuch.

6 THE WITNESS: Right. I can't tell you because the
7 insurance company would select an attorney to represent them.

8 MR. OWENS: Was that Bill Sheridan?

9 THE WITNESS: In each case the insurance company
10 would make that decision, and it would never be Bill Sheridan.
11 Bill Sheridan is our corporate attorney.

12 MR. OWENS: So Bill Sheridan did not represent the
13 company in the Tuch case?

14 THE WITNESS: That's correct. I misunderstood. That
15 is correct. Right.

16 Q. (By Mr. Moxon) Do you have any documents
17 concerning the Tuch case?

18 A. I don't, and I wasn't able to provide them to
19 Mr. Owens.

20 Q. Did you ask Mr. Sheridan to give you any of the
21 documents?

22 MR. OWENS: Hold on. It is attorney-client
23 privileged. Do you know whether Mr. Sheridan has any
24 documents regarding the Tuch case?

25 THE WITNESS: I don't. I don't know.

1 Q. (By Mr. Moxon) He represented you in that case
2 in some manner, correct, Ms. Nicol?

3 MR. OWENS: Well, that's vague.

4 Q. (By Mr. Moxon) Did Mr. Sheridan advise you with
5 respect to the Tuch case?

6 A. He is our corporate attorney. I would have to go
7 back and look at the records during that time, but I don't
8 have any records.

9 Q. Did Mr. Sheridan advise you with respect to the
10 Tuch case?

11 A. Our attorney at the time would have advised me --

12 Q. Who is that?

13 A. -- who the insurance company would have selected.
14 And since I don't have records, I can't tell you who that was.

15 Q. You don't know who the attorney was in the Tuch
16 case?

17 A. I do not.

18 Q. Have you made any effort to find out?

19 A. No, I haven't, because I don't have any records.

20 Q. Who was your insurance company?

21 MR. OWENS: Currently?

22 THE WITNESS: I'd have to look back.

23 MR. OWENS: Wait a minute.

24 Q. (By Mr. Moxon) Who was your insurance company in
25 the Tuch case that hired the attorney to represent you?

1 A. I don't have that memorized. I would have to go
2 look at that information.

3 Q. Have you changed insurance since the 1990s?

4 A. Yes, I have.

5 Q. So you do have records that would tell you who
6 the insurance company was?

7 A. That's correct.

8 MR. OWENS: In the 1990s?

9 THE WITNESS: In the 1990s.

10 Q. (By Mr. Moxon) Do you have records concerning
11 the case filed by Linda Andre against you?

12 A. I believe I produced -- well, I didn't produce
13 those. That's right. I think I have something.

14 MR. OWENS: The question, Robin, is not whether you
15 produced documents. The question is whether you have
16 documents with respect to the Linda Andre case.

17 THE WITNESS: I looked for a complaint and couldn't
18 find one.

19 Q. (By Mr. Moxon) Do you have any other documents?

20 A. I would have to look.

21 Q. You haven't looked yet?

22 A. I have looked and haven't found anything, but I
23 can look again because I do need to look further. I wasn't
24 able to locate a complaint.

25 Q. You have other places you can look?

1 A. I do.

2 Q. Do you have a copy of the complaint in the Torres
3 case?

4 MR. OWENS: We have produced it, Counsel, if that's
5 what you're curious about.

6 THE WITNESS: We have produced that, correct.

7 MR. MOXON: I may be wrong, Joe. I don't recall
8 seeing that, but I'm happy to be corrected.

9 MR. OWENS: We have produced it. If you go back to
10 your office and you don't find them, I am happy to provide
11 copies again.

12 MR. MOXON: Thank you.

13 Q. (By Mr. Moxon) Are there any arbitrations or
14 mediations that were filed with respect to alleged harm by
15 patients other than these suits that you have identified?

16 A. No.

17 Q. Have there been any claims which have been filed
18 against you or letters of complaint asking for compensation
19 which didn't go to litigation?

20 A. No.

21 Q. Was it your view that in each of the five cases,
22 the Andre case, Rohovit, Torres, Chick, and Tuch, that the
23 allegations of the complaints were false that the plaintiffs
24 received brain damage arising out of ECT from your machines?

25 MR. OWENS: Well, I'm going to object to the question

1 to the extent it assumes facts not in evidence. Go ahead.

2 You can answer.

3 THE WITNESS: Yes. My assumption was that the claim
4 was false as I don't accept the premise that ECT causes brain
5 damage.

6 Q. (By Mr. Moxon) That is your belief?

7 A. That's the belief of mainstream researchers of
8 ECT worldwide.

9 Q. Did you talk to any of these five people that
10 filed lawsuits against you to see why they felt that they had
11 been brain damaged by your machines?

12 A. No, I did not.

13 Q. Why not?

14 A. In most cases I was not available. I was not
15 even in the same state. They didn't go to trial. We had no
16 communication --

17 Q. Are you curious why --

18 A. In four of the six cases --

19 Q. Aren't you curious why at least six people now
20 have sued your company alleging serious harm and brain damage
21 arising out of your machines --

22 MR. OWENS: The question is argumentative. It is
23 vague and ambiguous. It is irrelevant.

24 Q. (By Mr. Moxon) Well, I didn't finish the
25 question. Aren't you curious as to why these people claim

1 they have been brain damaged by your machines enough to find
2 out what it is they're talking about?

3 MR. OWENS: It's argumentative.

4 THE WITNESS: Since it is not mainstream, not
5 accepted by the medical community, it is not a mainstream
6 philosophy, it's not proven in science by a very large
7 majority of the medical community, I would say that I'm not
8 curious because I would regard them as frivolous lawsuits.

9 Q. (By Mr. Moxon) You are a true believer?

10 MR. OWENS: Don't answer the question. It is
11 argumentative.

12 Q. (By Mr. Moxon) Do you have a philosophical
13 belief that ECT doesn't cause brain damage?

14 MR. OWENS: The question is vague and ambiguous.

15 THE WITNESS: No. I accept the research and the work
16 that is done by mainstream medicine in the United States and
17 around the world in all the major teaching hospitals and
18 leading university centers that ECT does not cause brain
19 damage.

20 Q. (By Mr. Moxon) So it's -- no point in arguing
21 with you or even commenting on it, I suppose. But it's your
22 position then that all the major universities all over the
23 world have found that ECT does not cause brain damage, flatly
24 does not?

25 MR. OWENS: Lacks foundation.

1 Q. (By Mr. Moxon) Correct?

2 A. I said mainstream community of researchers and
3 the majority, a very large majority.

4 Q. Have you seen any publication which flatly says
5 ECT does not cannot cause brain damage, any publication of any
6 type?

7 A. Yes, I have.

8 Q. Tell me what that is.

9 A. I'd have to go back, get you the reprints, the
10 articles.

11 Q. Tell me any one of the ones you claim that are
12 all over the world.

13 A. I don't have the articles memorized, but I can
14 provide them to you.

15 Q. Can you think of a single publication or author
16 who has flatly said unquestionably that ECT doesn't cause
17 brain damage?

18 A. Yes.

19 Q. Who?

20 A. But I can't give you the title of the article. I
21 can give you the author. Dr. Harold Sackeim is one.

22 Q. Okay.

23 A. I can get that information to Mr. Owens and he
24 can --

25 MR. OWENS: No. It is not your obligation to get

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7
8 UNITED STATES DISTRICT COURT
9 CENTRAL DISTRICT OF CALIFORNIA

10 ATZE AKKERMAN and
11 ELIZABETH AKKERMAN; each
12 suing individually and on behalf of
the general public,
13 Plaintiffs,
14 v.
15 MECTA CORPORATION, and
DOES 1-20.
16 Defendants.
17

Case No. 01-10362 RSWL(RZx)
**SECOND AMENDED COMPLAINT
FOR DAMAGES FOR PRODUCTS
LIABILITY; NEGLIGENCE; LOSS
OF CONSORTIUM; BREACH OF
WARRANTY, AND FOR
INJUNCTIVE RELIEF AND
RESTITUTION FOR CONSUMER
FRAUD AND FALSE AND
DECEPTIVE ADVERTISING
PURSUANT TO BUSINESS AND
PROFESSIONS CODE §§17200 &
17500 AND WEL.& INST. CODE**

JURY TRIAL DEMANDED

18
19
20 1. This is an action for damages against defendant MECTA Corporation
21 (“MECTA”), for grievous harm inflicted upon plaintiff Atze Akkerman, both to
22 his body and his mind, by electro-convulsive therapy (“ECT”), better known as
23 “shock treatment.” The shock treatment caused Mr. Akkerman to experience
24 substantial amnesia, including the loss of his knowledge and memories of his wife
25 and their 17-year marriage, knowledge and memories of his parents, loss of
26 knowledge and abilities including musical composition and most of his ability to

1 play music, loss of his job, and the loss of all memories of his teenage children and
2 their entire family life together. In short, his past memories of those things which
3 make life most important and skills he learned to make a living and survive, have
4 been taken from him, through fraud, lies and negligence; through the manufacture,
5 sale, distribution, and propagation by the defendants and their co-conspirators of a
6 device that is extremely dangerous to human beings. This action is brought by
7 plaintiffs individually for monetary damages, and also seeks to enjoin defendants
8 from defrauding and deceiving the public in violation of California Business and
9 Professions Codes Sections 17200 & 17500. As to the injunctive and declaratory
10 relief sought, the action is brought on behalf of the general public for false,
11 misleading and deceptive advertising and deceptive business practices relating to
12 the promotion, sale and use of electro-shock therapy devices; and equally false,
13 misleading and deceptive advertising which minimizes or ignores the permanent
14 injuries and often deadly results caused by "shock therapy."

15 **PARTIES**

16 2. Plaintiff Atze Akkerman is a resident of Ventura, California.

17 3. Plaintiff Elizabeth Akkerman is a resident of Camarillo, California.

18 4. MECTA Corporation is, on information and belief, an Oregon
19 corporation, engaged in the business of manufacturing and distributing shock
20 treatment devices in California. MECTA engages in advertising and sale of its
21 goods in Ventura County, and elsewhere within this federal judicial district.

22 **JURISDICTION AND VENUE**

23 5. This action was filed in Ventura County where plaintiffs live, however
24 was removed to federal court by defendant. Defendant MECTA advertises and
25 does business in this county, state and federal district.

26 //

1 knew his wife. He no longer recognized or knew his two teenage children. He no
2 longer knew or recognized his parents. His brother, who was a close companion
3 and best friend in his childhood years, is a stranger. Mr. Akkerman has essentially
4 no memory of past events with any of his family; they are all wiped out and
5 destroyed by the force of the shock treatment.

6 10. Mr. Akkerman was taken back to his home by persons he conceived
7 to be strangers, although in the case of his wife, she had lived with him and shared
8 his life for 17 years; and as to his children, they had shared their entire lives with
9 him. He has never recovered these memories. He has never recovered these
10 intimate relationships in the months following his shock treatment.

11 11. Mr. Akkerman was formerly engaged as a musician in the Navy,
12 playing keyboards and horns. He played French horn in a local philharmonic
13 orchestra. He played professionally for various events and performances on
14 keyboard, piano, synthesizer, and various horns and wind instruments. While over
15 the following months, Mr. Akkerman recovered parts of his once immense
16 abilities to play music, for the most part the ability and knowledge was lost and
17 destroyed by the shock treatment. He has disposed of most of his musical
18 equipment as it has become useless to him.

19 12. Prior to the shock treatment, Mr. Akkerman was employed in a
20 supervisory position with the Turning Point Foundation. After the shock
21 treatment, he was unable to remember what he did in his job, did not know how to
22 perform the duties of his job and no longer knew the people he formerly worked
23 with.

24 13. Although Mr. Akkerman had no recollection of the conversation
25 with Dr. Johnson prior to his shock treatment, he was informed by his wife that
26 Dr. Johnson told them both that any memory temporarily reduced would quickly

1 return. When after nearly two months Mr. Akkerman's memory did not return as
2 promised, Mr. Akkerman contacted Dr. Johnson and sought from him a letter for
3 his employer as to the reason he was unable to perform his work. On February 28,
4 2000, Dr. Johnson represented in writing that Mr. Akkerman's memory, "will
5 improve completely soon." Relying upon both the original representations of Dr.
6 Johnson told to him by his wife, and the February 28, 2000 representations, Mr.
7 Akkerman reasonably believed that his memory would return. He patiently waited
8 for his memory to return in accordance with the representations made to him.

9 14. Over the following months, Mr. Akkerman's position with his job
10 became more and more untenable. Unable to remember what his work entailed,
11 unable to contribute, finally he was fired in February 2001 as incompetent to
12 handle a position he competently performed prior to the shock treatment.

13 15. Mr. Akkerman's prior loving and intimate relationship with his wife
14 was also destroyed by the shock treatment. While he was informed that Liz
15 Akkerman was his wife, and he attempted for months to learn what he was
16 supposed to do, feel and think as a husband, he has been unable to do so.
17 Eventually, Mr. Akkerman developed psychosomatic ailments in proximity to his
18 wife, becoming physically ill and even vomiting when he spent more than a short
19 time with her.

20 16. In May of 2000, Mr. Akkerman finally realized that if he had not
21 regained his memory as of then, over a year after his shock treatments, that he had
22 been lied to and defrauded and that his memory would not likely return. The brain
23 damage and injuries to Mr. Akkerman caused by the shock treatment exacerbated
24 his inability to recognize his injuries – as often occurs with victims of shock
25 treatment.

26 17. Mr. Akkerman has attempted to re-unite with his family and re-

1 establish what he was told was a formerly loving relationship. However, he has
2 been unable to establish a viable relationship and remains separated from them,
3 but for short visits.

4 18. Unable to work, Mr. Akkerman has been unemployed for nearly 3
5 years and lives in a recreational vehicle in his parents' backyard.

6 19. Mrs. Akkerman has lost the support, love, affection and consortium
7 she previously enjoyed with her husband, arising out of the damage caused to him
8 by the shock treatments.

9 20. Defendant MECTA knew when it sold the ECT machine to Santa
10 Barbara Cottage Hospital and promoted the use of its machines in California and
11 elsewhere, that the history and literature regarding the use of ECT is littered with
12 stories of disabling injury, death, memory loss, extensive memory loss of long
13 duration, loss of substantial memory of events prior to ECT, loss of cognitive
14 abilities and loss of ability to experience normal emotional response to life and
15 relationships, a small part of which is addressed below.

16 **FACTUAL ALLEGATIONS REGARDING THE NATURE OF**
17 **SHOCK TREATMENT AND DEFENDANTS' FRAUD**

18 21. While the psychiatrist and hospital who inflicted shock treatment on
19 plaintiff Atze Akkerman, on information and belief, did so intentionally or with
20 gross negligence and with knowledge that he would be or would be expected to be
21 severely harmed, even the psychiatrists were not provided the full scope of the
22 harm expected to be caused by the machines to living subjects, which information
23 was fully known by MECTA. Practitioners of ECT, their patients, and the public
24 at large are also the subjects of fraudulent, misleading and deceptive advertising
25 and unfair and fraudulent business conduct by defendant MECTA Corporation,
26 which distributes false consumer information and misleading testimonial

1 information regarding the dangers and effects of shock treatment, which produces
2 an inherently dangerous machine for the purpose of causing brain damage and
3 memory loss. Ignoring the official patient surveys of the states which conduct
4 such surveys – including California – defendant publicly promotes that shock
5 treatment does not cause brain damage, and falsely promotes that shock treatment
6 causes little or no long term memory loss. In fact, shock treatment “works” by
7 damaging the brain, and permanent memory loss is experienced by virtually all
8 victims of this activity.

9 22. Shock treatment was developed in the early part of this century in
10 European slaughterhouses for the purpose of incapacitating animals without
11 killing them, so that their throats could be slit and the animals more easily bled
12 while alive. Personally observing such treatment, Italian psychiatrist Dr. Ugo
13 Cerletti experimented with the practice. Cerletti and his staff bribed authorities to
14 provide stray dogs that were experimented on with shock devices and many, in the
15 process, died. Cerletti persevered however, experimenting until he found an
16 appropriate voltage and duration of shock which did not kill many of the animals.
17 Cerletti decided to try the same practice on humans, for reasons that defy rational
18 explanation. The first human victim was a derelict found in the streets of Rome.
19 Cerletti shocked the “patient” and found that since he was not killed by the
20 treatment, and was substantially quieter than he had been before meeting Cerletti
21 and his staff, that the treatment was “effective” in relieving mental illness.

22 23. The most commonly manifested “side effect” of shock treatment was
23 that of broken bones, particularly of the spine. The patient would be strapped to a
24 table, with a rubber mouthpiece inserted to prevent the patient from biting off his
25 tongue or breaking teeth when his teeth involuntarily clenched during the
26 treatment. Electrodes would be placed on the temple of the patient, and varying

1 amounts and various durations of electricity would be forced through the brain
2 from temple to temple, causing immediate and violent convulsions, typically
3 resulting in compression fractures of the spine, broken teeth and dislocated joints.
4 Eventually, the dramatic and damaging results of shock treatment caused its
5 practitioners to apply muscle “relaxants” which made muscle contractions
6 impossible. While substantially lessening the number of bone fractures, such
7 medication, however, did not save the brain.

8 24. Early proponents of electro-shock therapy acknowledged as obvious,
9 what the current purveyors of this practice today hide: that a “change” in the
10 patient is brought about by damage to the brain and loss of memory. Such
11 concession was prevalent in the 1940s, as published by psychiatrist Walter
12 Freeman, M.D., in discussing “brain damage and the ‘therapeutic’ benefit resulting
13 from various psychiatric procedures, including ... shock therapy...” Freeman
14 admitted that the *intention* of these practices was to cause brain damage:

15 The apparent paradox develops, however, that the greater the damage,
16 the more likely the remission of psychotic symptoms ... It has been
17 said that if we don't think correctly, it is because we haven't 'brains
18 enough.' Maybe it will be shown that a mentally ill patient can think
19 more clearly and more constructively with less brain in actual
20 operation.

21 25. Medical reports and journals during the 1940s frequently repeated the
22 known physical damages caused by shock treatment, including “profound changes
23 in general circulation,” “coronary complications,” heart attacks, deaths, coma,
24 lung abscesses, and “Reversible or irreversible central nervous system changes
25 [which] must accompany the amnesia characteristic of the usual shock-induced
26 organic syndrome.” Such a result was acknowledged through the 1940's and
1950's as the source of the “effectiveness” of the treatment. As noted in one study
on “experimental neurosis,” caused by giving shock treatment to animals, “All in

1 all, these experiments support the growing conviction among psychiatrists that
2 electroshock and other drastic procedures, though possibly useful in certain
3 relatively recent and acute psychoses, produce cerebral damage which charges the
4 indiscriminate use of such 'therapies' with potential tragedy."

5 26. These "tragedies" were the intended result of this practice, as
6 reported by leading shock doctors in 1948 who reported the "treatment" of a
7 number of patients to reduce them to a state where they acted like small children
8 because they had shown no improvement from other psychiatric procedures:

9 We started by inducing two to four grand mal convulsions daily until
10 the desired degree of regression was reached. After about 10 days to
11 two weeks without treatment, regressed patients returned to their
12 previous levels, but usually without their symptoms. A number of
13 these patients were well enough to go home and carry on as they had
14 before the psychosis developed. We considered a patient had
15 regressed sufficiently when he wet and soiled, or acted and talked like
16 a child of four . . . Sometimes the confusion passes rapidly and
17 patients act as if they had awakened from dreaming; their minds seem
18 like clean slates upon which we can write. They are usually
19 cooperative and very suggestible, and thus amenable to
20 psychotherapy. . . This technique is a valuable asset to psychiatric
21 therapy, where less drastic measures have failed.

22 27. Damage to most patients was obvious, as during this period, a vast
23 number of victims of the treatment suffered compression fractures of the spine and
24 other broken bones. A publication from the National Institutes of Health
25 Consensus Development Conference Statement in 1985 placed the figure of spinal
26 fractures at approximately 20% of those receiving shock treatment. The NIH
27 Consensus report stated that some 40% of persons receiving ECT suffered what
28 has been referred to as "complications" from the treatment, which it noted "the
29 most common being vertebral compression fractures."

30 28. A psychiatrist who publicly argued for the effectiveness of
31 electroshock treatment claimed: "Improvement in effective disorders, follows the
32 induction of transient mental confusion which appears after treatment ... This

1 Severity of the deficit is related to the number of treatments, type of
2 electrode placement, and nature of the electric stimulus. ... research
3 conducted as long as three years after treatment has found that many
4 patients report that their memory was not as good as it was prior to
5 the treatment.

6 31. Psychiatrists and hospitals are able to make a great deal of money
7 through the application of ECT. The purchase of a shock machine from MECTA
8 or one its rivals for approximately \$25,000 permits the application of more than a
9 dozen treatments per day billed at over \$1,000 each – often paid by the state and
10 federal health care or by insurance.

11 32. In the face of the historical evidence of the grave danger of ECT,
12 manufacturers of shock machines such as MECTA Corporation utilized false,
13 misleading and deceptive advertising to sell this dangerous product.

14 **DISTRIBUTION OF FALSE, MISLEADING AND DECEPTIVE**
15 **STATEMENTS BY DEFENDANTS REGARDING CLAIMS OF**
16 **KNOWLEDGE AS TO THE CAUSE OF MENTAL ILLNESS**
17 **AND CURATIVE EFFECTS OF SHOCK TREATMENT**

18 33. Statistics from California surveys by the California Department of
19 Mental Health indicate that over 95% of all ECT patients reporting adverse effects
20 at all, reported long term memory loss.

21 34. Plaintiff Atze Akkerman is an example of the sort of memory loss
22 damage that can be caused by shock treatment. Mr. Akkerman has no memory of
23 the assertions made to him to induce him to consent to ECT, however, the
24 minimalistic information provided to him in writing by Dr. Johnson and the Santa
25 Barbara Cottage Hospital could not remotely provide him with consent which
26 could be considered “informed” consent, as required under California law.
27 However, plaintiff Elizabeth Akkerman was present during the discussion of the
28 effects of ECT, and knows that Mr. Akkerman was told only that he would
29 experience *temporary* memory loss, and even then, primarily of alleged depressive

1 thoughts. The entirety of the worthwhile events of Mr. Akkerman's past, his
2 childhood memories, his loving relationship with his wife of 17 years, the entirety
3 of the birth, growth and nurturing of his own children, is lost to him. His former
4 love of music is gone. His life with his parents and brother is lost and forgotten,
5 forced from his memory by a dangerous electric shock.

6 35. As MECTA knows, ECT does not "work" at all – it simply causes
7 brain damage, loss of memory and loss of will to live. Some patients would not
8 complain regarding a lack of efficacy, for fear of more "treatments" and greater
9 damage. Thus, the advertising and claims regarding how ECT "works" are
10 deceptive, manipulative and fraudulent.

11 36. MECTA disseminates a pamphlet to the public and to health care
12 providers in California and elsewhere, entitled, "Electroconvulsive Therapy
13 (ECT), The Treatment, the questions and the answers," regarding the efficacy and
14 safety of shock treatment. Numerous false statements and deceptive statements
15 are made in the pamphlet, intended to encourage doctors to give patients ECT, to
16 refer patients to practitioners who give ECT, and to convince individuals that ECT
17 is safe and effective. Among the false and deceptive statements in the pamphlet
18 are the following:

- 19 • "Many people have heard that ECT can be uncomfortable or damaging, and
20 they react with fear when it is suggested as a treatment. However, the way
21 ECT is administered has greatly improved. ECT, as performed today, is a
22 safe and effective treatment for severe depression.
- 23 • "During ECT, a small amount of electrical current is sent to the brain. This
24 current produces a seizure which affects the entire brain, including centers
25 which control thinking, mood, appetite, and sleep. Repeated treatments
26 normalize the messengers in these centers. Consequently, patients return to

1 a higher level of functioning and begin to recover from their illness.

- 2 • “We know that ECT works – over 80 percent of depressed patients who
3 receive it respond favorably, making ECT the most affective treatment for
4 severe depression. People who have responded to ECT report it made them
5 feel “like themselves again” and as if “life was worth living again.”
- 6 • “ECT is a very safe procedure. The rates of significant injury or mortality
7 with ECT are very low even though ECT is very commonly performed on
8 elderly patients ...”
- 9 • “When people are seriously depressed they have a difficult time
10 concentrating and learning new material. When patients recover with ECT,
11 there is often marked improvement in concentration and many other aspects
12 of thinking. However during and shortly following treatment with ECT,
13 patients will usually experience specific difficulties with memory. Many
14 patients experience problems in remembering some events from the recent
15 past. These memory problems typically subside within a few weeks
16 following the ECT course.”
- 17 • “Regardless of the form of ECT you receive, within a few weeks after
18 receipt of ECT, your ability to learn and remember new information should
19 return to normal. Patients with bilateral ECT may occasionally complain
20 that their memory is not as sharp as before the ECT treatments. The only
21 lasting effect you may experience is a gap in memory for events that
22 occurred in the weeks surrounding the ECT treatment. Some of this loss is
23 likely due to the ECT treatment, and some of it is likely due to the
24 difficulties in learning that arise when people are depressed.”

25 37. The pamphlet distributed by MECTA makes no mention of memory
26 loss under the sections “Are there any risks involved with ECT” or the section,

1 “Side effects and what to do about them.” Brain damage is not mentioned
2 anywhere in the pamphlet. Although MECTA is aware of the vast dangers of
3 ECT, and although it had the opportunity to provide adequate warnings of the
4 danger of shock treatment and MECTA’s product through such pamphlet, it failed
5 to do so, and intentionally not done so – choosing to leave consumers of this
6 “product” in ignorance of the true nature of the dangers thereof. Worse, through
7 the pamphlet MECTA has chosen to distribute, it has grossly misrepresented the
8 known dangers of the machine it manufacturers and sells, such as misrepresenting
9 that patients will experience an enhanced ability to think, when in fact virtually all
10 persons who receive ECT are impaired in their thinking and their memory. The
11 assertion, “The only lasting effect you may experience is a gap in memory for
12 events that occurred in the weeks surrounding the ECT treatment,” is also false,
13 fraudulent and deceptive, as virtually all persons who receive ECT experience
14 permanent memory loss for substantial amounts of memory and abilities they
15 possessed prior to the ECT. The assertion, “Many patients experience problems in
16 remembering some events from the recent past. These memory problems typically
17 subside within a few weeks following the ECT course,” is also a knowingly false
18 and deceptive statement, as MECTA knows that while some patients certainly
19 recover a large amount of their lost memory in few weeks, nearly all persons
20 receiving ECT experience massive and long lasting memory loss for years and for
21 the rest of their lives. The statement, “Some of this loss is likely due to the ECT
22 treatment, and some of it is likely due to the difficulties in learning that arise when
23 people are depressed” is also quite deceptive, by diverting the cause of the
24 memory loss to the alleged depression, and using this as a ready justification for
25 the nearly universal memory loss experienced by patients.

26

1 **FIRST CAUSE OF ACTION**

2 (Products Liability - Strict Liability)

3 38. Plaintiffs hereby incorporate by reference as though fully set forth
4 herein, paragraphs 1 to 37, above.

5 39. The Electro-Convulsive Therapy device manufactured and sold by
6 MECTA was known by MECTA to be extremely dangerous, causing memory loss
7 and brain damage to patients against whom it was used. On information and
8 belief, MECTA has known for as long as it has manufactured machines about the
9 dangers of its machines to cause brain convulsions in humans. MECTA knows
10 that the basis for the machines' effect in seeming to temporarily "relieve" some
11 mental conditions is by causing brain damage and by causing memory to be
12 eradicated.

13 40. Defendant MECTA provided no warning to Mr. Akkerman or doctors
14 or hospitals purchasing or utilizing its machines that the alleged "benefits" of its
15 machines are the direct result and sole result of brain damage and loss of memory.
16 Defendant MECTA provided no warning to Mr. Akkerman or other patients who
17 were the recipients of electric shocks from its machines, or the practitioner who
18 might use the machines, that the alleged "benefits" of its machines are the direct
19 result and sole result of brain damage and loss of memory. Defendant MECTA
20 provided no warning to Mr. Akkerman or patients who were the recipients of
21 electric shocks from its machines, or the practitioners who might use the
22 machines, that most patients never recover major portions of their memories, and
23 all patients lose some portion of their memories after "treatment" with its
24 machines. MECTA provided no warning to the purchasers and users of the
25 machines, nor to the end user patients, including Mr. Akkerman, who would
26 receive shock treatment with the machines, that bilateral shock treatment would

1 substantially increase the memory loss and brain damage.

2 41. Defendant MECTA provided no warning to the doctors and hospitals
3 purchasing the machine, or to plaintiff Atze Akkerman, that the machine which
4 would be used on him would cause him brain damage and permanent memory loss.
5 The defects in the machines sold by MECTA were both design defects and
6 inadequate or entirely absent warnings regarding its product. Plaintiffs allege the
7 machine also has a manufacturing defect, in that its machines are made in a
8 manner which is likely to cause additional harm through faulty manufacture –
9 even beyond the intended harm of ECT machines. There is no benefit to
10 consumers that remotely outweighs the damages caused to consumers arising out
11 of use of the machines against them. The danger to Mr. Akkerman and to other
12 consumers by MECTA's product is unreasonable and unfair, and cannot be
13 justified by insulating the company and the consumer with doctors or hospitals
14 who are also not provided specific facts relating to the inherent danger of the
15 product.

16 42. MECTA knew that the machine it was placing on the market would be
17 used by doctors and hospitals on patients, without inspection for defect and
18 knowing that the machine was certain to cause brain damage and loss of memory.
19 Mr. and Mrs. Akkerman, reasonably believing the representations of Dr. Johnson
20 that shock treatments would help Mr. Akkerman, and that any minimal memory
21 loss would be quickly restored, were injured thereby. MECTA knew of the defect
22 in its machines as described herein: that its design ensures brain damage and harm
23 to recipients of the shock, causing memory loss and other cognitive disabilities.

24 43. After the series of shock treatments, plaintiff Atze Akkerman was
25 unable to function at his former place of work, no longer remembering how to do
26 his job, the persons in his place of work or any of the functions of his former

1 work. Although he sought reasonable accommodation at his work for the
2 disabilities he now possesses arising from the shock treatment, he was eventually
3 found to be unemployable as a result of the shock treatments and incapable of
4 functioning in any position at his former employment, and was thus terminated.

5 44. MECTA acted with fraud, oppression and malice for the reasons set
6 forth herein, and that it knew and intended that its product would both
7 temporarily and permanently harm patients, including Mr. Akkerman, but acted
8 with a conscious disregard of the rights and safety of others out of a pecuniary
9 motive to defraud and trick patients, doctors and hospitals in order to sell its
10 product. MECTA's conduct was despicable, subjecting Atze Akkerman (and
11 many other patients in this State) to cruel and unjust hardship in disregard of their
12 rights. Defendant, MECTA, is strictly liable for failing properly to prepare and/or
13 warn of the dangerous propensities of ECT. Defendant MECTA knew that electric
14 shock treatment was defective and that those who were prescribed and
15 administered ECT would experience, and did experience, severe physical, mental,
16 and emotional damages/injuries and yet, notwithstanding this knowledge,
17 MECTA, despicably, and in willful and conscious disregard of the safety of those
18 who were prescribed electric shock treatments and of the plaintiff herein, without
19 giving any notice of the defect to the purchasers of electric shock treatment, placed
20 and persisted in placing electronic shock treatment machines in the stream of
21 commerce. Plaintiffs are entitled to compensation in the amount of no less than
22 \$2,000,000 in compensatory damages and punitive damages in an amount to be
23 determined by the jury, under this cause of action.

24 **SECOND CAUSE OF ACTION**

25 (Negligence)

26 45. Plaintiffs hereby incorporate by reference as though fully set forth

1 herein, paragraphs 1 to 44, above.

2 46. Any reasonably prudent manufacturer of a device intended to be
3 applied to humans which directs a potentially lethal and dangerous electrical shock
4 through the brains of the patients to receive the treatment offered, would have
5 warned plaintiffs of the dangers inherent in the machine: that the machine would
6 cause brain damage; that the machine would cause some level of memory loss; and
7 the machine would cause amnesia for events prior to the application of the shock
8 treatment. The risks inherent in shock machines are known and knowable to
9 MECTA, but, by failing to provide reasonable warning either to the purchasers
10 and users of its machines (doctors and hospitals), or to the patients victimized by
11 its machines; and by minimizing the dangers, MECTA acted in a grossly negligent
12 fashion without regard to the health, safety or lives of persons who were likely to
13 be harmed by its machines.

14 47. Plaintiffs are entitled to compensation in the amount of no less than
15 \$2,000,000 in compensatory damages, and punitive damages in an amount to be
16 determined by the jury, under this cause of action.

17 **THIRD CAUSE OF ACTION**

18 (Breach of Warranty)

19 48. Plaintiffs hereby incorporate by reference as though fully set forth
20 herein, paragraphs 1 to 47, above.

21 49. Defendant MECTA, expressly and impliedly warranted to the
22 physicians and their health-care patients, including Mr. Akkerman, that electric
23 shock treatments was a treatment fit for the use for which it was intended and was
24 of merchantable quality despite the fact that the product was unfit and unsafe for
25 use by health-care patients in light of its known propensity to cause serious side-
26 effects, including, but not limited to physical, mental and emotional injuries to

1 her husband was permanently injured and that he would be lost to her. It was not
2 until after May of 2001 that Mrs. Akkerman realized or could have been
3 reasonably expected to know that she was injured, and could reasonably know the
4 cause and source of her injuries.

5 54. Plaintiff Liz Akkerman is entitled to compensation in the amount of
6 no less than \$2,000,000 in compensatory damages and punitive damages in an
7 amount to be determined by the jury, under this cause of action.

8 **FIFTH CAUSE OF ACTION**

9 (Violation of Business and Professions Code 17200)

10 55. Plaintiffs hereby incorporate by reference as though fully set forth
11 herein, paragraphs 1 to 56 above.

12 57. Plaintiffs are suing on their own behalf and on behalf of all members
13 of the
14 public who have received shock treatment over the past four years.

15 58. The acts and practices described above violate Business and
16 Professions Code 17200 in at least the following respects:

17 a) Defendant, by its conduct described above, engaged in false
18 advertising in violation of Cal. Business and Professions Code Section 17200,
19 which prohibits “any unlawful, unfair or fraudulent business act or practice and
20 unfair, deceptive, untrue or misleading advertising and any act prohibited by
21 Section 17500 of the California Business and Professions Code.”

22 b) Defendant sells and distributes booklets in California which
23 contain false and deceptive advertising regarding shock treatment, and instruction
24 manuals that contain false and deceptive information. It also distributes
25 information on its machines to psychiatrists and agents of hospitals and clinics.
26 MECTA realizes that shock treatment is very cheap to deliver and that

1 psychiatrists can charge a substantial fee for each shock delivered – up to \$2,000 –
2 making the practice financially attractive, notwithstanding the permanent harm
3 caused to patients receiving the treatment. MECTA capitalizes upon this financial
4 incentive by promoting to psychiatrists and hospitals the low cost of the shock
5 machine compared to the high income potential of the treatment.

6 c) The fraudulent, misleading and deceptive publications distributed
7 by MECTA are given or sold to doctors, hospitals, associations, and sold or given
8 to the public and other doctors and health care professionals.

9 d) Patients are caused the harms described above by these acts by
10 suffering physical and mental damages, including brain damage, loss of memory,
11 loss of livelihood, and loss of quality of life. Defendant's practices constitute an
12 unfair business act or practice within the meaning of Business and Professionals
13 Code section 17200.

14 e) The harm to plaintiffs and to members of the general public
15 outweighs the utility of this experimental and inherently dangerous practice upon
16 the brains of members of the public.

17 f) Defendant's practices and conduct has and is likely to continue to
18 mislead the general public and consequently constitutes a fraudulent business act
19 or practice within the meaning of Business and Professionals Code section 17200.

20 g) Defendant's acts of untrue, misleading and deceptive advertising
21 and promotion of the alleged benefits of shock treatment are, by definition,
22 violations of Business and Professionals Code section 17200.

23 59. The unlawful, unfair and fraudulent business practices and false and
24 misleading advertising of the defendants present a continuing threat to members of
25 the public in that members of the public are likely to believe defendants'
26 assertions and claims and thereby permit themselves to be subjected to shock

1 treatment without realizing the dangers and certainly the permanent damages
2 inherent in such treatment.

3 60. As a direct and proximate result of the aforementioned acts, defendant
4 MECTA received and continues to hold funds received from the sale of its shock
5 treatment machines, and funds from the sale of the pamphlets described above,
6 from doctors and hospitals who paid for the machines.

7 61. As a direct and proximate result of the aforementioned acts, MECTA
8 has received ill gotten gains. MECTA is an indirect recipient of funds provided by
9 Mr. Akkerman and other patients to doctors and hospitals and insurance
10 companies because of the false, misleading and deceptive statements by each of
11 the defendants respectively. In good conscience, defendant should make
12 restitution to the patients who have received ECT, to the state which has paid for
13 shock treatment through public welfare funds, and to insurance companies which
14 have paid for shock treatments.

15 62. Unless enjoined, defendant will continue to engage in the practices set
16 forth above in the future, as they continue in the present to disseminate the false,
17 misleading and deceptive advertising and fraudulent business practices described
18 herein.

19 63. Plaintiff prays for the relief set forth below.

20 **SIXTH CAUSE OF ACTION**

21 (Violation of Business and Professions Code Section 17500)

22 64. Plaintiffs hereby incorporate by reference as though fully set forth
23 herein, paragraphs 1 to 63 above.

24 65. Plaintiffs are suing on their own behalf and on behalf of all members
25 of the public who have received shock treatment over the past four years.

26 66. As set forth above, beginning at an exact date unknown to plaintiffs,

1 MECTA engaged in acts of false and misleading advertising as defined by
2 Business and Professions Code section 17500, with the intent to induce members
3 of the public to receive shock treatment, to their extreme and permanent detriment
4 and harm. As set forth above, beginning at an exact date unknown to plaintiffs,
5 MECTA has also engaged in acts of false and misleading advertising as defined by
6 Business and Professions Code section 17500, with the intent to induce health care
7 providers to administer shock treatment to patients in this State, to their extreme
8 and permanent detriment and harm. As set forth above, beginning at an exact date
9 unknown to plaintiffs, defendants have also engaged in acts of false and
10 misleading advertising as defined by Business and Professions Code section
11 17500, with the intent to induce insurance companies and state welfare agencies
12 administering health care assistance and funding, to pay for the administration of
13 shock treatment to patients in this State, to their extreme and permanent detriment
14 and harm.

15 67. The acts of untrue and misleading advertising by defendants
16 described above present a continuing threat to the safety, health and welfare of Mr.
17 Akkerman and to members of the public and a continuing threat to the financial
18 resources of insurance companies and state health care and welfare agencies.
19 Unless enjoined, MECTA will continue to engage in the practices set forth above
20 in the future, as they continue in the present to disseminate the false, misleading
21 and deceptive advertising and fraudulent business practices described herein.

22 Wherefore, plaintiff prays for relief as set forth hereinafter.

23 //
24 //
25 //
26 //

1 **PRAYER FOR RELIEF**

2 Wherefore, plaintiffs pray for judgment as follows:

3 1. For compensatory damages against MECTA Corporation in an amount
4 no less than \$10,000,000.

5 2. For punitive damages against MECTA Corporation in an amount to be
6 determined by the jury.

7 3. For injunctive relief to prohibit MECTA from engaging in false
8 advertising of the efficacy of ECT; engaging in false advertising by failing to
9 inform doctors and consumers that ECT causes brain damage, and that ECT causes
10 both temporary and permanent loss of memory in all or virtually all persons who
11 receive the treatment.

12 4. For equitable relief of requiring defendants to inform hospitals, doctors
13 and clinics utilizing ECT that the information provided to them regarding the
14 safety and efficacy of ECT was inaccurate, that ECT causes brain damage, and that
15 ECT causes permanent memory loss.

16 5. For equitable relief of requiring defendants to inform the known
17 victims of electro shock therapy that the information set forth in the pamphlet
18 distributed by MECTA is inaccurate.

19 6. For restitution by defendant to all shock treatment victims experiencing
20 brain damage and/or memory loss within the appropriate statutory period, state
21 agencies and insurance companies in California bearing the costs of shock
22 treatment. The expenses of determining the identity of all such victims to be borne
23 by defendants.

24 7. Costs and expenses of suit.

25 8. For reasonable attorneys' fees incurred in prosecuting this action as
26 provided by law.

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9. For such other relief as the Court may deem just and proper.

Dated: November 15, 2004

Respectfully submitted,

MOXON & KOBRIN

(S)

Kendrick L. Moxon
Ava M. Paquette

Attorneys for Plaintiffs
ATZE AKKERMAN and

ELIZABETH AKKERMAN

COPY

CAUSE NO. 96-15067

TERRI ADAMCHICK,
Plaintiff,

vs.

DR. DAVID G. JOSEPH, DR. JAMES
E. KREISLE, JR., DR. ROBERT
ZAPALAC, ST. DAVID'S HOSPITAL
and MECTA CORPORATION,
Defendant.

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IN THE DISTRICT COURT OF

TRAVIS COUNTY, TEXAS

201 JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE DISTRICT JUDGE:

NOW COMES, Terri Adamchick, Plaintiff herein, complaining of Defendants herein, and for cause of action, would respectfully show unto the Court and Jury the following:

I.
PARTIES

Plaintiff, Terri Adamchick is a resident of Round Rock, Williamson County, Texas.

Defendant, Dr. David G. Joseph is a resident of Austin, Travis County, Texas and may be served with process in this case in person at his residence address which is located at 4208 Farhills Drive, Austin, Texas 78731, or by sending a copy of the citation and petition by registered or certified mail, return receipt requested, WITH DELIVERY RESTRICTED TO THE ADDRESSEE ONLY pursuant to Tex. R. Civ. P. 106(a)(2).

Defendant, Dr. James E. Kreisle, Jr. is a resident of Austin, Travis County, Texas and may be served with process in this case in person at his business address which is located at 720 West 34th Street, Austin, Texas 78705, or by sending a copy of the citation

II.
VENUE

Venue of this case is proper in Travis County, Texas in accordance with Section 15.002 of the Texas Civil Practice and Remedies Code because the incident made the basis of this suit occurred in Austin, Travis County, Texas.

III.
FACTS

The evidence will show upon trial of this case that Plaintiff was caused to undergo Electroconvulsive Shock Therapy (ECT) prescribed for her by Defendant Physicians and administered by Defendant St. David's. The manufacturer of the machine involved in the shocking was Defendant MECTA Corporation. The evidence in this case will further show that Defendants did not perform a sufficient history and physical of Plaintiff to determine the appropriateness of this treatment for Plaintiff and, together with incorrect administration of this treatment and a defective product, Plaintiff was caused to incur damages and injuries as more particularly set out below.

IV.
CAUSE OF ACTION

As a direct and proximate result of the conduct of the Defendants, Plaintiff has sustained personal injuries and damages. Defendants are negligent, as that term is known and understood in the law, with such negligence constituting a proximate cause of the injuries and damages made the basis of this suit.

M 00828

V.
DAMAGES

As a result of the conduct of the Defendants, Plaintiff has suffered pain, anguish, memory loss, seizures, loss of income, medical expenses and other damages, general and special, such damages exceeding the minimum jurisdictional limits of this Court.

VI.
JURY DEMAND

Plaintiff makes application and demand for jury trial of this cause, and concurrently with the filing of this Petition tenders her jury fee.

WHEREFORE PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear herein and answer and that on final hearing, Plaintiff have judgment against Defendants for her damages, plus pre-judgment and post-judgment interest at the legal rate, for costs of suit, and for such other and further relief, both general and special, at law and in equity, to which Plaintiff may show herself justly entitled under the attending facts and circumstances.

Respectfully submitted,

TERRI ADAMCHICK
510 Quail Creek
Round Rock, Texas 78664
(512) 310-7844

By: 

TERRI ADAMCHICK
Pro Se

Dated: 12/13/96

M 00829

7.5.00 path

File

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

IMOGENE LORETTA ROHOVIT, an Individual;
JULIE LYNN ROHOVIT, an individual;
and LORI JANELLE ROHOVIT, an individual;

Plaintiffs,

vs.

MECTA CORPORATION, a corporation;
STATE OF IOWA;
EDWARD SATHOFF, M.D., an individual;
KEITH ROGERS, M.D., an individual;
BRUCE PFOHL, M.D., an individual;
D. W. BLACK, M.D., an individual;
MARK FULTON, M.D., an individual;
and J. LIESVELD, M.D., an individual;

Defendants.

LAW NO: CL 56175

PETITION AT LAW

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COME NOW the Plaintiffs, above named, and in support of all their causes of action against the above-named Defendants, state as follows:

JURISDICTIONAL FACTS

1. That Plaintiff, Imogene Loretta Rohovit, is an individual who at all material times hereto lived and continues to live in Iowa City, Johnson County, Iowa.
2. That Plaintiff, Julie Lynn Rohovit, is an individual who at all material times hereto also lived in Iowa City, Johnson County, Iowa. She is the natural daughter of Plaintiff, Imogene Loretta Rohovit.
3. That Plaintiff, Lori Janelle Rohovit, is an individual who at all material times hereto also lived in Iowa City, Johnson County, Iowa. She too is the natural daughter of Plaintiff, Imogene Loretta Rohovit.
4. Defendant, MECTA Corporation, is a duly organized Oregon corporation with its principal place of business located at 56 S.W. Kelly Street, Portland, Oregon. Defendant, MECTA Corporation, is the manufacturer of an electrical shock therapy machine, Model No. "D"; Serial No. 7039BB.

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Said machine was owned and used by the physicians within the Psychiatry Department at the University of Iowa Hospitals and Clinics in Iowa City, Iowa, during the calendar years 1987, 1988 and 1989.

5. Defendant, the State of Iowa, is a duly organized governmental entity. Suit against the State of Iowa is authorized under Chapter 25A of the *Iowa Code* and it is pursuant to said Chapter that this litigation is commenced. That the University of Iowa Hospitals and Clinics in Iowa City, Johnson County, Iowa, is a duly authorized agency of the Defendant, State of Iowa; it is by reason of the negligent acts or omissions of various employees, agents or representatives of said agency, including those specifically named as Defendants herein, that this action is commenced against Defendant, State of Iowa.

6. Jurisdiction for this suit against the State of Iowa is conferred upon this Court by reason of the fact that Plaintiffs have exhausted their administrative remedies by filing a claim before the State Appeal Board on January 7, 1991; said claim was formally denied on October 15, 1991, by Craig Kellinson, Special Assistant to the Attorney General. Specifically, jurisdiction is conferred upon this Court by reason of *Iowa Code*, Sections 25A.4 and 25A.13.

7. That Defendant, Edward Sathoff, is an individual who at all material times hereto was a duly licensed Iowa physician. Defendant, Sathoff, was a staff physician at the University of Iowa Hospitals and Clinics in the Department of Psychiatry. He was one of the treating staff physicians of Plaintiff, Imogene Loretta Rohovit, during her hospitalization at the University of Iowa Hospitals and Clinics during the calendar years 1988 and 1989.

8. That Defendant, Keith Rogers, at all material times hereto was a duly licensed Iowa physician. He too was a staff physician at the University of Iowa Hospitals and Clinics within the Psychiatry Department. He also was one of treating staff physicians of Plaintiff, Imogene Loretta Rohovit, during her hospitalization at the University of Iowa Hospitals and Clinics during the calendar years of 1988 and 1989.

9. That Defendant, Bruce Pfohl, at all material times hereto was a duly licensed Iowa physician. He too was a staff physician at the University of Iowa Hospitals and Clinics within the Department of Psychiatry. He too was one of the treating staff physicians of Plaintiff.

Imogene Loretta Rohovit, in connection with the care that she received at the University of Iowa Hospitals and Clinics during the calendar years 1988 and 1989.

10. That Defendant, D. W. Black, at all material times hereto was a duly licensed Iowa physician. He was a staff physician at the University of Iowa Hospitals and Clinics within the Psychiatry Department during the calendar year of 1987. He was one of the treating staff physicians for Plaintiff, Imogene Loretta Rohovit, in connection with care that she received at the University of Iowa Hospitals and Clinics during the calendar year 1987.

11. That Defendant, Mark Fulton, at all times material hereto was a duly licensed Iowa physician. He was a resident within the Department of Psychiatry at the University of Iowa Hospitals and Clinics during the calendar year 1987. He was one of the resident physicians who provided care to Plaintiff, Imogene Loretta Rohovit, during the calendar year of 1987.

12. That Defendant, J. Liesveld, at all material times hereto was a duly licensed Iowa physician. He too was a resident within the Department of Psychiatry at the University of Iowa Hospitals and Clinics during the calendar year 1987. He was another resident who provided care to Plaintiff, Imogene Loretta Rohovit, at the University of Iowa Hospitals and Clinics during the calendar year of 1987.

THE FACTS

13. That on August 21, 1987, Plaintiff, Imogene Loretta Rohovit, was hospitalized at the University of Iowa Hospitals and Clinics because of depression.

14. That upon being admitted at the University of Iowa Hospitals and Clinics, Plaintiff, Imogene Loretta Rohovit, was diagnosed as suffering from a "major depressive disorder with mood congruent and incongruent psychotic features".

15. That even though the initial plan was to treat Plaintiff, Imogene Loretta Rohovit's depression "with a combination of tricyclic antidepressants and neuroleptics", such medication treatment was not pursued; instead, Plaintiff, Imogene Loretta Rohovit, was given a series of six treatments of electroconvulsive therapy (ECT) which began on August 28, 1987, and continued on August 31, September 2, September 4, September 9 and September 11, 1987.

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16. That following the series of six ECT treatments in August and September of 1987, Plaintiff, Imogene Loretta Rohovit, was discharged from the University of Iowa Hospitals and Clinics on September 18, 1987; her discharge diagnosis was that of "major depressive disorder with psychotic features in remission" and "hypothyroidism".

17. That following her discharge in September of 1987, Plaintiff, Imogene Loretta Rohovit, experienced memory difficulties and an inability to concentrate which deterred her from returning to work as a registered nurse within the Obstetrical Department of the University of Iowa Hospitals and Clinics.

18. That on June 17, 1988, by reason of her continued problems with memory and forgetfulness, she returned to the University of Iowa Hospitals and Clinics for a neurobehavioral evaluation. By reason of that evaluation, she was told that there was no indication of "cognitive impairment suggestive of brain dysfunction". She was reassured and told that the electrical shock therapy had nothing to do with her perceived memory and concentration problems.

19. That on December 14, 1988, Plaintiff, Imogene Loretta Rohovit, returned to the University of Iowa Hospitals and Clinics, again for depression. She was diagnosed as having a "bipolar affective disorder, not otherwise specified".

20. That in connection with the December 14, 1988, admission, Plaintiff, Imogene Loretta Rohovit, had recommended to her a second series of electroconvulsive therapy (ECT).

21. That without being given any options, Plaintiff, Imogene Loretta Rohovit, received a series of seven more ECT treatments on December 19, 1988, December 21, 1988, December 23, 1988, December 28, 1988, December 30, 1988, January 4, 1989, and January 6, 1989.

22. That following the series of seven additional ECT treatments, Plaintiff, Imogene Loretta Rohovit, continued to follow up at the University of Iowa Hospitals and Clinics where she primarily saw Defendants, Edward Sathoff and Keith Rogers. She consistently voiced concern to them over her impaired memory following ECT treatments but was consistently reassured that she had no such problems or that the shock therapy was not an explanation.

23. That Plaintiff, Imogene Loretta Rohovit, continued to voice concerns and complaints about memory problems and lack of concentration but continued to get no direction, advice, explanation or treatment for those problems at the University of Iowa Hospitals and Clinics.

24. That as a result, Plaintiff, Imogene Loretta Rohovit, referred herself to the Veterans Hospital in Iowa City for care and treatment.

25. That on March 29, 1990, Plaintiff, Imogene Loretta Rohovit, received a complete neuropsychological evaluation at which time it was determined that she demonstrated symptoms consistent with a marked frontal lobe syndrome and that she had a clearly impaired memory retention in the context of superior intelligence and concentration (i.e., a partial amnesic syndrome).

26. That on November 30, 1990, Plaintiff, Imogene Loretta Rohovit, saw a television show which addressed the issue of brain damage resulting from electrical shock therapy; it was on that date that she first reasonably knew or had reason to know that her ongoing problems with memory, lack of concentration and cognitive deficits were related to the electrical shock therapies that she had received in August and September of 1987 and in December of 1988 and January of 1989.

27. That the representatives, agents or employees of the university of Iowa Hospitals and Clinics, including the specific physicians named as Defendants herein, concealed any relationship between her ongoing memory and lack of concentration problems and the ECT treatments from Plaintiff, Imogene Loretta Rohovit; it was not until she saw the television show on November 30, 1990, that the relationship became apparent to her.

28. That Plaintiff, Imogene Loretta Rohovit, now suffers from permanent brain damage, producing diminished cognitive capabilities, decreased memory, an inability to concentrate and learn, and other related problems; said brain damage is permanent.

COUNT I

Strict Products Liability--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count I of their Petition at Law against Defendant, MECTA Corporation, states as follows:

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1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That at the time Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987 and in December of 1988 and January of 1989, the electrical shock therapy machine identified in the preceding two paragraphs, manufactured by Defendant, MECTA Corporation, was in a defective condition.
6. That when said electrical shock therapy machine was used to zap the brain of Plaintiff, Imogene Loretta Rohovit, in both August and September of 1987 and in December of 1988 and January of 1989, said machine was used in a reasonably foreseeable manner.
7. That the defective condition of the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in both August and September of 1987 and then again in December of 1988 and January of 1989, rendered said machine unreasonably dangerous to Plaintiff, Imogene Loretta Rohovit.
8. That Defendant, MECTA Corporation, was in the business of manufacturing the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and in December of 1988 and January of 1989.

9. That the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, Model No. "D", Serial No. 7039BB, was expected to and did reach the University of Iowa Hospitals and Clinics without substantial change in condition from the time of manufacture; in other words, the defect in said machine which rendered it unreasonably dangerous to Plaintiff, Imogene Loretta Rohovit, existed at the time of manufacture and sale.

10. That the defect in the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and then again in December of 1988 and January of 1989 was a proximate cause of the permanent brain injury sustained by Plaintiff, Imogene Loretta Rohovit, including her permanent memory deficit, her permanent inability to concentrate and her permanent diminished ability to learn.

11. That more specifically, as a proximate result of the defective and unreasonably dangerous condition of the electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB, Plaintiff, Imogene Loretta Rohovit, has sustained damage and seeks compensation for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

12. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain

injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

13. That the conduct of Defendant, MECTA Corporation, demonstrates an intentional, reckless and conscious disregard for the safety of the patients undergoing electrical shock therapy; as a result, Plaintiffs do hereby make claim for punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT II

Negligence--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count II of their cause of action against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That as the manufacturer of the electrical shock therapy machine utilized to zap the brain of Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and again in December of

1988 and January of 1989, Defendant, MECTA Corporation, had a duty to use reasonable care in the research, design, manufacture, inspection and testing of the final product, installation, maintenance and in the labeling, advertising, instructing and warning with regard to said product.

6. That Defendant, MECTA Corporation, breached one or more of said duties of reasonable care.

7. That said breach of one or more of the above-referenced duties of reasonable care by Defendant, MECTA Corporation, with regard to the electrical shock therapy machine used on Plaintiff, Imogene Loretta Rohovit, in August and September of 1987 and again in December of 1988 and January of 1989, constituted negligence.

8. That the negligence of Defendant, MECTA Corporation, was a proximate cause of the resulting injuries and damage sustained by Plaintiff, Imogene Loretta Rohovit.

9. That more specifically, as a proximate result of the negligence of Defendant, MECTA Corporation, Plaintiff, Imogene Loretta Rohovit, seeks recovery for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

10. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain

injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

11. That the conduct of Defendant, MECTA Corporation, demonstrates an intentional, reckless and conscious disregard for the safety of the patients undergoing electrical shock therapy; as a result, Plaintiffs do hereby make claim for punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT III

Negligent Misrepresentation--Fraud--MECTA Corporation

COME NOW the Plaintiffs, and in support of Count III against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovlt, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovlt, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.

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5. That in connection with the manufacture and sale of the electrical shock therapy machine, specifically Model No. "D", Serial No. 7039BB, Defendant, MECTA Corporation, provided and made available a MECTA Instruction Manual concerning said machine.

5a. That in addition to the MECTA Instruction Manual concerning the electrical shock therapy machine in question, Defendant, MECTA Corporation, also made available and aggressively marketed other written and video presentations concerning electrical shock therapy and the safety of its machines.

6. That the MECTA Instruction Manual as well as the other written and video information distributed by Defendant, MECTA Corporation, is written and/or produced so as to minimize any concern on the part of the health care practitioner contemplating the use of electrical shock therapy with regard to the potential for permanent brain injuries resulting therefrom. Specifically, the risk of permanent brain injury and permanent cognitive deficits, including memory, concentration and an inability to learn are substantially minimized. The procedure was represented within the Manual as being "easy and safe to use"; it further represented that the practitioners utilizing the device could not "conduct safe, effective procedures" and that "the design of said machine incorporates many fail safe features, which assure maximum patient safety".

7. That the MECTA Instruction Manual and the other written or video materials, when read or viewed as a whole, constitute a representation or representations concerning the safety of the electrical shock therapy machine in question, Model No. "D", Serial No. 7039BB.

8. That said representation/representations were false and misleading.

9. That Plaintiff, Imogene Loretta Rohovlt, reasonably and indirectly relied on said false representations by Defendant, MECTA Corporation, in that she was advised by her physicians at the University of Iowa Hospitals and Clinics that the electrical shock procedure being contemplated was totally safe. The information upon which those representations were made by the staff at the University of Iowa Hospitals and Clinics to Plaintiff, Imogene Loretta Rohovlt, included in part the information submitted in the

MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation.

10. That the false representations by Defendant, MECTA Corporation, as contained in the MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation, contributed to the persistence of the use of damaging electrical shock treatments and specifically contributed to the recommendation and implementation of electrical shock therapy as part of the treatment received by Plaintiff, Imogene Loretta Rohovit, for her depression.

11. That as a result of the justifiable reliance on the part of her physicians at the University of Iowa Hospitals and Clinics, which advice was based in part upon the false representations contained in the MECTA Instruction Manual and the other written and/or video information distributed by Defendant, MECTA Corporation, Plaintiff, Imogene Loretta Rohovit, went ahead and consented to the electrical shock therapy treatments which were done in August and September of 1987 and then again in December of 1988 and January of 1989.

12. That as a proximate cause of Plaintiff, Imogene Loretta Rohovit's justifiable reliance on the false representations of Defendant, MECTA Corporation, she has been permanently and seriously damaged; she seeks recovery for the following elements:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

13. That at the time Defendant, MECTA Corporation, wrote, published and began distributing the information contained in the MECTA Instruction Manual and the other written and/or video

information distributed, it knew or should have known that the information contained therein was false; it knew or should have known that the information contained in its instruction manual did not accurately set forth the controversial nature of electrical shock therapy, the damaging effects of the therapy; the fact that said therapy was the most controversial treatment in psychiatry; the fact that many doctors and many institutions refuse to use electrical shock therapy; the fact that many doctors believe that shock therapy causes permanent brain damage; the fact that electrical shock therapy causes permanent memory loss spanning a period of time before and after the treatment that impairs recollection for many months and even years of time; that shock therapy can impair the ability of a person to learn new material and to use one's mental abilities; and the fact that there are no controlled studies showing beneficial impact beyond one month after treatment.

14. That in marketing said instruction manual and the other written and/or video information, defendant, MECTA Corporation, did so in reckless and conscious disregard for the safety of patients who would likely consent to electrical shock therapy in part by reason of the false representations contained in said instruction manual.

15. That as the natural daughters of plaintiff, Imogene Loretta Rohovit, plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

16. That by reason of the reckless and conscious disregard for the safety of patients undergoing electrical shock therapy, plaintiffs do hereby seek recovery for exemplary and/or punitive damages.

WHEREFORE, plaintiffs do hereby seek judgment against defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT IVRestatement (Second) of Torts, Section 402B—MECTA Corporation

COME NOW the Plaintiffs, and in support of Count IV of their claim against Defendant, MECTA Corporation, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 4 of the "Jurisdictional Facts" and incorporate the same by reference herein.
2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.
3. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in August and September of 1987, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
4. That when Plaintiff, Imogene Loretta Rohovit, received the electroconvulsive therapy (ECT) in December of 1988 and January of 1989, the electrical shocks used to zap her brain were generated from an electrical shock therapy machine manufactured by Defendant, MECTA Corporation, Model No. "D", Serial No. 7039BB.
5. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 5, 5a and 6 of Count III of this Petition and incorporate the same by reference herein.
6. That Defendant, MECTA Corporation, through its advertising, labels, instruction manuals, other written materials distributed, and/or video presentations, has made to the public a misrepresentation of a material fact concerning the character and quality of its electrical shock therapy machine, Model No. "D", Serial No. 7039BB.
7. That Defendant, MECTA Corporation, is, therefore, subject to liability for the permanent and irreversible brain injury sustained by Plaintiff, Imogene Loretta Rohovit, by reason of her reasonable, indirect and justifiable reliance upon the misrepresentation of Defendant, MECTA Corporation. Her reasonable, indirect and justifiable reliance occurred by reason of the fact that she was advised by her

physicians at the University of Iowa Hospitals and Clinics that the electrical shock procedure being contemplated was totally safe. The information upon which those representations were made by the staff of the University of Iowa Hospitals and Clinics to Plaintiff, Imogene Loretta Rohovit, included in whole or in part the advertising, instruction manual, labels, other written materials, and/or video tape presentations distributed by Defendant, MECTA Corporation.

8. That pursuant to this Count, Plaintiff, Imogene Loretta Rohovit, is relying on the *Restatement (Second) of Torts*, Section 402B.

9. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 10 through 16 of Count III of this Petition and incorporate the same by reference herein.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendant, MECTA Corporation, in an amount which would reasonably compensate them for their injuries and loss, together with punitive damages; they also seek interest thereon at the maximum legal rate plus the costs of this action.

COUNT V

Negligence--1987 Shock Therapy--As Against Defendants, State of Iowa, Black, Fulton and Liesveld

COME NOW the Plaintiffs, and in support of their cause of action against Defendants, State of Iowa, Black, Fulton and Liesveld, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 3, paragraphs 5 and 6, and paragraphs 10 through 12 of the "Jurisdictional Facts" and incorporate the same by reference herein.

2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.

3. That when Plaintiff, Imogene Loretta Rohovit, came to the University of Iowa Hospitals and Clinics in August of 1987 in a depressed condition, the Defendant, State of Iowa, through its agents, representatives and/or employees, and Defendants, Black, Fulton and Liesveld, had a duty to exercise reasonable care under the circumstances in connection with the medical evaluation, diagnosis, care, treatment and advice rendered to Plaintiff, Imogene Loretta Rohovit.

4. That Defendant, State of Iowa, by and through one or more of its duly authorized agents, representatives or employees, and Defendants, Black, Fulton and Liesveld, breached one or more of the duties set forth in the preceding paragraph and were, therefore, negligent. More specifically, said Defendants were negligent in one or more of the following particulars:

- a. In failing to properly inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with electroconvulsive therapy (ECT);
- b. In failing to inform Plaintiff, Imogene Loretta Rohovit, of alternative methods of treatment other than electroconvulsive therapy (ECT) for her depression;
- c. In failing to pursue alternative forms of treatment for the depression of Plaintiff, Imogene Loretta Rohovit, other than electroconvulsive therapy (ECT);
- d. In recommending electroconvulsive therapy (ECT) when they knew or should have known that the documented beneficial impact of such therapy was far outweighed by the risk of permanent brain dysfunction and lessened cognitive abilities;
- e. In failing to survey and review the medical literature concerning electroconvulsive therapy (ECT) so as to be in a position to inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with said therapy, the minimal documented beneficial impact of said therapy, and the alternative forms of treatment other than electroconvulsive therapy (ECT); and
- f. In failing to exercise that degree of skill, care and learning required under the circumstances for the diagnosis and treatment of Plaintiff, Imogene Loretta Rohovit's condition of depression.

5. That the negligence of Defendants, State of Iowa, Black, Fulton and Liesveld, was a proximate cause of the resulting injuries and damages sustained by Plaintiff, Imogene Loretta Rohovit.

6. That more specifically, Plaintiff, Imogene Loretta Rohovit, has been injured in that she has sustained a permanent brain injury resulting in diminished cognitive functioning and abilities, including decreased memory, decreased ability to concentrate, and decreased ability to learn and retain new information, all of which entitles her to recover for the following elements of loss:

- a. Past medical expense;
- b. Future medical expense;

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- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

7. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

8. That the conduct of Defendants, State of Iowa, Black, Fulton and Liesveld, demonstrates an willful, wanton and/or reckless disregard for the safety of Plaintiff, Imogene Loretta Rohovit, and thereby entitles her to punitive and/or exemplary damages.

WHEREFORE, Plaintiffs do hereby seek judgment against Defendants, State of Iowa, Black, Fulton and Liesveld, in an amount which would reasonably compensate them for their injuries and loss; they also seek punitive damages in an amount which would reasonably deter such future conduct; in addition, Plaintiffs seek interest on said judgment at the maximum legal rate plus the costs of this action.

COUNT VI

Negligence--December of 1988 and January of 1989 Shock Therapy--Defendants, State of Iowa, Sathoff, Rogers and Pfohl

COME NOW the Plaintiffs, and in support of Count V of their Petition against Defendants, State of Iowa, Sathoff, Rogers and Pfohl, state as follows:

1. That Plaintiffs repeat and reallege each and every material allegation contained in paragraphs 1 through 3, and paragraphs 5 through 9 of the "Jurisdictional Facts" and incorporate the same by reference herein.

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2. That Plaintiffs repeat and reallege each and every material allegation set forth in paragraphs 13 through 28 of "The Facts" and incorporate the same by reference herein.

3. That when Plaintiff, Imogene Loretta Rohovit, came to the University of Iowa Hospitals and Clinics in December of 1988 and January of 1989 in a depressed condition, the Defendant, State of Iowa, through its agents, representatives and/or employees, and Defendants, Sathoff, Rogers and Pfohl, had a duty to exercise reasonable care under the circumstances in connection with the medical evaluation, diagnosis, care, treatment and advice rendered to Plaintiff, Imogene Loretta Rohovit.

4. That Defendant, State of Iowa, by and through one or more of its duly authorized agents, representatives or employees, and Defendants, Sathoff, Rogers and Pfohl, breached one or more of the duties set forth in the preceding paragraph and were, therefore, negligent. More specifically, said Defendants were negligent in one or more of the following particulars:

- a. In failing to properly inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with electroconvulsive therapy (ECT);
- b. In failing to inform Plaintiff, Imogene Loretta Rohovit, of alternative methods of treatment other than electroconvulsive therapy (ECT) for her depression;
- c. In failing to pursue alternative forms of treatment for the depression of Plaintiff, Imogene Loretta Rohovit, other than electroconvulsive therapy (ECT);
- d. In recommending electroconvulsive therapy (ECT) when they knew or should have known that the documented beneficial impact of such therapy was far outweighed by the risk of permanent brain dysfunction and lessened cognitive abilities;
- e. In failing to survey and review the medical literature concerning electroconvulsive therapy (ECT) so as to be in a position to inform Plaintiff, Imogene Loretta Rohovit, of the risks associated with said therapy, the minimal documented beneficial impact of said therapy, and the alternative forms of treatment other than electroconvulsive therapy (ECT);
- f. In failing to exercise that degree of skill, care and learning required under the circumstances for the diagnosis and treatment of Plaintiff, Imogene Loretta Rohovit's condition of depression; and

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- g. In using bilateral electroconvulsive therapy (ECT) when they know or should have known that the bilateral electroconvulsive therapy increased the risk of permanent brain injury to Plaintiff, Imogene Loretta Rohovit.

5. That the negligence of Defendants, State of Iowa, Sathoff, Rogers and Pfohl, was a proximate cause of the resulting injuries and damages sustained by Plaintiff, Imogene Loretta Rohovit.

6. That more specifically, Plaintiff, Imogene Loretta Rohovit, has been injured in that she has sustained a permanent brain injury resulting in diminished cognitive functioning and abilities, including decreased memory, decreased ability to concentrate, and decreased ability to learn and retain new information, all of which entitles her to recover for the following elements of loss:

- a. Past medical expense;
- b. Future medical expense;
- c. Past loss of function of her brain and body;
- d. Future loss of function of her brain and body;
- e. Past pain and suffering, including loss of enjoyment of life;
- f. Future pain and suffering, including loss of enjoyment of life;
- g. Past lost earnings; and
- h. Future lost earning capacity.

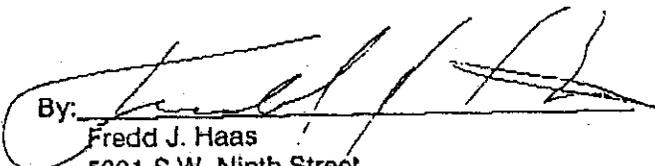
7. That as the natural daughters of Plaintiff, Imogene Loretta Rohovit, Plaintiffs, Julie Lynn Rohovit and Lori Janelle Rohovit, do hereby seek damages for loss of parental consortium by reason of their loss of the full and complete affection, comfort, society, companionship and services of their natural mother. Their claim for loss of parental consortium is made from the time of their mother's brain injury from the electrical shock therapy treatment up until the present; further, said loss will continue into the future.

8. That the conduct of Defendants, State of Iowa, Sathoff, Rogers and Pfohl, demonstrates an willful, wanton and/or reckless disregard for the safety of Plaintiff, Imogene Loretta Rohovit, and thereby entitles her to punitive and/or exemplary damages.

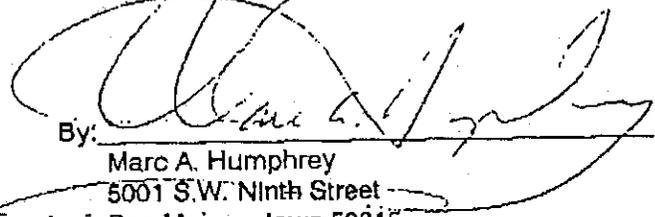
M 00848

WHEREFORE, Plaintiffs do hereby seek judgment against Defendants, State of Iowa, Sathoff, Rogers and Pfohl, in an amount which would reasonably compensate them for their Injuries and loss,, they also seek punitive damages in an amount which would reasonably deter such future conduct; in addition, Plaintiffs seek interest on said judgment at the maximum legal rate plus the costs of this action.

HUMPHREY AND HAAS, P.C.

By: 

Fredd J. Haas
5001 S.W. Ninth Street
Des Moines, Iowa 50315
Telephone: (515) 287-4490

By: 

Marc A. Humphrey
5001 S.W. Ninth Street
Des Moines, Iowa 50315
Telephone: (515) 287-4490
AIN: PK1000044

ATTORNEYS FOR PLAINTIFFS

COPY

No. 98 11317

THE HEIRS OF JESUS G. TORRES §
by and through BEN TORRES, ELFIDA §
MARTINEZ, DAMASIO TORRES, §
NINFA DELEON, FRANCES REYNA, §
GUADALUPE TORRES and ERMA TORRES, §

IN THE 353 JUDICIAL

Plaintiffs, §

V. §

TEXAS DEPARTMENT OF MENTAL §
HEALTH AND MENTAL RETARDATION, §
TERRELL STATE HOSPITAL, §
DON GILBERT, in his official capacity §
as former Commissioner of Texas Department §
of Mental Health and Mental Retardation, §
KAREN HALE, in her official capacity as §
Acting Commissioner of Texas Department §
of Mental Health and Mental Retardation, §
BEATRICE BUTLER, Superintendent of §
Terrell State Hospital, GLORIA P. OLSEN, §
Superintendent of Kerrville State Hospital, §
MONTE GOEN, M.D., Attending Physician, at §
Terrell State Hospital, and VERNON E. §
GROVE, JR., M.D., Attending Physician at §
Kerrville State Hospital, §
individually and in their official capacities, §
and MECTA Corporation. §

DISTRICT COURT OF

Defendants. §

TRAVIS COUNTY, TEXAS §

PLAINTIFFS' ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW Ben Torres, Ninfa DeLeon, Elfida Martinez, Damasio Torres, Frances Reyna,
Guadalupe Torres and Irma Torres, as natural siblings of Jesus G. Torres (deceased) and in their

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DISTRICT CLERK
TRAVIS COUNTY, TEXAS

M 00811

capacity as heirs of his estate, collectively hereinafter referred to as "Plaintiffs, complain of the above-referenced persons and entities, known hereinafter collectively referred to as "Defendants" and for cause of action would show:

I. BENEFICIARIES

1. The deceased, Jesus G. Torres, never completed a will and thus his legal beneficiaries under

Texas law, in said action are:

Ben Torres (Brother)
409 East Poplar
Sonora, Texas 76950

Ninfa DeLeon (Sister)
1214 Oak Street
Grand Prairie, Texas 75211

Elfida Martinez (Sister)
605 Orient
Sonora, Texas 76950

Damasio Torres (Brother)
501 South Church
Winters, Texas 79567

Frances Reyna (Sister)
315 South Church
Winters, Texas 79567

Guadalupe Torres (Brother)
2926 Reforma Street
Grand Prairie, Texas 75052

Erma Torres (Sister)
2944 Gladstone Street
Dallas, Texas 75211

STATEMENT OF CLAIM

2. Plaintiffs file this civil action seeking monetary relief for the deprivation of the rights guaranteed to Jesus G. Torres under the Texas Mental Health Code and for tortious acts under other Texas statutory, regulatory and common law.

II. JURISDICTION

3. This Court has jurisdiction over the subject matter of Plaintiffs' claims under Tex. Health & Safety Code Ann. § 321.003 and Texas tort law.

III. VENUE

4. Venue is proper in Travis County under Tex. Health & Safety Code Ann. § 321.003 (e)(2), because the Kerrville State Hospital and the Terrell State Hospital are inpatient mental health facilities operated by Defendant Texas Department of Mental Health and Mental Retardation ("TDMHMR"). Defendant TDMHMR conducts business in Travis County.

IV. PARTIES

5. Jesus G. Torres, hereinafter also referred as to "the deceased" had been involuntarily committed to the Kerrville State Hospital, in Kerrville, Texas and was transferred to the Terrell State Hospital in Terrell, Texas in and around October 1, 1996. He was receiving treatment at that mental health facility when he died on October 8, 1996. His natural brothers and sisters, known collectively as Plaintiffs, and as representatives of the deceased estate, bring this action to recover for the injuries the deceased suffered while alive as a result of Defendants negligence and violations of statutory and regulatory law, and the injuries and damages they too have received because of such actions by Defendants.
6. Defendant TDMHMR administers and enforces rules and regulations relating to the management of state mental health facilities, the duties of officers and employees of those hospitals, and the provision of care and treatment to persons in state mental health facilities,

as adopted by the Texas Board of Mental Health and Mental Retardation. Defendant TDMHMR may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested, to Karen Hale, Acting Commissioner, TDMHMR, P.O. Box 12668, Capitol Station, Austin, Texas 78711-2668.

7. Defendant Terrell State Hospital ("TSH") is a state mental health facility operated by Defendant TDMHMR in Terrell, Kaufman County, Texas. TSH employs Defendant Beatrice Butler as its superintendent and Defendant Monte Goen, M.D., as physician. TSH may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested to Beatrice Butler, Superintendent, TSH, 1200 East Brin Street, Terrell, Texas 75160.
8. Defendant Kerrville State Hospital ("KSH") is a state mental health facility operated by Defendant TDMHMR in Kerrville, Kerr County, Texas. KSH employs Defendant Gloria P. Olsen as its superintendent and Defendant Vernon Groves, M.D., as physician. KSH may be served process by mailing a copy of the citation and petition, by registered or certified mail, return receipt requested to Gloria P. Olsen, Superintendent, KSH, 721 Thompson Drive, Kerrville, Texas 78028.
9. Defendant Don Gilbert was the duly appointed Commissioner of TDMHMR at the time the deceased was treated at KSH and TSH. In that capacity, he served as the chief executive and administrative officer of TDMHMR. His duties included observing, executing, and enforcing the mandates and regulations established pursuant to state and federal law. Among the legal mandates and regulations with which he and his agency must comply were the Texas Health and Safety Code and the rules and regulations promulgated pursuant to the Texas Health and Safety Code. As the Commissioner of TDMHMR, Defendant Gilbert was also responsible

for ensuring compliance by TDMHMR and its employees and facilities with these laws and regulations. Defendant Gilbert is sued in his official capacity as Commissioner of TDMHMR. Defendant Gilbert may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, at the Texas Health and Human Services Commission, 4900 North Lamar, 4th Floor, Austin, Texas 78751.

10. Defendant Karen Hale is the Acting Commissioner of TDMHMR. In that capacity, she serves as the chief executive and administrative officer of TDMHMR. Her duties include observing, executing, and enforcing the mandates and regulations established pursuant to state and federal law. Among the legal mandates and regulations with which she and her agency must comply are the Texas Health and Safety Code and the rules and regulations promulgated pursuant to the Texas Health and Safety Code. As the Acting Commissioner of TDMHMR, Defendant Hale is also responsible for ensuring compliance by TDMHMR and its employees and facilities with these laws and regulations. Defendant Hale is sued in her official capacity as Acting Commissioner of TDMHMR. Defendant Hale may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, at TDMHMR, P. O. Box 12668, Capitol Station, Austin, Texas 78711-2668.
11. Defendant Gloria P. Olsen is the Superintendent of KSH. As such, she is the supervisor of all KSH staff. She is responsible for ensuring that KSH is in compliance with Texas law and TDMHMR regulations. At all relevant times, Defendant Olsen was acting as the agent, servant, and employee of Defendants KSH and TDMHMR. Defendant Olsen is sued in her official and individual capacities and may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, at the KSH, 721 Thompson Drive, Kerrville, Texas 78028.

12. Defendant Vernon E. Grove, Jr. M.D. was one of the attending physicians of the deceased Jesus Torres, at KSH. As such, Defendant Groves was responsible for assessing the deceased's mental condition and ordering psychiatric care and medical treatment for him. At all relevant times, Defendant Groves was acting as the agent, servant, and employee of Defendants KSH and TDMHMR. Defendant Groves is sued in his official and individual capacities and may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, at the KSH, 721 Thompson Drive, Kerrville, Texas 78028.
13. Defendant Beatrice Butler is the Superintendent of TSH. As such, she is the supervisor of all TSH staff. She is responsible for ensuring that TSH is in compliance with Texas law and TDMHMR regulations. At all relevant times, Defendant Butler was acting as the agent, servant, and employee of Defendants TSH and TDMHMR. Defendant Butler is sued in her official and individual capacities and may be served process by mailing to her a copy of the citation and petition, by registered or certified mail, return receipt requested, to the Terrell State Hospital, 1200 East Brin Street, Terrell, Texas 75160.
14. Defendant Monte Goen, M.D. was one of the attending physicians of the deceased while he was at TSH. As such, Defendant Goen was responsible for assessing the deceased's mental condition and ordering psychiatric care and medical treatment for him. At all relevant times, he was acting as the agent, servant, and employee of Defendants TSH and TDMHMR. Defendant Goen is sued in his official and individual capacities and may be served process by mailing to him a copy of the citation and petition, by registered or certified mail, return receipt requested, to 4630 Parkwood Drive, Rockwall, Texas 75087.

15. Defendant MECTA, is a foreign corporation and not incorporated under the laws of the State of Texas. At all times material to this action, MECTA has been engaged in business in Texas, as more particularly described below. Defendant does not appear to have a regular place of business in Texas, nor has any known designated agent on whom service may be made in this cause. The causes of action asserted arose from or are connected with purposeful acts committed by this Defendant in Texas, as MECTA manufactures and provides electro convulsive shock therapy machinery to Defendants TDMHMR, KSH and TSH. Accordingly, Defendant may be cited by serving the Secretary of the State of Texas provided that citation and petition are forwarded to Defendant home address, by certified mail, return receipt requested at MECTA Corporation, 7015 McEwan Road, Lake Oswego, Oregon, 97035-7830.
16. Whenever Plaintiffs use the word "Defendants" in this petition, they mean defendants, their agents, employees, successors, and all persons acting in concert with them or at their direction.

V. FACTUAL ALLEGATIONS

17. On and around September of 1993, Jesus Torres (deceased) was admitted to the KSH. In 1993 Mr. Torres weighed over 133 pounds and was about 66.5" tall. Upon admission he was in emotional distress but nevertheless had all his faculties, was capable of self-care, but treated with substantial amounts of neuroleptics. These caused neuroleptic malignant syndrome (NMS) from which he never fully recovered.
18. On or about August 1995, Jesus Torres was again in involuntarily commitment status at the Kerrville State Hospital. He was in very poor physical health due to a long history of deteriorated health due to the NMS which occurred as a result of the psychiatric treatment

at KSH. Mr. Torres had genuinely drug induced brain damage and was increasingly withdrawn. He was treated with amphetamines and amphetamine like drugs that caused increased agitation, appetite suppression and significant weight loss. Defendant physicians and other professionals and agents of KSH and TDMHMR, recommended Mr. Torres receive electroconvulsive treatment (ECT) and initiated transfer to TSH. Mr. Torres was transferred to TSH on or about December 19, 1995, where he was under the care of Dr. Monte Goen, M.D.

19. Defendant MECTA corporation provided to TSH the machinery used for the provision of ECT therapy. MECTA is responsible to assure such machinery meets and exceeds standards of care for such equipment.
20. Despite abundant documentation that Mr. Torres was not competent, his "mark" was finally coerced from him, and put on a consent form. Within his first course of ECT he was reduced to being tied up in a "geri-chair" and wearing a diaper until he began more and more and more vocal about refusing the ECT treatment. Nevertheless, up to and through February of 1996, Jesus Torres underwent several sessions of ECT under Goen's care and supervision. He was soon transferred back to KSH.
21. Months later, after more and more amphetamines and even further weight loss while at KSH, he was again transferred by Defendants KSH and Grove, to TSH where he was provided ECT. Again there is ample evidence Mr. Torres was not competent so as to provide the requisite informed consent for such treatments. The nursing assessment of 10/2/96 notes reads "I am not sure he understands medication instructions." The psychological assessment of 10/4/96 states that "... insight and judgement are both seriously impaired and essentially nil." Yet Defendant Goen states that Jesus Torres gave him informed consent for ECT treatment.

22. Further, Jesus Torres was not medically stable at the time he received the ECT treatment. For instance, upon transfer from KSH and admission to TSH he weighed about 85 pounds. Yet unbelievably Defendant physicians at both KSH and TSH state that "he was not in need of nasal gastric or any sort of replenishment of volume or nutrition ..."
23. Further and addition to the above, Jesus Torres' received treatment at KSH for seizures. Yet upon admission to TSH this fact is unaddressed by TSH medical personnel, including Defendant Goen. None of his seizure medications, including Ativan, were provided to him upon transfer from KSH to TSH. On 10/4/96 he does have a seizure, ostensibly due to the fact Ativan therapy was prematurely stopped.
24. On October 7, 1996 the deceased was again provided ECT against his will and without informed consent and in violation of state law. On October 8, 1996 Jesus Torres was found in a chair in the group room, unresponsive and later pronounced dead. He was found while already in a state of rigor mortis. The autopsy revealed that Mr. Torres was in severe malnutrition and had a ruptured bowel. The deceased had burns marks on his head due to and among other things, the malfunctioning of the ECT machinery provided by Defendant MECTA.

VI. STANDARDS OF CARE

25. All Defendants have an obligation to comply with the provisions of, or any rules adopted under, the Texas Mental Health Code, Tex. Health & Safety Code Ann. § 571.001 *et seq.* In accordance with Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108, a person receiving care and treatment in a state mental health facility is prohibited from receiving ECT unless he or she has provided informed consent to ECT.

26. Defendants Gilbert and TDMHMR have general supervision and control over Defendants KSH and TSH. As such, Defendants Gilbert and TDMHMR have a duty to see that persons who are receiving medical and psychiatric care and treatment at KSH, and medical and psychiatric care, including ECT at TSH, are not administered ECT unless those persons provide informed consent.
27. Defendant Olsen, as superintendent of KSH, and Defendant KSH owed Mr. Torres a duty to see that he was provided the highest standards of medical care so that his physical health did not deteriorate. Further, Defendant Olsen owed Mr. Torres a duty of care to assure he was not transferred when he was in a medically unstable state. Further, this Defendant owed Mr. Torres a duty to assure all his patient rights were fully provided, including but not limited to the administration of ECT unless Torres was able to provide informed consent. Defendant Olsen was aware of the fact that Mr. Torres lacked the capacity to consent to his transfer or provision of ECT. Upon information and belief, Defendant Olsen was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.
28. Defendant Groves, as the attending physician for Mr. Torres at KSH, owed him a duty to see that he was provided the highest standards of medical care. Further, Defendant Groves owed Mr. Torres a duty of care to assure he was not transferred when he was in a medically unstable state. Further, this Defendant owed Mr. Torres a duty to assure all his patient rights were fully provided, including but not limited to the administration of ECT unless Torres was able to provide informed consent. Defendant Groves was aware of the fact that Mr. Torres lacked the capacity to consent to his transfer or provision of ECT. Upon information and

belief, Defendant Groves was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.

29. Defendant Butler, as superintendent of TSH, and Defendant TSH owed Mr. Torres a duty to see that he was not administered ECT unless he was able to provide informed consent. Defendant Butler was aware of the fact that Mr. Torres lacked the capacity to consent to ECT. Upon information and belief, Defendant Butler was aware of the administration of ECT to Mr. Torres despite the fact that he lacked the capacity to consent to such treatment.
30. Defendant Goen, as the attending physician for Mr. Torres, owed him a duty to see that he was not administered ECT unless he was able to provide informed consent. Defendants completely failed to fulfill this duty owed to Plaintiff and provided him with ECT in direct violation of Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108.
31. As a result of the Defendants' failure to ensure that Mr. Torres was not administered ECT unless he was able to provide informed consent to such treatment, Jesus Torres did reasonably suffer mental, psychological and emotional anguish, discomfort, worry, distress, and anxiety. Additionally, Mr. Torres suffered bodily discomfort and pain as a result of receiving ECT. He also suffered headaches, muscle soreness and confusion from the ECT treatment that ultimately was the proximate cause of his untimely decease.

VII. CAUSES OF ACTION

32. All the factual and legal allegations addressed in the above and below numbered paragraphs are thereby incorporated into the remainder of this petition.

A: NEGLIGENCE PER SE-TEXAS HEALTH AND SAFETY CODE

33. Under Tex. Health & Safety Code Ann. § 321.003, Defendants are liable for the actual damages caused by their violations of any provisions of, or any rules adopted under, the Texas Mental Health Code at the Tex. Health & Safety Code Ann. § 571.001 *et seq.* Further, and in addition to the above, Defendants' administration of ECT without obtaining informed consent from Jesus Torres violated Tex. Health & Safety Code Ann. § 578.002(c) and 25 Tex. Admin. Code § 405.108 and proximately caused him to suffer mental anguish, fear, bodily discomfort, headaches, pain, muscle soreness, confusion, permanent and temporary memory loss and memory dysfunction and ultimately death.

B: TORT CLAIMS ACT

34. Under the Texas Tort Claims Act (TEX. CIV. PRAC. & REM. CODE ANN. § 101.021), Defendants are liable for the personal injuries proximately caused by the Defendants' improper use of tangible personal property. Defendants' misuse of the ECT stimulus apparatus that was used to administer ECT to Jesus Torres proximately caused him to have mental anguish, fear, bodily discomfort, headaches, pain, muscle soreness, confusion, permanent and temporary memory loss and memory dysfunction and ultimately death. Plaintiffs have previously provided notice to Defendants and complied with all prerequisites contemplated by this act.

C: INTENTIONAL TORT

35. Defendant Goen intentionally committed battery upon Mr. Torres person in violation of Texas law by causing ECT to be administered to him without his informed consent.

D. SURVIVAL CAUSE OF ACTION

36. Under the "Survival of Cause of Action" statute, at Texas Civil Practices and Remedies Code § 71.021, Defendants are liable for the personal injuries, pain and suffering, medical expenses, funeral expenses, and other costs related to the probate of the deceased's estate. Further, Defendants are liable to the heirs for the mental anguish and loss of companionship they have suffered because of their beloved brother's untimely demise.

D. MEDICAL NEGLIGENCE

37. Under the Texas Medical Liability and Insurance Act, Texas Revised Civil Statutes Annotated, Article 4590i, Defendants are liable to Jesus Torres' heirs for the medical negligence that was the proximate cause of his untimely demise. Plaintiff's have given notice of their claims to Defendants, as contemplated by this statute.

E. GROSS NEGLIGENCE

38. The negligence of the Defendants described herein was of such character as to make the Defendants guilty of gross negligence. The conduct of Defendants, viewed objectively from the standpoint of the Defendants at the time of its occurrence, involved an extreme degree of harm, considering the medical history of the deceased, Jesus Torres. Moreover, Defendants engaged in the conduct with the conscious indifference to the rights, safety and welfare of the deceased, despite the Defendants actual, subjective awareness of the risks involved. Plaintiffs are thereby entitled to recover exemplary damages in such an amount as may be found to be proper under the facts and circumstances.

XIII. FEES AND DAMAGES

39. By reason of all the above Jesus Torres has been damaged, as had his estate, and all within the jurisdictional limits of the Court.

IX. JURY DEMAND

40. Plaintiffs demand a trial by jury on all issues so triable.

X. PRAYER FOR RELIEF

41. WHEREFORE, Plaintiffs request and pray that Defendants be cited to appear and answer, and on the final trial Plaintiffs have:

- a. Judgement against Defendants, jointly and severally for damages within the jurisdictional limits of the Court;
- b. Attorney fees as permitted, *inter alia*, by the Tex. Health & Safety Code § 321.003 and the Tex. Civ. Prac. & Rem. Code § 37.009;
- c. Prejudgement and postjudgement interest as permitted by Tex. Civ. Prac & Rem. Code § 71.021;
- d. Exemplary damages as permitted by, *inter alia*, the Tex. Health & Safety Code § 321.003(d), the Tex. Civ. Prac & Rem. Code at § 71.021 for Defendants gross negligence, and also under the Tex. Const. Art. 16 § 26 and the Tex. Civ. Prac & Rem. Code § 41.003(a)(3); all with such amounts to be determined by the trier of fact;
- e. Costs of suit including expert fees;
- f. Such other and further relief to which Plaintiffs may be entitled in this action, at law or in equity.

Dated: October 7, 1998.

Respectfully submitted,

MARTIN J. CIRKIEL
State Bar No. 00783829

Cirkiel & Associates, P.C.
1901 Palm Valley Boulevard
Round Rock, Texas 78664
(512) 244-6658
(512) 244-4355 (Fax)

ATTORNEYS FOR PLAINTIFFS

1st Person Project: Search Results

Search Results

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Record 1 of 136

*Name:	Faith
*Age when you had ECT:	24
*Your gender:	Female
*Country:	United States
State/Province if applicable:	FL
Where was ECT performed (if different than above):	Florida
Number of ECTs, if known:	Unknown
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Lots of medications all at once.
Why was ECT prescribed (symptoms, diagnosis):	Major depression
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	I lost my memory and it did not help the depression except very short term
What negative side effects, if any, did you experience:	Memory loss, Verbal recall of phrases, people, my life memories.

If you felt harmed by ECT; what was the reaction of your doctor to your complaints:

I was told there were no side effects to ECT.

Do you still see the same doctor who administered your ECT:

No, he committed suicide.

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

Absolutely not.

*In one sentence, sum up your thoughts on your ECT experience:

The biggest medical mistake of my life.

Email (optional):

Squeaks@aol.com

Additional comments/your ECT story:

ECT has affected my longterm and short term memory and cognitive skills. I have suffered from many bouts of depression and been suicidal since. Prior to ECT I had never been depressed and never contemplated suicide. The doctor who gave me ECT has committed suicide. It should be outlawed. I sought counseling and ended up instead permanently changed by medications and ECT.

1st Person Project: Search Results

Search Results

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Record 4 of 136

*Name:	trent lynn
*Age when you had ECT:	30
*Your gender:	Female
*Country:	Italy
Where was ECT performed (if different than above):	In a private hospital
Number of ECTs, if known:	15
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	ANTI DEPPRESAANTS
Why was ECT prescribed (symptoms, diagnosis):	GRAVE DEPRESSION
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	To forget why I was depressed
What negative side effects, if any, did you experience:	I suffer from epilepsy, I feel stigmatized, I suffer from electrical pollution
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	That I need them

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

I lost my soul

Email (optional):

ibis33@hotmail.com

Additional comments/your ECT story:

I was never told the side effects, it was offered as the only treatment available, it was preformed in a private hospital and cost at the time quite a lot, the doctor told me I needed it once a month. I take no medicines now I'm still depressed but get along with my life, the depression was caused while I was teaching using unorthodox methods like alice in wonderland, no alternative was given to cure me, shocks were given to me like handing out candy, I nearly died in one they couldn't wake me up for two days, my memory pops up at times I do not expect bringing back all, I lost my capacity to speak languages I used to speak five fluently and had to relearn. ect ect ect

1st Person Project: Search Results

Search Results

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*Name:	Sylvia Caras
*Age when you had ECT:	32
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MA
Where was ECT performed (if different than above):	private facility
Number of ECTs, if known:	don't know
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	long hospitalization, neuroleptics, talk, milieu
Why was ECT prescribed (symptoms, diagnosis):	almost catatonic depression
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	I don't remember much before or after
What negative side effects, if any, did you experience:	memory loss, flat affect, disorientation

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: too depressed to complain

Do you still see the same doctor who administered your ECT: no

*Choose one to describe the effects of ECT on you: Somewhat harmful

Would you willingly have ECT again, or recommend it to another: no

*In one sentence, sum up your thoughts on your ECT experience: I didn't know that what I felt was a result of ect; I thought my prognosis was accurate and that I was deteriorating.

Email (optional): sylvia@peoplewho.org

Additional comments/your ECT story: If I'd been offered a choice, I would have done what was recommended. I was too depressed to evaluate options and too desperate for relief. I didn't know memory loss was an effect. When I couldn't remember names I was *so* embarrassed; when people knew me and I didn't know who they were, I was disoriented. I had no one to support me because I told no one about these events - I thought I was continuing to lose my mind. And mind was what I valued about myself.

1st Person Project: Search Results

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*Name:	Wendy Funk
*Age when you had ECT:	32
*Your gender:	Female
*Country:	Canada
State/Province if applicable:	BC
Where was ECT performed (if different than above):	Medicine Hat, Alberta
Number of ECTs, if known:	43
Type, if known:	Bilateral
Treatments/alternatives tried prior to ECT:	prozac for 10 days
Why was ECT prescribed (symptoms, diagnosis):	original diagnosis was sore throat with fever. After prozac I stopped eating and sleeping.
*Was your ECT:	Coerced
In what ways did ECT help you (short & long term):	none
What negative side effects, if any, did you experience:	memory loss for Everything prior. Kneecap was removed (and not replaced) due to dislocations resulting from ect. Heart valves are not good causing severely low blood pressure since ect.
If you felt harmed by	

ECT, what was the reaction of your doctor to your complaints: rolling of eyes and laughter

Do you still see the same doctor who administered your ECT: no

*Choose one to describe the effects of ECT on you: Greatly harmful

Would you willingly have ECT again, or recommend it to another: NO!

*In one sentence, sum up your thoughts on your ECT experience: ECT ect is a barbaric, humiliating, and dangerous procedure. It is not a medical treatment - but torture!

Email (optional): wendyf@telus.net

1st Person Project: Search Results

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Record 7 of 136

*Name:	george ebert
*Age when you had ECT:	28
*Your gender:	Male
*Country:	United States
State/Province if applicable:	NY
Where was ECT performed (if different than above):	ohio
Number of ECTs, if known:	15
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	they drugged me first
Why was ECT prescribed (symptoms, diagnosis):	they said I was paranoid schizophrenic
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	n/a
What negative side effects, if any, did you experience:	instant memory loss, loss of self, loss of hope, fear, confusion
If you felt harmed by	

ECT, what was the reaction of your doctor to your complaints: this is for your own good

Do you still see the same doctor who administered your ECT: he hid behind a white mask

*Choose one to describe the effects of ECT on you: Greatly harmful

Would you willingly have ECT again, or recommend it to another: no

*In one sentence, sum up your thoughts on your ECT experience: it showed me the extent of man's inhumanity and gave me mission to try to expose and stop it.

Email (optional): georgeebert@yahoo.com

Additional comments/your ECT story: contact me

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*Name:	Terry Grimes
*Age when you had ECT:	49 & 50
*Your gender:	Female
*Country:	United States
State/Province if applicable:	VA
Number of ECTs, if known:	16-18
Type, if known:	Unilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Just about all available appropriate pschotropic med, cognitive behavioral and talk therapy, inpatient hospitalization
Why was ECT prescribed (symptoms, diagnosis):	severe depression, suicidal urges, OCD with psychotic features, severe agitation and anxiety
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	I did not experience significant mood change until about 7 treatments. Then my view of life brightened and I was definitely not plagued by suicidal thoughts and urges not tormenting obsessive thinking . I completed a second course about a year later because of similar sytoms
What negative side effects, if any, did you	I really don't remeber any very uncomfortable side effects, certainly

experience: nothing like some of the effects of some meds I've taken. There was some initial confusion. I did not experience headache or severe memory loss due to the ECT. While I have experience memory loss due to dissociative state because of severe anxiety

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: I never felt harmed. I was given a thorough physical exam which included x-rays, an MRI (which was abnormal), a consult with a neurologist, a second confirming consult with another psychiatrist, full explanation of the procedure, a video to review and ample opportunity to think about my decision and have all my questions addressed as well as any concerns

Do you still see the same doctor who administered your ECT: Yes, see about him on my web site www.EFHM.com

*Choose one to describe the effects of ECT on you: Greatly beneficial

Would you willingly have ECT again, or recommend it to another: Definitely

*In one sentence, sum up your thoughts on your ECT experience: It saved my life, and offered an alternative treatment that was not nearly as invasive as I had imagined.

Email (optional): tgrimes@rbnet.com

Additional comments/your ECT story: I am glad that this treatment is available although I am concerned that due to certain perhaps misguided zealots it may not be considered by persons who could benefit greatly from the relief obtained. I am sorry that it is no longer used in VA state hospitals. I do believe if fully informed that people can make their own decision and should consider both the pluses and minuses, not just somebody's horror story from 20-30 years ago. We should do this with every treatment we consider. We

all know now how dangerous Freudian therapy can be for some of us. I am deathly allergic to GEODON. I look at ECT just as a treatment alternative, certainly no worse than depot haldol for some. As always, we need to be informed mental health consumers and use what we are comfortable with.

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*Name: peggy

*Age when you had ECT: 43? &55

*Your gender: Female

*Country: United States

State/Province if applicable: SD

Number of ECTs, if known: 26+

Type, if known: Bilateral

Voluntary/Involuntary patient at time of ECT: Voluntary

Treatments/alternatives tried prior to ECT: medication

Why was ECT prescribed (symptoms, diagnosis): major depression

*Was your ECT: Unsure/Other

In what ways did ECT help you (short & long term): In 80's - helpful, symptoms releived
This time disasterous

What negative side effects, if any, did you experience: Total loss of memory of my past except childhood, documented brain damage

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: Changed doctor after ECT - New one encourages me to sue for damages

Do you still see the same doctor who administered your ECT:

He was never my dr. - He never spoke to me

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NO

*In one sentence, sum up your thoughts on your ECT experience:

By the dr's lack of monitoring my cognitive changes, he has taken away the little bit of life I had remaining after my husband's death

Email (optional):

Pegsalt977@cs.com

Additional comments/your ECT story:

I was not seen by my regular psychiatrist while having the ECT on an outpatient basis, nor did the dr. doing them ever speak to me. Now I have no memory of the past 30-40- years of my life, have difficulty reading, have difficulty organizing, and can't find my way anywhere without written directions. I am unable to work as a nurse practitioner anymore. I have been tested extensively by a neuropsychologist and found to have extensive frontal and right sided brain damage. Even though there are many areas of my medical records that fall short of the standards set by the APA, I have run out of money trying to find a doctor willing to say the standards were breached. The dr. couldn't have killed me better if he had put a gun to my head!

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*Name: Sue Clark

*Age when you had ECT: 17

*Your gender: Female

*Country: Canada

State/Province if applicable: ON

Number of ECTs, if known: 5

Type, if known: Bilateral

Voluntary/Involuntary patient at time of ECT: Involuntary

Treatments/alternatives tried prior to ECT: psychiatric drugs

Why was ECT prescribed (symptoms, diagnosis): severe depression

*Was your ECT: Coerced

In what ways did ECT help you (short & long term): None

What negative side effects, if any, did you experience: I have a permanent short term memory loss as a result of having these ECTs. I had an 8 hour memory test done at a local Ottawa Hospital whereby it was established by the tests I do have a short term memory disorder. Some of my long term memory has also been affected to some degree.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

Just laughed and mocked me

Do you still see the same doctor who administered your ECT:

No

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

No

*In one sentence, sum up your thoughts on your ECT experience:

My ECT experience has had a negative effect on my life.

Email (optional):

sueclark2001@hotmail.com

Additional comments/your ECT story:

The ECTs were given to me against my will in 1973 at the age of 17. I had 5 ECTs given to me. I was supposed to have more series of the ECTs but it was discontinued as my heart stopped and I was revived on my 5th ECT. I was allergic to one of the medications given to me prior to having ECT.

I feel I was tortured against my will. The permanent damage by the short term memory loss has had a negative effect on my life. I find it difficult to learn anything new. Prior to having ECT, I had an good memory and no learning difficulties.

Many in the medical community are aware of the potential dangers of ECT and refuse to abolish ECT. I want ECT abolished now.

I don't want anyone to go through what I did. It is a crime against humanity. I was tortured in my own country, paid by the Ontario Ministry of Health. It is horrendous.

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*Name:	Emma Pierce
*Age when you had ECT:	24
*Your gender:	Female
*Country:	Australia
Number of ECTs, if known:	4-6?
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Chemo-therapy - Psycho Therapy
Why was ECT prescribed (symptoms, diagnosis):	diagnosed manic depressive
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	Loss of memory - let me in a state of 'unconcern'
What negative side effects, if any, did you experience:	Memory loss had its frightening side in the short term, and in the long term I still have occasions when I suddenly go blank and have to wait several seconds to remember where I am and what I'm doing. And I am now 58 years old.
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	The harm was only temporary, he said, and the long terms benefits were worth the short term 'inconvenience'!

Do you still see the same doctor who administered your ECT:

I do not see any doctor, nor have I taken any medication for some 30 years. I fully recovered by getting away from the medical model. My story has been told in a book published in 1986. The book is called "Ordinary Insanity", the first of 9 books writt

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

Never!!!

*In one sentence, sum up your thoughts on your ECT experience:

One human being taking a shot in the dark at the most sacred organ of another human being, violating human dignity in the process.

Email (optional):

epierce@brokenbay.catholic.org.au

Additional comments/your ECT story:

As I said, my story has been told in "Ordinary Insanity". As a result of my diagnosis, treatment and prognosis, I am now researching/studying to write my doctoral thesis "A Theology of Mental Health". Obviously my discipline is theology ... which has more comprehensive understanding of what it means to be human than any of the human sciences. At least, that has been my experience of recovery from mental illness ... and after some 30 years, I believe I can validly call it 'recovery'.

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*Name:	Grace Heckenberg
*Age when you had ECT:	17
*Your gender:	Female
*Country:	United States
State/Province if applicable:	OR
Where was ECT performed (if different than above):	Portland Oregon
Number of ECTs, if known:	6 (I think)
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	neuroleptic drugs
Why was ECT prescribed (symptoms, diagnosis):	Ostensibly for "paranoid schizophrenia" but probably more to diminish my memory of sexual contact with psychiatrist who prescribed it
*Was your ECT:	Physical force was used
In what ways did ECT help you (short & long term):	Have slight, vague memory of a period of head injury high lasting perhaps two weeks
What negative side effects, if any, did you experience:	The amnesia from ECT was TERRIFYING. I thought I was really going insane. Long term, the emotional trauma has led me to have great fear of

doctors and hospitals. And I'm bothered by the gaps in my memory. And it seems pretty clear that I lost some cognitive functioning. I feel very bitter about it.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

He pretended that he didn't order the ECT and didn't know it was going to be done to me. He called the doctor who did the procedure "The Mad Shocker" and fumed about it being done to me. But the doctor who actually shocked me wrote several times in his notes that he didn't believe it would help me and was only doing it at that doctor's request.

Do you still see the same doctor who administered your ECT:

NO!

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

It was a lesson in my lack of value in this society -- as was my entire experience of psychiatry. Such cruel things would not be done to people who are cared about.

Email (optional):

grace@pcez.com

Additional comments/your ECT story:

My ECT was not only involuntary but surprise ECT: I was told that I needed to spend a week in the hospital for medical tests, but when I arrived there was sent to a psych ward and involuntarily shocked. It's sort of like a little murder: They strap you down, force the rubber dam into your mouth, and then knock you unconscious with electricity to the head. If you weren't really traumatized before the experience, you will be afterwards, and if, like me, you were really traumatized beforehand, you'll need some luck to

survive after that as it will increase your pain and fear. The amnesia was the worst part. They can't really expect people who are so essentially uncared for that they wind up being shocked to have any sort of support in dealing with the memory loss. In my case, forced, surprise ECT was one of the main factors that led me to being sent for warehousing in a state hospital a couple months later.

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*Name: Liz Carter

*Age when you had ECT: 39

*Your gender: Female

*Country: United States

State/Province if applicable: FL

Number of ECTs, if known: 30

Type, if known: Bilateral

Voluntary/Involuntary patient at time of ECT: Voluntary

Treatments/alternatives tried prior to ECT: All antidepressants, they would work for a while and then stop working, I remained depressed with suicidal ideation.

Why was ECT prescribed (symptoms, diagnosis): Severe depression, suicide attempt, self harming behavior, lack of care of anything.

*Was your ECT: Completely my choice

In what ways did ECT help you (short & long term): First time it seemed to help the depression, got me out of the suicidal ideation. Less depression, was able to function. Lasted for about a year and then we had to go through another session which did not help, nor did the third.

What negative side effects, if any, did you experience: First off was memory problems, which I was led to believe would be temporary. My last ect was in 1997 and

my memory problems have progressively gotten worse. I started having severe daily headaches after my last treatment Dec 1997. Tests were run and nothing could be found. I was started on pain medication which eventually led to addiction

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

He said he could not say the headaches were caused by the ects, but that it had never been documented.

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NEVER, to both questions

*In one sentence, sum up your thoughts on your ECT experience:

The most horrible experience in my life.

Email (optional):

bettepod@yahoo.com

Additional comments/your ECT story:

I just wish I could get help. No one can help me and I still have daily headaches, and now that I have been labeled as an "addict" I can receive no medication to ease the pain. I am going through spinal blocks in my neck but they are not completely helpful. I feel they have ruined my life.

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*Name:	Karen
*Age when you had ECT:	31
*Your gender:	Female
*Country:	Australia
State/Province if applicable:	WA
Number of ECTs, if known:	49
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Anti-Depressants
Why was ECT prescribed (symptoms, diagnosis):	Nothing worked
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	none
What negative side effects, if any, did you experience:	huge memory loss, back to childhood
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	ect doesn't cause these problems

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

never

*In one sentence, sum up your thoughts on your ECT experience:

my life was taken from me, I have little recollection of anything

Email (optional):

karenrichardson@bigpond.com

Additional comments/your ECT story:

Myself and my husband were not informed that the memory loss could ever be anything like I experienced. I knew who my husband and children were, but knew nothing about them or us. I have lost all the years of the kids growing up, meeting my husband, getting married etc... We renewed our wedding vows 3 years ago because I didn't remember the wedding. I lost my career as a registered nurse, I can no longer work. I can only drive a car in the area where I live because I get so lost. I have found a new life with Jesus as my guide, my true Saviour, who set me free from the depression as no other Dr or the ECT could!!! This treatment should be totally banned, it destroys so much

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*Name:	Katey
*Age when you had ECT:	23
*Your gender:	Female
*Country:	United States
State/Province if applicable:	WI
Number of ECTs, if known:	5
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	over 25 times in psych wards
Why was ECT prescribed (symptoms, diagnosis):	suicidal, cutter, eating disorder, depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	I seem to be a little less depressed
What negative side effects, if any, did you experience:	I had a 15 minute seizure. They had trouble getting me out. I was in ICU for 2 days. I lost almost all memory.
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	they think it was at least worth a shot and I would have gotten worse if it was not done so it was ok.

Do you still see the same doctor who administered your ECT:

hell no!

*Choose one to describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

would recommend it to another but I would not do it again

*In one sentence, sum up your thoughts on your ECT experience:

it may have helped to get rid of some of the depression but it also caused some more cause of the severe memory loss.

Email (optional):

KTanAngel@aol.com

Additional comments/your ECT story:

I only had 5 shocks cause on my 5th I had a 15 minuter seizure. I was in ICU for 2 days. I mentally missed my mom's 50th birthday. I have lost my best feature (my memory) Hopefully I will get it back.

Thinking about suing the doctor. He did the ECT when my body was not in the condition to handle it. I had low electrolytes from my eating disoders.

My best friend had ECT so I knew what to expect but i did not expect to almost lose my life. But because of this I saw how my family would have been affected and I dont want to die and put them throught that. God used this horrible experiance and made good come out of it

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*Name:	Zetron
*Age when you had ECT:	20 to 27
*Your gender:	Male
*Country:	United States
State/Province if applicable:	IN
Where was ECT performed (if different than above):	same
Number of ECTs, if known:	140
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Not sure
Treatments/alternatives tried prior to ECT:	Psychotherapy, every antidepressant available
Why was ECT prescribed (symptoms, diagnosis):	endogenous depression with suicidal ideation
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	It saved my life.
What negative side effects, if any, did you experience:	Memory loss from 1962 to 1976, at various levels.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

ECT is safe.

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

Only to save my life.

*In one sentence, sum up your thoughts on your ECT experience:

The most horrible thing that CAN EVER happen to me.

Additional comments/your ECT story:

When the time came my name was called. I was required to defecate and urinate, I removed my belt, everything in my pockets and my shoes. In those last horrifying minutes before the doctor came I would say an act of contrition to God over and over again (once they caught me kneeling and doing this). During the treatment I was held down by the doctor, who worked alone behind a LOCKED door. From what I would hear and smell of the others treated before me I was able to figure out what was going on. I could hear the patient convulsing and then the deep gasps for air, then the smell of flatus. After the treatment I was able to walk out of the office on my own with some difficulty. It usually took a whole day in bed to recover. The headache was intense and many times I had a bitten tongue. A pschologist told me in 1995 that I had been tortured. I feel there is noone who I can relate with except maybe a Holocost survivor!!!!

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*Name:	lexie
*Age when you had ECT:	50
*Your gender:	Female
*Country:	United States
Number of ECTs, if known:	67
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	medication, therapy, hospitalization
Why was ECT prescribed (symptoms, diagnosis):	depression, self mutilation, borderline personality
*Was your ECT:	Coerced
In what ways did ECT help you (short & long term):	eased depression for 7-10 days at a time
What negative side effects, if any, did you experience:	memory loss, headaches, muscle aches
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	changed current and increased frequency of treatments
Do you still see the same doctor who administered your ECT:	yes

*Choose one to describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

yes

*In one sentence, sum up your thoughts on your ECT experience:

somewhat helpful but not completely helpful

Additional comments/your ECT story:

still in treatment. still attempted suicide during maintenance phase of treatment

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*Name:	kate
*Age when you had ECT:	18
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MO
Where was ECT performed (if different than above):	St. Louis, MO
Number of ECTs, if known:	7
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	a vast array of medications, including zyprexa, many anti-depressants and antipsychotics.
Why was ECT prescribed (symptoms, diagnosis):	"major depression". this diagnosis was modified after i began to display symptoms of mania, roughly six weeks after i withdrew from ECT treatments.
*Was your ECT:	Coerced
In what ways did ECT help you (short & long term):	it didn't. except that i didn't know what was going on around me for days and days, so i therefore didn't care.
What negative side effects, if any, did you experience:	vomiting, headaches (chronic migraines, onset roughly 2 months after discontinuation of ECT),

disordered thinking symptomatic of ADD, nervousness, paranoia.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

my doctor was reasonable about agreeing that ECT had done nothing to help me, and that i never was symptomatic of bipolar disorder or psychosis/mania until i had ECT.

Do you still see the same doctor who administered your ECT:

i occasionally see a psychiatrist in the same practice.

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NO!

*In one sentence, sum up your thoughts on your ECT experience:

i would have been better off seeking no psychiatric treatment in lieu of pursuing psychiatric treatment which rendered me sicker than i previously was.

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*Name:	eliza
*Age when you had ECT:	24, 28, 30
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MA
Number of ECTs, if known:	20
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	every medication under the sun
Why was ECT prescribed (symptoms, diagnosis):	severe depressions, suicide attempts and ideation
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	very brief periods of relief
What negative side effects, if any, did you experience:	severe retroactive amnesia/long term memory loss and confusion
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	"This is temporary; you'll feel just fine."

Do you still see the same doctor who administered your ECT: NO!

*Choose one to describe the effects of ECT on you: Greatly harmful

Would you willingly have ECT again, or recommend it to another: No!

*In one sentence, sum up your thoughts on your ECT experience: ECT provided very little relief and many terrible side effects.

Additional comments/your ECT story: I am not sure why I have made the decisions I have made. I was very sick, suicidally depressed and unable to see or understand the side effects of this barbaric treatment. The confusion and memory loss was so bad. To this day I have a very hard time with recall and other cognitive abilities. I wish I never had ECT.

I ask this question. Why would we treat an individual who suffers from epilepsy with anti-convulsant medication while at the same time treating an individual with depression with seizures?

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*Name:	Michele
*Age when you had ECT:	18 & 22
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MI
Where was ECT performed (if different than above):	Missouri
Number of ECTs, if known:	Over 40
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Psychotherapy, Drug Therapy
Why was ECT prescribed (symptoms, diagnosis):	Severe Major Depression, auditory hallucinations
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	Very short-term relief of depression
What negative side effects, if any, did you experience:	Scared me so much I decided I would deny symptoms after the ECTs were through. Had complete loss of memory for the entire year of 1995 in which over 30 of my ECTs were given.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

He denied that ECTs would cause long-term memory loss or brain damage.

Do you still see the same doctor who administered your ECT:

No way!

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

No

*In one sentence, sum up your thoughts on your ECT experience:

Having the ECTs was traumatizing every time I went and left me with no memory. Although it has some short term help of my depression, it was eventually discovered that my illness was dissociation -- which is not helped in the least by ECTs.

Email (optional):

DeafBornert@aol.com

Additional comments/your ECT story:

I had 9 ECTs at the age of 18 and over 30 more in 1995. I was finally diagnosed correctly with multiple personality disorder in 2001 and it was determined that the reason the ECTs didn't work was because my illness isn't the type to be helped by them. I got them for nothing.

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*Name:	Rick
*Age when you had ECT:	23
*Your gender:	Male
*Country:	United States
State/Province if applicable:	SC
Where was ECT performed (if different than above):	NJ
Number of ECTs, if known:	7
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	some therapy
Why was ECT prescribed (symptoms, diagnosis):	depression
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	It left me confused and disoriented in short term. Did not help in long term.
What negative side effects, if any, did you experience:	difficulty in concentration. Memory loss.
If you felt harmed by	

ECT, what was the reaction of your doctor to your complaints:

Was too confused to complain.

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

I have permanent brain damage from this "treatment".

Additional comments/your ECT story:

If it weren't so serious it would be funny. I can't believe they get away with this sham.

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*Name:	Sara
*Age when you had ECT:	13 and 14
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MN
Where was ECT performed (if different than above):	Minnesota
Number of ECTs, if known:	15 unilateral, and a few months later 8 bilateral
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Several antidepressants, and a few anti-psychotics, Several inpatient, and partial hospitalizations, talk therapy
Why was ECT prescribed (symptoms, diagnosis):	Severe depression, suicidal thoughts and attempts, self injury
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	Almost immediately became less depressed and suicidal, became much more hopeful about future
What negative side effects, if any, did you experience:	Temporary short term memory loss and disorientation, very tired after treatments, headaches

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

n/a

Do you still see the same doctor who administered your ECT:

I see the dr who prescribed it, but not the one who administered it

*Choose one to describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

Yes, as long as they fully understood the possible risks and benefits, I would definitely be willing to have it again

*In one sentence, sum up your thoughts on your ECT experience:

It kept me alive and gave me the best 3 months of my life, but the effects didn't last as long as hoped for

Email (optional):

Saire33@hotmail.com

Additional comments/your ECT story:

Without ECT I highly doubt I'd still be alive. And I don't regret having it at all. However the effects only lasted approximately 6 months after the first round (15 unilateral). So I went through another round (8 bilateral) which only lasted about 3 months. Because the effects weren't long lasting and because I'm younger than the majority of people who they treat with ECT (I'm now 15 years old) they have refused to use it on me again, even though it's the only thing that's helped me. My parents and I are still hoping to find a doctor who will agree to do maintenance ECT

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*Name:	t. b.
*Age when you had ECT:	16
*Your gender:	Male
*Country:	United States
State/Province if applicable:	NY
Number of ECTs, if known:	12-18
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Not sure
Treatments/alternatives tried prior to ECT:	psychotherapy
Why was ECT prescribed (symptoms, diagnosis):	depression
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	some short term,immediate relief
What negative side effects, if any, did you experience:	extreme amnesia,numbness,learning disabilities,antereograde amnesia
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	sign of my

Do you still see the same doctor who administered your ECT:

nope

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

absolutely not

*In one sentence, sum up your thoughts on your ECT experience:

ECT is a criminal ,money generating scam that has destroyed countless people and their loved ones,and is proof that psychiatric stigma is alive and well.

Email (optional):

sonnar35@aol.com

Additional comments/your ECT story:

I have to reteach myself the same things over and over, no matter how simple. I have had some sucess with a careeer, but the short-term and long term memory problems have made it quite an ordeal. Despite an above normal IQ, I cannot do simple things (like count backwards or remember sequences) I still suffer from Post Traumatic Stress Syndrome from the ordeal of not being warned of amnesia while being thrust back into high school. I was sent to a "snake pit" era State Institutuion with the the "knowledge" that I was "incurable " . I thought I was crazy because nobody believed my amnesia. I think that short of an outright ban, there should be post-shock rehab simular to what Brain Injury victoms recieve. No where else in the annals of Medicine is amnesia taken so lightly, due mostly I feel from the ongoing discrimination from psychiatric labels. In addition, there needs to be studies done on the psychological impact of induced amnesia and a subsequent therapy protocol.

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*Name:	Trado
*Age when you had ECT:	32/33
*Your gender:	Male
*Country:	United States
State/Province if applicable:	MN
Number of ECTs, if known:	45
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	6 different meds, hospitalization
Why was ECT prescribed (symptoms, diagnosis):	severe depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	got me out of depression temporarily
What negative side effects, if any, did you experience:	memory loss, huge memory loss.
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	necessary side effects to accomplish depression treatment

Do you still see the
same doctor who
administered your ECT:

yes

*Choose one to
describe the effects of
ECT on you:

Somewhat beneficial

Would you willingly
have ECT again, or
recommend it to
another:

depends on situation most likely yes

*In one sentence, sum
up your thoughts on
your ECT experience:

is saved my life but hard to live with
after affects

Email (optional):

muddlo@yahoo.com

Additional
comments/your ECT
story:

it was nessary but has made my life
harder to live because of memory
proplems. I would only use this
treatment as a last resort which was
my case

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*Name:	JoRob
*Age when you had ECT:	35-44
*Your gender:	Female
*Country:	United States
State/Province if applicable:	OH
Where was ECT performed (if different than above):	Toledo, Ohio and Ann Arbor, Michigan
Number of ECTs, if known:	four series-4-12 each series
Type, if known:	Unilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	every antidepressant medications legal in US and one from Canada, also psychotherapy
Why was ECT prescribed (symptoms, diagnosis):	severe depression, medication resistant
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	improved mood and function for months to one year
What negative side effects, if any, did you experience:	memory loss, concentration and overall cognitive function deficits

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: understanding but tended to believe problems were from depression not ect

Do you still see the same doctor who administered your ECT: yes

*Choose one to describe the effects of ECT on you: Greatly beneficial

Would you willingly have ECT again, or recommend it to another: willingly, yes, but with strong reservations

*In one sentence, sum up your thoughts on your ECT experience: I absolutely hate ect, but at four different times in my life, when death seemed prefereable to life, ect brought me back when nothing else did.

Additional comments/your ECT story: I have struggled with depression for twenty years. I have been on every antidepressant medication that exists. I have had four separate series of ect, the first about ten years ago and the most recent one year ago. I hate ect, despise it. I feel somewhat like I imagine a cancer patient must feel about chemotherapy. But ect brought me back from the abyss. I experienced memory loss, difficulty concentrating, and other cognitive problems. I still have these problems to some extent. All I know is that now when I wakeup in the morning I usually want to get up, and not want to die. I refused to have 'maintenance ect'.

I am blessed to have a wonderful doctor. She is a caring, compassionate, knowledgeable healer. I would, and have, trusted her with my life.

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*Name:	Jack Hunt
*Age when you had ECT:	20
*Your gender:	Male
*Country:	New Zealand
Number of ECTs, if known:	16
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	Medications
Why was ECT prescribed (symptoms, diagnosis):	Psychosis
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	It did not help me
What negative side effects, if any, did you experience:	Painful headaches
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	Indifference
Do you still see the same doctor who administered your ECT:	No

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

Never

*In one sentence, sum up your thoughts on your ECT experience:

An adventure of medical experimentation.

Additional comments/your ECT story:

This was performed at Lake Alice Hospital Marton New Zealand where many patients were physically sexually abused and tortured.

Former Patients are invited to write a short letter of complaint regarding their treatment at Lake Alice irrespective of years between 1960 to 1980 making this available for the

Lake Alice Hospital
"Patients Action Group"
POB 563 Bondi Junction NSW 1355.

These letters will be collected collated and decimated to certain media groups including selected newspapers, television non government organisations and the United Nations.

The objective being to bring pressure to bear so that fair and reasonable compensation be paid to all survivors of this abuse of ethical medical practice.

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*Name:	ELLARAY
*Age when you had ECT:	BTWN 18-44
*Your gender:	Female
*Country:	Zimbabwe
Number of ECTs, if known:	40+
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	DRUG THERAPY,PYSCHOTHERAPY
Why was ECT prescribed (symptoms, diagnosis):	SEVERE DEPRESSION/SUICIDE ATTEMPTS
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	I HAVEN'T OVERDOSED FOR SOME TIME NOW AND THE SUICIDAL FEELINGS ARE NOT AS CONSTANT, I'M MORE FUNCTIONAL THEN I WAS WHEN I COMMENCED TREATMENT
What negative side effects, if any, did you experience:	LOSE OF MEMORY,CONFUSION, DE JAVU,MUSCULAR PAIN,HEADACHES
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	DOCTOR IS SUPPORTIVE OF MY DESCISION TO TRY AND DO WITHOUT ECT
Do you still see the	

same doctor who administered your ECT:

YES

*Choose one to describe the effects of ECT on you:

Greatly beneficial

Would you willingly have ECT again, or recommend it to another:

YES

*In one sentence, sum up your thoughts on your ECT experience:

ONLY FOR USE IN DESPERATE SITUATIONS.

Additional comments/your ECT story:

I MAY HAVE TO TRY GOING ON A MAINTENANCE DOSE, HIGHEST INCENTIVE FOR AVOIDING TREATMENT AT THE MOMENT IS MY HOPE OF CHANGING MY EMPLOYMENT IN THE NEAR FUTURE.

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*Name:	Jacqui
*Age when you had ECT:	38
*Your gender:	Female
*Country:	United States
State/Province if applicable:	IA
Number of ECTs, if known:	7
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	Prozac, Zoloft
Why was ECT prescribed (symptoms, diagnosis):	Psychotic Episode
*Was your ECT:	Physical force was used
In what ways did ECT help you (short & long term):	It didn't, depression returned.
What negative side effects, if any, did you experience:	Headaches, Severe Memory Loss.
Do you still see the same doctor who administered your ECT:	No
*Choose one to	

describe the effects of ECT on you:

Greatly harmful .

Would you willingly have ECT again, or recommend it to another:

No.

*In one sentence, sum up your thoughts on your ECT experience:

Just a moneymaking scheme, very harmful.

Email (optional):

chmibauer@hotmail.com

Additional comments/your ECT story:

I have severe memory loss, I didn't even remember September 11, until my son told me about it.

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*Name:	Pat W.
*Age when you had ECT:	40
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MD
Where was ECT performed (if different than above):	Shephard Pratt, Baltimore Md
Number of ECTs, if known:	12
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	everything I could do I did
Why was ECT prescribed (symptoms, diagnosis):	treatment resistant depression, OCD, panic, anxiety
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	it helped for one year and I started to decline again
What negative side effects, if any, did you experience:	lost words, memory, concentration
Do you still see the	

same doctor who
administered your ECT: no done at a different hospital

*Choose one to
describe the effects of
ECT on you: Somewhat beneficial

Would you willingly
have ECT again, or
recommend it to
another: Yes, if I get as bad as I was before. I
would recommend it but it does not
work the same on every person, I was
lucky

*In one sentence, sum
up your thoughts on
your ECT experience: I cannot remember much, a little here
and there. I did not like the IV
everytime, otherwise I'd do it right now
without hesitation

Email (optional): kayak@friend.ly.net

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*Name:	Brit
*Age when you had ECT:	21 to 22
*Your gender:	Female
*Country:	United States
State/Province if applicable:	WI
Number of ECTs, if known:	I think like 12 or so
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	I tried *MOST anti-depressants, and when they didn't work, they put me on anti-psychotics with the AD's. They didn't work either. I was hospitalized 8 times and put in a mental institution all after being found cutting on myself.
Why was ECT prescribed (symptoms, diagnosis):	Major depression, PTSD, OCD, Suicidal ideation
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	I am still sad, but I know the difference between sad and depressed now. I feel more in control of my feelings.
What negative side effects, if any, did you experience:	I had/still have a little problem with my short term memory. And even a tinier bit with my long term. I hate forgetting peoples names that i haven't seen in a long time, something I have never had

a problem with before.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: Last time I was to have a treatment, I freaked out on the table right before, and the doctor was completely supportive that I didn't want it even though the nurses thought I was just being stupid. He had to tell them to take out my IV and let me go.

Do you still see the same doctor who administered your ECT: I see the doctor who helped me into ECT, not the Dr. that gave the treatments to me.

*Choose one to describe the effects of ECT on you: Greatly beneficial

Would you willingly have ECT again, or recommend it to another: Yes, I would. Others I would try to inform them of the bad sides as well as the good to the best of my ability.

*In one sentence, sum up your thoughts on your ECT experience: If/When my depression comes back, I would have it again.

Email (optional): crzybth2@yahoo.com

Additional comments/your ECT story: I had a series when I was 21. I felt great afterwards, but slowly the depression started creeping back in. That led to another series at 22, and with the possibility of "maintenance ECT". I am still 22 at this point, and I am still waiting for my depression to come back again before I get more interested in getting a treatment once a month. I will get one once a week for a month or so, then the once a month for an undetermined period. I don't know why I freaked out. Some people might think something inside of me was telling me something, but I think I just want support. Depression is a hard thing for me to deal with. I have battled with it since I was 12ish. I do have more of a story.... but I don't wanna bore you more. Sorry for this being SOOOO long. Email me if you wanna talk.

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*Name:	Angie
*Age when you had ECT:	37
*Your gender:	Female
*Country:	Australia
Where was ECT performed (if different than above):	Calvary Hospital Canberra
Number of ECTs, if known:	15
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Prozac, Dothiepen, Cipramil, Exffor, many others
Why was ECT prescribed (symptoms, diagnosis):	Post Tramatic Stress
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	It didn't help, only made it worse by loosing my memory
What negative side effects, if any, did you experience:	Memory loss and confusion
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	Totally ingored my questions about it, treats me like I know nothin..

Do you still see the same doctor who administered your ECT:

Yes

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

No never

*In one sentence, sum up your thoughts on your ECT experience:

Disgusting, I wouldnt wish it to my worst enemy

Email (optional):

snookie@bigpond.net.au

Additional comments/your ECT story:

It has distroyed my life, I can't remember anything anymore... I can't even work....

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*Name:	Maria
*Age when you had ECT:	20
*Your gender:	Female
*Country:	United Kingdom
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	psychotherapy, antipsychotics, antidepressants
Why was ECT prescribed (symptoms, diagnosis):	psychotic depression, borderline personality disorder
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	lifted my depression initially
What negative side effects, if any, did you experience:	memory loss, 'zombie' feeling - even now
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	laughter
Do you still see the same doctor who administered your ECT:	yes
*Choose one to describe the effects of	Somewhat beneficial

ECT on you:

Would you willingly
have ECT again, or
recommend it to
another:

NO

*In one sentence, sum
up your thoughts on
your ECT experience:

Helpful initailly, but has taken away
many memories. Still feel like a zombie
even today in many ways

Additional
comments/your ECT
story:

I was taken into hospital against my
will and told that if I didn't agree to
'treatment', then a court order would
be obtained and I wouldn't have a
choice. I agreed. Although I think it
helped me initially, I'm left now with
memory loss and often feel displaced
from my feelings, surroundings, life and
emotions. I don't know if this is a result
of having had ect, I just feel my
emotions have been dampened down,
numbed. I'm sure it has been helpful
for many people and perhaps even
saved lives with an immeadiate threat
of suicide for example. I think for
myself though, the long term effects
have outweighed the short term effects.
I believe, for me anyway, it's caused
more harm then good.

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*Name:	Lisa
*Age when you had ECT:	33
*Your gender:	Female
*Country:	United States
State/Province if applicable:	GA
Number of ECTs, if known:	11
Type, if known:	Unilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Prozac, Welbutrin, Effexor, Celexa
Why was ECT prescribed (symptoms, diagnosis):	Major Depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	Short Term it relieved the depression. No more feelings of guilt for being alive and am not crying all the time.
What negative side effects, if any, did you experience:	Extreme confusion, major memory loss-continued, headaches, not able to cry, panic attacks,
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	"it will clear up with time" and basic ignoring of my concerns

Do you still see the same doctor who administered your ECT:

NO!!!!!!

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

NO!!!!

*In one sentence, sum up your thoughts on your ECT experience:

While it did accomplish what was intended, I wish I had NEVER done that to my brain.

Email (optional):

lisa1bug@aol.com

Additional comments/your ECT story:

I don't know how many were planned and I can't imagine what my personallity would be like with any more than the 11 I endured. It has been 3 weeks since my last treatment. I still get lost in the grocery store, I can't remember people, locations, directions or instructions. I wish I would have had a second opinion and thought a little longer about what I was doing to my brain but at the time I was really in no condition to be making decisions about myself. In the long run, my husband feels there are positives that I do not acknowlege because he see's a big positive change in not being depressed. He doesn't feel or understand the frustration that goes with the confusion, the memory loss, the inability to think! So to him, it was all worth it. To me it wasn't.

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*Name:	Horizon
*Age when you had ECT:	19
*Your gender:	Female
*Country:	Turkey
Number of ECTs, if known:	6
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Psychotherapy, anti-depressants
Why was ECT prescribed (symptoms, diagnosis):	Major depression, suicidal ideation
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	It didn't help me at all, i even got "more" suicidal afterwards.
What negative side effects, if any, did you experience:	Mild memory loss: I still can't remember things like books I read and things I did before the treatment. I have difficulty concentrating too.
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	I didn't complain...
Do you still see the same doctor who	No

administered your ECT:

*Choose one to describe the effects of ECT on you:

Neither beneficial nor harmful

Would you willingly have ECT again, or recommend it to another:

I don't know... maybe i would.

*In one sentence, sum up your thoughts on your ECT experience:

I still don't understand why it hasn't done anything for me.

Email (optional):

horizontina@thefragile.com

Additional comments/your ECT story:

I am now 21 years old and still having therapy and medication. Nothing seems to work, i don't know what to do anymore.

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*Name:	Cindy
*Age when you had ECT:	39
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MN
Number of ECTs, if known:	10+
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	drugs, psychotherapy (i think)
Why was ECT prescribed (symptoms, diagnosis):	dr told husband that this was the last resort
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	helped me out of serious depression. doctor thought it was my only chance left
What negative side effects, if any, did you experience:	short term memory loss, confusion, long term memory loss, inability to concentrate
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	he said it was a side effect of the treatment

Do you still see the same doctor who administered your ECT:

sort of

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

not sure

*In one sentence, sum up your thoughts on your ECT experience:

it saved my life - but now i have half memories of that life

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*Name:	Thomas
*Age when you had ECT:	52
*Your gender:	Male
*Country:	United States
State/Province if applicable:	IL
Number of ECTs, if known:	5
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Zoloft, Paxil, Serzone, Effexor, Valium, and many hours of therapy with several therapists
Why was ECT prescribed (symptoms, diagnosis):	Major Depression
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	No help at all
What negative side effects, if any, did you experience:	Significant memory loss Significant memory impairment
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	Suggested to allow time for memory to recover

Do you still see the same doctor who administered your ECT:

Yes

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NO and NO

*In one sentence, sum up your thoughts on your ECT experience:

Biggest disappointment of my life

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*Name:	G. Christiane Starks
*Age when you had ECT:	24
*Your gender:	Female
*Country:	United States
State/Province if applicable:	NH
Where was ECT performed (if different than above):	Beth Israel Hospital, Boston, MA
Number of ECTs, if known:	6
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Antidepressants
Why was ECT prescribed (symptoms, diagnosis):	Severe depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	ECT relieved my depression for one whole WEEK
What negative side effects, if any, did you experience:	Permanent memory loss; confusion; inability to concentrate
If you felt harmed by	

ECT, what was the reaction of your doctor to your complaints:

The side effects will go away 'soon'.

Do you still see the same doctor who administered your ECT:

No

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NO

*In one sentence, sum up your thoughts on your ECT experience:

ECT erased most of my college degree, my memory of high school and college friends, and has left me with day-to-day memory loss and the inability to concentrate.

Email (optional):

gcstarks@attbi.com

Additional comments/your ECT story:

Before ECT, one of my goals was to return to B.U. for a Master's Degree. I became severely depressed. After I was quite desperate, I agreed to ECT. After 6 treatments my brains felt so 'scrambled'. The doctors assured me that this feeling would be temporary. I refused further treatments and was sent home. At home I was generally 'confused'. My attention span was short, and my memory was poor. Today is 8 years later. I have been in touch with persons who claim to have been good friends with me at one time - but I don't remember them. I will never work as an Engineer again. I have a Boston University diploma - class of 1991 - that is on paper only. When I am asked to describe my experience, my state of mind, this is what I tell people:
Take a brand new jigsaw puzzle, shake the box vigorously to thoroughly mix all of the pieces, then remove a random hand full of pieces and throw them away. Now try to put the puzzle back together.

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*Name:	pam
*Age when you had ECT:	14-18
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CA
Number of ECTs, if known:	60
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	this was done in a state hospital in the 1950's
Why was ECT prescribed (symptoms, diagnosis):	to control behavior in
*Was your ECT:	Physical force was used
In what ways did ECT help you (short & long term):	none as i was not really
What negative side effects, if any, did you experience:	loss of most childhood memories and continued difficulty with concentration and retention
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	they didn't care, we were kids under their complete control

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

Never/No unless it was a life or death situation for someone so gravely mentally ill taht it was truely a last resort attempt to restore them to a functioning level

*In one sentence, sum up your thoughts on your ECT experience:

it was inhumane and given without regard for my overall well being and used as a punishment and a control over emotionally disturbed kids who were not

Email (optional):

itspk@aol.com

Additional comments/your ECT story:

I am 58 year old woman and am just now begining to be able to speak openly about my experiences 45 years ago in a state mental hospital. My first series of 20 ECT was given when i was only 14, and in many ways i was arrested there in time and my "essence" my way of being in the world is still 14. There is not enough room here for me to tell you how this has affected my life. If anyone is interested, email me .

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*Name:	bhagel
*Age when you had ECT:	48, 50
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CT
Where was ECT performed (if different than above):	New Haven, Bridgeport CT
Number of ECTs, if known:	28 total
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	many hospitalizations, almost every antidepressant available
Why was ECT prescribed (symptoms, diagnosis):	suicidal depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	I have severe memory loss--i don't remember any of my oldest daughter's accomplishments during her senior year, etc., short term confusion was very difficult to deal with--i've had them twice and still can't get over the initial confusion and how rottenly that affects my life

What negative side effects, if any, did you experience:	confusion, memory loss, difficulty in speaking
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	he continues to believe that the ects are what
Do you still see the same doctor who administered your ECT:	different doctor from my usual administered my ects, so no
*Choose one to describe the effects of ECT on you:	Somewhat beneficial
Would you willingly have ECT again, or recommend it to another:	don't know
*In one sentence, sum up your thoughts on your ECT experience:	My feelings about ect are ambivalent.
Additional comments/your ECT story:	The memory loss i have experienced has been devastating. However, after the second series last December, i experienced the feeling of pure happiness for the first time in my adult life. was it the ects or the combination of three different antidepressants? I don't know. I do know that i am feeling derpressed again and my doctor has once again recommended ects because the "bring me back."

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*Name:	Josephine
*Age when you had ECT:	35 and 51
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CA
Number of ECTs, if known:	12 and 17
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	numerous meds, psychotherapy
Why was ECT prescribed (symptoms, diagnosis):	suicidality' double refractory depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	I'm still alive
What negative side effects, if any, did you experience:	severe present, short & long term memory impairments and cognitive deficits
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	initially claimed my cognitive deficits and memory impairments were due to dissociation

Do you still see the same doctor who administered your ECT:

yes

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

It might have been more beneficial to just be in hospital protected environment to prevent suicide.

Email (optional):

mjy688@cs.com

Additional comments/your ECT story:

I have such severy memory and cognitive impairments I am unable to perform my chosen profession and fear that I may never be able to resume that work. The ECT did not help my basic depression, it just dealt w/immediate crisis probably by making me so out of it I couldn't have committed suicide for about 1 month. Then suicidality and severe depression returned and has stayed. I had forgotten that ECT did not work for me during my round in 1985 or was just so suicidal I was convinced/pressured to do it again in 2001. I should have never done it again.

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*Name:	thomas mack
*Age when you had ECT:	42
*Your gender:	Male
*Country:	United States
State/Province if applicable:	CA
Where was ECT performed (if different than above):	northridge, california
Number of ECTs, if known:	13
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Psychotherapy and at one time or another all the various types of psychopharmaceuticals and I mean all; lithium, tricyclics, mao, major and minor tranquilizer, ssri's, and anti-convulsants.s
Why was ECT prescribed (symptoms, diagnosis):	manic depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	It would be difficult to say that it helped me without stretching the definition of remedy. During the course of the treatment and for several weeks following I had too little short term

memory to feel much of anything. But then as my cognitive function improved I immediately fell back into my usual rollercoaster mood cycles. having a full-bl

What negative side effects, if any, did you experience:

I have a memory gap extending back roughly eighteen months prior to the first treatment. I also experienced a decline in my language skills though within a year they were gradually recovered.

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

Totally dismissive, patronizing.

Do you still see the same doctor who administered your ECT:

No. I was referred to him by a psychiatrist I'd been seeing for two years and only met with him once before the first treatment and never after.

*Choose one to describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

absolutely not

*In one sentence, sum up your thoughts on your ECT experience:

Dreadful

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*Name:	Tina Brooks
*Age when you had ECT:	22
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MI
Where was ECT performed (if different than above):	Pine Rest in Grand Rapids, MI
Number of ECTs, if known:	8
Type, if known:	Unilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Therapy, Medications
Why was ECT prescribed (symptoms, diagnosis):	Severe Depression, Anxiety, didn't respond to medication
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	It's only been a couple weeks since my last one, so short term has been frustrating because of confusion and memory loss. But I don't feel I have depression at all.
What negative side effects, if any, did you experience:	Confusion, memory loss (short and long term), migraines, throwing up constantly after treatment

Do you still see the same doctor who administered your ECT:

various dr.'s did it, so no

*Choose one to describe the effects of ECT on you:

Greatly beneficial

Would you willingly have ECT again, or recommend it to another:

yes

*In one sentence, sum up your thoughts on your ECT experience:

I would do it again in a heartbeat!

Email (optional):

spanky@wmis.net

Additional comments/your ECT story:

I'd do this again in a heartbeat! I wanted to die anyway, so I hoped it either would work, kill me, or make me a vegetable. And I can't believe the difference! My mother, husband and friends all keep telling what a great difference there is. Only complaint is, very frustrating with the memory loss. Can't rememeber a question right after it is asked and if I do, I can't comprehend it. Like someone speaking another language. Can't drive, forget to watch the road. Can't watch television, forget to watch it and just stare down at the carpet. Some long term memory is coming back, but short term is very rough. Also, first treatment they over did the electricity and my seizure lasted over 2 minutes. I don't remember though, the nurses told my husband. Feel free to e-mail me.

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*Name:	caroline
*Age when you had ECT:	56
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MI
Number of ECTs, if known:	9
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	all meds and therapies for major depression
Why was ECT prescribed (symptoms, diagnosis):	last resort
*Was your ECT:	Completely my choice
What negative side effects, if any, did you experience:	short term memory loss getting worse, ability to remember how to do tasks
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	not taken seriously
Do you still see the same doctor who administered your ECT:	yes

*Choose one to describe the effects of ECT on you: Greatly harmful

Would you willingly have ECT again, or recommend it to another: no

*In one sentence, sum up your thoughts on your ECT experience: blank spot in life, no memories of what happened in those two weeks

Additional comments/your ECT story: Have others experienced the same side effects as I have? I forget everything even when written down and displayed. My ability to think a project through and remember is gone. Don't cook, cannot remember how. miss appointments even when reminded. Life altering experience and very scary and frustrating. Definitely made depression worse.

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*Name:	Leanne
*Age when you had ECT:	21
*Your gender:	Female
*Country:	Canada
State/Province if applicable:	ON
Number of ECTs, if known:	18
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	medications
Why was ECT prescribed (symptoms, diagnosis):	treatment resistant bi-polar
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	short term relief, it did not last long
What negative side effects, if any, did you experience:	memory loss. still have problems with memory loss to this day.
Do you still see the same doctor who administered your ECT:	no
*Choose one to	

describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

yes

*In one sentence, sum up your thoughts on your ECT experience:

ect can be a valuable tool when other treatments failed , but the final decision MUST be left to the patient

Additional comments/your ECT story:

thanks to muscle relaxants and short term anesthetics the procedure itself was not that bad but i remember feeling awful after the treatment when i woke up. it did help but it was short term. i do not think i would have it again but you never know, if i feel bad enough i might consider it again

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*Name:	DENISE M.
*Age when you had ECT:	33
*Your gender:	Female
*Country:	United States
State/Province if applicable:	VA
Where was ECT performed (if different than above):	Salem,va
Number of ECTs, if known:	17 I think????
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	therapy for number of years, medication, hospitalizations, you name it weve tried it
Why was ECT prescribed (symptoms, diagnosis):	DEPRESSION, SUICIDAL ATTEMPTS AND TENDENCIES, NOTHING ELSE LEFT TO TRY
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	ECT HELPED ME FOR ABOUT 14 DAYS UNTIL I HAD THE LAST ONE NOW IT ONLY HELPED FOR ABOUT A WEEK OR LESS.
What negative side effects, if any, did you experience:	I DO NOT KNOW WHO I AM ANYMORE, I CANT REMEMBER PARTS OF MY LIFE, I CANT READ SOMETHING AND

REMEMBER IT FIVE MINUTES LATER, MY CHILDREN GET UPSET BECAUSE I DO NOT REMEMBER EVENTS OF THERE LIVES, I SEE THINGS AT THE CORNER OF MY EYES THAT ARE NOT THERE AND IT SCARES ME. I HAVE TO WRITE DOWN ALL APPT FOR ME AND MY FAMILY BECAUSE FROM ONE DAY TO THE

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

YOUR MEMORY WILL RETURN IN TIME OR ON A GOOD VISIT HE WOULD SAY THAT IS JUST A SIDE EFFECT OF ECT. WHICH HE DIDNT TELL ME BEFORE I HAD IT DONE

Do you still see the same doctor who administered your ECT:

MY DOCTOR IS BLIND, HIS COLLEGE IS THE ONE WHO ADMINISTERED THE TREATMENTS

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NOT NOW AFTER I HAVE READ OTHER TESTIMONIES, I THOUGHT I WAS LOOSING MY MIND NOW I SEE THAT IT IS NORMAL WHAT I AM GOING THRU

*In one sentence, sum up your thoughts on your ECT experience:

I FEEL DOCTORS NEED TO TELL ALL THE RISKS OF ECT AND THAT IT IS HARMFUL TO YOUR BRAIN

Email (optional):

KCMDLM@AOL.COM

Additional comments/your ECT story:

MY DEPRESSION HAS GOTTEN WORSE SINCE THE ECTS, NOW I AM DEPRESSED AND CONFUSED ABOUT THINGS IN MY LIFE. I WOULD LIKE TO TALK TO OTHER PEOPLE WHO HAVE HAD THEN DONE AND ARE EXPERIENCING SIMILAR SIDE EFFECTS. I FEEL ALONE AND SCARED.

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*Name:	David
*Age when you had ECT:	33
*Your gender:	Male
*Country:	United States
State/Province if applicable:	CA
Number of ECTs, if known:	12
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	medications
Why was ECT prescribed (symptoms, diagnosis):	depression
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	none, didn't work
What negative side effects, if any, did you experience:	memory loss, get lost all the time, headaches
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	Ignored me completely

Do you still see the
same doctor who
administered your ECT:

NO

*Choose one to
describe the effects of
ECT on you:

Greatly harmful

Would you willingly
have ECT again, or
recommend it to
another:

NO WAY

*In one sentence, sum
up your thoughts on
your ECT experience:

It sucked!

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*Name:	JJ
*Age when you had ECT:	38
*Your gender:	Female
*Country:	United States
State/Province if applicable:	AZ
Number of ECTs, if known:	unkown
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Not sure
Treatments/alternatives tried prior to ECT:	hospitalizations, involuntary commitment, various medications
Why was ECT prescribed (symptoms, diagnosis):	Severe depression. I had had an involuntary commitment because I am a diabetic and I refused to eat. I was in my third hospitalization in six weeks.
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	It did help the depression. I had been off SSD (Social Security Disability) and working full time for four years at the time, but I was preparing to apply to go back on SSD. I ended up being able to return to work.
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	Memory Loss

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly beneficial

Would you willingly have ECT again, or recommend it to another:

I'm not sure. The circumstances would have to be pretty severe. ECT is not a treatment to be undertaken lightly.

*In one sentence, sum up your thoughts on your ECT experience:

I have mixed feelings about this very strange and life changing experience.

Additional comments/your ECT story:

I am very frustrated about my memory. I returned to my job immediately after finishing the treatment. I didn't tell my co-workers I had ECT and I find it very frustrating and embarrassing that I don't remember some things I should know. Also, I have no memory of my relationship with my girlfriend prior to the ECT. That is very frustrating. I don't know what to say when she brings up something I have absolutely no memory of. I spend a lot of time pretending I remember things I don't know anything about.

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*Name:	Paul
*Age when you had ECT:	37
*Your gender:	Male
*Country:	United States
State/Province if applicable:	CA
Where was ECT performed (if different than above):	Sutter Center for Psychiatry, Sacramento
Number of ECTs, if known:	21
Type, if known:	Mixed
Voluntary/Involuntary patient at time of ECT:	Involuntary
Treatments/alternatives tried prior to ECT:	lithium nardil... previously numerous anti-depressants, mood stabilizers, and anti-psychotic medications.
Why was ECT prescribed (symptoms, diagnosis):	bipolar disorder, severe depressive episode (stopped eating).
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	It brought me out of my depression.
What negative side effects, if any, did you experience:	I can't remember very much of the 5-7 years previous to the ECT, I couldn't drive for a year because I was too afraid and would get lost, I couldn't

read a book for 3 years without falling asleep (I'm still having these difficulties), I've had difficulty making plans and remembering them, my short term memory was extremely poor for 3 years

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:

Dr. Goodman wanted to give me more ECT treatments.

Do you still see the same doctor who administered your ECT:

no

*Choose one to describe the effects of ECT on you:

Greatly harmful

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

Short term effect at the expense of long term memory and concentration issues resulting in a dependence upon disability income.

Additional comments/your ECT story:

I was diagnosed with bipolar disorder 20 years ago. Before ECT, I'd worked and/or went to school. I've been on disability since.

Previous to the ECT, I read the AMA reference book about ECT. It did not address many of the short term nor any of the long term side effects of the ECT that I experienced.

I feel the HMO promoted ECT (an outpatient treatment) rather than hospitalization.

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*Name:	Patricia
*Age when you had ECT:	50
*Your gender:	Female
*Country:	United States
State/Province if applicable:	NY
Number of ECTs, if known:	6
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	many different antidepressants
Why was ECT prescribed (symptoms, diagnosis):	severe depression
*Was your ECT:	Completely my choice
In what ways did ECT help you (short & long term):	not sure
What negative side effects, if any, did you experience:	terrible breaks in time, memory problems
Do you still see the same doctor who administered your ECT:	no
*Choose one to	

describe the effects of ECT on you:

Somewhat harmful

Would you willingly have ECT again, or recommend it to another:

probably not

*In one sentence, sum up your thoughts on your ECT experience:

It was my last hope, it didn't help, it ruined my memory

Email (optional):

pkelley922@aol.com

Additional comments/your ECT story:

After trying it as a last hope and having it not work, I just want to die. What is there left for me? Medications haven't worked, I am incapable of maintaining relationships, jobs, etc.

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*Name:	ALI
*Age when you had ECT:	33
*Your gender:	Male
*Country:	United Kingdom
Where was ECT performed (if different than above):	UK. SCOTLAND
Number of ECTs, if known:	10
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	TRICYCLICS,MAOI, LITHIUM
Why was ECT prescribed (symptoms, diagnosis):	TREATMENT-RESISTIVE DEPRESSION
*Was your ECT:	Coerced
In what ways did ECT help you (short & long term):	MODERATLY SUCESSFUL WITH DEPRESSION, EFFECTIVE ON AGITATION/ AGGRESSION AND SELF-HARM.
What negative side effects, if any, did you experience:	MEMORY OF THE PERIODS BEFORE, DURING AND AFTER ARE VERY SKETCHY (approx 1 year). SEVERE HEADACHES AND CONFUSION POST-TREATMENT.
Do you still see the	

same doctor who administered your ECT:

YES

*Choose one to describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

I WOULD CONSIDER TREATMENT IF SEVERE ENOUGH.

*In one sentence, sum up your thoughts on your ECT experience:

MODERATELY HELPFUL BUT SCAREY AND A LAST RESORT.

Additional comments/your ECT story:

I HAD TO BE CONVINCED TO GO AHEAD WITH ECT. IWAS ALLOWED TO VISIT THE ECT SUITE AND SPEAK TO THE ECT NURSE PRIOR TO TREATMENT. I FOUND THIS HELPED TO MAKE MY DESISION AND WOULD RECOMMEND THIS PRACTICE.

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*Name:	Joan Spurling
*Age when you had ECT:	49
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CA
Number of ECTs, if known:	60+
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	medications, therapy
Why was ECT prescribed (symptoms, diagnosis):	suicidal depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	less depression
What negative side effects, if any, did you experience:	short and long term memory loss
If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	distressed

Do you still see the
same doctor who
administered your ECT:

No

*Choose one to
describe the effects of
ECT on you:

Greatly harmful

Would you willingly
have ECT again, or
recommend it to
another:

No

*In one sentence, sum
up your thoughts on
your ECT experience:

ECT was the worst mistake of my life

Email (optional):

spurmom@attbi.com

Additional
comments/your ECT
story:

Ect cost me my job and the memory of
most of my life, including my kids'
growing up.

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*Name:	K
*Age when you had ECT:	20
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CT
Number of ECTs, if known:	Can't remember
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Involuntary
Why was ECT prescribed (symptoms, diagnosis):	Depression after a rape and forced abortion
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	It didn't help at all
What negative side effects, if any, did you experience:	Significant (nearly total) memory loss for life before ECT
Do you still see the same doctor who administered your ECT:	No, he was disbarred
*Choose one to	

describe the effects
of ECT on you:

Greatly harmful

Would you willingly
have ECT again, or
recommend it to
another:

No

*In one sentence,
sum up your
thoughts on your ECT
experience:

It left me as a shell - I still have no real
identity

Additional
comments/your ECT
story:

I had my treatment some 28 years ago.
My parents signed the papers - I had no
choice. They had forced me to have an
illegal abortion after a rape - anyone
would have been depressed.

Now I am left with few memories before
that time and no remembered references
as to who I am. My family have tried for
years to help me remember but
everything is still a blank.

I have an IQ of 157, yet I will look at
something and not remember the word
for what it is.

I feel like a shell, a husk of an individual
without my memories. I feel angered that
the medical professional still use ECT.
Perhaps a taste of their own medicine
would convince them of the devastation it
can cause. If they are unwilling, then
perhaps they will give me back my
memories!

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*Name: joy2friends

*Age when you had ECT: 22

*Your gender: Female

*Country: United States

State/Province if applicable: WI

Where was ECT performed (if different than above): University of Wisconsin Hospital

Number of ECTs, if known: 6

Type, if known: Bilateral

Voluntary/Involuntary patient at time of ECT: Involuntary

Treatments/alternatives tried prior to ECT: all types of anti-depressants: SSRI,

Why was ECT prescribed (symptoms, diagnosis): severe depression

*Was your ECT: Pressured by others

In what ways did ECT help you (short & long term): short term: it did liberate my spirit. A long lost self was so strange and phenonmenonal. But, relapse two weeks right after the treatments. The adverse effects were so much more pain and were understated.

What negative side effects, if any, did you: nauseated, non stop vomitting throughout the day of every treatment,

experience: violent headache and memory loss

If you felt harmed by ECT, what was the reaction of your doctor to your complaints: i asked right before admission. I was told there are minimal side effects and they would go away

Do you still see the same doctor who administered your ECT: no

*Choose one to describe the effects of ECT on you: Greatly harmful

Would you willingly have ECT again, or recommend it to another: i probably would like to try it again if situation doesn't improve and my memory loss is already here. Seem like nothing to lose, but, i definitely won't recommend to others.

*In one sentence, sum up your thoughts on your ECT experience: Be more educated about ECT, don't let your doctor lure you into anything, and be prepared for the consequence that can sink you right back into the first desperate place you were in.

Email (optional): joy2friends@hotmail.com

Additional comments/your ECT story: I definitely recommend not to jump into the ECT options even recommended by your healthcare provider(S).

It was during one of my sessions that my psychiatrist refers me to the ECT option. She admitted me into the hospital right away. I was told minimal adverse effects and they are temporary.

Now, I ended up with \$16k medical bills not covered by insurance. They told me it would only cost \$5k. Talk about health "CARE", ha! The terrible vomiting and violent headache after each session and permanent behavioural change, my temper got worst. Worst of all, Irreversible memory loss, which jeopardize my academic career.

Now, I am forced to drop out of college with enough debts to put my life and anything worth living for behind.

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*Name:	Lyn
*Age when you had ECT:	21
*Your gender:	Female
*Country:	United Kingdom
Number of ECTs, if known:	6
Voluntary/Involuntary patient at time of ECT:	Not sure
Treatments/alternatives tried prior to ECT:	Anti depressants
Why was ECT prescribed (symptoms, diagnosis):	Attempted suicide
*Was your ECT:	Unsure/Other
What negative side effects, if any, did you experience:	Long term memory loss, large chunks of my memory still missing 25 years on.
Do you still see the same doctor who administered your ECT:	No
*Choose one to describe the effects of ECT on you:	Somewhat harmful
Would you willingly have ECT again, or recommend it to another:	No
*In one sentence, sum	

up your thoughts on
your ECT experience:

Total waste of time and electricity!

Additional
comments/your ECT
story:

It was not explained to me what the long term effects of ect would be. I still suffer with depression. I did not realise how bad my memory loss was because obviously you do not know that you have forgotten large chunks of your life. I am now 46 and in the last couple of years, memories I did not know I had lost are beginning to come back. I feel ect is quite barbaric and in this day and age when new drugs and therapies are being discovered all the time, it should be banned. In another 50 years children in their history classes will look back with amazement that we did this to each other!

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*Name:	David Greer
*Age when you had ECT:	45
*Your gender:	Transgendered
*Country:	United States
State/Province if applicable:	NC
Type, if known:	Bilateral
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	drugs, therapy
Why was ECT prescribed (symptoms, diagnosis):	Nothing else stopping the rapid cycling
*Was your ECT:	Coerced
In what ways did ECT help you (short & long term):	cycling stopped for about 6 weeks
What negative side effects, if any, did you experience:	Massive memory loss, both long and short term
Do you still see the same doctor who administered your ECT:	HELL NO!!
*Choose one to describe the effects of ECT on you:	Greatly harmful

Would you willingly have ECT again, or recommend it to another:

NEVER -----EVER .

*In one sentence, sum up your thoughts on your ECT experience:

Mislead, Misinformed, misjudged = Massive permanent Memory LOSS!!

Email (optional):

ncdg55@att.net

Additional comments/your ECT story:

I wrote over the 1000 word limit about the negative costs of ECT. Short version. I have massive loss of both long and short term memory. Memories of my children growing up--gone. My marriage over 6 weeks ago---gone. What I did over 6 weeks ago--gone. My self esteem, my self respect and the respect I used to have from others--gone or replaced by pity. I have been reduced to being disabled and unemployable at 47. My children don't understand and hold me at arms length. Try living with this one--because of the meds that work in keeping me level my sexual ability is gone and thanks to ECT I can't remember EVER making love with my loving wife. So if you think all the BS about ECT being "safe" is true then go right ahead and get you some, for it is true-- MISERY LOVES COMPANY!!!

ECT IS DANGEROUS AND CAN FOREVER HARM YOU AND YOUR FAMILY. DON'T DO IT!!!

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*Name:	Renee
*Age when you had ECT:	19
*Your gender:	Female
*Country:	United States
State/Province if applicable:	MO
Number of ECTs, if known:	12
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	lithium, zoloft, prozac, etc...
Why was ECT prescribed (symptoms, diagnosis):	clinical depression
*Was your ECT:	Unsure/Other
In what ways did ECT help you (short & long term):	Discontinued suicidal tendencies, significantly less depressive symptoms
What negative side effects, if any, did you experience:	memory loss, aggressive behavior, apathy, lethargy, short attention span
Do you still see the same doctor who administered your ECT:	no
*Choose one to	

describe the effects of ECT on you:

Somewhat beneficial

Would you willingly have ECT again, or recommend it to another:

no

*In one sentence, sum up your thoughts on your ECT experience:

I would only recommend ECT as an absolute last resort in patients who have tried other multiple treatments without success

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*Name:	Catherine
*Age when you had ECT:	33
*Your gender:	Female
*Country:	United States
State/Province if applicable:	CT
Where was ECT performed (if different than above):	Hartford, CT
Number of ECTs, if known:	6
Type, if known:	Not sure
Voluntary/Involuntary patient at time of ECT:	Voluntary
Treatments/alternatives tried prior to ECT:	Antidepressants
Why was ECT prescribed (symptoms, diagnosis):	Major Depression
*Was your ECT:	Pressured by others
In what ways did ECT help you (short & long term):	Its only been 4 months depression is back
What negative side effects, if any, did you experience:	Lost large chunks of memory from last 2 yrs, some brain damage, can't get thoughts out, can't do math the same, can't spell the same

If you felt harmed by ECT, what was the reaction of your doctor to your complaints:	passed it off; dismissive, said it'll pass
Do you still see the same doctor who administered your ECT:	yes
*Choose one to describe the effects of ECT on you:	Greatly harmful
Would you willingly have ECT again, or recommend it to another:	NO
*In one sentence, sum up your thoughts on your ECT experience:	I will separate from my husband if he threatens me with it again
Email (optional):	minmei88@attbi.com
Additional comments/your ECT story:	I had learning disabilities b4 the ect's, but I have a college degree and am self taught in many fields. I have become even more disabled than I had been because of this, thinking is harder, learning is harder, I have to go over something over and over so many time so I will remember it. And I've stopped asking my family whether or not I did or didn't do something over the last two years, it's become humiliating. I have an educational toy belonging to my children and it ranges in from 6-8th grades and I play with it and I've notices that I now can't do math problems I used to be able to be able to do, and I no longer know my 4s tables. I could go on...

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EXHIBIT 20

KENDRICK L. MOXON *
HELENA K. KOBRIN #
AVA PAQUETTE

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February 9, 2010

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

Docket No. FDA-2009-N-0392

**Medical Devices: Neurological Devices; Electroconvulsive Therapy
Device; Establishing a Public Docket**

As indicated in my Comment on the Public Docket, FDA-2009-N-0392, I am an attorney and have been involved in extensive litigation with MECTA Corporation regarding their devices. In such litigation, I acquired substantial information regarding practices by the ECT Manufacturers, harms caused by ECT, and the lack of efficacy thereof.

This letter addresses inaccuracies and misrepresentations made by MECTA and Somatics, Inc. ("Manufacturers"), in their responses to the FDA's Order dated April 2, 2009, set forth at Docket No. FDA-2009-M-0101, "Medical Devices; Order for Certain Class III Devices; Submission of Safety and Effectiveness Information." ("Submissions") This letter also addresses information, which should have been, but was not provided to the FDA by the Manufacturers in compliance with the Order.

Summary:

The Manufacturers have failed to demonstrate why they should not be required to submit premarket approval applications for their devices.

Submissions from the Manufacturers in response to the FDA's Order, indicate they have made material misrepresentations to the FDA, concerning both the lack of

safety and lack of efficacy of ECT. And, they have failed to reveal the existence of many injurious events – including deaths caused by their devices.

The Manufacturers assert throughout their submissions that the ECT devices used now are safer than the machines previously used for ECT. This alone would seem to refute the only lawful basis permitting their distribution and sale of their devices at all over the past 35 years – that the devices are substantially the same as the devices in use pre-amendment.

In any event, the Manufacturers claims for safety of the current devices are not accurate. The Manufacturers have refused to acknowledge or have belittled evidence that ECT can cause grave harms to patients and that learning disabilities and long term memory loss and permanent amnesia is a ubiquitous result – manifesting that brain damage accompanies the procedure.

Somatics and MECTA have also obscured the fact that ECT lacks the ability to resolve the only mental condition for which it is promoted – and note that no claim has been made by the Manufacturers or proponents of ECT that it addresses any physical or medical disorder.

Evaluations of the studies relied upon by the Manufacturers reveal that many of the conclusions therein, which seemingly support the Manufacturers claims, are unsupported by the raw data in the studies. Thus, the studies relied upon by the Manufacturers to support the safety and efficacy of the devices, do not.

ECT is the singular form of medical treatment opposed by organized bodies of self-described victims; opposed by hundreds or thousands of individual recipients of the treatment; and by numerous professionals. The purported benefit of ECT is questionable and temporary under the most liberal interpretation of the evidence and the harms are “universal” and, are often devastating. The Manufacturers seek to avoid the PMA process as they have successfully done for decades, because they cannot reasonably demonstrate that ECT is effective and they cannot demonstrate that the known harms outweigh the alleged benefits.

The Manufacturers Failed to Comply with the Order

The Manufacturers were ordered 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]

The Manufacturers have failed to comply with the Order.

The Manufacturers are well aware of the thousands of reports of damage, debility and anguish arising out of ECT, none of which were revealed in the Manufacturer's Submissions as required by the Order. MECTA failed to reveal the five lawsuits which had been filed against it,¹ for physical damage arising out of treatment with their devices. Both manufacturers failed to reveal the evidence and assertions of victims addressed in what Somatics characterizes as "anti-ECT websites." (Somatics Submission, p. 5.) They have chosen to ignore or merely belittle this information rather than honestly admit it existed and address it.

Each Manufacturer submitted only conclusions and articles selected to support their positions, avoiding and ignoring studies and articles that provided evidence and conclusions indicating the danger, the harms and the lack of efficacy of ECT. As the makers of these devices, they share a greater responsibility in showing transparency by fully informing the FDA about both pro and adverse studies, since the Order required their submissions "include all relevant data available from pertinent clinical studies, including negative or ambiguous results as well as positive findings."

Further, the articles, studies and publications which the Manufacturers did supply, were inaccurately cited and portrayed by the Manufacturers—drawing upon conclusions insufficiently supported by the data therein, as addressed below.

The Manufacturer's Assertions of Safety of ECT are False and Misleading

Generally, the Manufacturers portray ECT as benign, and claim that with alleged advances in the "wave form" of the electricity used, muscle paralyzing drugs and the use of oxygen, that the form of treatment is safe. But support for these claims is insufficient and misleading.

For example, Somatics asserts that there have been only 20 reports of adverse events to the MAUDE database respecting ECT, and only 6 reports of death or disability. (Somatics Submission, p. 3.) However, former FDA Commissioner David Kessler has estimated that "only about 1% of serious events are reported to the FDA,"² so the actual number of adverse events could literally be up to 100 times higher than reported. And, the characteristic of ECT in which the patient is stultified by the treatment for days, weeks, months or permanently, also explains the low reporting rate to MEDWATCH and MAUDE.

Harold Robertson and Robin Pryor examined this issue in their extensive systematic review of patients' experiences with ECT, published in *Advances in*

Psychiatric Treatment in 2006.³ They found that patients might not even be fully aware of the memory loss and damage they have experienced:

“Patients cannot be meaningfully evaluated in hospital during or soon after ECT. Neither self-reports nor crude memory tests may be reliable (Cronholm & Ottoson, 1963). A patient may do well on the MMSE [Mini-Mental State Examination] or counting serial sevens but may not know that her friend visited her the day before – and will not know she doesn’t know. Having had no reason theretofore not to trust her memory, and not having been warned to expect severe dysfunction, she will adamantly insist that her memory cannot be faulty. It is not the psychological defence mechanism of denial, nor is it only the acute organic brain syndrome which occurs with ECT, that causes this genuine unawareness. Most patients have never before experienced a day in their life when they did not know what they ate for dinner or who they had seen or what they had read the day before. They do not even know that this is possible, let alone that it is happening to them.”

The fact that over 1,000 comments *were* received to the public docket which are *critical* of ECT, (many vilifying its destructive effects), and the hundreds of first-person reports of debilitation and harm which have elsewhere been reported, confirms that the reporting to MAUDE is not an accurate reflection of the actual adverse events.

Somatics’ limitation in its Submission to responding to the reports made to the MAUDE database, (Somatics Submission, p. 3-5), is therefore disingenuous and incomplete. Neither MECTA nor Somatics represent that they have sought after other adverse incidents not reported to MAUDE, and MECTA’s president conceded in sworn deposition that no effort is made to acquire information of harms caused by its devices.⁴

ECT Causes Death

MECTA falsely asserts that the rate of mortality from ECT is equivalent to minor surgery, or 1 in 10,000 patients. (MECTA Submission, p. 5.) MECTA even represents that, “No deaths resulting from ECT treatments have been recorded in 35 years of MECTA’s adverse event reporting.” Somatics’ response similarly, but inaccurately asserts, that since 1984, “there has been no occurrence of a reported adverse event (death or serious injury) related to the use of a Thymatron ECT device.” (Somatics Submission, p. 3.)

These assertions are sophistry at best, as while few deaths are reported on the operating table, there are many deaths soon after the receipt of ECT – a fact well known to MECTA and Somatics which were simply not reported by them to the FDA.

In 1998, the heirs of Jesus Torres sued MECTA, alleging that the ECT caused him to have a ruptured bowel, caused substantial weight loss, spontaneous seizures, and caused his death. (Exhibit A.) Though MECTA was sued for this death, it withheld that fact from the FDA and continues to do so in its Submission.

Moreover, Texas is one of only two states that require practitioners of ECT to provide information to the state regarding harms arising out of ECT. In 2008 alone, five patients died soon after receipt of ECT out of the several hundred that received ECT.⁵ The machines utilized at each of the facilities where patients died after receiving ECT, were manufactured by MECTA and Somatics.⁶ In 2006, there were 3 additional deaths in Texas reported following this treatment,⁷ and again, the machines utilized were from Somatics and MECTA. In the first three years of mandated reporting in Texas in the early 1990's (long after the advent of so-called safety "advances" by the Manufacturers), 21 patients were reported as having died soon after receiving ECT.⁸ From June 1993, through August 1994, eight deaths were reported among nearly 1,700 patients subjected to the treatment.⁹ Note that California also requires reports of injury from ECT, but unlike Texas, providers do not have to report deaths and injuries which are not manifested at the time of the treatment. Texas requires reports of death within 2 weeks of ECT. Since it would seem unlikely that any practitioner would give a patient ECT who is on his dying from other causes, the 2-week rule demonstrates deaths caused by the ECT.

In 1997, it was reported that a 57-year-old man suffered cardiovascular collapse, culminating in cardiac arrest with electromechanical dissociation following his eighth ECT treatment. Despite resuscitative measures, the patient died.¹⁰

That ECT quickly and drastically shortens the lifespan of recipients has been well known for decades. For example, in a large retrospective study of 3,288 patients receiving ECT in Monroe County, NY, recipients were found to have a substantially increased death rate from all causes.¹¹

In another study by researchers at Brown University of 65 elderly patients hospitalized and treated for depression, the 37 patients who had received ECT had survival rates of 73.0% at one year, 54.1% at two years, and 51.4% at three years. In contrast, depressed patients who *did not* receive ECT had survival rates of 96.4%, 90.5% and 75.0% at 1, 2 and 3 years respectively.¹² In another study, the death rate was doubled in depressed patients who received ECT in a seven-year follow up study of 188 patients.¹³ Thus, besides the immediate impact of the electrical shock to the

brain, ECT has a debilitating effect on the body's systems, the brain evidently losing its ability to control delicate systems.

Extrapolating from these figures, there are potentially hundreds of deaths caused by ECT shortly after treatment, and patients can expect a shortened longevity from various causes. Clearly the shock to the brain causes other deleterious breakdowns in the body and brain that the Manufacturers have not been required to study. And, so long as they can continue to sell devices without having to do so, they have no intention of acquiring such bad news.

Brain Damage/Memory Loss

The Manufacturers also falsely deny that their devices cause brain damage. MECTA does concede that “[s]ome degree of memory loss is universal...” but then offers an untrue and misleading assertion “... but most often very limited in extent.” (MECTA Submission at 6.) It also misrepresents, “as a *rare* side effect, persistent and marked memory loss has been recorded.” (Emphasis added) But marked memory loss is far from “rare.” Somatics similarly concedes “all forms of ECT are capable of causing immediate adverse effects on memory shortly after each individual treatment and after a course of treatments.” (Somatics Response, p. 9.)

First, it is axiomatic that the “universal” memory loss is caused by something, and the only “universal” common denominator of all ECT patients is the passage of electricity through their brains. Electricity passing through matter generates heat, causes burns and can readily destroy tissue. In large quantity it is used to weld steel, and in a relatively small quantity, is used to execute murders by passing electricity through the brain. While MECTA, Somatics and ECT proponents assert that they do not know the “therapeutic” agent of ECT, as noted in my Comment of January 6, 2010, it was long recognized that brain damage and resulting memory loss is that “therapeutic” cause.

Indeed, both manufacturers assert that requiring ECT to be performed with unilateral electrode replacement rather than bilateral would allegedly reduce the universal memory loss experienced by patients. Somatics however notes that a substantial greater amount of electricity is needed with unilateral treatments “to maximize efficacy.” (Somatics Submission, p. 15.) Given this, as well as the purported need for supra-threshold “dosing” of electricity, it could not be clearer that it is not the convulsion that creates some purported benefit. Rather, it is the electricity ripping through the brain that causes memory loss and scrambling of reason, essentially knocking the patient's problems from his view. One psychiatrist who publicly argued for the effectiveness of electroshock treatment, in a letter published in the magazine *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. This transient, induced, organic, psychotic reaction makes the patient forget his worries, breaks up introspection and obsessive thinking and reverses the effect, frequently changing depression into mental elation.”¹⁴

Yet, under a section heading called, “Claims of Brain Damage – History”, MECTA states (MECTA Submission, p. 8), referring to the brain damage caused by ECT:

This claim has not been supported by any scientific evidence. Since the 1978 APA Task Force #14 recommended brief pulse devices to be utilized with modified ECT, this has been the standard of care for ECT in the United States. The history of scientific research from 1984 to 2008 demonstrates that there are no measurable negative effects on the brain from ECT and in fact their [sic] may be some positive effects ...

Yet the same 1978 APA Task Force Report cited by MECTA also 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.¹⁵ Coming from this source—before the time of vast public relations assaults by Manufacturers and other vested interests—the fact of brain damage from ECT should be deemed conceded.

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. 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.”¹⁶

There are a number of studies relating to brain damage caused by ECT. 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.¹⁷ Another brain scan study reported in *Acta Psychiatrica Scandinavia* confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.¹⁸ *Archives of General Psychiatry* reported that MRI scans demonstrate a strong correlation between the numbers of previous ECT treatments to loss of brain tissue.¹⁹ A study appearing in *Psychological Medicine* 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. The authors’ stated:

“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.”²⁰

Neurology magazine also published a review of the literature on the well-known ECT complication of epilepsy—a complication that neither of the Manufacturers revealed in response to the Order. The article’s researchers concluded:

“The age-adjusted incidence of new seizures after ECT was fivefold greater than the incidence found in the non-psychiatric population.”²¹

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.²² 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.

“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.’ The Food and Drug Administration must rescrutinize today's SW and BP devices, withdrawing their ‘grandfathered in’ status under compulsive therapy devices. Because they utilize an entirely different principle,... *all modern EST device manufacturers must be required to prove machine safety to the Food and Drug Administration, prior to further utilization of new machines.*” [Emphasis added.]²³

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.”²⁴

While both Somatics and MECTA provided substantial bibliographies and obviously took a great deal of time to prepare their submissions, they eschewed such negative information – and did so in a disingenuous fashion. Of course, as MECTA’s President conceded in deposition, the company has never conducted any studies to determine the effect on the brain, the deleterious impact on the brain or body, or any other damage its machines cause.²⁵

Yet the Manufacturers could not wholly avoid conceding the memory loss caused to all ECT patients. Under a heading, “(c) Cognitive Side Effects,” MECTA admits “some degree of memory loss is universal,” but then immediately contradicts 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, shocking only one side of the brain, using a “brief pulse” waveform of the shock, 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.

But the “therapeutic agent” is obviously simply the electricity, which disrupts and destroys brain tissue and scrambles memory and causes a patient to “forget” problems for a time. It eliminates no purported mental illness, and neither the Manufacturers nor a single commentator claim that ECT can cure anything. It causes memory loss and confusion, and they consider this to be a beneficial state. Demonstrative of the fact that the electricity causing injury to the brain is the “therapeutic agent,” is the fact that ECT scientists and commentators – as well as the Manufacturers themselves—concede that mere a convulsion *does 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 MECTA Submission, p. 6, 10, 23 ___; Somatics Submission, p. 9, 10, 16, 17.)

This is important, because even though the Manufacturers now assert that only unilateral ECT should be used, their own materials provided to practitioners do not. MECTA’s Manual asserts that unilateral has “less extensive and less severe cognitive side effects” than bilateral placement of the electrodes, but then says it is an individual choice to be made on a case by case basis. (MECTA Manual, p. 26.) Aside from the concession that both forms of the treatment cause “severe” cognitive effects, it reveals disingenuous positioning in the Submission.

Worse, the MECTA Manual appended to its Submission, asserts 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 astounding notes:

“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.)

MECTA’s Manual then goes on to recommend that the “dosage” of electricity given, should be 4-6 times the seizure threshold. (*Id.*)

The manifest conclusion to be drawn from these recommendations regarding the amount of electricity deemed necessary to produce the desired effect upon the patient, is that:

- The Manufacturers know that seizures are not the basis for the alleged benefit from ECT.
- They recommend unilateral ECT, but assert that practitioners to get the same efficacy need to double the electricity;
- That translates to 4 to 6 *times* the amount of electricity need to throw the patient into a grand mal seizure.

You will ask the Manufacturers in vain as to what this additional electricity for the “suprathreshold” shocks does to the brain. The most they will suggest is that somehow heightens the convulsion in a manner *no one* can explain. But that is logical poppycock. As addressed herein, *the electricity* causes the damage; causes severe cognitive effects; causes the memory loss; causes the confusion; causes the learning disability; and causes death.

Conflicts of Interest and Refuting Authority Withheld by Manufacturers

Significantly, the references cited by the Manufacturers for the purported “elimination” of the memory loss and other damage ECT does by using supposedly modern methods, are an article from psychologist Harold Sackeim article from 2004 and an APA article from 2001 that also heavily relies on Sackeim. Harold Sackeim is the most published author of ECT studies over the past 25 years, and the most oft-cited reference by either Manufacturer.

Although MECTA relied very heavily upon Sackeim’s earlier pronouncements to support its misrepresentations regarding memory loss and efficacy, it failed to inform the FDA 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—in all, over \$100,000 (some of which apparently remained with his school). (Exhibit B, Sackeim Deposition, p. 64-68.)

However, as a UK Department of Health study found, Sackeim's use of the Autobiographical Memory Interview does not sufficiently measure the level of amnesia patients' experience:

"...the 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."²⁶

MECTA is certainly well aware from other sources that universal memory loss and often long term and massive memory loss is caused by ECT. In the case of *Akkerman v. MECTA*, referenced in my original Comment, it was revealed that the facility that gave ECT to my client, Atze Akkerman, reported that *every one of the hundreds of patients* who received ECT over a period of more than 5 years, experienced the "complication" of memory loss. (Exhibit C.)

Perhaps one of the most concise analyses of memory loss and cognitive damage caused by ECT 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.²⁷ Their conclusions are a further refutation of MECTA and Somatics' claims:

"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).

“... former 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 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]

Indeed, further to this, in June 2005 in Columbia, South Carolina, a jury awarded \$635,000 in a malpractice suit against a psychiatrist, Eric Lewkowiez, who referred a patient for electroshock treatment. The plaintiff, Peggy Salters, is a former nurse who lost her memory for many years of her life, including her professional training and the raising of her children. Her cognitive abilities remain impaired for new learning as well. Though she’d held a Masters of Science degree and had had a long career in nursing, she could not return to work, as she no longer possessed the skills or knowledge of nursing. She was found permanently disabled—including memory loss and cognitive impairment—by the shock treatment. Palmetto Baptist hospital where the ECT was administered settled out of court for an undisclosed sum.²⁸

The Royal College of Psychiatrists (2005: p. 19) and NICE (2003) “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’.”²⁹

In a particularly disingenuous aspect of the Manufacturers’ Submissions, they fail to reveal that their most important researcher, psychologist Harold Sackeim, essentially withdrew his prior conclusions regarding ECT which the Manufacturers cite. Sackeim published another article in 2007, “The Cognitive Effects of Electroconvulsive Therapy in Community Settings,” *Neuropsychopharmacology* (2007) 32, 244–254, Sackeim, et al., which largely *refuted* his prior work and work of others, and flatly contradicted the assertions MECTA now makes. The study was done in major part, to compare the differing types of ECT, between unilateral (placing both electrodes on one side of the head so that the electricity arguably shocks only one half of the brain) and bilateral (where the electrodes shock both sides of the brain).

It should be well-noted that unilateral ECT causes the same convulsion of the brain – but merely inhibits the flow of electricity to one of the sides of the brain, thereby protecting that one side from the deleterious effects of the damage the electricity must cause.

Of great significance for the consideration of the import of prior studies on the effects of ECT, is that the 2007 Sackeim study purports to be the *very first study* conducted of long-term memory loss; i.e., 6 months after the treatments. This is important, as the proponents of ECT and both Manufacturers assert that the long-term effects of memory loss are essentially nil. As Somatics erroneously asserts, “Thus, follow up studies up to 6 months after a course of bilateral brief-pulse square-wave ECT find no evidence for persistent anterograde or retrograde amnesia.” (Somatics Submission at 10.) That is clearly not what the hundreds of adverse comments in the public docket reveal, nor do the hundreds of surveys from ww.ect.org attached to my Comment, from actual shock patients reveal. And now, the recent Sackeim study demonstrates that the prior studies upon which MECTA and Somatics rely are simply not true. While finding that bilateral ECT is more harmful than unilateral ECT, his admissions include:

- “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.”
- 12.4% 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.

While I do not endeavor to provide all significant studies and publications relating to ECT, certainly the manufacturers were obligated to do so in their Submissions. This is particularly true given the huge differences of viewpoint respecting this most controversial of all forms of permissible treatment in our modern world. Many recipients of ECT decry the practice, as noted by the United States National Council of Disability, a federal agency, which conducted its own survey of ECT patients, and concluded that ECT causes grave disabilities. The federal publication, “From Privileges to Rights: People With Psychiatric Disabilities Speak for Themselves, January 20, 2000, stated, in part:

Even proponents of electroconvulsive therapy (ECT or shock treatment) admit that it is a high 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.)

The above information is only a sampling—a small sampling—of available information on the deleterious effects of ECT, which the Manufacturers declined to reveal to the FDA now or at time in the past when it *should* have been acknowledged.

MECTA and Somatics therefore failed to comply with the FDA's order to provide, "all adverse safety and effectiveness information that has not been submitted under section 519 of the act, particularly the most significant information..." Obviously, information regarding brain damage and death is "significant information" which the Manufacturers should have revealed. The Manufacturers eschewed a duty to patients and duty to the FDA to be forthright and complete. Given the failures of the Manufacturers, the FDA may have an equally great responsibility not to allow the public to be harmed.

The Manufacturer's Assertions of Efficacy of ECT are False and Misleading

MECTA asserts that there is "an overwhelming consensus on efficacy and safety" (MECTA Submission, p. 4), and that ECT has a "proven 70 to 80% efficacy." (Pg. 5.) Somatics asserts similarly that "ECT is a highly effective treatment for depression." (Somatics Submission at 14.) These representations are refuted by more than 1,000 comments to the contrary to the public docket from persons knowledgeable of harm and many hundreds personally harmed by ECT and for whom no benefit was experienced. They are also refuted by a fair examination of the history of ECT and studies undertaken which attempted to prove its effectiveness. (See my Comment dated January 6, 2010 and attachments thereto.)

It is undeniable that many articles and pro-ECT references claim that the efficacy of ECT is "well-established," and the like. However, these are conclusions only, and a careful review of the studies which allegedly support the conclusion show a far different result. Somatics concedes, for example that "none of the studies" it referenced which allegedly show efficacy in treating depression "included a control

group” and thus it concedes, “the question arises whether this apparent efficacy might merely be a placebo effect.” (Somatics Submission p. 14.)

Indeed, a famous story by the *Chicago Daily News* in 1974 about a psychiatric facility in Northern England is testimony to the so-called “placebo” effect. The story was originally reported by *World Medicine*, a magazine for doctors and was a first-hand experience of a doctor who said for two years patients at the hospital were given electric shock treatments and, unknown to anyone, the device wasn’t working (operational). A new model that was “obviously a great improvement on the previous edition” was used, with “switches for different wave forms.” But, although the red light went on and needles moved as they were supposed to, he noticed the patients were not twitching as they had under the old machine. He asked if the machine might not be working but was assured by the head nurse that it was as this machine didn’t produce visible twitching and verified this in the instructions. For two years all the ECT patients received was “thiopentone and a shot of scoline (anesthetic to put them to sleep)—and no one had noticed,” the doctor said.³⁰

To address the issue of the apparent superiority of placebo over ECT, Somatics references studies undertaken over the past 50 years referred to as “sham ECT” studies, in which some patients are given ECT, and others are anesthetized, but not given ECT. Somatics claims that 5 of 6 studies it references show a statistically significant benefit of ECT. (Somatics Submission, p.15.) Yet both Somatics and MECTA failed to reference the recent analysis of the “sham ECT” studies that demonstrates that even the purported favorable studies do not support the claim. Colin Ross, “The Sham ECT Literature: A Review,” *Ethical Human Psychology and Psychiatry*, 2006 Spring; 8(1):17-28. It concludes, after an exhaustive analysis of all the sham ECT studies:

The sham ECT studies indicate that real ECT is no more effective than placebo, except during the period of time the 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 cost-benefit analysis is due to deaths, cardiovascular complications, and memory and cognitive impairment caused by ECT.

Moreover, Somatic’s submission concedes 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.” (Somatics Submission, p. 15.) Thus, it complains, it is necessary to continue *other* forms of treatment for patients after the ECT, or to continue “maintenance” ECT if any improvement is to be expected. (*Id.*) In short, once the patent “comes around” from the insult to the brain

from having electricity forced through it, and begins to recover some memory and some sensibility, the “effectiveness” of ECT is absent. ECT does not work.

To cite again the UK Department of Health analysis (2006), the FDA should take into account the potential risk for patients undergoing ECT. This 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 Manufacturers Provide No Risk/Benefit Analysis

As noted above, there is no long-term benefit from these devices, but rather, according to the Manufacturers, unless other treatments are utilized *after* the ECT, the patients immediately relapse.

And, the Manufacturers conceded “universal” memory loss, at least of a temporary nature. In fact, is far from temporary. The sole conclusion to be drawn from this universal harm is structural damage. And, there are myriad other risks, as also addressed above. Yet literally no risk/benefit analysis has been done, and the Manufacturers have declined to submit any risk/benefit analysis in any 501(K) these many years, or in response to the FDA’s Order.

Pre-amendment Status Abuse and Contradictory Filings by Manufacturers

Finally, the manufacturers assert throughout their Submissions that the machines used now are safer than the devices previously used for ECT. This would seem to refute the only lawful basis permitting their distribution and sale of their devices at all – that the devices are substantially *the same as* the devices in use pre-

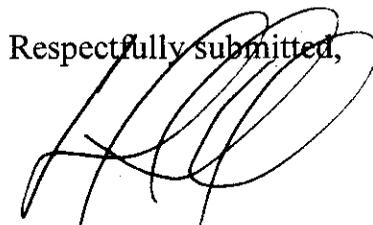
amendment. In their filings with the FDA since 1974, the manufacturers implicitly and explicitly asserted that the devices are substantially the same. Now they assert that their devices are substantially *different* – refuting 35 years of contrary representations. This alone warrants that a full PMA be required for these “new” devices.

Conclusion

The use of ECT should be suspended. Only if and when a full PMA submission is made and approved should this practice and these devices be permitted. Under no circumstances should the ECT devices risk classification be reduced to Class II.

Dated: February 9, 2010

Respectfully submitted,



Kendrick Moxon

¹ See Comment of Kendrick Moxon, submitted docket- FDA-2009-M-0392, and Exhibits B, C, D, and E attached thereto.

² “Introducing MEDWATCH: A new Approach to Reporting Medication and Adverse Effect and Product Problems,” JAMA, June 2, 1993, Vol. 269, No. 21.

³ Harold Robertson & Robin Pryor, “Memory and cognitive effects of ECT: informing and assessing patients,” *Advances in Psychiatric Treatment* (2006), vol. 12, 228–238, <http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>

⁴ See Comment of Kendrick Moxon, submitted docket- FDA-2009-M-0392, and deposition testimony of MECRA President Robin Nichol attached thereto.

⁵ [http://www.dshs.state.tx.us/mhquality/ECT2008/FY08 Annual ECT Facility Summary.pdf](http://www.dshs.state.tx.us/mhquality/ECT2008/FY08%20Annual%20ECT%20Facility%20Summary.pdf)

⁶ [http://www.dshs.state.tx.us/mhquality/ECT2008/ECT Equipment Registration History.pdf](http://www.dshs.state.tx.us/mhquality/ECT2008/ECT%20Equipment%20Registration%20History.pdf)

⁷ [http://www.dshs.state.tx.us/mquality/FY06/FY06 ECT-data.pdf](http://www.dshs.state.tx.us/mquality/FY06/FY06%20ECT-data.pdf)

⁸ Don Gilbert, Commissioner, Texas Department of Mental Health and Mental Retardation, 1996.

⁹ <http://www.garynull.com/documents/ECT/SideEffects2.htm>, Gary Null, citing Peter R. Breggin M.D., “Electroshock: scientific, ethical, and political issues,” *International Journal of Risk & Safety in Medicine* 11 (1998) 5-40 IOS Press.

¹⁰ <http://www.garynull.com/documents/ECT/SideEffects2.htm>, Gary Null, Ali PB, Tidmarsh MD, “Cardiac rupture during electroconvulsive therapy,” *Anaesthesia* 1997 Sep;52(9):884-6.

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- ¹² Kroessler, D. and Fogel, B., "Electroconvulsive Therapy for Major Depression in the Oldest Old." *Am J Geriatr Psych* 1993;1:1:30-37.
- ¹³ O'Leary, D. and Lee, A. "Seven Year Prognosis in Depression - Mortality and Readmission Rates in the Nottingham ECT Cohort." *British J of Psychiatry* 1996;169: 423-429.
- ¹⁴ Dr. A.E. Bennett, letter published in *Electroconvulsive Therapy*, Correspondence, Vol. 14, No. 2.
- ¹⁵ *Electroconvulsive Therapy. Report of the Task Force on Electroconvulsive Therapy of the American Psychiatric Association.* (1978)
- ¹⁶ Report to the New York Assembly reviewing the safety of ECT, 2001.
<http://www.survivorlink.org/electroshock/nyassemblyreport/AR-safety.html>
- ¹⁷ Weinberger, et al. 'Structural abnormalities in the cerebral cortex of chronic schizophrenic patients.' *Archives of General Psychiatry*, 1979; 36:935-939.
- ¹⁸ Calloway, et al., 'ECT and cerebral atrophy: a CT study.' *Acta Psych Scand*, 1981; 64:442-445.
- ¹⁹ Andreasen, et al., 'MRI of the Brain in Schizophrenia.' *Arch Gen Psych*, 1990; 47:35-41.
- ²⁰ Dolan, R.J.; et al., 'The cerebral appearance in depressed subjects.' *Psychol Med*, 1986; 16:775-779.
- ²¹ Devinsky and Duchowny, 'Seizures after convulsive therapy: A retrospective case survey.' *Neurology*, 1983; 33:921-5.
- ²² "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>
- ²³ Report to the New York Assembly reviewing the safety of ECT, 2001.
<http://www.survivorlink.org/electroshock/nyassemblyreport/AR-safety.html>
- ²⁴ Harold Robertson & Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* (2006), vol. 12, 228-238,
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>
- ²⁵ See Comment of Kendrick Moxon, submitted docket- FDA-2009-M-0392, and deposition testimony of MECRA President Robin Nichol attached thereto.
- ²⁶ Harold Robertson & Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* (2006), vol. 12, 228-238,
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>
- ²⁷ Harold Robertson & Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* (2006), vol. 12, 228-238,
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>
- ²⁸ <http://www.laborlawtalk.com/showthread.php?t=113321>
- ²⁹ Harold Robertson & Robin Pryor, "Memory and cognitive effects of ECT: informing and assessing patients," *Advances in Psychiatric Treatment* (2006), vol. 12, 228-238,
<http://apt.rcpsych.org/cgi/reprint/12/3/228.pdf>
- ³⁰ Raymond R. Coffey, "Hospital Shocked by Finding No Sock in Its Shock Machine," *Chicago Daily News*, 10 Sept. 1974

EXHIBIT 21

TO Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

FROM Moira Dolan, MD
PO Box 849
Manchaca, TX 78652

RE: Docket No. FDA-2009-N-0392
"Medical Devices: Neurological Devices; Electroconvulsive Therapy Device;
Establishing a Public Docket"

Testimony of Moira Dolan, MD

2 October 2009

There is insufficient evidence that general or special controls will provide reasonable assurance of safety and effectiveness of the use of electroconvulsive delivery devices.

Manufacturers of electroshock machines should be required to submit pre-market approval (PMA) documents according to the usual route currently required for approval of medical devices.

Background: Electroconvulsive therapy has been in use since 1938. The purpose of the ECT machine is to cause a disruption of brain electrical activity in order to cause a series of grand mal seizures. Despite over 70 years of the use of various versions of electro-shocking machines to deliver jolts of electricity through the scalp and skull into the brain, there remains no evidence that confirms the safety or effectiveness of the device or the procedure. This testimony will show that, while the medical literature contains an abundance of articles asserting safety and effectiveness, the actual data found within the reports does not substantiate those claims. [52 citations follow.]

1. CLAIMS THAT ECT SAVES LIVES ARE NOT BACKED BY LONGEVITY STUDIES OR DEATH STUDIES

Recent ECT literature continues to make the claim that the procedure saves lives.ⁱ Over the course of 70 years there has been plenty of opportunity to conduct long term safety and effectiveness studies. In fact, there has not been a longevity or long term death study comparing ECT to usual medical treatment since the 1993 study done by researchers at Brown University. They reported that elderly patients receiving ECT had *profoundly higher death rates* compared to depressed elderly who got usual medical treatment:

Patients who 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.ⁱⁱ

The largest death study was done in Monroe County, NY where 3,288 ECT recipients were found to have increased death rates from all causes.ⁱⁱⁱ The more recent literature which claims to give mortality data, such as the 2004 study from the Mayo Clinics, only reports mortality rates a month or less after ECT.^{iv} Reports of extremely short term follow-ups are entirely insufficient and do not qualify as convincing evidence of safety.

Extensive literature reviews have been published which clearly explain that *there is a lack of data* about long term death and suicides after ECT, particularly in the elderly. A comprehensive review of the international literature was published in 2003 which concluded:

“Important questions such as the relative efficacy of ECT over antidepressants, the long-term efficacy of ECT, morbidity and mortality related to ECT, cost-effectiveness and the efficacy of ECT in subgroups of patients cannot be answered and need to be studied further.”^v

There have been no such safety studies since this urgent call for such research. The internationally recognized evidence-based Cochrane Collaboration concludes:

“All [ECT studies] had major methodological shortcomings; data were mostly lacking essential information to perform a quantitative analysis.”^{vi}

The authors further describe the lack of studies proving safety or effectiveness in the elderly:

“Randomised evidence on the efficacy and safety of ECT in depressed elderly with concomitant dementia, cerebrovascular disorders or Parkinson's disease is completely lacking. Possible side-effects could not be adequately examined because the lack of randomized evidence and the methodological shortcomings. None of the objectives of this review could be adequately tested because of the lack of firm, randomised evidence.”^{vii}

The literature is no more sufficient to establish a long term benefit for ECT in the general (non elderly) population of depressed patients. Even studies which seem to show immediate protection against suicide are highly flawed, as commented upon by authors of this large review published in 2001:

“Due to the significant limitations of studies in this area, however, the data need to be interpreted with caution.”^{viii}

There have been a few attempts at partial patient tracking, such as the death registry mandated by the State of Texas. Decades of use of ECT continues without any accountability to long term outcomes reporting.

2. ECT HAS AN UNKNOWN MECHANISM OF ACTION

One of the challenges to an effective study of ECT is that, notwithstanding seven decades of use, the mechanism of action of ECT has never been determined.

There are many theories of the allegedly therapeutic mechanism of ECT, but there remains no conclusion as to how ECT effects mental changes in the patient. Here is just one of many examples of how muddled the research is in this area: a 2009 study looked at the unique brain wave patterns of psychiatric patients and concluded that these patterns undergo adjustment by ECT. However the authors failed to appreciate the established fact the pre-ECT psychotropic medications themselves cause abnormalities in the brain wave patterns.^{ix} Other researchers that report on pre- and post-ECT

physiologic changes *groundlessly conclude* that various biochemical alterations caused by brain cell disruption “must” be the therapeutic mechanism of ECT.^x

The *accidental* exposure of brain tissue to sudden raw electricity is universally recognized as profoundly brain-damaging. In fact, brain tissue shows the exact same gross and microscopic changes after ECT as seen after traumatic brain injury. For example, the most obvious response to brain injury is the proliferation of glial cells. When electricity is delivered *intentionally* to the brain as a therapy, these very changes are claimed to be indications of its *therapeutic* effect. A recent (2009) publication on the temporary glial cell proliferation following electroconvulsive stimulation (ECS) to lab rodents caused the authors to wonder if they were seeing brain damage or a therapeutic effect:

“In conclusion, ECS treatment induced transient glial cell activation in several brain areas. Whether similar processes play a role in the therapeutic effect of clinically administered ECT or contribute to its side effects will require further investigations.”^{xi}

In other words, to date, the researchers who shock animals can’t even decide if the effects of the shock machine are damaging or therapeutic. This is not a device that has even the most basic therapeutic performance standards.

Other brain changes that occur after trauma are also seen with ECT, including brain cell loss, increased serotonin, new neuron growth and alterations in gene expression.^{xii} One particular effect of ECT that has just recently been documented is up-regulation of “cocaine and amphetamine-related transcript”. It is completely unknown if this bizarre effect is therapeutic or simply deranging.^{xiii}

Electric shock to the brain also shocks the body. Immediate effects of ECT on the rest of the body include spikes in blood pressure, speeded up heart rates, dangerously slowed heart rate, severely abnormal heart rhythms and even temporarily stunning of the heart muscle itself.^{xiv} ECT has been shown to cause everything from blindness and stroke to cardiac rupture and vaginal bleeding.^{xv}

3. THE EVIDENCE ABUNDANTLY DESCRIBES BRAIN DAMAGE FROM ECT

The brain-damaging effects of ECT are consistently documented in the literature on animal experimentation and human application.

Over thirty years ago it was reported in *Science* that ECT disrupts (protective) protein production by brain cells.^{xvi} More recent studies show that electric shocks to the brain also cause an increase the production of inflammatory proteins inside brain cells.^{xvii}

More obvious brain damage was shown in a study at Duke University Medical Center and the Durham VA Hospital which looked at the brain scans (by MRI) of patients before and after ECT. Out of 35 patients studied, 8 had new changes on MRI after shock. That’s 22%, or greater than one in 5, with anatomic brain effects. Among those with the brain changes, one patient suffered a stroke and two had new abnormal neurologic signs on exam within 6 months of the ECT.^{xviii}

One study compared the brain CT scans of schizophrenics who had ECT were compared with those of schizophrenics who never received shock. It documented cerebral atrophy (brain shrinkage) was significantly more common in those who had ever been shocked.^{xix} The study was done nearly 30 years ago, at a time when bilateral ECT was the norm, and now we see bilateral ECT getting popular again.

Another CT scan study confirmed that frontal lobe atrophy (brain shrinking) was significantly more common in ECT recipients.^{xx} MRI scans have been used to demonstrate a strong correlation between the numbers of previous ECT treatments to enlarged ventricles (loss of brain tissue).^{xxi}

A study in England compared the brain CT scans of 101 depressed patients who had received ECT to 52 normal volunteers. They found a significant relationship between treatment with ECT and brain atrophy. In fact 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 age, alcohol use, gender, family history of mental illness, age at the time of psychiatric diagnosis, or severity of mental illness”.^{xxii} (Italics in the original)

There are no special controls or guidance documents (as required for Class II devices) that would alter the basic effect of seizure-inducing electricity on the brain.

4. ECT CAUSES MEMORY LOSS

The memory loss associated with ECT is its most well-documented effect.^{xxiii} In an issue exclusively dedicated to a comprehensive review of the cognitive effects of ECT, the editor of the *Journal of ECT* states:

“On the other hand, virtually all patients experience some degree of persistent and, likely, permanent retrograde amnesia. A series of recent studies demonstrates that retrograde amnesia is persistent, and that this long-term memory loss is substantially greater with bilateral than right unilateral ECT.”^{xxiv}

The editorial concludes:

“It has also become clear that for rare patients the retrograde amnesia due to ECT can be profound, with the memory loss extending back years prior to receipt of the treatment.”^{xxv}

The admission that “virtually all” subjects get memory loss is verified by the publically-available data from the State of California Department of Health data documenting a 99% incidence of significant memory loss after ECT.^{xxvi}

While some ECT proponents claim that the memory loss is due to concomitant psychiatric drugs^{xxvii}, the evidence shows otherwise. In fact, post-ECT cognitive deficits correlate directly with EEG changes.^{xxviii} This is objective proof of the brain-damaging effects of ECT.

A comprehensive review of the literature shows that amnesia increases with increasing number of treatments; amnesia is worse with sine wave stimulus than with brief pulse stimulus; slowing of brain waves (as measured by EEG) is more common as the number of treatments increases.^{xxxix}

Some researchers claim that the memory loss attendant to ECT is in fact its therapeutic effect, essentially causing the patient to forget his troubles.^{xxx} Others claim that memory actually improves.^{xxxi} It has been shown that people who suffer significant memory loss are far less likely to consent to more ECT.^{xxxii}

Memory loss directly reduces the independence of its victims, as can be seen in natural models of memory loss such as Alzheimer's dementia. The impact on the long term care needs of the cognitively-deficient ECT patients has never been appraised.

5. DEFICIENT MEDICAL STUDIES

It is popular in the ECT literature to blame immediate adverse effects of ECT on concomitant psychiatric medications or on anesthesia.^{xxxiii} The complete failure to compare ECT recipients to a control group is representative of the profoundly defective studies being done in this area. ECT studies have high drop-out rates due to treatment failure, adverse effects and refusal to continue the treatment. For example, one recent study documents a typical withdrawal rate of 38 out of 70 subjects.^{xxxiv} In fact the studies are so defective in design and poor in methodology that hardly any of them meet the standards for Evidence Based Medicine.^{xxxv}

A significant confounding factor in studying ECT is the inherent coercion that is commonly present in the treatment environment. Patients who identify themselves as "shock survivors" describe the terrorizing effect of being shoved a piece of paper to sign (this substitutes for informed consent) under threat of involuntary commitment. The bewildered patient is offered treatment that they feel they cannot refuse. Then, after a series of being repeatedly knocked out with general anesthesia and repeatedly shocked, they testify that they say anything to "get themselves out of there".^{xxxvi} A recent study concluded:

"Neither current nor proposed safeguards for patients are sufficient to ensure informed consent with respect to ECT..."^{xxxvii}

Obviously any psychiatric assessments done in such a milieu would be expected to be significantly skewed, but this singular factor is conspicuously not addressed in most ECT articles.

CONCLUSIONS:

1. A detailed review of the ECT literature makes it clear that there is entirely insufficient safety and effectiveness evidence on the electroconvulsive delivery machines to currently qualify such devices for an immediate upgrade in classification.
2. In the interest of public safety, any change in the status of ECT machines should be dependent upon a careful review of pre-market approval (PMA) documents according to the usual route currently required for approval of medical devices.

ENDNOTES

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^{xxxv} ^{xxxv} ECT research reports rarely if ever apply the checklist of the Consolidated Standards of Reporting Trials (CONSORT) statement.^{xxxv} CONSORT is an effort to create ethical and scientific standards for the reporting of randomized controlled clinical trials. It is a 21-item checklist of items developed by an international group of clinical trialists, statisticians, epidemiologists and biomedical editors. Adherence to CONSORT requirements eliminates some of the more deceptive data manipulation ploys that can be difficult to otherwise perceive.

Meta-analysis is a useful and popular way to assess the outcomes of multiple randomized trials that have been done across a period of years. While CONSORT addresses a single study, the Quality Of Reporting Of Meta-analyses (QUORUM) statement deals with criteria for meta-analysis reports. It is an 18-item checklist requiring the disclosure of literature searches, article selection, validity assessment methods, data abstraction, study characteristics, quantitative data synthesis and trial flow. A QUORUM-qualified meta-analysis report would be more trustworthy than a meta-analysis that didn't follow these quality guidelines. The CONSORT statement is available at <http://www.consort-statement.org/>, last accessed 9/1/09 and The QUORUM checklist is available at <http://www.consort-statement.org/QUORUM.pdf>, last accessed 9/1/09.

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