



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

Isadore M. Chait

Joyce Gaines

Michael Baybak

COMMISSIONERS

Founding Commissioner

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.

Joan Mathews-Larson, Ph.D.

Craig Newnes, M.D.

Megan Shields, M.D.

Alan Sosin, M.D.

David Tanton, Ph.D.

Michael Wisner

Julian Whitaker, M.D.

Spice Williams-Crosby, BSc.

Law

Timothy Bowles, Esq.

Sandro Garcia Rojas

Guillermo Guzmán de la

Garza

Kendrick Moxon, Esq.

Steven Russell, Esq.

Center for Devices and
Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, Rm. 1615,
Silver Spring, MD 20993

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. 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:

- The company “does not do research.”¹⁶
- 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. Nichol 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.¹⁷ ...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.”¹⁸
- “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.”¹⁹
- 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.”²⁰

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.²¹ [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.²²

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.”²³ [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.²⁴ 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.²⁵

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.”²⁶ He described the sensations they experienced as “callous and perhaps brutal.”²⁷ He accepted their recollections and evidence “as correct.”²⁸

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."²⁹
- 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."³⁰
- 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."³¹
- 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...."³²
- 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.'" ³³

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."³⁴ 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 2011.³⁵ 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).³⁶

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."³⁷ 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."³⁸

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.³⁹

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.*"⁴⁰ [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.⁴¹

- 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.⁴² 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.⁴³

- 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.⁴⁴ MECTA has also funded his ECT studies.⁴⁵ In 1981, NIMH began giving Dr. Sackeim grants to study the "affective and cognitive consequences of ECT."⁴⁶ 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...."⁴⁷
- Dr. Richard D. Weiner has a long-standing relationship with MECTA and consulted for SOMATICS, Inc.⁴⁸ 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.⁴⁹ 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.⁵⁰ In 1995, he filed a patent for an "electroconvulsive therapy method using ictal EEG data as an indicator of ECT seizure adequacy."⁵¹ He was Chairman of the APA ECT Task Force 1990. In 2005, he was on the Speaker's Bureau of MECTA.⁵² He is a co-inventor on a Duke University-patent licensed to MECTA but says he receives no royalties for the patent.⁵³
- 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.⁵⁴ 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.⁵⁵

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)....”⁵⁶

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.⁵⁷ 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.⁵⁸ 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)⁵⁹ 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].⁶⁰
- 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]⁶¹ Later quoted in media, she said it was unlikely ECT manufacturers could "*finance the studies required to get it approved...*"⁶² 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."⁶³ 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.⁶⁴ In March 2015, Dr.

Lisanby was chosen to be the director for NIMH's Division of Translational Research.⁶⁵

- 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.*"⁶⁶
- 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."⁶⁷
- "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.*"⁶⁸
- "...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."⁶⁹
- "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](#))."⁷⁰
- "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.*"⁷¹

- *"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'."*⁷²
- *"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."*⁷³
- *"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."*⁷⁴
- *"[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."*⁷⁵
- *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."⁷⁶

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."⁷⁷
- 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."⁷⁸
- "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."⁷⁹

- "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."⁸⁰
- 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.⁸¹

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.⁸² 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.⁸³

- 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.⁸⁴ 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.⁸⁵ Krystal and Weiner are the inventors listed on a U.S. patent that Duke University has licensed to MECTA Corporation.⁸⁶ Krystal was a member of the APA's 2010 ECT Task Force under the chair of Sarah Lisanby.⁸⁷
- 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."⁸⁸

- 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...”⁸⁹
- *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.⁹⁰
- 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.”⁹¹

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.⁹²

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.”⁹³

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).⁹⁴

PTCA catheters and spinal cages have risks⁹⁵ 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.”⁹⁶

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....”⁹⁷

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.”⁹⁸

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.”⁹⁹ 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.¹⁰⁰

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.¹⁰¹ 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.¹⁰² 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.”¹⁰³

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.¹⁰⁴

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.”¹⁰⁵

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*.”¹⁰⁶ [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.”¹⁰⁷ 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.¹⁰⁸

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.¹⁰⁹ 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.¹¹⁰

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."¹¹¹

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."¹¹²

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."¹¹³

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."¹¹⁴

“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.¹¹⁵

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.”¹¹⁶

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 2011.¹¹⁷

However, per MECTA’s President, “MECTA does not do research”¹¹⁸ and no effort was made to acquire adverse information caused by its devices.¹¹⁹ 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.”¹²⁰ 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 rate¹²¹ 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.¹²²

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.

For further information:

CCHR International
6616 Sunset Blvd.
Los Angeles, California 90028, USA
(323) 467-4242
(800) 869-2247
Fax (323) 467-3720

www.cchr.org
Email: humanrights@cchr.org

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.¹²³ 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.¹²⁴
- 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."¹²⁵

- 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.¹²⁶
- 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."¹²⁷

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](#))¹²⁸
- “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....”¹²⁹
- 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](#)).¹³⁰

REFERENCES

- ¹ <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1210-0001>
- ² <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=860.7>
- ³ Dr. Colin A. Ross, submission to the FDA, 10 January 2011, http://www.electricschocktherapy.info/uploads/4/0/7/6/4076267/colin_a_ross_md_ect_psychiatrist.pdf.
- ⁴ 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>
- ⁵ 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>
- ⁶ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 101.
- ⁷ Charles Kellner, M.D., "Electroconvulsive Therapy: The Second Most Controversial Medical Procedure," *Psychiatric Times*, 8 Feb. 2011, <http://www.psychiatrictimes.com/mdd/content/article/10168/1793704>
- ⁸ Case 03CP4004797, Richland County, South Carolina, Filed October 03, 2003, Decided June 17, 2005, <http://suemypsychiatrist.wordpress.com/category/ect/>
- ⁹ <http://www.trapaniok.it/2641/Salute-trapani/vietato-l-uso-dell-elettroshock-come-strumento-terapeutico-in-sicilia#.UxICFM7Xlqy>
- ¹⁰ "Lawrence T. Park, MD," Advisory Board, Mass. General Hospital, <http://www2.massgeneral.org/allpsych/ced2/clinicians/park.html>.
- ¹¹ "Lawrence Park, MD, Find a Doctor Page, Georgetown University Hospital, http://www.georgetownpsychiatry.org/body_dept_fw.cfm?id=556736&action=detail&ref=3584&dept=556736; "Somatotherapies Unit (ECT)," Mass. General Hospital, <http://www2.massgeneral.org/allpsych/PsychNeuro/ect.asp>.
- ¹² "Somatotherapies Unit (ECT)," Mass. General Hospital, <http://www2.massgeneral.org/allpsych/PsychNeuro/ect.asp>.
- ¹³ Jennifer M. Park, et al., "Factors Associated with Extended Length of Stay for Patients Presenting to an Urban Psychiatric Emergency Service: A Case-Control Study," *Journal of Behavioral Health Services & Research*, July 2009.
- ¹⁴ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, pp. 143-144
- ¹⁵ American Psychiatric Association, *The Practice of Electroconvulsive Therapy Recommendations for Treatment, Training, and Privileging (A Task Force Report of the American Psychiatric Association)*, Second Ed (Washington, D.C.: American Psychiatric Association, 2001).
- ¹⁶ Deposition from civil case Atze Akkerman vs MECTA, cited in submission to the FDA, 6 Jan. 2010.
- ¹⁷ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, p. 143-144
- ¹⁸ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, p. 144
- ¹⁹ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, p. 144
- ²⁰ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, p. 147

21

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%2011.1/27/11>, Pp. 148-49

²² “Proposed Rule” dated 29 December 2015, Docket ID: FDA-2014-N-1210-000, under “Summary of Reasons for Reclassification.” <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1210-0001>.

²³ “Proposed Rule” dated 29 December 2015, Docket ID: FDA-2014-N-1210-000, <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1210-0001>.

²⁴ The Hon. Mr. Acting Justice, J.P. Slattery, A.O., “Report of the Royal Commission Into Deep Sleep Therapy,” NSW Royal Commission, Vol. 5, “The Experts,” p. 75.

²⁵ *Ibid.* Vol. 3, DST & ECT, pp. 237-311.

²⁶ *Ibid.* p.306.

²⁷ The Hon. Mr. Acting Justice, J.P. Slattery, A.O., “Report of the Royal Commission Into Deep Sleep Therapy,” NSW Royal Commission, Vol. 3, DST & ECT, p. 302.

²⁸ *Ibid.*, DST & ECT, p. 309.

²⁹ *Ibid.* p. 307

³⁰ *Ibid.*

³¹ *Ibid.* p. 307.

³² *Ibid.*, pp. 308-309.

³³ *Ibid.*, pp. 309.

³⁴ *Ibid.*, Vol. 6., p. 96.

³⁵ <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1210-0001>

36

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247595.pdf.%20Accessed%20December%2011.1/27/11>

³⁷ Deposition from civil case Atze Akkerman vs MECTA, cited in submission to the FDA, 16 Jan. 2011, p. 7.

³⁸ Rick Moxon’s statement to FDA Hearing; Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 194.

³⁹ Duff Wilson, “F.D.A. Is Studying the Risk of Electroshock Devices,” *The New York Times*, 23 Jan. 2011, http://www.nytimes.com/2011/01/24/business/24shock.html?_r=1&pagewanted=print

⁴⁰ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 148, citing J.M, Davis, “Official Actions: The Council of Research,” *American Journal of Psychiatry*, 138 (4), 1981, p. 572.

⁴¹ “F.D.A. Is Studying the Risk of Electroshock Devices,” *The New York Times*, 23 Jan. 2011,

<http://www.nytimes.com/2011/01/24/business/24shock.html>; Susan FitzGerald,

“Despite Protests, Shock Treatment Gains New Respect,” *Philly.com (Philadelphia Inquirer)*, 17. Oct.

1998, http://articles.philly.com/1988-10-17/news/26272212_1_ect-mental-patient-harold-sackeim

⁴² Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) pp.192-196;

https://books.google.com/books?id=SFw5SLgAm9sC&pg=PA239&lpg=PA239&dq=Matthew+Rudorfer++Harold+Sackeim+ECT&source=bl&ots=VHMLYw1vOZ&sig=vkao14xRnIZfCUilbva90taldCA&hl=en&sa=X&ved=0ahUKEwjJ-fuL8M_KAhVJ2GMKHZtEAEQ6AEIJTAC#v=onepage&q=Matthew%20Rudorfer%20%20Harold%20Sackeim%20ECT&f=false

⁴³ P. 239,

https://books.google.com/books?id=SFw5SLgAm9sC&pg=PA239&lpg=PA239&dq=Matthew+Rudorfer++Harold+Sackeim+ECT&source=bl&ots=VHMLYw1vOZ&sig=vkao14xRnIZfCUilbva90taldCA&hl=en&sa=X&ved=0ahUKEwjJ-fuL8M_KAhVJ2GMKHZtEAEQ6AEIJTAC#v=onepage&q=Matthew%20Rudorfer%20%20Harold%20Sackeim%20ECT&f=false

⁴⁴ Chris Dubey, “A summary of references against electroshock treatment,” *Examiner*, Nov 21, 2012,

<http://www.examiner.com/article/a-summary-of-references-against-electroshock-treatment>; New York State

Assembly Report on Electroconvulsive Therapy (ECT), March 2002,

http://assembly.state.ny.us/member_files/125/20020416/.

⁴⁵ Comprehensive CV of Sackeim, as published by *Clinical Neuropsychiatry Journal of Treatment Evaluation*, www.clinicalneuropsychiatry.org/biografie/sackeim.php.

⁴⁶ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 195-198.

⁴⁷ Testimony of the Director of Committee for Truth in Psychiatry, New York State Assembly, May 18, 2001, <http://www.ect.org/news/newyork/andretest.html>; Max Fink Interviewed by David Healy, Dec. 8, 2008, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0ahUKEwj06Ki4x9_KAhVS2WMKHbRNCbIQFggxMAQ&url=http%3A%2F%2Fd.plnk.co%2FACNP%2F50th%2FTranscripts%2FMax%2520Fink%2520by%2520David%2520Healy.doc&usq=AFQjCNHX0I7dLfpvp_YaSNgDRGzqSkIYfg&sig2=KxT9o-6JP4sPL9I84oYIFg.

⁴⁸ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 198-199.

⁴⁹ *Electroconvulsive Therapy*, ECT Task Force report, (APA) Sept. 1978, pp. iii; Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 198-199.

⁵⁰ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 145, p. 154, p. 161-162.

⁵¹ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 198-199.

⁵² Program, American Psychiatric Association 2005 Annual Meeting, Atlanta, GA, May 2005; http://journals.lww.com/ectjournal/Citation/1990/06000/The_1978_and_1990_APA_Task_Force_Reports_.2.aspx.

⁵³ Mehul Mankad, MD, et al., "Clinical Manual of Electroconvulsive Therapy," American Psychiatric Publishing, Inc., 2010,

http://psychoreanimatology.org/download/books/Clinical_Manual_of_Electroconvulsive_Therapy_2010.pdf.

⁵⁴ "ECT Experts' Ties to Shock Machine Industry," <http://www.ect.org/news/posta.html>.

⁵⁵ Arline Kaplan, "Through the Times With Max Fink, M.D.," *Psychiatric Times*, September 1, 2005, <http://www.psychiatrictimes.com/articles/through-times-max-fink-md/page/0/5>; Mount Sinai Hospital webpage, <http://www.mountsinai.org/profiles/charles-kellner>.

⁵⁶ Douglas G. Cameron, "ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation," *The Journal of Mind and Behavior*; Winter and Spring 1994, Vol. 15, Nos. 1 and 2; Pages 177-198, <http://www.brown.uk.com/brownlibrary/CAMERON.htm>.

⁵⁷ "Electroconvulsive Therapy: An Exchange: [William H. Nelson](#) and [Marilyn Rice](#), reply by [Israel Rosenfield](#)," *The New York Review of Books*, 30 May 1985,

<http://www.nybooks.com/articles/archives/1985/may/30/electroconvulsive-therapy-an-exchange/?pagination=false>

⁵⁸ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 148-149.

⁵⁹ <http://neurosciencecme.com/library/MM027-day3-1030-goodman-winstead.pdf>

⁶⁰ American Psychiatric Association, 163rd Annual Meeting, New Orleans, LA, May 22-26, 2010, Program Book, p. 40; American Psychiatric Association, 162nd Annual Meeting, San Francisco, Shaping Our Future: Science and Service, May 16-21, 2009, Program Book, p. xxxii; American Psychiatric Association, 162nd Annual Meeting, San Francisco, Shaping Our Future: Science and Service, May 16-21, 2009, Program Book, p. xxxii.

⁶¹ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%202011>, 1/27/11, PP. 32-35

⁶² Jim Amos, "Future of ECT as Life-Saving Treatment at Risk?" *The Practical Psychosomaticist*, March 10, 2011, <http://jajsamons.wordpress.com/2011/03/10/future-of-ect-as-life-saving-treatment-at-risk/>; "Study: Electromagnets Can Relieve Depression," CBS News, 5 May, 2010, http://www.cbsnews.com/2100-500368_162-6462525.html.

⁶³ <http://psychcentral.com/lib/informed-consent-for-ect/>

⁶⁴ *Journal of ECT* Editorial Board, <http://journals.lww.com/ectjournal/pages/editorialboard.aspx>.

⁶⁵ <http://www.nimh.nih.gov/news/science-news/2015/lisanby-chosen-to-lead-nimh-division-of-translational-research.shtml>

⁶⁶ Charles Kellner, MD, "The FDA Advisory Panel on the Reclassification of ECT Devices," *Psychiatric Times*, 5 July 2012, <http://www.psychiatristimes.com/electroconvulsive-therapy/content/article/10168/1897020>

⁶⁷ 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>

⁶⁸ 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>

⁶⁹ 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>

⁷⁰ 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>

⁷¹ 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>

⁷² 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>

⁷³ 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>

⁷⁴ 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>

⁷⁵ 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>

⁷⁶ 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>

⁷⁷ Diana Rose, Pete Fleischmann, Prof. Til Wykes, Morven Leese, Jonathan Bindman, "Patients' perspectives on electroconvulsive therapy: systematic review," *BMJ*, doi: <http://dx.doi.org/10.1136/bmj.326.7403.1363> (Published 19 June 2003), <http://www.bmj.com/content/326/7403/1363.full.pdf+html>

⁷⁸ Diana Rose, Pete Fleischmann, Prof. Til Wykes, Morven Leese, Jonathan Bindman, "Patients' perspectives on electroconvulsive therapy: systematic review," *BMJ*, doi: <http://dx.doi.org/10.1136/bmj.326.7403.1363> (Published 19 June 2003), <http://www.bmj.com/content/326/7403/1363.full.pdf+html>

⁷⁹ Diana Rose, Pete Fleischmann, Prof. Til Wykes, Morven Leese, Jonathan Bindman, "Patients' perspectives on electroconvulsive therapy: systematic review," *BMJ*, doi: <http://dx.doi.org/10.1136/bmj.326.7403.1363> (Published 19 June 2003), <http://www.bmj.com/content/326/7403/1363.full.pdf+html>

⁸⁰ Diana Rose, Pete Fleischmann, Prof. Til Wykes, Morven Leese, Jonathan Bindman, "Patients' perspectives on electroconvulsive therapy: systematic review," *BMJ*, doi: <http://dx.doi.org/10.1136/bmj.326.7403.1363> (Published 19 June 2003), <http://www.bmj.com/content/326/7403/1363.full.pdf+html>

⁸¹ Linda Andre, Julie Lawrence, "The contribution of ECT survivors to research on the permanent effects of ECT on memory, memory ability and cognition," 2002, <http://www.ect.org/?p=557>

⁸² Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 237.

- ⁸³ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 242.
- ⁸⁴ Linda Andre, *Doctors of Deception: What They Don't Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 237.
- ⁸⁵ Leye Jeannette Chrzanowski "ECT Document Reverberates Over the Internet Copyright," *The Disability News Service, Inc.*, Oct 13, 1999, <http://www.ect.org/resources/surgeongeneral/disabnewsserv.html>
- ⁸⁶ Nagy A. Youssef, *et al.*, "Does change in ECT electrode placement help temporomandibular joint pain?," *Annals of Clinical Psychiatry*, 2014, https://www.aacp.com/pdf%2F0514%2F0514ACP_Letters_Y.pdf; Andrew D. Krystal, M.D., Curriculum Vitae, 1 Apr 2010, <http://www.medfusion.net/templates/groups/6176/10622/Krystal.%20Andrew%20CV.pdf>
- ⁸⁷ Jun Yan, "Task Force Finalizing New ECT Guideline," *Psychiatric News*, Vol 44, No 13, Pg 7, 3 Jul 2009, <http://psychnews.psychiatryonline.org/doi/full/10.1176/pn.44.13.0007>.
- ⁸⁸ Cheryl van Daalen-Smith, *et al.*, "The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock," *CHILDREN and SOCIETY*, Vol. 28, 205-217 (2014) , http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf
- ⁸⁹ Miriam Feliu, *et al.*, "Neuropsychological effects and attitudes in patients following electroconvulsive therapy," *Neuropsychiatric Disease and Treatment*, 2008, vol 4, no 3, pp 613-617.
- ⁹⁰ D. W. Falconer, J. Clelanda, S. Fieldinga and I. C. Reid, "Using the Cambridge Neuropsychological Test Automated Battery (CANTAB) to assess the cognitive impact of electroconvulsive therapy on visual and visuospatial memory," *Psychological Medicine* (2010), 40: 1017-1025, <http://www.ncbi.nlm.nih.gov/pubmed/19775495>.
- ⁹¹ Samant, Sydney, *Clinical Psychiatry News*, Mar. 1983, web <http://www.ect.org/effects/psychnews.html>.
- ⁹² "Proposed Rule" dated 29 December 2015, Docket ID: FDA-2014-N-1210-000, <https://www.federalregister.gov/articles/2015/12/29/2015-32592/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-intended-for-use-in>; Duff Wilson, "F.D.A. Panel Is Split on Electroshock Risks," *The New York Times*, 28 Jan 2011, <http://www.nytimes.com/2011/01/29/health/29shock.html>; CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE NEUROLOGICAL DEVICES PANEL January 28, 2011, P. 439-462.
- ⁹³ CENTER FOR DEVICES AND RADIOLOGICAL HEALTH MEDICAL DEVICES ADVISORY COMMITTEE NEUROLOGICAL DEVICES PANEL January 28, 2011, P. 460-462. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247595.pdf.%20Accessed%20December%2013>
- ⁹⁴ <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247595.pdf.%20Accessed%20December%2013>, pp. 427-28, 431
- ⁹⁵ <https://www.nhlbi.nih.gov/health/health-topics/topics/angioplasty/risks>; <http://www.spine-health.com/treatment/spinal-fusion/interbody-cages-spine-fusion>
- ⁹⁶ "Minister Lynch: 'Unwilling' patients no longer to receive electric shock therapy," *TheJournal.ie*, 22 Jul 2013, <http://www.thejournal.ie/electro-shock-therapy-unwilling-patients-ireland-983018-Jul2013/>
- ⁹⁷ A/HRC/22/53, "Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez," United Nations, General Assembly, Human Rights Council, Twenty-second Session, Agenda Item 3, 1 Feb. 2013, p. 21, para 85, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf.
- ⁹⁸ A/HRC/22/53, "Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez," United Nations, General Assembly, Human Rights Council, Twenty-second Session, Agenda Item 3, 1 Feb. 2013, pp. 7-8, para 32, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf.
- ⁹⁹ Page 6. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM240933.pdf>

- ¹⁰⁰ <http://www.scotsman.com/news/scots-get-electric-brain-shocks-against-their-will-1-3604496>;
<http://www.stuff.co.nz/national/health/65394326/electricschocktherapyinthemodernday>; ; Jess Mcallen, "Electric shock therapy in the modern day", [stuff.co.nz](http://www.stuff.co.nz), Jan 25 2015,
<http://www.stuff.co.nz/national/health/65394326/Electric-shock-therapy-in-the-modern-day>
- ¹⁰¹ <http://www.jaapl.org/content/34/3/406.full.pdf>
- ¹⁰² <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3381633/>
- ¹⁰³ *Ibid.*, Vol. 6., p. 96.
- ¹⁰⁴ <http://bjp.rcpsych.org/content/186/1/54>.
- ¹⁰⁵ Thomas Insel, "Transforming Diagnosis," NIMH Website, 20 Apr. 2013,
<http://www.nimh.nih.gov/about/director/2013/transforming-diagnosis.shtml>
- ¹⁰⁶ <http://www.medscape.com/viewarticle/803752>
- ¹⁰⁷ <http://brainblogger.com/2011/05/30/electroconvulsive-therapy-in-pediatric-psychiatry/>
- ¹⁰⁸ Cheryl van Daalen-Smith, et al., "The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock," CHILDREN and SOCIETY, Vol. 28, 205-217 (2014) , http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf
- ¹⁰⁹ Australian Capital Territory Mental Health Bill 2015,
- ¹¹⁰ "Electroshock therapy on under-14s banned in WA after law passes Parliament," *ABC News*, 17 Oct. 2014,
<http://www.abc.net.au/news/2014-10-17/mental-health-bill-passes-wa-parliament/5822874>
- ¹¹¹ Cheryl van Daalen-Smith, et al., "The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock," CHILDREN and SOCIETY, Vol. 28, 205-217 (2014) , http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf
- ¹¹² Cheryl van Daalen-Smith, et al., "The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock," CHILDREN and SOCIETY, Vol. 28, 205-217 (2014) , http://www.breggin.com/ECT/vanDaalen-Smith&Breggin2014_ECTchildren.pdf
- ¹¹³ Benedetto Saraceno, MD, "WHO RESOURCE BOOK ON MENTAL HEALTH, HUMAN RIGHTS AND LEGISLATION WHO 2005," p. 64.
- ¹¹⁴
- "Poll: Consumers Say Govt Failed to Protect them from Dangerous Prescription Drugs; Americans Back Host of Drug Safety Reforms: Senate Health Panel Scheduled to Vote Wednesday on Legislation," *ConsumerUnion.Org*, 16 Apr. 2007,
<http://consumersunion.org/news/poll-consumers-want-host-of-drug-safety-reforms/>
- ¹¹⁵
- <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/UCM061319>
- ¹¹⁶
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm#special>
- ¹¹⁷
- <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevicesAdvisoryCommittee/neurologicalDevicesPanel/UCM247594.pdf.%20Accessed%20December%20>
- ¹¹⁸ Deposition from civil case Atze Akkerman vs MECTA, cited in submission to the FDA, 6 Jan. 2010.
- ¹¹⁹ See Rick Moxon, LLB, lawsuit and comment submitted to Docket 2009-M-0392, deposition testimony of Mecta president, Robin Nichol.
- ¹²⁰ <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1210-0001>
- ¹²¹ <http://www.psychiatrytimes.com/major-depressive-disorder/treatment-resistant-depression>.
- ¹²² Joseph Glenmullen, M.D., *Prozac Backlash*, (Simon & Schuster, NY, 2000), p. 76.
- ¹²³ <http://endofshock.com/litigation.htm>.
- ¹²⁴ Max Daily, "Electric Shock Victims Win Historic Victory," *Big Issue*, UK, 3 Oct. 1999.
- ¹²⁵ Sarah Chester, "The shock of an unwanted treatment," *The Age*, 9 May 1984.
- ¹²⁶ Juli Lawrence, "Leeds Man Awarded Half A Million Pounds," *Healthy Place*, America's Mental Health Channel, 18 Feb 2007, <http://www.healthyplace.com/depression/shocked-ect/leeds-man-awarded-half-a-million-pounds/menu-id-1362/>

¹²⁷ “ECT: Memories and Trust Lost,” Letters from readers, *Los Angeles Times*, 1 Dec. 2003.

¹²⁸ 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>

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>

¹³⁰ 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>