



International Center for the Study of Psychiatry and Psychology

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Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Docket #FDA 2009-N-0392: Electroconvulsive Therapy Safety and Effectiveness

The International Center for the Study of Psychology and Psychiatry (ICSPP) is a network of people concerned with how mental health theories affect public policy and individuals at large. Our varied membership includes psychiatrists, psychologists, neurologists, pediatricians, social workers, educators and professors, researchers and lawyers, “psychiatric survivors” and concerned family members, and advocates at large. The considerable scientific evidence available suggests the efficacy of electroconvulsive therapy (ECT) is very questionable, at best, it causes brain damage to all, and very serious brain damage to many. For these reasons, we urge the FDA to maintain the Class III scheduling of the ECT device until and unless clinical trials are conducted as part of the Premarket Approval application process, which validly demonstrates such reclassification is warranted. There is ample evidence and controversy regarding the lack of safety regarding these devices.

In 1979, the FDA categorized the ECT device as a Class III, high risk device, meaning that its benefits have not been shown to outweigh its risks, and that it presents a “potential unreasonable risk of injury or illness.” It ruled that brain damage and memory loss were risks of the procedure. Thirty years later, no evidence has accumulated to disprove these findings, but rather there has been a stream of continued evidence in the research demonstrating significant harmful effects. Here we briefly summarize the evidence on ECT’s lack of safety and efficacy.

On safety to the brain:

Prior to modern brain imaging technology, dozens of human and animal autopsy studies documented brain damage from ECT.ⁱ In the modern era, brain scan studies of psychiatric patients show a correlation between treatment with ECT and cerebral atrophy.ⁱⁱ The very few studies which set out to investigate the question of ECT’s effects on brain structure are both seriously methodologically flawed and inconclusive (i.e. they did not use normal controls, and allowed patients who had previously had shock to be considered as “before shock” or non shock subjects.)ⁱⁱⁱ

On safety to memory:

There are seventy years of reports of permanent extensive amnesia and memory dysfunction in a large percentage or majority of patients.^{iv} Reviewing the evidence to date, in 1985 the NIMH Consensus Conference on ECT found that the average loss was eight months of life and that the majority of ECT patients had chronic memory impairment three years after shock.^v More recently, *the first-ever systematic review of all the evidence to that date (2003) found that at least one-third of ECT*

patients experienced permanent memory loss.^{vi} An even more recent prospective study found that at least 45% of patients experienced permanent amnesia, and 40% reported loss of intelligence.^{vii}

The research on permanent amnesia can be summarized as follows: researchers have mostly avoided conducting any long term, six months or longer, studies, but whenever they have looked for permanent memory deficits, they have found them. There have been only two long term (e.g. six month) studies of amnesia done in the past 33 years, and both, despite serious methodological problems, show that permanent extensive amnesia is common.^{viii} One found “provocative evidence for autobiographical memory loss lasting at least six months” and the other, *the largest study of memory ever done*, concluded “adverse effects can persist for an extended period, and (usage) characterizes routine use of ECT in community settings.”

On efficacy:

In seven decades there have been only two methodologically sound randomized controlled clinical trials investigating whether ECT is more effective than drugs, and neither of these studies compared shock to drugs currently in use today.^{ix}

In 1992 and again in 2006 researchers systematically reviewed the literature on real vs. sham ECT and concluded the studies show no advantage for real ECT.^x Even the most recent American Psychiatric Association Task Force report, though it asserts ECT’s efficacy, did not cite a single study showing real ECT having a superior outcome to a sham ECT, when treating depression.

In 1985, the NIMH found there was no evidence for any benefit of ECT lasting more than four weeks, and there are no studies since 1985 showing any longer benefit. A large recent study indicated approximately one half of patients had no significant improvement to ECT, even in the very short term, and the majority who relapsed within one and six months later were suffering long term adverse effects, while overall only 10% were in remission.^{xi} An even more recent study found claims of 70-90% efficacy to be wildly inflated, with the actual rates from 30 to 46%; however, these positive outcomes were measured only in the few days immediately after ECT.^{xii}

Despite claims repeatedly made by ECT practitioners, including in the current docket, *research shows that ECT has no protective effect against suicide either in the short or long term.*^{xiii} A very recent study found that ECT patients committed suicide more frequently than those who had not received ECT, even when level of depression was taken into account.^{xiv}

If the FDA must consider the overwhelming evidence that does supports the continued need for ECT devices to be categorized as a Class III, device. Clinical trials on the device are long overdue and in need for professionals and practitioners to make informed decisions. The FDA’s original determination of ECT’s risk was and is accurate. The International Center for the Study of Psychiatry and Psychology is calling upon the FDA to keep the Class III schedule until PMAs are performed on the devices. In truth, we would suggest an impartial review of the evidence requires the withdrawal of ECT machines from the market.

Respectfully,

Dr. Toby Watson, PsyD
Executive Director

Board Members & Members:

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- ⁱ L. Andre, Doctors of Deception: What They Don't Want You to Know About Shock Treatment (Rutgers University Press, 2009), 44-48.
- ⁱⁱ D. R. Weinberger, E. F. Torrey et al, "Lateral Ventricular Enlargement in Chronic Schizophrenia," *Archives of General Psychiatry* 36 (1979), 735-739. S. P. Calloway, J. R. Dolan et al, "ECT and Cerebral Atrophy," *Acta Psychiatrica Scandinavica* 64 (1981), 442-445. P. J. Shah, M. F. Glabus et al, "Chronic, Treatment-Resistant Depression and Right Frontal-Striatal Atrophy," *British Journal of Psychiatry* 1980 (2002), 434-440.
- ⁱⁱⁱ C.E. Coffey, R. D. Weiner et al, "Effects of ECT on Brain Structure: A Pilot Prospective Magnetic Resonance Imaging Study," *American Journal of Psychiatry* 145(6), (1988), 701-706. C. E. Coffey, R. D. Weiner et al, "Brain Anatomic Effects of Electroconvulsive Therapy: A Prospective Magnetic Resonance Imaging Study," *Archives of General Psychiatry* 48 (1991), 1013-1021.
- ^{iv} The literature on permanent memory loss from the 1940s through 2009 is summarized in L. Andre, *op. cit.*
- ^v "Consensus Conference: Electroconvulsive Therapy," *Journal of the American Medical Association* 254 (15), (1985, October 18), 2103-2108.
- ^{vi} D. Rose, P. Fleischmann et al, "Patients' Perspectives on Electroconvulsive Therapy: Systematic Review," *British Medical Journal* 326 (7403), (2003, June 21), 1363-1367.
- ^{vii} M. Philpot, C. Collins et al, "Eliciting Users' Views of ECT in Two Mental Health Trusts with a User Designed Questionnaire," *Journal of Mental Health* 13(4), (2004, August), 403-413.
- ^{viii} R. Weiner et al, "Effects of Stimulus Parameters on Cognitive Side Effects," *Annals of the NY Academy of Sciences* 462 (1986), 315-325; H. Sackeim, J. Prudic et al, "The Cognitive Effects of Electroconvulsive Therapy in Community Settings," *Neuropsychopharmacology* 32 (2007), 244-254.
- ^{ix} A. Rivkin, "Shock Therapy: A History of Electroconvulsive Treatment in Mental Illness" (book review), *New England Journal of Medicine* 358(2), (2008, January 10), 204-205.
- ^x G. Shepard, S. Ahmed, "A Critical Review of the Controlled Real vs. Sham ECT Studies in Depressive Illness," paper presented at the First European Symposium on ECT, Graz, Austria, March 1992. C. Ross, "The Sham ECT Literature: Implications for Consent to ECT," *Ethical Human Psychology and Psychiatry* 8(1), (2006), 17-28.
- ^{xi} H. Sackeim, R. Haskett et al, "Continuation Pharmacotherapy in the Prevention of Relapse Following Electroconvulsive Therapy," *Journal of the American Medical Association* 285(10), (2001, March 14), 1299-1307.
- ^{xii} J. Prudic, M. Olfson et al, "Effectiveness of Electroconvulsive Therapy in Community Settings," *Biological Psychiatry* 55 (2004), 301-312.
- ^{xiii} V. Milstein, J. G. Small et al, "Does Electroconvulsive Therapy Prevent Suicide?" *Convulsive Therapy* 2(1), 1986, 3-6.

^{xiv} T. Munk-Olsen, P. Videbech et al, “All-Cause Mortality Among Recipients of Electroconvulsive Therapy,” *British Journal of Psychiatry* 190 (2007), 435-439.