

January 4, 2010

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

SUBJECT: Electroconvulsive Therapy Device (882.5940), Docket #FDA-2009-N0392

Our organization is aware that the FDA is considering the reclassification of the device used to administer electroconvulsive therapy from its current category as a Class III medical device to Class II. The agency plans to take this action based at least in part on information submitted by ECT device manufacturers.

We strongly oppose this decision. There is ample valid scientific evidence extant in the medical literature that electroconvulsive therapy can cause *irreversible brain damage* and *long term, permanent impaired cognitive function and accidental death*. See Research Summaries and Citations attached hereto.

Since the procedure for which the ECT device is intended has thus been proven unsafe, the device itself *cannot* be considered a Class II low-risk device.

Per this valid scientific evidence, the device, when operated *as directed by the manufacturers*, presents a “potential, unreasonable risk of illness or injury” which, per 21 CFR Part 814, makes it a Class III device. It is therefore not possible for the device to have a “performance standard” of instructions and protocol that assures that precautions can be taken to protect a patient, as is required for a Class II device.

The American Psychiatric Association has put forth an argument that the safety of the device itself must be separated from the safety of ECT, giving as an example X-ray machines that can administer potentially harmful doses of radiation if used incorrectly. This is a flawed comparison since the ECT device, unlike an X-ray machine, is harmful *when used as directed by its manufacturer*.

As with any medical device, the burden of proof must be on ECT device manufacturers to prove that their devices are safe and effective. Had the manufacturers submitted to the FDA “any information known or otherwise available to them” as was required by the FDA in its April 9, 2009 notice (Federal Register Vol. 74, No. 67, p.16214-16217), it should have been clear that there is *no valid scientific evidence that the device is safe*.

Our organization requests that the FDA calls for pre-market approval applications of these devices, which includes proof of safety and efficacy as a result of valid scientific evidence per 21 CFR Part 860.7(c)(2) of Part 860. We also request that the FDA prohibits their marketing and use until such pre-market approval has been given.

Sincerely,
Hakan Johanson
Citizens Commission for Human Rights of Florida
1217 North Fort Harrison Avenue
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ATTACHMENT: RESEARCH SUMMARIES AND CITATIONS

There is strong valid scientific evidence in medical literature, from the 1940s to the present, that electroconvulsive therapy—and therefore by extension the ECT device—causes *structural brain damage, cognitive damage and accidental death*.

NATIONAL COUNCIL ON DISABILITY

In the year 2000, the National Council on Disability, the federal agency that is responsible for making disability policy recommendations to the president and Congress, after reviewing such scientific evidence, made a policy recommendation that ECT should be eliminated as an *"unproven and inherently inhumane procedure"*.

STRUCTURAL BRAIN DAMAGE FROM ECT

- ECT can form scar tissue (gliosis) around nerve cells damaged by the electricity. This is otherwise seen in Alzheimer's disease and multiple sclerosis;
- ECT can cause brain hemorrhages, large and small;
- ECT can kill nerve cells;
- ECT can cause nerve cells to disappear;
- ECT can cause what psychiatry refers to as "Large Areas of Devastation" in the brain;
- ECT can cause brain tissue to shrink (atrophy);
- ECT can cause brain swelling (edema);
- ECT can cause the formation of "shadow" brain cells—where genetic material and other cellular components have just disappeared, leaving only the shell of the cell.

REFERENCES

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COGNITIVE DAMAGE FROM ECT

- ECT can cause long term or permanent sudden amnesia;
- ECT can cause inattention and an inability to concentrate;
- ECT can cause a patient to become dazed and stupefied;
- ECT can cause a difficulty carrying out manual tasks for which a patient has been trained;
- ECT can cause a reduction in intellectual abilities—known in psychiatry as the “taming effect”;
- ECT can cause a drop in IQ, as measured by tests.

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FATALITY RATE FROM ECT

The fatality rate of the modern modified ECT can be as high as 1 in 200 for people over sixty years of age. This rate is *higher* than the rate for the unmodified ECT administered in the 1940s and early 1950s when the electrical current required to trigger a convulsion was lower (the use of anesthesia in modern ECT raises the brain seizure threshold, requiring more electricity to override the body's defense mechanisms).

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PSYCHIATRY'S OWN ADMISSION OF ECT DAMAGE

- ECT works to “*knock out the brain and reduce the higher activities, to impair memory [so that] the pathological state is forgotten*”.
- “*Disturbance of memory is ... an integral part of the recovery process...people have...more intelligence than they can handle and a reduction in intelligence is an important factor in the curative process.*”
- “*There must be ... organic changes in the brain, and the cure is related to these organic changes*”.
- “*A socially adaptable individual with a little brain pathology is preferable to a psychotic patient with no demonstrable brain changes.*”

REFERENCES

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