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

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

This is a request that the FDA evaluate appropriate tests of efficacy and safety on electro-convulsive therapy (ECT) devices as part of its current assessment of their classification status.

Since the arrival on the US market of ECT devices in the early 1940s, the FDA has not required their manufacturers to sponsor their own studies of safety and efficacy and submit them for analysis to the FDA. Instead, the FDA has accepted other forms of evidence—selective literature reviews, personal testimonies of doctors and patients, and position statements by professional associations such as the American Psychiatric Association—that ECT devices are safe and effective.

An ECT device is used for the single purpose of inducing a full seizure in a human being. The use of ECT devices in humans requires a physician's prescription. The devices cause harm in the short and longer-term to neurological and cognitive functions in at least some humans and animals. Sackheim and colleagues reported adverse cognitive deficits in humans 6 months following an acute course of ECT (*Neuropsychopharmacol* 2007; 32:244-254). For these reasons, a program of study and evaluation of the devices equivalent to a pre-market approval application, should be evaluated by the FDA prior to the continued use of ECT devices. Such a program of study is at present the only scientifically acceptable way to establish an independent risk-benefit ratio concerning ECT devices.

Proper testing of ECT machines is necessary as the basis for any change—or no change—in their classification. Such testing is precisely why the FDA exists: to protect the public from the harm of unregulated medical devices by requiring the makers of such devices to document their safety and efficacy before marketing.

Such testing should include:

1. pre-clinical (animal) studies, including standard neurobehavioral observation batteries and post-mortem examinations;

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2. pre- and post-ECT (acute, short-term, and long-term) detailed brain-imaging studies in healthy animals and healthy humans; and

3. clinical trials testing the hypothesis that a standard course of ECT is superior to active placebo (e.g., sham ECT) to relieve the symptoms of a specified condition in at least one usual population of people who receive it nowadays. Usual data in the clinical trials must be supplemented by pre- and post-ECT brain imaging data collected at appropriate, scientifically and clinically justified intervals. Appropriate cognitive batteries and other tests of psychological functioning must be employed in all human studies.

The FDA should act promptly on this matter in accordance with its own scientific standards. Short of such a program of evaluation of ECT devices, the FDA will lose credibility, regardless of the decision it makes with respect to classification of the devices.

It seems evident that nothing short of such a program of evaluation can enable the FDA to fulfill its legal and ethical mission to protect the public from harm of unregulated medical devices, and to generate *an independent, reliable estimate of the adverse effects that patients and physicians may routinely expect from the use of ECT devices*.

Thank you for your consideration.

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