ALLIANCE FOR HUMAN RESEARCH PROTECTION
A catalyst for public debate
142 West End Avenue Suite 28P
New York, NY 10023
212-595-8974
www.ahrp.org

The Alliance for Human Research Protection (AHRP) is a catalyst for public debate on biomedical research, promoting openness, full disclosure, and accountability.

We are concerned about the possibility that the FDA may exempt manufacturers of electroconvulsive therapy (ECT) devices from the regulatory requirement to prove their devices safe and effective through the PreMarket Approval (PMA) process.

ECT machines have been designated as Class III devices since 1979, when the FDA recognized that its use pose risks outweighed by any proven benefits, and that those serious risks include permanent amnesia and brain damage. Nevertheless, the agency has allowed ECT devices be used for thirty years on patients who have not been informed of these risks and have. Patients have been unwitting subjects in a vast uncontrolled experiment whose outcome has not been publicly reported.

Now the FDA is under edict from the General Accounting Office to call for PMAs on the few remaining untested Class III devices, including ECT devices. The agency has said it is considering taking the unprecedented step of reclassifying ECT devices to Class II without scientific evidence of its safety and in the absence of a single clinical trial.

Proponents of ECT, who have a financial stake in ECT, oppose having to prove the devices safe in scientifically controlled trials. They are writing to the FDA to demand reclassification by asserting that ECT is safe—without evidence. If they actually believed the devices to be safe, why would they oppose demonstrating their safety?

Indeed, FDA's own files contain evidence of ECT's permanent adverse effects, and their devastating effects on patients' lives. (The 40+ volumes of evidence in Docket #82P-0316 is summarized in the book Doctors of Deception: What They Don't Want You to Know About Shock Treatment by Linda Andre, published by Rutgers University Press in February 2009.)

FDA must consider all the evidence in this docket, including patient reports, neuropsychological testing, and research findings by non-industry researchers including ECT survivors. In contrast, comments by members of the American Psychiatric Association and the users of ECT devices consist of repeated assertions of the device's safety and efficacy---including the unfounded claim that it saves lives---without evidence. Indeed, ECT device manufacturers are on record as stating that they refuse to

conduct clinical trials or to participate in the PMA process at all, even to the extent of paying a filing fee. And the APA has lobbied on manufacturers' behalf for reclassification of ECT devices—without safety testing—since 1982.

Research on ECT, much like drug research, is so rife with financial conflict of interest that unbiased objective scientific studies are nearly nonexistent. The fact is, ECT have been small, uncontrolled, conducted by financially conflicted researchers. The studies, by the researchers' own admission, have been inconclusive. Furthermore, **there have been no such studies done at all in the past 20 years using modern technology—such as before and after brain scans.**

There is no evidence that ECT has any beneficial effect that lasts longer than four weeks.

There is no evidence that ECT prevents suicide.

ECT amnesia has rarely been studied in the long term but whenever it was, it has been found to be both extensive and permanent.

Especially remarkable are the recently published research findings by ECT's most prominent researcher, the author of over 200 journal articles on ECT, Dr. Harold Sackeim. Dr. Sackeim is the recipient of the bulk of funding in federal (NIMH) research grants for the purpose of studying ECT who authored most of the ECT practice guidelines for the American Psychiatric Association.

In 2000, Dr. Sackeim acknowledged in an editorial in the *Journal of ECT*, that **"virtually all patients experience some degree of persistent, and likely permanent retrograde amnesia.** A series of recent studies demonstrates that retrograde amnesia is persistent and that this long-term memory loss is substantially greater with bilateral than with unilateral ECT." (See: Sackeim, HA. Memory and ECT: From Polarization to Reconciliation. *Journal of ECT* 16(2): 87-96, June 2000.)

And in a published large prospective study of ECT efficacy, Dr. Sackeim and colleagues found claims of 70-90% efficacy to be wildly inflated: with the actual efficacy rates being closer to 30-46%--and efficacy only demonstrated within the few days immediately after ECT. (Prudic, J et al. Effectiveness of Electroconvulsive Therapy in Community Settings," *Biological Psychiatry* 55: 301-213, 2004.)

In the largest study of memory loss ever conducted, Dr. Sackeim et al acknowledged: "Despite ongoing controversy, there has never been a large scale, prospective study of the cognitive effects of electroconvulsive therapy."

In other words, there is no credible scientifically valid evidence to support the claimed safety / efficacy of electroconvulsive therapy.

The findings of the first large, prospective study conducted by ECT's most prominent researcher confirm its harm-producing results: " **This study provides the first evidence in a large, prospective sample that the adverse cognitive effects can persist for an extended period, and that they characterize routine treatment with ECT in**

community settings." (Sackeim HA, et al. The Cognitive Effects of Electroconvulsive Therapy in Community Settings, *Neuropsychopharmacology* 32: 244-154, 2007.)

Finally, it is important to address the issue of whether there exists any possible justification, other than capitulation to the financial interests of the ECT industry, for reclassification to Class II. In order to reclassify, FDA would have to assert that ECT's safety can be assured by special and general controls, and would have to describe how this could be done. Such controls include the maintenance of records on the devices, labeling, performance standards or practice guidelines for use, and post-market surveillance such as patient registries.

None of these will spare human brains the effects of electrical current and grand mal seizures, both of which are recognized by physicians outside of the field of psychiatry as inherently brain damaging.

Post-market surveillance programs such as Medwatch already exist, are underutilized and can only document adverse effects, not ameliorate them.

Attempts by FDA in the mid-1990s to standardize labeling for ECT devices were unsuccessful. Attempts by the American Psychiatric Association to develop a performance standard for the ECT device failed in the 1980s. The only existing practice guidelines are written by those who have financial interests in ECT manufacturers (acknowledged, belatedly, in the third edition of the guidelines)—and who therefore have a conflict of interest. These industry-influenced guidelines have existed since 1978 and have not made ECT any safer.

We are especially concerned that FDA will reclassify simply on the basis of a review of a biased literature whose authors are overwhelmingly stakeholders in ECT. Why should the agency assume the responsibility of manufacturers whose job it is—by law—to prove the device safe? Given the serious risks posed by ECT, manufacturers should not be exempted from proving their devices safe.

ECT manufacturers must be made to adhere to unbiased, scientific methods—by conducting controlled clinical trials—as is required of all other medical device manufacturers.

But the FDA has a responsibility to call for PMAs on the ECT device no matter what the outcome and without regard to the financial interests of the device manufacturers. And like Sackeim, once the trials are conducted it should issue a public apology to the generation of people who underwent this untested procedure without being informed of its risks.

Vera Hassner Sharav
President
Alliance for Human Research Protection
veracare@ahrp.org