Chuck Ruby, Ph.D.
Executive Director

Dominick Riccio, Ph.D.
Chairman of the Board of Directors

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

Re: Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and FDA Staff; Availability; Docket ID: FDA-2014-D- 1318 & FDA–2014–N–1210

To Whom It May Concern:

I am writing on behalf of the International Society for Ethical Psychology and Psychiatry (ISEPP) in opposition to the proposal to reclassify electroconvulsive therapy (ECT) as specified in the referenced docket. Information relied on by the Food and Drug Administration (FDA) to support this reclassification of ECT is no different than the information the FDA has relied on in the past to keep its current classification. The data regarding the effectiveness and safety of ECT has not changed. ECT continues to be harmful, it impairs cognitive functioning, it is ineffective over the long term, and it is a barbaric procedure.

The only reason ECT is said to "work" is because it disrupts brain functioning so much that the person temporarily stops making complaints about significant life issues and they become easier to manage. But in doing so, it transforms meaning-making, emotional, and complex human beings into docile, simple-minded creatures, stripping away the essence of what makes them human. Stunning a person with ECT is an electrical version of a hard slap in the face. It is similar to other outdated, harmful, and equally barbaric procedures such as chemically induced seizures and comas, rotational therapy, hydrotherapy, lobotomy, and trepanation.

The phenomenon called depression can be a serious problem. But there is no scientific evidence it is caused by real brain pathology that can be corrected in a mechanical, chemical, or surgical way. This is because depression is a manifestation of meaningful and complex human struggles with emotional upheaval, confusion, and intense personal consequences. Therefore, sending an electrical current through the brain ostensibly as a medical procedure to correct it is absurd.

ISEPP implores the FDA to deny this reclassification.

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Executive Director