Committee for Truth in Psychiatry
P.O. Box 1214
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To: Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

CITIZEN PETITION

The Committee for Truth in Psychiatry submits this petition pursuant to 21 CFR 10.30 to request the Commissioner of Food and Drugs to maintain the electroconvulsive therapy device (882.5849) in Class III for all indications.

Part A. SPECIFIC ACTION REQUESTED

The FDA is charged with the responsibility of categorizing medical devices according to the degree of risk they pose and the degree of oversight they require. The electroconvulsive therapy (ECT) device is a pre-amendments device which has never been tested for safety or efficacy; for which manufacturers have never presented any evidence of safety or efficacy although ordered to do so by the FDA on August 14, 1995 (FR 60: 41984); and for which no Premarket Application has been called for or submitted.

On September 4, 1979, the FDA classified the ECT device into Class III under the Federal Food, Drug and Cosmetic Act (FR 44:51777), identifying eight risks to health including brain damage and memory loss.

FDA's original classification was correct. Since that time, more valid scientific evidence has accumulated as to the risks of the device. Since that time, the manufacturers have not conducted a single study nor submitted any evidence showing that the original classification was incorrect. Under Section 515(i) (21 U.S.C. 360e(i)) of the Safe Medical Devices Act of 1990 (SMDA), manufacturers of ECT devices were required to submit all safety and effectiveness information known to them by August 14, 1997. No manufacturer ever submitted anything in response to the order.

We are asking FDA *not* to take an action: we are asking that it *not* reclassify the Device to Class II. We ask that it maintain the device as Class III under Section 515(i) of the SMDA. This petition is necessary because FDA has begun the process leading to reclassification.

Another way of stating our request is that we are asking that the ECT device be regulated in the same manner as other medical devices. Currently, this is not the case.

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Part B. STATEMENT OF GROUNDS

The Committee for Truth in Psychiatry, founded in 1984, is the only national organization of patients who have been treated with the ECT device. We all had ECT without being truthfully informed of the risks of the device, and as a result we all suffered permanent harm to varying degrees (including memory loss, cognitive disability, and brain damage). The majority of our members lost our ability to work and to contribute to society due to ECT. We are fully familiar with the nature and history of FDA's regulatory proceedings regarding the ECT device. Obviously, we have a vital interest in protecting future patients from the preventable harm we experience.

On September 5, 1990, FDA published a proposed rule to reclassify the ECT device to Class II for depression. However, this proposed rule was never acted upon and was withdrawn by FDA on April 21, 2003.

We are aware that FDA is currently considering acting unilaterally, in the absence of any evidence or petition from the manufacturers or any other parties, to reclassify the ECT device based on a selective "literature review". An internal committee has been convened for this purpose. We are aware that reclassifying a device in the absence of *any* evidence from manufacturers is highly unusual if not totally unprecedented. FDA has never before reclassified a Class III device based solely on its own selective review of *some* of the literature on the device.

(N.B: For examples of what a rigorous *systematic* literature review looks like, see Source Documents #32 and #35.)

Section 513(3) (21 U.S.C. 360(e)) of the Act provides that device classifications may be changed by regulation only when there is "new information" supporting the change. Any reclassification is required to consist of "valid scientific evidence" as defined in section 513(a)(3)of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). This valid scientific evidence must be publicly available.

According to 21 CFR Ch 1 860.7 (c)(2), FDA recognizes five forms of valid scientific evidence:

(1) Well-controlled investigations
(2) Partially controlled studies
(3) Studies and objective trials without matched controls
(4) Well-documented case histories conducted by qualified experts
(5) Reports of significant human experience with a marketed device.

A selective literature review does not constitute valid scientific evidence.

FDA has specified no criteria for inclusion of studies and has no plans to identify and make publicly accessible those studies not selected for inclusion. By its very nature, such a review can be tailored to any position. At all times since the American Psychiatric Association (the lobby for the device users) began its campaign to change the classification of the ECT device in the early 1980s, FDA has stated its intention to reclassify the device to Class II. There is no reason to think the agency has changed its position, and thus every reason to believe the "literature" can and will be selected to support that position.

Valid scientific evidence---now even more than in 1979 when the FDA correctly classified the device in Class III---shows that the device, when manufactured correctly and used as directed for any indication, presents an unreasonable risk of injury or harm. Further, its risks far outweigh its benefits, which are less than previously thought.

We have diligently searched for new evidence unfavorable to our petition. Our criteria were as follows:

1) Studies conducted by researchers free of financial, career, or other conflict of interest
2) Valid scientific evidence as defined above
3) Studies not previously considered by FDA
4) Studies documenting ECT's safety and efficacy:
   a) Brain-imaging studies settling the question of whether ECT causes brain pathology or damage in the negative; or
   b) Studies documenting the full return of memory, memory ability, and cognitive function to normal after treatment with the ECT device; or
   c) Studies documenting long term (i.e. lasting more than one month) benefit from ECT, or its ameliorative effect on suicide risk or rate.

We found no such evidence.

We submit some of the new, valid scientific evidence supporting our petition in an appendix. The evidence is of the following nature:

The Manufacturers' Silence. This speaks for itself.

FDA's Own Files. More than 40 volumes of evidence is contained in the FDA's own files, Docket #82P-0316. We do not believe that anyone on the current FDA staff has read the entire file. Much of the material postdates the FDA' s last evaluation of the device in 1990. A representative of our organization has read all the volumes and reports that more than 90% of the comments oppose the reclassification of the ECT device to Class II. Almost all who support reclassification are psychiatrists who use ECT. There are hundreds of reports of significant human experience with the device in the file. 97% of persons who identify as former ECT patients oppose reclassification, most of them on the grounds that it caused them permanent memory loss and/or disability.

A representative sample of these documents is included herein: Source Documents 10, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50

New Evidence for Permanent Memory Loss: Source Documents Nos. 7, 9, 11, 12, 13, 16, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 31, 32, 37

New Evidence for Permanent Memory or Cognitive Disability: Source Documents Nos. 1, 7, 8, 9, 11, 12, 13, 15, 16, 18, 19, 20, 21, 24, 25, 26, 27, 28, 29, 32. 37

New Evidence for Brain Damage: Source Documents Nos. 8, 9, 11, 14, 16, 22, 33, 34, 37

New Evidence of Lack of Efficacy: Source Documents Nos. 3, 6, 17, 25, 29, 30, 32, 35, 36, 37

New Evidence of Mortality and Morbidity: Source Documents Nos. 2, 4, 5, 29, 37

Sections 501(f), 513, and 515(b) of the act (21 U.S.C. 351(f), 360c, and 3603(b)), taken together, establish as a general requirement that a preamendments device that FDA has classified into Class III is subject, in accordance with Section 515 of the Act, to premarket approval. Premarket approval is appropriate for a device that has never been subjected to safety testing by the manufacturers nor subjected to any independent safety evaluation. It is crucial where there is decades of scientific evidence documenting permanent, serious adverse effects including death, and no evidence for longterm efficacy of the device in question.

We realize it may be awkward and challenging for the FDA to have to call for Premarket Approval Applications from manufacturers who have thus far been unresponsive to the agency, and who have successfully evaded the regulatory process for decades. However, this is exactly the reason why the United States government created the FDA: to regulate the drug and device manufacturers in the interest of protecting the public health. We realize that the device users' lobby, the American Psychiatric Association, has successfully pressured the FDA for over 20 years to prevent a call for PMAs. We believe that together, these factors help account for FDA's unwillingness to regulate the ECT device as all other medical devices. However, the agency has a legal duty and responsibility to ensure the safety of the American public. The ECT device must not be treated any differently from other medical devices because it has a well-financed and influential user lobby behind it.

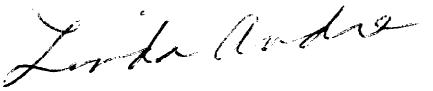
Part C. ENVIRONMENTAL IMPACT

Not applicable.

Part D. CERTIFICATION

The undersigned, in her capacity as Director of the Committee for Truth in Psychiatry, certifies that, to the best of her knowledge and belief, this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

Respectfully submitted,



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Petition to Maintain the ECT Device in Class III

Committee for Truth in Psychiatry

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Source Documents

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