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To: Food and Drug Administration
Dockets Management Branch (HFA-305)
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Rockville, MD 20852
Docket Number FDA-2009-N-0392

To whom it may concern:

As a survivor and opponent of electroshock (ECT, electroconvulsive “treatment”) who, over the years, has communicated with hundreds of other survivors of the procedure and has studied the subject and written extensively about it, I am responding to the Food and Drug Administration’s call for information and comments regarding the current classification of the ECT devices. I urge the FDA not to reclassify these devices from Class III (high risk) to Class II (low risk) because the procedure continues to be, as it has been since its introduction in 1938, an extremely harmful method used on persons diagnosed as “mentally ill.”

Here, in summary form, is my case against ECT:

1. Electroshock is a brutal, dehumanizing, memory-destroying, intelligence-lowering, brain-damaging, brainwashing, and life-threatening technique. ECT robs people of their memories, their personality and their humanity. It reduces their capacity to lead full, meaningful lives; it crushes their spirits. Put simply, electroshock is a method for gutting the brain in order to control and punish people who fall or step out of line, and intimidate others who are on the verge of doing so.
2. Brain damage is the most ruinous effect of ECT and lies at the root of most of ECT’s other harmful effects. It is also the 800-pound gorilla in the living room whose existence electroshock psychiatrists refuse to acknowledge, at least publicly. Nowhere is this more clearly illustrated than in the American Psychiatric Association’s *Practice of Electroconvulsive Therapy*, which states that “in light of the accumulated body of data dealing with structural effects of ECT, ‘brain damage’ should not be included [in the ECT consent form] as a potential risk of treatment” (2001, p. 102). The exclusion of brain damage as a risk of ECT makes a sham of the entire ECT informed-consent process and turns what is ostensibly a medical procedure into an act of criminal assault. The following statements and reports, all by psychiatrists or neurologists, refute the APA’s position on the risk of brain damage from ECT.

A. “The importance of the [foregoing autopsied] case lies in that it offers a clear demonstration of the fact that electrical convulsion treatment is followed at times by structural damage of the brain” (Alpers and Hughes, 1942).

B. “This brings us for a moment to a discussion of the brain damage produced by electroshock.... Is a certain amount of brain damage not necessary in this type of treatment? Frontal lobotomy indicates that improvement takes place by a definite damage of certain parts of the brain” (Hoch, 1948). Paul H. Hoch, a Hungarian-born U.S. psychiatrist, had been commissioner of the New York State Department of Mental Hygiene.

C. In a report “based on the study of 214 electroshock fatalities reported in the literature and 40 fatalities heretofore unpublished, made available through the kindness of the members of the Eastern Psychiatric Research Association,” David Impastato found that 66 ECT patients had died from “cerebral” causes among the 235 patients for whom the cause of death had been stated (Impastato, 1957). Impastato, a Sicilian-born U.S. psychiatrist, was a leading figure in the early history of ECT in the United States.

D. An extensive American Psychiatric Association membership survey found that 41 percent of the respondents agreed with the statement, “It is likely that ECT produces slight or subtle brain damage”; 26 percent disagreed with the statement (American Psychiatric Association, 1978).

E. “Electroshock ‘works’ by damaging the brain.... [T]he changes one sees when electroshock is administered are completely consistent with any acute brain injury, such as a blow to the head with a hammer” (Coleman, 1978).

F. “The principal complications of EST are death, brain damage, memory impairment, and spontaneous seizures. These complications are similar to those seen after head trauma, with which EST has been compared” (Fink, 1978). Eleven years later, Fink was quoted in a magazine article as saying, “I can’t prove there’s no brain damage [from ECT]. I can’t prove there are no other sentient beings in the universe, either. But scientists have been trying for thirty years to find both, and so far they haven’t come up with a thing” (Rymer, 1989). Max Fink, an Austrian-born U.S. psychiatrist, is the world’s leading proponent of ECT.

G. “After a few sessions of ECT the symptoms are those of moderate cerebral contusion, and further enthusiastic use of ECT may result in the patient functioning at a subhuman level. Electroconvulsive therapy in effect may be defined as a controlled type of brain damage produced by electrical means.... In all cases the ECT “response” is due to the concussion-type, or more serious, effect of ECT. The patient “forgets” his symptoms because the brain damage destroys memory traces in the brain, and the patient has to pay for this by a reduction in mental capacity of varying degree” (Sament, 1983).

H. “A vast medical literature provides strong evidence that electroconvulsive therapy causes permanent brain damage, including loss of memory and catastrophic deterioration of personality” (Polk, 1993).

I. “There is an extensive animal research literature confirming brain damage from ECT. The damage is demonstrated in many large animal studies, human autopsy studies, brain wave studies, and an occasional CT scan study. Animal and human autopsy studies show that ECT routinely causes widespread pinpoint hemorrhages and scattered cell death. While the damage can be found throughout the brain, it is often worst in the region beneath the electrodes. Since at least one electrode always lies over the frontal lobe, it is no exaggeration to call ECT an electrical lobotomy” (Breggin, 1998).

3. The most immediate, obvious, and distressing effect of electroshock is amnesia. In her book *Doctors of Deception: What They Don't Want You to Know About Shock Treatment*, electroshock survivor Linda Andre described what that is like: “The memory ‘loss’ that happens with shock treatment is really memory erasure. A period of time is wiped out as if it never happened. Unlike memory loss associated with other conditions, such as Alzheimer’s, which come on gradually and allow patients and families to anticipate and prepare for the loss to some extent, the amnesia associated with... ECT is sudden, violent, and unexpected. Your life is essentially un-lived.... You didn’t just lose your suitcase; you can’t say where you got it, what it looks like, what you packed in it, what trips you’ve taken it on. You don’t know that you ever had it” (Andre, 2009).

4. Electroshock’s harmful effects can be long-lasting. Electroshock psychologist Harold A. Sackeim and colleagues concluded their recent study with this statement: “[T]his study provides the first evidence in a large, prospective sample that adverse cognitive effects can persist for an extended period, and that they characterize routine treatment with ECT in community settings” (Sackeim, 2007).

5. Electroshock causes a significant number of deaths. A 1995 report from the Texas Mental Health Department (Smith, 1995) revealed that there were eight deaths among approximately 1,600 patients (1 in 200 cases) who had undergone ECT in Texas over a then recent 15-month period, a rate 50 times higher than the death rate (“about 1 in 10,000 patients”) given in the consent-form sample in the American Psychiatric Association’s *Practice of Electroconvulsive Therapy* (2001, p. 320). Reports in the professional literature give further evidence that the ECT death rate is much higher than the rate claimed by ECT proponents (Frank, 2007).

6. There are no scientifically sound studies showing that ECT is an effective method of suicide prevention. The authors of a large study published in the *Annals of Clinical Psychiatry* (Black, 1989) reported there was no significant difference in the suicide rate for depressed patients treated with ECT, anti-depressants, and neither of these treatments.

7. Unlike its harmful effects, electroshock’s supposedly “therapeutic” effects are brief at best. No study shows that these effects persist for more than at most a few months

following the last treatment. One study indicates the relapse rate for ECT patients is up to 50 percent within six months following treatment, “even though antidepressant drugs are continued” (Fink, 1999). Another study of patients diagnosed with “unipolar major depression” concluded “that without active treatment virtually all remitted patients [i.e., patients whose symptoms diminished following ECT] relapse within 6 months of stopping ECT” (Sackeim, 2001). From this, it is clear that an ECT patient with a diagnosis of depression or manic-depression runs the serious risk of becoming a permanent outpatient which usually entails ongoing drug treatment, “maintenance” ECT, and/or occasional inpatient stays.

8. Contrary to claims by ECT defenders, newer technique modifications have made electroshock more harmful than ever. For example, the drugs accompanying ECT to reduce certain risks, including bone fractures, raise seizure threshold so that more electrical current is required to induce the convulsion (Saltzman, 1955): the more current applied, the greater is risk of brain damage and amnesia. Moreover, whereas formerly ECT specialists tried to induce seizures with minimal current, suprathreshold amounts of electricity are commonly administered today in the belief that they are more effective.

9. Not only does the federal government stand by passively as psychiatrists continue to use electroshock, it also actively supports ECT through the licensing and funding of hospitals where the procedure is used, by covering ECT costs in its insurance programs (including Medicare), and by financing ECT research, including some of the most damaging ECT techniques ever devised. One study provides an example of such research. This ECT experiment was conducted at Wake Forest University School of Medicine/North Carolina Baptist Hospital, Winston-Salem, between 1995 and 1998. It involved the application of electric current at up to 12 times the individual’s convulsive threshold on 36 depressed patients. This reckless disregard for the safety of ECT subjects was supported by grants from the National Institute of Mental Health (McCall, 2000).

10. The use of ECT is increasing. More than 100,000 Americans are being electroshocked each year; half are 60 and older, and two-thirds are women. Seventy percent of all ECT is insurance-covered. ECT specialists on average have incomes twice that of other psychiatrists. The cost for inpatient ECT ranges from \$50,000 to \$75,000 per series (usually 8 to 12 individual sessions). Electroshock is a multibillion-dollar-a-year industry.

11. Electroshock is especially dangerous and life-threatening for elderly patients. One Rhode Island study conducted between 1974 and 1983 divided 65 hospitalized depressed patients, 80 years and older, into two groups. Thirty-seven patients in one group were treated with ECT and the 28 in the other group were treated with antidepressant drugs. The death rate after one year for the ECT group was 7.5 times higher than that of the non-ECT group: 10 deaths among the 37 ECT patients (27%) compared with 1 death among the 28 drug-treated patients (3.6%). The authors, 2 psychiatrists, reported that “two patients had only 2 ECTs: one withdrew consent, and the other developed CHF [congestive heart failure] and died before ECT could be continued.” They also reported that there was “lasting recovery” for 22% in the ECT group and 71% in the non-ECT

group. The authors attributed the poor outcomes of the ECT patients to “their advanced age and physical illness” (Kroessler and Fogel, 1993). In his extensive study of ECT deaths (referred to in paragraph 2C above), Impastato estimated that the ECT death rate for patients over 60 is one in 200, or 5 times greater than the death rate of 1 in 1,000 for ECT patients of all ages (1957, p. 31).

12. As a destroyer of memories and thoughts, electroshock is a direct, violent assault on these hallmarks of American liberty: freedom of conscience, freedom of belief, freedom of thought, freedom of religion, freedom of speech, freedom from assault, and freedom from cruel and unusual punishment.

Tens of thousands of people every year in the United States are deceived or coerced into undergoing electroshock. The FDA should do everything in its power to discourage the use of electroshock by:

- keeping ECT’s Class III, high-risk rating;
- insisting that electroshock psychiatrists, manufacturers of ECT devices, and executives and administrators in hospitals where ECT is administered, substantiate with scientific proof their claims that the procedure is “safe and effective”; and
- calling upon the Congress and the Department of Justice to investigate the fraudulent and coercive use of this cruel and inhuman procedure.

References:

Alpers, B.J., Hughes, J. (April 1942). “The Brain Changes in Electrically Induced Convulsions in the Human,” *Journal of Neuropathology and Experimental Neurology*, pp. 172-177.

American Psychiatric Association. *Electroconvulsive Therapy* (Task Force Report 14). (1978). Washington, DC: Author, p. 4.

American Psychiatric Association (A Task Force Report). (2001). *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging* (2nd Edition). Washington, DC: Author.

Andre, L. (2009). *Doctors of Deception: What They Don’t Want You to Know About Shock Treatment*. New Brunswick, New Jersey: Rutgers University Press, p. 2.

Black, D.W., Winokur, G. et al. (September 1989). “Does Treatment Influence Mortality in Depressives?: A Follow-up of 1076 Patients with Major Affective Disorders,” *Annals of Clinical Psychiatry*, vol. 1, no. 3, pp. 165-173.

Breggin, P.R. (1998). “Electroshock: Scientific, Ethical, and Political Issues,” *International Journal of Risk & Safety in Medicine*, vol. 11, pp. 5-40.

Cameron, D.O. (Winter-Spring 1994). "ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation," *Journal of Mind and Behavior*, vol. 15, no. 1-2, pp. 177-198.

Coleman, L. (1978). Introduction to Frank, L.R. (Ed.), *The History of Shock Treatment*, San Francisco: Author, p. xiii.

Fink, M. (January-February, 1978). "Efficacy and Safety of Induced Seizures (EST) in Man," *Comprehensive Psychiatry*, pp. 1-18.

Fink, M. (1999). *Electroshock: Restoring the Mind*, New York: Oxford University Press, p. 12.

Frank, L.R. (Ed.). (1978). *The History of Shock Treatment*. San Francisco: Author.

Frank, L.R. (Spring 2002). "Electroshock: A Crime Against the Spirit," *Ethical Human Sciences and Services*, pp. 63-71.
<http://www.endofshock.com/leonard.htm>

Frank, L.R. (2006). *The Electroshock Quotationary* (an e-book).
http://www.endofshock.com/102C_ECT.PDF

Frank, L.R. (Ed.). (2007). "Electroshock and Death" (an internet posting).
<http://endofshock.com/101i%20brochure%20on%20deaths%203-29.pdf>

Hoch, P.H. (1948). "Discussion and Concluding Remarks," *Journal of Personality*, vol. 17, p. 48.

Impastato, D.J. (July 1957). "Prevention of Fatalities in Electroshock Therapy," *Diseases of the Nervous System*, p. 31. This 42-page report of 254 deaths is the largest and most detailed study of ECT deaths ever published. It is rarely cited in the writings of ECT proponents.

Kroessler, D., Fogel, B.S. (Winter 1993). "Electroconvulsive Therapy for Major Depression in the Oldest Old," *American Journal of Geriatric Psychiatry*, pp. 30-37.

McCall, W.V., Reboussin, D.M. et al. (May 2000). "Titrated Moderately Suprathreshold vs Fixed High-Dose Right Unilateral Electroconvulsive Therapy," *Archives of General Psychiatry*, May 2000, pp. 438-444.

Morgan, R.F. (Ed.) (1999). *Electroshock: The Case Against*. Mangilao, Guam: Morgan Foundation Publishers.

Polk, H.L. (August 1, 1993). Letter to the editor, *New York Times*.

Rymer, R. (March-April 1989). "Electroshock," *Hippocrates*, p. 71.

Sackeim, H.A., Haskett, R.F. et al. (March 14, 2001). "Continuation Pharmacotherapy in the Prevention of Relapse Following Electroconvulsive Therapy" (abstract), *Journal of the American Medical Association*, pp. 1299-1307.

Sackeim, H.A., Prudic, J. (January 2007). "The Cognitive Effects of Electroconvulsive Therapy in Community Settings," *Neuropsychopharmacology*, pp. 244-254.

Saltzman, C., Konikov, W. et al. (May 1955). "Modification of Electroshock Therapy by Succinylcholine Chloride," *Diseases of the Nervous System*, p. 154.

Sament, S. (March 1983). Letter to the editor, *Clinical Psychiatry News*. p. 11.

Smith, M. (March 7, 1995). "Eight in Texas Die after Shock Therapy in 15-Month Period," *Houston Chronicle*, pp. 1A, 6A.

Autobiographical Sketch:

Leonard Roy Frank, a native of Brooklyn, graduated from the Wharton School of the University of Pennsylvania in 1954. While committed to a private psychiatric facility near San Francisco in 1963, he was forced to undergo 50 insulincoma and 35 electroconvulsive procedures, which caused him severe memory loss, wiping out the preceding three-year-period and effectively destroying his high school and college educations. Following years of study reeducating himself, he became active in the psychiatric survivors movement first by becoming a staff member of *Madness Network News* (1972) and then co-founding Network Against Psychiatric Assault (1974), both based in San Francisco and Berkeley and opposed to all forms of coercive, fraudulent psychiatric interventions. In 1978 he edited and self-published *The History of Shock Treatment*. Since 1995, he has edited *Influencing Minds: A Reader in Quotations* (Los Angeles, Feral House), *Random House Webster's Quotationary* (New York, Random House, 1998), and 7 other collections of quotations for Random House. In 2006, he self-published *The Electroshock Quotationary*, an e-book. A resident of San Francisco since 1959, he is a member of MindFreedom International (Eugene, Oregon) and The Coalition for the Abolition of Electroshock in Texas (Austin). Here are two Internet links relevant to his work and his encounter with psychiatry: *The Electroshock Quotationary*: http://www.endofshock.com/102C_ECT.PDF; "The Journey of Transformation": <http://www.mindfreedom.org/kb/mental-health-abuse/force/journey-of-transformation/view?searchterm=%22leonard%20roy%20frank%22>

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