



*Testimony by Daniel B. Fisher, MD, PhD to the FDA
Neurological Devices Panel Meeting on possible reclassification
of ECT devices from Class III to Class II
Jan. 27, 2011, Gaithersburg, MD*

*I have no financial relationship with the manufacturers of
ECT devices. I am on the Steering Com. of the National Coalition
of Mental Health Recovery which represents millions of mental
health consumer/survivors.*

I base my testimony on my practice as a board-certified psychiatrist, my neurochemical research at NIMH, and my 19 years of directing a federally-funded technical assistance center. I am appalled that the FDA is considering downgrading ECT devices from Class III to Class II- the same classification as a wheelchair.

In my expert opinion and that of a recent review of the ECT literature by Drs. Read and Bentall, any short-term gains of ECT are offset by its risks. I recommend:

1. That ECT devices continue to be designated as Class III
2. That their use be suspended until meaningful long-term efficacy and minimal risks of memory loss, cognitive deficits, brain damage, and mortality are independently demonstrated by premarket approval

Two of my cases illustrate the negative aspects of ECT:

Case A: I saw a 19 year-old man in an outpatient clinic. He suffered from major depression and was slow to respond to the

antidepressant Prozac. He was admitted to an inpatient facility where the psychiatrist immediately started a series of 8 ECT treatments. Upon discharge, his depression had slightly lifted, but he could no longer recognize his friends. He was so distraught over this side effect of the ECT that he hung himself. This case points out that ECT not only does not decrease suicidality but can actually increase it.

Case B: In my capacity as a consultant, I learned that a 51 year-old woman was experiencing memory loss and confusion which intensified once a month. Belatedly, she acknowledged that she was given monthly outpatient ECT. She had been threatened with rehospitalization by her doctor if she disclosed. She wanted to stop the ECT, and in my presence she was able to tell her doctor she wanted to leave his care. She did so and was successfully switched to an antidepressant with fewer side effects. This case illustrates that ECT causes cognitive deficits and memory loss. The most detailed studies of memory were carried out by Janis who found, gross gaps and subtle losses of memory and a general slowness and a great effort in recalling details. In some cases, details returned. These side effects were also validated by a proponent of ECT, Dr. Harold Sackheim who found memory deficits and said, "This study provides the first evidence in a large, prospective sample that adverse cognitive effects can exist for an extended period and that they characterize routine treatment by ECT in community settings."

The APA guidelines for ECT inaccurately contend that the memory loss with ECT is minimal. Furthermore, the APA consent form drastically underestimates the mortality associated with ECT by stating the risk of death is 1 in 10,000 whereas the average of numerous studies indicate a 10-fold higher rate of death than suggested by the APA. The APA also suggests that "brain damage should not be included[in the informed consent process] as a risk of treatment ."

It appears that the APA task force on ECT overlooked the considerable evidence that ECT produces brain damage as summarized by neuroscientist, Dr. Sterling:

1) [ECT] is designed to evoke a grand mal epileptic seizure causing an acute rise in blood pressure well into the hypertensive range, and this frequently causes small hemorrhages in the brain.

2) [ECT] ruptures the “blood-brain barrier.” This barrier normally prevents many substances in the blood from reaching the brain. Where this barrier is breached, nerve cells are exposed to insult there is brain “edema”, anoxia, and neuron death.

3) [ECT] causes neurons to release large quantities of the neurotransmitter, glutamate, which releases more glutamate, leading to “excito-toxicity”-- neurons literally die due to over activity.

According to Dr. Breggin, "The brain-disabling hypothesis states that the more potent somatic therapies in psychiatry, that is, ... ECT, and psychosurgery, produce brain damage and dysfunction, and that this damage and dysfunction is the primary, clinical or so-called beneficial effect. The individual subjected to the dysfunction becomes less able and more helpless, ultimately becoming more docile."

On a personal note, in my 20's I was a psychiatric inpatient. Whenever I or other patients failed to act “appropriately,” the staff would threaten us with ECT. On one visit my friends brought me a copy of One Flew Over the Cuckoo's Nest. For the remainder of my stay on the ward I lived in constant fear

that I might be given ECT just like Randle McMurphy in the book.

How is it possible that in a democracy with the most advanced constitution of any country, a whole class of people can be subjected to brain disabling procedures without regulation by the government? I can only conclude that being labeled mentally ill means your lose your rights and protection under that constitution. I entreat you to protect these labeled people by regulating these devices as they should be under their Class III designation.