

The FDA's Regulation of ECT (Shock Treatment): A Beginner (or Refresher) Course

Why does the Food and Drug Administration have anything to do with ECT?

In 1976, the agency became responsible for regulating, not just orange juice and diet pills, but all medical devices sold in the U.S., including the machines used to administer ECT (electroconvulsive therapy, or shock treatment). In practice, of course, the machines and the procedure are inseparable. FDA's first responsibility was to classify all medical devices based on the degree of risk to health they posed. The degree of risk would then determine the degree of oversight necessary by the FDA.

What do the different classes mean?

There are three classes of medical devices. Class I devices are virtually no risk, and are required only to comply with general standards of good manufacturing. Class II devices are low risk; safety is to be assured through strategies like performance standards (guidelines for use), labeling, postmarket surveillance, patient registries, etc. Class III devices are high risk, meaning they present a potentially unreasonable risk of injury or illness and that benefits have not been shown to outweigh risks.

What class is the ECT machine in?

In 1979, after hearing testimony from former patients who suffered permanent memory loss and brain damage, the FDA placed the devices in Class III, listing these effects as risks of the treatment. The device still is and always has been in Class III.

What is the significance of a Class III rating?

For devices like the ECT machine which were on the market prior to 1976, and thus have never been subjected to the safety investigation required of new devices, Class III means that the devices must ultimately go through this process, called a "PreMarket Approval Application." They must be proven safe by scientific evidence, including clinical trials.

The ECT device has never undergone a safety investigation? Why not?

Soon after the device was classified in Class III, in 1982, the American Psychiatric Association, led by its ECT Task Force (a small group of men who promote and profit from ECT), petitioned the FDA to reclassify the device to Class II. This meant that a docket (#82P-0316) was opened on ECT for public comments, and thousands of comments poured in, the vast majority of them against reclassification and in favor of a safety investigation. But the APA used its greater power and influence to lobby the FDA not to investigate ECT, and in the end they carried the day. In 1983, the FDA stated its intention to grant the APA's petition. It never did so, perhaps swayed by the evidence of ECT's adverse effects in its files. In 2003, it rescinded its notice of intent to reclassify the ECT device, simply because too much time had passed. But then it did nothing and seemed content to keep it in limbo indefinitely. That changed in 2009, when higher-ups in government criticized the agency for its failure to protect patients from risky devices.

How have ECT survivors, advocates, and concerned citizens tried to get the FDA to investigate ECT and to warn patients of its dangers?

Survivors of ECT formed an organization, the Committee for Truth in Psychiatry (founded in 1984) and filed petitions to the FDA. They asked the agency to adopt a patient-written consent form which would truthfully inform future patients of the risks of ECT. They filed a petition asking the FDA to conduct before-and-after-ECT brain scan studies on humans and animals. They even offered up their own brains for study. They publicized the risks of ECT and the FDA's failure to follow its own law and investigate the procedure. Meanwhile, the ECT docket steadily grew to over 40 volumes as patient advocates, concerned

professionals, family members, politicians, and the general public wrote with a simple message: If ECT is as safe as psychiatrists claim it is, why not prove it with a safety investigation?

What is going on now with the ECT device at the FDA?

In April 2009---a full thirty years after FDA first ruled that it considered the ECT device dangerous---the Government Accounting Office finally took the FDA to task for its inaction on pre-Amendments Class III devices (those on the market prior to 1976). It set a deadline for the FDA to call on the manufacturers of these devices, including the ECT device, to provide evidence of their devices' safety and efficacy, including information about adverse effects. The manufacturers had to respond by August 7, 2009. If there is no evidence submitted, or if the evidence is inadequate, the FDA is required to call for PMAs. If the PMAs show that a device is unsafe, it must be taken off the market.

What role have the device manufacturers placed in the regulatory process?

The two manufacturers of ECT devices have never participated in the regulatory process. The American Psychiatric Association has stood in for the companies in all dealings with the FDA---for instance, filing the petition to reclassify. However, the APA could not legally respond to the August 7 call for submissions, nor can it file a PMA. The deadline for submissions is now past, and the manufacturers have publicly stated that they have chosen not to conduct any safety investigations of their devices. Instead, they are calling on the FDA to simply reclassify their devices to Class II without any investigation. They say that the FDA should exempt them from having to go through the PMA process because they don't have the expertise to conduct safety studies and can't afford to pay for them anyway. They are putting pressure on the FDA by claiming they will go out of business if they even have to pay the PMA filing fee. They clearly believe the FDA cares more about their survival than about protecting patients.

How can the public be involved in the FDA's decision-making process on ECT?

Even had the manufacturers made a full submission, the FDA is aware that it cannot base its decision solely on this information, which is likely to be inadequate and biased. In a notice published in the Federal Register on September 10, 2009, the FDA recognized the long history of "significant public interest" in ECT and opened up a new docket for public comments on the safety and efficacy of the device. The docket will stay open for a period of 120 days, through January 8, 2010. All comments become a public record.

Can the FDA still decide to declare the ECT device safe without a safety investigation?

Yes, it can, and FDA insiders say that reclassification to Class II is the most likely outcome... *unless we all act now to lobby for a safety investigation.* Even if the agency has no evidence that ECT is safe or effective from the manufacturers, it can decide that ECT is safe enough for Class II (for example, if the APA persuades it that conducting ECT according to their newest practice guidelines can make the procedure safe). It would be unprecedented for the agency to declare a device safe without any submission of safety data from its manufacturers, but the FDA has always treated shock machines differently from all other medical devices because of the power of the APA. The agency has never wavered from the position it took in 1983: it considers shock safe and wants to reclassify.

What can I do to make sure ECT devices remain in Class III?

Write to the FDA opposing reclassification without an investigation, and asking for PMAs. The address is:

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

Re: Docket #FDA 2009-N-0392

It's an excellent idea to send copies of your letter to your U.S. Senator and Representative.