FDA Wants to Declare ELECTRO SHOCK (ECT) Machines Safe

~~~ Without a Safety Investigation ~~~

RED FLAG ALERT!

ECT = ELECTROCONVULSIVE SHOCK THERAPY?

ECT = severe brain damage and memory loss

ECT = cognitive impairment and sometimes death

Don't let the FDA rubber stamp ECT "safe"!

TELL THEM NO!

NOT without a Safety Investigation

The Food and Drug Administration is in charge of regulating medical devices just as it does drugs, including the machines used to give shock treatment. But it's not doing its job. It has allowed these machines to be used on millions of patients over the past generation without requiring any evidence whatsoever that shock treatment is safe or effective! This is so even though shock machines are Class III---high risk---devices, which by law are supposed to be investigated by clinical trials as thoroughly as new drugs and devices just coming onto the market. But because of intense lobbying by the American Psychiatric Association---which claims the devices are safe but opposes an investigation---the FDA has disregarded its own law. (For the full story of how shock survivors have fought for a scientific safety investigation of ECT for the past 25 years, see the new book Doctors of Deception: What They Don't Want You to Know About Shock Treatment by Linda Andre.)

In April 2009---30 years after it first ruled the devices high-risk and named brain damage and memory loss as risks of the treatment---the FDA belatedly announced it would call on the manufacturers of the devices to provide evidence of safety and efficacy. The deadline for submissions has passed, but the manufacturers have not conducted any clinical trials, claiming they cannot afford them. They simply point to the opinions of shock doctors (including those who have financial interests in the device companies) as evidence that shock is safe.

The FDA is now supposed to require the ECT device to undergo the rigorous Pre-Market Approval process (PMA) that is required of new devices, including clinical safety trials. But the FDA could have called for this investigation any time in the past 30 years and has steadfastly refused to do so. The FDA has never wavered from its intention (as stated in 1990) to declare the shock machine safe, and down-classify it to the low-risk Class II, *without* scientific evidence of its safety. As a Class II device, the shock machine would never have to go through the PMA process. After all, if a PMA showed shock to be unsafe, the FDA would have to take shock machines off the market, and it knows that the American Psychiatric Association would never allow that.

CALL TO ACTION: *TELL THEM NO!* *DEMAND A SAFETY INVESTIGATION!*

The FDA has opened up a new docket for public comments on the device. If we don't write in, they will almost certainly reclassify. Comments will be accepted up through January 8, 2010. Do you think shock is safe? Have you evidence you want FDA to consider, including your personal experience? Write a letter to the address below or send in the coupon. You can also make electronic comments at www.regulations.gov by entering "Notices" and then the docket number FDA-2009-N-0392.

MAIL To: Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: Docket #FDA-2009-N-0392

Just say NO!

Don't let the FDA rubber stamp ECT "safe"

The undersigned opposes the reclassification of the ECT device to Class II by the FDA in the absence of adequate scientific evidence of its safety, and asks the agency to call for Pre-Market Approval Applications for the device.

Name: _____ Address: _____

Signature: _____ City: _____

NO ECT without a Safety Investigation!

State:_____ Zip:_____