CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL

OFFICE OF THE PRESIDENT

Established in 1969 by the Church of Scientology to investigate and expose psychiatric violations of human rights

Abiy B. Desta
CDRH Ombudsman
Office of the Center for Devices
and Radiological Health
U.S. Food and Drug Administration
WO32 Room 4282
10903 New Hampshire Avenue
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Dear Mr. Desta

I testified about the ECT Device at the FDA's Neurological Devices Advisory Panel meeting held January 27-28, 2011 in Gaithersburg, MD. I am the international president of the Citizens Commission on Human Rights (CCHR), which represents a large consumer population in the mental health field.

In November 2011, Assistant Commissioner Jeanne Ireland wrote to Senator Charles Grassley that the FDA's review of the ECT devices would be completed by December 31, 2012. Twenty-seven months later, consumers have yet to be informed of the FDA's decision.

I understand that Loretta Wilson, an ECT survivor and independent of CCHR, contacted the former Deputy Ombudsman Lawrence "Jae" Romanell numerous times about the FDA's procrastination regarding the safety of the ECT device.

Please consider my correspondence as an official complaint on behalf of consumers who expected the FDA to act in a timely manner and to be more transparent about its failure to ensure that ECT Device Makers provided PMAs for the device—which Congress directed in 1990.

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In fact, twice the FDA has ordered the device makers to submit a PMA with the appropriate clinical data to support safety (1979 and 1995). Each time the manufacturers failed to comply.

In fact, in deposition, the President of Mecta, one of he ECT device manufacturers, said the company "does not do research."

At the January 2011 FDA advisory hearing, Dr. Malvina Eydelman said the agency would not necessarily require new trials *if existing evidence was strong enough to prove safety and effectiveness.* Yet in more than 30 years, this has never been scientifically substantiated.

Conflicts of Interest

The FDA has relied, in part, upon American Psychiatric Association ECT Task Force reports, which since 1978 have been prepared by committees whose members include psychiatrists with conflicts of interest with ECT device manufacturers.

Dr. Matthew Rudorfer, who oversees NIMH grants, has co-authored a text on ECT with Dr. Harold Sackeim, a leading ECT researcher and consultant for MECTA and Somatics, Inc. Dr. Sackeim has been a recipient of at least $8 million in NIMH grants to study ECT. In January 2011, Dr. Rudorfer told *The New York Times* that clinical trials for ECT "might be too expensive" as the manufacturers "tend to be mom-and-pop operations." Arguably, for years the FDA has put the potential "costs" to manufacturers above patient safety.

Electro-shocking Children

Meanwhile, the 110,000 American citizens administered ECT each year continue to be put at potential risk. The lack of monitoring of ECT usage, its adverse effects, including accurate reporting of deaths, is a national scandal. That it is still administered to children and adolescents, despite the device being in a Class III device and without a PMA, is unconscionable.

Moreover, it has failed to send a message to state regulators that no child or adolescent should be administered ECT. Last year the Western Australian Mental Health Act banned the use of ECT on those younger than 14 years old. The law imposes a (AUS)$15,000 fine on anyone performing the therapy on a child under 14. A child aged between 14 and 18 who is a voluntary patient also cannot have the treatment without informed consent and approval by a Mental Health Tribunal and has the right for state-covered legal representation to oppose the procedure.

At the 2011 hearing, FDA was also considering a "split" classification—Class III for treatment of depression and schizophrenia and Class II for catatonia. The most obvious question is: If two people with different mental disorders were to stick their fingers in an electric socket, wouldn't the damaging outcome be the same?

This type of illogic has consumers concerned.

Public Citizen also wrote the FDA in 2011 insisting that the FDA require that “rigorous, ethically justifiable clinical trials be conducted to evaluate the safety and effectiveness of ECT devices for their current indications for use, and that data from such trials be submitted to FDA for review and evaluation under a Premarket Approval Application.”

I am seriously concerned that in its deliberation the FDA has or will not properly address the concerns as outlined above and in the attached, or of the more than 80 percent of respondents to its ECT Executive Summary asking for stricter oversight or even a ban on electroshock treatment.

As the FDA has not acted in a “timely manner,” what is the Ombudsman’s Office doing to get this corrected and to ensure that there is full transparency and a final determination that is not based on biased industry studies steeped in conflicts of interest?

Sincerely

Ms. Jan Eastgate
President CCHR International