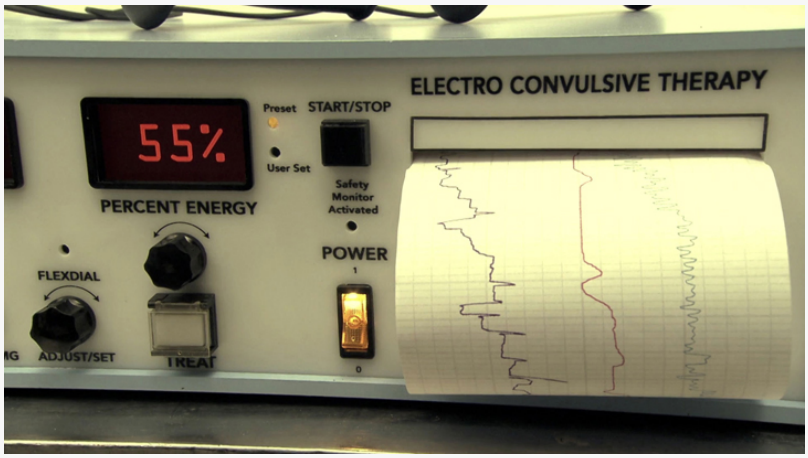
Consumers Unaware that Brain-Damaging Electroshock Devices are not FDA Approved

CCHR says thousands of Americans have been misled that electroshock treatment and its devices are FDA-approved, reinforcing group's demand to ban ECT entirely.



The United Nations Committee against Torture has stated since 2013 that electroshock constitutes torture when forcibly given or administered without a patient's consent—a practice that needs to be outlawed.

LOS ANGELES, CALIFORNIA, UNITED STATES, June 26, 2023 /EINPresswire.com/ -- Electroshock treatment, also known as electroconvulsive therapy or ECT, is documented to cause debilitating and severe side effects, yet according to Mental Health America, it is given to 100,000 Americans, including children, annually. Deplorably, an estimated 1.4 million individuals worldwide undergo this treatment documented to cause memory loss and brain damage. Despite its 85 years of use in the psychiatric field, there are no clinical trials proving its safety and effectiveness. In fact, the Food and Drug Administration (FDA) has never officially "approved" any electroshock device. A lack of awareness of this has led patients and their families to assume that electroshock is an approved medical treatment, when in fact it is not. This misinformation has further strengthened the Citizens Commission on Human Rights' call for a global ban on electroshock treatment.

> The long-term safety and effectiveness of ECT treatment has not been demonstrated."
> *Food and Drug Administration*

The confusion lies in the semantics and processes of how the FDA "approves" or "clears" a medical device. In the case of ECT devices, they fall under the category of "clearance" rather than "approval." As one Los Angeles-based law firm explains on its website: "The difference between FDA approval and 'clearance' is significant. The FDA spends approximately 1200 hours reviewing a manufacturer's submission of scientific data concerning the safety and efficacy of a proposed medical device prior to officially approving it, but the FDA spends only about 20 hours to 'clear' a device that is similar to one on the market prior to 1976 (i.e., the

grandfathering' procedure)."[1]

Electroshock had been in use since it was invented in Italy in 1938 when psychiatrist Ugo Cerletti observed its effects on calming pigs before they were killed in a Rome slaughterhouse. Its subsequent use in America allowed the shock devices to be grandfathered in under the FDA's highest risk classification for medical devices known as Class III.

A Class III device normally requires a manufacturer to obtain a "premarket approval"—the "most detailed type of device marketing application and review the FDA requires. A premarket approval application must include sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). It also requires clinical testing."

The FDA's "grandfathering" provision is a rule that allows for a medical device to stay on the market without further study or review into the device's safety or efficacy because it was used on consumers before the FDA gained full regulatory authority of the medical device industry in 1976.

In the case of the electroshock device, the shock device manufacturers have never conducted stringent clinical testing processes to ensure safety.

There are two manufacturers of ECT devices in the U.S. The FDA wrote to one of them: "This letter does not in any way denote official FDA approval of your device or labeling. Any representation that creates an impression of official approval of this device…is misleading and constitutes misbranding." (Misbranding is a term that means making a false or misleading representation on the label or in other informational materials, which is a violation of FDA regulations.)[2]

The FDA's position on ECT machines is: "The long-term safety and effectiveness of ECT treatment has not been demonstrated."

Despite the associated risks, manufacturers have the ability to create and distribute new ECT devices by demonstrating their "substantial equivalence" to the grandfathered devices. The clearance process relies on older medical devices, referred to as predicates, which have already received FDA clearance. However, it is important to note that previous FDA clearance does not guarantee safety. It is worth emphasizing that, once again, there is a lack of expected clinical trials for these devices.

Jan Eastgate, president of CCHR International, said, "Electroshock treatment is a barbarism that has remained on the market, masquerading as medical care. Many thousands have been damaged by its effects."

Psychiatrists continue to electroshock their patients while admitting that they also do not know how ECT or electricity even "works." A Psychiatric News article stated: "We don't know exactly

how electroconvulsive therapy works…. At least a dozen theories have been proposed…but few, if any, have found much acceptance." One theory was that "ECT caused a good kind of brain damage."[3]

Dr. Kenneth Castleman, biomedical and electrical engineer, and former Senior Scientist at NASA's Jet Propulsion Laboratory, summarizes the damage electroshock inflicts: "[To] put this all in perspective, the amount of electric current that an ECT machine puts through a patient's head is about 200 times what is considered dangerous for accidental electric shock, approximately 100 times what Tasers, cattle prods, and electric fences use, about the same as what is used for stunning pigs before slaughter, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. Clearly, this amount of electricity has the potential to cause injury to the brain."[4]

The widespread dissemination of misinformation and misbranding of ECT is so rife that in 2019, CCHR released a documentary on ECT to spell out the facts: Therapy or Torture: The Truth about Electroshock.

Survivors call electroshock "barbaric" and "torture." The United Nations Committee against Torture agrees, stating since 2013 that when forcibly given or administered without a patient's consent, electroshock constitutes torture—a practice that needs to be outlawed.[5]

CCHR continues to press for a ban on the entire practice of electroshock and related psychiatric brain intervention procedures. You can support this by signing CCHR's online petition to ban electroshock.

Read full article here.

[1] "ECT – Electroconvulsive Therapy," Wisner Baum, https://www.wisnerbaum.com/defective-medical-device-injuries/ect/

[2] "ECT – Electroconvulsive Therapy," Wisner Baum

[3] "Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses," Draft Guidance for Industry, Clinicians and FDA Staff, 29 Dec. 2015, https://www.federalregister.gov/documents/2015/12/29/2015-32591/electroconvulsive-therapy-devices-for-class-ii-intended-uses-draft-guidance-for-industry-clinicians

[4] "ECT – Electroconvulsive Therapy," Wisner Baum

[5] A/HRC/22/53, "Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez," United Nations, General Assembly, Human Rights Council, Twenty-second Session, Agenda Item 3, 1 Feb. 2013, p. 21, para 85,

http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf

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