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FDA panel advises more testing of 'shock-therapy' devices

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An expert panel advising the Food and Drug Administration decided Friday that electroconvulsive therapy (ECT) machines should undergo the same rigorous testing as new medical devices coming onto the market - a decision that could drastically affect the future of psychiatry's most controversial treatment.

The majority of the 18-member committee said not enough is known about ECT, also known as "electroshock" or simply "shock" therapy, to allow the devices to be used without more research into its usefulness and hazards.

If the agency follows the panel's advice, which it usually does, the two companies whose machines are used in the United States will have to provide evidence of the therapy's safety and effectiveness either from existing research or new studies. If the FDA isn't convinced, the devices could be removed from use.

The panel's opinion is the latest chapter in ECT's seven-decade history, during which the treatment has been lauded as a lifesaver, villified as a form of legally sanctioned torture, and has seen its popularity rise in recent years after a long decline.

ECT machines deliver an electrical current to the brain, inducing a generalized seizure in which the patient briefly loses consciousness. How that may be therapeutic or cause permanent memory loss - the side effect most frequently mentioned by patients - isn't known.

About 100,000 Americans undergo ECT each year, usually getting about a dozen treatments over several weeks. Some then get "maintenance" ECT every few weeks, as the therapeutic effect, when it occurs, often doesn't last. The treatment is most often used for depression and has also been prescribed to patients with schizophrenia, catatonia, and more recently, to some violent children with autism.

"It was the best possible outcome we could have gotten," said John Breeding, 58, a clinical psychologist from Austin who says the procedure should be banned. He testified before the panel at a two-day meeting in Gaithersburg.

For some patients, ECT epitomizes what they view as the coercion and lack of respect for the patient's point of view that is unique to psychiatry. That's also largely how it's been depicted in popular culture, most famously in the book and film "One Flew Over the Cuckoo's Nest," where it was a tool of punishment and social control of mental patients.

"I lost not only my memories of the time I was subjected to this torture but I was robbed of almost all memories from about 2003, two years before treatment, to 2008, three years after treatment stopped," testified Evelyn Scogin, a special-ed teacher who got ECT after a suicide attempt. Her statement was read by

a friend because Thursday's snowstorm stranded her in the Charlotte airport.

Other patients described ECT as a lifesaving, if mysterious, treatment worthy of wider use.

Among them was Kitty Dukakis, the 74-year-old wife of 1988 Democratic presidential nominee and former Massachusetts governor Michael Dukakis. She first got ECT at age 63, and continues to get it once a month.

"It is not an exaggeration to say that I don't think I would be alive without ECT. It has been a miracle in my life," she said.

One proponent, a nurse from Baltimore, drove through the snow on her day off to read a grateful Christmas card from a patient, choking up as she did.

"I actually think it's more controversial than abortion," Amy Lutz, a 40-year-old mother of five from Villanova, Pa., said of ECT, which her 12-year-old autistic and manic-depressive son gets regularly.

She brought with her two poster-size photographs of the boy, his face and hands bloodied from self-inflicted blows. She told the committee that ECT, tried after a half-dozen other therapies, stopped the violent behavior and increased her son's achievement in school.

A 1976 law requiring safety and effectiveness of all new medical devices permitted ones in longstanding use, including ECT machines, to stay on the market. Later, however, Congress told the FDA that those grandfathered-in devices either had to undergo rigorous testing or be officially "reclassified" as already-proven to be safe and effective (although, in some cases with special warnings about their use).

In addition to patient testimony, the advisory panel heard FDA staffers describe their analysis of hundreds of ECT studies.

As a group, the studies tended to be poorly designed and with too few patients to allow the drawing of firm conclusions. Many failed to follow patients long enough to discover the duration of ill effects. Ones done decades ago studied techniques and electricity dosages different from current practice.

The FDA staff reported the existing research suggests that for depression, ECT is more effective than placebo or "sham" shocks and after a month more effective than antidepressants.

In terms of hazards, the FDA staff's review found the treatment is associated with "impairment in orientation, memory and global cognitive function immediately after ECT and up to 6 months." Certain aspects of memory may return to baseline after six months. "Autobiographical memory" - recollection of events in one's life - appears to be at greatest risk. High-dose electric current and current applied to both sides of the brain are associated with more thinking and memory problems.

Panel member Christopher A. Ross, a psychiatrist and neuroscientist at Johns Hopkins University, asked if the published studies identified any risk factors that predisposed patients to memory loss and thinking impairment.

"Evidence-based data for that issue just doesn't exist," said Peter G. Como, a neuropsychologist at the FDA.

Panel Chairman Thomas G. Brott, a neurologist at the Mayo Clinic's campus in Jacksonville, Fla., said he was amazed that essentially no research had been done on ECT's effects using functional MRI imaging, repeated brain wave (EEG) studies, or autopsy examinations of patients.

"I tried to look and saw very little. I concluded that the evidence is not there to decide either way," he said.

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