

The New York Times® Reprints

This copy is for your personal, noncommercial use only. You can order presentation-ready copies for distribution to your colleagues, clients or customers [here](#) or use the "Reprints" tool that appears next to any article. Visit www.nytreprints.com for samples and additional information. Order a reprint of this article now.



January 23, 2011

F.D.A. Is Studying the Risk of Electroshock Devices

By **DUFF WILSON**

Federal regulators are weighing whether to downgrade the risk classification of electroshock devices, reinforcing what many [psychiatrists](#) consider a deepening acceptance of electroshock in modern therapy.

The procedure has had a resurgence in recent years. And an estimated 100,000 Americans — two-thirds of them women — undergo the treatment for [major depression](#) and other illnesses each year. Patients, anesthetized, receive a jolt of electricity from electrodes for several seconds, inducing a brain [seizure](#) and [convulsions](#) of up to a minute.

The [American Psychiatric Association](#) and other leading specialists are [recommending](#) that the [Food and Drug Administration](#) downgrade the devices to a medium-risk category from high risk, a move that will be reviewed by an [agency advisory panel](#) in Gaithersburg, Md., this week.

To some extent, the review has renewed the debate over electroshock. In 1990, F.D.A. staff proposed declaring the devices safe for major depression, but never took final action amid an uproar by opponents.

If the F.D.A. downgrades the devices to a medium-risk category, the equipment could be promoted and sold without new testing. Such a downgrade would place the devices in the same risk category as syringes and surgical drills.

If the F.D.A. leaves the devices in the high-risk category, however, manufacturers may, depending on the agency, have to withdraw them from the market.

The F.D.A. could require safety and effectiveness tests that have not previously been done. By regulating the devices, the F.D.A. is indirectly regulating the procedure.

The agency could make a formal decision later this year. The F.D.A. usually, but not always,

follows recommendations of its advisory panels.

Supporters, including mainstream psychiatrists, say the treatment is much safer than it once was and could pass a rigorous F.D.A. review. But they assert that the device manufacturers cannot afford those tests.

“These tend to be mom-and-pop operations,” said Dr. Matthew V. Rudorfer, a psychiatrist and top specialist at the National Institute of Mental Health. “So I think the dilemma might be that undergoing new expensive clinical trials might be too expensive.”

Opponents, including some groups of former patients, maintain that electroshock can cause [memory loss](#) and brain damage that outweigh its short-term benefits.

“It’s all trial and error — it’s all experimental,” said Vera Hassner Sharav, president of the Alliance for Human Research Protection, an advocacy group in New York. “All the years it’s been controversial and there have not been clinical trials. Why not?”

Only two manufacturers, Somatics L.L.C. of Lake Bluff, Ill., and the Mecta Corporation of Lake Oswego, Ore., make the devices in the United States. The F.D.A. has asked them to submit all safety and effectiveness information as part of an agency review to be released before the advisory committee meeting beginning on Thursday.

Dr. Richard Abrams, who founded Somatics in 1983 with Dr. Conrad M. Swartz, and has written a textbook on electroshock, [wrote the F.D.A.](#) to say that none of his patients in more than 10,000 sessions over three decades had reported prolonged memory loss.

Dr. Swartz, who, like Dr. Abrams, is a retired [psychiatry](#) professor, said in an e-mail that any cognitive side effects from Somatics’ latest device “are distinctly less than they had been.” But he said Somatics could not afford an in-depth safety study that the F.D.A. could require if it left the devices in the high-risk category. That could cost millions of dollars.

“There is not nearly enough money in this industry to begin to pay for clinical trials that would be substantially larger than those already in the medical scientific literature,” Dr. Swartz wrote.

Mecta would not comment. “We always get negative press,” said a woman who answered the telephone at the company’s headquarters and did not give her name. “Too bad, because it’s good equipment.”

Somatics and Mecta each have annual revenue exceeding \$1 million, according to [Dun &](#)

Bradstreet. Dr. Swartz, asked about the revenue figure, said Somatics, like Mecta, was a private company. Their Web sites do not list prices or sales figures.

More than 1,000 **hospitals** and outpatient clinics in the United States use the two companies' devices, according to Dr. Charles H. Kellner, **a leading researcher**, professor and chief of geriatric psychiatry at Mount Sinai School of Medicine in New York.

"It's a treatment for the most severe form of **depression**," Dr. Kellner said. "It can really be life-saving."

The F.D.A. review was recommended by the **Government Accountability Office** in 2009 as part of an examination of the regulatory status of electroshock and about 20 other less controversial medical devices, like pacemaker electrodes and implanted blood access devices for **hemodialysis**. They were grandfathered into F.D.A. regulations when the agency was given more authority over medical devices in 1976.

The G.A.O. said those devices should go through the stringent approval process for high-risk devices or be reclassified as medium or low risk. A medium-risk designation could include adding controls like performance standards and patient registries.

The treatment costs \$1,000 to \$2,500 a session, and typically involves three sessions a week for two to four weeks, Dr. Kellner said. The fee includes the services of a psychiatrist and anesthesiologist. The equipment itself costs about \$15,000 and may last years.

Patients are given short-term full **anesthesia**, a powerful muscle relaxant to prevent pain and subdue convulsions, and a mouth guard. The electrical current causes a grand mal seizure with convulsions usually lasting less than a minute, doctors say. Five to 10 minutes later, the patient awakens and can usually go home within two hours.

A federally financed study in 2007 found long-term memory loss and other cognitive problems, especially for female patients, from the treatment at seven New York facilities. The study, of 347 patients, was the first such large-scale study of side effects, despite what its authors called "over 50 years of clinical use and ongoing controversy." The study also said methods and voltage varied widely among practitioners.

Dr. Rudorfer, associate director of treatment research in a division of the National Institute of Mental Health, says modern **electroconvulsive therapy**, or E.C.T., as its supporters prefer to call it, is much better than earlier practices, like those portrayed in "One Flew Over the Cuckoo's

Nest.”

“As surprising as it might seem, it never went away,” Dr. Rudorfer said of the treatment. “The field has had ample opportunity to get rid of E.C.T. and it’s still with us because it seems to occupy a small but important niche in treatment.”

But Dr. Rudorfer and other scientists still do not know just how the treatment or brain [seizures](#) act to improve moods. “We’re still looking,” he said. “It’s been very difficult to tease out the ‘active ingredient’ from among the many changes in the brain that accompany having, and stopping, the therapeutic seizure activity.”

Patients appear to have mixed views, judging from comments to the F.D.A. and [electroshock-related Web sites](#). Some say it saved their lives, some say they suffered too much memory loss, and some say both.

In addition to its use in cases of severe depression, the treatment is used in some cases where speed is essential, like [psychosis](#) or [suicidal behavior](#), for catatonia and in elderly patients who take so many other drugs that they cannot safely add a powerful psychiatric drug.

Dr. James H. Scully Jr., medical director and chief executive of the American Psychiatric Association, wrote the F.D.A. recently to say the treatment was “extremely effective and safe.” It provides relief some 80 percent of the time, he wrote. Dr. Scully and the psychiatry association also say there is no evidence it causes brain damage.

A task force is updating the association’s 2001 recommendations on the treatment. Its report is at least a year away.

“People use it because it works,” said Dr. Laura J. Fochtmann, a member of the task force, professor and director of the [Electroconvulsive Therapy Service at Stony Brook University Medical Center](#), Long Island.

“These disorders can be extremely life-threatening, and when it works, it can be dramatically effective,” she said.

Opponents of electroshock include some patient advocacy groups, but the opponents, clearly, are outnumbered among physicians.

[Dr. Peter R. Breggin](#), author of more than a dozen books including one about electroshock and a consultant in personal injury cases involving drugs and the therapy, says he is the only American

psychiatrist he knows who opposes the treatment.

“It’s a big money-maker,” he said. “I would say if anything it’s been on the increase because there’s a market that’s been exploited, that is the elderly depressed women on [Medicare](#). The reason for that is they’re covered, and there’s no one to protect them. What commonly stops shock treatment is a family member saying ‘over my dead body.’ ”

Depressed older people, Dr. Breggin said, can be helped more by a pet or conversation.

Last year, two [psychology](#) professors, John Read of the University of Auckland, New Zealand, and Richard Bentall of Bangor University, Wales, criticized electroshock after reviewing studies comparing it with simulated treatment. [Their findings](#) were published in *Epidemiologia e Psichiatria Sociale*, a peer-reviewed European psychiatric journal. “The cost-benefit analysis is so poor that its use cannot be scientifically justified,” Dr. Read wrote in an e-mail.

John Breeding, a psychologist and member of the Coalition for Abolition of Electroshock in Texas, said that state had banned electroshock for youths under 16 and required second opinions for treating the elderly, giving it the strictest rules in the nation.

“It’s a very strong treatment for despair and hopelessness,” he said. “It’s a temporary blunting of your feelings, so you feel better for a while, then you feel worse, and now you’ve got the memory loss and brain damage.”