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# F.D.A. Panel Is Split on Electroshock Risks

By **DUFF WILSON**

A federal advisory panel was sharply divided on Friday about whether to recommend that regulators designate electroshock devices as high risk. The change could increase oversight on a controversial treatment used by about 100,000 Americans a year.

The **Food and Drug Administration**, after a two-day advisory meeting, said it would now take more than a year to decide the issue. Even then, manufacturers could be given 30 months longer to submit proof of safety and effectiveness, an F.D.A. official said.

Supporters of the treatment, including the **American Psychiatric Association**, say the devices should be classified as medium-risk to encourage use for life-threatening illness and avoid the threat of a manufacturer withdrawal.

The F.D.A. has described a scientific conundrum: studies show short-term benefits for severely depressed patients, but there is no evidence of any benefit after 30 days. In a 154-page report this week, the agency also described frequent but usually short-term **memory loss**. And the most powerful and effective treatment has the worst side effects.

Dr. Thomas G. Brott, a professor of neurosciences at the **Mayo Clinic** and the panel's chairman, said he wanted the devices to be proved safe and effective in the high-risk class.

If they can pass that test, he said, "I don't see that the reclassification would decrease access of psychiatric patients to this procedure."

A brief electrical jolt is given to fully anesthetized patients, inducing a brain **seizure** of less than a minute, relieving symptoms by a mechanism experts are still trying to identify. The patients also take a powerful muscle relaxant to avoid **convulsions**.

The equipment and by extension the treatment itself were grandfathered into F.D.A. regulation in 1976. New devices have been automatically approved as long as they were similar to old ones. In 2009, the **Government Accountability Office** urged the F.D.A. to

review all such grandfathered devices and assign them to low-, medium- or high-risk categories with commensurate oversight.

Nearly 80 percent of 3,045 comments sent to the F.D.A. asked for stricter oversight or even a ban on electroshock treatment. It remains controversial with some advocacy groups and former patients who say it is unsafe, ineffective and causes brain damage.

The neurological devices advisory panel to the F.D.A delivered a mixed verdict. Ten panel members favored and eight opposed classifying electroshock devices as a high risk for the treatment of severe **depression**, its main use. The panel favored high-risk designations for **schizophrenia** and three other disorders by votes of 13 to 4, 12 to 5, 14 to 3 and 16 to 1, as the advisers said there was little proof of any benefit for them.

But the panel voted 9 to 8 in favor of making it easier to use electroshock for catatonia, citing a lack of other treatment.

In general, the doctors on the panel who practice electroshock therapy or refer patients for it were more likely to favor a lower-risk designation.

Dr. Christopher A. Ross, a professor of **psychiatry** and director of neurobiology at John Hopkins University, said he had seen “remarkable” improvement in **psychotic**, suicidal and catatonic patients. The **memory** problems, he said, usually receded.

Dr. Jane S. Paulsen, a **University of Iowa** professor who studies brain dysfunction, said she agreed the treatment was effective, but worried about memory problems.

Dr. Scott Y. H. Kim, a **University of Michigan** psychiatry professor and bioethicist, was not fazed by the lack of evidence of long-term benefit from the treatment, which is increasingly called **electroconvulsive therapy**, or E.C.T.

“Psychiatrists don’t refer patients to E.C.T. for long-term benefit,” he said. “It’s because we’re in the situation where we need to change the trajectory of the disease.”

Dr. Jonas H. Ellenberg, a professor of biostatistics at the **University of Pennsylvania**, said, “I’m not ready to say based on the evidence we’ve seen that E.C.T. has an overall effectiveness that is clear and unquestionable.”

Only two companies sell the equipment in the United States, Somatics of Lake Bluff, Ill., and the Mecta Corporation of Lake Oswego, Ore. The industry has said a high-risk classification could drive them out of business because they cannot afford new clinical trials.

But Dr. Malvina Eydelman, director of the F.D.A. division covering neurologic devices, said the agency would not necessarily require new trials if existing evidence was strong enough to prove safety and effectiveness.

Karen Riley, a spokeswoman for the F.D.A., said the agency would take more than a year to make a decision. The staff report and advisory committee is just the first of a five-step process, followed by an F.D.A. assessment of risks and benefits, a formal agency proposal, another comment period and final action.