

Devices & Diagnostics Letter
Sept. 21, 2009 | Vol. 36 No. 37

ECT Makers Seeking Class II for Pre-Amendment Devices

With the FDA selecting electroconvulsive therapy (ECT) machines as the first of 25 types of Class III pre-amendment devices to undergo review of their classification, manufacturers are concerned about their survival if the product is not designated Class II.

The agency is reviewing the ECT machines, which are used to treat extreme depression, first as a result of “significant public interest” in the devices, it says in a Sept. 10 Federal Register notice. The devices were on the market when the Medical Device Amendments (MDA) were passed in 1976.

To help it determine whether ECT devices should remain Class III, which would require a PMA review, or be reclassified as Class II, the FDA is asking for public comment on the safety and efficacy of the machines by Jan. 8, 2010.

So far, ECT machines are the only pre-amendment devices whose classification has been opened to the public, CDRH spokeswoman Peper Long told D&DL last week.

The FDA required manufacturers of 25 types of pre-amendment devices, including ECT, to submit a summary of adverse safety or efficacy data about the products by Aug. 7 (D&DL, April 13). The agency received more than 120 responses, Long said. She was unsure how many comments focused on ECT devices, adding that the comments are not yet available to the public.

Having been on the market for more than 30 years, ECT “has been proven to be safe and effective,” Conrad Swartz, co-owner of Somatics, told D&DL. “It is much safer than antipsychotics, which can change a person’s personality, cause obesity, cardiac problems or strokes.” Somatics is one of two U.S. ECT manufacturers.

Gorham Nicol, co-owner of Mecta, the other domestic manufacturer, told D&DL, “People who would have been committed before are now living normal lives,” thanks to this therapy.

If the FDA determines the devices should remain Class III, Somatics and Mecta would have to file PMAs for their devices, which would entail a \$217,787 user fee as of Oct. 1 (D&DL, Aug. 10). Paying the fee isn’t feasible for Mecta, Nicol said, and it could close the company.

The prospect of going through a PMA process would be a challenge for Somatics, Swartz said, adding that it leaves him with a “nervous uncertainty” about the U.S. ECT manufacturing market. He isn’t thrilled with the FDA’s request for public comment on ECT, saying that his company’s future may depend on people outside the medical industry. “This complicates things because the public doesn’t know any more about ECT than they do about surgery,” he said.

Mark Fink, author of *Electroshock: Restoring the Mind* and a former member of task forces on ECT for the American Psychiatric Association, agrees that requiring PMAs could put ECT manufacturers out of business, which would be bad news for patients with few options. “The reality is that there are

thousands of patients who have benefited from ECT. When people don't get better with pills, ECT is all people have," Fink told D&DL.

Meanwhile, the demand for ECT has increased over the past few years. Tatyana Shteinlukht, medical director of ECT at UMass Memorial Medical Center, told D&DL the number of people seeking ECT treatment has doubled from three to six patients daily over the past three months.

"We had more patients than we had slots," she said. She credits the demand to patients sharing their experiences in support groups. Should ECT be taken off the market, "it would deprive patients of a very effective treatment," she added.

Other psychology experts argue that ECT should undergo PMA review. "The idea of not subjecting ECT to rigorous study by the FDA is disgraceful," Peter Breggin, author of *Electroshock: Its Brain-Disabling Effects*, told D&DL. He has testified on Capitol Hill about the dangers of ECT.

Studies have shown that ECT contributes to memory loss and other serious injuries, Breggin said, adding that "we have so much evidence of its dangers, and it should be examined."

Prior to the passage of the MDA May 28, 1976, Class III devices did not have to undergo PMA reviews. The Safe Medical Devices Act (SMDA) of 1990 instructed the FDA to reclassify pre-amendment devices or establish a schedule for requiring PMAs for all Class III devices, which present the greatest risk. The FDA announced plans to implement the SMDA a few years later, but the August deadline was the first step it has taken to do so.

The Federal Register notice requesting comment can be found at www.fdanews.com/ext/files/FDA-2009-N-0392-0001.pdf.