FDA Panel Votes to Curtail Cranial Electrotherapy Stimulators

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The FDA Neurological Devices Panel met to consider the Agency's proposal to reclassify cranial electrotherapy stimulator (CES) devices to Class III with premarket approval.

Depending on your point of view, a recent FDA advisory committee recommendation could either reduce availability of helpful nondrug technology for psychiatric conditions or reduce availability of unproven devices that can do more harm than good.

The Neurological Devices Panel met in February to consider the Agency's proposal to reclassify cranial electrotherapy stimulator (CES) devices to Class III with premarket approval (PMA) and to respond to the petitions of 3 manufacturers of currently marketed devices who are opposing the new classification, with its corresponding requirement to submit sufficient evidence of safety and effectiveness for the PMA.

The CES devices, one marketed for 30 years, had been approved by the FDA as Class III for the indication of "insomnia, depression, and anxiety" through a "pre-amendment" regulatory pathway (510[k]), which required only demonstration of substantial equivalence to legally marketed devices predating FDA regulation. These devices are distinct from separately regulated transcranial magnetic stimulation, transcutaneous electrical stimulation, and electroconvulsive therapy, and from transcranial direct stimulation, which is not yet regulated.

Advocates for the less restrictive Class II category, which requires general or special postmarket controls without PMA, include Jerrold Rosenbaum, MD, Chief of Psychiatry at Massachusetts General Hospital in Boston.

"I support CES receiving Class II status in light of its safety in fairly extensive use and positive results observed by many who use it," Rosenbaum related in a correspondence included in one manufacturer's petition. "This appears to be a very low risk device without serious side effects."

Correspondence supporting the lower-risk classification was also received from the Department of the Army. Colonel Dallas Hack, MD, Director of the US Army Combat Casualty Care Research Program, indicated, "CES devices have been prescribed for the treatment of soldiers and veterans with neuropsychiatric conditions who do not respond to psychotropic medications or do not comply with prescriptions."

FDA seeks proof of effectiveness, safety

The FDA provided the panel with a review of studies conducted since 1970 on the use of the CES devices for their labeled indications. The Agency reported finding mixed results and problems in study size, design, and methodology. The reviewers concluded, "FDA believes the available valid scientific evidence does not demonstrate that CES will provide a reasonable assurance of

effectiveness for the indication of 'insomnia, depression, anxiety.'"
Because 2 of the manufacturer petitions had requested consideration of CES use in patients with comorbid substance abuse, the Agency also reviewed available studies in these populations. There were relatively few studies, generally small and with methodology limitations, which the reviewers also found insufficient to indicate safety or effectiveness.
Although common adverse effects of the devices, such as skin irritation, headaches, and dizziness, were generally found to be tolerable and were characterized by the advisory panel as "appropriate risks," the Agency report also noted the potential risk of seizure "or other adverse effects from electrical stimulation of the brain."
The principle safety concern, however, is the worsening of the condition being treated if the device is not effective. "A key concern stemming from our review of the literature," the FDA reported, "is that use of CES in lieu of more effective, proven therapies may present undue risk to patients whose psychiatric conditions may worsen if untreated."
Lowering the risk category of the CES devices to Class II would group them with an array of devices that are marketed with general or special controls, including syringes, infusion pumps, and condoms. Postmarket controls include patient registration and monitoring programs as well as guidance documents. The Class III devices for which PMA of safety and effectiveness data are required include implantable pacemakers, implantable spinal cord stimulators, and replacement heart valves.
The majority of the panel concurred with the Agency report and recommended reclassifying the CES devices from "pre-amendment" Class III to the current Class III category with PMA requirement. Two panel members, however, along with the patient representative and the industry representative recommended Class II, and an additional panel member recommended Class II for use in anxiety.
In determining that the CES devices should be reclassified as Class III with PMA, the panel rejected the manufacturers' petitions for the devices to remain on the market with special controls. The panel meeting summary explained, "In light of the available scientific evidence, the panel generally concluded that since the benefits did not outweigh the risks, the devices should be Class III, thus negating the need for discussion of special controls."

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