NEUROLOGICAL DEVICES PANEL
Electroconvulsive Therapy

January 27th and 28th, 2011

24 Hour Summary

The Neurological Devices Panel met on January 27 and 28, 2011 to discuss and make recommendations regarding reclassification of electroconvulsive therapy (ECT) devices indicated for use in the treatment of depression and other severe psychiatric conditions.

The first day began with the FDA presenting a general regulatory background, brief clinical history of ECT use, and ECT-specific regulatory history. This was followed by an open public hearing (OPH). The panel heard personal experiences from individuals who had received ECT for treatment of a variety of psychiatric conditions ranging from major depression to autism. The public experiences about ECT ranged from negative to positive and many speakers expressed an opinion regarding reclassification of ECT. Representatives from professional societies also spoke, describing the current practice of ECT treatment and advocating for the availability of the treatment for patients. Panel members asked several questions to the public speakers on topics including the informed consent process adverse event experiences, and how recent changes in ECT technology related to the personal experience of receiving the treatment.

The afternoon session consisted of the FDA presentation of the agency's safety analysis, which included a review of responses to a public docket on ECT reclassification, manufacturer docket responses, and an adverse event database review. In addition, FDA presented a focused review of specific adverse events, including cognitive and memory adverse events, neuropathological changes and death. Following the safety review, FDA presented a review of the effectiveness of ECT, identification of key risks, and proposed risk mitigation factors. A second opportunity was provided to OPH speakers who could not arrive on time due to inclement weather. The advisory panel then had questions for the FDA review team regarding their presentation and analysis of existing studies on the safety and effectiveness of ECT.

On the second day, the FDA presented a brief summary of the previous day's review of safety and effectiveness of ECT. In addition, some information was presented in response to specific panel questions. This was followed by some additional questions by the panel to the FDA review team. The panel then proceeded to their deliberations regarding the questions posed by FDA. The panel agreed that the list of risks provided by FDA were appropriate for inclusion with some minor modifications and deletions. The panel recommended physician labeling recommendations for pre-ECT assessment, including pertinent history, physical examination, and other clinically relevant studies, appropriate procedure monitoring and administration, and appropriate clinical management. When presented with potential regulatory controls that FDA could apply to ECT to mitigate risks of adverse cognitive and memory effects (especially with respect to anterograde and retrograde memory functioning), the panel agreed that cognitive function should be monitored prior to ECT and throughout the course of treatment. The panel agreed that the use of an additional checklist (Acceptance of Risk and Informed Decision Agreement) signed by the patient and physician would be beneficial in conveying the risks of

ECT and enhance the informed consent process. The panel also agreed that the existing clinical data do not provide evidence that ECT treatment is associated with neuropathological changes. Finally, the panel provided overall recommendations for the classification (Class II or III) of ECT devices for specific indications for use, including depression (unipolar and bipolar), schizophrenia, bipolar manic (and mixed) states, schizoaffective disorder and schizophreniform disorder.

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