

NEWS RELEASE

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APA Urges Reclassification of Electroconvulsive Therapy (ECT) by FDA in order to Maintain Availability

ARLINGTON, Va. (Dec. 23, 2009) – The American Psychiatric Association (APA) is urging the Food and Drug Administration (FDA) to reclassify electroconvulsive therapy (ECT) devices as Class II devices based on the strong evidence of ECT's safety and efficacy. ECT is a medical treatment administered by physicians and generally used with severely mentally ill patients when other forms of treatment have not been effective.

The Food and Drug Administration (FDA) is mandated by law to reclassify a number of medical devices, including devices for ECT. The FDA is seeking information to evaluate the risk-level of ECT devices and determine if the devices should be maintained in Class III, requiring submission of a premarket approval application, or reclassified into Class I or II.

If ECT devices are not reclassified, it could potentially result in drastically limited availability of the devices and make it more difficult for new devices to make it to market. Reclassifying the devices could help ensure that ECT is available for patients who could benefit from it.

The safety of ECT when properly administered is well documented in the scientific literature and its effectiveness in treating severe mental illnesses is recognized by the American Psychiatric Association, the American Medical Association, and others in the United States and many other countries. The medical risks associated with ECT are well characterized, and are weighed carefully before a physician prescribes ECT. For some patients the potential risks may be less dangerous than extended treatment with medications.

FDA has opened a public docket specifically on the ECT reclassification and the deadline for public comment is Jan. 8. (FDA Docket No. FDA-2009-N-0392; Electroconvulsive Therapy Device.) FDA has already received extensive safety and efficacy documentation from ECT device manufacturers based on 70 years of scientific publications and clinical experience.

The American Psychiatric Association is a national medical specialty society whose 38,000 physician members specialize in diagnosis, treatment, prevention and research of mental illnesses including substance use disorders. Visit the APA at www.psych.org and www.HealthyMinds.org.

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