Doctors raise questions, concerns about FDA suicide warning

December 9 2008

Medical specialists at the nation's largest professional meeting on epilepsy discussed multiple questions and concerns they have about data presented by the FDA in support of its recent suicide alert on anticonvulsant drugs (AEDs) and the potential effect of the federal agency's analyses on clinical practice and the way AED drug trials are to be conducted in the future.

It is well known that non-adherence to antiepileptic drug therapy can lead to a dramatic increase in accidents and deaths. For these reasons, epileptic experts believe it is imperative that patients continue their antiepileptic therapy to prevent the occurrence of serious accidents and death.

During the American Epilepsy Society's annual meeting, epidemiologists, epileptologists and psychiatrists offered a critical review of the FDA's methodology and analyses, describe the suicide alert's potential impact on patient compliance and seizure management, and its likely effect on the selection of patients for AED regulatory studies.

Among the doctors' concerns is that news reports of the FDA's analyses have confused patients and, perhaps, some physicians on the risks associated with epilepsy drugs. They cite data showing that the risk of suicide possibly associated with AEDs is extremely small compared to the potential danger of leaving patients untreated. Also of concern is that epilepsy patients prone to suicidal ideation or behavior will be excluded

from clinical trials of new AEDs.

Source: American Epilepsy Society