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## FDA Warns Epilepsy Drugs May Raise Suicide Risk

Agency will ask drug makers to put warning labels on entire class of medicines

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HealthDay

Thursday, January 31, 2008



THURSDAY, Jan. 31 (HealthDay News) -- Commonly used antiepileptic drugs may boost the risk of suicide among patients who use them, the U.S. Food and Drug Administration warned Thursday.

A review of 199 studies comparing 11 of these drugs to placebos found that patients taking the drugs had about twice the risk of suicidal behavior compared with patients taking a placebo. In fact, of the almost 44,000 patients in the studies, four people taking antiepileptic drugs committed suicide while none of the patients receiving a placebo did.

"We have been looking at these drugs since 2005," said FDA spokeswoman Sandy Walsh. "We have just come to the conclusion that it's time to alert health-care providers."

Currently, some of drug labels do list suicide or suicidal behavior as a side effect, but others don't, Walsh noted.

The drugs included in the warning are: Carbamazepine (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR), Felbamate (marketed as Felbatol), Gabapentin (marketed as Neurontin), Lamotrigine (marketed as Lamictal), Levetiracetam (marketed as Keppra), Oxcarbazepine (marketed as Trileptal), Pregabalin (marketed as Lyrica), Tiagabine (marketed as Gabitril), Topiramate (marketed as Topamax), Valproate (marketed as Depakote, Depakote ER, Depakene, Depacon) and Zonisamide (marketed as Zonegran). Some of these drugs are also available as generics.

According to the FDA, antiepileptic drugs are used to treat epilepsy, bipolar disorder, migraine headaches and other conditions.

Over the next several months, the agency intends to work with drug companies to change the labels of the drugs to reflect this risk, Walsh said. "We will be working with the companies to make sure the latest data is reflected in their prescribing information and labeling," she said. In addition, the agency will hold an advisory committee meeting on the issue.

The 11 drugs listed above were included in the studies the FDA analyzed. However, the agency expects that the increased risk of suicidality is present in all antiepileptic drugs and so the labeling changes will be applied to all drugs in the class.

As of now, the FDA is advising patients not to make any changes in their medication without talking to their doctor, Walsh said. "Caregivers should pay close attention to changes in mood, behavior and actions," she said. "They should be aware of the development of these symptoms."

One expert supported the FDA's move to require drug makers to have a warning about the possibility of suicidal behavior on the product label.

"This is not new, it's something that has been known for a long time," said Epilepsy Foundation Vice President John Schneider.

Schneider noted that some people with epilepsy may be clinically depressed, so it's hard to tell whether it's the medication or the condition that is causing the suicidal behavior.

"Patients need to know their medications," Schneider said. "The goal should be no seizures and no side effects."

Another expert finds the association between antiepileptic medicines and suicide surprising.

"We do know that the incidence of comorbid affective [emotional] disorders and risk of suicide is higher in patients with epilepsy compared with the general population, and therefore it is not surprising to see higher incidence of suicide in the FDA report," said Dr. Gholam Motamedi, director of the Epilepsy Service at Georgetown University Hospital, in Washington, D.C.

However, the data showing a raised risk of suicide with medication use is surprising, Motamedi said.

"It's also surprising to attribute suicide to the antiepileptic drugs, per se, because a good number of these drugs are used in psychiatry for their *positive* effects on mood and depression," Motamedi said. "Nevertheless, this emphasizes the importance of screening for signs and symptoms of depression and suicidal tendencies in the epilepsy clinics."

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Date last updated: 01 February 2008