

erocurrent

Monthly newsletter from the **epilepsy** RESOURCE CONNECTION

FDA Alert: Risk of Suicidal Thoughts and Behavior with Antiepileptic Medications

The FDA has issued new information to health care professionals to alert them about an increased risk of suicidal thoughts and behaviors (suicidality) in patients who take antiepileptic drugs (AEDs) to treat epilepsy.

An FDA analysis of suicidality reports from placebo-controlled studies of 11 AEDs shows that patients taking these drugs have about twice the risk of suicidal thoughts and behaviors, compared with patients receiving placebo. This risk corresponds to an estimated 2.1 per 1,000 more patients in the drug treatment groups who experienced suicidality than in the placebo groups.

"We want health care professionals to have the most up to date drug safety information," said Russell Katz, M.D., director of the Division of Neurology Products in FDA's Center for Drug Evaluation and Research. "This is an example of FDA working with drug manufacturers throughout products' lifecycles to keep health care professionals informed of new safety data."

Patients who are currently taking antiepileptic medicines should not make any changes without first talking to their health care provider. Health care providers should notify patients, their families, and caregivers of the potential for an increase in the risk of suicidal thoughts or behaviors so that patients may be closely observed for notable changes in behavior.

FDA received and reviewed data from 199 placebo-controlled studies of 11 drugs.

The analysis included 27,863 patients in drug treatment groups and 16,029 patients in placebo groups. There were four suicides among patients in the drug treatment groups and none among patients in placebo groups. There were 105 reports of suicidal thoughts or behaviors in the drug-treated patients and 35 reports in placebo-treated patients.

The higher risk of suicidal thoughts and behaviors was observed at one week after starting a drug and continued to at least 24 weeks. The results were generally consistent among all the different drug products studied and were seen in all demographic subgroups. There was no clear pattern of risk across age groups.

Antiepileptic drugs in the analyses included the following:

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); Zonisamide (marketed as Zonegran)

Some of these drugs are also available in generic form.

Although only the drugs listed above were part of the analysis, the FDA expects that all medications in the antiepileptic class share the increased risk of suicidality.

FDA will be working with manufacturers of marketed antiepileptic drugs to include this new information in labeling these products.

✦ FDA.GOV

Epilepsy Scholarship Programs

Applications are being accepted for these scholarships.

PFIZER Scholarships (Due March 1, 2008)

<http://www.epilepsy-scholarship.com/>

KEPPRA Scholarships (Due May 2, 2008)

<http://www.epilepsyadvocate.com/>

Recipients are chosen based on their academic performance and personal achievements. Scholarships are available to persons with epilepsy in both programs. KEPPRA also offers scholarships to caregivers and family members.

ADA Restoration Act of 2007

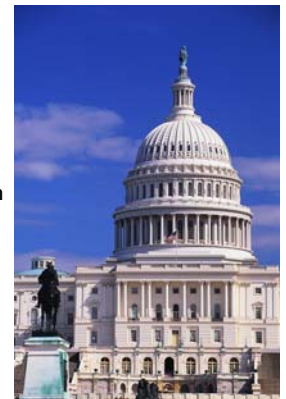
The House Education and Labor Committee recently held a January hearing on the ADA Restoration Act of 2007. This third such hearing in Congress indicates a growing commitment to this important legislation. It is crucial that this legislation be passed in order to ensure that all individuals with disabilities are restored their right to protection against unfair discrimination in the workplace because of physical or mental impairments.

"Various courts, including the Supreme Court, have diluted this landmark legislation," said Eric R. Hargis, President and CEO of the Epilepsy Foundation. "Restoration of the ADA is a top priority because it is critical for people with epilepsy who want to work and deserve their right to be fully included in the American work force."

In these decisions, the Supreme Court ruled that if a mental or physical condition can be managed through the use of "mitigating measures," such as medication, prosthetics or the use of devices, the individual will be viewed as too functional to have a disability and will be denied the ADA's protection against employment discrimination. People with a broad range of disabilities — including epilepsy, diabetes, cancer, multiple sclerosis, depression, bipolar disorder, post-traumatic stress disorder, HIV, missing limbs and intellectual and developmental disabilities — have been found not to be disabled under the ADA.

"People are being unfairly denied a job or fired because an employer mistakenly believes they cannot perform the job — or because the employer does not want 'people like that' in the workplace," said former Congressman Tony Coelho, primary author of the ADA and immediate past chair of the Epilepsy Foundation. "The case is thrown out of court without the individual ever having the chance to show he or she is qualified for the position. The courts have decided that people with disabilities must prove they're disabled enough to be protected. This is not what I intended when I wrote the ADA, nor what Congress intended when it passed it. It meant to protect all Americans with disabilities, and it is now time to restore the full promise of the ADA."

✦ EPILEPSY FOUNDATION



Are Clinical Trials Right For You?



Treatments cannot advance without clinical trials. Clinical trials are biomedical or health-related research studies in human beings that follow a pre-defined protocol. They are necessary to test the effectiveness of new therapies and to develop better ways of using known treatments. In some cases, they can make the difference between life and death for patients or a significantly improved quality of life.

To this end, those with epilepsy are in a special position to help others through participating in medical research that can lead to effective treatments.

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research. All clinical trials have guidelines about who can participate. Participating in a clinical trial, however, is a significant commitment and one should always have a good understanding about the study and clinical trials in general before any agreement is made.

There are risks to clinical trials. There may be unpleasant, serious or even life-threatening side effects to experimental treatment. The experimental treatment may not be effective for the participant.

Your own health care provider may be conducting research for which you are eligible or may know of other studies looking for volunteers.

Choosing to participate in a clinical trial is an important personal decision. People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it.

Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies (e.g., National Institutes of Health). Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits.

↳EPILEPSY FOUNDATION & CLINICALTRIALS.GOV

Adult Epilepsy Support Group

**Meets Second Tuesday of Month,
5:00 PM ▪ 2919 W. 2nd Street, Wichita**

February 12th: "Stress Management"

March 11th: "Recognizing Seizure Triggers"

NEW START TIME of 5:00 PM will allow for Wichita Transit bus service to and from the group!!! The West Central bus passes in front of our building on 2nd Street.

The Arc of Sedgwick County
2919 West Second Street
Wichita, Kansas 67203



Hurdle the barriers to successful employment in

...GETTING THE JOB

Employment & Epilepsy

▪A Hands-On Workshop▪

Friday, April 4, 2008

9:00 AM — NOON

@ Office This (4031 E Harry, Wichita)



This workshop is cosponsored by **Job Force Employment Solutions** and **Epilepsy Resource Connection**.

Role-playing and discussion will focus on the process of getting a job and the issues and misconceptions of epilepsy in the workplace. This is not a job fair; NO jobs will be offered. There is no cost to attend.

Who should attend: Anyone with epilepsy interested in gaining employment, who has questions how to get a job, and/or feels epilepsy is a barrier to getting/keeping a job. Caregivers and family members are welcome to attend.

Get help with these common questions:

What do I say in an interview about my epilepsy?

How do I get a job despite my epilepsy?

What is my next step in trying to get a job?

*TO ATTEND:

**Please reserve a seat by calling
(316) 943-2453**

Wichita Transit's East Harry bus passes in front of Office This on the hour.

Conference Committee Forming

ERC's **2008 Brain Storms Conference Committee** is looking for volunteers. If you would like to help us plan this year's conference /OR/ if you are interested in speaking as one of our patient advocates, please call Matthew at 943-2453 or send an email to: erc@arc-sedgwickcounty.org.

Coming in March!

Clinical Trials & Eligibility in Kansas



February 2008

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