

If you or a family member were prescribed
NEURONTIN[®]
and it resulted in suicide or attempted suicide

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May 20, 2004

By ANNA WILDE MATHEWS

Staff Reporter of THE WALL STREET JOURNAL

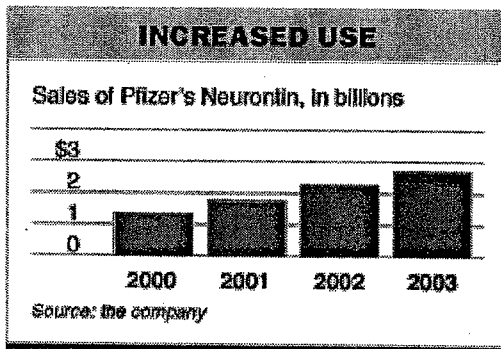
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Pfizer Inc.'s drug Neurontin, at the heart of a controversy over an illegal marketing scheme, is facing a new challenge: a petition asking the Food and Drug Administration to act on claims that it may be tied to suicidal behavior.

The petition to the FDA came from Finkelstein & Partners, a personal-injury law firm in Newburgh, N.Y., that has filed three suits against Pfizer on behalf of people who committed suicide or attempted it. The suits allege that Neurontin played a role in the suicidal behavior.

Andrew Finkelstein, the managing partner at the firm, says he plans to file hundreds of more suits. Largely by running television ads raising questions about the drug, he has accumulated a list of 160 suicides and 2,000 attempts by people who were taking Neurontin for a variety of ailments, he says.

The petition to the FDA, however, is based on the FDA's own adverse-event reporting database, not Mr. Finkelstein's list of clients. It asks the agency to add a warning to the labeling for Neurontin and to send a letter to doctors and other health-care professionals.



According to the petition, the number of suicides reported by Pfizer to the FDA jumped to 17 in the first six months of 2003, the latest information available, compared with a total of eight from 1998 through 2002. Drug companies are required by law to file such reports.

Mr. Finkelstein said he filed the petition because the "sudden uptick in reports" meant that FDA officials "have enough in their own data set to take action without any delay."

In a statement, Pfizer said it remains "confident of the safety and effectiveness of this product" and it would be "extremely irresponsible if the petition or accompanying publicity were used to promote the false impression that there is a causal link between Neurontin and suicide." The company said it hasn't seen the petition, but is aware that law firms are soliciting as clients current and former Neurontin patients.

Neurontin brought Pfizer revenue of \$2.7 billion in 2003. The drug is sold in more than 100 countries and has been prescribed to about 10 million patients since it was launched in 1994.

Last week, Pfizer unit Warner-Lambert pleaded guilty to illegally promoting the drug for a variety of uses not approved by the FDA, and agreed to pay a total of \$430 million in fines and damages. Neurontin originally was approved as a supplemental antiseizure treatment for epilepsy, but it is widely used "off label" for a variety of other conditions, including migraines, bipolar disorder and pain.

An FDA spokesman said the agency "looks forward to reviewing and responding" to the petition.

The agency frequently doesn't regard information from its own adverse-event reporting system as a definitive measure of risk. In addition, it often is tough for regulators and drug companies to clearly tie suicidal behavior to specific medication, particularly in patients suffering from psychiatric disorders.

In the early 1990s the FDA rejected a petition from a group funded by the Church of Scientology to ban the antidepressant Prozac because of concerns it could lead to suicidal behavior and other bad effects, and an age advisory committee voted against a label warning. That issue has re-emerged recently because of concerns that some antidepressants may somehow be tied to suicidal tendencies in young people. The FDA recently asked drug makers to add a new, generally worded warning to their labels urging doctors and others to closely monitor all patients on antidepressants.