

[Huge penalty in drug fraud](#)
[Pfizer settles felony case in Neurontin off-label promotion](#)

- [Bernadette Tansey, Chronicle Staff Writer](#)

Friday, May 14, 2004

A division of Pfizer Inc., the world's largest drugmaker, has agreed to plead guilty to two felonies and pay \$430 million in penalties to settle charges that it fraudulently promoted the drug Neurontin for a string of unapproved uses.

In an agreement announced by government prosecutors Thursday, Pfizer unit Warner-Lambert admitted that it aggressively marketed the epilepsy drug by illicit means for unrelated conditions including bipolar disorder, pain, migraine headaches, and drug and alcohol withdrawal.

A company whistle-blower, whose 1996 civil suit spurred government investigations of Neurontin's marketing campaign, will receive about \$26.6 million through the settlement under legal provisions that reward citizens for helping to recover government money obtained by fraud.

The settlement includes \$152 million to pay back amounts spent on Neurontin by the federal Medicare program and 50 state Medicaid programs for the poor. In addition, Pfizer will pay a \$240 million criminal fine, the second-largest such fine ever imposed in a health care fraud prosecution, the Department of Justice said.

Prosecutors said Warner-Lambert turned Neurontin into a blockbuster drug with tactics like paying doctors to listen to pitches for unapproved uses and treating them to luxury trips to Hawaii, Florida or the 1996 Olympics in Atlanta. One doctor received almost \$308,000 to tout Neurontin at conferences.

"This illegal and fraudulent promotion scheme corrupted the information process relied on by doctors in their medical decision making, thereby putting patients at risk," said U.S. Attorney Michael Sullivan, chief prosecutor for the federal district based in Boston.

Doctors are free to prescribe drugs for uses not specified on their FDA-approved labels, but the FDA forbids drug companies from promoting them for those off-label uses. Prosecutors said Neurontin's manufacturers decided not to seek an expanded FDA label for the drug, an expensive process requiring solid proof from clinical trials. Instead, the company boosted sales through aggressive promotional strategies, even when scientific studies had demonstrated that it was not effective, the Justice Department said.

The tactics included planting company operatives in the audience at medical education events to contradict unfavorable comments about Neurontin, and paying doctors to allow sales representatives to sit in on patient visits, prosecutors said.

Such methods were first revealed by the whistle-blower, David Franklin, a former medical liaison for Warner-Lambert who filed suit on behalf of the

government. By some estimates, as much as 90 percent of Neurontin prescriptions were for off-label uses during the marketing campaign that prosecutors said dates back to about 1995. Neurontin's sales soared from \$97.5 million in 1995 to nearly \$2.7 billion in 2003.

In a written statement, Pfizer said the illegal practices took place before Pfizer acquired Warner-Lambert in 2000.

"Pfizer has cooperated fully with the government to resolve this matter, which did not involve Pfizer practice and employees," the company said. "Pfizer is committed to compliance with all health care laws and FDA requirements and to high ethical standards."

Under the settlement with prosecutors, Pfizer agreed to bolster its corporate compliance program with measures to detect and prevent off-label marketing. The agreement also requires the firm to pay \$38 million in civil penalties for harm caused to consumers in the 50 states and the District of Columbia. Part of that amount will fund an education campaign to dispel false information about Neurontin.

The settlement does not cover damages for any patients who may have been sickened by Neurontin, said Tom Dresslar, a spokesman for California Attorney General Bill Lockyer. Those patients can file personal-injury suits, he said.

Lockyer said California's share of the settlement will total about \$15 million, of which \$7.5 million will be used to reimburse the state Medi-Cal program for unnecessary Neurontin prescriptions. But California must return more than \$7 million to the federal government, which covers about half the cost of state Medicaid programs.

Dresslar said Lockyer's office will continue to scrutinize drug marketing for evidence of off-label promotion. "We're not going to let drug companies profit by essentially making guinea pigs out of poor, elderly and other patients, or by defrauding taxpayers," he said.

The Pfizer settlement comes as government scrutiny of off-label promotion is widening and as public health insurance programs as well as private medical plans look for ways to deal with the rising cost of prescription drugs.

Pfizer faces a separate civil suit in California to recover amounts paid for off-label Neurontin by individual patients and private health plans. It also faces government investigations of the marketing of additional drugs it obtained when it bought other drug companies.

Pfizer disclosed two months ago in a regulatory filing that the Justice Department is scrutinizing the marketing of the Genotropin growth hormone and Bextra painkiller, two drugs the company added to its portfolio when it bought Pharmacia Corp. last year. Pfizer and a dozen other drug companies are also accused in a lawsuit by Pennsylvania Attorney General Jerry Pappert of inflating drug prices with marketing costs.

Pfizer also disclosed in March that a federal grand jury in Maryland has sought testimony from former Warner-Lambert employees about the diabetes drug Rezulin, which was pulled off the U.S. market in March 2000 after it was linked to at least 63 liver-related deaths.

The Associated Press and Bloomberg News contributed to this report. E-mail Bernadette Tansey at btansey@sfgate.com.

Page C - 1

URL: <http://sfgate.com/cgi-bin/article.cgi?file=/c/a/2004/05/14/BUGKK6L0LB1.DTL>