

# Abbott Labs Settles Depakote Marketing Charges with Justice Department

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Abbott Labs has entered a guilty plea and agreed to pay \$1.5 billion to settle charges with the U.S. Department of Justice (DOJ) regarding its marketing of Depakote. Federal prosecutors had alleged that Abbott illegally promoted Depakote for uses not approved as safe and effective by the Food and Drug Administration (FDA).

According to a press release issued by the DOJ yesterday, the Depakote settlement includes a criminal fine and forfeiture totaling \$700 million. Another \$800 million will go towards civil settlements with the federal government and the states. Abbott also will be subject to court-supervised probation and reporting obligations for Abbott's CEO and Board of Directors, the DOJ said.

The FDA approved Depakote for epileptic seizures, bipolar mania and the prevention of migraines. But according to the DOJ, Abbott trained its sales force to promote Depakote to health care providers and employees of nursing homes as advantageous over antipsychotic drugs for controlling agitation and aggression in elderly dementia patients. At the time, Depakote was not subject to certain provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA) and its implementing regulations designed to prevent the use of unnecessary medications in nursing homes. Abbott sales representatives stated that by using Depakote, nursing homes could avoid the administrative burdens and costs of complying with OBRA, the DOJ said.

In 1999, Abbott was forced to discontinue a clinical trial of Depakote in the treatment of dementia due to an increased incidence of adverse events, including somnolence, dehydration and anorexia experienced by the elderly study participants administered Depakote.

"Not only did Abbott engage in off-label promotion, but it targeted elderly dementia patients and downplayed the risks apparent from its own clinical studies," said Acting Associate Attorney General Tony West.

According to the DOJ statement, Abbott also admitted that from 2001 through 2006, it misbranded Depakote by marketing the drug to treat schizophrenia. Abbott funded two studies of the use of Depakote to treat schizophrenia, and both failed to meet the main goals established for the study. Abbott waited nearly two years to notify its own sales force about the results of the second study and another two years to publish those results. During this time, Abbott continued to promote Depakote off-label to treat schizophrenia, federal prosecutors say.