

Abbott Laboratories ("Abbott") recently announced that it will pay \$1.6 billion to settle various federal and state claims that it improperly marketed the prescription drug Depakote for off-label uses. Abbott will pay \$800 million to resolve civil claims brought by the federal government and states, \$700 million in criminal penalties, and another \$100 million to states to resolve consumer protection claims. Under the terms of the deal, Abbott will plead guilty to a violation of the Food, Drug, and Cosmetic Act for misbranding. Abbott will also be prohibited from further marketing Depakote for off-label uses.

Depakote, an anti-seizure and mood-stabilizing drug, was approved by the FDA to treat epilepsy, bipolar disorder, and migraines. In lawsuits filed by whistleblowers, it was alleged that Abbott improperly marketed the drug for off-label uses, including treatment of schizophrenia, dementia, and autism. The lawsuits alleged that Abbott trained and encouraged its sales force to market Depakote off-label to nursing home directors, geriatric doctors, and other long-term care providers. Abbott also gave doctors illegal kickbacks to talk about off-label uses of Depakote so as to boost sales.

Doctors are permitted to prescribe drugs "off-label," or for conditions for which the drug was not originally intended. However, drug companies are expressly prohibited from marketing drugs to treat conditions not approved by the FDA. Abbott's actions in training its sales force to engage in off-label marketing violates federal law. The \$1.6 billion settlement resolves claims that Abbott violated various civil and criminal laws, including creation of fraudulent charges to be covered by Medicare and Medicaid.

The Abbott settlement is one of a number of recent significant settlements with drug companies over illegal marketing claims. In November, GlaxoSmithKline acknowledged that it would pay the federal government \$3 billion to settle civil and criminal charges related to illegal marketing of the diabetes drug Avandia and others. In 2009, Pfizer, Inc. paid \$2.3 billion to resolve illegal marketing claims in connection with its painkiller Bextra. That same year, Eli Lilly & Co. paid \$1.4 billion to settle illegal marketing claims related to its schizophrenia drug Zyprexa. These cases demonstrate the importance of whistleblowers in helping the federal and state governments reign in unlawful conduct by drug companies. Exposing drug companies' unlawful marketing schemes helps government agencies recoup past overcharges and to avoid them with future billings.

Read the [LA Times article](#).

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