



U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200

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PHARMACEUTICAL COMPANY ELI LILLY TO PAY RECORD \$1.415 BILLION FOR OFF-LABEL DRUG MARKETING

Criminal Penalty is Largest Individual Corporate Criminal Fine

PHILADELPHIA – United States Attorney General Michael B. Mukasey and Acting United States Attorney Laurie Magid today announced the filing of a criminal information¹ against, and a civil settlement with, pharmaceutical company Eli Lilly and Company, headquartered in Indianapolis, Indiana, for the off-label marketing of the anti-psychotic drug Zyprexa. The monetary settlement, totaling \$1.415 billion, is the largest amount paid by a single defendant in the history of the United States Department of Justice (“DOJ”).

Joining Mukasey and Magid in today’s announcement were Assistant Attorney General Gregory Katsas, who is in charge of DOJ’s Civil Division; Director of DOJ’s Office of Consumer Litigation, Eugene Thirolf; Special Agent-in-Charge of the Defense Criminal Investigative Service Ed Bradley; Special Agent-in-Charge of the Food and Drug Administration, Office of Criminal Investigations Kim Rice; and Special Agent-in-Charge Patrick Doyle of the Office of Inspector General of the Department of Health and Human Services.

The Criminal Charge

The information charges Eli Lilly with the misdemeanor of introducing misbranded drugs into interstate commerce between September 1999 and November 2003. The Food and Drug Administration (“FDA”) had approved Zyprexa for use by adults for treatment of schizophrenia and certain types of bipolar disorder. Eli Lilly has admitted that it illegally marketed Zyprexa for uses never approved by the FDA. Among other things, the government alleges that these uses included treatment of elderly patients for such things as sleep disorders and dementia.

According to the information, Eli Lilly targeted its illegal marketing of Zyprexa to two types of doctors: those who treat the elderly in nursing homes and assisted living facilities, and primary care physicians. In September 1999, Eli Lilly began encouraging doctors to prescribe the drug for the treatment of dementia, Alzheimer’s, agitation, aggression, hostility, depression, and

¹A information is an accusation. A defendant is presumed innocent unless and until proven guilty.

generalized sleep disorder. Zyprexa was not approved for use for any of these disorders, which, unlike schizophrenia, are prevalent in the elderly population. Nevertheless, Eli Lilly's long-term care sales force promoted the use of Zyprexa in elderly populations for these symptoms. Because one of Zyprexa's side effects is sedation, Eli Lilly directed its long-term care sales force to tell doctors that Zyprexa would help patients with sleep problems, behavioral issues, and dementia. They claimed this side effect was a therapeutic benefit, not an adverse event, with the sales slogan "5 at 5," that five milligrams of Zyprexa at 5 p.m. would help their patients sleep. Then in 2000, Eli Lilly expanded its illegal marketing to primary care physicians with its primary care sales force in the "Viva Zyprexa" campaign, adding even more sales representatives. The goal of the campaign was to make Zyprexa an "everyday agent in primary care" even though the company recognized that schizophrenia and bipolar disorder were not viewed as conditions typically treated by primary care physicians. Lilly instructed the sales force to recommend Zyprexa for all adult patients with behavioral symptoms like agitation, aggression, hostility, mood and sleep disturbances, and depression.

The information alleges that Eli Lilly's illegal off-label marketing campaign raised safety issues and posed potential risk to patients. Eli Lilly knew that significant weight gain and obesity were adverse side effects of Zyprexa and that weight gain and obesity were factors in causing hyperglycemia and diabetes. Yet despite written caution from the FDA, Eli Lilly continued to promote these adverse events as therapeutic benefits of Zyprexa use, particularly in the elderly.

Eli Lilly's management created marketing materials promoting Zyprexa for off-label uses, trained its sales force to disregard the law, and directed its sales personnel to promote Zyprexa for off-label uses. Anticipating the possibility of resistance from primary care physicians to prescribing Zyprexa, defendant Eli Lilly specifically trained its sales representatives on how to respond to doctors' concerns about off-label uses of Zyprexa, and how to continue to promote Zyprexa for off-label conditions. Eli Lilly retained medical professionals to speak to doctors during peer-to-peer sessions about off-label uses of Zyprexa. When promoting Zyprexa to health care providers, Lilly emphasized that the weight gain side effect of the drug was a therapeutic benefit for patients who had trouble maintaining their weight.

"When pharmaceutical companies interfere with the FDA's mission to insure that drugs are safe and effective, they undermine the doctor-patient relationship and put the health and safety of patients at risk," said Magid. "People have a legal right to know that pharmaceutical companies are marketing their drugs only for uses approved by the FDA and that their doctors' judgment has not been affected by misinformation from a pharmaceutical company trying to boost revenues."

In a plea agreement with the United States, Eli Lilly will pay a total of \$615 million, including a \$515 million fine and \$100 million in forfeiture.

"Off-label promotion of pharmaceutical drugs is a serious crime because it undermines the FDA's role in protecting the American public by determining a drug is safe and effective for a particular use before it is marketed," said Gregory G. Katsas, Assistant Attorney General for the

Civil Division. “This settlement demonstrates the Department’s ongoing diligence in prosecuting cases involving violations of the Food, Drug, and Cosmetic Act, and recovery of taxpayer dollars used to pay for drugs sold as a result of off-label marketing campaigns.”

The Civil Settlement

In a separate civil settlement agreement, Eli Lilly agreed to pay the United States approximately \$438,171,543.58 to settle allegations that it caused invalid claims for payment for Zyprexa to be submitted to various government programs such as Medicaid, TRICARE, and the Federal Employees Health Benefits Program and caused purchases of Zyprexa by the Department of Veterans Affairs, the Bureau of Prisons, the Department of Defense, the Defense Logistics Agency, the Department of Labor, and Public Health Service entities for unapproved off-label uses. Also, Eli Lilly agreed to pay various state Medicaid programs more than \$361,828,456.42 to settle similar claims.

“Today’s announcement of the filing of a criminal charge and the unprecedented terms of this settlement demonstrate the government’s increasing efforts aimed at pharmaceutical companies that choose to put profits ahead of the public’s health,” said Special Agent-in-Charge Kim Rice, of FDA’s Office of Criminal Investigations. “The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the safeguards of the drug approval process and recklessly promote drugs for uses for which they have not been proven to be safe and effective.”

“The illegal scheme used by Eli Lilly significantly impacted the integrity of the Department of Defense’s healthcare system,” said Special Agent-in-Charge of the Defense Criminal Investigative Service Ed Bradley. “This illegal activity increases patients’ costs, threatens their safety and negatively affects the delivery of healthcare services to the more than nine million military members, retirees and their families who rely on this system. Today’s charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its partners in law enforcement to investigate and prosecute those that abuse the government’s healthcare programs at the expense of the taxpayers and patients.”

“Today’s disclosures should send a clear message to those doing business with the Government that they will be held accountable for their decisions and actions that have an adverse impact on health care programs, such as Medicare and Medicaid,” said Special Agent-in-Charge Patrick Doyle, HHS, Office of Inspector General, Office of Investigations. “Our office is committed to pursuing those companies and individuals who choose to put profits ahead of the law.”

The civil settlement also resolves four whistle-blower lawsuits filed in federal court here: United States of America ex rel. Robert Rudolph v. Eli Lilly and Company, Civil Action No. 03-943; United States of America ex rel. Joseph Faltaous v. Eli Lilly and Company, Civil Action No. 05-1471; United States of America ex rel. Steven Woodward v. Eli Lilly and Company, Civil Action No. 06-5526; and United States of America ex rel. Jaydeen Vincente v. Eli Lilly and

Company, Civil Action No. 07-1791. Those cases were filed by former sales representatives who identified Eli Lilly's off-label marketing practices. To encourage individuals to come forward and identify companies and individuals that defraud the government, federal law permits whistle blowers to share in the recovery for such fraud. In this case, the whistle blowers will share in 18%, or \$78,870,877, of the federal share of the (civil) settlement.

The HHS Office of Inspector General and Eli Lilly entered into an agreement that requires Eli Lilly to cease off-label marketing and to put certain programs in place to prevent the illegal conduct from recurring. This agreement, called a Corporate Integrity Agreement, requires Eli Lilly to send doctors letters advising them of this resolution and give them a way to report questionable conduct of sales representatives, list payments to doctors on its website, and assure that its board of directors and top management regularly certify that the company obeys the law and has an effective compliance program.

This case was investigated by the Defense Criminal Investigative Service, the FDA's Office of Criminal Investigations, and the Department of Health and Human Services Office of the Inspector General. The case is being prosecuted by Assistant United States Attorneys Catherine L. Votaw, Marilyn May, Joseph Trautwein, and Denise S. Wolf, and DOJ Office of Consumer Litigation Trial Attorneys Jeffrey Steger and Ross Goldstein.

Assistance was provided by representatives of FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

The Corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services.

Eli Lilly's guilty plea and sentence are not final until accepted by the United States District Court.

**UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT, PENNSYLVANIA
Suite 1250, 615 Chestnut Street
Philadelphia, PA 19106**

Contact:

**PATTY HARTMAN
Media Contact
215-861-8525**

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