



U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

615 Chestnut Street

*Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200*

For Immediate Release

January 30, 2009

PHARMACEUTICAL COMPANY ELI LILLY PLEADS GUILTY TO MISBRANDING DRUGS

PHILADELPHIA – Pharmaceutical company Eli Lilly and Company, headquartered in Indianapolis, Indiana, pleaded guilty today in U.S. District Court to a misdemeanor for the off-label marketing of the anti-psychotic drug Zyprexa, announced Acting United States Attorney Laurie Magid. Eli Lilly was charged in a criminal information¹ with introducing misbranded drugs into interstate commerce between September 1999 and November 2003. U.S. District Court Judge Robert F. Kelly immediately imposed sentence, ordering the pharmaceutical company to pay \$615 million, including a criminal fine of \$515 million and \$100 million in forfeiture. The charge against Eli Lilly was announced earlier this month simultaneously with a civil settlement in the amount of \$800 million. The total monetary settlement totaled \$1.415 billion.

Background:

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 alleged that these uses included treatment of elderly patients for such things as sleep disorders and dementia; that the illegal off-label marketing campaign raised safety issues and posed potential risk to patients; that Eli Lilly knew significant weight gain was an adverse side effect of Zyprexa but touted it as a therapeutic benefit; and that 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.

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

In the 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.

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 was 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.

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

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

*COPIES OF NEWS MEMOS AND RELATED DOCUMENTS CAN ALSO BE FOUND AT
<http://www.usdoj.gov/usao/pae>*