



January 15, 2009

MADIGAN: ELI LILLY TO PAY \$1.4 BILLION FOR OFF- LABEL DRUG MARKETING

Chicago — Attorney General Lisa Madigan today announced an agreement with Eli Lilly and Company to settle allegations that it engaged in an off-label marketing campaign to improperly promote the anti-psychotic drug, Zyprexa, for unapproved uses. As part of the settlement, Eli Lilly will pay a total of \$800 million in damages and penalties to compensate Medicaid and federal healthcare programs. The Illinois Medicaid program will receive \$27 million as part of the agreement, and the State of Illinois will recover \$17 million.

"Eli Lilly aggressively and inappropriately promoted Zyprexa for uses that the FDA had not approved," Madigan said. "My office has consistently taken action to demonstrate that we will not tolerate pharmaceutical companies' efforts to market products for unacceptable medical applications that put patients' health at risk."

The U.S. Attorney for the Eastern District of Pennsylvania today also filed a criminal information in U.S. District Court charging Eli Lilly with a misdemeanor violation of the Food, Drug and Cosmetic Act. In a plea agreement filed with the court, Eli Lilly has agreed to pay a \$615 million criminal fine to resolve the charge.

In her complaint filed along with the settlement agreement, Attorney General Madigan alleged that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses. Zyprexa is one of a newer generation of antipsychotic medications (called atypical antipsychotics) used to treat certain psychological disorders, including schizophrenia and bipolar disorders. Between September 1999 and Dec. 31, 2005, Eli Lilly allegedly promoted the sale and use of Zyprexa, primarily through a marketing campaign called "Viva Zyprexa," for certain uses which the Food and Drug Administration (FDA) had not approved.

As a result of the company's aggressive marketing campaign, physicians prescribed Zyprexa for unapproved uses to children and adolescents and dementia patients in long-term care facilities, and in unapproved dosage amounts. All of these uses were not medically accepted for state Medicaid reimbursement.

As part of the settlement, Eli Lilly will enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of the Inspector General, which will closely monitor the company's future marketing and sales practices.

Patrick Keenan, Chief of Attorney General Madigan's Medicaid Fraud Bureau, was part of a national team of eight attorneys from the National Association of Medicaid Fraud Control Units that represented all of the settling and worked with the federal government in investigating and conducting settlement negotiations with Eli Lilly.

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