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MADIGAN REACHES LANDMARK \$62 MILLION SETTLEMENT WITH ELI LILLY

Madigan-led Investigation, Joined by 32 AGs, Results in Largest Ever Consumer Pharmaceutical Settlement

Chicago—Attorney General Lisa Madigan announced today that she, along with 32 other Attorneys General, reached a record \$62 million settlement with Eli Lilly and Company arising from alleged improper marketing of the antipsychotic drug Zyprexa. This settlement, led by Madigan and Oregon Attorney General Hardy Myers, is the largest ever multi-state pharmaceutical consumer protection settlement.

"Eli Lilly aggressively promoted Zyprexa for unapproved uses. The company's deceptive marketing practices were illegal and highly dangerous, and unfairly targeted doctors serving extremely vulnerable populations, including children and elderly patients with dementia," Madigan said. "This settlement will protect patients by banning marketing campaigns aimed at promoting this drug for unapproved uses and prohibiting false or misleading statements about the drug's benefits."

In a complaint filed today along with the settlement agreement, Madigan alleged that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses.

From Lilly's home state, Indiana Attorney General Steve Carter, who participated in the investigation, said, "We are pleased that Eli Lilly has agreed to take measures to ensure that doctors and consumers throughout the nation get accurate, objective and balanced information about Zyprexa."

Madigan and the Oregon Attorney General led a 1 ½-year investigation into Eli Lilly's practices in marketing Zyprexa. As a result of this aggressive investigation, Eli Lilly has agreed to significantly change how it markets Zyprexa and to cease promoting its "off-label" uses, which are not approved by the U.S. Food and Drug Administration (FDA). The company also will pay \$62 million nationally. As part of this settlement, Illinois will receive nearly \$3.6 million in settlement funds from the company, of which \$1.8 million will be used to directly benefit low-income persons in need of mental health services and to enforce the consumer fraud laws.

"Our goal is to direct this settlement money to help low-income and uninsured Illinoisans obtain needed mental health care," said Madigan.

Madigan's investigation focused on Eli Lilly's aggressive Zyprexa marketing campaign, which involved illegal promotions of off-label uses to doctors. Specifically, as part of its "Viva Zyprexa!" campaign, Eli Lilly encouraged doctors to prescribe Zyprexa for pediatric uses, for treating symptoms rather than diagnosed conditions, and for elderly patients with dementia. While physicians may prescribe drugs for any uses, the law clearly prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

Zyprexa is the brand name for the prescription drug olanzapine, which the FDA approved for treating schizophrenia and bipolar disorders. It causes dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions.

As a result of Madigan's investigation, the settlement requires that for six years, Eli Lilly:

- Is prohibited from making false or misleading claims about Zyprexa,
- Is prohibited from promoting Zyprexa for off-label uses,

- Must clearly indicate the FDA's approved uses for the Zyprexa in any marketing promotions,
- Must make its medical department, and not its sales and marketing personnel, ultimately responsible for the content of medical letters and references regarding Zyprexa,
- Is prohibited from using grants or continuing medical education (CME) activities as a means of promoting Zyprexa,
- Must disclose payments made to medical providers who are promotional speakers or consultants for Eli Lilly,
- Must distribute samples of Zyprexa only to medical practitioners whose practice is consistent with the FDA's approved uses for the drug, and
- Must publicly issue accurate, objective and balanced research reports about Zyprexa.

Madigan and Oregon Attorney General Myers led the investigation into Eli Lilly's marketing and promotional practices. The Attorneys General of the following states and the District of Columbia participated in the settlement: Arizona, Alabama, California, Delaware, Florida, Hawaii, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington and Wisconsin.

Consumer Fraud Bureau Chief Jim Kole, Assistant Attorneys General Ryan Lipinski, Susan Danial and Sean Morales-Doyle, Dr. Arnie Widen and Dr. Babs Waldman handled the case for Madigan's Office.

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