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MADIGAN: ILLINOIS RECEIVES \$20 MILLION IN LANDMARK SETTLEMENTS WITH ABBOTT LABS***Abbott to Pay \$1.6 Billion Over National Civil, Criminal Claims of Illegal Marketing of Depakote***

Chicago — Attorney General Lisa Madigan joined her federal counterparts, 44 other states and the District of Columbia in announcing two national settlements with Abbott Laboratories, totaling \$1.6 billion, over allegations of illegal off-label marketing of its Depakote drug. Madigan said Illinois will receive \$20 million under the agreements.

In the first settlement, Madigan and the states alleged in a civil complaint that Abbott engaged in deceptive practices to market Depakote, which is FDA-approved for treating seizure disorders, mania associated with bipolar disorder and prophylaxis of migraines. But Madigan alleged the company deliberately opted to bypass the regulatory approval process and instead promoted off-label uses, including as treatments for schizophrenia, dementia and autism, when medical studies failed to adequately prove the drug to be effective for these conditions. Off-label drug use occurs when a drug is used for certain treatments and conditions that the U.S. Food and Drug Administration has not approved.

In a separate agreement with federal authorities, Madigan and the states alleged the company's off-label marketing resulted in hundreds of millions of dollars in false claims to Medicaid, Medicare and other federal health care programs. Madigan said Abbott improperly marketed Depakote for off-label uses in nursing homes and illegally paid health care professionals and long-term care pharmacy providers to promote or prescribe the drug.

"Abbott made a deliberate decision to circumvent the regulatory approval process, opting instead to deceptively market Depakote for treating seniors with dementia and mental health patients despite a lack of convincing medical evidence for such uses," Attorney General Madigan said.

In the civil complaint filed today along with the settlement, Madigan and the states detail how Abbott allegedly conducted off-label promotions through a variety of deceptive practices. The company distributed studies that showed Depakote could be used to treat off-label conditions and instructed its sales representatives to draw attention to the studies. In one such study, Abbott sought to determine Depakote's effectiveness to treat schizophrenia. The final results showed the drug was mostly ineffective for treating schizophrenia, but the company allegedly delayed releasing the negative results while it continued to promote Depakote for treating the mental condition.

As a part of the civil settlement, Abbott has agreed to significantly change how it markets Depakote and cease promoting off-label uses, in addition to a \$100 million payment. Additionally, under the settlement, Abbott is prohibited from making false or misleading claims about Depakote, and the company is required to ensure financial incentives for sales of the drug do not promote off-label uses. Abbott also must restrict other specific practices it used to promote off-label uses of the drug.

The second settlement with the states and federal government resolves false claims to Medicaid, Medicare and other federal health care programs. As a condition to that agreement, Abbott pled guilty this morning to a violation of the federal Food, Drug and Cosmetic Act. As part of this settlement, Abbott has agreed to pay a criminal fine and forfeiture of \$700 million.

Joining Madigan in today's announcement were attorneys general in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, the District of Columbia, Florida, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia and Wisconsin.

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