STATE OF CONNECTICUT
ATTORNEY GENERAL GEORGE JEPSEN

# Attorney General: Connecticut Receiving $6 Million From Abbott Laboratories Settlements Over Marketing of Depakote

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HARTFORD – Attorney General George Jepsen said Connecticut will receive approximately $6 million from federal and state civil and criminal settlements announced today with Illinois-based Abbott Laboratories over allegations the company promoted sales and use of prescription drug Depakote for uses that were not approved by the U.S. Food and Drug Administration (FDA) as safe and effective.

"These settlements were the result of hard work and cooperation at both the federal and state levels. They will serve as a deterrent to other companies who seek to benefit unfairly from government healthcare programs," Attorney General Jepsen said. "Most importantly, they will help to protect consumers who were prescribed an expensive drug with little evidence the drug could help their condition."

A $1.5 billion civil and criminal healthcare fraud settlement settles claims that the company's alleged conduct resulted in false claims to Medicaid and other federal healthcare programs. Abbott agreed to pay the states and federal government $800 million in civil damages and penalties. The net state share for Connecticut Medicaid claims is more than $3.9 million. Connecticut also will be receiving an additional $499,000 for state-funded benefit programs administered by the state Department of Social services.

Social Services Commissioner Roderick L. Bremby said, "Our claims data indicated a significant and inappropriate impact on Medicaid expenditures, a factor that will now be mitigated by this major settlement. We thank the Attorney General's Office and Office of the Chief State Attorney for their continued vigilance on behalf of the Medicaid program, our beneficiaries, and Connecticut taxpayers in general."

The company also agreed to a $700 million criminal fine and forfeiture for violating the federal Food, Drug and Cosmetic Act.

Connecticut Chief State's Attorney Kevin T. Kane commended the continued collaboration by the Medicaid Fraud Unit in the Office of the Chief State's Attorney and other state and federal government agencies to protect the integrity of the Medicaid program and protect against the loss of taxpayer dollars.

Another $100 million settlement with 45 states and the District of Columbia, resolves civil consumer protection claims that the company engaged in unfair and deceptive practices by illegal off-label

marketing of Depakote. Connecticut's share of the consumer protection settlement is more than $1.5 million, including $150,000 for the state Department of Consumer Protection's Prescription Drug Monitoring Program.

Depakote is approved by the FDA for treatment of seizure disorders, mania associated with bipolar disorder and to prevent migraine headaches. According to the complaints filed concurrently with the settlement agreements, Abbott also marketed the drug for uses not approved by the FDA, including behavioral disturbances in dementia patients, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention deficit disorder, autism and other psychiatric conditions.

Consumer Protection Commissioner William M. Rubenstein said "this settlement's positive impact for Connecticut consumers extends well beyond the specific practices identified in the Complaint."

"The funding that the settlement provides for Connecticut's Prescription Monitoring Program will directly benefit patient health by assisting pharmacists and physicians to better monitor potentially dangerous drug interactions and prescription errors," Commissioner Rubenstein said.

The healthcare fraud settlement was based on four qui tam cases, filed under federal and state false claim statutes, that were consolidated and are pending in U.S. District Court in Virginia. The healthcare fraud complaint alleged that Abbott knowingly promoted the sale and use of Depakote for uses unapproved by the FDA and as a result, knowingly caused false and/or fraudulent claims for Depakote to be submitted to, or caused purchases by, Medicaid.

According to the allegations in the complaint, Abbott promoted Depakote for unapproved uses by: making false and misleading statements about the safety, efficacy, dosing, and cost-effectiveness of Depakote for some of these uses; improperly marketing the product for use in nursing homes; and by offering and paying illegal remuneration to health care professionals and long-term care pharmacy providers to induct them to promote and/or prescribe Depakote.

Abbott also agreed to enter into a corporate integrity agreement with the federal government. The consumer protection settlement also prohibited the company from: making false or misleading claims about Depakote; promoting Depakote for off-label uses; and ensuring that financial incentives on sales do not promote off-label uses.

For a period of five years, Abbott must also limit: the creation and use of responses to requests by physicians for non-promotional information about off-label uses of Depakote; dissemination of reprints of clinical studies relating to off-label uses of Depakote; and use of grants and continuing medical education. It must also disclose payments to physicians and register and disclose clinical trials.

Assistant Attorney General Thomas Saadi handled the consumer protection settlement for the Attorney General with Assistant Attorney General Phillip Rosario, head of the Consumer Protection unit.

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