

MEDIA Release

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State of Iowa Receives \$7.299 Million in Johnson & Johnson Settlement

DES MOINES, IOWA (November 5, 2013) – The State of Iowa will receive nearly \$7.3 million as part of a national settlement between Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. and the federal government. “The settlement resolves civil and criminal allegations of unlawful marketing practices to promote the sale of the company’s atypical antipsychotic drugs, Risperdal and Invega,” said Iowa Department of Inspections and Appeals (DIA) Director Rod Roberts. The settlement compensates Iowa’s Medical Assistance Program (Medicaid) for harm allegedly suffered as a result of illegal conduct, the Director added.

The federal government contends that Johnson & Johnson and its subsidiary allegedly promoted and marketed, and introduced Risperdal and Invega into interstate commerce, for uses that were not approved by the Food and Drug Administration (FDA) and for uses that were not medically indicated. Once the FDA approves a drug as safe and effective, a manufacturer cannot market or promote a drug for an “off-label” use, i.e., any use not specified in the FDA-approved product label. The government contends that during the period January 1, 1999 through December 31, 2005, the companies promoted Risperdal for off-label uses, made false and misleading statements about the safety and efficacy of Risperdal, and paid illegal kickbacks to health care professionals and long-term care pharmacy providers to induce them to promote or prescribe Risperdal to children, adolescents and the elderly when there was no FDA approval for Risperdal use in these patient populations.

The government further contends that from January 1, 2007 through December 31, 2009, the companies promoted Invega for off-label uses and made false and misleading statements about the safety and efficacy of Invega. The manufacturers’ alleged unlawful conduct caused false and/or fraudulent claims to be submitted to or caused purchases by government funded health care programs, including the state Medicaid programs.

A team from the National Association of Medicaid Fraud Control Units worked closely with the federal government on the investigation and conducted the settlement negotiations with the pharmaceutical manufacturers on behalf of the states. Team members included representatives from the Offices of the Attorneys General for the states of New York, Massachusetts, Ohio and California.

In Iowa, allegations of fraud committed by Medicaid providers are investigated by DIA's Medicaid Fraud Control Unit (MFCU), which participated in the Iowa portion of the Johnson & Johnson investigation. In addition to provider fraud cases, MFCU investigates alleged abuse and neglect of residents in long-term care facilities that receive Medicaid reimbursements. MFCU also looks into allegations that residents have been defrauded of personal funds or possessions.

The settlement resolves four qui tam, or whistleblower, lawsuits filed in the United States District Court for the Eastern District of Pennsylvania, under the provisions of the federal False Claims Act and similar state False Claims statutes. In addition, Janssen Pharmaceuticals, Inc. will plead guilty in federal court to a criminal misdemeanor charge of misbranding Risperdal in violation of the Food, Drug, and Cosmetic Act. Iowa's False Claims Act is overseen by the State Attorney General's Office, which approved the settlement agreement on the part of the State of Iowa.

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