



PRESS RELEASE

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COLORADO REACHES LANDMARK \$181 MILLION SETTLEMENT WITH 37 OTHER STATE ATTORNEYS GENERAL AND JANSSEN PHARMACEUTICALS

Improper Marketing of Antipsychotic Drugs Nets \$4 Million for Colorado

DENVER – [Colorado Attorney General Suthers](#) announced today that he and 37 other Attorneys General reached a record \$181 million dollar settlement with Janssen Pharmaceuticals, Inc., a subsidiary of Johnson and Johnson (NYSE: JNJ). This is the largest ever multistate, consumer-protection settlement with a pharmaceutical company and follows [similar ones reached](#) with other drug manufacturers. Janssen was accused of improperly marketing the antipsychotic drugs Risperdal, Risperdal Consta, Risperdal M-Tab and Invega. Colorado’s share of the settlement will be approximately \$4 million.

“This settlement will change for the better how Janssen does business,” said Attorney General Suthers. “The company will no longer be able to market its product for uses not approved by the U.S. Food and Drug Administration.”

The complaint alleges that Janssen engaged in unfair and deceptive practices when it marketed [Risperdal](#) for unapproved or “off-label” uses. Risperdal is among a class of drugs known as atypical or second generation antipsychotics.

After an extensive four-year investigation, Janssen agreed to change how it promotes and markets its atypical antipsychotics, and also agreed to refrain from any false, misleading or deceptive promotion of the drugs. In addition to the record-setting payment, the settlement restricts Janssen from promoting its atypical antipsychotic drugs for off-label uses that are not approved by the U.S. Food and Drug Administration (FDA). Additionally, for a five-year period, Janssen:

- Must clearly and conspicuously disclose, in promotional materials for atypical antipsychotic products, the specific risks identified in the black-box warning on its product labels;

- Must present information about effectiveness and risk in a balanced manner in promotional materials;
- Shall not promote its atypical antipsychotics using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses;
- Shall require its scientifically-trained personnel, rather than its sales and marketing personnel, to develop the medical content of scientific communications to address requests for information from healthcare providers regarding Janssen's atypical antipsychotics;
- Must refrain from providing samples of its atypical antipsychotics to healthcare providers whose clinical practices are inconsistent with the FDA-approved labeling of those atypical antipsychotics;
- Must not use grants to promote its atypical antipsychotics nor condition medical education funding on Janssen's approval of speakers or program content;
- Must contractually require medical-education providers to disclose Janssen's financial support of their programs and any financial relationship with faculty and speakers; and
- Must have policies in place to ensure that financial incentives are not given to marketing and sales personnel that encourage or reward off-label marketing.

Federal law prohibits pharmaceutical manufacturers from promoting their products for off-label uses; although physicians may prescribe drugs for those uses. The complaint alleges that Janssen promoted Risperdal for off-label uses to both geriatric and pediatric populations, targeting patients with Alzheimer's disease, dementia, depression, and anxiety, when these uses were not FDA-approved and for which Janssen had not established that Risperdal was safe and effective.

The Attorney General's complaint filed in Denver District Court today, was based on an investigation led by the Florida Attorney General into Janssen's marketing and promotional practices. The Attorneys General of the following states and the District of Columbia participated in the settlement: Alabama, Arizona, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, Wisconsin and Wyoming.

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