



August 30, 2012

MADIGAN, 36 ATTORNEYS GENERAL REACH LANDMARK SETTLEMENT WITH JANSSEN PHARMACEUTICALS OVER UNLAWFUL MARKETING OF RISPERDAL

Chicago — Attorney General Lisa Madigan joined 36 other attorneys general to announce the largest multistate consumer protection settlement ever with a pharmaceutical company, Janssen Pharmaceuticals Inc., over its unlawful marketing of the antipsychotic drug Risperdal.

The record \$181 million settlement with Janssen, a subsidiary of Johnson & Johnson, alleges the company improperly marketed Risperdal, Risperdal Consta, Risperdal M-Tab and Invega, all antipsychotic drugs. Illinois will receive \$8.3 million under the agreement.

In a complaint filed today, Madigan and the other attorneys general allege Janssen engaged in unfair and deceptive practices when it marketed Risperdal “off-label” for certain treatments and conditions that the U.S. Food and Drug Administration has not approved.

The complaint alleges Janssen promoted Risperdal for off-label uses to both geriatric and pediatric populations, targeting patients with Alzheimer’s disease, dementia, depression and anxiety, though those uses were not FDA-approved and for which Janssen had not established that Risperdal was safe and effective.

“Janssen falsely marketed this drug to extremely vulnerable patients in spite of any recognized medical evidence that the drug would be safe or effective for individuals with these conditions,” Madigan said.

Following an extensive, four-year investigation, Janssen agreed to change not only how it promotes and markets its antipsychotics but also agreed to refrain from any false, misleading or deceptive promotion of the drugs. In addition to the record-setting payment to the states, the settlement addresses specific concerns identified in the investigation, including restricting Janssen from promoting its antipsychotic drugs for off-label uses.

Additionally, over a five-year period, Janssen must:

- Clearly and conspicuously disclose, in promotional materials for antipsychotic drugs, the specific risks identified in the black-box warning on its product labels;
- Present information about effectiveness and risk in a balanced manner in its promotional materials;
- Not promote its antipsychotic drugs using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses;
- 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 health care providers regarding Janssen’s antipsychotics;
- Refrain from providing samples of its antipsychotics to health care providers whose clinical practices are inconsistent with the FDA-approved labeling of those antipsychotics;
- Not use grants to promote its antipsychotics nor condition medical education funding on Janssen’s approval of speakers or program content;
- Contractually require medical education providers to disclose Janssen’s financial support of their programs and any financial relationship with faculty and speakers; and
- Implement policies to ensure that financial incentives are not given to marketing and sales personnel that encourage or reward off-label marketing.

Joining Madigan in today's settlement were attorneys general from: Alabama, Arizona, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii, Idaho, 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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