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## ATTORNEY GENERAL MASTO SECURES $181 MILLION SETTLEMENT WITH JOHNSON & JOHNSON PHARMACEUTICAL

*Pharmaceutical Company Will Not Promote "Off-Label" Uses of Atypical Antipsychotics for Children and Seniors*

**Las Vegas, NV –** Nevada Attorney General Catherine Cortez Masto announced today that she and 36 other Attorneys General reached a record $181 million settlement, the largest multi-state consumer protection settlement of its kind reached with a pharmaceutical company, with Janssen Pharmaceuticals, Inc., a subsidiary of Johnson and Johnson. Nevada's share of the settlement will be $3,328,432.

"Nevadans have a right to know the risks presented by atypical antipsychotic drugs," said Masto. "The settlement will protect Nevadans from further promotion of Janssen's atypical antipsychotic drugs for 'off-label' uses."

The multi-state investigation found that Janssen improperly marketed the antipsychotic drugs Risperdal, Risperdal Consta, Risperdal M-Tab and Invega. Filed today, 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 not only how it promotes and markets its atypical antipsychotics but also agreed to refrain from any false, misleading or deceptive promotion of the drugs. In addition to the record-setting payment, the settlement targets specific concerns identified in the investigation. The settlement agreement restricts Janssen from promoting its atypical antipsychotic drugs for "off-label" uses that the U.S. Food and Drug Administration ("FDA") has not approved. 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 its 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 health care providers regarding Janssen's atypical antipsychotics;
- Must refrain from providing samples of its atypical antipsychotics to health care 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.

Senior Deputies Attorney General Jo Ann Gibbs and Paul E. Stuhff of the Attorney General's Bureau of Consumer Protection represented Nevada in the settlement. The Attorney General from Florida led the investigation into Janssen's marketing and promotional practices.

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