



DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS  
Office of Consumer Protection

## News Release

**NEIL ABERCROMBIE**  
GOVERNOR

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### **Janssen Pharmaceuticals to Pay \$180M to Settle Deceptive Marketing Claims**

Hawai'i to Receive Nearly \$2.7 Million

HONOLULU – In the largest multi-state consumer protection settlement with a pharmaceutical company, the State of Hawai'i Office of Consumer Protection today announced that it joined with 35 other states and the District of Columbia in reaching a record \$180 million settlement with Janssen Pharmaceuticals, Inc., which includes \$2.7 million in settlement of Hawai'i's claims.

Janssen is a subsidiary of Johnson and Johnson.

In a suit filed today by the Office of Consumer Protection, the State alleged that Janssen improperly marketed the antipsychotic drugs Risperdal, Risperdal Consta, Risperdal M-Tab and Invega.

"Consumers in Hawai'i have the right to expect that their health and well-being-- not profit -- drives decisions about their care," said Bruce Kim, Executive Director of the Office of Consumer Protection. "This settlement protects consumers and stops unscrupulous marketing practices."

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 State of Hawai'i Office of Consumer Protection's suit 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 suit 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.

"Promoting drugs for unapproved, off-label uses is a potentially deadly practice that can threaten patients' lives. This settlement will make drug manufacturers like Janssen think twice before exposing innocent patients to unacceptable risks," Kim said.

The Attorney General from Florida led the investigation into Janssen's marketing and promotional practices. The State of Hawai'i Office of Consumer Protection and the Attorneys General of the following states and the District of Columbia participated in the settlement: Alabama, Arizona, Colorado, Connecticut, Delaware, 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.

Lisa Tong, a staff attorney at the Office of Consumer Protection, led Hawai'i's investigation on the Janssen case and represented the Office of Consumer Protection in the State's lawsuit.

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