



DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
OFFICE OF CONSUMER PROTECTION

DCCA News Release

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HAWAII AND 37 OTHER STATES REACH A LANDMARK \$68.5 MILLION SETTLEMENT WITH ASTRAZENECA PHARMACUETICALS

HONOLULU – In the largest ever multi-state consumer protection-based pharmaceutical settlement, the State of Hawaii Office of Consumer Protection announced today that Hawaii, along with 37 other states, reached a record \$68.5 million dollar settlement with AstraZeneca Pharmaceuticals, LP arising from alleged improper marketing of the antipsychotic drug Seroquel.

Hawaii's share of the settlement is \$967,000.

The complaint, filed today along with the settlement agreement, alleges that AstraZeneca engaged in unfair and deceptive practices when it marketed Seroquel for unapproved or off-label uses, failed to adequately disclose the drug's potential side effects to health care providers, and withheld negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

"This important agreement will help to ensure that prescription drugs are properly marketed in the United States," said Stephen Levins, executive director of the State of Hawaii Office of Consumer Protection.

Following a 3-year investigation, AstraZeneca agreed to change how it markets Seroquel and to not promote Seroquel in a false, misleading or deceptive manner, including for "off-label" uses, which are not approved by the U.S. Food and Drug Administration. In addition to the \$68.5 million payment, the terms of the settlement include injunctive provisions which address specific concerns

identified in the investigation. Along with other prohibitions and requirements, the agreement specifically requires AstraZeneca to:

- Publicly post its payments to physicians on a website;
- Have policies in place to ensure that financial incentives are not given to marketing and sales personnel for off-label marketing;
- Have policies in place to ensure that AstraZeneca sales personnel do not promote to health care providers who are unlikely to prescribe Seroquel for an FDA-approved use; and
- Cite to Seroquel's FDA-approved indications when referencing selected symptoms, rather than promoting Seroquel by highlighting symptoms only.

Although a physician is allowed to prescribe drugs for off-label uses, law prohibits pharmaceutical manufacturers from marketing their products for off-label uses. As alleged, AstraZeneca unlawfully marketed Seroquel for a number of off-label uses, including for use in pediatric and geriatric populations, specifically in nursing homes for Alzheimer's Disease and Dementia, as well as for anxiety, depression, sleep disorders, and post traumatic stress disorder. AstraZeneca promoted Seroquel for such uses, even though Seroquel was not, at the time it was marketed, approved for the treatment of these conditions and AstraZeneca had not established that Seroquel was safe and effective for these uses.

Atypical antipsychotics, including Seroquel, can produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions.

According to Levins, "most people know drugs can have dangerous side effects. That is one of the reasons why off-label usage is carefully monitored and controlled by the regulatory authorities. Unless they have a valid legal basis for doing so, drug companies simply have no business to prod medical providers to prescribe drugs in this way."

The Attorneys General from Florida and Illinois led the investigation into AstraZeneca's marketing and promotional practices. The following states and the District of Columbia participated in the settlement: Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Idaho, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, 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, West Virginia and Wisconsin.

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