



DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
Office of Consumer Protection

News Release

NEIL ABERCROMBIE
GOVERNOR

BRUCE KIM
EXECUTIVE DIRECTOR, OFFICE OF CONSUMER PROTECTION
Phone (808) 586-2636

KEALI'I S. LOPEZ
DIRECTOR
Phone: (808) 586-2850
Fax: (808) 586-2856

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States Reach \$100 Million Settlement with Abbott Laboratories

Hawai'i to Receive Nearly \$1.2 Million

HONOLULU – The Hawai'i Office of Consumer Protection today joined 45 other states and the District of Columbia in announcing a \$100 million settlement with Abbott Laboratories over allegations of illegal off-label marketing of its Depakote drug.

"The agreement marks the largest consumer protection-based pharmaceutical settlement ever reached," said Hawai'i Office of Consumer Protection Executive Director Bruce Kim. "As a result of the states' investigation and this settlement, Hawai'i will receive nearly \$1.2 million and Illinois-based Abbott Laboratories will be restricted from marketing the drug for off-label uses not approved by the U.S. Food and Drug Administration."

In complaints filed today, the states alleged that Abbott engaged in unfair and deceptive practices when it marketed Depakote for off-label uses. Depakote is approved for treatment of seizure disorders, mania associated with bipolar disorder and prophylaxis of migraines, but the Hawai'i lawsuit also alleged that Abbott marketed the drug for treating unapproved uses, including schizophrenia, agitated dementia and autism.

Abbott has agreed to significantly change how it markets Depakote and to cease promoting off-label uses. The company also will pay \$100 million nationally. As part of this settlement, Hawai'i will receive nearly \$1.2 million in settlement funds from the company for consumer education and consumer protection enforcement actions.

Under the settlement, Abbott Laboratories is:

- prohibited from making false or misleading claims about Depakote;
- prohibited from promoting Depakote for off-label uses; and
- required to ensure financial incentives on sales do not promote off-label uses of Depakote.

In addition, for a 5-year period Abbott must:

- limit the creation and use of responses to requests by physicians for non-promotional information about off-label uses of Depakote;
- limit dissemination of reprints of clinical studies relating to off-label uses of Depakote;
- limit use of grants and CME (continuing medical education);
- disclose payments to physicians; and
- register and disclose clinical trials.

The following states and the District of Columbia participated in today's settlement: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Hawai'i, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia and Wisconsin.

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For media inquiries, please contact:

Bruce Kim

Executive Director

Office of Consumer Protection

Phone: 586-2636

E-mail: bruce.b.kim@dcca.hawaii.gov