ATTORNEY GENERAL DAVID M. LOUIE CALLS FOR ABUSE-DETERRENT FORMULATIONS OF GENERIC PRESCRIPTION PAIN RELIEVERS

HONOLULU – Attorney General David M. Louie joined 40 other state and territorial attorneys general in sending a letter to the U.S. Food and Drug Administration (FDA) urging it to require manufacturers of generic prescription pain relievers to develop abuse-deterrent formulations of their products. Prescription drug abuse has reached epidemic levels in many states; requiring abuse-deterrent pain relieving prescription drugs (opioids) is a commonsense improvement that provides yet another important tool in the fight against this epidemic.

Opioid pain relievers are often manipulated for purposes of abuse. Most abuse-deterrent formulations developed to date are designed to make manipulation of the drug more difficult or to make abuse of the drug less attractive or rewarding.

Until these abuse-deterrent formulations have been fully developed, Attorney General Louie stated that it is “critical that Hawaii vigorously combat the growing abuse of prescription drugs.” According to Keith Kamita of the Narcotics Enforcement Division (NED) of the Hawaii Department of Public Safety, the abuse of prescription drugs is impacting both adults and children in Hawaii and is steadily growing due to its availability. Unused prescription drugs are frequently left in medicine cabinets and are easily accessible. Just in Hawaii, in the month of November 2013 alone pharmacies and dispensing physicians dispensed the following controlled substances to a total of 72,308 patients: 3,532,814 doses of pain relievers, 1,159,172 doses of tranquilizers, 464,258 doses of sedatives, and 398,918 doses of stimulants.

Mr. Kamita stated that “Hawaii, like the rest of the nation, is seeing the rise in prescription controlled substance abuse and has developed programs such as the NED’s Electronic Prescription Accountability System that tracks all dispensed controlled substance prescriptions as required by State law.” Hawaii has also joined the Drug Enforcement Agency in holding pharmaceutical drug take back events throughout the year to help reduce the amount of pharmaceutical drugs that possibly could end up on
the street. In 2013, the Hawaii National Take Back Initiative collected a total of 4,545.856 pounds of prescription drugs.

In their letter, the attorneys general thanked the FDA for its recent efforts to require abuse-deterrent formulations for branded opioid drugs. However, they also urged the FDA to go even further by ensuring that generic opioids, like their branded counterparts, have abuse-deterrent properties.

“Accordingly, the undersigned State Attorneys General respectfully request that the FDA provide clear and fair regulatory standards for the incorporation of abuse-deterrent technologies into generic opioids,” reads the National Association of Attorneys General (NAAG) letter.

The 41 attorneys general who signed the NAAG letter are from: Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Guam, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Washington, West Virginia and Wisconsin.

A copy of the letter can be found at: http://www.naag.org/assets/files/pdf/signons/Final%20FDA%20Abuse%20Deterrent%20Letter.pdf

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