LATE TESTIMONY

COMMENTS OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
TWENTY-EIGHTH LEGISLATURE, 2016

ON THE FOLLOWING MEASURE:
S.B. NO. 2181, S.D. 1, RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

BEFORE THE:
SENATE COMMITTEE ON JUDICIARY AND LABOR

DATE: Friday, February 26, 2016 **TIME:** 10:00 a.m.

LOCATION: State Capitol, Room 016

WRITTEN COMMENTS ONLY. For more information, call Wade H. Hargrove III, Deputy Attorney General, at 587-3050.

Chair Keith-Agaran and Members of the Committee:

The Department of the Attorney General appreciates the intent of this measure but has concerns about the bill. This measure would make it lawful in Hawaii to provide terminally ill patients with drugs, biological products, and medical devices that have not successfully completed the United States Food and Drug Administration's (FDA) application and approval process. In doing so, it creates conflicts with existing state law governing drugs and medical devices and runs counter to a comprehensive scheme of federal regulation. Any inconsistency with state law can be remedied by inserting the customary "notwithstanding any other provision of law" wording. But it may be impossible to provide the drugs and medical devices in the manner this measure proposes without violating federal law that governs the sale and distribution of those same drugs and devices. Due to the inherent conflicts that exist between the intent of this measure and federal law, this measure may be subjected to constitutional challenge and found to be preempted. Therefore we ask that this measure be deferred.

This measure would add a new section to chapter 321 of the Hawaii Revised Statures to allow manufacturers of investigational drugs, biological products, and devices to make their unapproved products available to terminally ill patients with a recommendation from the patients' physicians. An investigational drug, biological product, or device is defined in section 2 of the measure (at page 4, lines 5-10) as "a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a United States Food and Drug Administration–approved clinical trial." Federal law, however, prohibits the sale or distribution of unapproved drugs and devices.

Under the Supremacy Clause of the United States Constitution, federal law can preempt state law by explicit provisions of federal statutes or regulations. State law can also be preempted by implication where there is a direct conflict between the state law and its federal counterpart such that it is impossible to comply with both. Implied preemption may also occur when the context suggests that the federal statute was designed to occupy a complete area of law with the consequence of crowding out any possibility for state regulation. See Larsen v. Pacesetter Sys., Inc., 74 Haw. 1, 837 P.2d 1273 (1992).

Section 505 (21 USC section 355) of the federal Food, Drug and Cosmetic Act (FDCA) states that "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application is filed pursuant to [the subsections relating to new drug applications] is effective with respect to such drug." Additionally, section 301 of the FDCA (21 USC section 331a) treats the sale and distribution of "unapproved drugs" as the sale and distribution of "adulterated" products subject to both civil and criminal penalties. While there is no express preemption clause that applies directly to drugs, the case law strongly suggests that while the FDCA will not preempt state law that seeks to enhance protections for consumers above and beyond what the federal law would otherwise require, federal law will serve as a "floor" and state law can supplement but not relax those protections. See Wyeth v. Levine, 555 U.S. 555 (2009) (no preemption of state tort action for failure to warn about dangers of a drug because FDA did not explicitly reject a "better" warning label). Where state legislation looks to bypass the consumer protections for new drugs that Congress seems to have intended, preemption seems a far more likely outcome.

With respect to medical devices, there is an express preemption provision. This provision provides, in relevant part, that "no state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 USC section 360k. Where state legislation would seek to control how to evaluate the safety of a medical device prior to sale or distribution, and particularly where, as is the case with this measure, the law would

lessen the scrutiny applied to that device, section 360k would appear to preempt that law. See Riegle v. Medtronic, Inc., 552 U.S. 312 (2008).

The case law in this area consistently favors finding that the tort actions should be allowed to proceed rather than be preempted, in the name of preserving Congress' intent to allow state tort and negligence actions to supplement the FDCA, not compete with it. Where the Hawaii Supreme Court has found that an implied warranty claim was not preempted despite the FDCA's express preemption for medical devices, it did so while observing that Congress had only intended for the FDCA to *increase* consumer protections, not restrict state protections where they already existed. Larsen, 74 Haw. at 17, 837 P.2d at 1282 ("Thus, meritorious claims of the type brought by plaintiff would not contravene FDA 'approval' of the device and would further Congressional intent by providing [device] manufacturers a product safety incentive in those areas where the premarket approval process has failed adequately to protect the consumer.").

While the intent of this measure is only to increase terminally ill patients' access to unapproved drugs and devices, the process of doing so clearly conflicts with the spirit of the FDCA and its provisions for introducing new drugs and devices into the marketplace (regardless of whether there is monetary compensation). In addition, regardless of the possible preemption by federal law, this measure may not be able to achieve its intended purpose. It is unlikely that manufacturers will risk violating federal law to supply Hawaii patients non-FDA-approved drugs and devices simply because it not also a violation of state law. For these reasons, we respectfully ask this measure to be deferred.