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

ON THE FOLLOWING MEASURE:
S.B. NO. 2181, S.D. 2, RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

BEFORE THE:
HOUSE COMMITTEE ON HEALTH

DATE: Friday, March 18, 2016 **TIME:** 9:00 a.m.

LOCATION: State Capitol, Room 329

TESTIFIER(S): Douglas S. Chin, Attorney General, or
Wade H. Hargrove III, Deputy Attorney General

Chair Belatti and Members of the Committee:

The Department of the Attorney General appreciates the intent of this bill, but has legal concerns. This measure would make it lawful in Hawaii to provide terminally ill patients with investigational drugs and biological products that have not successfully completed the United States Food and Drug Administration's (FDA) application and approval process. In doing so, it seeks to create an alternative pathway to investigational drugs that would bypass a comprehensive scheme of federal regulation. It may be impossible to provide the drugs and biological products in the manner this measure proposes without running counter to the federal law that governs this activity. Due to the inherent conflicts that exist between the purpose and effect of this measure and federal law, this measure may be subjected to constitutional challenge and found to be preempted. Therefore we recommend that this bill be deferred.

This measure would add a new section to chapter 321 of the Hawaii Revised Statutes (HRS) to allow manufacturers of investigational drugs and biological products to make their unapproved products available to eligible patients with a recommendation from the patients' physicians (page 6, lines 1-5). An investigational drug or biological product is defined as "a drug or biological product 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." (Page 3, lines 13-18). An "eligible patient" is defined as a patient who (1) has a terminal illness, (2) has considered all other FDA-approved treatment options, (3) is unable to participate in an FDA-approved clinical trial, (4) has a physician's recommendation for treatment and

certification that the requirements of this measure have been met, and (5) has provided informed consent for the experimental treatment (page 2, line 7-page 3, line 8).

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).

It would appear that this measure competes with an area of law that the federal government has made an effort to fully occupy. Section 505 (21 USC section 355) of the federal Food, Drug and Cosmetic Act (FDCA) provides 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. Section 505 (21 USC section 355(i)) defines how experimental drugs may be provided in the context of clinical trials and on an emergency basis. While there is no express preemption clause in the FDCA that applies directly to drugs, the case law strongly suggests that while preemption of state laws is unlikely where they enhance protections for consumers above and beyond what the federal law would otherwise require, federal law must serve as a "floor" such that 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 and investigational drugs that Congress seems to have intended, preemption seems more likely.

The federal regulations that specifically govern access to investigational drugs (21 CFR part 312) allow manufacturers to provide these drugs to patients under circumstances not unlike those this measure seeks to address. The federal regulations, however, outline a process that requires accountability and FDA supervision and already occupy the field. Subpart I of 21 CFR

Part 312, entitled "Expanded Access To Investigational Drugs for Treatment Use," provides that its goal is "to facilitate the availability of [investigational] drugs to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition." 21 CFR section 312.300. Subpart I permits, with FDA approval, the distribution of investigational drugs to patients for "serious diseases" and not just "terminal" ones, a limitation of this measure that even current federal law does not have. The FDA's "expanded access" requirements set forth in 21 CFR section 312.305 provide among other things, FDA review and approval, treatment data reporting, and patient-centered safeguards. 21 CFR section 312.310 is designed specifically to increase access to investigational drugs for individual patients under the care of a physician whose conditions could be described as "emergencies." To the extent that this measure can be construed as a vehicle for drug manufacturers and patients to bypass the federal process prescribed in part 312 of the federal regulations, the measure may be preempted by the federal law it seeks to avoid.

It should be noted that the case law in the area of drugs and federal preemption consistently favors finding that state tort actions should be allowed to proceed rather than be preempted, but this is done in the name of preserving Congress' intent to allow tort and negligence actions to supplement the FDCA, not compete with it. This measure is fundamentally different in purpose and effect than a state tort action, thus the outcome of any future litigation concerning this measure may be different as well. While 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."). Consequently, the cases examining federal preemption of state drug law suggests this measure, if viewed as attempting to weaken the federal government's patient protections, may be struck down due to the preemptive effect of the existing federal law governing investigational drugs.

A federal scheme regulating access to new and investigational drugs already occupies the field and state laws to that effect will likely be preempted. And, as a practical matter, it is unlikely that drug manufacturers will seek to utilize this measure's pathway as an alternative to the FDA-approved expanded access program because doing so places them in violation of existing federal law. For these reasons, we respectfully ask that this measure be deferred.

COMMENTS OF SHAWN CHING ON BEHALF OF THE HAWAII ASSOCIATION FOR JUSTICE (HAJ) IN SUPPORT OF S.B. NO. 2181, SD 2

Date: Friday, March 18, 2016
Time: 9:00 am

To: Chairperson Della Au Belatti and Members of the Senate Committee on Health:

My name is Shawn Ching and I am presenting testimony on behalf of the Hawaii Association for Justice (HAJ) in SUPPORT of S.B. No. 2181, SD 2 Relating to Access to Treatment for Terminally Ill Patients.

The Hawaii Association for Justice generally opposes any limitation of civil liability which reduces protection for consumers and limits or lessens the incentive for everyone to act responsibly to reduce or eliminate harm to others. This measure does reduce civil protections for patients by eliminating strict products liability and strict liability for use of hazardous material, however, it does at least prohibit unreasonable conduct and requires good faith compliance with its terms in order to qualify for reduced liability.

Many states that have adopted similar legislation, commonly referred to as "Right to Try" laws require the exercise of reasonable care provisions that are substantially similar, if not identical, to the liability provisions found in this measure where a person or entity complies in good faith with the terms of this chapter and has exercised reasonable care.

Colorado uses the same phrase: "complying in good faith with the terms of this Part 1, unless there was a failure to exercise reasonable care." Oklahoma also uses that phrase: "unless there was a failure to exercise reasonable care." Tennessee uses the similar language: "complying in good faith with the terms of this part and has exercised reasonable care." So does South Dakota, Florida, Michigan and Montana. North Dakota states the same principle in the affirmative allowing a cause of action "if there was a failure to exercise reasonable care."

The terminally ill are often in desperation of seeking a cure and are therefore extremely vulnerable. They will, quite understandably, grasp at anything that is presented to them as offering even a glimmer of hope. Accordingly, some basic protections for these vulnerable people are appropriate. Many states have struck a reasonable balance between making non-

approved treatments available to terminally ill people who cannot wait for completion of the approval process on the one hand, and protecting these vulnerable people against unreasonable conduct on the other hand, by allowing non-approved treatments when used with reasonable care.

HAJ recognizes that this measure is well intended and addresses an important option for those who are terminally ill and cannot wait for FDA approval of potential life saving or life extending treatments. Accordingly, HAJ does not object to the liability provision as currently drafted, but will object to any amendments that decrease patient protection or provide additional immunity.

Thank you very much for allowing me to testify regarding this measure. Please feel free to contact me should you have any questions or desire additional information.

An Independent Licensee of the Blue Cross and Blue Shield Association

March 18, 2016

The Honorable Della Au Belatti, Chair
The Honorable Richard P. Creagan, Vice Chair
House Committee on Health

Re: SB 2181, SD2 – Relating to Experimental Treatments

Dear Chair Au Belatti, Vice Chair Creagan, and Committee Members:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 2181, SD2, which authorizes investigational drugs, biological products, and devices to be made available to terminally ill patients, with informed consent. HMSA offers comments.

HMSA certainly is empathic to the physical and emotional pain endured by terminally ill individuals. While we appreciate the intent of this measure, we are most concerned about the overall wellbeing of our affected members and their families. We would not want our members to experience any more unwarranted pain that may result from using an experimental product.

While the Bill shields the patient's estate from any outstanding debt resulting from the use of investigational product, SB 2181, SD2, does allow the producer of the product to "(r) equire an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product." We hope that there would not be circumstances in which members and their families find themselves in financial straits as a result of making a potentially emotional decision to pay for the investigational product.

Thank you for allowing us to testify on SB 2181, SD2.

Sincerely,

Jennifer Diesman
Vice President, Government Relations