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

ON THE FOLLOWING MEASURE:
H.B. 1013, H.D. 2, RELATING TO EXPERIMENTAL TREATMENTS.

BEFORE THE:
HOUSE COMMITTEE ON JUDICIARY

DATE: Thursday, March 3, 2016 **TIME:** 2:00 p.m.

LOCATION: State Capitol, Room 325

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

Chair Karl Rhoads 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 chapter to the Hawaii Revised Statutes 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 1 of the measure (at page 2, lines 11-16) 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.

An Independent Licensee of the Blue Cross and Blue Shield Association

March 3, 2016

The Honorable Karl Rhoads, Chair
The Honorable Joy A. San Buenaventura, Vice Chair
House Committee on Judiciary

Re: HB 1013, HD2 – Relating to Experimental Treatments

Dear Chair Rhoads, Vice Chair San Buenaventura, and Committee Members:

The Hawaii Medical Association (HMSA) appreciates the opportunity to testify on HB 1013, HD2, 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, HB 1013, HD2, 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, or device." We hope that there would not be circumstance 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 HB 1013, HD2.

Sincerely,

Jennifer Diesman
Vice President, Government Relations.

KURT M. ALTMAN
OF COUNSEL and formerly
DIRECTOR OF NATIONAL AFFAIRS & SPECIAL COUNSEL
GOLDWATER INSTITITUE
Right to Try Testimony HB1013
March 3, 2016

Good afternoon Chairman Rhoades, members of the Committee. My name is Kurt Altman. I currently am "of Counsel" to the Goldwater Institute where I was formerly the Director of National Affairs and Special Council. We are based in Phoenix, Arizona. First I'd like to express my appreciation for the opportunity to write to this Committee today on this very important issue. I'd like to share a brief background of myself and my involvement in the Right to Try legislation that is currently sweeping the nation. I am one of the original drafters of the model legislation that is the basis for most, if not all the state legislation running around the country. I have been to and testified before committees in approximately 30 states. I have had the opportunity to meet with stakeholders throughout the our country, including patients and patient groups, physicians, researchers, medical associations and various representatives of the pharmaceutical industry. I have participated in scientific and legal panels and debates, which included representatives of the legal and medical community, some even with FDA representatives and physicians. I give you these details only to let you know that I am able to answer any questions you may have regarding Right to Try laws, why they are needed, how they work, why the few criticisms are unfounded, how the laws were designed to take into account and rely on the current FDA approval process, to compliment current clinical trials and not jeopardize them, and why they will eventually help give terminally ill patients the control they so desire and one last opportunity to fight for more time with their loved ones, another year, another day, another hour, should they so choose.

What is Right to Try and what does HB1013 do? Right to try laws give terminally ill patients, with the recommendation of their treating physician, the opportunity to access Investigational New Drugs (INDs), that have passed Phase I of the FDA approval process, if their doctor believes at this stage of the disease, the IND is the patients last and best chance. Importantly, to be eligible under RTT, a drug must not only have passed Phase I, the safety testing phase, but must REMAIN in ongoing clinical trials, Phase II or III, moving toward ultimate approval. This ensures that the drug is considered legitimated by its sponsor company, showing promise, oft times getting very positive results. It also means that a manufacturer is willing to continue to invest significant amounts of money in the clinical testing process, typically resulting in a final expense nearing 1 billion dollars.

These laws are designed for patients who are ineligible or unable to access current clinical trials for the needed IND. This is especially important for residents of Hawaii, who may have great difficulty traveling in their current conditions great distances to clinical trial locations. Clinical trials accept only about 3% of given patients afflicted with the condition the therapy is being tested for. That leaves 97% of folks in this situation unable to access therapies that could potentially benefit them. I like to say that a patient has to be sick enough to qualify for the trial but not too sick. They cannot have other conditions that could skew the trial results. As a result,

many patients are left without an option to access these medications other than the current, arduous and largely unworkable FDA Compassionate Use/Expanded Access program. I say largely unworkable when I reference expanded access, not because the FDA refuses to grant approvals though the program. In fact, nearly 99% of requests are approved. I say largely unworkable because it is a time consuming process for patients, doctors and manufacturers to navigate. Time consuming at a period in a person's life where time is truly of the essence. Each year only approximately 1000 people are able to navigate the FDA's program. Compare that to last year's cancer death in the U.S., which topped 450,000. That number represents cancer alone. That does not account for other terminal illnesses. That 1000 number is too small and that is why Right to Try laws have taken off in the States, been signed into law in 24, and hopefully will be successfully voted on here in the State of Hawaii. Finally, Right to Try is no mandate. It does not require doctors, manufacturers or even insurance companies to participate, however it does create the avenue and the opportunity for each; an opportunity that does not currently exist for most.

I often like to end by talking about what Right to Try is not. It is certainly no guarantee. It is not something a patient can do on their own without the recommendation from their doctor. It is not something that can financially benefit a manufacturer or take advantage of a desperate patient. And it importantly is not something that can damage the current FDA approval process. I have had the distinct honor of speaking with patients and doctors all across our nation and have consistently heard a single theme that Right to Try laws preserve. That theme is control. Patients, at this stage of their lives want to feel some semblance of control over their destiny. They hold no grand illusion that the passage of this law will be the cure all end all. But they do know that Right to Try laws give them a little more control over how they choose to fight to see a graduation, maybe a walk down the aisle, or even see just one more sunrise. Not too long ago that theme was echoed by my side before the Assembly Health Committee in the State of California, by a man named Dr. David Huntley and his wife. Dr. Huntley was a College professor at the University of San Diego. Just two years ago he participated in and finished an iron man triathlon. Shortly thereafter he was stricken with ALS. His wife Linda and he became huge advocates of giving patients opportunities to access medications that could be beneficial when there was nothing else left. ALS currently has nothing to treat it on the market. They agreed to testify by my side in California because they believed Right to Try represented that control, that freedom, that choice that patients in his situation so desperately needed. Sadly, in July, Dr. Huntley succumbed to his ALS as he knew he would, without an opportunity to try to help himself with investigational therapies. His hope was that others like him would not have to die without that chance.

I could go on and on with the importance of Right to Try laws but I'm mindful of this Committee's time. I would now like to offer myself for any questions you may have. Please address anything that may not be clear about Right to try: Why is it needed? Is the FDA changing its program? Legalities? Practical application? Access? I would be happy to answer these and any other questions at any time in the future. I can be reached at kaltman@goldwaterinstitute.org or 602-689-5100, anytime. If necessary, I will attend the next committee hearings personally and look forward to doing so.

Thank you again for your time and consideration of this very important bill