An Independent Licensee of the Blue Cross and Blue Shield Association

February 10, 2016

The Honorable Angus L. K. McKelvey, Chair
The Honorable Justin H. Woodson, Vice Chair
House Committee on Consumer Protection and Commerce

Re: HB 1013, HD1 – Relating to Experimental Treatments

Dear Chair McKelvey, Vice Chair Woodson, and Committee Members:

The Hawaii Medical Association (HMSA) appreciates the opportunity to testify on HB 1013, HD1, 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, HD1, 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, HD1.

Sincerely,

Jennifer Diesman
Vice President, Government Relations.

COMMENTS ON BEHALF OF THE HAWAII ASSOCIATION FOR JUSTICE (HAJ) REGARDING H.B. NO. 1013, HD 1

Date: Wednesday, February 10, 2016
Time: 2:10 pm

To: Chair Angus McKelvey and Members of the House Committee on Consumer Protection and Commerce:

My name is Shawn Ching and I am presenting COMMENTS on behalf of the Hawaii Association for Justice (HAJ) regarding H.B. No. 1013, HD 1, relating to Experimental Treatments.

These comments are limited to the liability portion of this measure found in section 8, on page 8, lines 5-14. The Hawaii Association For Justice generally opposes any limitation of civil liability. This measure does reduce civil protections by eliminating strict products liability and strict liability for use of hazardous material, however, it does at least prohibit unreasonable conduct and requires compliance with its terms in order to qualify for reduced liability.

Many states that have adopted 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."

Tennessee uses the same language: "complying in good faith with the terms of this part and has exercised reasonable care." So does South Dakota: "complying in good faith with the terms of this Act and exercised reasonable care." Florida, Michigan and Montana also use the same language requiring the use of reasonable care. Colorado uses a similar phrase stated in the negative: "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." 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. Accordingly, HAJ does not object to the liability provision as currently drafted, but will object to any amendments that decrease patient protection or provides 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.

KURT M. ALTMAN
OF COUNSEL and formerly
DIRECTOR OF NATIONAL AFFAIRS & SPECIAL COUNSEL
GOLDWATER INSTITITUE

Right to Try Testimony HB1013

February 10, 2016

Good afternoon Chairman McKelvey, 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.

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

LATE

LATE

LATE TESTIMONY

ON THE FOLLOWING MEASURE:
H.B. NO. 1013, H.D. 1, RELATING TO EXPERIMENTAL TREATMENTS.

BEFORE THE:
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE

DATE: Wednesday, February 10, 2016 **TIME:** 2:10 p.m.

LOCATION: State Capitol, Room 325

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

Chair McKelvey and Members of the Committee:

The Department of the Attorney General provides comments regarding concerns it has about this bill. The interaction between federal and state regulation of medical drugs and devices raises complex questions of federal constitutional law. Specifically, under the Supremacy Clause of the United States Constitution, federal law is the supreme law of the land. There are intricate principles of federal preemption law that determine when and how that provision prohibits states from regulating when federal law has already done so.

Upon further review, we have determined that there may be additional preemption issues beyond those addressed in the testimony we submitted when a similar bill was heard by the Senate Committee on Commerce, Consumer Protection, and Health. Due to the complexity of this area of law, we are still analyzing the possible constitutional implications of this bill. We respectfully request that this Committee agree to hear this bill at a later date or to delay decision-making until we can provide a further analysis that will be more helpful to the Committee. We apologize for the delay but believe that a few days' additional time will allow us to provide the Committee with the advice necessary for a complete consideration of this measure.