ALASKA STATE LEGISLATURE
SENATE HEALTH AND SOCIAL SERVICES STANDING COMMITTEE
January 24, 2018
1:30 p.m.

MEMBERS PRESENT

Senator David Wilson, Chair
Senator Natasha von Imhof, Vice Chair
Senator Cathy Giessel
Senator Tom Begich

MEMBERS ABSENT

Senator Peter Micciche

COMMITTEE CALENDAR

COMMITTEE SUBSTITUTE FOR HOUSE BILL NO. 43(JUD)
"An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill for the purpose of sustaining the patient's life; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements."

- HEARD & HELD

PREVIOUS COMMITTEE ACTION

BILL: HB 43
SHORT TITLE: NEW DRUGS FOR THE TERMINALLY ILL
SPONSOR(s): REPRESENTATIVE(s) GRENN

01/18/17	(H)	PREFILE RELEASED 1/13/17
01/18/17	(H)	READ THE FIRST TIME - REFERRALS
01/18/17	(H)	HSS, JUD
02/28/17	(H)	HSS AT 3:00 PM CAPITOL 106
02/28/17	(H)	Heard & Held
02/28/17	(H)	MINUTE(HSS)
03/02/17	(H)	HSS AT 3:00 PM CAPITOL 106
03/02/17	(H)	Heard & Held
03/02/17	(H)	MINUTE(HSS)
03/07/17	(H)	HSS AT 3:00 PM CAPITOL 106

03/07/17	(H)	Moved HB 43 Out of Committee
03/07/17	(H)	MINUTE(HSS)
03/08/17	(H)	HSS RPT 5DP 1NR 1AM
03/08/17	(H)	DP: JOHNSTON, TARR, EDGMON, SULLIVAN-LEONARD, SPOHNHOLZ
03/08/17	(H)	NR: KITO
03/08/17	(H)	AM: EASTMAN
03/29/17	(H)	JUD AT 1:00 PM GRUENBERG 120
03/29/17	(H)	Heard & Held
03/29/17	(H)	MINUTE(JUD)
04/03/17	(H)	JUD AT 1:00 PM GRUENBERG 120
04/03/17	(H)	Moved CSHB 43(JUD) Out of Committee
04/03/17	(H)	MINUTE(JUD)
04/05/17	(H)	JUD RPT CS(JUD) NT 5DP 1NR
04/05/17	(H)	DP: EASTMAN, KOPP, FANSLER, LEDOUX, CLAMAN
04/05/17	(H)	NR: REINBOLD
04/10/17	(H)	MOVED TO BOTTOM OF CALENDAR
04/10/17	(H)	MOVED TO BOTTOM OF CALENDAR
04/10/17	(H)	TRANSMITTED TO (S)
04/10/17	(H)	VERSION: CSHB 43(JUD)
04/11/17	(S)	READ THE FIRST TIME - REFERRALS
04/11/17	(S)	HSS, JUD
01/24/18	(S)	HSS AT 1:30 PM BUTROVICH 205

WITNESS REGISTER

REPRESENTATIVE JASON GRENN
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Sponsor of HB 43.

BROOKE IVY, Staff
Representative Grenn
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Presented an overview of HB 43

DEBORA STOVERN, Executive Administrator
Alaska State Medical Board
Juneau, Alaska
POSITION STATEMENT: Answered questions about HB 43.

CLAIRE RADFORD, Staff
Legislative Legal Services
Alaska State Legislature
Juneau, Alaska

POSITION STATEMENT: Answered questions about HB 43

STARLEE COLEMAN, Senior Policy Advisor
Goldwater Institute
Phoenix, Arizona
POSITION STATEMENT: Provided information on Right to Try laws.

KEN LANDFIELD, Representing Self
Homer, Alaska
POSITION STATEMENT: Testified in support of HB 43.

ACTION NARRATIVE

1:30:05 PM

CHAIR DAVID WILSON called the Senate Health and Social Services Standing Committee meeting to order at 1:30 p.m. Present at the call to order were Senators Giessel, von Imhof, Begich, and Chair Wilson.

HB 43-NEW DRUGS FOR THE TERMINALLY ILL

1:31:09 PM
CHAIR WILSON announced the consideration of HB 43 with his intent to hear and hold the bill. [CSHB 43(JUD), version 30-LS0207\J, was before the committee.]

1:31:31 PM
REPRESENTATIVE JASON GRENN, Alaska State Legislature, sponsor of HB 43, paraphrased the first paragraph of his sponsor statement:

> House Bill 43 would allow terminally ill patients who have exhausted other available treatments and do not qualify for clinical trials to gain faster access to safe, but experimental drugs in an effort to save their own lives. By providing certain immunities to prescribing physicians, manufacturers and distributors acting in good faith, this bill would allow terminal patients, in consultation with their doctor, the freedom to try new treatments as they fight to survive, without the burden of waiting for federal approval.

REPRESENTATIVE GRENN noted that since 2014, 38 states have signed similar legislation into law with strong bipartisan

support. HB 43 is supported by the Alaska State Medical Board, the Alaska Commission on Aging, individual providers, and countless Alaskans. Last session the bill passed the House 40-0.

He said more than 1 million Americans die from a terminal illness every year. Fewer than three percent of patients who try to be become part of a clinical trial are accepted. The United States Food and Drug Administration (FDA) has a compassionate care process to allow patients to access experimental drugs. Nationally, estimates are that only 1,200 people make it through this federal process. HB 43 provides the same access the FDA program gives, but on a shorter timeline.

He said HB 43 is similar to the FDA compassionate care program, but on a shorter timeline. "HB 43 attempts to offer new hope when all other FDA-approved options have been exhausted," he said.

1:34:15 PM
REPRESENTATIVE GRENN read from a letter of support from a man whose father died of ALS, often known as Lou Gehrig's disease, at the age of 58. The man wished his father had had options to try other treatments.

1:35:33 PM
BROOKE IVY, Staff, Representative Grenn, Alaska State Legislature, provided an overview of HB 43 paraphrasing the following sectional analysis:

> **Section 1:** Prohibits disciplinary action of physicians by the State Medical Board for prescribing, dispensing or administering an investigational drug, biological product or device to terminally ill patients that are ineligible or unable to participate in a current clinical trial, have considered all other treatment options approved by the FDA and have provided written consent.
>
> Defines "investigational drugs, biological products and devices" as those that have successfully completed Phase 1 of the FDA drug review process and remain in ongoing Phase 2 or 3 clinical trials or the marketing application process, but have not been approved for general use.

Defines "terminal illness" as a disease that will result in death in the near future or permanent state of unconsciousness from which recovery is unlikely.

Section 2: Establishes immunity for physicians, medical team members, manufacturers and distributors in the case of injury or death of a terminally ill patient from the use of an investigational drug, biological product or device, provided informed consent was obtained from the patient and notice of immunity was given in advance.

Establishes immunity for physicians and manufacturers who choose not to participate in the distribution of an investigational drug, biological product or device.

Section 3: Amends statute limiting the sale and distribution of new drugs (AS 17.20.110) so as not to apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1.

Section 4: Prohibits the Department of Health and Social Services from requiring a licensed health care facility to increase its services solely to accommodate physicians prescribing, dispensing or administering investigational drugs to a patient.

1:37:55 PM
MS. IVY reviewed the FDA's Drug Review Process. Prior to Phase One, sponsors of a drug submit an Investigational New Drug (IND) Application.

1:38:32 PM
MS. IVY said the FDA then reviews preclinical testing results to determine whether the drug is reasonably safe for testing in humans. Phase One studies occur after the approval of the IND application. The goal of Phase One testing is to determine possible side effects and toxicity levels.

1:39:09 PM
MS. IVY said drugs that pass Phase One are considered relatively safe and Phase Two focuses on a drug's effectiveness.

1:39:26 PM
MS. IVY said drugs considered effective pass onto to Phase Three, where more information is gained on safety and

effectiveness, particularly with varying populations and in combination with other drugs.

1:39:38 PM
MS. IVY said that after Phase Three, sponsors have a drug review meeting with the FDA and complete a New Drug Application (NDA). If approved the drug can be marketed in the United States.

1:40:00 PM
SENATOR VON IMHOF asked how long each phase is and how the clinical trials fit into the four phases.

1:40:38 PM
MS. IVY said although she did not have specifics for each phase, the average time is 10 to 15 years for the FDA approval process. Clinical trials are part of Phases One, Two, and Three. HB 43 is about drugs that have completed Phase One clinical trials, which tests toxicity, so drugs are in Phases Two and Three.

1:41:46 PM
MS. IVY said with the FDA's compassionate care program, designed for terminally ill patients without access to clinical trials, patients must first work with their doctors to apply to the FDA. By the FDA's own estimate, the application took 100 doctor hours to complete. Recently the FDA has been trying to reduce that time, but the application is only the first step in the process. Manufacturers must also submit lengthy documentation. After an application has made its way through the FDA internal process, an individual must seek out an institutional review board for approval.

1:42:53 PM
SENATOR BEGICH asked if any of the laws passed in the other 38 states impede the clinical trial process.

1:43:42 PM
MS. IVY said that has been a concern in other states with Right to Try and the bill includes language that patients must be unable to participate in clinical trials.

1:44:52 PM
SENATOR BEGICH asked if the bill applies only to people who could not participate in clinical trials.

1:45:08 PM
MS. IVY said yes, and the goal is that clinical trials continue to benefit from the process in place.

1:45:24 PM
SENATOR VON IMHOF asked what kind of data is collected in what she would call a subset of clinical trials and how is it used, if collected.

1:46:12 PM
MS. IVY explained that data, whether inside or outside the clinical trials, is always important to manufacturers. They must report that data to the FDA. That data is collected under existing federal law

SENATOR VON IMHOF said that although there are no controls outside of clinical trials, data is always important.

MS. IVY said 38 states have Right to Try legislation, and 11 states have legislation pending, including Alaska.

SENATOR GIESSEL asked why Hawaii vetoed its Right to Try bill.

1:48:07 PM
MS. IVY said Governor [Jerry] Brown in California vetoed this legislation in 2015, but later reversed his veto. But Hawaii Governor [David] Ige noted his veto before he later changed it. Governor Ige listed four reasons for vetoing the bill: 1. The FDA compassionate care process already provided access. 2. It intervened with FDA system, which may have the inadvertent consequence of delaying new drugs. 3. It violated the supremacy clause. 4. He was unsure of patient benefits.

SENATOR VON IMHOF asked when the legislation was introduced and vetoed in Hawaii and if there have been further discussions about that legislation.

MS. IVY said it was vetoed in May 2016, and she would report later on the current status of the legislation in Hawaii.

MS. IVY drew attention to *Clinical Trials: A student's interview of nurses, patients and survivors experience and opinions of cancer and clinical trials in Alaska* document in committee members' packets. She said these stories helped to illustrate the benefit of having access to new treatments.

1:51:18 PM
CHAIR WILSON pointed out that Claire Radford, from Legislative Legal Services and Deb Stovern, the executive administrator, the Alaska State Medical Board, were available to answer questions.

He asked how many Alaskans would benefit from the law.

MS. IVY replied that it is difficult to say, but for individuals who would benefit, the impact would be enormous because it could be the difference between life and death. Even if only one person benefits, it would be worth it.

CHAIR WILSON asked if there was a time restriction for a patient to be on a trial drug. If the FDA approval for a new drug is 10 to 15 years, could someone stay on a trial drug until the FDA denied or approved the drug?

MS. IVY said every clinical trial is designed differently and has different lengths and qualifications, so she could not specifically address the question of time.

1:53:38 PM
SENATOR GIESSEL noted that in a February 2017 letter the Alaska State Medical Board took a neutral position because a no use clause is not included in the bill. Her interpretation is that refers to a removal of the liability for a person who chooses a clinician who chooses not to prescribe this. She did think the bill addressed it on page 3, lines 10 and 11, but asked Ms. Ivy to respond.

MS. IVY said that statement about no use referenced a Senate bill. HB 43 does include language that would protect physicians, manufacturers, and other stakeholders who would choose not to participate for a variety of reasons.

1:55:12 PM
SENATOR GIESSEL asked if the no use issue was addressed in the bill on line on page 3, lines 10 and 11, which reads, "a person, acting in good faith and with reasonable care, is not liable in an action for damages solely for declining to prescribe . . . and provide."

MS. IVY said that is correct.

SENATOR GIESSEL asked MS Stovern if the State Medical Board still stands by its neutral position on HB 43 as stated in its February 2107 letter.

1:55:57 PM
DEBORA STOVERN, Executive Administrator, Alaska State Medical Board, answered questions about HB 43. She apologized for

confusion in the letter, which was written for both SB 19, a similar bill, and HB 43. The neutral position was for SB 19. The board does support HB 43.

1:56:53 PM
SENATOR BEGICH asked if a drug being used under Right to Try would still be used if it was ruled unsafe during clinical trials.

MS. IVY said its use would be stopped. HB 43 clarifies investigational drugs must remain in ongoing clinical trials.

SENATOR BEGICH stated that clarification makes him more comfortable about the bill.

SENATOR GIESSEL called attention to the March 2017 letter from Premera. Premera suggested that a new section be added to the bill. Item B of this proposed section states that the patient's "insurance plan is not required to pay, and may deny coverage" if there's been demonstrated to be associated any harm or adverse effect. She asked Ms. Ivy what language in HB 43 addressed this issue.

She then identified the language as being on page 2, line 10. She brought up the suggested language in the Premera letter that said that a health care insurer may, but is not required to, pay for coverage for the investigative drug. She thought HB 43 did not address insurance.

2:00:05 PM
MS. IVY responded that insurance coverage being referenced in the letter is not required by state or federal statute. Clarifying language could be added, but the sponsor didn't include it since it is not required by state or federal law.

MS. IVY said the informed consent part of the bill involves a discussion between a patient and doctor regarding the lack of insurance for an investigational drug.

SENATOR GIESSEL said often pharmaceutical companies do not charge for experimental medications. She asked how often that happens with these types of experimental medications.

MS. IVY said federal law does allow for cost recovery, but manufacturers cannot sell experimental drugs for profit. She said she would need to do further research to find out how often they are given away for no charge.

SENATOR GIESSEL asked whether it was true that if a patient is accepted into a clinical trial, the patient does not pay for the medication.

MS. IVY said she believed that is usually true, although there are other costs a patient might have to pay for.

2:03:23 PM
SENATOR GIESSEL noted that part of the Premera letter suggested a definition of a terminal illness that stated, "a reasonable likelihood that death will occur within six months." HB 43 has a different definition on page two, lines 14-16. She asked why HB 43 did not have Premera's language.

MS. IVY said the House discussed the definition of terminal illness. The definition in the bill is one used by other states. Premera offered Medicare's definition of 6 months. The sponsor thought that timeframe was too narrow. The compassionate use program does not have a definition for terminal illness.

SENATOR GIESSEL said the bill's definition of a terminal illness on page 2, line 15, says "death in the near future," which is nebulous. She asked what is "the near future."

2:06:10 PM
CLAIRE RADFORD, Staff, Legislative Legal Services, Alaska State Legislature, answered questions about HB 43. She said the state medical board would define any definitions that are not clear.

SENATOR GIESSEL said Ms. Radford was pointing out that under AS 08.64, the medical board would have authority to do this.

2:07:08 PM
SENATOR VON IMHOF said she was concerned about Premera's request to add a section 5 to the bill of clarifying language for health insurance. She wondered whether it wasn't the health insurance policy that should state what coverage is. Health insurance policies are updated on a regular basis, but that is not usually true for statutes. She asked Ms. Ivy if she asked Premera/Blue Cross and Blue Shield of Alaska how they handle the issue in their policies and what they cover for clinical trials.

MS. IVY said in conversations with Premera/Blue Cross she did not ask for copies of policies and how they handled coverage. The sponsor may agree that referencing a point in time in statute can be problematic. The elements of pointing out what is

not covered is not currently required by state or federal statute. The suggested Section 5c in the Premera letter about what would be covered is mandated in the [federal] Affordable Care Act (ACA). If the ACA changes then the state statute would have to be changed. The bill's current language would not require any changes in current statutes. She offered to research how insurance policies currently address the issue.

2:10:24 PM
SENATOR BEGICH asked when the 38 states passed their laws and how are they working.

MS. IVY said the Right to Try legislation movement started in 2014. Florida, Oregon, and Texas have some success stories. In Texas, a doctor used a promising treatment available in Europe with 150 patients, but the FDA would not allow him to continue to treat his patients when the trials were completed. He was able to resume treatment after Texas passed its Right to Try law and many patients, who were given three to six months to live, are still alive a year later.

2:12:31 PM
SENATOR BEGICH relayed a story of a close friend with pancreatic cancer who was given 6 months to live. He left the country for a clinical trial. He lived long enough for his daughter, who was 4 years old at the time of his diagnosis, to have memories of him. It almost bankrupted his friend's family. He said the proposal is overdue because the opportunity to extend life is important.

SENATOR GIESSEL asked whether the states that did not have Right to Try laws have offered legislation.

MS. IVY said yes, all have Right to Try legislation introduced.

2:14:37 PM
CHAIR WILSON opened public testimony

2:14:55 PM
STARLEE COLEMAN, Senior Policy Advisor, Goldwater Institute, provided information on Right to Try laws. She said the FDA compassionate care program, particularly for patients in Alaska, is not a practical option. About 1,200 people a year make it through the FDA's compassionate care process. About 25,000 people a year are in a similar program in France. France, a country with a population one-fifth size of the United States, helps 2,000 percent more people. America has a red tape problem. The Institute receives two responses from doctors when

discussing the compassionate care program: the what program and oh, that is impossible.

2:16:43 PM
MS. COLEMAN said according to a doctor who ran the early stage clinical trials center, the largest in the world, at the MD Anderson Cancer Center in Houston, the center was only able to get one person a year into the FDA compassionate care program. Imagine the obstacles in Alaska. Practical opportunities for people who are not in big hospitals in big cities to have access to clinical trials are not good. Right to Try legislation is one of the only options for people in these situations. The institute has talked to hundreds of families and has heard the same thing. No one expects a guarantee, but they want the opportunity to try. "We feel we owe dying people and their families that opportunity," she said.

2:20:44 PM
MS. COLEMAN said the question has come up about whether these laws conflict with federal law. States have the authority to provide additional constitutional rights above the federal floor. States can go above what is guaranteed in the Constitution. There have been no efforts by the FDA to shut down these laws or intervene in treatment.

MS. COLEMAN said the U.S. Senate last summer unanimously passed a law to protect states that have passed Right to Try laws from federal interference. They are hoping the U.S. House will pass the law soon and Alaska will know it will have the federal stamp of approval for this law.

2:24:09 PM
SENATOR BEGICH asked if she said the federal law passed unanimously in the U.S. Senate.

MS. Coleman said that is correct.

2:24:35 PM
CHAIR WILSON opened public testimony.

2:25:02 PM
KEN LANDFIELD, Representing Self, testified in support of HB 43. He said he could not imagine any reason not to support this bill.

2:26:10 PM
CHAIR WILSON closed public testimony.

2:26:24 PM
CHAIR WILSON held HB 43 in committee.

2:26:53 PM
There being no further business to come before the committee, Chair Wilson adjourned the Senate Health and Social Services Committee at 2:26 p.m.