

**ALASKA STATE LEGISLATURE**  
**SENATE JUDICIARY STANDING COMMITTEE**

February 28, 2018

1:46 p.m.

**MEMBERS PRESENT**

Senator John Coghill, Chair  
Senator Mia Costello  
Senator Pete Kelly  
Senator Bill Wielechowski  
Senator Click Bishop

**MEMBERS ABSENT**

All members present

**COMMITTEE CALENDAR**

SENATE BILL NO. 173

"An Act relating to the liability of a person or the state for the release of certain pesticides during application on a utility pole."

- HEARD & HELD

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: SB 173

SHORT TITLE: LIABILITY: PESTICIDES & UTILITY POLES

SPONSOR(S): SENATOR(S) MICCICHE

02/02/18	(S)	READ THE FIRST TIME - REFERRALS
02/02/18	(S)	RES

02/12/18 (S) RES AT 3:30 PM BUTROVICH 205  
02/12/18 (S) Heard & Held  
02/12/18 (S) MINUTE(RES)  
02/14/18 (S) RES AT 3:30 PM BUTROVICH 205  
02/14/18 (S) Heard & Held  
02/14/18 (S) MINUTE(RES)  
02/16/18 (S) RES AT 3:30 PM BUTROVICH 205  
02/16/18 (S) Moved CSSB 173(RES) Out of Committee  
02/16/18 (S) MINUTE(RES)  
02/19/18 (S) RES RPT CS 2DP 3NR NEW TITLE  
02/19/18 (S) DP: GIESSEL, COGHILL  
02/19/18 (S) NR: BISHOP, VON IMHOF, MEYER  
02/19/18 (S) JUD REFERRAL ADDED AFTER RES  
02/28/18 (S) JUD AT 1:30 PM BELTZ 105 (TSBldg)

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  
01/24/18 (S) Heard & Held  
01/24/18 (S) MINUTE(HSS)  
01/29/18 (S) HSS AT 1:30 PM BUTROVICH 205  
01/29/18 (S) Moved CSHB 43(JUD) Out of Committee  
01/29/18 (S) MINUTE(HSS)  
01/31/18 (S) HSS RPT 3DP 1NR  
01/31/18 (S) DP: VON IMHOF, BEGICH, GIESSEL  
01/31/18 (S) NR: MICCICHE  
02/28/18 (S) JUD AT 1:30 PM BELTZ 105 (TSBldg)

**WITNESS REGISTER**

SENATOR PETER MICCICHE  
Alaska State Legislature  
Juneau, Alaska

**POSITION STATEMENT:** Sponsor of SB 173.

DAVID WILKINSON, Assistant Attorney General  
Civil Division  
Environmental Section  
Department of Law  
Anchorage, Alaska

**POSITION STATEMENT:** Answered questions related to SB 173.

EMILY NAUMAN, Legislative Counsel  
Legislative Legal Services  
Alaska State Legislature  
Juneau, Alaska

**POSITION STATEMENT:** Answered questions related to SB 173.

KRISTIN RYAN, Director  
Spill Prevention and Response  
Department of Environmental Conservation (DEC)  
Anchorage, Alaska

**POSITION STATEMENT:** Answered questions related to SB 173.

ERIC FJELSTAD, Attorney  
Perkins Coie LLP  
Anchorage, Alaska

**POSITION STATEMENT:** Testified in support of SB 173 on behalf of the Homer Electric Association.

MICHAEL ROVITO, Director of Member and Public Relations  
Alaska Power Association  
Anchorage, Alaska

**POSITION STATEMENT:** Testified in support of the CS for SB 173.

REPRESENTATIVE JASON GRENN  
Alaska State Legislature  
Juneau, Alaska

**POSITION STATEMENT:** Sponsor of HB 43

BROOKE IVY, Staff  
Representative Jason Grenn  
Alaska State Legislature  
Juneau, Alaska

**POSITION STATEMENT:** Delivered a sectional analysis for HB 43 and answered related questions.

#### **ACTION NARRATIVE**

[1:46:33 PM](#)

**CHAIR JOHN COGHILL** called the Senate Judiciary Standing Committee meeting to order at 1:46 p.m. Present at the call to order were Senators Costello, Wielechowski, Kelly and Chair Coghill. Senator Bishop arrived during the introduction.

#### **SB 173-LIABILITY: PESTICIDES & UTILITY POLES**

[1:47:14 PM](#)

**CHAIR COGHILL** announced the consideration of SB 173. He listed the individuals available to answer questions.

[1:48:09 PM](#)

**SENATOR MICCICHE**, Alaska State Legislature, Juneau, Alaska, sponsor of SB 173, said he introduced the legislation after an employee from the Kenai National Wildlife Refuge did an unscientific sampling and found residue of pentachlorophenol ("penta") around a power pole. The compound is used as an insecticide to extend the life of these poles. Utility companies worried that if they were asked to completely remove all 250,000 utility poles in the state, their potential exposure would be about \$7.5 billion. He continued the introduction speaking to the following sponsor statement:

The bottom-line purpose of my choice to bring SB173 forward is the financial protection of nearly every

Alaskan ratepayer who depends upon a utility to deliver electricity to their home, business or facility. SB173 conforms Alaska law to federal law with respect to wood poles treated with pesticides registered with the Environmental Protection Agency. The legislation is drafted narrowly to apply only to a "wood utility pole installed, removed or used by public utilities in connection with providing a utility service in the state."

In the State of Alaska, every wooden utility pole is factory-treated with a preservative/pesticide which prolongs the service life of the pole by protecting it from organisms that compromise structural integrity. It is logical to assume that soil coming in direct contact with treated utility poles for 30 or more years would include traces of that preservative.

The provisions of AS 46.03.822(a) are interpreted to assume public utility liability and indirectly, Alaskan ratepayers for remediating residual preservative when replacing or removing treated wooden utility poles. This liability does not exist under federal law because the companion federal statute to AS 46.03.822 contains a specific exemption for "the application of a pesticide product registered under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]."

SB 173 clarifies and eliminates the assumption of liability and remediation costs for trace elements by including the federal exemption within Alaska's statutes.

SENATOR MICCICHE said the expectation is that the Department of Environmental Conservation (DEC) will provide best practice guidelines for use requirements and disposal of preservative-treated utility poles to control or eliminate future contamination when poles are retired.

He expressed appreciation that the committee requested the additional referral because it's important that the liability matches that under the federal code. There is no desire to account for liability beyond that point.

[1:51:13 PM](#)

SENATOR WIELECHOWSKI asked what provision in FIFRA exempts the federal government from liability.

SENATOR MICCICHE deferred the question to DEC or the legislative drafter, Emily Nauman.

1:52:23 PM

SENATOR COSTELLO asked if SB 173 takes the same approach that other states facing this issue have taken.

1:54:20 PM

DAVID WILKINSON, Assistant Attorney General, Civil Division, Environmental Section, Department of Law, Anchorage, Alaska, advised that the exemption under federal law is found in Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 107 (i) [42 U.S.C. 9607(i)]. That exemption applies to registered pesticides broadly, not utility poles specifically. It exempts the application of a pesticide that has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) from liability under CERCLA. The provision includes savings language that provides that it does not affect or modify other statutory or common law obligations.

SENATOR WIELECHOWSKI read the first sentence of 42 U.S.C. 9607(i) into the record:

**(i) Application of a registered pesticide product**

No person (including the United States or any State or Indian tribe) may recover under the authority of this section for any response costs or damages resulting from the application of a pesticide product registered under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]. [Nothing in this paragraph shall affect or modify in any way the obligations or liability of any person under any other provision of State or Federal law, including common law, for damages, injury, or loss resulting from a release of any hazardous substance or for removal or remedial action or the costs of removal or remedial action of such hazardous substance.]

He said his staff found that courts have interpreted that as the actual application of the pesticide on poles or somewhere else. He asked Mr. Wilkinson if he had a different understanding of the courts' interpretation.

MR. WILKINSON said no. The focus is on the application, which is the intended use of a pesticide. The way federal case law has played out is if the pesticide is intended to be sprayed on one plant and it drifts onto a nearby property, that drift is not the application of the pesticide that is shielded under CIRCLA. Only the intended use of the pesticide is shielded.

SENATOR WIELECHOWSKI read the second sentence of 42 U.S.C. 9607(i) into the record:

Nothing in this paragraph shall affect or modify in any way the obligations or liability of any person under any other provision of State or Federal law, including common law, for damages, injury, or loss resulting from a release of any hazardous substance or for removal or remedial action or the costs of removal or remedial action of such hazardous substance.

He said his understanding is that the federal law only provides an exemption for the actual application of the pesticide, but it doesn't shield the product from any laws states or the federal government have adopted in that regard. He asked if it's fair to say that Alaska is not out of compliance.

MR. WILKINSON said he agreed with that reading of the provision.

CHAIR COGHILL said the bill is before the committee to make that determination.

SENATOR COSTELLO asked Ms. Nauman if this legislation was based on model law.

[1:59:27 PM](#)

EMILY NAUMAN, Legislative Counsel, Legislative Legal Services, Alaska State Legislature, Juneau, Alaska, said she was not aware of that, but she would look into it.

CHAIR COGHILL requested she send her response to both his office and the sponsor's.

SENATOR WIELECHOWSKI read AS 09.65.085(a) and opined that it gives utility companies the liability exemption they're looking for. He asked if she or Mr. Wilkinson have a different interpretation.

MR. WILKINSON said he would need to do additional research before he answered.

[2:01:49 PM](#)

SENATOR MICCICHE clarified that application is not spraying the pesticide. "The application is the use of the pesticide so there's a little misunderstanding there." He restated that he introduced SB 173 because he doesn't want there to be a need for a cleanup of the 250,000 poles in the state if they have residue of penta around the poles for a reasonable distance. There is no intent to entirely absolve liability. The intent is to find the right mix of liability that protects the normal, intended use and application of penta.

CHAIR COGHILL asked Senator Wielechowski to restate his question for Ms. Nauman.

SENATOR WIELECHOWSKI said he doesn't believe that current state law is at odds with the federal law 42 U.S.C. 4607(i) regarding the application of registered pesticides. The exemption under CERCLA applies to the application of pesticides that are registered under FIFRA. The second sentence of 42 U.S.C. 4607(i) specifically gives states and the federal government the right to enact whatever laws they wish on this topic.

[2:04:51 PM](#)

MS. NAUMAN said she would need to examine CERCLA more closely before giving a response.

CHAIR COGHILL asked what remedy would be available if the bill passes and people had trouble with penta residue on their property.

[2:05:46 PM](#)

MR. WILKINSON said other remedies are likely to survive exemption to AS 46.03.822 with two caveats, but it isn't clear how an exemption to .822 would alter those common law remedies. Also, common law remedies are not direct substitutes for AS 46.03.822. Some federal district courts have held that CERCLA preempts federal common law causes of action that are subsumed under the structure of CERCLA. However, in the pesticide context the FIFRA exemption in CERCLA section 107(i) expressly preserves those other statutory rights in common law, causative action.

He said he hasn't found similar case law in Alaska looking at the impact of .822 on common law claims. The Alaska Supreme Court has analyzed common law causes of action, which is negligence, nuisance, and trespass alongside .822 causes of action but hasn't squarely addressed whether .822 preempts those

common law claims. There is a question there and about the interplay between a statute and common law in these more traditional claims.

One example of this interplay is in the negligence context. Negligence cause of action, which would arguably survive for a landowner, requires duty, breach of duty, causation, and harm. But when courts look to find a duty, they look to statutes so there's a question raised by an exemption to .822. Does that alter the duty that a utility company might owe a landowner? They're exempt from liability for release of hazardous substances under a statute. Whether that changes the duty that they have to landowners is potentially a litigation question.

CHAIR COGHILL commented that the clearer we can speak in this statute, the better for common law remedies.

MR. WILKINSON agreed that clarity in the statute would lessen the argument that an exemption changes the common law somehow.

CHAIR COGHILL asked Ms. Ryan who a private individual would go to if they found pollution on their property that contaminated their well.

[2:10:23 PM](#)

KRISTIN RYAN, Director, Spill Prevention and Response, Department of Environmental Conservation (DEC), Anchorage, Alaska, said Mr. Wilkinson expressed that there are some unknowns as to how a court would interpret liability in that scenario. DEC would eliminate the exposure pathway by providing a drinking water source if the chemicals were carcinogenic when consumed but deciding who would pay for that or who would remedy the problem is a little murky. Based on the language, she guessed that the utility company would not be liable, and the homeowner probably would not be liable. It is clear that the state would be obliged to use its resources to remedy the problem.

CHAIR COGHILL asked if there has ever been a problem in Alaska.

MS. RYAN said not that she was aware of.

CHAIR COGHILL asked if she had experience with any of these common law remedies.

MS. RYAN said joint and several liability statutes are very clear that all the parties that spilled the contaminant are

responsible, as well as the land owner who inherited the contaminated property. She was not aware of any broad exemptions; this would be the first.

CHAIR COGHILL asked if contamination of groundwater [from residue around a power pole] was likely or highly speculative.

MS. RYAN said contamination of a private drinking water well from utility pole residue has not occurred in Alaska, but she was aware of it happening in one other state. The chance of this occurring is remote, but the question is what would occur if it did happen. DEC is working with industry to develop best management practices to minimize any migration of chemicals from the utility poles into an aquifer. DEC's focus has always been to be proactive instead of dealing with the problem after the fact.

2:16:26 PM

CHAIR COGHILL asked if DEC defines minimal standards for other contaminants instead of a blanket exemption.

MS. RYAN said she was unaware of any exemptions in the liability statutes, but the department believes that a minimal amount of leaching around a utility pole is to be expected and would not be a large concern. She suggested that if that was the utility companies' concern, it should be clearly stated in the legislation. That would provide the companies some relief and wouldn't tie the department's hands to deal with a significant contamination event.

2:18:03 PM

SENATOR WIELECHOWSKI summarized that the bill exempts both the utility company and the homeowner from liability. He asked if she interprets the language in Section 1 regarding liability of persons to include the state.

MS. RYAN agreed with the summary and that the Department of Labor and Workforce Development (DOLWD) would meet the definition in Section 1. She added that even though liability would not fall to DOT, DEC would need to utilize some funds to eliminate the exposure pathway so that human health isn't impacted.

SENATOR WIELECHOWSKI said he didn't want utility companies to replace 250,000 poles but somebody must be responsible if there is significant contamination. He asked her to think about an amendment he was working on that adds a paragraph under

subsection (b) in Section 1. It basically says, "there is no liability as long as the release does not contaminate soil, surface water or ground water beyond the radius depth and concentration specified by the Department of Environmental Conservation." The amendment goes on to determine by regulation what radius depth and concentration would potentially lead to the harm of public safety or welfare.

CHAIR COGHILL asked if contamination is measured in parts per million or if each pesticide is considered based on the latest health bulletin.

MS. RYAN replied DEC relies on the numbers in regulation regarding what is safe for dioxins in different receiving environments and human health. She also pointed out that while penta is approved for use on utility poles, it is not the main chemical of concern for leaching. It is dioxin, which is a byproduct of the manufacturing process. The EPA talks at great length about that in the record of decisions approving its use in these situations.

CHAIR COGHILL asked if she had any comment on Senator Wielechowski's proposed amendment.

MS. RYAN replied the department has been considering a similar improvement to the legislation. Setting a minimal level of contamination as acceptable would require the department to be very specific in its regulations, but before they could be drafted more information is needed to understand where the chemicals are migrating and how far.

[2:23:57 PM](#)

SENATOR WIELECHOWSKI asked if a homeowner would be required to disclose when they sold their property that utility poles in the right-of-way on their property were leaching pesticides or dioxins.

MS. RYAN said a homeowner would be required to disclose that information if they were aware of it, but she would assume most homeowners would not have that information.

CHAIR COGHILL said he'd like to hear from utility companies at this point.

[2:25:41 PM](#)

ERIC FJELSTAD, Attorney, Perkins Coie LLP, Anchorage, Alaska, said he was testifying in support of SB 173 on behalf of the

Homer Electric Association. He said he would offer the utility company's perspective on the issues that have been raised focusing on the state liability scheme under AS 46.03.822 and comparing it to the federal liability scheme under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). He said he agrees with Senator Wielechowski that this isn't a question of the state being out of compliance with federal law. The question is what the state should do as a matter of policy because it does have latitude.

Section 107 (i) of CERCLA says that if a pesticide has been registered and approved by EPA, then CERCLA cannot be used to require an investigation and cleanup of that pesticide. Similar provisions in CERCLA apply to other situations such as federal air or water permits and consumer product exception for asbestos. The policy issue is that while these products may be harmful, when they are used properly Congress through CERCLA should not create a liability scheme where something is used pursuant to its intended use. AS 46.03.822 is modeled on CERCLA and proposes to include pesticides in the state liability scheme.

MR. FJELSTAD said he was highly confident that these pesticides would fall within the exemption under CERCLA because the exemption in federal law is being actively regulated by another federal scheme. It's not just Congress making an exemption that some particular person or industry shouldn't be liable. This goes to Senator Coghill's question about whether this has been a problem in the past. It hasn't been a problem because the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is actively regulating how these materials can be applied in practice.

He explained that the utility companies are concerned because the question about pesticide leaching was raised in the one instance and there is an affirmative obligation for any party that is aware of a release to report it to DEC and that starts the cleanup process. There are hundreds of thousands of poles in the state and the question is whether the utility companies must go out and prove a negative, that there is nothing there or that it's de minimis.

[2:31:01 PM](#)

CHAIR COGHILL asked if the general liability in existing statute would apply in this situation.

MR. FJELSTAD said he would like to say it applies but he would be nervous doing so given that the courts generally construe exceptions to liability narrowly.

SENATOR WIELECHOWSKI asked what liabilities would be available to homeowners or affected individuals if the bill were to pass as currently drafted.

MR. WILKINSON said common law exceptions are likely to survive, but the Alaska Supreme Court has not directly addressed the question of whether AS 46.03.822 has an impact on the survival of common law claims. Chapter 46.03 does have the regulation of hazardous substances including the prohibition of releasing hazardous substances without a permit and prohibitions on pollution.

SENATOR COSTELLO asked if there is higher liability regarding utility easements near school grounds.

MR. WILKINSON said AS 46.03.822 doesn't change the liability based on the vulnerability of people who might be injured.

CHAIR COGHILL commented that it's an interesting question when school yards are often paved with asphalt.

[2:37:55 PM](#)

MICHAEL ROVITO, Director of Member and Public Relations, Alaska Power Association, Anchorage, Alaska, stated support for the CS for SB 173. He said large and small utility companies throughout Alaska utilize the pesticide pentachlorophenol on the hundreds of thousands of utility poles they own throughout the state. Use of this pesticide is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In 2008, the U.S. Environmental Protection Agency reregistered penta after issuing a report that found the benefits of penta outweighed any remaining risks. The FIFRA regulations ensure that using the pesticide according to specification will not cause unreasonable adverse effects on the environment. SB 173 ensures that the pesticide on utility poles is properly regulated as pesticide use and not spills. This is an important distinction missing in Alaska law. The bill also provides that the use of penta on utility poles will be regulated under Alaska's pesticide control program under FIFRA instead of under DEC's Division of Spill Prevention and Response.

[2:40:40 PM](#)

CHAIR COGHILL said he intended to look into Alaska's pesticide control program under FIFRA.

[2:41:45 PM](#)

SENATOR MICCICHE said his office has worked with DEC throughout this process to find the right balance on liability. This is about protection of Alaska ratepayers.

SENATOR BISHOP said he doubts there would be a spill from these poles, but there could be an inadvertent release.

SENATOR MICCICHE said there have only been two incidents in the history of the use of penta and he assumes that the penta was improperly applied during manufacture.

CHAIR COGHILL commented that even that would be identified as leaching, not a spill.

SENATOR BISHOP added that Kristen Ryan has a calculation for what is a reportable spill and what is not.

SENATOR MICCICHE reiterated that he wanted to get the right balance.

[2:45:21 PM](#)

CHAIR COGHILL held SB 173 in committee.

**HB 43-NEW DRUGS FOR THE TERMINALLY ILL**

[2:45:36 PM](#)

CHAIR COGHILL announced the consideration of HB 43.

[2:46:15 PM](#)

REPRESENTATIVE JASON GRENN, Alaska State Legislature Juneau, Alaska, sponsor of HB 43, introduced the legislation speaking to the following 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.

More than 1 million Americans die from a terminal illness every year. Many spend years searching for a potential cure, or struggle in vain to get accepted into a clinical trial. Unfortunately, FDA red tape and government regulations can often restrict access to promising new treatments, and sometimes for those who do get access, it is too late.

The United States Food and Drug Administration currently offers an "expanded access" or "compassionate use" exemption that allows terminally ill patients that meet certain criteria to access drugs in the clinical trial phase. However, even with recent efforts by the FDA to streamline the application process, this exemption program is known to be arduous and can take longer than patients facing terminal illness have to wait.

Since 2014, 38 states have signed "right to try" legislation into law with strong, bi-partisan support. It is clear this is a human issue that goes beyond state and party lines, and could provide Alaskans increased access to potentially life-saving treatments in the times they need it most.

In allowing Alaskans facing terminal illness the ability to access safe, though experimental drugs in consultation with a doctor they trust, this bill offers new hope when all FDA-approved options have been exhausted. I urge your support of House Bill 43.

REPRESENTATIVE GRENN read a letter of support from a constituent.

I write to you today in support of HB 43 with the short title, "New Drugs for the Terminally Ill." In June 2011, my father was diagnosed with ALS, sometimes known as Lou Gehrig's disease. For those unfamiliar, this disease slowly saps a person's ability to move, rendering them bed-ridden. Eventually it takes away their ability to breathe at which point they die. For my father, this deterioration began in June.

He had been working 12 hours days, five or six days a week as a machinist. He was, by all accounts, a very strong and health man at the time of his diagnosis. By late fall he had completely lost his ability to walk. At Thanksgiving, he held out five-month-old son for the last time in his arms as he had become to weak to be trusted with such precious cargo. In early morning of February 1, 2012, he died at the all too young age of 58.

In the end I wish the State had afforded him the right to fight his disease. Recently in the *Washington Post* there was an article detailing the experience of a man who had, for all intents and purposes, beaten ALS through advance therapies pioneered by doctors at the ALS Center in Atlanta, Georgia. In reading about this man, I became aware of the Right to Try movement. I cannot say for sure that these advance therapies may have saved my father's life, but they may yet save someone's father, mother, daughter, or son.

Thank you for your consideration on this important legislation.

REPRESENTATIVE GRENN stated that the goal of HB 43 is to provide the same access as the FDA's Compassionate Use Program, but on a shorter timeline. That program recognizes that 97 percent of people are not accepted in clinical trials. HB 43 seeks to offer new hope when all other FDA approved options have been exhausted.

[2:50:15 PM](#)

BROOKE IVY, Staff, Representative Jason Grenn, Alaska State Legislature Juneau, Alaska, paraphrased the following sectional analysis for HB 43:

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.

CHAIR COGHILL asked if 97 percent of Alaskans have been denied clinical trials.

MS. IVY replied that is a national number. She noted the clinical trials document in the packet has stories of Alaskans who have been admitted into clinical trials.

CHAIR COGHILL asked her to discuss the FDA drug review process.

MS. IVY explained that when a drug manufacturer's application for an investigational new drug (IND) is accepted, the drug moves into phase 1. The drug is studied for possible side effects and toxicity levels on healthy volunteers. Phase 2 looks

at how effective the drug is for the condition. Phase 3 looks at safety again as well as effectiveness.

CHAIR COGHILL asked if the informed consent form tells an individual they are part of a trial.

[2:55:22 PM](#)

MS. IVY clarified that the volunteer would not be in a clinical trial, but the data related to the experimental drug would be collected and sent to the FDA.

[2:57:32 PM](#)

CHAIR COGHILL held HB 43 in committee.

[2:57:46 PM](#)

There being no further business to come before the committee, Chair Coghill adjourned the Senate Judiciary Standing Committee meeting at 2:57 p.m.