

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

April 11, 2016

1:38 p.m.

**MEMBERS PRESENT**

Senator Lesil McGuire, Chair  
Senator John Coghill, Vice Chair  
Senator Mia Costello  
Senator Bill Wielechowski  
Senator Peter Micciche

**MEMBERS ABSENT**

All members present.

**COMMITTEE CALENDAR**

SENATE BILL NO. 108

"An Act repealing and reenacting the Alaska Securities Act, including provisions relating to exempt securities and transactions; relating to registration of securities, firms, and agents that offer or sell securities and investment advice; relating to administrative, civil, and criminal enforcement provisions, including restitution and civil penalties for violations; allowing certain civil penalties to be used for an investor training fund; establishing increased civil penalties for harming older Alaskans; retaining provisions concerning corporations organized under the Alaska Native Claims Settlement Act; amending Rules 4, 5, 54, 65, and 90, Alaska Rules of Civil Procedure; and providing for an effective date."

- MOVED CSSB 108(L&C) OUT OF COMMITTEE

SENATE BILL NO. 113

"An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill; and providing immunity for persons manufacturing, distributing, or providing investigational drugs, biological products, or devices."

- MOVED CSSB 113(HSS) OUT OF COMMITTEE

SENATE BILL NO. 211

"An Act relating to the limitation period to commence a false claims action; relating to recovery for false claims for state or municipal funds; and amending Rules 4, 24, and 46, Alaska Rules of Civil Procedure."

- SCHEDULED BUT NOT HEARD

**PREVIOUS COMMITTEE ACTION**

BILL: SB 108

SHORT TITLE: AK SECURITIES ACT; PENALTIES; CRT. RULES

SPONSOR(s): RULES BY REQUEST OF THE GOVERNOR

04/13/15	(S)	READ THE FIRST TIME - REFERRALS
04/13/15	(S)	L&C, JUD, FIN
02/09/16	(S)	L&C AT 1:30 PM BELTZ 105 (TSBldg)
02/09/16	(S)	Scheduled but Not Heard
02/11/16	(S)	L&C AT 1:30 PM BELTZ 105 (TSBldg)
02/11/16	(S)	Heard & Held
02/11/16	(S)	MINUTE (L&C)
02/18/16	(S)	L&C AT 1:30 PM BELTZ 105 (TSBldg)
02/18/16	(S)	Heard & Held
02/18/16	(S)	MINUTE (L&C)
03/03/16	(S)	L&C AT 1:30 PM BELTZ 105 (TSBldg)
03/03/16	(S)	Moved CSSB 108(L&C) Out of Committee
03/03/16	(S)	MINUTE (L&C)
03/04/16	(S)	L&C RPT CS 2DP 1NR NEW TITLE
03/04/16	(S)	DP: COSTELLO, GIESSEL
03/04/16	(S)	NR: MEYER
04/04/16	(S)	JUD AT 1:30 PM BELTZ 105 (TSBldg)
04/04/16	(S)	Scheduled but Not Heard
04/11/16	(S)	JUD AT 1:30 PM BELTZ 105 (TSBldg)

BILL: SB 113

SHORT TITLE: NEW DRUGS FOR THE TERMINALLY ILL

SPONSOR(s): WIELECHOWSKI

04/17/15	(S)	READ THE FIRST TIME - REFERRALS
04/17/15	(S)	HSS, JUD
02/24/16	(S)	HSS AT 1:30 PM BUTROVICH 205
02/24/16	(S)	Heard & Held
02/24/16	(S)	MINUTE (HSS)
03/30/16	(S)	HSS AT 1:30 PM BUTROVICH 205
03/30/16	(S)	Moved CSSB 113(HSS) Out of Committee
03/30/16	(S)	MINUTE (HSS)
04/01/16	(S)	HSS RPT CS 1DP 2NR NEW TITLE
04/01/16	(S)	DP: ELLIS

04/01/16 (S) NR: STEDMAN, STOLTZE  
04/11/16 (S) JUD AT 1:30 PM BELTZ 105 (TSBldg)

**WITNESS REGISTER**

KEVIN ANSELM, Director  
Division of Banking and Securities  
Department of Commerce, Community and Economic Development  
Anchorage, Alaska  
**POSITION STATEMENT:** Introduced SB 108 on behalf of the  
administration.

KRISTY NAYLOR, Securities Examiner  
Division of Banking and Securities  
Department of Commerce, Community and Economic Development  
Anchorage, Alaska  
**POSITION STATEMENT:** Stated the department has no concerns with  
the way SB 108 is drafted.

BROOKE IVY, Staff  
Senator Bill Wielechowski  
Alaska State Legislature  
Juneau, Alaska  
**POSITION STATEMENT:** Introduced SB 113 on behalf of the sponsor.

KURT ALTMAN, Attorney  
Goldwater Institute  
Phoenix, Arizona  
**POSITION STATEMENT:** Testified in support of SB 113.

MICHAEL MAHARREY, National Communications Director  
10th Amendment Center  
Lexington, Kentucky  
**POSITION STATEMENT:** Testified in support of SB 113.

CHARLOTTE WHITELEY, representing herself  
Homer, Alaska  
**POSITION STATEMENT:** Testified in support of SB 113.

KEN LANDFIELD, representing himself  
**POSITION STATEMENT:** Testified in support of SB 113.

**ACTION NARRATIVE**

[1:38:40 PM](#)

**CHAIR LESIL MCGUIRE** called the Senate Judiciary Standing Committee meeting to order at 1:38 p.m. Present at the call to order were Senators Wielechowski, Coghill, Costello, and Chair McGuire. Senator Micciche arrived soon thereafter. She reviewed the agenda and noted that SB 211 would not be heard.

**SB 108-AK SECURITIES ACT; PENALTIES; CRT. RULES**

[1:39:30 PM](#)

CHAIR MCGUIRE announced the consideration of SB 108. She noted that this is the first hearing and the committee is considering CSSB 108(L&C).

[1:39:58 PM](#)

KEVIN ANSELM, Director, Division of Banking and Securities, Department of Commerce, Community and Economic Development (DCCED), introduced SB 108 on behalf of the administration. She informed the committee that the bill separates securities statutes from the Alaska Native Claims Settlement Act (ANCSA) statutes to reduce confusion and improve understanding of both acts. It recognizes and incorporates current industry standards and terms. It synthesizes with other states' laws to make it easier for businesses, entrepreneurs, and investors to understand their rights, responsibilities, and opportunities in Alaska through adopting many of the Uniform Securities Act provisions from the 2002 model act. The bill deters investment scams and harm to Alaskans by increasing civil penalties and providing resources from those penalties for investor, consumer, or entrepreneurial education. SB 108 also enhances penalties against people who harm older Alaskans.

MS. ANSELM offered to review the summary of changes from version A to version W and the sectional analysis.

[1:41:13 PM](#)

SENATOR COGHILL requested a review of the changes.

CHAIR MCGUIRE asked Ms. Anselm to review the changes and noted that Senator Micciche joined the committee.

[1:41:34 PM](#)

MS. ANSELM read the following summary of changes between version A and version W of SB 108.

Structural Changes. The order of the sections has been reorganized. SB 108A was drafted with the new AS 45.56 Alaska Securities Act at the beginning of the bill

with other statutes amended in numerical order at the end. SB 108 CS W now follows the order of the statutes amended beginning with Title 06.

Drafting. Legislative Counsel made conforming drafting and legal improvements throughout the bill including consolidating definitions into Article 7, Sec 45.56.740 or citing to existing definitions in other statutes.

**Sec. 1 - 24.** Renumbered from SB108A and moved to the front of the bill. SB 108 A, Sec. 7. AS 21.42.315(k) is deleted because 'variable annuity' is removed from the definition of security (see Article 7 Definitions)

**Sec. 25. Chapter 56. Alaska Securities Act** (pg. 14)

**Article 1. General Provisions.** No changes.

**Article 2. Exemptions from Registration of Securities.** Small intrastate securities offerings (referred to as "Crowdfunding") was removed at the request of Senate Labor and Commerce (SB 126 contains similar provisions)

**Article 3. Registration of Securities and Notice Filing of Federal Covered Securities.** No substantive changes.

**Article 4. Broker-dealers, Agents, Investment Advisers, Investment Adviser Representatives, and Federal Covered Investment Advisers.** No substantive changes.

**Article 5. Fraud and Liabilities.** No substantive changes.

**Article 6. Administration and Judicial Review.** (pp. 66-86)

**Sec. 45.56.605(e)** relating to the securities education and training fund was moved to a **new Sec. 45.56.625 Securities investor education and training fund.**

**Sec. 45.56.625 Jurisdiction** contents were combined with **Sec. 45.56.635 Applicability of the chapter.**

**Sec. 45.56.660. Civil liability and Sec 45.56.665 Rescission Offers.** The legal rate of interest for rescission and civil enforcement is the legal rate of interest under AS 09.30.970 **or eight percent a year, whichever is greater.** (Bold is new)

**Article 7. Miscellaneous and Additional General Provisions.**

**Sec. 45.56.900. Definitions.**

(23) Older Person (formerly Older Alaskan)- a natural person that is age 60 or older (adapted from AS 47.26.290(6))

(32) Security - "variable annuity" is deleted from the definition

**Sections 26- 35.** No substantive changes.

[1:44:49 PM](#)

SENATOR COGHILL asked if the two statutes were separated for ease of application.

MS. ANSELM confirmed that it will be much easier for the public and the corporations if the statutes relating to securities are lifted out of the statutes that relate to the Alaska Native Claims Settlement Act proxy solicitations.

SENATOR COGHILL asked why variable annuity was removed.

MS. ANSELM said the insurance industry is concerned that including variable annuity in the Securities Act would result in more regulation over that section of the industry. The division does not agree and the topic will likely be discussed in the future.

SENATOR WIELECHOWSKI asked how variable annuities will be regulated in Alaska

MS. ANSELM replied the same as they are now, which is through the Insurance Act.

SENATOR WIELECHOWSKI asked if that is standard practice among states.

MS. ANSELM said they're regulated a variety of ways and it's something the division wants to vet further before bringing the issue up again.

SENATOR WIELECHOWSKI asked if the division has had many complaints about the way variable annuities are dealt with in Alaska.

MS. ANSELM said there have been complaints and often they bridge insurance and securities because variable annuity sales people are often also registered as securities sales people. She reported that the two divisions work well together to address the complaints.

CHAIR MCGUIRE informed the committee that Renee Wardlaw with the Department of Law and Kristy Naylor with the Division of Banking and Securities are available to answer questions.

SENATOR COGHILL asked if either has concerns with the bill.

[1:48:54 PM](#)

KRISTY NAYLOR, Securities Examiner, Division of Banking and Securities, Department of Commerce, Community and Economic Development (DCCED), stated the department has no concerns with the way SB 108 is drafted.

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CHAIR MCGUIRE closed public testimony on SB 108.

[1:49:36 PM](#)

SENATOR COGHILL moved to report the CS for SB 108(L&C) from committee with individual recommendations and attached fiscal note(s).

CHAIR MCGUIRE announced that without objection, CSSB 108(L&C) is reported from Senate Judiciary Standing Committee.

**SB 113-NEW DRUGS FOR THE TERMINALLY ILL**

[1:50:02 PM](#)

CHAIR MCGUIRE announced the consideration of SB 113. [This is the first hearing and CSSB 113(HSS) is before the committee.]

[1:50:27 PM](#)

SENATOR WIELECHOWSKI, Alaska State Legislature sponsor of SB 113, introduced the bill speaking to the following sponsor statement:

Senate Bill 113 would create a legal climate in which terminally ill patients who have exhausted other available treatments and do not qualify for clinical trials could 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.

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, but not fully approved. 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 can wait.

Since 2014, at least 44 states have seen "right to try" legislation introduced, 12 of which still have bills pending and 25 of which have signed bills into law with strong, largely unanimous, bi-partisan support. It is clear this is a human issue and one that goes beyond state and party lines.

In providing terminal patients the ability to access safe, but experimental drugs in consultation with a doctor they trust, this bill offers new hope when all FDA-approved options have been exhausted.

SENATOR WIELECHOWSKI said this bill is intended for the 97 percent of terminally ill people who apply for clinical trials but are not accepted.

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BROOKE IVY, Staff, Senator Wielechowski Alaska State Legislature, explained that the goal of SB 113 is to create a legal climate so that terminally ill people can work directly with their doctor and the drug manufacturer to access experimental drugs that have passed phase 1 of the FDA review process.

MS. IVY reviewed the sections of SB 113.

**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, 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.

**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.

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KURT ALTMAN, Attorney, Goldwater Institute, Phoenix, Arizona, testified in support of SB 113. He related he is the drafter of the model legislation commonly referred to as "The Right to Try Bill" and he has traveled across the country advocating for the legislation. He pointed out that there are significant protections in the bill and that this is a last chance for terminally ill patients. For investigational medicine to be eligible under right to try laws, it has to have passed the

safety testing phase 1 of the FDA approval process. More importantly, the drug must be in ongoing phase 2 or phase 3 clinical trials. He confirmed that this is for the 97 percent of terminally ill people who aren't accepted into clinical trials. By the end of this legislative session, he expects that quite a few more states will have passed similar legislation. This has been a two to three year process and patients are finally taking advantage of right to try laws, he said.

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SENATOR COGHILL asked if there have been liability issues or families that feel somebody has been coerced into a treatment program.

MR. ALTMAN said there has been no litigation to date with right to try laws. For someone to receive a trial drug, there has to be a detailed informed consent on behalf of the doctor and patient. In practice, the manufacturers that have agreed to provide these drugs also require a significant, detailed informed consent liability waiver. Each law that has passed has a similar liability waiver as SB 113 for any adverse effect from the investigational drug. It does not waive any claims of medical malpractice.

SENATOR COGHILL asked how the prohibition in Section 4 will work.

[2:00:53 PM](#)

MS. IVY said the provision seeks to allay concerns of health care facilities and hospitals about potentially losing their certificate for Medicare or Medicaid. Other states have passed this legislation with a similar provision. She noted that the Department of Health and Social Services (DHSS) has determined that SB 113 does not impact their operations due to that provision in SB 113.

[2:02:11 PM](#)

MICHAEL MAHARREY, National Communications Director, 10th Amendment Center, testified in support of SB 113. He said that when the Center heard about the issue from the Goldwater Institute, they knew they could support it without reservation. SB 113 will take the decision-making process regarding a patient's treatment options out of the hands of detached individuals and put it where it belongs, with the patient and their physician. He commented on the FDA approval process for new drugs that is slow and cumbersome, and described right to try laws as a bridge that spans the gap between federal

regulations and the needs of terminally ill patients. He urged the committee to pass SB 113.

[2:04:52 PM](#)

CHARLOTTE WHITELEY, representing herself, testified in support of SB 113. She shared a story about her father who was able to participate in an experimental drug trial that helped him live an extra 3 years. It was particularly important to him to know that his data would be used to help future generations who get multiple myeloma. She also described the case of a friend with multiple sclerosis who participated in a drug trial in Switzerland. A new and better drug is being developed as a result of that trial. SB 113 allows people who are going to die from their disease, a chance to give to the future.

[2:06:35 PM](#)

KEN LANDFIELD, representing himself, testified in support of SB 113. He said the situation is clear; the bill is designed to provide a last ditch option for someone who is going to die anyway. This is an opportunity for legislators to do the right thing and it has no downside he can see. Further, it will cost virtually nothing.

[2:08:22 PM](#)

CHAIR MCGUIRE closed public testimony on SB 113. She shared a story about her physician father who made the decision to develop a pilot program after the FDA denied the use of an innovative scientific technique for his patients.

SENATOR COGHILL asked if a report goes back to the FDA to add to the data on the experimental drug

MS. IVY said SB 113 does not include reporting requirements but her understanding is that it is a requirement in the contracts with manufacturers under both compassionate use and right to try.

SENATOR COGHILL expressed satisfaction.

CHAIR MCGUIRE commented further on the pilot program her father developed.

[2:13:23 PM](#)

SENATOR COGHILL moved to report the CS for SB 113, labeled 29-LS0783\E, from committee with individual recommendations and attached fiscal note(s).

2:14:04 PM

SENATOR WIELECHOWSKI said he was surprised and pleased to learn that the Goldwater Institute supports the legislation. He credited his staff for doing comprehensive research and described SB 113 as good legislation that could save lives in Alaska.

2:14:25 PM

CHAIR MCGUIRE announced that without objection, CSSB 113(HSS) is reported from Senate Judiciary Standing Committee.

2:14:29 PM

There being no further business to come before the committee, Chair McGuire adjourned the Senate Judiciary Standing Committee at 2:14 p.m.