SB 113

<TARGET><BILL>SB 113</BILL><SUBJECT>SB 113</SUBJECT><COMM>SJUD29</COMM></TARGET>

SENATE COMMITTEE REPORT

DATE: 4/1/16

FURTHER: Rules

DATE TURNED IN TO OFFICE: 4/11/16

Judiciary Committee considered SENATE BILL NO. 113

SB 113-NEW DRUGS FOR THE TERMINALLY ILL

"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."

and recommends:

[~~✓~~] be **replaced** with **CS** _____ (_____) *[ ] Same Title [ ] New Title*

[~~✓~~] adopt **previous CS** SB 113 (HSS) , *~~✓~~ Same Title [~~✓~~ New Title*

[ ] attached amendment(s)

[ ] adopt _____ Letter of Intent

[ ] further referral to _____ Committee

Dept Abbr.	
ADM	LWF
CED	LAW
COR	LEG
EED	MVA
DEC	DNR
DFG	DPS
GOV	REV
DHS	DOT
AJS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
CED			✓	1

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
John Coghill	Coghill	✓			
	Wielechowski	✓			
		✓			
CHAIR:	MCGUIRE				

29-LS0783\E

CS FOR SENATE BILL NO. 113(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 4/1/16
Referred: Judiciary

Sponsor(s): SENATOR WIELECHOWSKI

- 27 States
- Goldwater Institute

A BILL

FOR AN ACT ENTITLED

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

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 08.64.367 is amended by adding new subsections to read:

(c) A physician may not be subject to disciplinary action by the board for prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient if the patient

(1) has a terminal illness;

(2) is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;

(3) has considered, after consultation with the physician, all other treatment options currently approved by the United States Food and Drug Administration; and

(4) has given informed consent in writing for the use of the investigational drug, biological product, or device.

(d) In this section,

(1) "investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase 1 studies of clinical trials for investigation and remains in ongoing clinical trials under Phase 2 or Phase 3, but has not been approved for general use by the United States Food and Drug Administration;

(2) "terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

*** Sec. 2.** AS 09.65 is amended by adding a new section to read:

Sec. 09.65.325. Immunity relating to use of investigational drugs, biological products, and devices. (a) A person is not liable in an action for damages for the injury or death of a patient with a terminal illness resulting from the patient's use of an investigational drug, biological product, or device if the person, acting in good faith and with reasonable care, is a

(1) physician or member of the medical team who prescribed, dispensed, or administered the investigational drug, biological product, or device, or provided related treatment, to the patient and, before prescribing, dispensing, or administering the drug, product, or device, or providing related treatment, the physician or member of the medical team

(A) obtained the informed consent of the patient in writing after presenting to the patient all treatment options currently approved by the United States Food and Drug Administration for treatment of the patient's terminal illness; and

(B) provided written notice of the immunity provided under this section to the patient; or

(2) manufacturer, importer, or distributor of the investigational drug, biological product, or device and, before providing the drug, product, or device to the patient's physician, presented to the physician all treatment options currently approved by the United States Food and Drug Administration for treatment of the patient's terminal illness and provided written notice of the immunity provided under this section to the patient.

(b) In this section, "investigational drug, biological product, or device" and "terminal illness" have the meanings given in AS 08.64.367.

*** Sec. 3.** AS 17.20.110 is amended by adding a new subsection to read:

(b) This section does not apply to a physician who prescribes or administers a new drug in accordance with the conditions set out in AS 08.64.367(c).

*** Sec. 4.** AS 47.32.030 is amended by adding a new subsection to read:

(d) The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, "investigational drug, biological product, or device" has the meaning given in AS 08.64.367.

ALASKA STATE LEGISLATURE

Session

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Senator.Bill.Wielechowski@akleg.gov

Resources Committee

State Affairs Committee

Joint Armed Services Committee

Judiciary Committee

SENATOR BILL WIELECHOWSKI

Senate Bill 113 – Explanation of Changes
Version A to Version E

1. **Page 1, Lines 11 following "illness;":** Inserts a new subsection to read "is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;"

   The intent of this subsection is to prevent damage to clinical trial participation. By ensuring patients have already attempted to enter a clinical trial, this protects both the trial and helps to better target the 97% of patients who do not meet strict clinical trial requirements, and thus have no other recourse.

2. **Removes former Section 1(d) of the prior version A:** "A hospital or health facility may not interfere with the physician-patient relationship by restricting or forbidding the use of investigational drugs, biological products, or devices when prescribed, dispensed, or administered by a physician under (c) of this section."

3. **Page 2, Line 9 following "investigation":** Inserts "and remains in ongoing clinical trials under Phase 2 or Phase 3"

   Amends the definition of "investigational drug, biological product, or device" to require the investigational drug be in an *ongoing* clinical trial. This change protects patients by preventing manufacturers from stopping trials after Phase 1 simply to push their product. Remaining in ongoing trials through Phase 2 or 3 means that the investigational drug is moving toward approval, results are proving beneficial, and a company is investing money into the process because they believe it will eventually get to market.

4. **Page 2, Line 21 following "physician":** Inserts "or member of the medical team"

   Extends immunity protections to a physician's medical team members, as they may be involved in administering the investigational drug along with the physician.

5. **Page 3, Line 11 following "AS 08.64.367(c)":** Inserts Section 4 to read "The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, 'investigational drug, biological product, or device' has the meaning given in AS 08.64.367."

   Amends statute to prohibit 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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Resources Committee

State Affairs Committee

Joint Armed Services Committee

Judiciary Committee

SENATOR BILL WIELECHOWSKI

SECTIONAL ANALYSIS
Senate Bill 113 ver E
The Right to Try: New Drugs for the Terminally Ill

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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Resources Committee

State Affairs Committee

Joint Armed Services Committee

Judiciary Committee

SENATOR BILL WIELECHOWSKI

MEMORANDUM

March 31, 2016

TO: **Senator Lesil McGuire, Chair**
Senate Judiciary Committee

FROM: **Senator Bill Wielechowski**

SUBJ: **Hearing Request for SB 113 – New Drugs for the Terminally Ill**

I am writing to respectfully request a hearing for Senate Bill 113: New Drugs for the Terminally Ill. 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 and after exhausting other available options, the freedom to access safe, but experimental drugs in an effort to save their own lives.

Included in this bill packet:

- SB 113 Sponsor Statement
- SB 113 ver H
- SB 113 ver H Sectional Analysis
- SB 113 Fiscal Note – DCCED-CBPL-02-19-16
- SB 113 Explanation of Changes ver A to ver H
- SB 113 Supporting Documents
    - Legislative Map 3-31-16
    - Goldwater Institute Patient Stories
    - Goldwater Institute Fact Sheet
    - FDA Drug Review Process
    - Goldwater Institute Policy Report Summary 2-11-14
    - Clinical Trials in Alaska
    - Letter of Support Dr. Huang 2-1-16
    - Letter of Support 10th Amendment Center 2-9-16
    - Letter of Support Charlotte Whiteley 2-24-16
    - Letter of Support Dixie Hood 1-30-16
    - Letter of Support Dr. Urata 2-1-16

If you have any questions please feel free to contact me or my staff person, Brooke Ivy, at 465-2435. Thank you for your consideration of this request.

ALASKA STATE LEGISLATURE

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Resources Committee

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SENATOR BILL WIELECHOWSKI

SPONSOR STATEMENT

Senate Bill 113

The Right to Try: New Drugs for the Terminally Ill

"Patients should be free to exercise a basic freedom – attempting to preserve one's own life."
- Christina Corieri, Health Care Policy Analyst

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, 49 states have seen "right to try" legislation introduced, 26 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. I urge your support of Senate Bill 113.

29-LS0783\H
Bruce
1/28/16

CS FOR SENATE BILL NO. 113( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): SENATOR WIELECHOWSKI

A BILL

FOR AN ACT ENTITLED

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

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 08.64.367 is amended by adding new subsections to read:

(c) A physician may not be subject to disciplinary action by the board for prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient if the patient

(1) has a terminal illness;

(2) is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;

(3) has considered, after consultation with the physician, all other treatment options currently approved by the United States Food and Drug Administration; and

(4) has given informed consent in writing for the use of the investigational drug, biological product, or device.

(d) In this section,

(1) "investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase 1 studies of clinical trials for investigation and remains in ongoing clinical trials under Phase 2 or Phase 3, but has not been approved for general use by the United States Food and Drug Administration;

(2) "terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

* **Sec. 2.** AS 09.65 is amended by adding a new section to read:

Sec. 09.65.325. Immunity relating to use of investigational drugs, biological products, and devices. (a) A person is not liable in an action for damages for the injury or death of a patient with a terminal illness resulting from the patient's use of an investigational drug, biological product, or device if the person, acting in good faith and with reasonable care, is a

(1) physician or member of the medical team who prescribed, dispensed, or administered the investigational drug, biological product, or device, or provided related treatment, to the patient and, before prescribing, dispensing, or administering the drug, product, or device, or providing related treatment, the physician or member of the medical team

(A) obtained the informed consent of the patient in writing after presenting to the patient all treatment options currently approved by the United States Food and Drug Administration for treatment of the patient's terminal illness; and

(B) provided written notice of the immunity provided under this section to the patient; or

(2) manufacturer, importer, or distributor of the investigational drug, biological product, or device and, before providing the drug, product, or device to the patient's physician, presented to the physician all treatment options currently approved by the United States Food and Drug Administration for treatment of the patient's terminal illness and provided written notice of the immunity provided under this section to the patient.

(b) In this section, "investigational drug, biological product, or device" and "terminal illness" have the meanings given in AS 08.64.367.

* **Sec. 3.** AS 17.20.110 is amended by adding a new subsection to read:

(b) This section does not apply to a physician who prescribes or administers a new drug in accordance with the conditions set out in AS 08.64.367(c).

* **Sec. 4.** AS 47.32.030 is amended by adding a new subsection to read:

(d) The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, "investigational drug, biological product, or device" has the meaning given in AS 08.64.367.

ALASKA STATE LEGISLATURE

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Resources Committee

State Affairs Committee

Joint Armed Services Committee

Judiciary Committee

SENATOR BILL WIELECHOWSKI

SECTIONAL ANALYSIS
Senate Bill 113 ver H
The Right to Try: New Drugs for the Terminally Ill

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.

Fiscal Note

State of Alaska
2016 Legislative Session

Bill Version: SB 113
Fiscal Note Number:
() Publish Date:

Identifier: SB113-DCCED-CBPL-02-19-16
Title: NEW DRUGS FOR THE TERMINALLY ILL
Sponsor: WIELECHOWSKI
Requester: (S) Health and Social Services

Department: Department of Commerce, Community and Economic Development
Appropriation: Corporations, Business and Professional Licensing
Allocation: Corporations, Business and Professional Licensing
OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2017 Appropriation Requested	Included in Governor's FY2017 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2017**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							

Estimated SUPPLEMENTAL (FY2016) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2017) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By: Janey Hovenden, Director — Phone: (907)465-2536
Division: Corporations, Business and Professional Licensing — Date: 02/19/2016 10:35 AM
Approved By: Catherine Reardon, Director — Date: 02/19/16
Agency: Division of Administrative Services, DCCED

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2016 LEGISLATIVE SESSION

BILL NO. SB 113

Analysis

SB113 would provide certain immunities to prescribing physicians, manufacturers, and distributors acting in good faith to allow terminally ill patients who have exhausted other available treatments faster access to experimental drugs, without waiting for federal approval.

This legislation prohibits disciplinary action against physicians by the State Medical Board for prescribing, dispensing or administering an investigational drug, biological product, or device to terminally ill patients who have considered all other treatment options approved by the FDA. In addition, it prevents hospitals and health facilities from restricting the use of investigational drugs as provided.

This legislation establishes immunity for physicians, 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.

This legislation amends the statute limiting the sale and distribution of new drugs so as not to apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1.

The Division of Corporations, Business, and Professional Licensing does not anticipate fiscal impact from this legislation.

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Resources Committee

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Judiciary Committee

SENATOR BILL WIELECHOWSKI

Senate Bill 113 – Explanation of Changes
Version A to Version H

1. **Page 1, Lines 11 following "illness;":** Inserts a new subsection to read "is ineligible or unable to participate in a current clinical trial for the investigational drug, biological product, or device;"

   The intent of this subsection is to prevent damage to clinical trial participation. By ensuring patients have already attempted to enter a clinical trial, this protects both the trial and helps to better target the 97% of patients who do not meet strict clinical trial requirements, and thus have no other recourse.

2. **Removes former Section 1(d) of the prior version A:** "A hospital or health facility may not interfere with the physician-patient relationship by restricting or forbidding the use of investigational drugs, biological products, or devices when prescribed, dispensed, or administered by a physician under (c) of this section."

3. **Page 2, Line 9 following "investigation":** Inserts "and remains in ongoing clinical trials under Phase 2 or Phase 3"

   Amends the definition of "investigational drug, biological product, or device" to require the investigational drug be in an *ongoing* clinical trial. This change protects patients by preventing manufacturers from stopping trials after Phase 1 simply to push their product. Remaining in ongoing trials through Phase 2 or 3 means that the investigational drug is moving toward approval, results are proving beneficial, and a company is investing money into the process because they believe it will eventually get to market.

4. **Page 2, Line 21 following "physician":** Inserts "or member of the medical team"

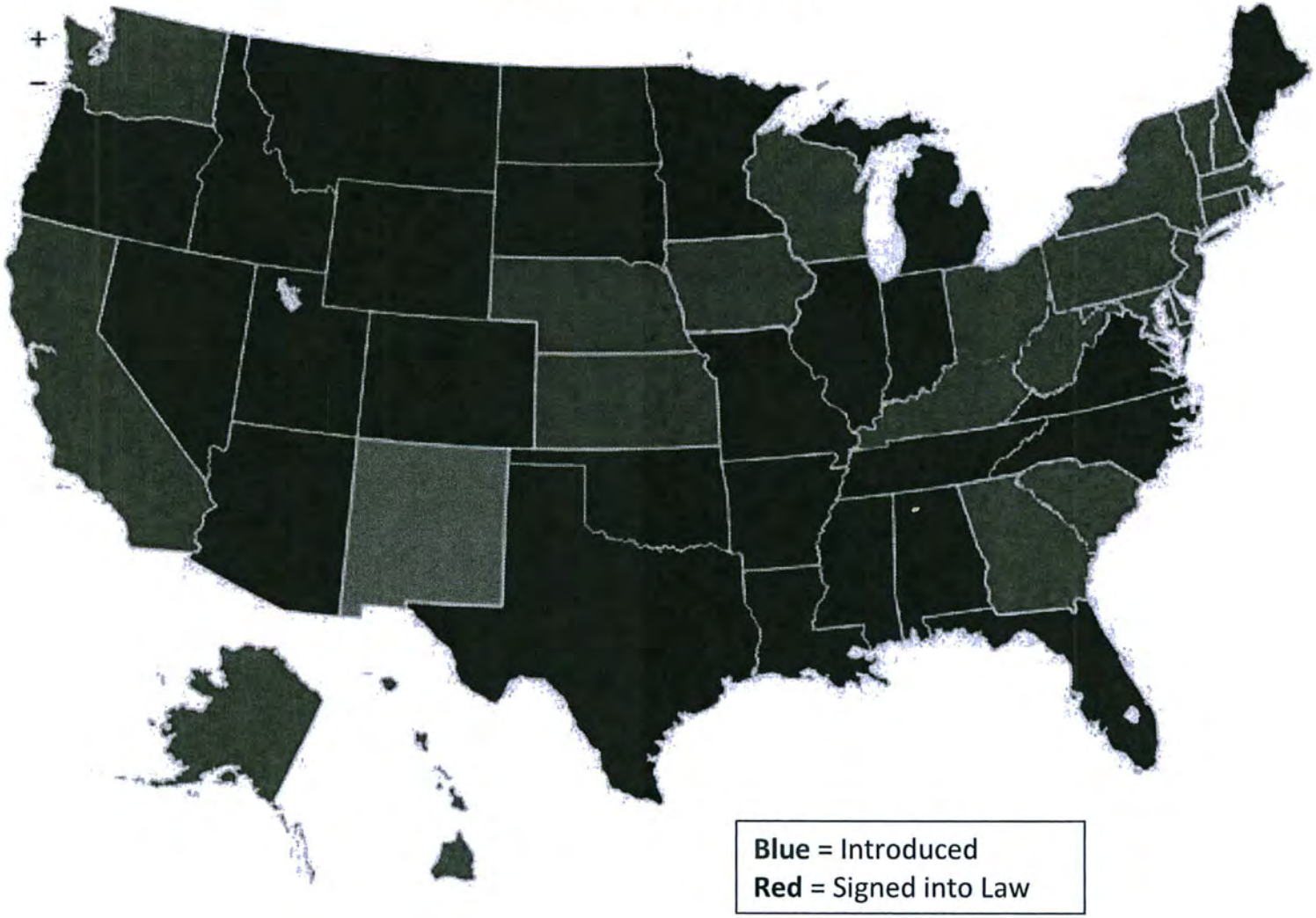
   Extends immunity protections to a physician's medical team members, as they may be involved in administering the investigational drug along with the physician.

5. **Page 3, Line 11 following "AS 08.64.367(c)":** Inserts Section 4 to read "The department may not require a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment, to a patient. In this subsection, 'investigational drug, biological product, or device' has the meaning given in AS 08.64.367."

   Amends statute to prohibit 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.

"Right to Try" Legislative Map

Updated: March 31, 2016



Source: http://tracking.tenthamendmentcenter.com/issues/right-to-try/#

Right To Try: Patient Stories

Jordan McLinn

Six-year-old Jordan says he wants to grow up to be a firefighter so he can save lives. Jordan has Duchenne muscular dystrophy, which could leave him paralyzed within 5 years and shortens his life expectancy to only 20 years. There is a drug being used in clinical trials now that is helping young children like Jordan. But it could take another seven years for the drug to be available. His parents say they cannot afford to wait for the FDA to give the drug its final approval. He could be in a wheelchair by then. An investigational drug could add years to Jordan's life, which would give him the chance to save others.

Josh Hardy

By the time Josh Hardy was seven years old he had already beat cancer four times. After a bone marrow transplant, he was infected with a rare virus that no drug on the market could effectively treat. But there was a new medicine being made in North Carolina that was having a positive effect in a small clinical trial. But Josh's doctors couldn't get access to it. Aimee, Josh's mom, started telling Josh's story to anyone who would listen. She created a social media campaign that got worldwide attention. Finally, the FDA and the drug company agreed to let Josh have the drug they were already safely giving to others enrolled in the clinical trial. Now, a year later, Josh is home and healthy. It's no exaggeration to say this investigational drug saved his life.

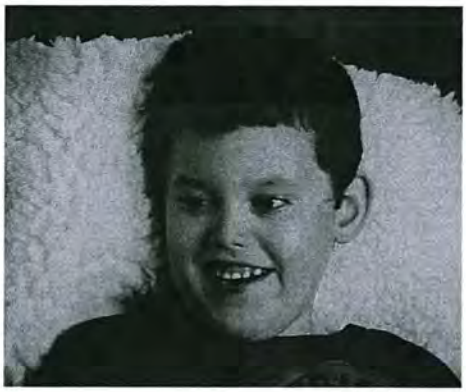
Mikaela Knapp

At 24, Mikaela was diagnosed with a deadly form of kidney cancer that had already migrated into her bones before she even knew she was sick. She went through every known treatment in a matter of months and nothing worked. Mikaela's high school sweetheart, Keith, heard about a drug under development that was successfully treating people with this same cancer. But Mikaela wasn't allowed to enroll in the clinical trial. Mikaela and Keith launched a social media campaign to try to get access to the drug. But it wasn't enough. The FDA didn't help. Mikaela died on April 24, 2014. Five months later, on September 4, the FDA gave final approval to the drug that could have saved her.

Right To Try: Patient Stories

Diego Morris

When 10-year-old Diego woke up with a sore leg, his mom thought "just another sports injury." When the pain didn't go away, they knew something was wrong. But they never expected Osteosarcoma, a rare form of bone cancer. After exhausting all treatment options available, Diego's doctors recommended he try, Mifamurtide, which wasn't available in the United States, but was being safely used and had been given the Prix Galien Award, the gold medal for pharmaceutical research and development, in England. The Morris family wasted no time, and made the move abroad to try to save Diego's life. The treatments worked and now Diego is home in Phoenix, Ariz. and back to playing his favorite sports. Without access to this drug, currently under approval in the U.S., Diego's story could have ended very differently.



Bertrand Might

Bertrand is a very special little boy. He was the first person ever to be diagnosed with a rare, fatal genetic disorder called NGLY1 that has left this seven-year-old paralyzed. Because the disease was only identified by scientists in 2012, and only a few people worldwide have been diagnosed with it, there is no cure and no treatment available. Because the disorder is so rare, a drug may not ever be developed to treat it. But, scientists have found that Bertrand responds to certain investigational therapies. So, Bertrand's family will have to rely on trying new, investigational medications as long as they have access to them.

Ted Harada

Ted was diagnosed with ALS at 38. With no cure, ALS is a certain death sentence—and usually within three years. Ted didn't want to leave his wife and three young children behind in his early 40s. That was just too soon. Lucky for Ted, he was able to enroll in a clinical trial testing a new ALS treatment. Within weeks of beginning the investigational treatment, something miraculous began to happen. Ted set aside his cane and started to regain his strength. While the ALS didn't go away, the symptoms began to subside, allowing him to walk 2.5 miles for ALS awareness in a local campaign. Ted is still going strong because of the investigational treatment he is receiving, and now he is fighting for the right of all terminally ill people to take investigational medications.

GOLDWATER
INSTITUTE
Where freedom wins.

Facts About "Right To Try"

For terminal patients who have exhausted their conventional treatment options, obtaining access to potentially life-saving investigational medications is often extremely difficult. The patient can attempt to enroll in a clinical trial, but many of the sickest individuals do not qualify. In fact, only 3 percent of patients today are enrolled in clinical trials. For everyone else, their only hope for obtaining potentially life-saving medications is to ask the FDA for special permission.

Only about 1,000 people make it through the FDA's "compassionate use" application process each year. The process is complicated, time-consuming, and expensive. The first step in the process requires a doctor to complete an application that the FDA estimates takes 100 hours. After the doctor submits the application to the FDA, the manufacturer must also submit lengthy documentation requirements. The FDA then has a month to review the submission and either grant or deny the request, but if there are any questions the one-month clock starts over. After the FDA approves a request, a separate committee not affiliated with the FDA, called an Institutional Review Board, also must approve the patient's use of the drug. The Institutional Review Board can sometime take up to a month to reach a decision.

Sadly, there are many documented cases of patients dying while their application is being considered. Almost a year ago the FDA announced plans to shorten the application, but the other steps will still remain in place. The shorter form is still not available. A shorter application for the first step is helpful, but it only addresses one part of the approval process. And ultimately, it's still an application to the government to ask permission to try to save your own life. If you have a terminal illness, you don't have time for a multi-step government process. If your child is dying from a terminal illness and you know there's an investigational medication that is already helping other children survive, a shorter form isn't good enough.

We need to remove barriers that limit doctors from providing the care they are trained to give—and this is exactly what Right To Try does.

Right To Try allows terminally ill Americans to try medicines that have passed Phase 1 of the FDA approval process but are not yet on pharmacy shelves. Right To Try expands access to potentially life-saving treatments years before patients would normally be able to access them.

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Under Right To Try, a terminal patient would be able to access an investigational medicine if:

- ✓ The patient has a terminal disease and has exhausted all conventional treatment options;
- ✓ The patient's doctor has advised the use of an investigational medication;
- ✓ The medication has successfully completed basic safety testing and is part of the FDA's on-going approval process;
- ✓ The patient has provided "informed consent" acknowledging the potential risk of the drug; and
- ✓ The company developing the medication is willing to make it available to the patient.

Right To Try includes important protections. The basic safety testing and informed consent requirements protect the patient. And doctors and the manufacturer are protected from liability if the investigational medication doesn't work. But this is not protection from medical malpractice.

Right To Try is already law in 24 states: Alabama, Arizona, Arkansas, Colorado, Florida, Illinois, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, North Carolina, North Dakota, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Virginia, and Wyoming. And it has passed with overwhelming bipartisan support in each state. It has been introduced in 12 additional states this year. Right To Try isn't a red or blue issue; it's a human dignity issue. That's why lawmakers from both sides of the aisle are coming together to give their citizens the Right To Try.

The FDA says providing dying people with investigational medications should be an exception. We think it should be the rule. People fighting for their lives should have access to medicines that could save them without needing a permission slip from the government.

For more information about Right To Try visit goldwaterinstitute.org. Or contact Kurt Altman, kaltman@goldwaterinstitute.org, (602) 462-5000.

The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective

The path a drug travels from a lab to your medicine cabinet is usually long, and every drug takes a unique route. Often, a drug is developed to treat a specific disease. An important use of a drug may also be discovered by accident.

For example, Retrovir (zidovudine, also known as AZT) was first studied as an anti-cancer drug in the 1960s with disappointing results. Twenty years later, researchers discovered the drug could treat AIDS, and Food and Drug Administration approved the drug, manufactured by GlaxoSmithKline, for that purpose in 1987.

Most drugs that undergo preclinical (animal) testing never even make it to human testing and review by the FDA. The drugs that do must undergo the agency's rigorous evaluation process, which scrutinizes everything about the drug--from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured.

Stages of Drug Development and Review

Animals Tested

Investigational New Drug Application (IND)--The pharmaceutical industry sometimes seeks advice from the FDA prior to submission of an IND.

Sponsors--companies, research institutions, and other organizations that take responsibility for developing a drug. They must show the FDA results of preclinical testing in laboratory animals and what they propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe for the company to move forward with testing the drug in humans.

Clinical Trials--Drug studies in humans can begin only after an IND is reviewed by the FDA and a local institutional review board (IRB). The board is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research.

IND Application

IRBs approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details. IRBs make sure the study is acceptable, that participants have given

consent and are fully informed of their risks, and that researchers take appropriate steps to protect patients from harm.

Phase 1 Testing

Phase 1 studies are usually conducted in healthy volunteers. The goal here is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. The number of subjects typically ranges from 20 to 80.

Phase 2 Testing

Phase 2 studies begin if Phase 1 studies don't reveal unacceptable toxicity. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually an inactive substance (placebo), or a different drug. Safety continues to be evaluated, and short-term side effects are studied. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300.

Phase 3 Testing

At the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale studies in Phase 3 should be done. How often the FDA meets with a sponsor varies, but this is one of two most common meeting points prior to submission of a new drug application. The other most common time is pre-NDA--right before a new drug application is submitted.

Phase 3 studies begin if evidence of effectiveness is shown in Phase 2. These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people.

Review Meeting

Postmarket requirement and commitment studies are required of or agreed to by a sponsor, and are conducted after the FDA has approved a product for marketing. The FDA uses postmarket requirement and commitment studies to gather additional information about a product's safety, efficacy, or optimal use.

NDA Application

New Drug Application (NDA)--This is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.

Application Reviewed

When an NDA comes in, the FDA has 60 days to decide whether to file it so that it can be reviewed. The FDA can refuse to file an application that is incomplete. For example, some required studies may be missing. In accordance with the Prescription Drug User Fee Act (PDUFA), the FDA's Center for Drug Evaluation and Research (CDER) expects to review and act

on at least 90 percent of NDAs for standard drugs no later than 10 months after the applications are received. The review goal is six months for priority drugs. (See "The Role of User Fees.")

"It's the clinical trials that take so long--usually several years," says Sandra Kweder, M.D., deputy director of the Office of New Drugs in the CDER. "The emphasis on speed for FDA mostly relates to review time and timelines of being able to meet with sponsors during a drug's development," she says.

POLICY report

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Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment

by Christina Corieri, Health Care Policy Analyst

EXECUTIVE SUMMARY

In 2002, Kianna Karnes, a 41-year-old mother of four children, was diagnosed with kidney cancer.[1] She was treated with interleukin-2, the only medication approved by the Food and Drug Administration (FDA) at the time to treat her disease. When that treatment failed, her father began researching investigational medications, learning in 2004 that both Pfizer and Bayer were conducting clinical trials for new investigational medications to treat kidney cancer. Karnes was ineligible for the clinical trial because her cancer had previously spread to her brain. Although her brain tumors had been removed, she was still disqualified from joining the clinical trial, so her father sought expanded access for his daughter. Months passed before he was able to secure access for his daughter. He contacted Congressman Dan Burton's (R-IN) office for assistance, and drew media coverage of Karnes' struggle in the *Wall Street Journal*. On March 24, 2005, the FDA notified the family that it had approved a single-patient IND for Karnes. Tragically, it was too late—Kianna Karnes died the same day access was approved.[2] Less than a year later, both drugs were given final FDA approval to treat advanced kidney cancer. Speaking after his daughter's death, her father said, "I don't know that either of these drugs would have saved Kianna's life, but wouldn't it be nice to give her a chance?"[3]

In the case of Kianna Karnes, she had a better chance than most patients at receiving expanded access. As her father explained, "Here is a case where her old man understood clinical trials. I knew about compassionate use; I had a friendship with a powerful member of Congress; I've got the *Wall Street Journal* behind me. But I still couldn't save her life. Now, what about the thousands of people out there who don't have these kinds of resources available to them?"[4] To most patients, and many physicians outside of major institutions, the process of obtaining expanded access is excessively time-consuming and extremely difficult to navigate.

For patients suffering from terminal illnesses, the FDA is the arbiter of life and death. These patients, suffering from diseases ranging from ALS to Zellweger Syndrome, face little chance of recovery. For patients like Kianna, investigational medicines provide a glimmer of hope. The FDA, however, often stands between the patients and the treatments that may alleviate their symptoms or provide a cure. To access these treatments, patients must either go through a lengthy FDA exemption process or wait for the treatments to receive FDA approval, which can take a decade or more and cost hundreds of millions of dollars. Sadly, over half a million cancer patients and thousands of patients with other terminal illnesses die each year as the bureaucratic wheels at the FDA slowly turn.[5]

Patients should be free to exercise a basic freedom – attempting to preserve one's own life. The burdens imposed on a terminal patient who fights to save his or her own life are a violation of personal liberty. Such people should have the option of accessing investigational drugs which have passed basic safety tests, provided there is a doctor's recommendation, informed consent, and the willingness of the manufacturer of the medication to make such drugs available.

States should enact "Right to Try" measures to protect the fundamental right of people to try to save their own lives. Designed by the Goldwater Institute, this initiative would allow terminal patients access to investigational drugs that have completed basic safety testing, thereby dramatically reducing paperwork, wait times and bureaucracy, and, most importantly, potentially saving lives.

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patient who met the stated criteria from accessing investigational medications. Likewise, other procedural burdens such as the IND application and IRB review requirement could be deemed undue burdens and either eliminated or drastically curtailed.

The concept of ordered liberty cannot include allowing a government agency to promulgate and enforce regulations that impair an individual's health or cause death by denying or delaying access to potentially life-saving medications. The way in which the FDA currently regulates access to investigational medications may be rational for non-terminal patients, but its application to terminal patients, who lack other treatment options, is not. Preventing such a patient from accessing a potentially life-saving medication will, without question, result in the fulfillment of the diagnosis — death.

Without the action of state lawmakers, terminal patients are at the mercy of a federal bureaucracy that can literally cause death by delays, denials, and unnecessary procedural requirements.

"It has long been established that the U.S. Constitution creates a floor of protection for individual rights – not a ceiling. States can and do provide additional and enhanced protections for individuals.

Conclusion

From her sickbed, Edie Bacon wrote of the travails a terminal patient faces and made a final plea for the only medication that might save her. "The government wants proof of efficacy before it will allow me to take this drug outside of an approved trial. But the 'proof' is years away, and I need the drug now. It's safe. It might work. Johnson & Johnson would let me have it if they could do so without the threat of a government hassle. But they're so caught up in the FDA web that the life of an individual patient has no importance whatsoever. Without ET 743, I'm a dead woman walking. Five kids are going to wonder why they're left without a mother. Won't somebody help me get this drug?"[130] Edie died two years later, but there are thousands of patients who face this same battle every day – patients who have to make the same pleas that Edie did for a chance to try to protect their own lives.

Such pleas should anger anyone who believes in the concept of personal liberty. No free person should have to come to the government as a supplicant to beg for a right to try to save his or her own life. In a country dedicated to the idea that all people have certain "unalienable Rights, that among these are Life, Liberty, and the Pursuit of Happiness," no government official should have the power to deny a person's last chance at all three – life, liberty, and happiness.[131] Yet that is the power the FDA wields today. States should challenge this regulatory authority by passing Right to Try and returning medical decision making back to the rightful hands of patients and doctors.

The Goldwater Institute

The Goldwater Institute was established in 1988 as an independent, non-partisan public policy research organization. Through policy studies and community outreach, the Goldwater Institute broadens public policy discussions to allow consideration of policies consistent with the founding principles Senator Barry Goldwater championed—limited government, economic freedom, and individual responsibility. Consistent with a belief in limited government, the Goldwater Institute is supported entirely by the generosity of its members.

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Clinical Trials

A student's interviews of nurses, patients and survivors experience and opinions of cancer and cancer clinical trials in Alaska.

Written by: Jennifer Kiser MSW | Edited by: Amanda McDade
& individual interviews final edited by Interviewee.

Introduction

Clinical Trials in Alaska

This booklet combines a student's interviews of nurses, patients and survivors experience and opinions of cancer and cancer clinical trials in Alaska.

A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments.

Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective.

Contents

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Krista Rangitsch

Research Nurse, Providence Cancer Center

Krista Rangitsch, a research nurse at Providence Cancer Center, works closely with doctors and their patients by providing them with information on clinical trials. She explains that "cancer clinical trials are research studies involving human subjects that look at ways of preventing, detecting, and/or treating cancer in the hopes of improving over all survival and patient quality of life. These trials help doctors find better ways of improving cancer care by answering certain scientific questions."

"Clinical Trials ... look at ways of preventing, detecting, and/or treating cancer."

She also explained "There are a variety of different ways cancer clinical trials are designed. Some trials look at new experimental treatments for cancer, while others look at treatments that are already approved by the United States Food and Drug Administration (FDA) for one type of cancer but are being studied in another type of cancer. Alternatively, clinical trials can compare the difference between two or more treatment regimens (i.e. medication "A" compared to medication "B"). Some trials investigate administering an FDA approved medication on a different schedule (i.e. once a week versus every three weeks) or in a different manner (i.e. oral versus intravenous)."

When discussing with a patient potentially interested in participating in a cancer clinical trial, Rangitsch informs them of the risks and benefits of participating and that their insurance may not cover some or all of the care associated with the clinical trial. Acting as an intermediary for the patient, Rangitsch will often contact their insurance provider to request coverage for the routine care costs associated with the clinical trial. Generally the items considered to be investigational are provided at no charge to the participants or their insurance company.

"These trials help doctors find better ways of improving cancer care by answering certain scientific questions"

Some insurance companies have been more difficult to work with than others. One company in particular refused to pay for routine care costs of a patient considering participating in a clinical trial for

her soft tissue sarcoma. Rangitsch stated that the sponsor of the study was willing to "pay for everything outside the standard of care"; meaning that all extra costs would be paid for. The only thing the insurance company was being asked to cover were the routine care costs associated with standard sarcoma care follow-up, which they would have incurred even if the patient was not enrolled in the clinical trial. The patient was very frustrated, saying that she has worked her entire life paying for health insurance coverage and expected that it would be there when she need it. Now, because they will not pay for routine care costs during this clinical trial she is actually considering paying for her treatment out of pocket.

"Clinical trials are the only way to get new drugs approved"

Other insurance companies have made things very easy. Rangitsch mentioned that working with one company in particular has been a great experience; they cover the routine care cost during a clinical trial and the process for approval is clear and simple. Rangitsch has testified as a private citizen in support of Senate Bill 10 which would mandate that insurance companies in Alaska cover the routine care costs associated with a clinical trial. Creating equal access to clinical trials is "so important because it is currently a huge barrier. Clinical trials are how we improve and advance medicine, and clinical trials are the only way to get new drugs approved."

Kathy

Clinical Trials Story

Kathy found a lump in her breast but was not alarmed by it, it just seemed kind of weird that there were little red dots on the outside of the breast and there was something on the inside that was a little bit hard. She thought that cancer was large, defined, marble size lumps, not something like this, so she thought it just might go away and went back to her busy life taking care of her children and supporting her husband. Kathy stated "I wasn't thinking about myself," too much seemed to be going on for her to worry about something that didn't seem like cancer.

Several months later she noticed the lump was still there, and her body started to get progressively weaker. She tried to make an appointment at the local Breast Cancer Detection Center for a mammogram, but was told she needed a prescription. Her insurance company insisted that she go to the urgent care clinic for doctor visits, so she decided to go there hoping they could give her a prescription. Still not too alarmed, because throughout her life she had taken precautions to reduce the risk of cancer, Kathy was checked by an urgent care doctor. Because the urgent care center doctor wouldn't give her a prescription for a mammogram, the Dr., with urgency in her voice, made an appointment for Kathy to be seen by a gynecologist - that hour! It was then that she experienced fear for the first time. She drove straight to the gynecologist's office, and was examined. He stated that he would call and order a mammogram and ultrasound, and that she should make the appointment as soon as possible. She went home a little shook up, and thought about how scared she was over the possibility that she might have breast cancer. Finally, after several days, she got enough nerve to call and make an appointment. However, the next available appointment was three weeks out, which gave her even more time to be frightened.

"I wasn't thinking about myself," too much seemed to be going on for her to worry about something that didn't seem like cancer.

During the mammogram, the radiologist just kept taking pictures. As he looked at the ultrasound he said he thought the mammogram looked "suspicious." Kathy said "I felt sick to my stomach." Not wanting to delay anything further, the radiologist set up an appointment for a biopsy later that week. Since they

were already booked solid, he set it for a time that was outside the normal "biopsy schedule." It was for 7 AM — a time that would be most inconvenient for her, because she had four kids at home to get ready for school. Unable to bare the thought of explaining to her kids why she had to leave so early in the morning, she got up in the middle of the night and left while everyone was sleeping. She left notes for her husband and kids telling them she had gone to her friend's house. Unbeknown to anyone, her friend was going to accompany her to the appointment. The next morning, the gynecologist called her while she was at school with her youngest daughter; he told Kathy it was a malignant tumor.

"I felt sick to my stomach."

According to Kathy, she got up, kissed her six year old daughter, and told her she'd still be at the school, but would be outside. She went to her car, and cried. After a while, she called her mother, her husband, and two of her friends. One of them came up to the school and sat with her in the parking lot — they both cried. She knew she had to collect herself because in just a little while school would be out, and not just for the day; it was the last day of school before summer, and there were year end traditions to uphold.

"Not knowing what her future held, she wondered if this would be the last time she'd ever see her kids poking their heads out the bus window, waving goodbye for the summer."

Things weren't going to change just because she had breast cancer. At her kids' elementary school, on the last day of school, once the kids board the buses for home, they do a bus parade and circle the parking lot several times. The entire school staff comes outside and waves goodbye to the kids. With four kids, this was a tradition she hadn't missed in ten years. She tried to pretend things were perfectly normal but did not do very well. Instead, she felt very emotional.

Not knowing what her future held, she wondered if this would be the last time she'd ever see her kids poking their heads out the bus window, waving goodbye for the summer. Her other daughter's teacher noticed she was teary eyed. Unable to speak at first, she finally got the words out – she was "just diagnosed with breast cancer three hours ago." As difficult as it was for her, she was trying to hide her emotions. She surely didn't want her two youngest daughters seeing her cry. She remembers him putting his arm around her, trying, in his most reassuring tone,

"Kathy wanted to do something... she found a press release on the Zometa clinical trial and showed it to her doctor."

to tell her that she would be okay. The most difficult part for Kathy was the fear of what would happen to her kids if she died.

After visiting the surgeon she felt hopeful because the tumor was less than two centimeters. Things were looking better, and the surgeon was very encouraging. After more than a week of not being able to eat, or even drink water, she was finally able to eat, and enjoyed a plate of fettuccine, which is her favorite food. She had already lost more than five pounds by then. Kathy remembered thinking how she wanted to go on a diet that summer, but the cancer diet was never in the plan.

Kathy wanted to do something. Shortly after her diagnosis, she heard about the drug Zometa. Manufacturer's had been working with Zometa, and found that the drug that has shown positive correlations with fewer reoccurrences of breast cancer. At the time, her Dr. told her Zometa was normally used to treat bone cancer, and they had not heard of it being used to treat breast cancer. A couple of weeks later, at the ASCO Conference in Chicago, it was announced that Zometa had shown promise is a limited clinical trial. Kathy found a press release on the Zometa clinical trial and showed it to her doctor. Her internet research quoted one doctor to say that Zometa will "probably become the standard of care."

It took a lot of thought to make sure it was something she would want to do and wondered if it would be beneficial.

After several months into chemotherapy, Doctor Cox mentioned the Zometa study was expanding and she would be a likely candidate. She advised her to read about the clinical trial to see if it was something she really wanted to pursue. This trial was a much more aggressive treatment than what she had heard about in the previous study. It took a lot of thought to make sure it was something she would want to do and wondered if it would be beneficial. Her initial reasons for participating in the clinical trial were so that she would receive additional treatment. It seemed as though the additional drug would be beneficial. After careful consideration, Kathy decided to enroll in the clinical trial. She was hoping to be randomized to the Zometa arm of the study. Instead, she was selected to take Clodronate, which is not approved in the United States. The three drugs within the study are all in the same drug family and, to her knowledge Clodronate has only been used in the UK, Canada, and Italy. This led her to weigh her options to see if she wanted to drop out or remain in the study. Kathy knew remaining in the study was optional. She began to research Clodronate but she could not find much information about it. What she did find she was conflicting, and there were not any significant end result findings from using this drug. The study is looking at its effectiveness in the reoccurrence of cancer as compared to the other two drugs, Zometa being one of them. Kathy said "I will just go ahead and do it. There are thousands and thousands of women before me that

this was not even offered to, and it has promise. I am fortunate to have this option. A year ago, I would not have had the option to be on this drug." She now has follow-up care scans which would have not been done otherwise. According to Kathy "people are going to monitor me for a long time." In Kathy's case, the standard of care was going to be less than what she will get from the clinical trial.

It was not easy to get on this study. Kathy encountered several challenges when dealing with her insurance company even though she pays $900 dollars a month for health insurance coverage. They denied her requests to participate in the study three times. That was no surprise to her - they denied more than half the cost of her surgery too, possibly due to doing a double mastectomy, rather than the suggested lumpectomy or single mastectomy. Kathy researched her cancer type and felt there was a high chance of the cancer occurring in both breasts, so she opted for the double mastectomy to reduce her risk of reoccurrence. In Kathy's clinical trial, only the drug is paid for by the manufacturer, the follow up care is not. Without approval, remaining on the study would not be an option for her because she could not afford it on her own. Finally, with only three days to spare in the 8 week window, they agreed to cover the costs associated with it.

"There are thousands and thousands of women before me that this was not even offered to, and it has promise. I am fortunate to have this option. A year ago, I would not have had the option to be on this drug."

Kathy continues to fight her breast cancer, and is learning to live with the diagnosis. As the interview ended, she stated "Where ever you go, there you are" because she can't get away from herself. Her diagnosis will follow her wherever she goes. She left me with a quote that she often tells her daughters "The sky is always blue above the clouds. Its always sunny somewhere." This left me with an understanding that Kathy is a fighter, looking for a silver lining in a sky full of gray.

"The sky is always blue above the clouds. Its always sunny somewhere."

Claire

Clinical Trials Story

Claire's sister had breast cancer eight years ago. When Claire found out she too had breast cancer, it was shocking but not surprising. It was found during a mammogram and after three scans, the doctors found the cancerous cells. Claire ended up having a mastectomy which found a small node of cancer. Doctors recommended that she also undergo radiation and chemotherapy but Claire chose not to do either. According to Claire it took a lot of research and studying statistics to figure out her chances of survival.

It took a lot of research and studying statistics to figure out her chances of survival.

In 2006, Claire had the opportunity to be enrolled in a clinical trial for bone strengthening, and she thought it would be beneficial. The trial had several different groups which would be receiving different forms of treatment. Claire would be randomly assigned to a group, but because of her fear of needles, she projected which group she would be in. Just as she had guessed, she was assigned to be in the only group that required an IV. At first, Claire was going to the hospital quite often to have treatments done. As time progressed, she had the IV treatments less often and did not require as many hospital visits. She has had no side effects from the IV treatments unlike the other groups who received different drugs. Because Claire chose to take part in the clinical trial she will receive lab tests and doctors visits to monitor the effectiveness of the treatment for years to come. Claire is convinced that this clinical trial will help her bone strength and decrease the probability of bone cancer.

Not only did Claire receive numerous personal benefits from the clinical trial, she also helped advance research.

Even though there were several positive aspects to the clinical trial, Claire did encounter one problem. During the clinical trial the insurance company would only cover a part of routine care cost during the clinical trial even though some of the treatment options on the clinical trial were well established and widely prescribed in other countries. When Claire's sister went through treatment, she was living in Britain and did not encounter any problems when participating in research. She received fabulous care with universal health coverage.

Claire — Clinical Trials Story

Not only did Claire receive numerous personal benefits from the clinical trial, she also helped advance research. Claire thinks of herself as a statistic that could be measured and studied through her clinical trial journey. It is important to have these statistics and patients associated with new treatment options in order to give the treatment more credibility and help it become well-established. As Claire stated, "How do we find out about new drugs or treatments if we do not conduct clinical trials?"

"How do we find out about new drugs or treatments if we do not conduct clinical trials?"

Connie

Clinical Trials Story

In early 1999, there was a lump on the side of Connie's neck. The lump did not come with a cold or any sickness, so she let it go. Three months later the lump had not gone, yet there was still no pain, illness or anything substantial that would cause her to worry. As a precautionary measure she went to her doctor and received blood work.

In April 1999, Connie was diagnosed with Non-Hodgkin's Lymphoma, a cancer that affects the immune system and the bodies' ability to fight infection. She learned that this type of cancer is less aggressive than Hodgkin's Lymphoma; however, there is also no cure.

Non-Hodgkin's Lymphoma, a cancer that affects the immune system and the bodies' ability to fight infection.

Through the use of her computer and her husband by her side, Connie learned as much as she could about the Non-Hodgkin's' Lymphoma which helped ease some fears. She found that this type of cancer is slow growing which gave her time to look at various treatment options and how the disease progressed in the body.

By looking at treatment options for this type of diagnosis, Connie learned that it would be treated with chemotherapy. As Connie continued to learn about her disease she discovered a clinical trial her doctor had mentioned from the National Cancer Institute. She would be able to advance medical treatment through this clinical trial. The vaccine study would take a sample of one of Connie's nodes and mix it with another enzyme to try to create a vaccine which would attack her specific cancer. According to Connie the study "gave me hope for a possible cure," and although the study was a double blind study, she would be able to take part in possible advances in cancer research. In this study Connie will be followed for the next ten years which is much longer than a person who just receives standard treatment.

Clinical trials "gave me hope for a possible cure."

Statistically 30 to 40 percent of those with Non-Hodgkin's Lymphoma convert to a more aggressive type. Connie's did while on vacation in New Zealand in 2004. She began to have severe stomach pains and flew to Australia for a scan. The scan showed that her belly was full of cancer. Connie chose to come back to Alaska for treatment. At this point the cancer had blocked

the blood flow to the legs which caused a clot. The clot then traveled to her pulmonary artery which caused a pulmonary embolism, leaving her weak, short of breath and her body atrophied. The doctors suggested that she begin chemotherapy. After treatment she felt much better however the doctor suggested a stem cell transplant which sifts old and new cells, and stores the new cells. She received a high level of chemotherapy treatment with the hope of killing off all cancer affected cells in her body & essentially destroying her immune system. Then, they reintroduce the saved stem cells which were also treated with chemotherapy and put back into her body with the hope of introducing a healthy immune system. About this time she was offered a second clinical trial. The new trial involved a medication that would help to stimulate the mucus membrane cells in the mouth. This trial would help those who receive chemo have less pain and sores in the mouth. In Connie's case, the drug helped reduce the number of days with sores by a day or two.

Connie chose to come back to Alaska for treatment.

Connie also participated in a third clinical trial which was very different from the first two. The researchers conducted a psychological study to gage feelings about the stem cell treatment before and after the treatment. It gave her the opportunity to find how her feelings have changed over time. The study also gave researchers insight on mood and attitude during and after treatment.

A third Clinical trial...

Throughout the three clinical trials Connie was worried about insurance covering the costs. But the National Institute of Health paid for all of the clinical trials and gave her a partial stipend for travel, room, and board. All of her clinical trials had to be preapproved by the insurance company and she worries that the insurance she has will soon run out because the cost of treatment is so expensive.

Clinical trials "made me feel like I was advancing medical treatment and patient care."

Connie feels supported by her family, friends and doctors. She stated the clinical trials "made me feel like I was advancing medical treatment and patient care." She is encouraged by clinical trials and feels like there are not nearly enough people in them. After all, no cancer advancement can occur without participation in clinical trials. Connie also feels that each person has to choose for themselves if they want to participate, weighing the benefits and risks of the trial.

Each person has to choose for themselves if they want to participate, weighing the benefits and risks of the trial.

Dennis

Clinical Trials Story

Late summer early fall of 2007, Dennis started to notice a change. It was prostate cancer, not that he knew it at the time. He had problems urinating and a sore left shoulder. The year also involved a broken ankle, which took several months to heal, and continual shoulder pain. By early April of 2008 Dennis became very ill. His roommate was very concerned and convinced him to see a doctor. After the appointment was set up, Dennis began to feel better so he thought about just skipping it because going to the doctor seemed like overreacting. Though he was feeling better, he kept his appointment. The doctor gave him several blood draws and he waited to hear the results from the doctor's office.

Dennis stated "On April 9th 2008 I was told I had kidney failure." He was directed by his primary care physician, Dr. Reeves, to report immediately to the hospital emergency room. Dennis went through a series of tests and was then admitted to Providence Hospital where he remained for one week. Further testing revealed that prostate cancer was blocking the urinal tubes. Short term treatment for the kidneys was dialysis for several days a week for up to a year. Stents were placed to drain the kidneys and they were so effective that his dialysis treatment was rescinded.

Dennis stated "I had Stage 4 prostate cancer; Dr. Ferucci, my urologist, explained that normal PSA (Prostate Specific Antigen) levels range from .1 to 4, and my PSA level was well over 400." Dennis was ready to fight prostate cancer. Dr. Ferucci suggested hormone treatment which is the standard treatment for those with stage 4 prostate cancer. This treatment halts testosterone and attempts to prevent the cancer from growing. A group of medical professionals, including a urologist, oncologist and hospital staff teamed up to help Dennis fight his cancer. They began hormone treatment which consisted of monthly injections of Lupron along with an oral medication called Casodex which is consumed once a day. In addition, they began radiation treatment in both shoulders and the left and right femur areas to reduce the heavier concentration of the cancer which had spread to other parts of his body. The hormone treatment was very effective and within 30 days Dennis' PSA level

"I had Stage 4 prostate cancer."

Dennis was ready to fight prostate cancer.

dropped to around 20. Within another 60 days his PSA level was below 4.

Dr. Ferucci introduced Dennis to Krista a research nurse who knew of a clinical trial for prostate cancer taking place in Alaska. Dennis jumped on board "not in an effort to get better, but to participate in research. Prostate cancer research is ten years behind that of breast cancer, and men are less likely to participate in clinical trials." The clinical trial utilized a new type of drug substituting Lupron to Zoladex. The use of Zoladex was monitored through blood draws. After PSA levels began increasing it was decided by Dennis and his doctor that removal from the study was the best option.

Prostate cancer research is ten years behind that of breast cancer, and men are less likely to participate in clinical trials."

During this clinical trial, Dennis incurred very little out of pocket expenses because his insurance company was very supportive by covering the cost of his routine care during the clinical trial.

After the clinical trial, Dennis' medications were returned to current treatment options. He plans to bring his team back together to look at treatment options for cancer in his femurs, along with trying a new diet plan for a more natural treatment option.

Though Dennis has gone through a very difficult time his presence is felt when he walks into a room. He has personal strength and support from his friends. Through this difficult time Dennis is encouraged that research will help future generations find better options to cancer treatment.

Hannah

Clinical Trials Story

Brice Smith, a cancer research nurse, screens people to determine whether or not they are eligible for clinical trials. She educates staff and patients on what clinical trials are. When patients are enrolled in a clinical trial she is the liaison and case manager during the trial.

During one experience in attempting to enroll a patient in a clinical trial the patients' physicians' office staff and the data center staff, both called the insurer to attain coverage and both were declined three separate times. The data center staff contacted Hannah regarding the insurance companies' decline of coverage for the patient during the clinical trial. When Hannah contacted the insurer they referred her to the case management group where she spoke with a lead case manger who would review the patient's file. The lead case manger stated the insurance company was "emphatic" that no payment for treatment would be provided while the patient was participating in clinical trials and none of the clinical trial would be paid for. Hannah then asked the lead case manager for something with the insurance companies' logo on it stating the reasons the client was declined, because the Clinical Trials Workgroup is gathering documentation for legislation. The lead case manager from the insurance company called back three days later stating the company needed more information in the form of a letter on some of the benefits of the clinical trails for example: while in the clinical trial all medications will be paid for. After sending in the letter identifying the benefits of the clinical trial an approval was granted within 48 hours.

The best care a patient can receive is when enrolled in clinical trials.

Attaining coverage for this one patient was five weeks of work; the amount of money spent in time to get the coverage would have cut the cost of insurance company's time and the cost of time for hospital staff.

Hannah pointed out that NCI released a statement that the best care a patient can receive is when enrolled in clinical trials. Under the scrutiny of clinical trials patients are monitored more closely. This particular patient will receive ten years of follow up care. By participating in a clinical trial, this person is on the radar when they would not normally be on the radar.

Judy

Clinical Trials Story

For over fifteen years doctors have told Judy that she had a fibroid in her pelvis. In the summer of 2006 it started to interfere with the flow of her urine, the kidney was not draining properly. It was probably never a fibroid, she was diagnosed with Leiomyosarcoma. It was probably a low grade cancer but somehow it had kicked up into high gear and spread. The cancer Judy has is very rare and there is not much research on it, she states "the research needs to get done."

"The research needs to get done."

During a hysterectomy the doctors did not do anything to the tumor but they urged her to go to a cancer center and get an appointment with an oncologist. She stated "it was difficult to get an appointment" and after contacting several hospitals she decided to go to Memorial Sloan Kettering Cancer Center. So Judy went to New York and was seen by a surgical oncologist who told her she needed to shrink the tumor before they removed it. She flew back to Alaska and had four rounds of chemotherapy, she went back and forth from Alaska to New York before the surgical oncologist and urologist at Sloan Memorial felt that they should go forward with surgery because the cancer was not diminishing in size.

According to Judy, Memorial Sloan did an incredible job. She returned home receiving cat scans every four months in Alaska and once a year in New York. In January of 2008 Judy learned that the tumor had returned, two more nodes were present in her right lung, she was able to have the two nodes removed. She was sent home for radiation with surgery on the primary pelvic tumor scheduled for the end of May. Returning in May, the surgeon decided removal was unsafe, she was sent back to Alaska for more chemotherapy. During this trip she was able to stay at a place called Hope Lodge sponsored by the American Cancer Society which provided free housing during her treatment in New York. When back in Alaska Judy received chemotherapy, the doctors stated if it stabilized there was an oral drug she could take; she just had to finish the fourth round of her chemotherapy. During the fourth round, the cancer grew and spread.

With all treatment options exhausted Judy is only left with clinical trials.

Now with all treatment options exhausted Judy is only left with clinical

trials, however the insurance company is not willing to pay for routine care costs during the clinical trial. They refuse to help with the cost even though the doctors are recommending them as a best option because all other treatments have failed. The health board for her insurance company will look at supporting clinical trials in April of 2009. If the health care plan still refuses coverage, she will have to pay out of pocket. Her next step is to have a metal plate put into her right femur from hip to knee, because of a tumor, doctors are worried it could break without this support. Judy is waiting to continue the clinical trial until after this treatment and radiation.

Judy mentions the importance of having a support network, and feels even if the clinical trial doesn't do anything for her at least we learn something. She stated "I would hate to think that this was all (the cancer) just a waste" in the mean time "I have worked, played, and seen my grandson." A team approach to health care is needed because it's a lot of work managing your own health care when you have cancer with oncologist, urologist, doctors, radiologist, and nurses at various places across the country. Judy continues to fight her battle with cancer; her strength is seen in her courage to continue to fight, even though getting around is sometimes a battle.

"I would hate to think that this was all (the cancer) just a waste."

Myths and Facts

About Cancer Clinical Trials

Myth: Cancer patients avoid clinical trials because they are too risky.

Fact: Many patients simply don't know that clinical trials are a treatment option. In one survey*, most of these patients said they would have enrolled if they had known. In clinical trials, patients are watched closely by their doctor. They are also watched by other members of their medical team.

Myth: Patients in clinical trials are treated like "guinea pigs."

Fact: 97 percent of people in one survey* said they were treated with dignity and respect. They also said that the care was very good.

Myth: Cancer clinical trial patients are given "sugar pills."

Fact: Patients who join clinical trials are given the best treatment available or the chance to receive a new treatment being considered.

Myth: Medicare does not cover the patient care costs of clinical trials.

Fact: Medicare has been covering these costs since June of 2000.

Myth

You need to be near a big hospital to take part in a clinical trial.

Fact: Many cancer clinical trials take place at local hospitals. Some also take place at local cancer clinics and doctors' offices.

—Coalition of cancer cooperative groups

*Harris Interactive Survey, 2000

Additional Resources

For More Information

Alaska

Anchorage

Alaska Regional Hospital
Cancer Care Center
2741 DeBarr Road. Building c-414
Anchorage, AK 99508
Phone: (907)264-1579 or 264-1431
http://www.alaskaregional.com

Alaska Clinical Research
Center, LLC
1200 Airport Heights Drive, Suite 330
Anchorage, AK 99508
Phone: (907)276-1455
http://www.centerwatch.com

Providence Cancer Center
Research Department
3851 Piper Street
Anchorage, Alaska 99508
Phone: (907) 212-6871
Fax: (907) 212-3674
http://www.providence.org/Alaska

Fairbanks

Oncology Data Center
Fairbanks Memorial Hospital
1640 Cowles St. Suite 2
Fairbanks, Alaska 99701
Phone: (907)458-5458 or 4458
Toll Free: 1-888-678-5458
http://www.bannerhealth.com/
Locations/Alaska/Fairbanks

Cancer Treatment Center
Cancer Treatment Center Entrance
1640 Cowles St. Suite 2
Fairbanks, AK 99701
Phone: (907) 458-5380
http://www.bannerhealth.com/Services/
Cancer

Nationwide

American Cancer Society Clinical
Trials Matching Service
http://www.cancer.org
or 1-800-303-5691

CenterWatch Clinical
Trials Listing Service
http://www.centerwatch.com/

Clinical Connection
http://www.clinicalconnection.com/

Coalition of Cancer
Cooperative Group
http://www.CancerTrialsHelp.org

NCI's Clinical Trials Locator
http://www.cancer.gov/clinical trials

U.S. National Institutes of Health
http://www.clinicaltrials.gov

Made available by:
Alaska Department of Health and Social Services
Division of Public Health
Section of Chronic Disease Prevention and Health Promotion
Comprehensive Cancer Control Program
& the Clinical Trials Work Group
Phone: 269-8092
December, 2009

ALASKA
Comprehensive Cancer Partnership

SOUTHEAST
Radiation
Oncology
CENTER

Eugene Huang, M.D.
1701 Salmon Creek Lane
Juneau, AK 99801
Phone: 907.586.5762
Fax: 907.586.5777

To Whom It May Concern,

I am writing this letter in support for Senate Bill 113 (Version W) "New Drugs for the Terminally Ill." I believe that this bill will help provide terminally ill patients greater access to new drugs that may potentially make a significant difference in their lives.

Sometimes in our practice, a patient may be in a situation where they have exhausted all available options, yet have not given up hope and want to try additional measures that may help them. Every other week, even just within my limited scope of cancer practice, there are new drugs being developed tested in early-phase clinical trials. The pace of biotechnology research and drug development has significantly accelerated in just the last few years, offering patients more options and hope for treatment.

I believe that Senate Bill 113 will help bring new scientific discoveries closer to patients whom need them, within the appropriate context and safeguards.

Sincerely,

Eugene Huang, MD
Medical Director
Southeast Radiation Oncology Center

P.O. Box 13458
Los Angeles, CA 90013
213.935.0553

Feb. 9, 2016
Re: Support for SB113

Dear members of the Alaska legislature,

The Tenth Amendment Center fully supports passage of SB113 enacting a "Right to Try" law in the state of Alaska.

Sometimes the wheels of bureaucracy move slowly. For most of us, this merely presents an inconvenience, but for a patient suffering from a life-threatening illness, a few months could mean the difference between life and death.

The FDA approval process is meant to protect the public and ensure only safe and effective treatments find their way into the marketplace. But sometimes the nature of the process means delays in getting medicines into the hands of those who desperately need them. "Right to Try" laws create a bridge spanning a gap between federal regulations and the needs of terminally ill patients.

This type of legislation illustrates the beauty of federalism. People have recognized a glaring need and met it through legitimate state action.

So far, 24 states have enacted "Right to Try," with 16 more including Alaska, considering the legislation this year.

We strongly urge you to vote yes on SB113.

Sincerely,

Michael Boldin, Tenth Amendment Center founder and executive director
Mike Maharrey, Tenth Amendment Center national communications director

February 24, 2016

I am writing in support of the 'right to try' bill, House bill 215, Senate bill 113, introduced by Scott Kawasaki and Bill Wielechowski.

My father was diagnosed with multiple myeloma in 2004. Multiple myeloma is an incurable disease, the average life expectancy is four years. My dad joined an experimental drug trial in the state of Wisconsin, in 2007, knowing that the study he was participating in might not help him much, but would absolutely help others in the future. The experimental drug and treatment he helped to test shows promise, and although my father has since died of his illness, the experimental drug treatment gave him several more happy years, doing the things he liked best, and the happy knowledge that he had helped all MM sufferers in the future.

I support science-based medicine, and i think for terminally ill patients who would like to continue to contribute to future generations, allowing them to participate in the testing and use of experimental drugs is a good idea.

One of my best friends currently suffers from M.S. Because the experimental drug trial he is participating in is not available in the US, he moved to the Czech Republic to take part in a Swiss trial. The treatment has helped him tremendously, he is even able to play racquet ball now: before the trial, he was often wheelchair bound. The trial

has had such good results, that a new treatment has been invented based on the same technique, and is now slowly becoming available to other sufferers of M.S.

I applaud his courage and the courage of all those who suffer terminal illnesses, and who are willing to take part in experiments that can help future generations to live longer, fuller lives. Please consider the merits of these drug trials, and pass this bill.

Charlotte Whiteley
Homer, AK

Dixie A. Hood, LMFT
Juneau, Alaska

January 30, 2016

Senator Bert Stedman, Chair
Senate Health & Social Services Committee
State Capitol, Room 30
Juneau, AK 99801

Subject: Senate Bill 113 – The Right to Try

Dear Senator Stedman,

This letter is in support of Senate Bill 113, the Right to Try: New Drugs for the Terminally Ill.

For 30 years as a licensed marriage and family therapist, substance abuse counselor and present member of the Juneau Suicide Prevention Coalition, I have provided mental health services and support to many individuals who were suffering from life-threatening diseases, as well as their families. Some were referred to Hospice and Home Care. When help and hope seemed unobtainable, several patients turned to suicide.

I have had HIV clients who were eligible to receive medical marijuana, but moved away from long-time friends and relatives because Alaska state law required administering physicians to be publicly identified. Their doctor believed that was professionally unethical and violated privacy laws. Therefore, they refused to provide marijuana as treatment for their illness. Protection of both patient and physician is critical when the patient's well-being, and even life, are at stake.

SB 113 would enable a patient who has provided "informed consent" acknowledging the potential risk of investigational medication to receive treatment of a drug which has successfully completed Phase 1 of the U.S. Food and Drug Administration's drug review process. It would provide immunity from disciplinary action and liability of doctors and manufacturers who have been willing to make the investigational medication available to the patient.

This would enable a terminal patient the ability to access safe, but experimental drugs when their doctor has exhausted all the FDA-approved options.

This is a humanitarian issue, not a political one. I urge support of Senate Bill 113.

CC: Senator Cathy Giessel
Senator Pete Kelly
Senator Bill Stoltze
Senator Johnny Ellis
Senator Bill Wielechowski

Valley Medical Care
1801 Salmon Creek Lane • Juneau, Alaska 99801
Phone: (907) 586-2434 • Fax: (907) 586-2446

Bob Urata, M.D.
Sharon Fisher, M.D.
Priscilla Valentine, M.D.
Lindy Jones, M.D.
Anya Maier, M.D.
Richard Welling, M.D.
Joseph Roth, M.D.
Dorothy Hernandez, M.D.
Don Schneider, M.D.
Daniel Kim, M.D.
Taylor Dunn, M.D.
Justine Emerson, F.N.P.
Matthew Jones F.N.P.
Rebecca Young, F.N.P.
Kim Gardner, F.N.P.
Tina Pleasants, F.N.P.
Rachel Gladhart, C.N.M.

February 1, 2016

Senator Bert Stedman
Senate Health and Social Services Committee
State Capitol, Room 30
Juneau, Alaska 99801

Dear Senator Stedman:

This is a letter in support of Senate Bill 113, which would protect physicians and hospitals for treating terminally ill patients with experimental medications that have passed the first stage of approval for the FDA.

I personally have not had to use this, but feel that if this is available it would make me more likely to pursue this more aggressively as I will know that there is protection from potential lawsuits, should something go wrong.

I hope you will find that this bill will be favorable for your support. I urge passage by your committee.

Thank you for your service.

Sincerely yours,

Bob Urata, M.D.
907-723-4144

BU/cmm

Fiscal Note

State of Alaska
2016 Legislative Session

Bill Version: SB 113
Fiscal Note Number:
() Publish Date:

Identifier: SB113CS(HSS)-DCCED-CBPL-04-07-16
Title: NEW DRUGS FOR THE TERMINALLY ILL
Sponsor: WIELECHOWSKI
Requester: (S) Judiciary

Department: Department of Commerce, Community and Economic Development
Appropriation: Corporations, Business and Professional Licensing
Allocation: Corporations, Business and Professional Licensing
OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2017 Appropriation Requested	Included in Governor's FY2017 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2017**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Fund Source (Operating Only)

None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Positions

Full-time							
Part-time							
Temporary							

Change in Revenues							

Estimated SUPPLEMENTAL (FY2016) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2017) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Updated analysis.

Prepared By:	Janey Hovenden, Director	Phone:	(907)465-2536
Division:	Corporations, Business and Professional Licensing	Date:	04/07/2016 05:50 PM
Approved By:	Catherine Reardon, Director	Date:	04/08/16
Agency:	Division of Administrative Services, DCCED		

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2016 LEGISLATIVE SESSION

BILL NO. CSSB 113(HSS)

Analysis

SB113 establishes immunity for physicians or member of the medical team, manufacturers and distributors in the case of injury or death of a terminally ill patient from the use of an investigational drug, biological product, device, or related treatment, provided informed consent was obtained from the patient and notice of immunity was given in advance.

This legislation prohibits disciplinary action against physicians by the State Medical Board for prescribing, dispensing or administering an investigational drug, biological product or device to terminally ill patients who have considered all other treatment options, approved by the FDA, and are ineligible or unable to participate in a current clinical trial.

SB113 prevents the Department from requiring a licensed entity to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering investigational drugs as provided.

This legislation amends the statute limiting the sale and distribution of new drugs so as not to apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1.

The Division of Corporations, Business, and Professional Licensing does not anticipate fiscal impact from this legislation.