**ALASKA STATE LEGISLATURE**
**SENATE LABOR AND COMMERCE STANDING COMMITTEE**
March 7, 2017
1:31 p.m.

**MEMBERS PRESENT**

Senator Kevin Meyer
Senator Gary Stevens
Senator Berta Gardner
Senator Shelley Hughes, Vice Chair
Senator Mia Costello, Chair

**MEMBERS ABSENT**

All members present

**COMMITTEE CALENDAR**

SENATE BILL NO. 16
"An Act adopting and relating to the Revised Uniform Fiduciary Access to Digital Assets Act."

- HEARD AND HELD

SENATE BILL NO. 32
"An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

- HEARD AND HELD

**PREVIOUS COMMITTEE ACTION**

BILL: SB 16
SHORT TITLE: FIDUCIARY ACCESS TO DIGITAL ASSETS
SPONSOR(s): SENATOR(s) HUGHES

| | | |
|---|---|---|
| 01/13/17 | (S) | PREFILE RELEASED 1/13/17 |
| 01/18/17 | (S) | READ THE FIRST TIME - REFERRALS |
| 01/18/17 | (S) | L&C, JUD |
| 03/07/17 | (S) | L&C AT 1:30 PM BELTZ 105 (TSBldg) |

BILL: SB 32
SHORT TITLE: PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS

SPONSOR(s): SENATOR(s) HUGHES

| | | |
|---|---|---|
| 01/23/17 | (S) | READ THE FIRST TIME - REFERRALS |
| 01/23/17 | (S) | HSS, L&C |
| 02/10/17 | (S) | HSS AT 1:30 PM BUTROVICH 205 |
| 02/10/17 | (S) | Heard & Held |
| 02/10/17 | (S) | MINUTE(HSS) |
| 02/15/17 | (S) | HSS AT 1:30 PM BUTROVICH 205 |
| 02/15/17 | (S) | Moved SB 32 Out of Committee |
| 02/15/17 | (S) | MINUTE(HSS) |
| 02/17/17 | (S) | HSS RPT 2DP 1NR 1AM |
| 02/17/17 | (S) | NR: WILSON |
| 02/17/17 | (S) | DP: VON IMHOF, BEGICH |
| 02/17/17 | (S) | AM: GIESSEL |
| 03/07/17 | (S) | L&C AT 1:30 PM BELTZ 105 (TSBldg) |

**WITNESS REGISTER**

BUDDY WHITT, Staff
Senator Shelley Hughes
Alaska State Legislature
Juneau, Alaska
**POSITION STATEMENT:** Delivered the sectional analysis for SB 16.

DEBORAH BEHR, Member
Alaska Delegation, Uniform Law Commission
Juneau, Alaska
**POSITION STATEMENT:** Provided information on SB 16.

AIMEE BUSHNELL, Staff
Senator Shelley Hughes
Alaska State Legislature
Juneau, Alaska
**POSITION STATEMENT:** Provided information on SB 32.

ASHLYN ANTONELLI, representing herself
Anchorage, Alaska
**POSITION STATEMENT:** Testified in support of SB 32.

BECKY HULTBERG, President and CEO
Alaska State Hospital and Nursing Home Association
Anchorage, Alaska
**POSITION STATEMENT:** Testified in support of SB 32.

MARK GUIMOND, Director
State Legislative Affairs
Arthritis Foundation

Washington, D.C.
**POSITION STATEMENT:** Testified in support of SB 32.

SHAINA SMITH, Director
U.S. Pain Foundation
North Grosvenordale, Connecticut
**POSITION STATEMENT:** Testified in support of SB 32.

PHIL SCHNEIDER, Associate Dean and Professor
University of Arizona Health Sciences
College of Pharmacy
Chair - Advisory Board
Alliance for Safe Biologic Medicine
Phoenix, Arizona
**POSITION STATEMENT:** Testified in support of SB 32.

CAREY MCCLELAND, Healthcare Advocate
Anchorage, Alaska
**POSITION STATEMENT:** Testified in support of SB 32.

LEIF HOLM, Member
State Board of Pharmacy
North Pole, Alaska
**POSITION STATEMENT:** Stated support for SB 32, provided the language in Section 5 is amended.

DR. DAVID CHARLES, Chair
Alliance for Patient Access
Nashville, Tennessee
**POSITION STATEMENT:** Testified in support of SB 32.

RYLAN HANKS, Pharmacist
Director of Policy
Amgen, Inc.
Thousand Oaks, California
**POSITION STATEMENT:** Testified in support of SB 32.

**ACTION NARRATIVE**

1:31:19 PM
**CHAIR MIA COSTELLO** called the Senate Labor and Commerce Standing Committee meeting to order at 1:31 p.m. Present at the call to order were Senators Gardner, Stevens, Meyer, Hughes, and Chair Costello.

## SB 16-FIDUCIARY ACCESS TO DIGITAL ASSETS

1:32:06 PM
CHAIR COSTELLO announced the consideration of SB 16 and noted that this was the first hearing.

1:32:15 PM
SENATOR SHELLY HUGHES, Alaska State Legislature, sponsor of SB 16, stated her belief that technological advances are key to Alaska's economic future. She noted the advances in online digital tools, storage devices, social media sites, music and photos that individuals use and retain and questioned what would happen to these personal items when someone passes away. SB 16 provides guidance for this internet age that is lacking in current law. It offers digital users the opportunity to specify whether their digital assets should be preserved, distributed to heirs, or destroyed. She explained the need for an overarching law in order to provide access to digital assets to loved ones in other states.

She listed the entities that support the bill: National Academy of Elder Law Attorneys, Facebook, Google, Center for Democracy and Technology, AARP, and others.

1:35:01 PM
BUDDY WHITT, Staff, Senator Shelley Hughes, Alaska State Legislature, delivered the sectional analysis for SB 16: [Original punctuation provided.]

> **Section 1** of the bill adds a new chapter, the Revised Fiduciary Access to Digital Assets Act, to AS 13.
>
> Sec. 13.63.010 sets out user direction for disclosure of digital assets. This proposed section addresses the relationship of online tools, other records documenting the user's intent, and terms of service agreements. The section establishes a three-tier priority system for determining the user's intent with respect to a digital assets. Subsection (a) gives top priority to the user's wishes as expressed using an online tool. Subsection (b) gives next tier priority to user's direction in will, trust, power of attorney, or other record. Subsection (c) recognizes the terms-of-service agreement if the user left no other direction.
>
> Sec. 13.63.020 sets out the relationship of the terms-of-service agreement to the fiduciary. This section clarifies that to the extent a custodian gives a

fiduciary access to digital assets, the terms- of - service agreement apply as well to the fiduciary.

Sec. 13.63.030 sets out procedures for disclosing digital assets. Subsection (a) gives the custodian of digital assets a choice of methods for disclosing digital assets to an authorized fiduciary. Subsection (b) allows the custodian to charge a reasonable administrative charge for the cost of disclosure. Subsection (c) states that a deleted digital asset of the user need not be disclosed, because deletion is a good indicator that the user did not intend access to the fiduciary. Subsection (d) addresses requests that are unduly burdensome and authorizes a process to obtain court direction on the request.

Sec. 13.63.040 sets out process for disclosure of the content of electronic communications of a deceased user. This section gives the personal representative of the estate access to digital assets if the user consented or if the court orders disclosure. Certain procedures set out in the section must be met.

Sec. 13.63.050 sets out procedures for the disclosure of other digital assets of a deceased user. This section gives the personal representative access to the catalogue of electronic communications and other digital assets, if the requirements of the section are met.

Sec. 13.63.060 sets out procedures for disclosure of content of electronic communications of a principal under a power of attorney. The procedures and process are similar to those given a personal representative under Sec. 13.63.040.

Sec. 13.63.070 sets out procedures for disclosure of other digital assets of the principal under a power of attorney. The procedures and process are similar to those given to a personal representative under Sec. 13.63.050.

Sec. 13.63.080 sets out procedures for disclosure of digital assets when held in a trust when the trustee is the original user. This section provides that trustee who is an original account holder can assess all digital assets held in the trust.

Sec. 13.63.090 sets out procedures for disclosure of content of electronic communications held in trust when the trustee is not the original user. The procedures and process are similar to those given a personal representative under Sec. 13.63.040.

Sec. 13.63.100 sets out procedures for disclosure of other digital assets held in trust when the trustee is not the original user. The procedures and process are similar to those given to a personal representative under Sec. 13.63.050. The trustee also must supply information about the trust specified in this section.

Sec. 13.63.110 sets out procedures for disclosure of digital assets to conservator of a protected person. This section applies when a conservator is appointed by the court to handle the assets of protected person who is physically or mentally unable to manage those assets. The proposed section provides an opportunity for a hearing concerning disclosure. Otherwise the procedures and process are similar to those given a personal representative under Sec. 13.63.050. The proposed section finally sets out a process to suspend or terminate an account of a protected person for good cause.

Sec. 13.63.120 sets out standards of a fiduciary's duty and authority under this chapter.

Sec. 13.63.130 sets out the standards for the custodian of digital assets compliance with the act. Subsection (f) immunizes the custodian of digital assets and its officers, employees, and agents from liability for an act or omission done in good faith in compliance with this chapter.

Secs. 13.63.140 and 13.63.150 are standard provisions included in uniform acts to facilitate their implementation among the states that enact them.

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Sec. 13.63.160 establishes the coverage of digital assets under the chapter. In the chapter, a digital assets does not apply to the underlying asset or liability unless the asset or liability is itself an electronic record. The chapter does not apply to the digital asset of an employer used by the employee in the ordinary course of the employer's business.

Sec. 13.63.170 sets out the application of the chapter if the user resides in Alaska or resided in Alaska at the time of the user's death.

Sec. 13.63.190 sets out definitions of terms used in the chapter.3

**Section 2** of the bill sets out applicability of the Act.

1:41:27 PM
MR. WHITT said Deborah Behr will answer technical questions about the bill.

SENATOR GARDNER asked if a fiduciary would have access to all financial information and whether the bill provides that they would not have access to other property.

MR. WHITT clarified that a fiduciary is appointed to manage property when someone dies or loses capacity to manage it him/herself. The bill provides access to anything the fiduciary was authorized to manage.

SENATOR GARDNER asked how the fiduciary knows what has value and is relevant. She questioned the executor's role in the process.

MR. WHITT deferred the question to Ms. Behr.

1:43:51 PM
CHAIR COSTELLO said the definition for “fiduciary” is on page 13.

SENATOR STEVENS said he, too, is concerned about the privacy of certain records.

CHAIR COSTELLO asked about the effective date and applicability clause. On page 13, line 6, it mentions "a person acting under a will or power of attorney executed before, on, or after the effective date of this Act." She asked if SB 16 will be a retroactive statute.

MR. WHITT said he would follow up with an answer.

1:45:25 PM
SENATOR MEYER asked how other states handle this.

MR. WHITT replied 16 states have passed similar legislation. Most states saw a problem with what would happen with digital assets.

1:46:11 PM
DEBORAH BEHR, Member of the Alaska Delegation, Uniform Law Commission, said the issue of how to handle digital assets when someone passes away has been a problem in many states because it's not addressed in the typical will. She provided an account of what happens when a spouse can’t get access to digital photos because they do not have a contract with the service provider; the deceased spouse has the contract. The typical will does not work, nor does the business partnership.

She clarified that 23 states have passed this model law and 17 others are considering it. The Alaska Uniform Law Delegation approached the sponsor saying this bill will be good for seniors.

With regard to applicability, SB 16 becomes effective 90 days after it is signed. It is not retroactive. It applies to existing wills and contracts.

She said the question about privacy is important. SB 16 is an opt-in statute. If nothing is in the will, the terms of service agreement will apply and the spouse or family or business partner will not have access to the digital material. It is

similar to the designated beneficiary in retirement accounts that is separate from the will.

She emphasized that this is a thoroughly vetted process.

CHAIR COSTELLO said she is still confused about the applicability. She referenced page 13 and asked for clarification.

1:53:24 PM
SENATOR STEVENS stressed the importance of updating wills to include digital assets.

MS. BEHR said it is not necessary, if you have no digital assets, but most probate attorneys are asking how the person wants digital assets handled.

SENATOR GARDNER related her personal experience as a trustee for her sister. She asked who judges who has access to digital assets.

MS. BEHR stressed that the bill provides for an opt-in system. A person can determine whether they want anyone to see their emails after they die. If a person does not give consent, the most a fiduciary can do is get a catalogue of communication. She provided examples of who would be a fiduciary; the husband if the wife died, or someone appointed as a fiduciary. To be a fiduciary requires a court order and includes specific duties.

CHAIR COSTELLO asked whether a person is liable for unknowingly accessing a Facebook page of a decedent.

MS. BEHR said she believes that is controlled by other federal laws, not this statute.

CHAIR COSTELLO asked if this law will change the forms that are available at the office supply stores.

MS. BEHR said this bill does not address forms. It’s an overlay statute.

CHAIR COSTELLO asked if there have been unintended consequences in other states that have passed similar legislation.

MS. BEHR said she is not aware of any unintended consequences.

2:01:35 PM

SENATOR HUGHES said the third tier in the bill is the terms of service agreement. She asked how she would get photos on Flicker if she isn't designated and her husband passes away.

MS. BEHR said she could hope that her husband used the online tool designated in the bill or updated his will, otherwise she would be denied access to those photos.

MR. WHITT added that with advances in technology comes the duty to look at this sort of thing and ensure the family has access to records.

SENATOR STEVENS asked if the online tool is done generally or whether each provider has its own style.

MS. BEHR said each provider has its own style.

2:05:33 PM
MR. WHITT added that you can designate who has access to your Facebook page.

SENATOR STEVENS said only his staff has been on his Facebook page.

MR. WHITT suggested he discuss access with his staff.

SENATOR HUGHES asked if there is an educational effort to ensure that seniors, in particular, are aware of these online tools.

MR. WHITT said it is becoming a larger issue and AARP is addressing how to educate members.

2:07:32 PM
CHAIR COSTELLO opened public testimony for SB 16.

SENATOR HUGHES thanked the committee for hearing the bill.

CHAIR COSTELLO held SB 16 in committee for future consideration. Public testimony was held open.

2:08:32 PM
At ease

## SB 32-PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS

2:10:18 PM

CHAIR COSTELLO reconvened the meeting and announced the consideration of SB 32. She noted that this is the first hearing. The intent is to hear from the sponsor, take questions, and hear public testimony.

2:11:16 PM
SENATOR SHELLY HUGHES, Alaska State Legislature, sponsor of SB 32, introduced SB 32 speaking to the following sponsor statement:

> Senate Bill 32 allows for Alaskans to have access to safe, new, and effective treatment options called interchangeable biological products. Under current state law, pharmacists are allowed to substitute a generic product for drugs that are identical to their proprietary product, but cannot do the same with interchangeable biological products. Under SB 32, pharmacists will be able to dispense an FDA approved interchangeable product as a substitute for the proprietary biological product.
>
> Due to the complexity and nature of biological products, an exact replication of these drugs is impossible, so a new category of interchangeable products was created by the FDA. This category of drug allows for pharmaceutical companies to create safe and affordable substitutes for drugs that help treat conditions including cancer, multiple sclerosis, severe rheumatoid arthritis, heart disease, and other immune system, neurological and hematologic disorders.
>
> In addition to the clear benefits to patients, the lower costs and competition should also bring measurable costs savings to Alaska's Medicaid program and budget. The Center for Medicare and Medicaid Services recommends that state Medicaid programs "view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions."
>
> SB 32 allows pharmacists to dispense interchangeable biological products if they communicate this with the prescribing doctor. This bill only allows a pharmacist to substitute an interchangeable product if it is approved by the FDA, and it allows for doctors to require the pharmacist to only dispense the

proprietary product if they feel it is a more effective option.

Patient consent will also be required before any substitution is made for an interchangeable over the proprietary product. Senate Bill 32 allows for Alaskans to have access to safe, new, and effective treatment options called interchangeable biological products. Under current state law, pharmacists are allowed to substitute a generic product for drugs that are identical to their proprietary product, but cannot do the same with interchangeable biological products. Under SB 32, pharmacists will be able to dispense an FDA approved interchangeable product as a substitute for the proprietary biological product.

It is important for Alaska to address this issue now as more interchangeable products become available to patients. Senate Bill 32 will allow for new and effective options at a lower cost, without jeopardizing patient safety, and will allow for measurable Medicaid and budget savings for the State. Please join in supporting access to an affordable medication option for Alaskans.

SENATOR HUGHES said there has been a lot of talk about the balance between pharmacists and physicians and their respective ability to prescribe interchangeable biological products. An agreement is that the physician retains control about whether or not an interchangeable biological product can be prescribed. The pharmacist can make the substitution with consent from the doctor.

CHAIR COSTELLO asked if biologics can be offered now.

SENATOR HUGHES said not yet, but a number are in the pipeline. The reason not to wait on this legislation is to ensure that pharmacists can provide the biologic to patients once there is one available.

CHAIR COSTELLO asked about the types of conditions for which a biologic would be prescribed.

2:19:01 PM
SENATOR HUGHES listed serious conditions: cancer, Lupus, multiple sclerosis, rheumatoid arthritis, autoimmune diseases, and neurological disorders.

2:19:13 PM
SENATOR STEVENS asked why a pharmaceutical company would create cheaper [biologics].

SENATOR HUGHES said they realize how helpful and affordable biologics are. The expectation is this could help states with their Medicaid budgets.

SENATOR STEVENS asked if drug companies will be willing to lower costs.

2:21:12 PM
AIMEE BUSHNELL, Staff, Senator Shelley Hughes, Alaska State Legislature, said part of the reason for the legislation is to open up competition and eventually bring about lower prices.

SENATOR STEVENS said he would like a better explanation.

SENATOR HUGHES deferred the question to Rylan Hanks with Amgen.

SENATOR GARDNER said her understanding is these are often expensive drugs that are used as a last resort.

SENATOR HUGHES said that's correct and added that biosimilars have changed people's lives. "It is definitely something we want the people in Alaska to have access to."

2:24:52 PM
MS. BUSHNELL provided a sectional analysis for SB 32 speaking to the following document:

**Sec. 1 - AS 08.80.030**
Adds a new subsection requiring the Board of Pharmacy to have a link on the board's website to the United States Food and Drug Administration's (FDA) list of approved interchangeable biological products.

**Sec. 2 - AS 08.80.294**
Amends this section by requiring a pharmacist to include on the label of a biological product container the proprietary or proper name of the biological product. This section also includes language to differentiate between drugs that are and are not biological products to ensure that statutes regarding equivalent generic drugs are not substantively changed.

**Sec. 3 - AS 08.80.294**

Adds a new subsection to define the term "proper name" being the name that reflects scientific characteristics of a biological product. This new subsection also defines "proprietary name" which is the trademarked and registered name of the product.

**Sec. 4 - AS 08.80.295**

Adds language to differentiate between equivalent drug products and interchangeable biological products.

**Sec. 5 - AS 08.80.295**

Adds new subsections to provide guidelines as to how pharmacists or their designee will need to communicate with a prescribing doctor when dispensing a biological or interchangeable biological product if an interchangeable product is available.

Under subsection (c), a pharmacist must communicate to the prescribing doctor the name and manufacturer of the biological product provided to the patient. This communication must happen within three days after dispensing the product by an entry through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record. If an entry under this subsection is not possible, the pharmacist may communicate by e-mail, telephone, fax, or by any other prevailing means.

Under subsection (d) provides an exception to the communication requirement under (c) if the dispensed biological product is a refill of the prescription and is the same biological product. Subsection (e) provides that communication provided under (c)(1) of this section is providing notice to the prescribing doctor. Under subsection (f), a pharmacist is required to maintain a record for two years after a biological product is dispensed. Finally, subsection (g) defines "designee" as an agent or employee of a pharmacist who has been authorized to communicate information under subsection (c).

**Sec. 6 - AS 08.80.480(34)**

Changes language, and gives option to change the term "drug" and "equivalent drug" to "biological product" and "interchangeable biological product".

**Sec. 7 - AS 08.80.480**
Adds new subsection (37) to define term "biological product".

Adds new subsection (36) to define term "interchangeable biological product" as a biological product as determined by the United States Food and Drug Administration.

Under subsection (A) provides that it meets the standard for interchangeability under US code (Regulation of biological products, Safety standards for determining interchangeability).

Under subsection (B) provides that it is therapeutically equivalent in the most recent edition of the United States Food and Drug Administration evaluations.

**Sec. 8 - AS 08.80.480**
Amends this section by adding transition regulations if necessary to implement changes made by this Act. Having changes take place in accordance with AS 44.62 (Administrative Procedure Act) but not before the effective date of this Act.

**Sec. 9 - AS 08.80.480**
Adds language that section 8 of this Act takes effect July 1, 2017.

**Sec. 10 - AS 08.80.480**
Adds language that this Act will take effect January 1, 2018, except for a provided in section 9.

2:26:57 PM
MS. BUSHNELL noted SB 32 follows model consent language which has been agreed to by numerous patient advocacy, prescriber, and pharmacy groups throughout the country. Biologics are used primarily for treating specialty and serious conditions. There has also been significant outreach and discussion with Alaska stakeholders. The bill preserves the ability for the prescriber to have control over what their patient is taking, but it also

allows options for the patient if there are other things they could be taking.

She said there aren't any approved interchangeables because the regulations were only recently released.

SENATOR GARDNER asked who Section 1 is for.

MS. BUSHNELL said it is to be used by the public as well as prescribers.

2:29:26 PM
CHAIR COSTELLO opened public testimony on SB 32.

2:29:46 PM
ASHLYN ANTONELLI, representing herself, testified in support of SB 32. She is a brain cancer survivor who believes that Alaska should follow the lead of the states that have passed similar legislation. She described how expensive her drug treatment will be without this option. She expressed surprise that Senator Giessel did not support this legislation when it was heard in a previous committee. This class of drugs has been around for 10 years, yet there are no studies being done in the U.S.

CHAIR COSTELLO explained that this is the first time the committee has taken up the bill and there is a process to follow.

MS. ANTONELLI asked the committee to represent the interests of people like herself. In response to Senator Stevens' question, she explained that drug companies usually have a return on research and development in two years and can afford to sell the drugs at a lower rate.

SENATOR STEVENS noted that the committee has honest questions that need to be answered before moving the bill forward.

MS. ANTONELLI voiced appreciation for the committee's time and efforts.

2:35:22 PM
BECKY HULTBERG, President and CEO, Alaska State Hospital and Nursing Home Association (ASHNHA), testified in support of SB 32. She commented that ASHNHA consulted with hospital-based pharmacists and physicians to ensure that SB 32 would supply the guidance needed to ensure safe and effective treatment for patients while providing the potential to lower pharmaceutical

costs. Following this consultation, they made the decision to support the bill. Critical to their support is the communication that is needed in a variety of settings, including a three-day timeline for the pharmacists to notify the prescribing physicians. The bill offers flexibility in communication methods. SB 32 strikes the right balance for notification and communication. Biosimilars and interchangeable biological products offer potential for increasing accessibility and affordability, as well as competition. SB 32 protects patients and will benefit Alaska.

CHAIR COSTELLO asked if biologics are available in a prepackaged Mediset.

MS. HULTBERG said she didn't know.

2:38:04 PM
MARK GUIMOND, Director, State Legislative Affairs, Arthritis Foundation, testified in support of SB 32. He distinguished between biologics and other medications. Biologics have the ability to change lives. Biosimilars offer the opportunity for biologics to come to market, and because they are copies or are similar to the original product and they cost less and are more available. He explained that a biologic is a very complex product derived from living cells. They are not chemical compounds and not pills, and they are infused or injected. There is a very small market of biologics in Alaska. A concern is that a doctor must understand what they are prescribing for a person who has other prescriptions and therapies. He spoke in favor of the notification provisions in the bill.

CHAIR COSTELLO asked whether Mr. Guimond feels there could be a higher level of patient protection.

MR. GUIMOND said there are two levels of protection; one is inherently the initial dispense as written. If the prescriber wants only the referenced brand name product, he/she can request it. If there is an opportunity for a biosimilar to be used, the prescriber can allow it. The order to "dispense as written" cannot be changed.

CHAIR COSTELLO asked if the 13 biologic prescriptions in Alaska are statewide or centered in a particular area.

MR. GUIMOND said he does not have that data, but most are distributed from specialty pharmacies. They are extremely expensive because they are derived from living cells.

2:42:49 PM
SHAINA SMITH, Director, U.S. Pain Foundation, testified in support of SB 32. She read testimony into the record from the chronic pain patients, Robert Toms and his wife from Wasilla. Ms. Smith described his treatment with a biologic for chronic pain.

CHAIR COSTELLO asked Ms. Smith to provide that written testimony to her office and it will travel with the bill.

2:46:24 PM
PHIL SCHNEIDER, Associate Dean and Professor, University of Arizona Health Sciences, College of Pharmacy, and Chair, Advisory Board, Alliance for Safe Biologic Medicine, testified in support of SB 32. He said, as a pharmacist, he believes that interchangeable biosimilars are not generic biologics because of their molecular complexities. They are a new category of drugs. Historically, pharmacists have been able to substitute generic simple molecules without communication or prior approval from a physician. Without this bill a pharmacist would need to contact the prescriber before any change could be made. This results in delays in patient care. SB 32 will provide an efficient way for pharmacists to substitute interchangeable biosimilars that are less expensive.

He discussed the amount of work that has gone into crafting this bill, and the importance of the "dispense as written" provision that is included. He concluded that the bill retains control amongst health care providers and the patients they serve. He encouraged the committee to support SB 32.

2:50:46 PM
SENATOR STEVENS asked if these drugs would typically be used in an urban setting.

MR. SCHNIEDER said you'd be surprised how widespread the use of these drugs already is. There is also the potential for at home, self-administration.

2:53:04 PM
CAREY MCCLELAND, Healthcare Advocate, testified in support of SB 32. He described his colon cancer and said if it recurs he will consider a biologic and would like to be able to have access here in Alaska.

2:55:12 PM

LEIF HOLM, Member, State Board of Pharmacy, testified in support of SB 32 if the language in Section 5 is amended. In particular, the language in Section 5 undermines the intent of federal legislation, [the Biologics Price Competition and Innovation Act], which is to increase access to biologics. He stressed the importance of the difference between an interchangeable biological and a biosimilar. He opined if a medication is interchangeable, it is substitutable. The Board sees the benefit of this legislation and wants it to pass, but the language in Section 5 of having to notify the physician of use of an interchangeable biologic, needs to be amended.

SENATOR HUGHES asked if most pharmacists have the electronic system that provides notification of an interchangeable biologic.

MR. HOLM said it will work if everyone has access to electronic medical records. If their software is not able to do that, it would be an extra step of notifying a physician of an interchangeable.

SENATOR HUGHES said this will be infrequent at best, not even one per month.

MR. HOLM said he sees the point that it could be infrequent, but his goal is to increase access. He did not agree with the assumption that interchangeables are inferior.

SENATOR HUGHES said she appreciates the concern, but defended the consensus language in the bill.

3:02:03 PM
DR. DAVID CHARLES, Chair, Alliance for Patient Access, testified in support of SB 32. He said he is a neurologist and he prescribes biologics every week. This bill is timely because it will get at the interchangeable aspect of biosimilars. He clarified the issue between the pharmacists and the physicians and stated support as it is listed in the bill. He explained the importance of notification to the physician of a switch in medication. The bill strikes the right balance with three days after dispensing for the pharmacist to provide the notification.

SENATOR STEVENS asked him to describe how the notification occurs.

DR. CHARLES said it could be a variety of ways, including telephone call, fax, email, or via electronic medical record.

3:08:20 PM
RYLAN HANKS, Pharmacist and Director of Policy, Amgen, Inc., testified in support of SB 32. He related that he was formerly with the Food and Drug Administration (FDA) in the Office of Generic Drugs. He explained the history and the science behind the intent of the bill, which was ease and affordability. In 2010 Congress passed the Biologics Price Competition and Innovation Act which allowed for the FDA to designate and approve biosimilars. The intent of the BPCI Act was to increase competition and affordability for medicine. He emphasized that generic drugs are not the same as interchangeable biologics and biosimilars.

MR. HANKS said SB 32 is important now in order to have guardrails in place for the use of interchangeable biologics and biosimilars. He discussed the fact that the FDA has disclosed that there are 64 biosimilar programs under development to 23 difference reference products and 10 are currently under active review. Having proper legislation is key.

He noted it is important to make clear how biosimilars should not be used, such as being inadvertently substituted. He said the bill is balanced and patient-centric and would provide cost savings to Alaskans.

3:13:16 PM
SENATOR STEVENS asked him to address the issue whether he finds the three-day notification onerous.

MR HANKS said, as a pharmacist, he does not find that onerous or burdensome.

CHAIR COSTELLO pointed out that there is a provision that addresses notification options, including the telephone.

3:15:16 PM
CHAIR COSTELLO closed public testimony on SB 32 and held the bill in committee for further consideration.

3:17:24 PM
There being no further business to come before the committee, Chair Costello adjourned the Senate Labor and Commerce Standing Committee meeting at 3:17 p.m.