ALASKA STATE LEGISLATURE
SENATE HEALTH AND SOCIAL SERVICES STANDING COMMITTEE
February 10, 2017
1:30 p.m.

MEMBERS PRESENT

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

MEMBERS ABSENT

All members present

COMMITTEE CALENDAR

SENATE BILL NO. 20
"An Act classifying U-47700 as a schedule IA controlled substance; and providing for an effective date."

- MOVED CSSB 20(HSS) OUT OF COMMITTEE

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 & HELD

PREVIOUS COMMITTEE ACTION

BILL: SB 20
SHORT TITLE: LIST U-47700 AS A CONTROLLED SUBSTANCE
SPONSOR(s): SENATOR(s) MEYER

01/18/17	(S)	READ THE FIRST TIME - REFERRALS
01/18/17	(S)	HSS, JUD
02/08/17	(S)	HSS AT 1:30 PM BUTROVICH 205
02/08/17	(S)	Heard & Held
02/08/17	(S)	MINUTE(HSS)
02/10/17	(S)	HSS AT 1:30 PM BUTROVICH 205

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

WITNESS REGISTER

CHRISTINE MARASIGAN, Staff
Senator Kevin Meyer
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Explained the CS for SB 20 on behalf of the sponsor.

SENATOR KEVIN MEYER
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Sponsor of SB 20.

SENATOR SHELLEY HUGHES
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Sponsor of SB 32.

AIMEE BUSHNELL, Staff
SENATOR SHELLEY HUGHES
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Provided an overview and sectional analysis of SB 32 on behalf of the sponsor.

RYLAN HANKS, Director
Global R&D and Regulatory Policy
Amgen Incorporated
Los Angeles, California
POSITION STATEMENT: Testified in support of SB 32.

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

DR. PHILIP SCHNEIDER, Chair
Advisory Board

Alliance for Safe Biologic Medicines
Phoenix, Arizona
POSITION STATEMENT: Testified in support of SB 32.

MARK GUIMOND
Director of State Legislative Affairs
Arthritis Foundation
Washington, D.C.
POSITION STATEMENT: Testified in support of SB 32.

GARY MCCLELLAND
Patient Advocate
Anchorage, Alaska
POSITION STATEMENT: Testified in support of SB 32.

ROBERT THOMS, representing himself
Wasilla, Alaska
POSITION STATEMENT: Testified in support of SB 32.

CINDY CASERTA, representing herself
Wasilla, Alaska
POSITION STATEMENT: Testified in support of SB 32.

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

EMILY NENON, Alaska Government Relations Director
American Cancer Society Cancer Action Network
Anchorage, Alaska
POSITION STATEMENT: Testified in support of SB 32.

DR. BARRY CHRISTENSEN, Co-Chair
Alaska Pharmacist Association
Ketchikan, Alaska
POSITION STATEMENT: Testified that the Alaska Pharmacist Association is neutral on SB 32.

LIS HOUCHEN, Chair
National Association of Chain Drugstores
Anchorage, Alaska
POSITION STATEMENT: Testified that the National Association of Chain Drugstores is neutral on SB 32 if notification were changed from three-business days to five-business days.

ACTION NARRATIVE

1:30:19 PM
CHAIR DAVID WILSON called the Senate Health and Social Services Standing Committee meeting to order at 1:30 p.m. Present at the call to order were Senators Giessel, Begich, von Imhof, and Chair Wilson.

SB 20-LIST U-47700 AS A CONTROLLED SUBSTANCE

1:30:48 PM
CHAIR WILSON announced the consideration of SB 20. He noted the proposed committee substitute (CS), 30-LS0319\D.

1:31:19 PM
SENATOR VON IMHOF moved to adopt the work draft CS for SB 20, version 30-LS0319\D, as the working document.

CHAIR WILSON asked if there was an objection to adopting the CS.

SENATOR VON IMHOF objected for discussion purposes.

1:32:07 PM
SENATOR MICCICHE joined the committee meeting.

1:32:16 PM
CHRISTINE MARASIGAN, Staff, Senator Kevin Meyer, Alaska State Legislature, Juneau, Alaska, explained the CS for SB 20 as follows:

> **Page 4, line 30:**
> Misspelling corrected, adding a "z" in the word that was brought up by Dr. Butler.
>
> **Page 4, line 31:**
> There's a new Section 2, this new section continues on page 5, lines 1-6 which basically inserts the language to have tramadol be Schedule IVA controlled substance thus bringing Alaska statute in line with what has already happened on the national level of tramadol.

CHAIR WILSON asked if the objection to the CS is maintained.

1:33:05 PM
SENATOR VON IMHOF removed her objection.

CHAIR WILSON announced that without objection, the CS for SB 20, version D, is adopted by the committee.

SENATOR MICCICHE asked to comment prior to moving the bill out of committee. He stated that the things that he has been looking at to try and present more of a catch-all moving forward needs more work. He asserted that the bill definitely improves the situation and he is very supportive. He said he will be getting with those that are experts, including [Senator Giessel], to work on recommendations going forward.

CHAIR WILSON stated that he appreciated Senator Micciche's comment and noted that all committee members would like a more in-depth solution to the matter that plagues the state's communities.

SENATOR KEVIN MEYER, Alaska State Legislature, Juneau, Alaska, Sponsor of SB 20. Commented as follows:

> I certainly agree with Senator Micciche and I think we had a really good discussion on this topic and how we need to come up with a system so that we can react quicker, faster, be a little more nimble than waiting for us to come into session and go through the process of passing a law; although, we are creating a new law with a pretty severe crime. So, I think it does deserve a deliberative process, but I would agree I think Senator Giessel and her opioid task force might be a good place to start the discussion or this committee and we are certainly very supportive and want to help in any way we can, but at least what this will do now is get this particular bill or this particular drug which we know is currently a serious problem, unlawful and against the law, so that the police force can now start implementing appropriate penalties.

CHAIR WILSON disclosed that the plan in future weeks is to have the Statewide Drug Enforcement Unit and the Alaska Opioid Policy Task Force present options before the committee to solve the problem that SB 20 addresses.

SENATOR MEYER thanked Chair Wilson.

CHAIR WILSON asked if there is any objection to Senator von Imhof's motion to move SB 20.

1:35:29 PM
SENATOR VON IMHOF moved to report the CS for SB 20, version D, from committee with individual recommendations and attached fiscal note(s).

1:35:39 PM
CHAIR WILSON announced that seeing no objection, CSSB 20(HSS) moved from the Senate Health and Social Services Standing Committee.

1:35:48 PM
At ease.

SB 32-PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS

1:37:36 PM
CHAIR WILSON announced the consideration of SB 32.

1:38:05 PM
SENATOR SHELLEY HUGHES, Alaska State Legislature, Juneau, Alaska, sponsor of SB 32, set forth that the bill will provide Alaskans with safe access to new U.S. Food and Drug Administration (FDA) approved treatment options called, "interchangeable biological products." She detailed as follows:

> Under current state law pharmacists can prescribe lower-cost generic drugs for the prescribed drug, but currently there's absolutely no provision pertaining to biologic medicines.
>
> The urgency of this bill is twofold:
>
> 1. Right now a pharmacist could technically substitute a biosimilar for a biologic product and not be in violation of state law because we don't have anything preventing that.
> 2. Within a year the FDA will begin to be approving interchangeable biologic products.
>
> We've had biologic products around for years, Humira is one that is used for arthritis as an example; but, now being developed are the biosimilars and there also are a number of those on the market which a doctor can now prescribe and a pharmacist can dispense in Alaska. What we are talking about is a new category of interchangeable biosimilars.

> A generic drug is chemically based and so it can be reproduced identically, the chemistry, the cellular structure. A biological product is different, it is made from a living organism and so biosimilar does not have an absolutely identical structure to the original biological products. So, a biosimilar is going to be as the word indicates, "similar, but not absolutely identical;" however, the new category that FDA is working on, the interchangeable, the goal will be that it will be extremely similar so that if a substitute were dispensed, it would be expected that there would not be the adverse reactions of something that is quite different.

SENATOR HUGHES set forth that SB 32 would be very good for Alaska in reference to the state's Medicaid budget. She revealed that all of the states that have passed legislation similar to SB 32 have indicated savings expectations for Medicaid as well as family budgets. She noted that Missouri has "gone out on the limb" regarding interchangeable biological products and projected an overall savings between federal and state Medicaid budgets of over $100 million. She conceded that Alaska will not see similar savings due to the state's smaller population, but asserted that every dollar counts at this point in Alaska.

1:42:23 PM
AIMEE BUSHNELL, Staff, Senator Shelley Hughes, Alaska State Legislature, Juneau, Alaska, provided an introductory statement on SB 32 as follows:

> SB 32 follows model-consensus language that has been worked on extensively and agreed by numerous patient-advocacy groups, along with prescriber-association groups and pharmacists throughout the country; most of these specialty organizations and patient organizations use biologics primarily in treating specialty and serious conditions like cancer, rheumatoid arthritis, multiple sclerosis (MS), and other neurological disorders. There also has been significant outreach and discussion with Alaska stakeholders for months, some of which may be testifying today.

She explained that to allow access to interchangeable biologics with the necessary agreed upon safety provisions, SB 32 provides the following:

1. Defines the relevant terms of "biological product," "interchangeable biological product," consistent with federal law.
2. Limits substitution of biologics to only those biosimilars approved as interchangeable by the FDA.
3. Preserves the ability for prescriber to prevent substitution and allows prescribers to write, "Dispense as written" to keep the patient taking what they believe is in their best interest.
4. Requires the pharmacists to maintain communication with the prescriber of the specific drug dispensed by electronic means if accessible and if not, by phone, fax or prevailing means and to maintain a record; so it won't be to just the pharmacist's discretion, there is also communication involved between the prescriber, the pharmacist and the patient.

1:44:25 PM
MS. BUSHNELL proceeded with a sectional analysis of SB 32 as follows:

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 FDA's 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, it prevents substitution if the prescriber indicates

"Dispense only as written;" this is similar to what has already been in law for generic chemical drugs. Also provides that a pharmacist who substitutes a biologic in compliance with this section in law incurs no greater liability than what is incurred in filling the original prescription, also similar to what is already in law for generic chemical drugs.

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 U.S. 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.

1:46:08 PM
SENATOR VON IMHOF asked if physicians will be able to check a box on their prescription pads that says, "No biosimilar substitutions." She stated that she believed physicians currently have a check-box that says, "No generic substitutions."

SENATOR HUGHES explained that prescription pads are different. She suggested that [Senator Giessel] could possibly provide input on prescription pads. She said her understanding is that some prescribers can check-off or write, "Dispense as written." She added that a prescriber considering an interchangeable biologic may also write, "Call if the substitute is available"

and that way the prescriber will know exactly what the patient would or would not be taking.

SENATOR VON IMHOF noted that something similar has passed in 26 states already. She said sometimes there are questions from doctors on being notified within a certain time frame. She asked how many days the notification period is.

SENATOR HUGHES disclosed that the topic Senator von Imhof addressed involved a lot of groups and has been thoroughly debated and vetted. She revealed that the notification topic was initially a tug-of-war because pharmacists preferred to be able to just substitute like they do with the generics and they don't want to have to make a request or to even notify; on the other hand, the prescribers often wanted to make sure that a request came in first. She added that the patient wants their medicine as soon as possible, but a timely response from a prescriber is very unlikely. She reiterated that bearing in mind the patient's needs, prescribers can indicate, "Dispense as written" and also add, "Call if a substitute is available." She said the prescription-pad notations seemed to be the consensus language across the nation that seems to work and addresses the needs of busy pharmacists, patients who need their medicine right away, and prescribers who want to make sure they know what their patients are taking.

1:49:19 PM
CHAIR WILSON inquired if Senator Hughes knew what percentage of doctors actually write, "As prescribed" for their prescriptions. He noted that he is concerned about adverse effects for substituting medications for biologicals. He added that many doctors may not know about the side effects of substituting medications for biological drugs.

SENATOR HUGHES replied that once the FDA begins to put medicines in the new category of "interchangeable," the medicines will be extremely similar. She noted that as testing continues, the intent is to make sure biologicals are similar to a generic with no problems. She asserted that the drug manufacturers do not want problems and will be monitoring for adverse reactions.

She pointed out that the number of prescribers will tend to be specialists involved with chronic diseases such as arthritis and lupus. She asserted that the specialists will be aware that biologicals are available and more affordable for patients.

SENATOR HUGHES communicated that biological products were currently not inexpensive and asserted that SB 32 is needed for pharmacists to stock biologicals in order to be ready for prescriptions, otherwise pharmacists will not make biologicals available and Alaskans will miss out on the opportunity. She set forth that biological products are going to be a safe and affordable option upon FDA approval. She conceded that biological products are a new concept that will require a bit of education.

She noted that generics are accepted because they are chemically identical; however, there is confusion that a biological product like Humira will be substituted with a biosimilar. She pointed out that a biosimilar has not been approved to be interchangeable and that was another reason why SB 32 is needed because currently a pharmacist could interchange a biosimilar and that would not be a violation of state law and the patient could have an adverse effect.

She summarized that SB 32 is important to make sure that substituting occurs with the interchangeable biosimilars and that the practice is in law. She set forth that SB 32 is needed now rather than later because biosimilars are expected within six months to a year.

1:52:41 PM
SENATOR BEGICH revealed that all of the information he has received regarding interchangeable biological products has been very positive. He asked if there has been any organized opposition from Alaska or any of the states that have been reviewed.

SENATOR HUGHES replied that she is not aware of organized opposition. He disclosed that there have been some prescribers that have been concerned. She reiterated that there has been a tug-of-war between prescribers and pharmacists regarding notification. She added that the bill applies to an FDA interchangeable that should not cause the reactions that patients might be concerned about.

CHAIR WILSON pointed out that most of the biological medications are not stocked on pharmacy shelves and the majority are mail ordered. He noted that most people he knows that get their biologics directly through their doctor's office do so without having to go to a pharmacy. He asked how dealing directly with doctors impacts mail-order purchases.

SENATOR HUGHES revealed that the Alaska Pharmacists Association, a medical doctor and a pharmacist from the College of Pharmacy in Arizona are available to answer Chair Wilson's question.

1:55:43 PM
CHAIR WILSON opened public testimony on SB 32.

1:56:28 PM
RYLAN HANKS, Director, Global R&D and Regulatory Policy, Amgen Incorporated, Los Angeles, California, testified in support of SB 32. He explained that Amgen is a manufacturer of both innovative biologic medicines and has leveraged their 35 years of experience to start making biosimilar medications. He said Amgen sees the value in the importance of biosimilar medication to its patients.

He noted that generic drugs provide a bit of a conceptual overview or framework about today's biosimilars and interchangeable biologics, but noted that there is a difference. He detailed that biologics are much more complex in size and structure than traditional chemical drugs; i.e. small tablet-based pills. He revealed that the size difference is quite immense, on the order of 800 to 1,000 times larger than a chemical drug. He added that biologics are largely protein-based products that are much more complex than traditional medicines. He pointed out that biologics and biosimilars will be things that are highly similar, but not exactly the same as referred to earlier. He emphasized that biologics and biosimilars are products that have been rigorously tested by the FDA.

He disclosed that biologics, biosimilars and interchangeable biologics are granted authority to the FDA to approve. He explained that there are two standards to meet: biosimilar and interchangeable biologic. He specified that biosimilar meets a certain standard which means it can be used in practice and does not cause any clinical effect or adverse problems to a patient, and it should be in a "good standard."

He specified that an interchangeable biologic must meet a biosimilar standard with no clinical differences, including looking at switching back and forth between the original product and the proposed interchangeable product. He added that the interchangeable biologic must also show no significant differences in safety or efficacy.

He set forth that when an interchangeable biologic is approved, the product will have been vetted significantly with an

understanding that the FDA's process also addressed switching back-and-forth and safety when the products come to market.

1:59:52 PM
MR. HANKS summarized that biosimilars and interchangeable biologics are going to be highly important medicines for patients by providing additional access for affordable and cost saving medicines for Alaskan patients. He opined that SB 32 is truly a patient-first bill that will improve patients' lives for very serious and chronic medical conditions.

SENATOR MICCICHE asked if Amgen produces biologics and biosimilars.

MR. HANKS answered yes.

SENATOR MICCICHE said he referenced data that says no two biologics are exactly the same, just as no two finger prints are exactly the same. He asked if different batches of Amgen's biologics are also not the same.

2:01:06 PM
MR. HANKS answered that the biologics' batches can have slight variability, but manufacturers' batch-to-batch production of a biologic medicine have specific controls in place to manufacture within a tight spectrum. He added that the biologics are rigorously tested, have additional scientific criteria, and noted their long history with manufacturing the same product. He admitted that a slight variation can happen, but the variation is within a very tight and narrow window, so it does not cause an effect. He reiterated that the FDA reviews biologics' for causing changes. He detailed that biosimilars are a significant kind of development based on a novel product that takes the original product and a biosimilar process is created from scratch to make new biosimilars, so each batch is a little bit distinct.

2:02:04 PM
SENATOR MICCICHE referenced a Rand Corporation prediction that biosimilar savings between 2014 and 2024 will be $44.2 billion. He cited an Express Scripts estimation that potential savings between 2014 and 2014 will be $250 billion, a 500 percent difference from the Rand prediction. He asked why there are savings when the process sounds the same. He inquired if the biosimilar process is as rigorous.

MR. HANKS explained that the FDA looks at biosimilars as a product that already has an established and efficacious reference product. He specified that biosimilars have to meet a standard of comparable safety and efficacy where new safe and efficacious standards do not have to be established. He summarized that cost savings are realized from the biosimilars' development process.

SENATOR VON IMHOF asked what the benefits are from switching back and forth, other than cost.

MR. HANKS replied that switching back and forth will provide some flexibility for physicians when medication options are considered. He reiterated that biosimilars' profiles will not be exactly the same and prescribers will be able to establish the best product from multiple options.

2:04:23 PM
SENATOR VON IMHOF remarked that genetic research will allow medications to be fine-tuned for the person. She asked what can happen in three days between the time that the pharmacist dispenses an interchangeable biologic and the time that the doctor is notified.

MR. HANKS admitted that he is not an expert on immunogenicity; however, he disclosed that Amgen does not predict an immune response from a patient in a short period of time. He said Amgen does not expect to see concerns, issues or adverse events that happen quickly after a patient moves from one biologic product to interchangeable biologic products. He explained that Amgen's expectations are based on the extensive research done on moving back and forth between products. He pointed out that communication and updating patients' medical records are key.

SENATOR BEGICH asked if any projections were done for the potential savings in Alaska that might occur from the change.

MR. HANKS replied not to his knowledge.

2:06:32 PM
SENATOR GIESSEL asked when Mr. Hanks anticipates the FDA will approve the interchangeable biologics.

MR. HANKS answered that he could not provide a specific time, but noted that he expects interchangeables in the near future.

SENATOR GIESSEL asked why rush SB 32 if FDA approval is not known. She inquired why speeding up the FDA approval process would be considered when the diseases and medications are complex.

2:08:06 PM
MR. HANKS explained that the rationale behind introducing legislation at the current time is to clarify interchangeable biologic use and to make clear what a similar should not be used as. He opined that the urgency is based on the fact that biosimilars are coming to the market and being used by patients. He said there needs to be clearly defined rules on appropriate use of interchangeable biologic products.

He asked that Senator Giessel clarify her questions pertaining to speeding up the approval process.

SENATOR GIESSEL replied that when the FDA will provide approval is not known. She asked why not wait for FDA approval. She pointed out that approval could take two years.

MR. HANKS reiterated that interchangeables are coming with the need to clarify and provide rules around how to use biosimilars. He pointed out that Alaska has nothing in state law in the Pharmacy Practice Act about either biosimilar or an interchangeable. He noted that Senator Hughes discussed the possible impact if a pharmacist does not have clear ideas about how to use either of the two products. He added that multiple biosimilars are currently under FDA review and a robust increase could occur during the current year.

SENATOR GIESSEL asked Chair Wilson if the Board of Pharmacy will be available to address questions from the committee.

CHAIR WILSON replied that he did not see a representative from the Board of Pharmacy. He suggested that questions could be asked for follow up if the board could present.

2:10:53 PM
DR. DAVID CHARLES, Chair, Alliance for Patient Access, Nashville, Tennessee, testified in support of SB 32. He detailed that AFPA is a national organization consisting of several hundred physician members across various specialties including urology, rheumatology, dermatology, oncology, and so forth. He noted that many of the member specialists use biologics. He added that he is a neurologist and uses biologics in his practice.

DR. CHARLES stated that biologics are revolutionizing the care of people with a host of conditions including cancer, arthritis, inflammatory bowel disease, and multiple sclerosis. He said biologics are phenomenal and provide treatments that were not available before.

He declared that he endorsed SB 32 and remarked that the provisions in the bill are excellent. He agreed that there is some back-and-forth between physicians and pharmacists about the medication and how substitutions will be handled.

He explained that the FDA is addressing two types of biosimilars: regular biosimilars and interchangeable biosimilars. He specified that for the pharmacist to be able to substitute there are really only those that are interchangeable. He opined that many physicians may be comfortable with the pharmacy doing the change with interchangeable biosimilars. He remarked that SB 32 got it right because the bill keeps the ability of the physician to write, "Dispense as written."

He stated that SB 32 struck the right balance in notification. He added that communication is key between the pharmacists and prescribers. He opined that AFPA members would agree with a timely notification within 72 hours to update patient records and noted that SB 32 says 3 days. He noted that bills across the U.S. are striking the balance of compromise between physicians and pharmacists. He added that he agreed with including the, "Dispense as written" part if there was a concern by a physician when medically necessary.

2:16:43 PM
DR. PHILIP SCHNEIDER, Chair, Advisory Board, Alliance for Safe Biologic Medicines (ASBM), Phoenix, Arizona, testified in support of SB 32. He detailed that that ASBM is a group of patients, physicians, pharmacists and manufacturers working towards the safe introduction and use of biosimilars. He asserted that biologic medicines have helped patients with some of the serious chronic conditions like cancer, immune disorder, arthritis, diabetes, Crohn's disease, and multiple sclerosis (MS); copies of these medicines called biosimilars are becoming available in the U.S. and they have the potential for new therapeutic options for patients at lower costs.

He specified that unlike generic versions of simple chemical drugs, biosimilars are not exact duplicates of the reference product. He pointed out that due to the complexity of the

biologics in the proprietary manufacturing process, they are viewed as copies and can only be similar and never the same. He disclosed that the smallest structural difference between the biologic and its biosimilar can have a significant impact on patients. He disclosed that regulators, including the FDA and the World Health Organization, have made "naming" to distinguish products a priority in order to make inadvertent substitution less likely. He set forth that with biosimilars it is critical that the physician, pharmacist, patient and regulators know what medicine the patient is actually receiving.

DR. SCHNEIDER explained that current Alaska law does not provide a clear pathway to the substitution of biosimilar drug products; therefore, pharmacist will need to require advanced approval from the prescriber before substituting an interchangeable biologic for a brand-name biologic, a provision that SB 32 will remove. He detailed that SB 32 will allow Alaska pharmacists with the ability to dispense safe and less expensive biologic medicines to patients by allowing the substitution of interchangeable biologic that are prescribed for anything biologic. He asserted that SB 32 protects patients and ensures only FDA approved interchangeable biologic products may be substituted without prior prescriber consent, this is similar to substitution requirements of generic substitution. He added that physicians will retain the authority to write, "Dispense as written" which is identical to the authority for generic substitution.

He pointed out that because biologic products differ from generics in their complexity and are not identical, the legislation assures that there will be a clear and timely communication between pharmacists and prescribers to ensure patient records reflect which specific product is being dispensed to the patient. He said pharmacists will have up to three-business days to relay medication information that is being dispensed so all providers have an accurate patient medical record. He stated that having an accurate patient medical record allows providers to assess the patient's response to a particular treatment.

He set forth that ASBM and various pharmaceutical, pharmacy and insurance companies support SB 32 because the legislation provides a clear substitution process by which pharmacists can dispense a FDA approved interchangeable biologic without first seeking approval. He added that the bill also increases access to lower-cost medicines for patients. He added that SB 32 is

similar to legislation that has been passed in 26 states and Puerto Rico.

DR. SCHNEIDER summarized that ASBM supports SB 32 because the bill removes barriers to low-cost medicines and increases treatment options while recognizing the need for transparency and communication among health-care providers to ensure patient safety when using the promising new biologic medicines.

2:22:25 PM
MARK GUIMOND, Director of State Legislative Affairs, Arthritis Foundation, Washington, D.C., testified in support of SB 32. He set forth that biologics for the arthritis community are critical. He said biologics have changed in a generation, the difference for children in particular with juvenile arthritis that were living their lives in a wheelchair to going out and playing. He stated that the Arthritis Foundation wants to make sure biologics are available to everybody.

He pointed out that biosimilars as a science offers the opportunity to have new biologics come to market that are proven and safe. He revealed that the new drugs coming to market are innovative, less expensive and more available to people. He said the Arthritis Foundation wants to change lives in the arthritis community and biologics does that.

He set forth that the Arthritis Foundation supports a post-substitution notification as specified in the bill from the pharmacist to the prescriber because the mechanism in the legislation will be consistent with federal law.

2:25:53 PM
GARY MCCLELLAND, Patient Advocate, Anchorage, Alaska, testified in support of SB 32. He revealed that he is a cancer patient. He set forth that the additional options provided by biological medicine allows him to receive treatment in Anchorage rather than having to travel to the Lower 48. He added that making biosimilars available in a short period of time will be a cost-cutting measure for himself, other patients and the state.

2:28:19 PM
ROBERT THOMS, representing himself, Wasilla, Alaska, testified in support of SB 32. He revealed that he has rheumatoid arthritis and uses Humira. He revealed that using Humira has allowed him to enjoy a functional life.

2:32:27 PM

CINDY CASERTA, representing herself, Wasilla, Alaska, testified in support of SB 32. She disclosed that she is the wife of Mr. Thoms and confirmed that Humira has helped him. She asserted that Mr. Thoms and other Alaska residents can benefit from additional options if the FDA approves more biosimilars. She said the passage of SB 32 will allow patients to make informed choices about other, perhaps cheaper biologics. She added that patients' doctors and others will be notified within days and together they can modify the biologic's effect.

2:35:19 PM
ASHLYN ANTONELLI, representing herself, Anchorage, Alaska, testified in support of SB 32. She asserted that biological drugs are necessary and noted that she would not be at the committee meeting without the use 0f biologics. She added that she supported SB 32 due to the potential cost savings from biological drugs as well.

2:42:02 PM
EMILY NENON, Alaska Government Relations Director, American Cancer Society Cancer Action Network, Anchorage, Alaska, testified in support of SB 32. She set forth that SB 32 is an opportunity to update state statutes to keep up with the advances in medical science. She asserted that biologic drugs are providing tremendous promise in the treatment of cancer. She revealed that there are currently no FDA-approved interchangeable biosimilars for cancer treatment; however, there are a number in the research pipeline and statutes will need to be updated.

She revealed that biologic drugs are some of the most expensive cancer drugs on the market today. She noted that just as generics have done for small molecule drugs, interchangeable biosimilars have the potential to increase price competition with some of the older biologic drugs and result in lower cost burdens for cancer patients.

She summarized that there are three-basic principles that are important to the American Cancer Society Cancer Action Network regarding legislation: consent, notification and record keeping, and safety and interchangeability.

2:45:18 PM
DR. BARRY CHRISTENSEN, Co-Chair, Alaska Pharmacist Association, Ketchikan, Alaska, testified that the Alaska Pharmacist Association is neutral on SB 32. He addressed previous testimony and noted that most pharmacies in Alaska are currently

dispensing biological products, mostly in the form of insulin and drugs for rheumatoid arthritis.

DR. CHRISTENSEN announced that the Alaska Pharmacist Association is neutral on SB 32, mostly because the association has not had enough time to review the legislation. He noted that the association has asked for clarification on part of the naming portion of the bill on page 2. He detailed that naming will impact pharmacy software systems for correct labeling.

SENATOR GIESSEL asked if pharmacists in Alaska currently dispense biosimilars.

DR. CHRISTENSEN replied that biosimilars are new territory, but will definitely be part of the future. He said he believed that some biosimilars are being dispensed. He noted that one of the bigger biosimilars that have come on the market is one of the long-acting insulins that insurance companies are promoting for its lower costs.

2:48:04 PM
SENATOR GIESSEL asked if an Alaskan pharmacist at this time would make a substitution for either a biosimilar or a biologic without consulting the prescriber and getting affirmation from the prescriber.

DR. CHRISTENSEN answered no. He specified that currently all pharmacists should be getting a new prescription for the biosimilar product.

SENATOR BEGICH asked how consent communication would work with mail-order companies. He inquired if the consent requirement would essentially prohibit the use of mail order for biosimilars.

DR. CHRISTENSEN replied that he did not see a problem with compliance because information can be sent electronically via the insurance-side of things.

2:50:02 PM
LIS HOUCHEN, Chair, National Association of Chain Drugstores (NACDS), Anchorage, Alaska, testified that the NACDS is neutral on SB 32 if notification is changed from three-business days to five-business days. She set forth that a change to Section 5, line 28 from a three day to a five-day notification would provide a larger reporting window in the event that something outside of a pharmacist's control occurs.

2:51:52 PM
CHAIR WILSON closed public testimony on SB 32.

2:52:18 PM
CHAIR WILSON held SB 32 in committee for future consideration.

2:52:57 PM
There being no further business to come before the committee, Chair Wilson adjourned the Senate Health and Social Services Committee at 2:52 p.m.