SB 32

<TARGET><BILL>SB 32</BILL><SUBJECT>SB 32</SUBJECT><COMM>SHSS30</COMM></TARGET>

Alaska State Legislature

SESSION ADDRESS:
Alaska State Capitol
Juneau Alaska 99801
907-465-3743
800-565-3743
Sen.Shelley.Hughes@akleg.gov

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600 E Railroad Avenue
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Senator Shelley Hughes
Senate District F – Greater Palmer, Chugiak, Peters Creek, Eklutna, Fairview Loop, Gateway, Butte, Lazy Mountain

SB 32 Interchangeable Biological Products

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 biosimlar 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.

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.

Staff contact: Aimee Bushnell, (907) 465-3743

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SB 32 Interchangeable Biological Products

Sectional Analysis

"An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

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.

Staff contact: Aimee Bushnell, (907) 465-3743

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 32
Fiscal Note Number:
() Publish Date:

Identifier: SB032-DCCED-CBPL-02-03-17
Title: PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS
Sponsor: HUGHES
Requester: (S) HSS

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)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services	4.5						
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**4.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
1156 Rcpt Svcs (DGF)	4.5						
Total	**4.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
1156 Rcpt Svcs (DGF)	4.5						
Total	**4.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

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

Estimated CAPITAL (FY2018) 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? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 07/01/18

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By:	Janey Hovenden, Director	Phone:	(907)465-2538
Division:	Corporations, Business and Professional Licensing	Date:	02/03/2017 12:00 PM
Approved By:	Catherine Reardon, Director	Date:	02/03/17
Agency:	Division of Administrative Services, DCCED		

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 32

Analysis

SB 32 allows a substitution of a prescription for a biological product with an interchangeable biological product. If the original prescribed product is not available in the pharmacy or is more expensive than an interchangeable product, the pharmacist may choose to dispense the interchangeable product. Substitution would allow for more availability of a biological product, and lower cost to the patient. This bill requires the pharmacy to contact the prescribing practitioner if a substitution of the original prescription of a biological product is made with an interchangeable biological product.

In addition this bill requires the Board of Pharmacy to post and maintain a link to the US Food and Drug Administration's list of all currently approved interchangeable biological products on the board's website.

The bill does not specifically change the pharmacy licensing program. However, it does allow a broader scope for a pharmacist to dispense an equivalent product more available to a patient.

If the bill passes the division will require $4.5 for legal costs to amend regulations, printing, and postage in the first year.

Professional licensing programs within the Division of Corporations, Business and Professional Licensing are funded by Receipt Supported Services, fund source 1156 Rcpt Svcs (DGF). Licensing fees for each occupation are set per AS 08.01.065 so the total amount of revenue collected approximately equals the occupation's actual regulatory costs.

UNDERSTANDING BIOLOGIC AND BIOSIMILARS LEGISLATION

Current Alaska state law does not provide a clear pathway for pharmacists to substitute biological drug products. These biological products differ from traditional generics as biosimilars are not identical versions of biologics. Biologic medicines are used to treat serious and chronic diseases, such as rheumatoid arthritis, cancer and multiple sclerosis. Supporting transparent communication between what physicians prescribe and what pharmacists are dispensing will ensure patient safety while removing the barriers to potentially lower cost medicines.

CHEMICAL MEDICINES	BIOLOGIC MEDICINES
MANUFACTURING	
	
Developed from a chemical "recipe" and often comes in pill form.	Grown from living cells and are often developed as injections or infusions.
GENERICS vs BIOSIMILARS	
	
Generics and their ingredients can be duplicated exactly.	No two biologics are exactly the same just as no two fingerprints are exactly the same.
PATIENT SAFETY	
	
Because they have the same chemical formulas, generics and brand name medications often share similar side effects.	A biosimilar is highly similar to its originator biologic and has been found to not result in clinically meaningful differences from the originator biologic. Because the two products have different manufacturers and are not identical, however, some patients may experience certain differences in response with one versus the other.

26 states plus Puerto Rico have passed biologic substitution legislation.

WHY LEGISLATION IS NEEDED IN ALASKA

- Current Alaska state law does not provide a clear pathway for pharmacists to substitute biological drug products known as biosimilars. These biological products differ from traditional generics as biosimilars are not identical versions of their originator biologics.
- SB 32 updates current laws to allow biological substitution.
- SB 32 allows a pharmacist to substitute an FDA-approved interchangeable biosimilar for a prescribed originator biologic without first seeking approval from the physician.
- SB 32 requires that within a certain time after dispensing, the pharmacist must communicate to the physician the specific biologic product dispensed.
- Numerous providers and patient groups have advocated for this kind of transparent communication about the particular biologic that was dispensed.
- SB 32 will increase access to lower cost drugs for patients.
- SB 32 relies on electronic communication between the pharmacist and prescriber, which is intended to create a clear and accurate medical record of which product was ultimately dispensed to the patient.

Senate Bill 32

Alaska biosimilars legislation would enhance patient access to potentially less costly medications.

SB32:

- would allow substitutions of prescribed biological drugs with less expensive biological products determined by the U.S. Food and Drug Administration (FDA) to be interchangeable.
- would require the pharmacist to provide notice to the prescriber of the substitution within three business days.
- would not allow substitution if the prescriber indicates the drug prescribed is medically necessary for the patient or the patient refuses the substitution.

ACS CAN supports SB32 based on three principles:

- **Consent.** Physicians should have the ability to withhold consent for substitution.
- **Notification and recordkeeping.** Physicians should be notified of the biologic substituted to ensure an accurate and enduring patient medical record.
- **Safety and interchangeability**. The FDA is the sole entity responsible for ensuring the integrity and designation of "interchangeable biosimilars."

Biologics and biosimilars:

Biologic drugs are some of the most expensive cancer drugs on the market today. They have provided cancer patients and their physicians with access to improved treatment options. The unique properties of these drugs can result in precise targeting of cancer cells individually, enabling better clinical outcomes while minimizing debilitating adverse effects.

Biosimilars may offer some potential for increasing access and affordability as they provide competition for the original biologic drugs, similar to what generic drugs do for name-brand drugs. While a biosimilar may be highly similar to an FDA-approved biologic drug, because of the complexities of biologic manufacturing, it is not possible for a biosimilar to be an exact copy of the originator drug.

Federal and state biosimilar policies are needed to ensure safety and efficacy of all biologic drugs, and ensure access and affordability of biosimilars for cancer patients.

American Cancer Society Cancer Action Network / 3851 Piper Street, Suite U240, Anchorage, AK 99508
Emily Nenon, Alaska Government Relations Director / Emily.Nenon@cancer.org
www.acscan.org/alaska

January 12, 2017

The Hon. Pete Kelly
The Hon. David Wilson
The Hon. Kevin Meyer
The Hon. Shelley Hughes
The Hon. Bryce Edgmon
The Hon. Ivy Spohnholz
Alaska State Capitol
Juneau, AK 99801

On behalf of the undersigned organizations, we write to express the critical need for policy that allows for the substitution of biologics with biosimilars and ensures prescriber and pharmacist communication throughout a patient's treatment process. Biologic medicine legislation is an opportunity for Alaska to do what is right, by creating a pathway that facilitates a patient's access to affordable treatment options while ensuring a patient's doctor has accurate medical records through pharmacist communication.

Biologics are a class of medication that treat diseases like cancer, arthritis, lupus, and other autoimmune conditions. These medicines are uniquely complex, as they are made with living cells that work to relieve a patient's symptoms by targeting a disease at its source and providing much-needed relief to millions of patients. Now, similar versions of biologics called "biosimilars" have emerged on the market, making this level of treatment accessible to a wider range of patients.

It is important to know that biosimilars are not the same as generic medicines – which is the reason we need legislation. The Food and Drug Administration (FDA) determines the interchangeability of biologic products, while each state governs the substitution policies. Presently, four biosimilars have been approved by the FDA, with many more in the pipeline. Without updated legislation, Alaska pharmacists will lack the authority to substitute biologics deemed interchangeable by the FDA. Patients and their doctors need a safe and transparent process by which they can receive access to their medications and pharmacists need a firm standard for substituting biologic products with those that the FDA has deemed interchangeable.

Currently, 26 states and territories have passed biosimilar legislation.

We encourage the Alaska State Legislature to be among the states that bring affordable access to innovative medical treatment options to all Alaskans. On behalf of the undersigned patient and physician organizations, we hope to see this important legislation introduced in the legislative session.

Thank you for your consideration.

Contact: Mark Guimond, Director of State Legislative Affairs
Arthritis Foundation
202 887-2912
MGuimond@Arthritis.org


Arthritis
Foundation℠


Cancer Action
Network℠
American
Cancer
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LUPUS
and
ALLIED DISEASES
Association, Inc.


IFAA
AN INTERNATIONAL FOUNDATION FOR
AUTOIMMUNE & AUTOINFLAMMATORY DISEASES
WITH ARTHRITIS AS A MAJOR COMPONENT


AMERICAN COLLEGE
OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH


Academy of Integrative
Pain Management


GLOBAL HEALTHY LIVING
FOUNDATION


Spondylitis
Association
of America™

NATIONAL PSORIASIS FOUNDATION®

AfPA Alliance for Patient Access

NICA NATIONAL INFUSION CENTER ASSOCIATION

RNS RHEUMATOLOGY NURSES SOCIETY™

U.S. PAIN FOUNDATION

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

January 30, 2017

Senate Health and Social Services Committee
Alaska State Capitol

Dear Senators,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to urge you to **support Senate Bill 32 (SB 32)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, researchers and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a retired pediatric rheumatologist and a former president of the American Society of Health-system Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. "Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient, including reduced efficacy or unwanted immune responses.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in eleven countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Canada, Europe, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians found that 80% of those surveyed called communication in the event of a biosimilar substitution "very important" or "critical".**

- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating "do not substitute" or "dispense as written" on a prescription "very important" or "critical".**

These results are consistent with those of physicians around the world, including those surveyed in Canada and Europe, where biosimilars are currently in clinical use. All ASBM surveys are available on our website at www.safebiologics.org/surveys.

It is our view that **SB 32 appropriately reflects the importance of pharmacist-physician communication** and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) may ever be substituted.

- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing on the prescription "dispense as written".

- It provides that the pharmacist receive the patient's consent in order to make a substitution.

- Finally, SB 32 requires that the pharmacist communicate to the physician within a reasonable time frame (3 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

SB 32 will extend these valuable protections to Alaska's patients while increasing their access to biologic therapies. For these reasons, lawmakers in **26 states and Puerto Rico have passed similar bills** in the past few years.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Alaska by supporting Senate Bill 35.

Sincerely,

Harry Gewanter, MD
Chairman, The Alliance for Safe Biologic Medicines

Philip J. Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines
Associate Dean, University of Arizona College of Pharmacy

ASBM Steering Committee Members:
Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
Hepatitis Foundation International
International Cancer Advocacy Network
Kidney Cancer Association
National Psoriasis Foundation
ZeroCancer

Dr. David Charles, National Chairman, Alliance for Patient Access

Alliance for Patient Access is led by David Charles, M.D., who is a Chief Medical Officer and Professor of Neurology practicing in Nashville, Tennessee. Dr. Charles is a national leader in Movement Disorders research and is past Chairman of the Public Policy Committee for the American Neurological Association. Dr. Charles took leave from his practice in 1998 and spent a year on the staff of U.S. Senator Bill Frist, where he served as a health policy advisor. Following this experience in Washington, Dr. Charles conducted Parkinson's disease research in France as a Fulbright Senior Scholar. Charles' research is primarily focused on movement disorders including Parkinson's disease, cervical dystonia, tremor, spasticity and neurotoxin injections. He has authored over 60 research publications and is currently the principal investigator in the only FDA approved clinical trial testing the efficacy of Deep Brain Stimulation in people with early stage Parkinson's disease.

Dr. Philip J. Schneider, Professor and Associate Dean for Academic and Professional Affairs, University of Arizona College of Pharmacy

Philip J. Schneider, MS, FASHP - Philip J. Schneider is Clinical Professor and Associate Dean for Academic and Professional Affairs for the University of Arizona, College of Pharmacy at the Phoenix Biomedical campus. In this position, he provides oversight, development, and administration of educational initiatives including teaching, service and scholarship activities at the newly created Phoenix Biomedical Campus.

Prior to this position, for 33 years he held positions at the Ohio State University including most recently Clinical Professor and Director of the Latiolais Leadership Program at the Ohio State University, an inter professional program to advance leadership in pharmacy and improve the medication use system to reduce adverse drug events. Before taking this position, for 21 years he held pharmacy practice and administrative positions at the Ohio State University Medical Center and was responsible for the Pharmacy Residency program at which 99 residents were trained during his years as program director. Active in national organizations that establish standards for measurement and performance of medication use systems, he has recently served on the National Quality Forum Steering Committee on Serious Reportable Events in Healthcare and served as a member of the Institute of Medicine Committee on Patient Safety and Health Information Technology.

During his 41 years of professional and academic service, he has published more than 180 articles and abstracts in professional and scientific journals, 38 book chapters, edited seven books and given more than 500 contributed or invited presentations in 22 countries and the US. He is a past president of the American Society of Health-System Pharmacists (ASHP), and past president of the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), having served for ten years as the first Editor-in-Chief of Nutrition in Clinical Practice, one of its official publications. Active in international pharmacy, he has served Chairman of the Board of Pharmaceutical Practice of the International Pharmaceutical Federation (FIP), Secretary and newsletter editor of the Hospital Pharmacy Section, chairman of the Congress Planning Committee for FIP and is now a Vice President of FIP. In 2006, he was presented with the Donald E. Francke Medal for significant international contributions to health-system pharmacy. He was selected as the recipient of the 2008 Harvey A.K Whitney award, known as health-system pharmacy's highest honor for his outstanding contributions to the practice of pharmacy in health systems. In 2010, he was recognized as a Fellow of FIP (FFIP). In 2012, he was recognized as a Fellow up the American Society for Parenteral and Enteral Nutrition (FASPEN).

LUPUS and ALLIED DISEASES Association, Inc.

January 31, 2017

Senator David Wilson, Chair
Senate Health & Social Services Committee
Alaska State Capitol
Juneau, AK 99801

Senator Mia Costello, Chair
Senate Labor & Commerce Committee
Alaska State Capitol
Juneau, AK 99801

(via electronic delivery)

Re: Alaska SB 32- An Act relating to biological products

Dear Chairpersons Wilson and Costello:

On behalf of the Lupus and Allied Diseases Association and the many Alaska residents struggling to manage autoimmune conditions like lupus and other diseases of unmet need who eagerly await access to affordable, appropriate and safe therapies, I passionately urge you to support SB 32. This landmark legislation will update current state law regarding generic drug substitution to allow for the substitution of biologic products with FDA approved interchangeable biologics. This statute will create a new pathway for biologic substitution where none currently exists in Alaska, while at the same time enhancing patient access to new and potentially less costly medications.

The Lupus and Allied Diseases Association, Inc., is a passion driven, all-volunteer patient advocacy organization dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by fostering collaboration among all stakeholders and promoting innovative advocacy, awareness and biomedical research program initiatives.

As patient stakeholders who represent patients and loved ones dealing with serious chronic medical conditions on a daily basis, we support SB 32 as it promotes patient safety and collaboration among all members of the patient's health care team by facilitating consumer knowledge and communication between pharmacists and prescribing physicians when biosimilars designated as "interchangeable" are substituted for a prescribed biologic. It also gives the pharmacist authorization to select an alternative biological product if it is interchangeable and the prescriber does not indicate an intent to prevent substitution.

Furthermore, the proposed legislation ensures that the treating physician is aware of the exact biologic, indicated by manufacturer, given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occur. Pharmacist-Prescriber communication is paramount in identifying exactly which medicine was received if an adverse event occurs since biologics and biosimilars in reality will be administered to patients suffering from serious, life-threatening diseases who usually take several concomitant medications and are not participating in a controlled clinical study.

Unlike small molecules, biologics are extremely complex large molecules patterned after human tissue and cells that have the ability to target the underlying cause of some diseases. They have advanced with each generation; evolving from proteins that are naturally-occurring to monoclonal, and eventually to polyclonal and fusion proteins. Biosimilar drugs hold tremendous promise and therapeutic advantages for lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As more biosimilars become available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments.

SB 32 outlines the parameters for substitution of interchangeable biologics, guaranteeing patients have access to high quality, safe, and efficacious biologic medicines. Substitution should only occur when the FDA has designated a biologic product as interchangeable and proper patient protections are upheld including Pharmacist-Patient communication to ensure complete transparency. Pharmacist-Prescriber communication regarding the dispensed product must occur within three business days and be conveyed by making an entry that can be electronically accessed by the prescriber. Communicating through an electronic-record keeping system guarantees that the patient has a longitudinal health record and given that many patients have comorbidities requiring treatment by multiple health care providers, an accurate medical record is essential.

For the above reasons we ask you to please facilitate communication between patients, pharmacists, and healthcare providers and join the 26 other states that have passed similar legislation by supporting SB 32. This legislation is especially important given that the FDA has already approved four biosimilars with additional products in the pipeline. It is imperative that these safeguards are put in place to ensure that healthcare professionals continue to be empowered to provide the best medical care possible and that patients have access to lifesaving and life-enhancing therapies.

Please feel free to contact me at 315-264-9101 if you have any questions. Thank you.

Sincerely-

Kathleen A. Arntsen

Kathleen A. Arntsen
President/CEO

Cc: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

· PO Box 170 Verona, NY 13478 · 315-829-4272 · www.NoLupus.org · LupusInnovators@aol.com ·

Jody Simpson

From: LUPUSKAA@aol.com
Sent: Wednesday, February 01, 2017 4:07 PM
To: lupuskaa@aol.com
Cc: Sen. David Wilson; Sen. Natasha Von Imhof; Sen. Cathy Giessel; Sen. Peter Micciche; Sen. Tom Begich; Sen. Mia Costello; Sen. Shelley Hughes; Sen. Kevin Meyer; Sen. Gary Stevens; Sen. Berta Gardner; advocacyambassador@gmail.com
Subject: SB 32 Support
Attachments: LADAAK2017Biosimilars.pdf

Dear Chairpersons Wilson & Costello-

As an individual who struggles daily to manage my own complicated multi-autoimmune diseases and as the leader of a national patient organization, I have written the attached letter asking you to please support SB 32 regarding regulation of biological products. Having access to a full arsenal of treatments and knowing that the medications we are prescribed are safe and efficacious is extremely important to people like me.

Please feel free to contact me if you have any questions and thank you for your consideration.

Warm regards-

Kathleen A. Arntsen
President & CEO
Lupus and Allied Diseases Association, Inc.
P.O. Box 170
Verona, New York 13478
315-829-4272 office
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LupusKAA@aol.com
AdvocacyAmbassador@gmail.com
www.NoLupus.org
Twitter @KathleenArntsen

Our mission is to advocate for those affected by lupus and allied diseases through awareness and research program initiatives to improve quality of life.

Digestive Disease National Coalition

507 Capitol Court, N.E., Suite 200, Washington, D.C. 20002
(202) 544-7497 (202) 546-7105 - Fax WWW.DDNC.ORG

February 1, 2017

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Senator David Wilson
Chair, Senate Health & Social Services Committee

Alaska State Capitol
4th Ave and Main Street
Juneau, AK 99801

Re: Support for Alaska Senate Bill 32

Dear Chair Costello and Chair Wilson,

On behalf of patients suffering from digestive diseases and the physicians who treat them, Digestive Disease National Coalition (DDNC) respectfully urges you to support SB 32, which includes provisions to improve communication between prescribers and pharmacists in regards to biosimilar medications.

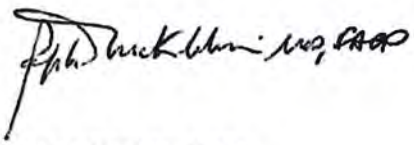
DDNC represents the major professional societies concerned with digestive diseases in order to further our goal of improving the quality and accessibility of health care options for patients. Biologic medicines, including biosimilars, are expanding treatment options for patients with digestive diseases, and we are advocating for their safe arrival into the market. For the sake of our patients, it is important that the entire medical team, including physicians and pharmacists, communicate about the proper course of treatment. This bill would facilitate that communication, ensuring that our patients receive the best, most thorough care.

Because of the complexity involved with manufacturing biologic medications, there is no way to create the "generic" medications that are so common in other drugs. While the development of biosimilars—which are similar to their innovator biologic

medication, but not exactly the same—is important for creating robust choices for patients, there are safety issues that must be addressed. The best way to address these concerns is through clear communication between prescribers and pharmacists. SB 32 creates a framework that will ensure that there is transparent, open communication between prescribers and pharmacists, reducing the chance of a biologic substitution causing serious side-effects.

With the first biosimilars already on the market, it is crucial that we act quickly to ensure that there are clear guidelines for prescribers and pharmacists. We strongly urge you to sign SB 32 for the benefit of those who suffer from digestive illnesses and those who treat them.

Sincerely,



Ralph McKibbin, MD
President

CC: Members, Senate Health & Social Services Committee

Members, Senate Labor & Commerce Committee

AfPA Alliance for Patient Access

National Physicians Biologics Working Group

February 1, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
State Capitol Room 115
Juneau, AK 99801

Senator Mia Costello
Chair, Senate Labor & Commerce Committee
State Capitol Room 504
Juneau, AK 99801

Re: Support for SB 32 – An Act Relating to Biological Products

Dear Chairman Wilson and Chairwoman Costello:

The Alliance for Patient Access (AfPA) would like to express support for SB 32, which allows for the substitution of biological medicines when certain conditions are met. The legislation as introduced contains the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications, notably physician communication of substitution, and is worthy of your support.

AfPA is a national network of more than 800 physicians with the shared mission of ensuring patient access to approved therapies including prescription pharmaceuticals, biologics, and medical devices. Since 2011, AfPA has convened the National Physicians Biologics Working Group (NPBWG) as a home for physicians interested in policy issues relating to access to biologic therapies.

NPBWG members identified key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. They are as follows:

1. FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic.
2. Pharmacist communication to the prescribing physician and patient any substitution within a reasonable timeframe.
3. Physician ability to specify no substitution or dispense as written.

SB 32 contains these safety provisions, most importantly the physician communication requirement. This provision helps ensure a complete medical record and facilitates the best medical response to a patient's adverse event. AfPA is pleased that SB 32 will allow for appropriate substitution while containing measures to implement these safeguards.

The Food and Drug Administration has already approved four biosimilars and may soon approve interchangeable biosimilar medicines. AfPA supports making potentially less costly medicines available to patients and physicians, but all efforts must be made to create policies that balance access, safety, and cost. SB 32 provides a quality pathway for biosimilar medicines by maintaining communication safeguards. As such, AfPA urges you to support this bill in its current form.

Sincerely,

Brian Kennedy
Executive Director

Cc: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

Alliance for Patient Access
1275 Pennsylvania Ave., NW | Suite 1100A
Washington, DC 20004

Biotechnology Innovation Organization

February 2, 2017

The Honorable David S. Wilson
Chair, Senate Health and Social Services Committee
State Capitol
Juneau, AK 99801

Dear Senator Wilson:

The Biotechnology Innovation Organization (BIO) is pleased to express our strong support for Senate Bill 32 by Senator Hughes, which permits substitution of biologic medicines by Alaska pharmacists. BIO represents over 1,000 biotechnology manufacturers, biotechnology centers and research centers across the United States and around the word.

BIO supports SB 32 because it contains important provisions that take into account the special and complex characteristics of biologic medicines. Unlike traditional chemically derived medicines, biologics are made from living organisms making them effective in treating life threatening diseases and conditions such as cancer, rheumatoid arthritis and diabetes. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biologics designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient. This bill contains those important provisions, which is why we encourage you and your colleagues on the Senate Health and Social Services Committee to support SB 32.

If you have questions or require any additional information, please do not hesitate to contact me at (916) 606-8016 or bwarren@bio.org.

Sincerely,

Brian Warren
Director, State Government Affairs
Western Region

cc: Members, Senate Health and Social Services Committee

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200
202.488.6301
bio.org

February 3, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Alaska State Capitol
4th Ave and Main Street
Juneau, AK 99801

Re: Support for Senate Bill 32

Dear Senator Wilson and Senator Costello:

On behalf of the patients in Alaska living with a rare disease, the National Organization for Rare Disorders (NORD) requests you to support SB 32, an act relating to interchangeable biologic products (biosimilars). This legislation has the potential to benefit many of our organization's members, and it will protect patients by including language calling for prescriber communication. With your support, this legislation will benefit the numerous patients suffering from rare disorders in Alaska.

According to the legislation, pharmacists will be required to communicate – to a patient's prescribing physician – any and all dispensations of a substitute biological product for another biologic drug. NORD applauds the development of these innovative and valuable therapeutic treatments and supports the expanded access that biological products will offer for rare disease patients. Given the distinctions between biologics, the substitution of a biological product must include communication between the prescriber and pharmacist to keep patient safety a top priority.

NORD is the leading voice of the rare disease community dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. Any disease affecting fewer than 200,000 Americans is considered rare. With nearly 7,000 rare diseases identified and 30 million Americans affected, the population represented by NORD is extraordinarily heterogeneous. We believe strongly that every patient deserves the medical care that is best suited for their medical situation and that is most likely to give them the best results. Based on the reports we receive from member organizations, as well as individuals, it is increasingly difficult for rare disease patients to receive optimum care if any degree of individual customization is required.

Considering this challenge, prescriber communication between a pharmacist and a doctor about which biological product has been dispensed can help ensure all rare patients receive optimum care.

Biological products differ from generics in that they are not identical to their biologic counterpart. Due to the sensitive manufacturing process of biological products, even the slightest change can have a significant negative impact on a patient's therapeutic regimen. This is a serious issue for a large segment of the rare disease community because not all drugs work the same for every patient, especially when dealing with unpredictable disease progression.

To ensure patient safety, health care providers need to know which medicine was dispensed to the patient, whether a substitution was made and to what alternative product. These factors are all critical information that needs to be taken into consideration when supplying a patient with medication.

NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. Patients in the rare disease community experience many unforeseeable variables and outcomes. By securing effective biological product substitution laws, Alaska can guarantee these patients prudence in prescriber communication that has the potential to alter dramatically the course of their treatment.

One again, on behalf of the NORD and the millions of Americans who face the struggles of a rare disease, we appreciate the opportunity to comment on this legislation. We strongly urge you to support SB 32, which includes prescriber communication, and will ensure increased access to this new age of medicines is done in a safe, reliable, and consistent way for patients and physicians.

If we can supply additional information, please do not hesitate to let us know. Tim Boyd, NORD's Associate Director of State Policy, is available to assist as needed. Tim can be reached at (202) 545-3830 or via email at tboyd@rarediseases.org.

Sincerely,

Peter L. Saltonstall, CEO

CC: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

NHMA
National Hispanic Medical Association

February 3, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Alaska State Capitol
Juneau, AK 99801

Senator Wilson and Senator Costello:

On behalf of the Board of Directors of the National Hispanic Medical Association, we urge you to vote yes for SB 32, FDA-designated interchangeable biological drug products.

These bills authorize a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the alternative biological products is designated as interchangeable with the reference product and communication is provided to the patient and physician that a substitution was made. These bills would also require that the substitution of a biological product be communicated to the patient.

We recognize the rising use of biologics and biosimilars in our population now aging with increased chronic disease. Biosimilars go through an extensive review process and manufacturers are required to submit immense studies and data demonstrating a products' efficacy and ensuring it is safe for use by consumers. A pathway for biosimilar regulation in the U.S. was established as a provision of the 2008 Patient Protection and Affordable Care Act (ACA) and in 2012 the FDA issued draft guidelines for biosimilars and a list of biosimilars and interchangeable biological products.

In summary, the National Hispanic Medical Association recommends your support for SB 32 before the end of session to clarify the procedures for biosimilar substitution for biologic treatments in a way that increases safety for the patient. We are especially supportive since these bills will provide increased access to quality treatment for Hispanics and all persons from Alaska with chronic diseases.

Sincerely,

Elena Rios, MD, MSPH, FACP
President & CEO

1920 L Street, NW, Suite 725 • Washington, DC 20036 • Tel (202) 628-5895 • Fax (202) 628-5898 • nhma@nhmamd.org • www.nhmamd.org

Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 3, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
Alaska State Legislature
State Capitol Room 115
Juneau AK, 99801

Senator Mia Costello
Chair, Senate Labor & Commerce Committee
Alaska State Legislature
State Capitol Room 504
Juneau AK, 99801

RE: Support for SB 32, Prescriptions for Biological Products

Dear Senators Wilson and Costello:

The Alliance of Specialty Medicine (Alliance) is a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons. We are dedicated to the development of sound health care policy that fosters patient access to the highest quality specialty care. The undersigned member organizations of the Alliance of Specialty Medicine write in support of SB 32 regarding the dispensing of interchangeable biosimilar products.

The Alliance has closely followed the development of federal and state policy related to biosimilars and the safety considerations that should be taken into account as more biosimilar versions of existing biologic medicines become a new treatment option for our patients. **Importantly, SB 32 addresses key policy issues to ensure patient safety is preserved, including physician authority to prevent substitutions and ensuring that the treating physician is notified if another version of the biologic medicine is substituted for the version prescribed by the doctor.**

Specifically, we appreciate that SB 32 does not allow for biosimilar substitution if the prescriber indicates that the script shall be dispensed as written. (p. 2, lines 15-17)

Also, we support that the bill requires notifying the prescribing practitioner of substitution *"within three business days after dispensing the biological product..."*. (p. 2, lines 27-28)

The practice of automatic substitution that is seen with generic drugs is not entirely appropriate for biosimilar products given that they are not simply "generic" versions of biologics. Physicians need to know what medicine their patient receives and therefore, the prescribing physician should be notified whenever a patient's biologic medicine is substituted. This will help to ensure the accuracy of patient medical records and identify any issues should there be an adverse event.

Advances in medical treatment have transformed the way we fight certain diseases. Biologics, and biosimilars, will continue to be an important treatment option for patients. The Alliance of Specialty Medicine appreciates that SB 32 ensures appropriate safeguards and urges that you advance the bill.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions

cc: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 348 0210 fax
www.ghlf.org

February 3, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

RE: **Senate Bill 32, An Act Concerning Biological Products– *Support***

Senators Wilson and Costello,

The Global Healthy Living Foundation (GHLF) is a 501 (c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. As a patient advocacy organization, GHLF represents more than 100,000 chronically ill patients, including your fellow Alaska residents. Many of these individuals have rheumatoid arthritis, take biologics, and stand to benefit greatly from the addition of biosimilars.

I am writing you today to express our support for SB 32 which addresses patient and physician communication during the substitution of a biosimilar and biologic product.

At GHLF, our focus is on improving the lives of patients with chronic illnesses through health care education and mobilization programs that stress the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement and therapeutic compliance. Using various channels of influence, we work to communicate and leverage new and improved medical treatments, such as biologics and biosimilars, to patients. As promising as these complex drugs are, GHLF believes that assuring their safety and transparency in the substitution process should be of paramount concern.

SB 32 takes positive steps toward updating Alaska law to cover biologics and biosimilars in a way that protects patients. As you know, unlike traditional chemical drugs, biologics are unique, complex structures made from living cells that are not easily replicated. A small change or difference in the biosimilar or biologic manufacturing process has the potential to adversely impact the patient.

There are four provisions in SB 32 that GHLF believes are key to ensuring patients' safety and needs are met in the best way possible.

- First, the bill requires a pharmacist dispensing an interchangeable biosimilar to notify the prescribing physician within three business days.

- Second, the bill clearly states that the pharmacist shall only substitute with the consent of the patient

- Third, it requires that physicians have the opportunity to prevent a substitution by instructing "do not substitute" or "dispense as written" on the prescription.

- Fourth, the legislation ensures that a pharmacist keep record of the substitution for a minimum of two years.

Communication is crucial to preserving the doctor/patient relationship as well as the integrity of medical records, which are invaluable if there is an adverse event from using the drug. A clear time frame of five days represents a compromise that many industry, provider, and patient stakeholders support – including GHLF.

If it is determined by the doctor and patient that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment, it is obvious to healthcare providers, patients and, we think, the majority of legislators, that proper communication and record keeping be in place in order to track any adverse events that may occur.

As patient advocates, it is our duty to ensure that physicians are in charge of the drugs prescribed and that both patients and their doctors are aware of what drugs they are taking. Patients and physicians are the primary individuals who report any adverse events that occur while on therapy. Adverse events can only be reported accurately if patients and physicians have received proper communication from a pharmacist about what medication has been dispensed. Patient safety is the top priority in the health care process and medical decisions must remain between a doctor and patient. We urge the passage of SB 32 because it introduces biosimilars in a way that ensures the safety of patients and preserves the physician-patient relationship.

We appreciate your thoughtful consideration of this legislation and would be pleased to provide any further information that you may require.

Sincerely,

Seth Ginsberg
President and Co-founder, Global Healthy Living Foundation

CC: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

39 Broadway, Suite 2700 New York, NY 10006-3003
Tel: 212-668-1000 | fax: 212-483-8179
www.liverfoundation.org
National HelpLine 800-GO-LIVER (800-465-4837

Your Liver. Your Life.™

February 3, 2017

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Senator David Wilson
Chair, Senate Health & Social Services Committee

Alaska State Capitol
4th Ave and Main Street
Juneau, AK 99801

Re: Support for SB 32

Dear Chair Costello and Chair Wilson,

On behalf of the American Liver Foundation and the millions of Americans who face the daily struggles of liver disease, we respectfully urge you to support SB 32. This bill updates current Alaska law to allow for the substitution of interchangeable biologic products at the retail pharmacy once they have been approved by the FDA. 26 states have passed similar biologic substitution legislation, which is necessary to allow for the retail substitution of these products.

Treatment of all forms of liver disease requires a great deal of clinical judgment. What works for one patient doesn't always work for another. The physician is in a unique position to consider the needs of individual patients, factoring in disease duration and severity, prognosis, treatment history and response, risk for adverse events, co-morbidities and potential impact on quality of life. It is to this end, that inappropriate therapy substitutions can result in disease progression and long-term consequences.

Biosimilars represent a new generation of drugs in liver and gastrointestinal diseases. Interchangeability, automatic substitution and switching are key issues to consider for safety and efficacy when treating patients with biosimilars in clinical practice. Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that proper communication between pharmacists and physicians is crucial to patient care to ensure that patients are receiving the best treatment as prescribed by their physicians.

SB 32 will also increase access to lower cost drugs for patients who rely on these medicines to treat serious and chronic diseases. SB 32 supported by many Alaskan patient and physician groups.

In order to protect Alaska's patients, the American Liver Foundation strongly supports SB 32, which includes language regarding prescriber communication. We appreciate the opportunity to comment on this legislation. Thank you for your support in considering this important legislation. Please contact Jonathan Martin, National Director of Programs at (646) 737-9403, should you require any additional information or clarification.

Sincerely,

Thomas F. Nealon, III
CEO and Board Chairman
American Liver Foundation

CC: Members, Senate Medical Affairs Committee

Members, House Medical, Military, Public & Municipal Affairs Committee

February 3, 2017

Re: SB 32—Urging Support for the Measure: "An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Senator David Wilson
Chair, Senate Health & Social Services Committee

Dear Chair Costello and Chair Wilson,

All over the country, state legislatures are considering legislation, and many have already passed bills, to ensure that their residents have access to interchangeable biological products and biosimilars. We are at the beginning of a new age of biological therapies, and laws and regulations must reflect this new reality.

SB 32 is an excellent example of legislation that does just that.

ICAN, the International Cancer Advocacy Network, is in strong support of SB 32 because of its patient safety protections when dispensing biosimilars and interchangeable biological products. ICAN, a five-star rated 501(c)(3) charitable cancer patient advocacy organization, helps late-stage cancer patients in Alaska and throughout the country. We deal daily with biologic therapies for our U.S. patients, and for our patients in 54 countries. Biologic therapies, and thus interchangeable biological products, will become a growing area for metastatic cancer patients.

This is a particularly timely issue given the first approval of a biosimilar in the United States in 2015, and the expected approval of many more in the future. SB 32 ensures that when an FDA-approved, lower-cost, interchangeable biological product is substituted by a pharmacist for a brand-name biologic, records will be kept, and the pharmacist will communicate to the patient and prescribing physician the precise drug that was dispensed—thus ensuring patient safety.

Communication to the patient and physician is essential because, unlike generic drugs that are an exact copy, the interchangeable biological product can be slightly different due to manufacture, transportation, or handling. If a patient experiences any adverse reactions, a physician needs to know all possible causes, including and especially, that the patient received an interchangeable biological product. Failing to communicate to the patient and physician when a substitution is made is an unnecessary risk to patient safety.

While we acknowledge (and welcome) the economic impact on healthcare of interchangeable biological products, patient safety can easily be protected by requiring communication to the patient and physician. Because of their complexity, size, and sensitivity, all biologics—whether reference, biosimilar, or interchangeable biological products—have potential for unintended induction of potent, immunologic reactions. Each and every patient may respond differently to any biologic, depending on their individual genetics and immunologic status.

Your support for SB 32 throughout the legislative process is a powerful voice for the safety of ICAN's Alaska patients, and for all Alaska patients. It is also supporting well-crafted legislation that can serve as a model for other states.

We are honored that Susan Knight of Anchorage is joining this letter as a co-signee, on behalf of the Jim Fling Pancreatic Cancer Patient Advocacy Program at ICAN.

Please do not hesitate to contact me at marcia@askican.org, or at (602) 618-0183 if you need any additional information.

Thank you for your consideration, and for your support.

Respectfully submitted,

Marcia K. Horn, J.D.
President and CEO
International Cancer Advocacy Network (ICAN)
27 West Morten Avenue
Phoenix, AZ 85021-7246
602-618-0183 (phone)
602-926-8109 (fax)
www.askican.org
marcia@askican.org

Susan Knight

Susan Knight, on behalf of the
Jim Fling Pancreatic Cancer Patient Advocacy Program at ICAN.
Anchorage, Alaska

cc: Members, Senate Health & Social Services Committee

STATEMENT

PhRMA
RESEARCH PROGRESS HOPE

Statement of the Pharmaceutical Research and Manufacturers of America (PhRMA)
In Support of
Alaska SB 32
February 5, 2017

Position: PhRMA supports Alaska House Bill 32 which would amend the Revised Statutes of Alaska to reflect recent changes to federal law that created an abbreviated pathway for the FDA approval of biosimilar products. SB 32 will put into place several patient protections that recognize the unique attributes of biosimilar products. Because patient safety is paramount, we are pleased that SB 32 will ensure that patient safety is protected when interchangeable biosimilars become available.

Unlike traditional medicines which are chemically synthesized, biologic medicines are complex and manufactured from living organisms. A biosimilar product is highly similar to, but not the same as, its FDA-licensed reference biological medicines. Recent federal legislative and regulatory activity has created an abbreviated regulatory pathway for the approval of biosimilar products and states are beginning to consider legislation to ensure that patient health and safety is protected when biosimilar interchange occurs.

SB 32 applies several important patient health and safety protections to the biosimilar substitution process. PhRMA supports provisions that place patient safety first, affirm the decision-making authority of physicians, and require that proper safeguards are in place in case of a future need for information on prior substitution of medicines.

Substitution should only occur when the FDA has designated a biologic product as interchangeable.

SB 32 would permit substitution of a biosimilar only when the FDA has designated a biologic product as interchangeable. Biosimilars will not be exactly the same as the reference product, so it is essential that only those the FDA has determined are interchangeable be dispensed.

Prescribers should be able to prevent substitution.

Any decision to substitute a biosimilar medicine should be made with the oversight and guidance of the treating physician, and the well-being of patients must remain the paramount concern. SB 32 permits a prescriber to prevent substitution by expressly prohibiting product selection. This provision ensures that the physician, who is knowledgeable about a patient's specific health history and therapeutic regimen, have ultimate decision-making authority for patient care.

A physician should be notified when a substitution occurs.

SB 32 requires that a pharmacist provide notification to the prescriber of the substitution when dispensing an interchangeable biosimilar. Record keeping will aid in facilitating efficient patient care in the event that an adverse reaction to the substituted drug occurs and will ensure proper product attribution if an adverse event were to occur.

Patients should be notified when a substitution occurs.

Additionally, this legislation requires that a patient must be informed of a substitution. Patients who are managing chronic conditions often have tried many therapies before finding the one that best manages their condition or multiple conditions. It is important that a patient realizes that a substitution has taken place so they can continue to be informed and in control of their disease management.

For these reasons, PhRMA respectfully urges members of the Alaska House of Representatives to support SB 32.

NATIONAL PSORIASIS FOUNDATION®

Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

February 6, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
State Capitol Room 103
Juneau AK, 99801

RE: Support SB 32 – Prescriptions for Biological Products

Dear Senator Wilson:

The National Psoriasis Foundation (NPF) is a non-profit, voluntary health agency dedicated to curing psoriatic disease and improving the lives of those affected. The Psoriasis Foundation is the leading patient advocacy group for the 8.3 million Americans and 25,800 Alaskans living with psoriasis and psoriatic arthritis.

The introduction of biologic products for the treatment of psoriasis and psoriatic arthritis has been the most significant advancement in care for the psoriasis and psoriatic arthritis community in recent decades. Biologics have provided some patients with an effective therapy—many for the first time in their lives. While the community welcomes new and affordable treatments, patients with psoriasis and psoriatic arthritis are keenly aware of the risks associated with biologics, including suppression of the immune system and the lack of long-term safety data for new treatments.

In contrast to the case with generic drugs, which are chemically identical to their branded counterparts, biosimilars are not chemically identical to their branded biologics counterparts because, as large, complex molecules derived from living cells using recombinant DNA technology, biologics can never be exactly replicated due to their inherent variability. The NPF believes that legislation concerning biologics is both an access and safety issue and neither should be sacrificed for the other, a balance can and has been found. As the committee considers this legislation we urge you to report this measure favorably with the communication provision intact.

Sincerely,

Randy Beranek
President & CEO

CC: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

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1800 Diagonal Rd., Suite 360 | Alexandria, VA 22314 | Fax 703-739-9800
www.psoriasis.org

RetireSafe
Standing Up For America's Seniors!

February 6, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee

Senator Mia Costello
Chair, Senate Labor & Commerce Committee

Alaska State Capitol
4th Ave and Main Street
Juneau, AK 99801

Dear Senators Wilson and Costello,

As the President of RetireSafe, a nationwide non-partisan non-profit organization with more than 150,000 supporters (629 in Alaska), I urge you to support Senate Bill 32, a bill that addresses how your state will deal with biosimilars, also referred to as "interchangeable biological products." We have seen the significant impact biologic medicines have had in improving the quality of the health of Americans, and this has given us a vested interest in seeing biosimilar medicines introduced to the U.S. market. This bill, with its communication requirements included, is essential to providing a higher quality of care for patients in Alaska.

SB 32 updates current Alaska law to allow for the substitution of interchangeable biologic products at the retail pharmacy, and will increase access to lower cost drugs for patients who rely on these medicines to treat serious and chronic diseases. While biosimilars are revolutionizing treatment possibilities for millions of patients, there are inherent safety challenges associated with this class of medicines. The issue of substitution has been a new challenge for policymakers, and we fear that if safety is not made a paramount concern moving forward, then it will inhibit widespread trust in this class of medical treatment and delay the overall acceptance of biosimilars by healthcare professionals.

We believe that when interchangeable biosimilar products are substituted by a pharmacist, communication between patients, pharmacists and health care providers is essential to safe patient care.

Because this groundbreaking medicine and its structure is so complex and unique, it seems like common sense to require that a patient's physician is notified if a biosimilar is substituted by the pharmacist. A nationwide survey that our organization conducted received over 1,400 replies. Over 90% of the respondents thought that communication between the doctor, patient and pharmacist should be required when a substitution is made concerning biologics, biosimilars and interchangeable biologics.

Already, 26 states and Puerto Rico have passed similar biologic substitution legislation, and it is now Alaska's turn to pass SB 32 with the proper communications provisions. We know that you are also committed to protecting patient safety and want to safeguard the citizens of Alaska. It is because of that dedication to our community that we ask you for your support in this issue.

Thank you for your consideration.

CC: Members, Senate Health & Social Services Committee
Members, Senate Labor & Commerce Committee

Arthritis Foundation℠

ARTHRITIS FOUNDATION
www.arthritis.org

February 6, 2017

Senator David Wilson
Chair of the Senate Health and Human Services Committee
Alaska State Capitol
Juneau, AK 99801

RE: Senate Bill 32 (Hughes) - Support

Dear Senator Wilson,

The Arthritis Foundation urges the members of the Senate Health and Human Services Committee to support Senate Bill 32. This important bill will update current law and allow the substitution of biologic medicines with interchangeable biological products. This bill would also require a pharmacist, when dispensing an interchangeable biological product, to communicate the change to both the patient and the prescriber.

Arthritis is an umbrella term for more than 100 different conditions such as rheumatoid arthritis, lupus, ankylosing spondylitis that affects the spine, and uveitis that affects the eye and can lead to permanent vision loss. For more than 117,000 Alaskans suffering from this debilitating disease, ensuring they have access to life-changing medications is vital. In many cases that means the difference between a lifetime of disability and full participation in work and civic life. In addition to the ongoing management of a patient's arthritis, of which there is no cure, the vast majority of patients with arthritis also have multiple other chronic conditions. Because of the complexity to not only treat rheumatic conditions, but also the patient's comorbidities, it is imperative the patient and their physician are able to discuss their treatment options, changes with medications, as well as options available to them. Senate Bill 32 takes a step in the right direction to ensure the both the patient and the physician are notified and will encourage a high level of communication between all players on the healthcare team.

When therapeutic innovations come to market, patient safety must remain the number one priority in any discussion; even if a drug is less expensive, these advantages mean nothing if the drug does not successfully treat the patient. It is important to remember that these are complex medications, and that interchangeable biological products are not the same as generics. Because of this, the Arthritis Foundation is committed to ensuring that the concerns of people who take these medications, and the specialist physicians who treat them, are kept at the forefront. By doing so, the patient and physician can continue a dialogue ensuring they receive the optimal care with these game-changing medicines.

On behalf of the Arthritis Foundation, I thank you for your consideration and urge your support of SB 32 which will keep patients and providers informed when medications are substituted.

Sincerely,

Steven Schultz
Legislative Anaylst
(916) 340-0733
sschultz@arthritis.org

cc: Senator Natasha von Imhof, Vice Chair of Senate Helath & Human Services Committee
Members, Senate Health and Human Services Committee

National
Kidney
Foundation™

Submission Via Email

February 7, 2017

The Honorable David Wilson
Chairman, Senate Health and
Social Services Committee
Alaska State Senate
State Capitol Room 103
Juneau, AK 99801

The Honorable Mia Costello
Chairwoman, Senate Labor and Commerce Committee
Alaska State Senate
State Capitol Room 510
Juneau, AK 99801

Re: **Support SB 32 – Biological products-regulate/pharmacist substitution**

Dear Chairman Wilson, Chairwoman Costello, Members of the Senate Health and Social Services Committee, and Members of the Senate Labor and Commerce Committee:

The National Kidney Foundation (NKF) supports SB 32, which was introduced in the Alaska State legislature to regulate the substitution of biological products for certain biosimilars with prescriber and patient notification.

According to the legislation, Alaska pharmacists will be permitted to substitute a biologic drug for a medication that has been determined by the U.S. Food and Drug Administration (FDA) to be an interchangeable biosimilar. Pharmacists will be required to communicate – to the patient and patient's prescribing physician – any substitution of a biologic medication with an interchangeable biosimilar. NKF supports the expanded access that biosimilars will offer for patients, and as biosimilars enter the market, the substitution of a biosimilar must include communication between the pharmacist and the prescriber to ensure patient safety. NKF also supports patient choice in the decision making and is pleased that this legislation requires patients to be notified of substitutions and informed when an interchangeable biosimilar is available.

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We also provide professional and patient education, patient support services, and community health programs. We work with volunteers to offer the

scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states, including Alaska. In Alaska, there are nearly 900 patients with end stage renal disease (ESRD), however, there are an additional estimated 210 individuals on Medicare with CKD stages 1-4 in Alaska.

With biologics, we know that individual patients can respond differently to even seemingly insignificant changes in drug formulation, manufacturing process, packaging, storage, or handling. These unintended consequences could be life threatening. Since biosimilars are produced without access to the innovator's proprietary manufacturing processes, differences in composition compared to the original innovator product are likely to occur.

Over a decade ago the FDA collected information on 82 patients worldwide who had developed pure red-cell aplasia as a result of changes in the manufacture and/or packaging of a reference biological product used by kidney patients. More recently, a synthetic erythropoietin stimulating agent – peginesatide – was approved by FDA in March of 2012 and nearly a year later pulled from the market due to an allergic reaction not seen in patients during the clinical trial. Because of these experiences the kidney community has been especially cautious regarding the possibility of substituting or alternating between reference drugs and biosimilars or between biosimilars. NKF appreciates that the clear labeling of product name and manufacturer required under this legislation will aide in identifying the medication that was dispensed in the unique circumstance that an adverse event occurs.

In conclusion: NKF asks you, in order to protect Alaska's patients, to support SB 32, which includes prescriber and patient communication of substitutions. To monitor for adverse events, it is vital that patients and physicians know, which medication was dispensed.

Please contact me at Tonya.saffer@kidney.org or 202-244-7900 if you have any questions.

Sincerely,

Tonya L. Saffer

Tonya L. Saffer, MPH
Senior Health Policy Director

American Autoimmune
Related Diseases Association, Inc.

2/8/2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
State Capitol Room 115
Juneau, AK 99801

Senator Mia Costello
Chair, Senate Labor & Commerce Committee
State Capitol Room 504
Juneau, AK 99801

Re: Support for Senate Bill 32

Dear Senator Wilson and Senator Costello:

On behalf of the more than 75 thousand patients in Alaska with autoimmune diseases, the American Autoimmune Related Diseases Association (AARDA) would like to voice its support for SB 32. In accordance with the proposed legislation, pharmacists must communicate with the authorized prescriber should a substitution of a biologic drug take place. AARDA supports the cost benefits that might occur from biosimilars, and substituting a biosimilar with prescriber-pharmacist communication established between a patient's health care team will benefit patient safety.

The advent of biologic therapies has provided substantial progression for autoimmune patients suffering from serious diseases, such as MS, lupus, Crohn's, psoriasis, and rheumatoid arthritis in their treatment, which had not had any breakthrough treatments in many decades. Manufacturing a biosimilar is much more complex than manufacturing generics for small molecule drugs. Because biologics are manufactured in living organisms, biosimilars are not exact replications of their reference biologic products. Due to this variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. Even minor changes in the manufacturing process can significantly affect the efficacy of the biosimilar. Autoimmune patients by nature of their disease have a higher level of immune response than normal, which puts them at a higher risk for reacting to any change. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include their physician's medical judgment.

Legislation that requires physician communication of the substitution will ensure patient safety. Further, communication will ensure that both patients and prescribers know exactly what was dispensed to their patient. Having precise and adequate information on what medicines are dispensed is essential for patient safety.

In order to protect Alaska's patients, the AARDA supports SB 32, which would ensure the physician's role and medical judgment in the care of their patients. The patient community applauds the efforts of the Senate Health & Social Services Committee and Senate Labor & Commerce Committee to ensure that biosimilars are dispensed in a safe manner assures patient's safety and does not impede patient access.

Sincerely,

Virginia T. Ladd

Virginia Ladd, President & Executive Director

Alaska Rheumatology Alliance
P.O. Box 231131
Anchorage, Alaska 99523-1131
EIN: 81-4555870

February 8, 2017

RE: Senate Bill 32 Opposition

Dear Senator Wilson:

On behalf of the Alaska Rheumatology Alliance, I would like to thank you for taking the time to receive our concerns regarding the newly proposed legislation, Senate Bill 32. As you recall this is the legislation updating pharmacy substitution laws for prescription medications, specifically biological products and substitutability of FDA approved "interchangeable" products.

The concept of the legislation is to define previously undefined biological products (both currently available and future products), establish a way to identify equivalent, interchangeable products, and provide a mechanism for substitution of a prescribed medication at the pharmacy level. The legislation would also mandate communication between the prescribing practitioner and the dispensing pharmacy to document the medication actually provided in the case of a substitution. Though this is a state initiative, there has been significant pressure nationally to accomplish this across the country.

Senate Bill 32, as outlined for Alaska, would define the biologic products, use the FDA approved "interchangeable list", and allow a pharmacy to substitute a biologic medication without prescriber input, only requiring notification to the prescriber within 3 business days of dispensing the medication to the patient.

The Alaska Rheumatology Alliance strongly opposes the proposed Senate Bill 32 as it is currently written, specifically based on the unrestricted substitution allowance and the 3 days reporting requirement.

Rheumatology as a specialty uses a number of biologic medications to the benefit of our patients and will likely continue to have new agents available in the future. Biologic medications are typically last line agents. They are very specific and often a patient has taken years of unsuccessful treatments to find a medication that works for them. The right medication; however, can be life changing. The medications are also, understandably, very costly and we are sensitive to this in the medications we prescribe. Multiple factors, including patient co-morbidities, other concomitant medications, route of administration, cost, and other factors are taken in to consideration when selecting the right biologic medication.

When there is an unrestricted ability to switch a biologic medication, the patient is placed at a significant risk. As each patient is an individual, some patients will not respond as well to an alternative medication and this is a large concern. Also the practitioner-patient relationship is undermined in this situation. Furthermore with a 3 days post-dispensing reporting requirement, in most cases the medication will

already be administered before the knowledge of the switch becomes known to the provider and the ability to have an informed discussion with the patient is lost.

The Alaska Rheumatology Alliance is in support of cost saving measures for patients and in some cases an interchangeable product could be appropriate, but the determination needs to be made prior to the substitution. Therefore, the Alaska Rheumatology Alliance would be in support of a bill only if notification and authorization was done PRIOR to the dispensing of the interchangeable product. This open communication would be in the best interest of patient and not undermine our work as practitioners.

As a registered pharmacist and actively practicing rheumatologist who uses a significant number of biologic medications, I have been able to reflect on the impact of this proposed change and feel strongly about this legislation.

We have heard the argument for using the "Dispense As Written" or "DAW" code as a way to prevent substitution. While this would definitely stop the interchange of medication, from our perspective as physicians, the "Dispense As Written" code is a nonnegotiable order. At times this is appropriate, but often there are times when a "brand name product" would be preferred but not necessary. Having the legislation with pre-notification and authorization allows the pharmacist an open dialogue with regards to medication with the provider. In many instances, the physician will not have an opposition with the substitution, especially when given additional information, such as cost savings to the patient, which the pharmacist would be able to communicate immediately based on other factors such as insurance preferences and availability of the product.

Previously I worked as a pharmacist and know that the submissions to insurance from the pharmacy is a real time process. It is immediately known whether there would be a cost savings with using a "generic" (or in this case an interchangeable product). This is the valuable information that could be communicated to the provider and then make the best choice for the patient.

I also know that pharmacies are able to electronically submit refill request and notifications of "prior authorizations needed" insurance rejections immediately on a real-time basis to the prescribing provider. There is no reason that this could not be applied to interchangeable product substitutions.

I have personally been involved for months at the national level regarding the impact of such legislation and have worked closely with the Arthritis Foundation, Coalition of State Rheumatology Organizations, and with the American College of Rheumatology. Locally the Alaska Rheumatology Alliance has been working with the community rheumatologists and those at the Alaska Native Hospital. I have also provided feedback and attended a December 13th, meeting in Anchorage which was an informational discussion attended by Dermatologists, Rheumatologists, Pharmacists, Industry representatives, and political activists. I am quite confident that the concerns outlined above echo those of the professionals and practitioners in the community.

The legislation has been touted by its initiators as a way to provide better access to expensive medications and reduce overall pharmacy and healthcare costs while providing accountability and

tracking of the medications. This pressure is spearheaded by pharmaceutical companies, with no doubt, financial incentives in place. While this concept of cost saving to the medical system is a noble one, in other states this has not thus far come to fruition.

Each state has the ability to adopt its own legislation based on its own needs. Alaska has a unique set of challenges because of the remote nature of some pharmacies and clinics, the lack of standard electronic medical records, and the heterogeneity of the population we treat as practitioners. Alaska needs to take the lead in the country in caring for our own patients. What might work for other states is unlikely to work in Alaska and our legislation needs to reflect this difference.

This bill has the support of a number of National Organizations. These same organizations have supported bills in other states. What the initiators of this bill have failed to establish is the support of local Alaskan providers of medical care.

As a take away point, Alaska Rheumatology Alliance would support a bill with a change in language as follows:

22 * Sec. 5. AS 08.80.295 is amended by adding new subsections to read:

23 (c) Except as provided in (d) of this section, if an interchangeable biological

24 product exists for a biological product prescribed to a patient, the dispensing

25 pharmacist or the pharmacist's designee shall communicate to the prescribing

26 practitioner information regarding the **proposed** biological product **that would be** provided to the patient,

27 including the name and manufacturer of the biological product. The communication **must be provided and authorization from the prescribing practitioner**

28 must be **obtained** ~~provided within three business days after dispensing the biological product~~ **prior to dispensing the interchangeable biological product. The communication may be provided** as

29 follows:

Thank you for your attention to this matter and the discussion points above. Please do not hesitate to contact me with any additional questions or concerns.

Sincerely,

John Botson, MD, RPh

President, Alaska Rheumatology Alliance

Nancy Merriman
4983 Cape Seville Drive
Anchorage AK 99516

February 9, 2017

Senator David Wilson
Chair, Senate Health & Social Services Committee
State Capitol Room 115
Juneau AK, 99801

Senator Natasha von Imhof
Vice Chair, Senate Health & Social Services Committee
State Capitol Room 514
Juneau AK 99801

Re: Testimony, SB 32. Senate Health & Social Services Committee

Dear Chair Wilson and Vice Chair von Imhof,

I am writing to provide constructive comment on Senate Bill 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".

Thank you for the opportunity to provide comments on Senate Bill 32. I am one of the patients who would be directly and negatively affected by the implementation of this bill, should it be passed as written.

I have an array of chronic auto-immune conditions that are treated with biologic medications. I have tried four different brand-name biologic drugs – given by injection or infusion – over the course of fifteen years. I have developed life-threatening allergic reactions to some; others interact adversely with other medications I take; some are simply ineffective. I have landed on one which is working adequately – for now.

SB 32, as written, would allow the pharmacist – not my physician – to decide to substitute a "biosimilar" drug for the band-name biologic. And only requires that the pharmacist notify my physician up to three days after the substitute dispensing is done. This is unacceptable. This practice would put me in harm's way – and be counter to my physician's directive, which has been shaped and tested over 15 years of dealing with my co-morbidities.

I understand that the pharmacist has to notify the patient of the substitution, but if a less-well-informed patient is presented with the option, they could understand it in the same as getting a generic drug instead of name brand. And, that, in the case of biologics, is simply not true. Biologics are proteins generated from living organisms, and **biosimilars are not "bio-same"**. They are <u>different</u>.

Language could be changed in this bill to make it safer for patients and more respectful of the doctor-patient relationship, as follows (added/changed language is **bolded**):

> *** Sec. 5. AS 08.80.295 is amended by adding new subsections to read: (c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the proposed biological product that would be provided to the patient, including the name and manufacturer of the biological product. The communication must be provided and authorization obtained from the prescribing practitioner ~~must be provided within three business days after dispensing the biological product~~ prior to dispensing the interchangeable biological product. The communication may be provided as follows:**

I appreciate your consideration of these comments, and invite you to contact me for further information or clarification.

Sincere regards,

Nancy Merriman
Nan.merriman@gmail.com
907-360-0270

Arthritis Foundation℠
Champion of Yes™

Senator David Wilson
Chair, Senate Health & Social Services Committee

Senator Shelley Hughes
Alaska State Senate
State Capitol Room 125
Juneau AK, 99801

RE: Senate Bill 32, Biosimilars

Dear Chairman Wilson and Senator Hughes:

Because we believe it not in patients' interest, we respectfully oppose any amendment to SB 32 that, as a condition of dispensing an FDA-approved interchangeable biologic in accordance with a valid prescription, would require a pharmacist to contact the prescriber for consent and direction beyond what the prescriber has already provided in the prescription he or she wrote.

This requirement will ultimately harm patients with serious diseases by delaying prescription fulfillment through additional administrative requirements, including calls to prescribers; and by raising concerns among patients that the lower-cost biosimilars the FDA has determined to be interchangeable may somehow be less safe or inferior to their reference products.

Such an amendment would also conflict with federal law. The Biological Price Competition and Innovation Act (BPCIA) provides that interchangeable biological products "may be substituted without the intervention of the healthcare provider..." The FDA is aware of the complexity of these products, and, in order to be approved, interchangeable biological products will have to meet the rigorous safety standards set forth in the BPCIA. Due to these factors, we strongly feel that the current language of SB 32 protects patients and will benefit the state of Alaska.

Thank you for your attention to this matter. If you have any questions or require any additional information, please feel free to contact me directly.

Sincerely,

Mark Guimond, Director of State Legislative Affairs
1615 L St., N.W., Suite 320
Washington, D.C. 20036
202 271-3569
MGuimond@Arthritis.org

cc: Members, Senate Health & Social Services Committee

NAMSDL

National Alliance for Model State Drug Laws

Emergency Scheduling of Novel Psychoactive Substances and Controlled Substance Analogues – Model Language

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Emergency Scheduling of Novel Psychoactive Substances and Controlled Substance Analogues – Model Language

Policy Statement

The United States is experiencing a growing problem with novel psychoactive substances (i.e., synthetic drugs) and controlled substance analogues. Federal and state drug statutes control substances by listing them in their controlled substances act as a Schedule I, II, III, IV, or V substance. Each substance is listed according to its precise chemical structure. However, in today's world of the internet, no sooner is a substance made illegal than another appears to take its place. Novel psychoactive substances are cheap, easy to make, and return a high profit for manufacturers, distributors, and retailers. Novel psychoactive substances, particularly synthetic cannabinoids, substituted cathinones, and other synthetic substances, are sold as "legal" highs in convenience stores, gas stations, "head" shops, discount beer and tobacco shops, and on the internet. Typically, these substances are sold as "herbal incense," "bath salts," "plant food," "jewelry cleaner," and are labeled "not for human consumption."

In 2010, the American Association of Poison Control Centers ("AAPCC") received 2,906 calls relating to exposures to synthetic marijuana and 304 calls relating to exposures to bath salts (substituted cathinones). In 2011, the AAPCC received 6,959 calls relating to exposures to synthetic marijuana and 6,138 calls relating to exposures to bath salts. Those numbers dropped significantly in 2012 with the AAPCC receiving 5,202 calls relating to exposures to synthetic marijuana and 2,655 calls relating to exposures to bath salts. As of October 31, 2013, the AAPCC has received 2,222 calls relating to exposures to synthetic marijuana and 833 calls relating to exposures to bath salts.

Scheduling each of these substances as they appear can be a long process during which time more people may be injured through the use of a substance they believe to be harmless because they purchased it at their local gas station. The Model Law attempts to make it easier to address the problem of controlled substance analogues and novel psychoactive substances by providing emergency scheduling provisions of those substances.

Highlights of the Emergency Scheduling of Novel Psychoactive Substances and Controlled Substance Analogues Model Law

- Allows a state agency to schedule novel psychoactive substances and controlled substance analogues on an emergency basis
- Provides that a substance will be temporarily scheduled for a period not to exceed eighteen (18) months to allow the state agency and/or legislature an opportunity to review additional information or research related to the substance
- Provides that when notice is received by the state agency under the state equivalent of Section Two of NAMSDL's Model Controlled Substance Analogue Statute that the controlled substance analogue will be scheduled on an emergency basis for a period not to exceed eighteen (18) months unless permanently scheduled within that time period
- Provides a six (6) month extension of the temporary scheduling order for both emergency scheduling of substances without Section Two notice and with Section Two notice for state legislatures that meet every two years

Section One. Emergency Scheduling Model Language.

Option 1. For states that schedule controlled substances via the legislature.

(a) The [Board, Department, or other state agency charged with oversight of controlled substances], by rule and without regard to the scheduling requirements of [code section], may schedule a controlled substance analogue in Schedule I of the [state equivalent of the federal Controlled Substances Act schedules of controlled substances] regardless of whether the substance is substantially similar to a controlled substance in Schedule I or II if the [Board, Department, or other state agency charged with oversight of controlled substances] finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under Section 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 355.

(b) The [Board, Department, or other state agency charged with oversight of controlled substances], by rule and without regard to the scheduling requirements of [code section], may schedule a novel psychoactive substance in Schedule I, II, III, IV, or V of the [state equivalent of the federal Controlled Substances Act schedules of controlled substances] if the [Board, Department, or other state agency charged with oversight of controlled substances] finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under Section 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 355.

(c) In making the determination of whether to emergency schedule a substance, the [Board, Department, or other state agency charged with oversight of controlled substances] shall assess the degree of danger or probable danger of the substance by considering the following:

(1) The actual or potential abuse of the substance, including:

(A) Its history and current pattern of abuse;

(B) The scope, duration, and significance of abuse; and

(C) A judgment of the degree of actual or possible detriment that may result from the abuse of the substance; and

(2) The risk to public health.

The [Board, Department, or other state agency charged with oversight of controlled substances] shall also consider whether the substance has been scheduled on a temporary basis under federal law and may also consider clandestine importation, manufacture, or distribution of said substance.

(d) The [Board, Department, or other state agency charged with oversight of controlled substances] shall post a public notice thirty (30) days prior to the effective date of the emergency scheduling action, at the state capitol, in the office of the governor, and on the [Board, Department, or other state agency charged with oversight of controlled substances]'s website for public inspection.

(e) If a substance is added or rescheduled under this subsection, the control shall be for a period not to exceed [eighteen (18) months] unless the legislature does not meet during that time period, in which case the temporary control may be extended by a period not to exceed [six (6) months]. If, at the next regular session of the state legislature, the temporary designation of the added or rescheduled substance is not made permanent by the legislature, such addition or rescheduling shall expire.

(f) Upon receipt of a notice under [state equivalent of Section Five of NAMSDL's Model Controlled Substance Analogue Statute- see attached Appendix] and amendments thereto, the [Board, Department, or other state agency charged with oversight of controlled substances] shall initiate scheduling of the controlled substance analogue on an emergency basis pursuant to this subsection. The scheduling of a substance under this subsection shall be for a period of [eighteen (18) months] after the adoption of the scheduling rule unless the legislature does not meet during that time period, in which case the temporary scheduling may be extended by a period not to exceed [six (6) months]. If the substance is scheduled on a permanent basis by the legislature at the next regular session or it is determined prior to the expiration of [eighteen (18) months] plus any extension that the substance should not be scheduled, the temporary scheduling shall expire.

(g) Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in [code section].

COMMENT.

THIS SECTION IS TAKEN IN PART FROM HAW. REV. STAT. § 329-11, KAN. STAT. ANN. § 65-4102, AND WASH. REV. CODE § 69.50.201. SUBSECTIONS (A) – (E) ARE INTENDED TO ALLOW A STATE AGENCY TO SCHEDULE NOVEL PSYCHOACTIVE SUBSTANCES AND/OR CONTROLLED SUBSTANCE ANALOGUES ON AN EMERGENCY BASIS WHILE THE LEGISLATURE IS IN OR OUT OF SESSION AS THE NEED ARISES FOR THE PROTECTION OF THE PUBLIC HEALTH. THESE SUBSECTIONS ARE INTENDED TO PROVIDE A FAST MECHANISM TO SCHEDULE THESE SUBSTANCES ON A TEMPORARY BASIS. THE EIGHTEEN MONTH TIME PERIOD IS PROVIDED TO GIVE THE STATE AGENCY AND/OR THE LEGISLATURE AMPLE OPPORTUNITY TO GATHER INFORMATION REGARDING THE SUBSTANCE AND MAKE AN EDUCATED DETERMINATION AS TO WHETHER THE SUBSTANCE IS A THREAT TO THE PUBLIC HEALTH AND SAFETY AND SHOULD BE SCHEDULED ON A PERMANENT BASIS OR THAT THERE IS NO THREAT TO THE PUBLIC HEALTH AND SAFETY AND THE TEMPORARY BAN SHOULD BE REVOKED. THE SIX MONTH EXTENSION IS INCLUDED FOR THOSE STATE LEGISLATURES THAT MEET ON AN INFREQUENT BASIS. SUBSECTION (F) PROVIDES FOR THE EMERGENCY SCHEDULING OF A CONTROLLED SUBSTANCE ANALOGUE WHEN NOTICE IS RECEIVED BY THE RELEVANT AGENCY UNDER THE STATE STATUTORY EQUIVALENT OF SECTION TWO OF NAMSDL'S MODEL CONTROLLED SUBSTANCE ANALOGUE STATUTE THAT PROSECUTION HAS BEEN INITIATED AGAINST

A PERSON ACCUSED OF A CRIME RELATED TO A CONTROLLED SUBSTANCE ANALOGUE. AS WITH SUBSECTIONS (A) – (E), TEMPORARY SCHEDULING UNDER SUBSECTION (F) IS FOR A PERIOD NOT TO EXCEED EIGHTEEN MONTHS, WITH ONE SIX MONTH EXTENSION, TO PROVIDE AN OPPORTUNITY FOR THE LEGISLATURE OR STATE AGENCY TO GATHER INFORMATION ON THE SUBSTANCE AND MAKE AN EDUCATED DETERMINATION THAT THE SUBSTANCE SHOULD OR SHOULD NOT BE PERMANENTLY SCHEDULED. SUBSECTION (G) IS INTENDED TO PROVIDE THAT THE EMERGENCY SCHEDULING POWERS UNDER THIS SECTION DO NOT INCLUDE THE SCHEDULING OF CERTAIN SUBSTANCES.

Option 2. For states that schedule controlled substances via a state agency.

(a) The [Board, Department, or other state agency charged with oversight of controlled substances], by rule and without regard to the scheduling requirements of [code section], may schedule a controlled substance analogue in Schedule I of the [state equivalent of the federal Controlled Substances Act schedules of controlled substances] regardless of whether the substance is substantially similar to a controlled substance in Schedule I or II if the [Board, Department, or other state agency charged with oversight of controlled substances] finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under Section 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 355.

(b) The [Board, Department, or other state agency charged with oversight of controlled substances], by rule and without regard to the scheduling requirements of [code section], may schedule a novel psychoactive substance in Schedule I, II, III, IV, or V of the [state equivalent of the federal Controlled Substances Act schedules of controlled substances] if the [Board, Department, or other state agency charged with oversight of controlled substances] finds that scheduling of the substance on an emergency basis is necessary to avoid an imminent hazard to the public safety and the substance is not included in any other schedule or no exemption or approval is in effect for the substance under Section 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 355.

(c) In making the determination of whether to emergency schedule a substance, the [Board, Department, or other state agency charged with oversight of controlled substances] shall assess the degree of danger or probable danger of the substance by considering the following:

(1) The actual or potential abuse of the substance, including:

(A) Its history and current pattern of abuse;

(B) The scope, duration, and significance of abuse; and

(C) A judgment of the degree of actual or possible detriment that may result from the abuse of the substance; and

(2) The risk to public health.

The [Board, Department, or other state agency charged with oversight of controlled substances] shall also consider whether the substance has been scheduled on a temporary basis under federal law and may also consider clandestine importation, manufacture, or distribution of said substance.

(d) The [Board, Department, or other state agency charged with oversight of controlled substances] shall post a public notice thirty (30) days prior to the effective date of the emergency scheduling action, at the state capitol, in the office of the governor, and on the [Board, Department, or other state agency charged with oversight of controlled substances]'s website for public inspection.

(e) If a substance is added or rescheduled under this subsection, the control shall be for a period not to exceed [eighteen (18) months] and, if the temporary designation is not made permanent by the [Board, Department, or other state agency charged with oversight of controlled substances] with such time period, such addition or rescheduling shall expire.

(f) Upon receipt of a notice under [state equivalent of Section Five of NAMSDL's Model Controlled Substance Analogue Statute – see attached Appendix] and amendments thereto, the [Board, Department, or other state agency charged with oversight of controlled substances] shall initiate scheduling of the controlled substance analogue on an emergency basis pursuant to this subsection. The scheduling of a substance under this subsection shall expire [eighteen (18) months] after the adoption of the scheduling rule unless the substance is scheduled on a permanent basis or it is determined prior to the expiration of [eighteen (18) months] that the substance should not be scheduled.

(g) Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in [code section].

COMMENT.

THIS SECTION IS TAKEN IN PART FROM HAW. REV. STAT. § 329-11, KAN. STAT. ANN. § 65-4102, AND WASH. REV. CODE § 69.50.201. THIS SECTION IS IDENTICAL TO OPTION 1 EXCEPT THAT IT REMOVES ANY REFERENCE TO THE STATE LEGISLATURE AND REMOVES THE SIX (6) MONTH EXTENSION AS UNNECESSARY FOR STATE AGENCIES.

APPENDIX A

Model Controlled Substances Analogue Statute

Section Five. Controlled Substance Analogue Treated as Schedule I Substance.

A controlled substance analogue, must be treated, for the purposes of this [Act], as a substance included in Schedule I. Within [ ] days after the initiation of prosecution with respect to a controlled substance analogue by indictment or information, the [prosecuting attorney] shall notify the [appropriate person or agency] of information relevant to emergency scheduling. After final determination that the controlled substance analogue should not be scheduled, no prosecution relating to that substance as a controlled substance analogue may be commenced or continued.

COMMENT

THIS SECTION IS TAKEN FROM § 214 OF THE UNIFORM CONTROLLED SUBSTANCES ACT (1990). THIS SECTION PROVIDES THAT A CONTROLLED SUBSTANCE ANALOGUE BE TREATED AS A SCHEDULE I SUBSTANCE AND FURTHER PROVIDES FOR THE EMERGENCY SCHEDULING OF SUCH SUBSTANCE.

Jody Simpson

From: Christine Marasigan
Sent: Friday, February 10, 2017 2:38 PM
To: Sen. David Wilson; Sen. Natasha Von Imhof; Sen. Cathy Giessel; Sen. Peter Micciche; Sen. Tom Begich
Cc: Jody Simpson; Konrad Jackson; Shareen Crosby; Jane Conway; Rachel Hanke; Richard Benavides; anthony.newman@alaska.gov; Butler, Jay C (HSS); Burkhart, Kate (HSS); 'Hanzawa, Allison F (DPS)'; 'Schroeder, Kaci K (LAW)'
Subject: Follow up on discussion during SB 20 hearing
Attachments: NAMSDL Emergency Scheduling of Novel Psychoactive Substances.pdf

Hello,
This is a follow up to the Senate Health & Social Service meeting on SB 20. Many thanks for moving the bill from committee.

Attached is a National Alliance for Model State Drug Laws (NAMSDL), "Language for Emergency Scheduling of Novel Psychoactive Substances and Controlled Substances." This was a topic of discussion during the committee hearing--how can the State of Alaska move more quickly to ban substances, keeping in mind that by putting something on the controlled substances list takes time and creates a class of crime and penalties.

Much of the language and requirements would of course have to be calibrated for Alaska, but the basic framework and policy considerations are addressed in this model language—it even cites the other states where similar laws have passed. Between the Opioid Taskforce recommendations, the Controlled Substances Advisory Committee, Statewide Drug Enforcement Unit, and Department of Law there could some very good adjustments that will help to make Alaska better able to react to the rate that new drugs are being produced. I hope you find this useful, if I can be of any assistance please let me know.

Christine

Christine R. Marasigan, Legislative Aide
Office of Senator Kevin Meyer
Senate Rules Committee Chair
Alaska State Capitol
Juneau, AK 99801
907.465.4945

POTENTIAL COST SAVINGS OF BIOSIMILAR DRUGS

Given marketplace uncertainty, there is a broad range of projected biosimilars savings in the U.S.:

- **RAND Corporation** predicts biosimilars will lead to a $44.2 billion reduction in spending on biologic drugs from 2014 to 2024.[i]
- **Express Scripts** estimates potential biosimilar savings of $250 billion from 2014 to 2024.[ii]
- **Congressional Budget Office (CBO)** projects savings from biosimilars to be $25 billion from 2009 to 2018.[iii]
- **Centers for Medicare and Medicaid Services (CMS)** has not released savings estimates, but notes that "state Medicaid programs should 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."[iv]

State legislative fiscal analyses on laws related to biologic medications and substitution of biosimilars indicate the potential for savings and note the challenges of producing specific estimates:

- **Florida –** "It is anticipated that once biosimilars are approved by the FDA and deemed interchangeable with prescription biologics, Medicaid and the State Group Insurance program may realize cost savings due to substitution of less expensive biosimilars for prescription biologics. The estimate of cost savings is undetermined."[v]
- **Pennsylvania** - "SB 405 will generate savings to the Medicaid program in the Department of Public Welfare (DPR) and in The Pennsylvania Employees Benefit Trust Fund (PEBTF) program when a biosimilar is substituted for a more expensive prescribed medicine." Additionally, "The Governor's Budget Office noted that as biosimilars come to the market, the Commonwealth would expect that biosimilars would help reduce costs for DPW and PEBTF. Potential savings to the Commonwealth cannot be calculated at this time."[vi]
- **Missouri –** "Long term projected annual savings are estimated to be $0 to $137,801,707 of which, the Federal portion (63.228%) would be $87,129,263 and the State share (36.772%) would be $50,672,444."[vii]
- **Colorado –** "When biosimilar products are approved, the Medicaid program and state and local group health plans are expected to see savings in prescription drug costs."[viii]
- **Tennessee –** "Authorizing physicians to substitute biosimilars for biologics is expected to result in a decrease in health care costs. Only one biosimilar is currently FDA-approved; therefore, any cost savings in the short-term is difficult to determine and is based on many factors, including the rate at which additional biosimilars become FDA-approved, the rate at which biosimilars are prescribed over biologics, and the actual cost difference between the biologic and equivalent biosimilar."[ix]

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[i] RAND Corporation, "The Cost Savings Potential of Biosimilar Drugs in the United States." (2014). https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf

[ii] Express Scripts, 2015 Drug Trend Report. file:///C:/Users/lseaton/Downloads/Express%20Scripts%202015%20DTR%20(1).pdf

[iii] Congressional Budget Office, cost estimate for S. 1629 (2008). https://www.cbo.gov/publication/24808

[iv] Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Notice No. 169, March 30, 2015. https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2015/March/Medicaid%20biosimilars.pdf

[v] Florida House of Representatives Staff Analysis on HB 365 (2013): https://www.flsenate.gov/Session/Bill/2013/0365/Analyses/h0365c.HHSC.PDF

[vi] Pennsylvania Senate Appropriations Fiscal Note on PA SB 405 (2013): http://www.legis.state.pa.us/WU01/LI/BI/SFN/2013/0/SB0405P1554.pdf

[vii] Missouri Committee on Legislative Research Oversight Division Fiscal Note on SB 875 (2016): http://www.moga.mo.gov/OverSight/Over20161/fispdf/5452-02T.ORG.pdf

[viii] Colorado Legislative Council Staff Fiscal Note CO HB 1121 (2013): http://www.leg.state.co.us/clics/clics2013a/csl.nsf/fsbillcont3/4BC9F025AF7AFC1487257AEE0054B013?Open&file=HB1121_f1.pdf

[ix] Tennessee General Assembly Fiscal Review Committee Fiscal Note on HB 572 & SB 984 (2015): http://www.capitol.tn.gov/Bills/109/Fiscal/HB0572.pdf

2-8-17
Just by Sen Hughes

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Bruce
2/14/17

2-15-17 2:2 Failed Wilson Giessel Y

AMENDMENT

OFFERED IN THE SENATE BY SENATOR GIESSEL

TO: SB 32

Page 2, line 17:

Delete "equivalent drug product **or interchangeable biological product**"

Insert "**(1)** equivalent drug product**; or**

(2) interchangeable biological product after obtaining authorization under (c) of this section"

Page 2, line 25, following "shall":

Insert ", before dispensing the interchangeable biological product,"

Page 2, line 26:

Delete "biological product"

Insert "proposed biological product that may be"

Page 2, line 27, following "product":

Insert ", and obtain authorization from the prescribing practitioner"

Page 2, lines 27 - 29:

Delete "The communication must be provided within three business days after dispensing the biological product as follows:"

Insert "The communication may be provided as follows:"

Page 3, line 10, following "information":

Insert "to or obtain authorization from the prescribing practitioner"

Page 3, line 19, following "information":

Insert "and obtain the authorization"

Page 3, lines 21 - 22:

Delete ", without the prescriber's expressed authorization,"

Page 3, line 23, following "**(A)**":

Insert "without the prescriber's expressed authorization,"

Page 3, line 25, following "**(B)**":

Insert "**with the prescriber's authorization,**"

SENATE COMMITTEE REPORT
First Committee of Referral

DATE: 1/23/17

FURTHER: Labor and Commerce

DATE TURNED IN TO OFFICE: 2/15/17

Health and Social Services Committee considered SENATE BILL NO. 32

SB 32 PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS

"An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

and recommends:

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

[ ] adopt **previous CS** _____ (_____) *[ ] 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 #
CED	X			1

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

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
	von Imhof	✓			
	Giessel				✓
	Begich	✓			
CHAIR:	Wilson			✓	

Drug Schedules

Drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential.

The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychological and/or physical dependence.

As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represents the least potential for abuse.

A Listing of drugs and their schedule are located at Controlled Substance Act (CSA) Scheduling or CSA Scheduling by Alphabetical Order. These lists describes the basic or parent chemical and do not necessarily describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be classified as controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances.

Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance which is intended for human consumption and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule.)

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are:

heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:

Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

2-2-11 Distributed by Sen Gresser

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:

Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:

cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

http://www.dea.gov/druginfo/ds.shtm

Drug Enforcement Administration website

Distributed by Senator Giessel for SB 55

State of New Mexico
House of Representatives
STATE CAPITOL
Santa Fé

March 14, 2007

American Academy of Ophthalmology
Governmental Affairs Division
1101 Vermont Avenue, NW, Suite 700
Washington, DC 20005-3570

To Whom It May Concern:

The NM House of Representatives Business and Industry Committee has been listening with interest to legislation with regard to House Bill 1186-Surgery Types Considered as Optometry - and Senate Bill 367 – Optometry Exclusions and Certification.

All of us on the committee have been working hard with advocates on both sides of the issue. Randy Marshall and John Anderson have worked well with us and continue to advocate successfully on your behalf. We feel that our understanding of this legislation has allowed us to make educated decisions with regard to both bills. We believe our support of this legislation is based on good, sound judgment.

The offensive ads that you have been running on television and radio are both appalling and ill-founded. Resorting to scare tactics with regard to the citizens of this state, most especially the children is egregious. We are elected to represent the people of this state and the insinuation in these ads that we would put the health of the public at risk is outrageous and offensive.

A personal approach to the members of this committee to discuss your issues with this legislation would have been a more professional and ethical method of promoting your viewpoint.

It is unfortunate that organizations like the American Academy of Ophthalmology choose to deceive the public with this type of negative and misleading advertising.

The members of the Business and Industry ask that you cease and desist these ads immediately. The people of New Mexico deserve better.

Sincerely,

New Mexico House Business and Industry Committee

Cc: NM Medical Society/NM Ophthalmology Board/American Medical Association

AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ®

Executive Office
444 East Algonquin Road • Arlington Heights, IL 60005-4664
847-228-9900 • Fax: 847-228-9131 • www.plasticsurgery.org

February 13, 2017

The Alaska State Senate
Senate Health and Social Services Committee
State Senator David Wilson, Chair
State Capitol, Room 115
Juneau, AK 99801

RE: Oppose SB 36, An Act Relating to the Practice of Optometry

Honorable Committee Members:

On behalf of the American Society of Plastic Surgeons (ASPS), I urge you to oppose Alaska Senate Bill 36, which would expand the scope of practice for optometrists beyond their professional training. As surgeons, we encourage you to maintain the high level of patient care that has been established and maintain current standards that permit only licensed Medical Doctors (MD) or Doctors of Osteopathic Medicine (DO) who meet appropriate education, training and professional standards to perform surgery in the ocular region.

If passed, SB 36 would allow non-physician optometrists to perform surgical procedures on the face. This includes procedures that fall squarely within the practice of medicine. SB 36 also grants the Alaska Board of Examiners in Optometry with complete authority over their own scope of practice, including determining what surgeries they are and are not qualified to perform. Alarmingly, the bill also does not include any educational requirements for optometrists to perform surgery. In sum, allowing optometrists to practice medicine without the requisite medical school and residency training would jeopardize patient safety and lower the standard of surgical care in the state.

SB 36 also gives optometrists the authority to use a wide range of pharmaceuticals that require a fundamental and systematic medical understanding of the human body. This understanding is gained through the clinical and educational rigor of a physician's training. Physicians are uniquely qualified to treat patients in the rare instance when an allergic reaction or some other life-threatening complication arises when these drugs are administered. Optometrists do not receive the same education and training ophthalmologists and plastic surgeons receive. Optometrists have insufficient training in disease management, for example, which is critical in identifying, understanding and effectively treating underlying conditions that can cause eye disease, like diabetes and hypertension. Sadly, in 2009, several patients at a VA facility received inadequate treatment for glaucoma from optometrists. An investigation found that as a result of the poor treatment 22 patients were found to have progressive vision loss.[1] Ophthalmologists and plastic surgeons must attain a core medical and surgical education while completing seven to ten years of training, which includes increasing responsibility and decision-making authority in the hospital setting. Optometrists only complete four to five years of education with significantly less clinical exposure and responsibility.

[1] Dremann, Sue. VA investigates glaucoma patients' treatment: 'Exhaustive' internal review found inadequate referrals; optometry chief sidelined. Palo Alto Weekly, July 23, 2009.

Due to patient safety issues, such as the possibility of complications arising from surgery, it is critical that such procedures are performed by physician surgeons who have the comprehensive training and board certification to handle those complications when they do occur. We urge you to **OPPOSE** Senate Bill 36 in order to protect the high standard of patient safety in Alaska.

Please do not hesitate to contact Patrick Hermes, ASPS's Senior Manager of Advocacy and Government Affairs, with any questions at Phermes@plasticsurgery.org or (847) 228-3331.

Sincerely,

Debra Johnson, MD
President, American Society of Plastic Surgeons

Jody Simpson

From: Carmen Moore <bellybaby1009@gmail.com>
Sent: Sunday, February 05, 2017 12:22 PM
To: Sen. David Wilson; Sen. Natasha Von Imhof; Sen. Tom Begich; Sen. Peter Micciche; Sen. Cathy Giessel
Subject: I OPPOSE SB 36

Follow Up Flag: Follow up
Flag Status: Completed

Categories: In 2D

Please be advised I cannot even comprehend why a consideration is being given to non-surgeons being able to do eye surgery in Alaska. I am a R.N. My eyes are precious to me.

I am appalled at this potential action and hope every one of you votes this down totally!

Sincerely

Carmen Claire Moore

P.O. Box 58493

Fairbanks, Alaska 99711

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

February 14, 2017

Honorable David Wilson
Alaska State Senate
State Capitol Room 115
Juneau, AK 99801

RE: Senate Bill 32

Dear Senator Wilson:

The Alaska State Medical Association (ASMA) represents physicians statewide and is primarily concerned with the health of all Alaskans.

ASMA supports lowering health care costs by including "biosimilars" as a substitutable medication. However, ASMA opposes Senate Bill 32 as it is written based on our opinion that the very specific language utilized in this bill will result in a reduction in expected cost savings on biologic medications. Our interpretation of the studies modeling cost reductions from the use of "biosimilar medications" assumes a marketplace similar to the European marketplace where the standard for substitution is set at "biosimilar" and not such that a biologic would require FDA designation as "interchangeable" which is a bar that no medication has achieved in this country to date nor for which there is evidence indicating improved safety or efficacy. Biosimilars have been used in Europe with excellent safety and efficacy profiles since 2006 and have resulted in significant cost savings. To meet a standard of biosimilar, a biologic must be "highly similar to the reference biologic, even when considering the differences in clinically inactive components, and that there are *no clinically meaningful differences between the biologic and the reference biologic in terms of safety, purity, and potency.*"

Recognizing the increased costs of health care, our organization is committed to providing the highest value of care for the patients we serve. As health care costs continue to escalate, with costs in this area specifically increasing 15-20% per year, we must be very judicious to ensure robust competition in the marketplace in a manner that is safe and effective for our patients. The use of "interchangeable" in this bill rather than "biosimilar" inadvertently sets a standard for substitution that will stifle competition in the biosimilar marketplace and will thus decrease the realization of cost savings quoted in the RAND report due to the unnecessary burden and costs associated with achieving the FDA designation of interchangeable. This possibility is actually noted in the RAND report:

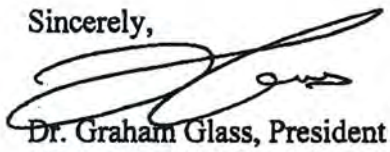
> *"Several critical features of the biosimilar regulatory pathway have yet to be finalized, such as guidanceon clinical trial requirements, criteria for a finding of similarity and interchangeability, and whether or not a biosimilar approval will apply across all originator indications. These policy decisions will have a significant impact on the evolution of the U.S. biosimilars market. Every study that*

projected biosimilar cost savings assumed (out of necessity) some final form of the FDA regulations that may or may not resemble the actual regulation."

"Competition is the final and most important driver of cost savings. The number of competitors and the extent of competition in the biosimilars market will depend on factors such as the costs of entry; the costs of manufacturing; firm-specific scientific, regulatory and commercial expertise; and the overall return that biosimilar manufacturers believe they can realize from their investment in advancing a product."

The costs and burden placed on companies to achieve the "interchangeable" designation include an additional several hundred million dollars spent on clinical trials showing that one can switch between a biosimilar and back to the reference medication. As in the generic "small molecule" drug marketplace, a number of "generic" competitors have to enter the marketplace to actually drive costs down significantly (as evidenced by a number of recent scandals involving single companies producing generic drugs resulting in massive price increases). Based on the above we would request that this bill be rejected unless the term "interchangeable" is amended and replaced with "biosimilar" where applicable such that Alaska pharmacists can substitute "biosimilar" products to the maximal degree allowed by the FDA and within the scope of the pharmacy board. While we oppose the current language we applaud and support Senator Hughes and the Legislature's efforts to expand the ability to substitute "biosimilars."

Sincerely,



Dr. Graham Glass, President
Alaska State Medical Association

Alaska State Legislature

SESSION ADDRESS:
Alaska State Capitol
Juneau Alaska 99801
907-465-3743
800-565-3743
Sen.Shelley.Hughes@akleg.gov

INTERIM ADDRESS:
600 E Railroad Avenue
Wasilla AK 99654
907-376-3725

Senator Shelley Hughes
Senate District F – Greater Palmer, Chugiak, Peters Creek, Eklutna, Fairview Loop, Gateway, Butte, Lazy Mountain

SB 32 Interchangeable Biological Products

Clarification on Questions Asked in the Committee

Question 1: Why is prior authorization by prescriber not required in this bill for interchangeable?

This would conflict with federal law. The Biological Price Competition and Innovation Act (BPCIA) provides that interchangeable biological products "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." Act (42 U.S.C. 262(i)) (3)

Question 2: Why this bill at this time?

To address biosimilars available now

Right now the law does not prevent a pharmacist from substituting a biosimilar that has not been approved as "interchangeable" for an originally prescribed biological product, even though the Ketchikan pharmacist, who testified on February 10th, testified that a pharmacist in Alaska would not. AS 08.80.295 (a) currently states "Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product." In Section 4 of Senate Bill 32, language is added to clarify 'drug' and 'biological product', and the bill further clarifies that only FDA approved "interchangeables" can be substituted for the original prescription.

To address interchangeable biologics soon to be approved by FDA and soon to be available in Alaska.

The FDA could designate a biosimilar product as interchangeable tomorrow. The Federal law that created the biosimilar pathway provides the FDA the ability to progress the pathway without the need for guidance. Although, at this time, we can't say with accuracy when the first interchangeable will be approved, we do believe that there are a couple of signals that may point towards an approval sooner, rather than later.

Some companies have publicly disclosed their active pursuit of interchangeability. There are also a number of companies that have completed studies with one or more switches that could support an interchangeable designation, but at this time any pending interchangeable application is confidential. The FDA will not disclose a submitted application unless the company that submits an application publically discloses. Last year, in a House, Energy, and Commerce Committee hearing, Janet Woodcock (FDA CDER Director) shared that she expected the approval of the first interchangeable before the release of a draft interchangeability guidance. The draft guidance was released this year.

Once there ARE interchangeable products approved by the FDA, we don't want suffering patients to wait what could be a year of more for legislation to pass to fix the statute. A cancer patient may not have the luxury of a year or more to wait.

Arthritis Foundation℠

ARTHRITIS FOUNDATION
www.arthritis.org

February 6, 2017

Senator David Wilson
Chair of the Senate Health and Human Services Committee
Alaska State Capitol
Juneau, AK 99801

RE: Senate Bill 32 (Hughes) - Support

Dear Senator Wilson,

The Arthritis Foundation urges the members of the Senate Health and Human Services Committee to support Senate Bill 32. This important bill will update current law and allow the substitution of biologic medicines with interchangeable biological products. This bill would also require a pharmacist, when dispensing an interchangeable biological product, to communicate the change to both the patient and the prescriber.

Arthritis is an umbrella term for more than 100 different conditions such as rheumatoid arthritis, lupus, ankylosing spondylitis that affects the spine, and uveitis that affects the eye and can lead to permanent vision loss. For more than 117,000 Alaskans suffering from this debilitating disease, ensuring they have access to life-changing medications is vital. In many cases that means the difference between a lifetime of disability and full participation in work and civic life. In addition to the ongoing management of a patient's arthritis, of which there is no cure, the vast majority of patients with arthritis also have multiple other chronic conditions. Because of the complexity to not only treat rheumatic conditions, but also the patient's comorbidities, it is imperative the patient and their physician are able to discuss their treatment options, changes with medications, as well as options available to them. Senate Bill 32 takes a step in the right direction to ensure the both the patient and the physician are notified and will encourage a high level of communication between all players on the healthcare team.

When therapeutic innovations come to market, patient safety must remain the number one priority in any discussion; even if a drug is less expensive, these advantages mean nothing if the drug does not successfully treat the patient. It is important to remember that these are complex medications, and that interchangeable biological products are not the same as generics. Because of this, the Arthritis Foundation is committed to ensuring that the concerns of people who take these medications, and the specialist physicians who treat them, are kept at the forefront. By doing so, the patient and physician can continue a dialogue ensuring they receive the optimal care with these game-changing medicines.

On behalf of the Arthritis Foundation, I thank you for your consideration and urge your support of SB 32 which will keep patients and providers informed when medications are substituted.

Sincerely,

Steven Schultz
Legislative Anaylst
(916) 340-0733
sschultz@arthritis.org

cc: Senator Natasha von Imhof, Vice Chair of Senate Helath & Human Services Committee
Members, Senate Health and Human Services Committee