

Letters of Support for SB32

1. Alaska Commission on Aging (ACoA)
2. Alaska State Hospital & Nursing Home Association (ASHNHA)
3. Alaska State Medical Association (ASMA)
4. Alliance for Patient Access (AfPA)
5. Alliance for Safe Biologic Medicines
6. Alliance of Specialty Medicine
7. American Autoimmune Related Diseases Association (AARDA)
8. American Cancer Society Cancer Action Network (ACS CAN)
9. American Liver Foundation (ALF)
10. Arthritis Foundation
11. Biotechnology Innovation Organization
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13. Global Healthy Living Foundation (GHLF)
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17. National Hispanic Medical Association (NHMA)
18. National Kidney Foundation (NKF)
19. National Organization for Rare Disorders (NORD)
20. National Psoriasis Foundation (NPF)
21. Pharmaceutical Research and Manufacturers of America (PhRMA)
22. Retire Safe
23. State Medical Board
24. U.S. Pain Foundation - State Advocacy & Alliance Development

- Alaska ACS CAN Biosimilars Fact Sheet



American Cancer Society
Cancer Action Network
555 11th Street, NW, Suite 300
Washington, DC, 20004

February 15, 2017

The Honorable David Wilson
Chair, Senate Health & Social Services Committee
Alaska State Senate

The Honorable Shelley Hughes
Alaska State Senate

Re: Support for SB 32

Dear Senators Wilson and Hughes,

The American Cancer Society Cancer Action Network of Alaska (ACS CAN) is an organization dedicated to leveraging the power of government to end suffering and death from cancer and ensuring that investments in research and medical innovation remain a priority. Biologic drugs have provided cancer patients and their physicians with access to improved therapeutic options.

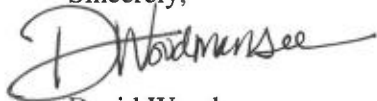
Biosimilars and interchangeable biological products offer potential for increasing accessibility and affordability as they provide competition for biologic drugs in a similar way that generic drugs do for brand-name drugs. The U.S. Food and Drug Administration (FDA) ensures the safety and efficacy of all drugs and biologics. 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. FDA is also the sole entity responsible for deeming a biosimilar drug interchangeable. Interchangeable biosimilar versions of some intravenous cancer drugs are currently in the FDA approval pipeline.

ACS-CAN of Alaska was pleased to work collaboratively in the months leading to session with Senator Hughes and representatives of fellow patient organizations and members of the health care team – physicians, pharmacists, and others – to explore legislation for Alaska that would supply the guidance needed to ensure safe and effective treatments for patients throughout the state, while providing the potential to lower cost burdens for cancer patients. We believe that SB 32 strikes the right balance and, therefore, urge its passage.

We understand there is an amendment under consideration that would require “prior consent,” in essence requiring a pharmacist to gain additional consent from a prescriber who has already authorized substitution in a valid prescription. This would impose an unnecessary administrative burden on pharmacists and prescribers that would conflict with federal law, potentially delay the dispensing of needed medication to patients with serious illnesses, and defeat the purposes of the underlying bill. We join our fellow patient organizations and other health care stakeholders in urging any such amendment not be adopted.

Thank you for your consideration in supporting this important legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "D Woodmansee", with a large, stylized initial "D" that loops around the first part of the name.

David Woodmansee

Director, State and Local Campaigns

American Cancer Society Cancer Action Network, Inc.

CC: Members, Senate Health & Social Services Committee



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

Department of
Health and Social Services

ALASKA COMMISSION ON AGING

P.O. Box 110693
Juneau, Alaska 99811-0693
Main: 907.465.3250
Fax: 907.465.1398

March 4, 2017

Senator Shelley Hughes
Alaska State Capitol, Room 125
Juneau, AK 99801-1182

Subject: Support for SB 32, Prescriptions for Biological Products

Dear Senator Hughes:

The Alaska Commission on Aging is pleased to offer our support for SB 32, a bill authored by you, that would update regulations of the Board of Pharmacy to allow for the substitution of biologic medications deemed interchangeable by the Federal Drug Administration (FDA) and which are approved by a patient, their doctor, and pharmacist as appropriate for a patient's health care. Based on our understanding, this legislation will provide greater access to new and potentially less costly treatment options and update current state law regarding generic drug substitution and the use of FDA approved biologic medications. Currently, Alaska has no laws regarding the use of biologics which limits the use of new treatment options that could provide enhanced care at an affordable cost for Alaskans.

The Alaska Commission on Aging (ACoA) is a Governor-appointed board within the Department of Health and Social Services that is responsible for planning services for seniors, educating Alaskans about senior issues, and making recommendations directly to the Legislature and the Governor regarding policy and budget items that affect the growing senior population, who now number approximately 126,000 people age 60+. As a disclaimer, ACoA's views do not necessarily reflect those held by the Department of Health and Social Services.

Although this legislation affects medical treatment for all Alaskans, our letter focuses on the benefits we perceive for older people. Biologics are used in current medical practice to treat the most serious, life-changing illnesses such as cancer, rheumatoid arthritis, diabetes, and others. These diseases impact many older Alaskans. Reportedly biologic medicines, including hormone therapies, have contributed to significant advances in cancer treatment. This biologic treatment has greatly enhanced oncology supportive care for patients receiving chemotherapy with compromised immune systems. Biologic medications have also advanced treatment for patients with autoimmune inflammatory disorders such as rheumatoid arthritis, plaque psoriasis, Crohn's disease, and colitis. Biologic treatments allow for improved management of these diseases by specifically targeting the biochemical pathways of inflammation.

If a prescribed treatment is meeting the patient's needs – allowing them to live full and productive lives – then there may be no need to consider a biologic. However, if these medicines are not achieving the desired outcome and there is a biologic medicine available, then a biologic medication would offer a different option for the physician, patient, and the health care team to consider.

Decisions regarding medical care are personal and belong to a patient in consultation with their doctor and health care team. Our primary concern with this legislation is that biologics may not be covered by insurance companies at this time. To this end, we recommend that medical practitioners counsel their patients about

costs and payment responsibility for biologic treatments in order to promote transparency and reduce disappointment.

The Commission supports SB 32 and appreciates your leadership of this legislation to provide enhanced patient access to new and life-enhancing therapies. For further information about our position, please contact Denise Daniello, ACoA's executive director (465-4879). Please feel free to include the Commission's letter in the bill packet for SB 32.

Sincerely,

A handwritten signature in blue ink that reads "David A. Blacketer". The signature is written in a cursive style with a clear, legible font.

David A. Blacketer
Chair, Alaska Commission on Aging

Sincerely,

A handwritten signature in blue ink that reads "Denise Daniello". The signature is written in a cursive style with a clear, legible font.

Denise Daniello
ACoA Executive Director



February 17, 2017

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

Re: Support for SB 32, Biosimilars

Dear Senator Hughes,

The Alaska State Hospital and Nursing Home Association (ASHNHA) is writing this letter in support of SB 32. ASHNHA has been consulting with hospital-based pharmacists and physicians to ensure that the bill would supply the guidance needed to ensure safe and effective treatments for patients, while providing the potential to lower pharmaceutical costs.

Critical to our support for this legislation are the specific communication requirements and timelines for pharmacists associated with dispensing biosimilar medication. The legislation includes a three-day timeline for the pharmacist to notify the prescribing physician and offers flexibility in communication methods to meet the needs of pharmacists in a variety of settings. We believe that SB 32 strikes the right balance for notification and communication.

We support the original legislation as written and oppose any requirements for "prior consent," requiring a pharmacist to gain additional consent from a prescriber who has already authorized substitution in a valid prescription. Such a requirement would impose an unnecessary administrative burden on pharmacists and prescribers that would conflict with federal law, potentially delay the dispensing of needed medication to patients with serious illnesses, and raise 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. We urge that the existing notification and consent provisions be maintained.

Biosimilars and interchangeable biological products offer potential for increasing accessibility and affordability as they provide competition for biologic drugs in a similar way that generic drugs do for brand-name drugs. We believe that the original language of SB 32 protects patients and will benefit the state of Alaska. Please let us know if there is anything we can do to support this legislation moving forward.

Sincerely,

Becky Hultberg
President/CEO

Alaska State Medical Association

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

March 12, 2017

Honorable Mia Costello
Alaska State Senate
State Capitol, Room 504
Juneau, AK 99801

RE: Senate Bill 32

Dear Senator Costello:

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

ASMA has been following the debate around Senate Bill 32 during this Legislative Session. While we initially had concerns that the current bill language might not be sufficient to ensure biosimilars would be efficiently substituted, after further research we believe this bill is an appropriate step. We support the goal of lowering health care costs by including "biosimilars" as a substitutable medication for Alaska patients and support SB32. ASMA believes that the safe and efficient use of biosimilars will provide more options for patients while also lowering costs. We also strongly believe preserving physicians' ability to restrict a prescription as written when in the best interest and safety of the patient is a critical provision of the legislation.

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, ASMA 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.

We support Senator Hughes and the Legislature's efforts to expand the ability to substitute "biosimilars."

Sincerely,



Alec Glass, MD, President

Alaska State Medical Association



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

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.

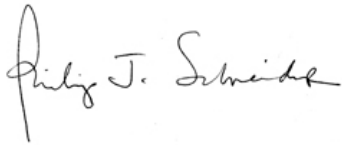
SB 32 will extend these valuable protections to Alaska's patients while increasing their access to biologic therapies. For these reasons, lawmakers in **26 states and Puerto Rico have passed similar bills** in the past few years.

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



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.

www.specialtydocs.org

info@specialtydocs.org

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

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



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,

A handwritten signature in cursive script, appearing to read "Virginia T. Ladd", written in dark ink.

Virginia Ladd, President & Executive Director



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)

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 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 Analyst
(916) 340-0733
sschultz@arthritis.org



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 world.

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.

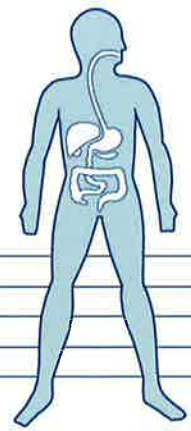
Sincerely,

A handwritten signature in blue ink, appearing to read 'Brian Warren', is positioned above the typed name.

Brian Warren
Director, State Government Affairs
Western Region

cc: Members, Senate Health and Social Services Committee

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

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Celiac Disease Foundation
Celiac Support Association/
United States of America, Inc.
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Global Colon Cancer Alliance
Crohn's & Colitis Foundation of America
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G-PACT
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New Jersey Gastroenterology & Endoscopy Society
New York Society For Gastrointestinal Endoscopy
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Society of Gastroenterology
Nurses and Associates, Inc.
South Carolina Gastroenterology Association
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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,

A handwritten signature in black ink, appearing to read "Ralph McKibbin, MD, PhD". The signature is fluid and cursive, with a long, sweeping underline.

Ralph McKibbin, MD
President

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



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.

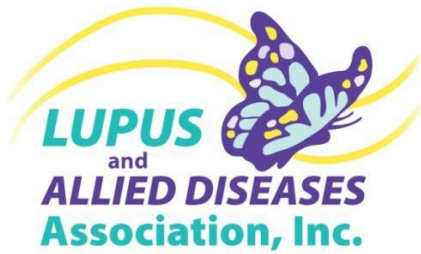
We encourage the Alaska State Legislature to be among the states that bring affordable access to innovative medical treatment options to all Alaskans. On behalf of the undersigned patient and physician organizations, we hope to see this important legislation introduced in the legislative session.

Thank you for your consideration.

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



**Arthritis
Foundation**



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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

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
315-264-9101 mobile
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.

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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



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

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



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,

A handwritten signature in blue ink, appearing to read "Randy Beranek", is written over a light blue rectangular background.

Randy Beranek
President & CEO

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



**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.



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.

A handwritten signature in black ink, reading "Shari Phillips". The signature is fluid and cursive, with the first name "Shari" and last name "Phillips" clearly distinguishable.

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



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

**Department of Commerce, Community,
and Economic Development**

STATE MEDICAL BOARD

550 West 7th Avenue, Suite 1500
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Main: 907.269.8163
Fax: 907.269.8196

February 24, 2017

The Honorable Shelley Hughes
State Senate
Alaska State Capitol
Juneau, Alaska 99801

Senator Hughes:

The Alaska State Medical Board has reviewed Senate Bill (SB) 32, which proposes to allow pharmacists to dispense interchangeable biological products as an equivalent to a written prescription, and to report the substitution to the prescribing practitioner within 3 days of dispensing. The Board also reviewed an FDA handout regarding approved biosimilar medications. It was noted that a prescribing practitioner may always write "no substitutions" on a prescription.

The Board determined to take a neutral position on the bill, so long as the reporting requirement remains, and recommend that the reporting occur at the time of dispensing instead of three days after dispensing.

Sincerely,

Grant Roderer, M.D.
Board President
Alaska State Medical Board

E-mail: medicalboard@alaska.gov

Website: <https://www.commerce.alaska.gov/web/cbpl/Professionallicensing/StateMedicalBoard.aspx>



The Honorable Senator David Wilson
Chair, Senate Health & Social Services Committee

The Honorable Senator Mia Costello
Chair, Senate Labor & Commerce Committee

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

February 3, 2017

Re: U.S. Pain Foundation Supports Alaska Senate Bill 32

Dear Senators Wilson and Costello:

Currently, there are more than 100 million Americans who suffer from chronic pain, including several in Alaska. On behalf of all Alaska residents who suffer from chronic pain, the U.S. Pain Foundation respectfully urges you to support SB 32, which includes prescriber communication.

We applaud the cost benefits that might occur from biosimilars; however, substituting a biosimilar or an interchangeable biological product without informing the prescriber could be detrimental to patient safety. Biosimilars are biological medicines that are produced by living cells for the prevention, treatment or cure of a disease. The U.S. Pain Foundation supports strong patient protections and transparency relative to state legislation for the substitution of biosimilars, such as SB 32. By securing effective biosimilar substitution laws, Alaska can increase access to this new age of medicines and do it in a safe, reliable and consistent way for patients and physicians.

Treatment of chronic pain requires a great deal of clinical judgment. Sometimes treatments that work for one patient with a chronic disease do not work for another. The physician must take into consideration the needs of each individual patient, factoring in many different variables that can affect a patient's treatment options. Therefore, inappropriate therapy substitutions can result in disease progression and long-term consequences. Since biosimilars differ from generics, they are not identical to their biologic counterpart. While generics can be interchanged for a brand-name drug because their basic compounds are matching, biologics and biosimilars are not identical and should not be treated as such. It is feasible that a patient could have a different reaction to a biosimilar than he/she would with its original biologic.

Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that communication between pharmacists and physicians is crucial to patient care to ensure that patients are receiving the best treatment as prescribed by their physicians.

On behalf of the U.S. Pain Foundation and the millions of Alaska residents and Americans who face the daily struggles of debilitating diseases, we appreciate the opportunity to comment on this proposed legislation. We strongly urge you to support SB 32, which includes prescriber communication and helps to protect patient safety.

Please contact Shaina Smith should you require any additional information or clarification. Thank you for your consideration.

Sincerely,

Shaina Smith

Shaina Smith

Director of State Advocacy & Alliance Development, U.S. Pain Foundation

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

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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.