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ican international cancer advocacy network
the virtual lifeline for proactive cancer patients

April 15, 2017

Re: SB 32—Urging Support for a Hearing to Consider 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."

Representative Neal Foster
Chair, Finance Committee
Alaska State House of Representatives
Alaska State Capitol
4th Ave. and Main Street
Juneau, AK 99801

Dear Chair Foster,

We have written previously (April 5) to you and the members of the Finance Committee urging support for SB 32 to allow Alaska residents to take advantage of the new age of interchangeable biological products that we are entering.

We write today to respectfully request that SB 32 be granted a hearing so that its significant merits can be fully considered.

It is ironic that SB 32 has that number because, as of this week, 32 states have passed similar legislation to allow their residents access to interchangeable biological products, while ensuring that patient safety is protected.

We are confident that if SB 32 is granted a hearing, then patients in Alaska will soon have these opportunities and protections.

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.

We know that SB 32 has been extensively developed by members of the Alaska health care community (patient groups and physicians, pharmacists, pharmacies, hospitals, and others), and their work has been refined by many legislators and approved by four committees (House Health and Social Services, Senate Health and Social Services, Senate Labor and Commerce, and Senate Finance).

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
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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: Jane Pierson, Legislative Aide

Alliance of Specialty Medicine

Sound Policy. Quality Care.

April 7, 2017

Representative Ivy Spohnholz
Chair, Health & Social Services Committee
Alaska State House of Representatives
State Capitol Room 421
Juneau AK, 99801

Representative Neal Foster
Chair, Finance Committee
Alaska State House of Representatives
State Capitol Room 410
Juneau AK, 99801

RE: Support for SB 32, Prescriptions for Biological Products

Dear Representatives Spohnholz and Foster:

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

cc: Members, House Health & Social Services Committee
Members, House Finance Committee

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

April 6, 2017

Representative Ivy Spohnholz
Chair, Health & Social Services Committee
Alaska State House of Representatives

Representative Neal Foster
Chair, Finance Committee
Alaska State House of Representatives

cc: Members, House Health & Social Services Committee
Members, House Finance Committee

Madam Chair and Mr. Chairman,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to urge you and your fellow committee members 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 prevent 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".

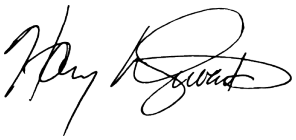
- It provides that the pharmacist receive the patient's consent in order to make a substitution.

- 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.

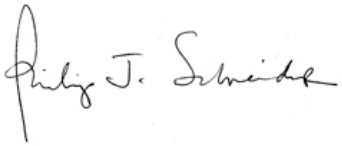
SB 32 will extend these valuable protections to Alaska's patients while increasing their access to biologic therapies. For these reasons, lawmakers in **28 states and Puerto Rico have passed similar bills** in the past few years.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Alaska by supporting Senate Bill 32.

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