



**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.