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