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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

