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March 4, 2016

Senator Carlo Leon, Co-Chair
Representative David Baram, Co-Chair
General Law Committee
Connecticut General Assembly
Legislative Office Building Room 3500
Harford, CT 06106

RE: **Senate Bill 313, An Act Concerning Biological Products– *Support***

Dear Co-Chairs Leon and Baram,

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 90,000 chronically ill patients, including your fellow Connecticut 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 313 which addresses patient and physician notification 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 innovative drugs are, GHLF believes that assuring their safety and transparency in the substitution process should be of paramount concern.

SB 313 takes positive steps toward updating Connecticut 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 313 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 five business days.

- Second, the bill clearly states that the patient for whom the biological product is prescribed must be informed of the substitution and has the right to refuse it.

- Third, it requires pharmacies to retain record of the substitution.

- Fourth, it requires that physicians have the opportunity to prevent a substitution by instructing "do not substitute" or "dispense as written" on the prescription.

Notification 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. While we believe that a notification requirement *prior to* dispensing would be most effective, 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 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 313 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, Global Healthy Living Foundation

CC: Members, Connecticut General Law Committee