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Representative Edward Clere
200 W. Washington St.
Indianapolis, Indiana 46204

HB 1315

Dear Representative Clere,

I am writing you today on behalf of the Global Healthy Living Foundation (GHLF) and the more than 56,000 members we represent to express our support for HB 1315. We represent patients living with chronic illnesses nationwide, from those with osteoporosis to those with chronic mental illness. Many of the patients we represent, including the nearly 30,000 with Rheumatoid Arthritis, take biologics.

At the 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, to patients. As promising as these innovative drugs are, GHLF believes that assuring their safety should be of paramount concern.

We believe that HB 1315 takes positive steps toward updating Indiana law to cover biologics and biosimilars in a way that protects patients. Unlike traditional chemical drugs, biologics have very unique, complex structures made from living cells that are not easily understood or replicated. A small change or difference in the biosimilar or biologic has the potential to either help or adversely affect the patient.

As an active member of the Alliance for Safe Biologic Medicines (ASBM), an organization dedicated to ensuring that patients are at the forefront of the biosimilar policy discussion, we have been working with both physicians and pharmacists to develop principles to determine the best solutions for these challenges.

In May 2012, ASBM convened a working group of our Advisory Board members to discuss the elements of a physician notification policy for interchangeable biosimilars that prioritizes patient safety and protects the relationship between physicians and their patients but also respects the sovereignty of pharmacists as healthcare providers. ASBM released a statement in October 2012 on the key principles that we believe should be included in a formal policy recommendations, which we see as aligning with SB 2190, specifically your inclusion that:

> A pharmacy may substitute a prescription biosimilar product for a prescribed product only if:

a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product for the specified indicated use;
b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription;
c. The pharmacist informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse;
d. The pharmacist notifies the prescribing practitioner in writing or via electronic transmission within twenty - four hours of the substitution;

As patient advocates, it is our duty to ensure that patients and physicians are in charge of the drugs prescribed, that patient safety is the top priority in the health care process and that medical decisions remain between a doctor and his or her patient. We urge the passage of HB 1315 because it introduces biosimilars in a way that ensures the safety of patients and preserves the physician-patient relationship.

We appreciate your thoughtful consideration on this legislation and would be pleased to provide any further information that you may require.

Sincerely,

Seth Ginsberg
President, Global Health Living Foundation