

March 7, 2016

The Honorable Carlo Leon, Co-Chair
The Honorable David Baram, Co-Chair
General Law Committee
Connecticut General Assembly
Legislative Office Building, Room 3500
Hartford, CT 06106

RE: SB 313 – FDA-designated interchangeable biological drug products; allow pharmacists to dispense.

Dear Senator Leon and Representative Baram:

The Alliance for Patient Access (AfPA) would like to express support for SB 313, allowing for the substitution of biological medicines when certain conditions are met. The legislation as drafted contains the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications, notably physician communication of substitution, and is worthy of your support.

AfPA is a national network of more than 700 physicians with the shared mission of ensuring and protecting patient access to approved medical treatments and therapies, including prescription pharmaceuticals, biologics, and medical devices. Since 2011, AfPA has convened the National Physicians Biologics Working Group (NPBWG) as a home for physicians interested in policy issues relating to access to biologic therapies.

The NPBWG identified key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. These include FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic, that pharmacists communicate to the prescribing physician and patient any substitution within a reasonable timeframe, that physicians be allowed to specify no substitution, and that patients be notified of any substitution. SB 313 contains these safety provisions, most importantly the physician communication provision that helps ensure a complete medical record and helps assure the best medical response to a patient adverse event. AfPA is pleased that SB 313 allows for substitution while containing provisions to implement these safeguards.

The Food and Drug Administration (FDA) has already approved one biosimilar medicine and may soon approve interchangeable biosimilar medicines. AfPA supports making potentially less costly medicines available to patients and physicians but all efforts must be made to create policies that balance access, safety and cost. SB 313 provides this pathway for biosimilar medicines by maintaining communication safeguards and is worthy of your support in its current form.

Sincerely,



Brian Kennedy
Executive Director

Cc: Members, General Law Committee