

COMMENTS SUBMITTED TO THE GENERAL LAW COMMITTEE
March 8, 2016

SB 313 AN ACT CONCERNING BIOLOGICAL PRODUCTS

Senator Leone , Representative Baram, Senator Witkos, Representative Carter, and Members of the General Law Committee,

Boehringer Ingelheim (BI) offers the following comments in support of **SB 313 An Act Concerning Biological Products**.

Boehringer Ingelheim is a family owned company committed to the discovery, development, manufacture and marketing of innovative health care products that have helped bring more health to patients and address unmet therapeutic needs. Boehringer Ingelheim was established in Connecticut in 1978, with our U.S. corporate headquarters located in the towns of Danbury and Ridgefield. As the State's largest headquartered biopharmaceutical company, we respectfully ask the Committee to support with changes SB 313 An Act Concerning Biological Products.

Connecticut has had a long proud tradition of being an innovator state and what SB 313 does is allows for the pathway of new medication technology to be accessed by patients under the state pharmacy practice act. The Patient Protection and Affordable Care Act (ACA) established an abbreviated approval pathway for the introduction of biosimilars called the Biosimilars Price Competition and Innovation Act (BPCIA)

Why is SB 313 needed? While the FDA is tasked with developing the approval pathway, evaluating the applications and approving the biosimilars, state pharmacy laws require updates to ensure biosimilars are included appropriately and address pharmacy-level automatic substitution.

SB 313 would allow a pharmacist to substitute a biosimilars (except those for epilepsy or used to treat seizures) if it is determined to be interchangeable by the FDA and the prescriber has not indicated that the prescription must be dispensed as written (also includes "brand medically necessary" and "no substitutions").

- The dispensing pharmacist is required to notify the prescriber of the substitution within a reasonable time frame
- The dispensing pharmacist may only substitute a biological product if the substituted product costs less than the prescribed biological product.
- The dispensing pharmacist is required to label the prescription container with the name of dispensed drug, if there is no brand name, the label should indicate the generic name of the drug.

- Each pharmacy is required to post a sign, in a location easily seen by patrons at the counter where prescriptions are dispensed stating “This Pharmacy May Be Able to Substitute a Less Expensive Drug, Or Interchangeable Biological, Product Which Is Therapeutically Equivalent to The One Prescribed By Your Doctor Unless You Do Not Approve

We understand that current draft before the committee still requires some technical changes to ensure consistency with the federal statute and that some additional language changes are needed to address consistency of the process.

We appreciate the committee addressing this issue and look forward to continuing to work with you. If you have any questions please contact Joseph Oros, Regional Director, State Government Affairs, Boehringer Ingelheim at 860-781-2126.