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March 7, 2016

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

Re: Senate Bill 313, An Act Concerning Biological Products, to be considered by the General Law Committee, Tuesday, March 8, 2016

Dear Co-Chairs Leon and Baram,

All over the country, state legislatures are considering legislation, and many have already passed bills, to ensure that their residents have access to biosimilars and interchangeable biological products. We are at the beginning of a new age of biological therapies, and laws and regulations must reflect this new reality.

Senate Bill 313, An Act Concerning Biological Products, to be considered by the General Law Committee tomorrow, is an excellent example of legislation that does just that.

ICAN, the International Cancer Advocacy Network, is in strong support of SB 313 because of its patient safety protections when dispensing therapeutically equivalent interchangeable biological products. ICAN, a five-star rated 501(c)(3) charitable cancer patient advocacy organization, helps late-stage cancer patients in Connecticut and throughout the country. We deal daily with biologic therapies for our U.S. patients, and for our patients in 53 countries. Biologic therapies, and thus interchangeable biological products, will become a growing area for metastatic cancer patients.

This is a particularly timely issue given the first approval of a biosimilar in the United States just last year, and the expected approval of many more in the future. SB 313 ensures that when an FDA-approved, lower-cost, interchangeable biological product is substituted by a pharmacist for a brand-name biologic, records will be kept, and the pharmacist will communicate to the patient and prescribing physician the precise drug that was dispensed—thus ensuring patient safety.

Communication to the patient and physician is essential because, unlike generic drugs that are an exact copy, the interchangeable biological product can be slightly different due to manufacture, transportation, or handling. If a patient experiences any adverse reactions, a physician needs to know all possible causes, including and especially, that the patient received an interchangeable biological product. Failing to communicate to the patient and physician when a substitution is made is an unnecessary risk to patient safety.

While we acknowledge (and welcome) the economic impact on healthcare of interchangeable biological products, patient safety can easily be protected by requiring communication to the patient and physician. Because of their complexity, size, and sensitivity, all biologics—whether reference, biosimilar, or interchangeable biological products—have potential for unintended induction of potent, immunologic reactions. Each and every patient may respond differently to any biologic, depending on their individual genetics and immunologic status.

Your support for SB 313 in the hearing on March 8, and throughout the legislative process, is a powerful voice for the safety of ICAN's Connecticut patients, and for all Connecticut patients. It is also supporting well-crafted legislation that can serve as a model for other states.

Please do not hesitate to contact me at marcia@askican.org if you need additional information.

Thank you for your consideration, and for your support.

Respectfully submitted,

Marcia K. Horn

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