Memorandum

To: Chairman Carlo Leone and Chairman David Baram, General Law Committee
From: Ritchard A. Engelhardt, Biotechnology Innovation Organization
Date: March 7, 2016
Re: Senate Bill 313, An Act Concerning Biological Products

On behalf of the Biotechnology Innovation Organization ("BIO"), which is the world's largest trade association representing biotechnology companies, academic institutions, and state biotechnology centers, I would like to express our support of SB 313, which allows a pharmacist to substitute a biological product for a different one that has been prescribed, so long as they are deemed interchangeable by the FDA. In addition, the bill requires that pharmacists communicate to the prescribing physician when an interchangeable biological product is dispensed.

Our organization supports SB 313 because it contains important provisions that take into account the special and complex characteristics of biological products. Unlike traditional chemically derived medicines, biological products are made from living organisms making them effective in treating life threatening diseases and conditions such as cancer, rheumatoid arthritis and diabetes. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biological products designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient. SB 313 contains those important provisions, which is why we encourage you and your colleagues on the General Law Committee to support SB 313.

In our initial review of the language in the raised bill, we found several minor technical issues that will need to be addressed in the bill before its final passage. We wanted to raise these with the committee now so that you are aware of these needed changes, and hope that you and your colleagues will incorporate these into the bill language during the next set of amendments. I have attached a list of the needed changes, as well as a mock-up of the bill.

We are encouraged that your committee is giving full consideration to SB 313. Please do not hesitate contacting me if you have questions or require any additional information.

Best Regards,

Ritchard A. Engelhardt
State Director of Government Affairs – Northeast Region

cc: Ranking Member Rep. Dan Carter
Ranking Member Sen. Kevin Witkos
Members of the General Law Committee

Biotechnology Innovation Organization

Proposed Amendments to Senate Bill 313, a Bill Relative to Biological Products

BIO supports Senate Bill 313, which updates the current generic substitution statute in the state of Connecticut to permit the substitution of interchangeable biologic products at retail pharmacies within the state. The raised bill, as drafted, requires a few minor technical change, detailed below:

Pg. 2, Line 14: "Secretary of the" should be deleted

Pg. 2, Line 15: "Determined" should be "determined"

Pg. 2, Line 17: "another biological product" should be "the prescribed biological product"

Pg. 3, Line 55: "biologic" should be "biological"

Pg. 3, Line 56: "Secretary of the" should be deleted

Pg. 3, Line 64: "biologic" should be "biological"

Pg. 3, Line 69: "interchangeable biological product" should be "prescribed biological product"

Pg. 3, Line 71: "interchangeable biological product" should be "prescribed biological product"

Pg. 4, Line 88-92: Proposed sign text should read: "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR, OR MAY SUBSTITUTE A LESS EXPENSIVE INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE BIOLOGICAL PRODUCT PRESCRIBED BY YOUR DOCTOR, UNLESS YOU DO NOT APPROVE."

Pg. 4, Line 99: (g) should be (i)

Pg. 4, Line 107: "product or interchangeable biological product" should be "product or non-proprietary name of the interchangeable biological product"

Pg. 5, Line 108-109: Should be "the name of the manufacturer of the drug product or interchangeable biological product."

Pg. 5, Line 117: (d) should be (f)

Pg. 6, Line 152: "biologic" should be "biological"

Pg. 6, Line 153: "biologic" should be "biological"

Pg. 6, Line 154: "biologic" should be "biological"

Pg. 6, Line 160: "The pharmacist may communicate" should be "Otherwise, the pharmacist shall communicate"

SB 313 AN ACT CONCERNING BIOLOGICAL PRODUCTS.

To add biological products to existing law regarding substitution of generic drugs.

Introduced by:

General Law Committee

General Assembly

February Session, 2016

Raised Bill No. 313

LCO No. **2130**

*02130_____GL_*

Referred to Committee on GENERAL LAW

Introduced by:

(GL)

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2016*):

(a) For the purposes of section 20-579 and this section:

(1) "Biological product" has the same meaning as provided in 42 USC 262 (i);

[(1)**]** (2) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

[(2)] (3) "Generic name" means the established name designated in the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(4) "Interchangeable" means, with respect to a biological product, a product that the federal Food and Drug Administration has: (A) determined to be interchangeable, pursuant to 42 USC 262 (k) (4), or (B) (i) determined to be therapeutically equivalent to the prescribed biological and (ii) granted an A-rating as set for in the latest edition of the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations";

[(3)] (5) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

[(4)] (6) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

[(5)] (7) "Epilepsy" means a neurological condition characterized by recurrent seizures;

[(6)] (8) "Seizures" means a disturbance in the electrical activity of the brain; and

[(7)] (9) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.

(b) Except as limited by subsections [(c), (e) and (i)] (e), (g) and (k) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength,

dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) Except as limited by subsections (e), (g) and (k) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed biological product if: (A) The federal Food and Drug Administration has determined that the biological product to be substituted is interchangeable with the prescribed biological product, and (B) the practitioner has not specified, in the manner described in subsection (e) of this section, that there shall be no substitution for the prescribed biological product.

(d) The pharmacist shall inform the prescribing practitioner and the patient or a representative of the patient at the earliest reasonable time of the substitution of a biological product for a prescribed biologic product.

[(c)**]** (e) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product or prescribed biological product specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product or prescribed biological product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

[(d)**]** (f) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR, OR MAY SUBSTITUTE A LESS EXPENSIVE NTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE BIOLOGICAL PRODUCT PRESCRIBED BY

YOUR DOCTOR, UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

[(e)**]** (g) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

[(f)**]** (h) Except as provided in subsection [g] (i) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section or interchangeable biological product as authorized by subsection (c) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product or interchangeable biological product. If the dispensed drug product or interchangeable biological product does not have a brand name, the prescription label shall indicate the generic name of the drug product or non-proprietary name of the interchangeable biological product dispensed along with the name of the manufacturer of the drug product or interchangeable biological product.

[(g)**]** (i) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or interchangeable biological product in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

[(h)**]** (j) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection (f)of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

[(i)**]** (k) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug or interchangeable biological product, unless the pharmacist (1) provides prior notice of the use of a different drug or interchangeable biological product manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient's prescribing practitioner. For purposes of obtaining the consent of the patient's prescribing practitioner required by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If

the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug or interchangeable biological product manufacturer or distributor or return the prescription to the patient or to the patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(l) Not later than five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer of the biological product. The entry shall be made in a manner that is electronically accessible to the prescriber through one of the following means: (A) An interoperable electronic medical records system, (B) an electronic prescribing technology, (C) a pharmacy benefit management system, or (D) a pharmacy record. Entry into an electronic medical records system is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone or electronic transmission, provided such communication shall not be required when there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed or when a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

[(j)**]** (m) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.