TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred Senate Bill No. 92 entitled "An act relating to interchangeable biological products" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. 18 V.S.A. § 4601 is amended to read:

§ 4601. DEFINITIONS

~~For the purposes of this chapter, unless the context otherwise clearly requires~~ As used in this chapter:

(1) ~~"Brand name" means the registered trademark name given to a drug product by its manufacturer or distributor;~~ "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition in human beings.

(2) ~~"Generic name" means the official name of a drug product as established by the United States Adopted Names Council (USAN) or its successor, if applicable;~~ "Brand name" means the registered trademark name given to a drug product by its manufacturer or distributor.

~~(3) "Pharmacist" means a natural person licensed by the state board of pharmacy to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons;~~

~~(4)~~ "Generic drug" means a drug listed by generic name and considered to be chemically and therapeutically equivalent to a drug listed by brand name, as both names are identified in the most recent edition of or supplement to the ~~federal~~ U.S. Food and Drug Administration's ~~"Orange Book" of approved drug products;~~ Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

(4) "Generic name" means the official name of a drug product as established by the U. S. Adopted Names Council (USAN) or its successor, if applicable.

(5) "Interchangeable biological product" means a biological product that the U.S. Food and Drug Administration has:

(A) licensed and determined, pursuant to 42 U.S.C. § 262(k)(4), to be interchangeable with the reference product against which it was evaluated; or

(B) determined to be therapeutically equivalent as set forth in the latest edition of or supplement to the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

(6) "Pharmacist" means a natural person licensed by the State Board of Pharmacy to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons.

~~(5)~~(7) "Prescriber" means any duly licensed physician, dentist, veterinarian, or other practitioner licensed to write prescriptions for the treatment or prevention of disease in man or animal.

(8) "Proper name" means the non-proprietary name of a biological product.

(9) "Reference product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which the interchangeable biological product was evaluated by the U.S. Food and Drug Administration pursuant to 42 U.S.C. § 262(k).

Sec. 2. 18 V.S.A. § 4605 is amended to read:

§ 4605. ALTERNATIVE DRUG OR BIOLOGICAL PRODUCT SELECTION

(a)(1) When a pharmacist receives a prescription for a drug which is listed either by generic name or brand name in the most recent edition of or supplement to the U.S. Department of Health and Human Services' publication Approved Drug Products With Therapeutic Equivalence **Evaluations** (the "Orange Book") of approved drug products, the pharmacist shall select the lowest priced drug from the list which is equivalent as defined by the "Orange

Book," unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug.

(2) When a pharmacist receives a prescription for a biological product, the pharmacist shall select the lowest priced **interchangeable** biological product ~~**that is listed as interchangeable in the U.S. Food and Drug Administration's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (the "Purple Book")**~~ unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced biological product.

(3) Notwithstanding subdivisions (1) and (2) of this subsection, when a pharmacist receives a prescription from a Medicaid beneficiary, the pharmacist shall select the preferred brand-name or generic drug or biological product from the Department of Vermont Health Access's preferred drug list.

(b) The purchaser shall be informed by the pharmacist or his or her representative that an alternative selection as provided under subsection (a) of this section will be made unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product.

(c) When refilling a prescription, pharmacists shall receive the consent of the prescriber to dispense a drug or biological product different from that originally dispensed, and shall inform the purchaser that a ~~generic~~ substitution shall be made pursuant to this section unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product.

(d) Any pharmacist substituting a generically equivalent drug or interchangeable biological product shall charge no more than the usual and customary retail price for that selected drug or biological product. This charge shall not exceed the usual and customary retail price for the prescribed brand.

(e)(1) Except as described in subdivision (4) of this subsection, within five business days following the dispensing of a biological product, the dispensing pharmacist or designee shall communicate the specific biological product provided to the patient, including the biological product's name and

manufacturer, by submitting the information in a format that is accessible to the prescriber electronically through one of the following:

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record.

(2) Entry into an electronic records system as described in subdivision (1) of this subsection shall be presumed to provide notice to the prescriber.

(3)**(A)** If a pharmacy does not have access to one or more of the electronic systems described in subdivision (1) of this subsection, the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using telephone, facsimile, electronic transmission, or other prevailing means.

(B) Option #1 (pharmacies): If a prescription is communicated to the pharmacy by means other than electronic prescribing technology, the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using the electronic process described in subdivision (1) of this subsection unless the prescriber requests a different means of communication on the prescription.

(B) Option #2 (VMS): If a prescription is communicated to the pharmacy by means other than electronic prescribing technology, the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using telephone, facsimile, electronic transmission, or other prevailing means.

(4) Notwithstanding any provision of this subsection to the contrary, a pharmacist shall not be required to communicate information regarding the biological product dispensed in the following circumstances:

(A) the U.S. Food and Drug Administration has not approved any interchangeable biological products for the product prescribed; or

(B) the pharmacist dispensed a refill prescription in which the product dispensed was unchanged from the product dispensed at the prior filling of the prescription.

(f) The Board of Pharmacy shall maintain a link on its website to the current lists of all biological products that the U.S. Food and Drug Administration has determined to be interchangeable biological products.

Sec. 3. 18 V.S.A. § 4606 is amended to read:

§ 4606. BRAND CERTIFICATION

If the prescriber has determined that the generic equivalent of a drug or the interchangeable biological product for the biological product being prescribed has not been effective or with reasonable certainty is not expected to be

effective in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient, the prescriber shall indicate "brand necessary," "no substitution," "dispense as written," or "DAW" in the prescriber's own handwriting on the prescription blank **or shall indicate the same using electronic prescribing technology** and the pharmacist shall not substitute the generic equivalent or interchangeable biological product. If a prescription is unwritten and the prescriber has determined that the generic equivalent of the drug or the interchangeable biological product for the biological product being prescribed has not been effective or with reasonable certainty is not expected to be effective in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient, the prescriber shall expressly indicate to the pharmacist that the brand-name drug or biological product is necessary and substitution is not allowed and the pharmacist shall not substitute the generic equivalent drug or interchangeable biological product.

Sec. 4. 18 V.S.A. § 4607 is amended to read:

§ 4607. INFORMATION; LABELING

(a) Every pharmacy in the ~~state~~ State shall have posted a sign in a prominent place that is in clear unobstructed view which shall read: "Vermont law requires pharmacists in some cases to select a less expensive generic equivalent drug or interchangeable biological product for the drug or biological

product prescribed unless you or your physician direct otherwise. Ask your pharmacist."

(b) The label of the container of all drugs and biological products dispensed by a pharmacist under this chapter shall indicate the generic or proper name using an abbreviation if necessary, the strength of the drug or biological product, if applicable, and the name or number of the manufacturer or distributor.

Sec. 5. 18 V.S.A. § 4608 is amended to read:

§ 4608. LIABILITY

(a) Nothing in this chapter shall affect a licensed hospital with the development and maintenance of a hospital formulary system in accordance with that institution's policies and procedures that pertain to its drug distribution system developed by the medical staff in cooperation with the hospital's pharmacist and administration.

(b) The substitution of a generic drug or interchangeable biological product by a pharmacist under the provisions of this chapter does not constitute the practice of medicine.

Sec. 6. **8 V.S.A. § 4089i is amended to read:**

§ 4089i. PRESCRIPTION DRUG COVERAGE

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(g) A health insurance or other health benefit plan offered by a health insurer or by a pharmacy benefit manager on behalf of a health insurer that provides coverage for prescription drugs shall apply the same cost-sharing requirements to interchangeable biological products as apply to generic drugs under the plan.

(h) As used in this section:

*** * ***

(6) "Interchangeable biological products" shall have the same meaning as in 18 V.S.A. § 4601.

~~(h)~~**(i)** The Department of Financial Regulation shall enforce this section and may adopt rules as necessary to carry out the purposes of this section.

Sec. 7. EFFECTIVE DATE

This act shall take effect on July 1, 2017.

(Committee vote: _____)

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Senator _____

FOR THE COMMITTEE