Adopted	Rejected

COMMITTEE REPORT

YES: 10
NO: 2

MR. SPEAKER:

Your Committee on ***Public Health****, to which was referred* *Senate Bill 272*, *has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill* ***be amended*** *as follows:*

Page 1, delete lines 1 through 17.
Delete pages 2 through 9.
Page 10, delete lines 1 through 24, begin a new paragraph and insert:
"SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 35.8. "Biological product", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-1.**
SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 36.2. "Biosimilar", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**

SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 288. (a) "Practitioner", for purposes of IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

(b) "Practitioner", for purposes of IC 16-41-14, has the meaning set forth in IC 16-41-14-4.

(c) "Practitioner", for purposes of IC 16-42-21, has the meaning set forth in IC 16-42-21-3.

(d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25,** has the meaning set forth in IC 16-42-22-4.5.

SECTION 5. IC 16-18-2-313.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 313.5. "Reference product", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-4.**

SECTION 6. IC 16-42-22-8, AS AMENDED BY P.L.204-2005, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 8. (a) For substitution to occur for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, **the biosimilar biological products requirements under IC 16-42-25,** or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must:

(A) sign on the line under which the words "May substitute" appear; or

(B) for an electronically transmitted prescription, electronically transmit the instruction "May substitute."; and

(2) the pharmacist must inform the customer of the substitution.

(b) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

SECTION 7. IC 16-42-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]:

Chapter 25. Drugs: Biosimilar Biological Products

Sec. 1. As used in this chapter, "biological product" means:

(1) a virus;

(2) a therapeutic serum;

(3) a toxin;

(4) an antitoxin;

(5) a vaccine;

(6) blood;

(7) a blood component;

(8) a blood derivative;

(9) an allergenic product;

(10) a protein (except any chemically synthesized polypeptide);

(11) a product analogous to a product described in subdivisions (1) through (10);

(12) arsphenamine;

(13) an arsphenamine derivative; or

(14) any other trivalent organic arsenic compound;

applicable to the prevention, treatment, or cure of a disease or condition for human beings.

Sec. 2. As used in this chapter, "biosimilar" means a biological product that:

(1) has been licensed as a biosimilar product under 42 U.S.C. 262(k); and

(2) is highly similar to the reference product, with:

(A) no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product; and

(B) only minor differences in clinically inactive components.

Sec. 3. As used in this chapter, "interchangeable" means a determination by the federal Food and Drug Administration that a biosimilar product may be substituted for a reference product without the intervention of the health care provider that prescribed the biological product.

Sec. 4. As used in this chapter, "reference product" means the single biological product licensed under 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted

under 42 U.S.C. 262(k).

Sec. 5. A pharmacist may substitute a biosimilar product for a prescribed biological product if the following conditions are met:

(1) The biosimilar product has been determined by the federal Food and Drug Administration to be interchangeable with the prescribed biological product.

(2) The prescribing practitioner has:

(A) for a written prescription, signed on the line under which the words "May substitute." appear; or

(B) for an electronically transmitted prescription, electronically transmitted the instruction "May substitute.".

(3) The pharmacist has informed the customer of the substitution.

(4) The pharmacist notifies the prescribing practitioner, orally, in writing, or electronically, within five (5) calendar days of the substitution.

(5) The pharmacy and the prescribing practitioner retain a written or electronic record of the interchangeable biosimilar substitution for at least five (5) years.

Sec. 6. (a) The Indiana board of pharmacy shall maintain a public Internet web site that contains a current list of biosimilar biological products that the federal Food and Drug Administration has determined to be interchangeable.

(b) The Indiana board of pharmacy may adopt rules under IC 4-22-2 necessary to implement this chapter.

Sec. 7. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6.".

Page 11, between lines 20 and 21, begin a new paragraph and insert:

"**(d) During the 2013 legislative interim, the commission shall study how Indiana law should address the prescribing and**

1 **substituting of biosimilar biological products for other drugs.**".

2 Page 11, line 21, delete "(d)" and insert "**(e)**".

3 Renumber all SECTIONS consecutively.

(Reference is to SB 272 as reprinted February 22, 2013.)

and when so amended that said bill do pass.

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Representative Clere