

COMMITTEE REPORT

MADAM PRESIDENT:

The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1315, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

- 1 Page 1, between the enacting clause and line 1, begin a new
- 2 paragraph and insert:
- 3 "SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA
- 4 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 5 [EFFECTIVE JULY 1, 2013]: **Sec. 35.8. "Biological product", for**
- 6 **purposes of IC 16-42-25, has the meaning set forth in**
- 7 **IC 16-42-25-1.**
- 8 SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA
- 9 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 10 [EFFECTIVE JULY 1, 2013]: **Sec. 36.2. "Biosimilar", for purposes**
- 11 **of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**
- 12 SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA
- 13 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 14 [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for**
- 15 **purposes of IC 16-42-25, has the meaning set forth in**
- 16 **IC 16-42-25-3."**
- 17 Page 2, line 13, delete "This chapter applies to a prescription for a
- 18 biological" and insert "**As used in this chapter, "biological product"**
- 19 **means:**

- 1 (1) a virus;
- 2 (2) a therapeutic serum;
- 3 (3) a toxin;
- 4 (4) an antitoxin;
- 5 (5) a vaccine;
- 6 (6) blood;
- 7 (7) a blood component;
- 8 (8) a blood derivative;
- 9 (9) an allergenic product;
- 10 (10) a protein (except any chemically synthesized
- 11 polypeptide);
- 12 (11) a product analogous to a product described in
- 13 subdivisions (1) through (10);
- 14 (12) arsphenamine;
- 15 (13) an arsphenamine derivative; or
- 16 (14) any other trivalent organic arsenic compound;
- 17 applicable to the prevention, treatment, or cure of a disease or
- 18 condition for human beings.

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

- 21 (1) has been licensed as a biosimilar product under 41 U.S.C.
- 22 262(k); and
- 23 (2) is highly similar to the reference product, with:
 - 24 (A) no clinically meaningful differences between the
 - 25 biological product and the reference product in terms of
 - 26 safety, purity, and potency of the product; and
 - 27 (B) only minor differences in clinically inactive
 - 28 components.

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

- 34 Page 2, delete lines 14 through 16.
- 35 Page 2, line 17, delete "3." and insert "4."
- 36 Page 2, line 24, delete "substitute"" and insert "**substitute.**"".
- 37 Page 2, line 27, delete "substitute"." and insert "**substitute.**".".
- 38 Page 2, line 30, after "practitioner," insert "**orally,**".

- 1 Page 2, line 31, after "writing" insert ",".
- 2 Page 2, line 31, delete "seventy-two (72) hours" and insert "**five (5)**
- 3 **calendar days**".
- 4 Page 2, line 36, delete "4." and insert "**5.**".
- 5 Page 2, line 42, delete "5." and insert "**6.**".
- 6 Page 3, after line 1, begin a new paragraph and insert:
- 7 "SECTION 5. [EFFECTIVE JULY 1, 2013] **(a) As used in this**
- 8 **SECTION, "commission" refers to the health finance commission**
- 9 **established by IC 2-5-23-3.**
- 10 **(b) During the 2013 legislative interim, the commission shall**
- 11 **study how Indiana law should address the prescribing and**
- 12 **substituting of biosimilar biological products for other drugs.**
- 13 **(c) This SECTION expires December 31, 2013."**
- 14 Renumber all SECTIONS consecutively.
(Reference is to HB 1315 as reprinted February 1, 2013.)

and when so amended that said bill do pass.

Committee Vote: Yeas 8, Nays 4.

Miller Patricia

Chairperson