

SENATE MOTION

MADAM PRESIDENT:

I move that Engrossed House Bill 1315 be amended to read as follows:

- 1 Delete the title and insert the following:
2 A BILL FOR AN ACT to amend the Indiana Code concerning
3 health.
4 Page 1, between the enacting clause and line 1, begin a new
5 paragraph and insert:
6 "SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA
7 CODE AS A **NEW SECTION TO READ AS FOLLOWS**
8 [EFFECTIVE JULY 1, 2013]: **Sec. 35.8. "Biological product", for**
9 **purposes of IC 16-42-25, has the meaning set forth in**
10 **IC 16-42-25-2.**
11 SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA
12 CODE AS A **NEW SECTION TO READ AS FOLLOWS**
13 [EFFECTIVE JULY 1, 2013]: **Sec. 36.2. "Biosimilar", for purposes**
14 **of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**
15 SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA
16 CODE AS A **NEW SECTION TO READ AS FOLLOWS**
17 [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for**
18 **purposes of IC 16-42-25, has the meaning set forth in**
19 **IC 16-42-25-4.**
20 SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS
21 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 288. (a) "Practitioner",
22 for purposes of IC 16-42-19, has the meaning set forth in
23 IC 16-42-19-5.
24 (b) "Practitioner", for purposes of IC 16-41-14, has the meaning set
25 forth in IC 16-41-14-4.
26 (c) "Practitioner", for purposes of IC 16-42-21, has the meaning set
27 forth in IC 16-42-21-3.
28 (d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25,**
29 **has the meaning set forth in IC 16-42-22-4.5.**
30 SECTION 5. IC 16-42-22-8, AS AMENDED BY P.L.204-2005,

1 SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
2 JULY 1, 2013]: Sec. 8. (a) For substitution to occur for a prescription
3 other than a prescription filled under the Medicaid program (42 U.S.C.
4 1396 et seq.), the children's health insurance program established under
5 IC 12-17.6-2, **the biosimilar biological products requirements under**
6 **IC 16-42-25**, or the Medicare program (42 U.S.C. 1395 et seq.):

7 (1) the practitioner must:

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

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

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

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

15 SECTION 6. IC 16-42-25 IS ADDED TO THE INDIANA CODE
16 AS A **NEW CHAPTER** TO READ AS FOLLOWS [EFFECTIVE
17 JULY 1, 2013]:

18 **Chapter 25. Drugs: Biosimilar Biological Products**

19 **Sec. 1. This chapter is effective beginning July 1, 2014.**

20 **Sec. 2. As used in this chapter, "biological product" means:**

21 (1) a virus;

22 (2) a therapeutic serum;

23 (3) a toxin;

24 (4) an antitoxin;

25 (5) a vaccine;

26 (6) blood;

27 (7) a blood component;

28 (8) a blood derivative;

29 (9) an allergenic product;

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

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

34 (12) arsphenamine;

35 (13) an arsphenamine derivative; or

36 (14) any other trivalent organic arsenic compound;

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

39 **Sec. 3. As used in this chapter, "biosimilar" means a biological**
40 **product that:**

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

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

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

1 **(B) only minor differences in clinically inactive**
2 **components.**

3 **Sec. 4. As used in this chapter, "interchangeable" means a**
4 **determination by the federal Food and Drug Administration that**
5 **a biosimilar product may be substituted for a reference biological**
6 **product without the intervention of the health care provider that**
7 **prescribed the biological product.**

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

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

13 **(2) The prescribing practitioner has:**

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

16 **(B) for an electronically transmitted prescription,**
17 **electronically transmitted the instruction "May**
18 **substitute."**

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

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

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

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

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

33 **Sec. 7. A written or electronic prescription for a biological**

- 1 **product must comply with the requirements under IC 16-42-22-6."**
- 2 Renumber all SECTIONS consecutively.
(Reference is to EHB 1315 as reprinted March 19, 2013.)

Senator MILLER PATRICIA