

Amendment to HB 117

1 Amend RSA 318:47-dd, I as inserted by section 1 of the bill by replacing it with the following:

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3 I. In this section:

4 (a) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine,
5 blood, blood component or derivative, allergenic product, protein (except any chemically synthesized
6 polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other
7 trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or
8 condition of human beings.

9 (b) **"Biosimilar" or "biosimilarity" means:**

10 (1) ***The biological product is highly similar to the reference product***
11 ***notwithstanding minor differences in clinically inactive components; and***

12 (2) ***There are no clinically meaningful differences between the biological***
13 ***product and the reference product in terms of the safety, purity, and potency of the product.***

14 ~~(b)~~ (c) "Proper name" means the nonproprietary name for a biological product
15 designated by the federal Food and Drug Administration license for use upon each package of the
16 product.

17 ~~(e)~~ (d) "Interchangeable biological product" means a biological product that ***meets the***
18 ***definition under 42 U.S.C. section 262(i)(3)*** ~~[the federal Food and Drug Administration:~~

19 (1) ~~Has licensed and determined meets the standards for interchangeability~~
20 ~~pursuant to 42 U.S.C. section 262(k)(4); or~~

21 (2) ~~Has determined is therapeutically equivalent as set forth in the latest edition of~~
22 ~~or supplement to the federal Food and Drug Administration's Approved Drug Products with~~
23 ~~Therapeutic Equivalence Evaluations].~~