FIFTY-THIRD LEGISLATURE
FIRST SESSION, 2017

February 10, 2017

Mr. Speaker:

Your **HEALTH AND HUMAN SERVICES COMMITTEE**, to whom has been referred

HOUSE BILL 260

has had it under consideration and reports same with recommendation that it **DO PASS**, amended as follows:

1. On page 1, line 24, after "antitoxin,", insert "vaccine, blood, blood component or derivative, allergenic product,".

2. On page 1, line 24, after "protein", insert ", except any chemically synthesized polypeptide" and after "product", insert ", or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound,".

3. On page 1, line 25, strike "diseases" and insert in lieu thereof "a disease".

4. On page 2, line 1, strike "injuries" and insert in lieu thereof "condition of human beings;", strike the remainder of the line and strike lines 2 through 23 in their entirety and insert in lieu thereof the following subsection:

"D. "biosimilar" or "biosimilarity" means, in reference to a biological product that the federal food and drug administration has licensed, that:

(1) the biological product is highly similar to the reference product notwithstanding minor differences in clinically active components; and

(2) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product;".

5. Reletter the succeeding subsections accordingly.

6. On page 7, strike lines 13 through 22 in their entirety and insert in lieu thereof the following:

"M. "interchangeable biological product" means a biological product that the federal food and drug administration has

licensed and has:

(1) determined that the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient;

(2) for a biological product that is administered more than once to an individual, determined that the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without alternation or switching; and

(3) determined to be therapeutically equivalent as set forth in the latest edition or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluation;.".

7. On page 12, line 9, strike "and".

8. On page 12, line 18, strike the period and the closing quotation mark and insert in lieu thereof "; and".

9. On page 12, between lines 18 and 19, insert the following new subsection:

"EE. "reference product" means the single biological product against which a biosimilar was evaluated in its marketing application to the federal food and drug administration."".

10. On page 14, lines 18 and 19, strike ", prior to dispensing an interchangeable biological product,".,

and thence referred to the **BUSINESS AND INDUSTRY COMMITTEE.**

Respectfully submitted,

Deborah Armstrong, Chair

Adopted _____ Not Adopted _____
(Chief Clerk) (Chief Clerk)

Date _____

The roll call vote was 5 For 0 Against
Yes: 5
No: 0
Excused: Thomson, Townsend
Absent: None

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