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## Substitution of Interchangeable Biologic Products—SB 514

**Status:** Senator Pat Vance (R-Cumberland) introduced SB 514, which passed the Senate on May 13, 2015. SB 514 now awaits consideration by the House Health Committee. There are aspects of SB 514 which PPA opposes. PPA supports legislation to amend the generic substitution law to include these products, in a more effective manner.



### Issue Background:

- Pharmacy fully supports interchangeable biologic products and their substitution when they come on the market and are appropriately approved as such by the FDA.
- An interchangeable biologic product is a biologic product that is highly similar to a biologic reference product except for minor differences in clinically inactive compounds. An interchangeable biologic product can have no clinically meaningful differences from the biologic product in terms of safety, purity and potency, similar to requirements for generic substitution of name brand drugs.
- The United States Food and Drug Administration (FDA) is working to create a process for both the approval of interchangeable biologic products and their interchangeability. Recently, an interchangeable biologic product for the cancer drug Neupogen was approved by an FDA advisory panel. It now awaits final consideration by the FDA; and will then need to be appropriately considered to be deemed interchangeable.
- The FDA plans to release four guidance documents in 2015 that relate to interchangeable biologic products, including their interchangeability.
- Brand biologic drug manufacturers do not want to wait for the FDA's action and are aggressively pushing legislation to limit competition and the use of interchangeable biologic products by creating artificial, and unnecessary barriers that will limit substitution. Extreme caution should be taken in rushing through legislation which may be contradictory to FDA guidance's on this matter. State law should not conflict federal regulations.
- If Pennsylvania does not want to wait for FDA guidance's, an appropriate solution would be to amend the Generic Substitution Law to include biologics and interchangeable biologic products in a similar fashion to current brand to generic.

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