



Academy of  
Managed Care  
Pharmacy®

February 27, 2018

The Honorable Carlo Leone  
Co-Chair, General Law Committee  
3500 Legislative Office Building  
Hartford, CT 06106

The Honorable Kevin Witkos  
Co-Chair, General Law Committee  
3500 Legislative Office Building  
Hartford, CT 06106

**RE: Senate Bill 197 – Interchangeable Biological Products**

Dear Senators Leone and Witkos:

The Academy of Managed Care Pharmacy (AMCP) writes to support and express concerns with specific provisions of Senate Bill 197. This legislation would regulate biological products and substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in the bill that allows a pharmacist to substitute an FDA approved “interchangeable biological product”. That language is consistent with the Biologics Price Competition and Innovation Act (BPCIA) which allows a pharmacist to substitute an interchangeable biologic product without the intervention of the health care provider who prescribed the “reference product”.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners, including members in Connecticut, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

**Senate Bill 197 Should Reference the FDA “Purple Book” not the “Orange Book”**

The language in Section 20-619 (a) (4) defines “interchangeable biological product” as “a biological product that: (A) the federal Food and Drug Administration has licensed and determined to meet the standards for interchangeability pursuant to 42 USC 262 (k) (4), or (B) is therapeutically equivalent to another biological product, as set forth in the latest edition of or supplement to the federal Food and Drug Administration’s publication ‘Approved Drug Products with Therapeutic Equivalence Evaluations’.” The underlined language is a reference to what is commonly referred to as the “[Orange Book](#)”. We are concerned with this section for the following reasons:

- Section A should include a reference to the FDA [Purple Book](#): Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations.

- Section B should be deleted because it refers to drugs (FDA Orange Book) that are approved under the Food, Drug and Cosmetics Act pathway
- Reference information for all licensed biologics, including biosimilars and interchangeable biologics under the BPCIA pathway, is only available in the Purple Book.

**Senate Bill 197 creates administrative burdens on Connecticut pharmacists**

Section 20-619(m) requires pharmacists to document and communicate with the prescriber within forty-eight hours of dispensing a biological product, which creates an additional administrative record keeping and post-dispensing communication requirement for dispensing an interchangeable biological product that is unnecessary and not required under Connecticut law for any other FDA approved drug category.

**FDA guidance not yet final on interchangeable biological products**

Although it was released more than a year ago, the FDA draft guidance titled “[Considerations in Demonstrating Interchangeability with a Reference Product](#)” is not final. The FDA will not accept an application for approval of an interchangeable biological product until the guidance is final. Once FDA draft guidance is final, AMCP encourages the Connecticut legislature to review it and determine whether additional legislation is necessary.

In conclusion, we urge you to amend section 20-619 (a) (4)(A) to include the “Purple Book” and strike the reference to the “Orange Book” for previously discussed reasons; and strike section 20-619 (m) which imposes additional administrative burdens on pharmacists. If you have any questions about our position, please contact AMCP’s Director of Legislative Affairs, Regina Benjamin, at (703) 683-8416 or [rbenjamin@amcp.org](mailto:rbenjamin@amcp.org).

Sincerely,



Susan A. Cantrell, RPh, CAE  
Chief Executive Officer