March 20, 2017

The Honorable Shane E. Pendergrass, Chair
House Health and Government Operations Committee
Room 241
House Office Building
Annapolis, MD 21401

**RE: Senate Bill 997 – Biological Product Substitutions**

Dear Delegate Pendergrass:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Senate Bill 997 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in Senate Bill 997 that is consistent with the Biologics Competition and Innovation Act (BPCIA) definition of "interchangeable biologic product" and the language that allows a pharmacist to substitute a FDA approved "interchangeable biological product". However, we oppose the language that defines an interchangeable biological product as therapeutically equivalent and imposes additional administrative requirements to dispense an interchangeable biological that are different from existing requirements for all other classes of medications. We are also concerned about enacting additional requirements prior to the FDA finalizing guidance on interchangeable biological products.

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 Maryland, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

*FDA guidance not yet final on interchangeable biological products*

To date, the FDA has not finalized guidance on the determination of biosimilar interchangeability. In fact, the FDA released a draft guidance on January 17 titled "Considerations in Demonstrating Interchangeability With a Reference Product" and the comment period closes on May 19, 2017. The FDA will not accept an application for approval of an interchangeable biological product until the guidance document is final.

*The FDA Purple Book: Designated List of Biologic Products*

The FDA has already created a publically available reference document: The Purple Book: Lists of Licensed Biological Products (Purple Book) with reference product exclusivity and biosimilarity or interchangeability evaluations. When the draft guidance on interchangeability is finalized, the FDA will begin accepting applications and information will be available on licensed products in the Purple Book. Therefore, we recommend that the language proposed to amend Section 12-101(M)(1), Article- Health Occupations, should include the title of the reference, i.e., the Purple Book. We also recommend that Section 12-101 (M)(2), should

be deleted. The Orange Book is the FDA's list of drug products approved under the Food, Drug and Cosmetic Act. As previously mentioned applications for and approval of interchangeable biological products are only authorized under the BPCIA and will be listed in the Purple Book.

*Additional administrative burdens on pharmacists*

Specifically, the language proposed to amend Section 12-504.1(A) and (B) Article- Health Occupations, is problematic because it requires additional notification by the pharmacist to the prescriber and additional record keeping not required for any other class or category of drugs approved by the Food and Drug Administration. These provisions are unduly burdensome and time consuming for pharmacists and there are no proposed amendments that require the prescriber to maintain a record of the required notifications. Although the proposed amendments provide that notification can take place via the use of electronic systems, the primary mode of communication between prescribers and pharmacists is not via an electronic system.

In conclusion, we urge you to adopt language that updates Maryland law to allow for the substitution of biologic products with FDA approved interchangeable biological products. We also urge you delete the amended language in Section 12-504.1(A) and (B) that would add additional requirements for dispensing interchangeable biologic products not required for any other class of FDA approved drugs. We also urge you to delete the reference in Section 12-101(M)(1)) to the Orange Book. Lastly, AMCP encourages the legislature to review the final FDA guidance and at that time determine whether additional legislation is necessary. If you have any questions about our position, please contact AMCP's Maryland advocacy leader Matthew D. Lennertz, MS, PharmD at matthew.lennertz@gmail.com or AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer