

May 27, 2016

The Honorable Shannon Jones  
Chairwoman  
Senate Health and Human Services Committee  
Senate Building  
1 Capitol Square, 2nd Floor  
Columbus, OH 43215

RE: Sub. H.B. No. 505 – Regulation of Interchangeable Biological Products and Substitution

Dear Senator Jones:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to comment on Sub. H.B. No. 505 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. AMCP is opposed to this legislation as it places an undue burden on the dispensing of interchangeable biological products once approved by the FDA.

AMCP is a professional association of pharmacists and other practitioners, including 268 members in Ohio, who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

As you know, biologic products already have an important role in today's health care system, both in terms of scientific improvements in the treatment of disease and in increased drug costs. Yet, the high costs of many of these products can threaten patient access to important therapies and place a strain on payers trying to manage prescription drug spending. Since the introduction of biosimilars 10 years ago, the European Union (EU) has experienced an average price reduction of 30 percent for products with competition from biosimilars, and it is reasonable to expect a similar impact in the United States.

That impact is consistent with the intent of Congress when it passed the Biologics Price and Competition Innovation Act (BPCIA) to foster competition and improve choices for American patients. AMCP supported its adoption and has been a strong advocate for the biosimilars pathway established under the BPCIA. The United States health care system should have the opportunity to benefit from similar savings experienced by the EU, as the cost of certain biologic drug products continue to rise in the United States.

We have two concerns with the proposed definition of “interchangeable biological product” in Section (21). Section 21 defines a biological product as both one that has been determined by the FDA to be interchangeable on the effective date of this amendment and as a biological product that prior to the effective date of this amendment is an interchangeable biological product. To date, there are no biological products that have been determined to be interchangeable by the FDA. In fact, the FDA has not yet released guidance on how an applicant can demonstrate interchangeability with a reference product. On January 22, 2016, the FDA’s Center for Drug Evaluation and Research (CDER) released its [guidance agenda](#) for CY 2016. The agenda lists the 102 guidance documents that the agency plans to publish before the end of the year, including the long awaited guidance document on interchangeability.

Second, in Section (21) (b) the reference to the “Approved Drug Products with Therapeutic Equivalence Evaluations” refers to what is commonly known as the “FDA Orange Book”. The FDA created the “Purple Book” which contains the list of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>. The Purple Book is the FDA recognized authority on interchangeability. So we recommend that the legislation be amended to reference the Purple Book.

Finally, Section 4729.38 (F) requires the pharmacist to communicate with the prescriber not later than 5 days of dispensing a drug for which an interchangeable biological product is available, which adds additional administrative record keeping and post-dispensing communication requirements for the dispensing of an interchangeable biological product that is unnecessary and not required for any other FDA approved drug category. The post-dispensing communication may be through the use of electronic methods. While the health care industry continues to increase its use of electronic technology, it has not yet reached a level of participation by a majority of prescribers and pharmacies.

At this time, the use of an interoperable health records system or other means of electronic interchange between a prescriber and a pharmacy is not the primary method of communication. In fact, written or telephonic communications continue to be the primary record in most health care settings. This presents an added duty in an already busy pharmacy dispensing setting. Additional communication from the pharmacist is not necessary. The proposed legislation does not contain any requirements that the prescriber has to maintain that information or record it. If a prescriber has reservations about an interchangeable drug product then the legislation provides that the prescriber can require that the prescription be dispensed as written [Section 4729.38 (B)]. AMCP supports the prescriber’s ability to prevent any substitution.

Contrary to the congressional intent expressed in the BPCIA, the provisions in this legislation referenced above have the potential to decrease competition, increase prescription costs to patients and payers in Ohio and, thereby, threatens patient access to more affordable treatments. Biosimilars and interchangeable biological products will bring value to your constituents as patients and payers by enhancing access to FDA approved, safe and effective, lower cost medications.

We appreciate the opportunity to share our views on this legislation. However, we respectfully request that you oppose this legislation. If you have any additional questions, you may contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703)683-8416 or [rbenjamin@amcp.org](mailto:rbenjamin@amcp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is written in a cursive style with a long horizontal line extending from the top of the name.

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer