MINUTES

HOUSE & SENATE HEALTH SERVICES SUBCOMMITTEES OF THE HOUSE & SENATE INTERIM COMMITTEES ON PUBLIC HEALTH, WELFARE AND LABOR

December 19, 2017

The House and Senate Health Services Subcommittees met Tuesday, December 19, 2017 at 10:00 a.m. in Committee Room A, of the Multi-Agency Complex (MAC) Building, Little Rock, Arkansas.

Senate Health Services members attending: Senator Missy Irvin, Co-Chair; Cecile Bledsoe, Eddie Cheatham, and John Cooper.

House Health Services members attending: Representatives Chris Richey, Chair; Aaron Pilkington, Vice Chair; Justin Boyd, Deborah Ferguson, and Jeff Wardlaw.

Other legislators attending: Senator Jonathan Dismang. Representatives Charles Blake, Trevor Drown, Kenneth Ferguson, Vivian Flowers, Justin Gonzales, Michelle Gray, Kim Hammer, Ken Hendren, Fredrick Love, Roger Lynch, Stephen Magie, Laurie Rushing, Johnny Rye, Brandt Smith, and James Sorvillo.

Comments by the Chairs
Representative Chris Richey called the meeting to order.

Consideration to Approve the December 4, 2017 Meeting Minutes (EXHIBIT C)
Representative Richey stated that without objection, the minutes from the December 4, 2017 meeting are approved.

Discussion of Interim Study Proposal (ISP) 2017-007 – "An Act to Allow Pharmacists to Make Biological Product Substitutions; and for Other Purposes." (3 Handouts: 1-the ISP, 2-the Proposed Amendments, and 3-Survey of States with Biological or Biosimilar Legislation)
Representative Stephen Magie, Sponsor of ISP2017-007, explained this ISP in detail, presented a brief history of this issue's legislative background, and showed how other states have handled prescribing and substitution of biologic medicines.

Nationwide, no state has acted upon this issue through rules and regulations, but have acted upon it through the legislative process of statute. Representative Magie would like the discussion of this ISP to be placed on the next Public Health Committee meeting agenda.

Senator Irvin briefly reviewed the interim study process, and clarified that Representative Magie will draft a new bill with the proposed amended changes included, to be introduced in the 2019 Legislative Session.

Greg Hoke, Director, State Government Affairs, BIO, Inc., Biotechnology Innovation Organization, supports ISP2017-007. Legislation on biologics and biosimilars has been passed in 36 other states. It is mainly about patient safety and cost savings to patients. The FDA (Federal Drug Administration) will determine which biosimilars have become interchangeable biologic drugs. After these interchangeable biologic drugs are approved by the FDA, states have the authority to implement substitution criteria for providers.

A coalition (chain drug stores, manufacturers, insurance companies, pharmacists, physicians, PBMs (Pharmacy Benefit Managers), and patient groups) have studied and researched this issue for the past five years. The coalition came up with five principles:

- Substitution should only be done when an interchangeable biologic has been approved by the FDA
- The prescribing physician should always be able to write 'do not substitute'
- The patient should always be notified of the substitution
- There should be communication between the pharmacist and the prescribing physician
- There should be a record of that transaction kept at the pharmacy

David Wroten, Executive Vice President, Arkansas Medical Society, commented on the ISP and the proposed amendments to this ISP. Representative Magie's amendments reference both the purple book and the orange book[1]. The FDA has stated that if there is an interchangeable biosimilar product, it can be substituted without the intervention of the physician. The FDA is completely silent on substitution and on whether or not you have to communicate that substitution to the physician. Mr. Wroten feels this issue needs to be handled through legislation.

Scott Pace, Pharm.D., J.D., Executive Vice President & CEO, Arkansas Pharmacist's Association, stated that biologics are not new and they are drugs grown inside living organisms. They have been around for generations in insulin, vaccines, and various other drugs. In addition, certain biologic products, such as low molecular-weight heparins have been used interchangeably in Arkansas, as well as nationwide.

Attention has been drawn to interchangeable biologics because The Affordable Care Act created a new federal law called, *The Biologics Priced Competition and Innovation Act of 2009,* which created a new licensure and approval process for these drugs. Therefore, these biologics were deemed interchangeable.

Scott Pace's legal analysis: The Arkansas State Board of Pharmacy has jurisdiction over drugs and is defined in the Arkansas Pharmacy Practice Act that all medicines and preparations recognized in the U.S. Pharmacopeia or the National Formulary are drugs. These two references specifically include biologics as drugs by definition, and are therefore, under the jurisdiction of state pharmacy boards through their rule-making ability. The Arkansas Pharmacist's Association and the Arkansas State Pharmacy Board hope this change is handled through the rules and regulations process, and not through the statutory process.

John Kirtley, Pharm.D, Executive Director, Arkansas State Board of Pharmacy, stated this is only about interchangeable biologics, which are basically considered biosimilars. The urgency of this issue is because FDA policies, timelines, and procedures have changed and/or been added.

Bart Calhoun, McDaniel, Richardson & Calhoun Company, an alliance for safe biologic medicines; presented his clarification of a prior legal analysis. "The broad provision of authority cannot be used to approve the board's authority to govern substitution of biologics. Such must be addressed by the legislature, with the legislature setting forth appropriate standards for the guidance of the board just like it did for substitution of generic drugs."

Mr. Calhoun stated that the pharmacy board does not have the authority to substitute or govern substitution of biologic drugs until this legislature addresses them by statute.

Senator Irvin requested for this discussion topic to be added to the next Public Health Committee meeting agenda, and Senator Bledsoe agreed. Representative Magie and Senator Cooper will collaborate together to draft a new bill with the proposed amendments included in the draft bill.

The meeting adjourned at 12:40 p.m.

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[1] **THE ORANGE BOOK** *lists approved drug products with therapeutic equivalence evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information. https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm

THE PURPLE BOOK *includes the date a biological product was licensed under 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act.*

The Purple Book, *in addition to the date licensed*, also includes whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product). The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the PHS Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the Affordable Care Act known as the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.

Healthcare providers can prescribe biosimilar and interchangeable biological products just as they would prescribe other medications. The BPCI Act describes an interchangeable product as a product that may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. In contrast, FDA expects that a biosimilar product will be specifically prescribed by the healthcare provider and cannot be substituted for a reference product at the pharmacy level.
https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm