INTERIM STUDY PROPOSAL 2015-188

REQUESTING THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR STUDY THE SUBSTITUTION OF BIOLOGIC PRODUCTS AND APPROACHES BY OTHER STATES REGARDING THE PROCESS UNDER WHICH PHARMACISTS ARE ALLOWED TO MAKE BIOLOGIC PRODUCT SUBSTITUTION.

WHEREAS, the Biologics Price Competition and Innovation Act was enacted on March 23, 2010, to create a new abbreviated process for approval of intended copies of biologic products, including biosimilars, and requires the United States Food and Drug Administration to apply different considerations for approval of generic products; and

WHEREAS, a biologic product is a medical product made from human, animal, or microorganism cells that is intended to treat diseases and medical conditions and is much more complex to manufacture than traditional chemically synthesized drugs; and

WHEREAS, a biosimilar product is a biologic product that is approved based on a showing that the product is highly similar to a biological product that has been approved by the United States Food and Drug Administration, also known as a reference product, and clinically has no meaningful differences in terms of safety and effectiveness from the reference product; and

WHEREAS, the United States Food and Drug Administration has approved three (3) biosimilars, with more currently under review; and

WHEREAS, twenty-five (25) states have passed legislation establishing state standards for substitution of biologic products; and

WHEREAS, Arkansas law contains standards for the substitution of generic drugs, but does not contain a provision for the substitution of biologic products; and
WHEREAS, the General Assembly should pursue all approaches to ensure that the citizens of Arkansas have equal access to all medical products available for use,

NOW THEREFORE,

BE IT PROPOSED BY THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR OF THE NINETIETH GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

THAT the House Committee on Public Health, Welfare, and Labor study the substitution of biologic products and approaches by other states regarding the process under which pharmacists are allowed to make biologic product substitution.

Respectfully submitted,

Representative Stephen Magie
District 72

By: JMB/JMB