

INTERIM STUDY PROPOSAL 2015-188

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3 REQUESTING THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND  
4 LABOR STUDY THE SUBSTITUTION OF BIOLOGIC PRODUCTS AND APPROACHES  
5 BY OTHER STATES REGARDING THE PROCESS UNDER WHICH PHARMACISTS ARE  
6 ALLOWED TO MAKE BIOLOGIC PRODUCT SUBSTITUTION.  
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8 WHEREAS, the Biologics Price Competition and Innovation Act was enacted  
9 on March 23, 2010, to create a new abbreviated process for approval of  
10 intended copies of biologic products, including biosimilars, and requires the  
11 United States Food and Drug Administration to apply different considerations  
12 for approval of generic products; and  
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14 WHEREAS, a biologic product is a medical product made from human,  
15 animal, or microorganism cells that is intended to treat diseases and medical  
16 conditions and is much more complex to manufacture than traditional  
17 chemically synthesized drugs; and  
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19 WHEREAS, a biosimilar product is a biologic product that is approved  
20 based on a showing that the product is highly similar to a biological product  
21 that has been approved by the United States Food and Drug Administration,  
22 also known as a reference product, and clinically has no meaningful  
23 differences in terms of safety and effectiveness from the reference product;  
24 and  
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26 WHEREAS, the United States Food and Drug Administration has approved  
27 three (3) biosimilars, with more currently under review; and  
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29 WHEREAS, twenty-five (25) states have passed legislation establishing  
30 state standards for substitution of biologic products; and  
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32 WHEREAS, Arkansas law contains standards for the substitution of  
33 generic drugs, but does not contain a provision for the substitution of  
34 biologic products; and  
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1           WHEREAS, the General Assembly should pursue all approaches to ensure  
2 that the citizens of Arkansas have equal access to all medical products  
3 available for use,  
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5 NOW THEREFORE,  
6 BE IT PROPOSED BY THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR OF  
7 THE NINETIETH GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:  
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9           THAT the House Committee on Public Health, Welfare, and Labor study the  
10 substitution of biologic products and approaches by other states regarding  
11 the process under which pharmacists are allowed to make biologic product  
12 substitution.  
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14 Respectfully submitted,  
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18 Representative Stephen Magie  
19 District 72  
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