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January 20, 2017

The Honorable Representative Daniel Hawkins
Kansas House Health and Human Services Committee
Topeka, KS

Dear Chairman Hawkins:

My name is Dr. Mark S. Box, M.D., and I am a rheumatologist practicing in Kansas City. I am currently the President of the Midwest Rheumatology Society representing rheumatologists in the Kansas City Metropolitan area and also serve on the Board of Directors of the Coalition of State Rheumatology Organizations This is a national organization representing rheumatology state organizations. I additionally serve as the Chair of the Kansas City Advisory Board to the Arthritis Foundation. I am planning to testify regarding House Bill 2107 on biosimilars medications. As a background, biologic drugs are medications used in the treatment of autoimmune diseases. They have been a revolutionary component of medical care in treating very complex and life-threatening diseases. These medications are large molecules produced by cell lines and are typically administered either by injection or IV infusion. Because of the nature of the medications, no exact generic versions have ever been produced. These medications are produced by cell lines which are unique; however, there is now approved biosimilar medications as options for therapy. Biosimilars while not exact copies are medications which are similar and proven in studies to have equal efficacy. Because of the manner in which these medications are produced, there are subtle differences in the molecules. Current Kansas Pharmacy Practice Acts do not really appropriately cover the prescribing of biosimilar medications. There are certain principles that I believe are very important in prescribing biosimilars, and the bill will address these issues. At this point in time, the FDA has not determined that any of the biosimilars are interchangeable. Therefore, we feel substitution should only be allowed when the FDA has designated a biologic product as interchangeable. Until that time, the prescription should be specific to either the originator medication or the biosimilar and pharmacies should not be allowed to make any substitution until the FDA has approved that these medications can be considered equivalent and interchangeable. There is believed to be significant risk of immune responses in individuals to these medications and change could lead to serious consequences in the individuals prescribed these medications. We believe that the prescribing physician should be allowed to prevent substitution if it is felt not to be in the interest of the patient or presents a risk of harm due to immune reaction or inefficacy with the biosimilar medication. We additionally strongly feel that once the FDA has

approved any interchangeability that if a product is switched in the pharmacy, that both the physician and patient be notified of the substitution and that clear records be kept of the substitution. As noted, there is a risk that the subtle differences in these molecules could lead to immune reactions in the patient that could be life-threatening or cause loss of the effectiveness of the medications. Without accurate knowledge of the substitution, these problems may not be clearly evident to the physician or patient should they occur. Biosimilars presents a potential for a significant cost savings and in no way should it be taken that these are not important options for future treatment of patients with autoimmune diseases; however, there are strong feelings that proper communication as well as accurate knowledge of the interchangeability of these medications be part of the prescribing pattern and part of the Kansas Pharmacy Practices Act. I will hope during my testimony to help the committee to understand the importance of the ammendment.

Sincerely,

Mark S. Box, M.D.

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