Testimony in Support of HB 2107
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Madam Chair, Committee Members:

I appreciate the opportunity to speak today in support of HB 2107, legislation I believe will benefit thousands of Kansas residents.

My name is Harry Gewanter, and I am a pediatrician and pediatric rheumatologist with over 3 decades of experience caring for children with rheumatic and other chronic and disabling diseases. I currently serve as the Chairman of the Alliance for Safe Biologic Medicines (ASBM). ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovator biologics and biosimilar medicines, researchers and others working together to ensure that patient safety is at the forefront of all biosimilar policy discussions.

Biologic medicines have revolutionized the treatment of many chronic and serious illnesses such as cancer, Rheumatoid Arthritis, Crohn's disease, Psoriasis, and Multiple Sclerosis. I can personally attest to the dramatic positive effect these medications have had on the lives of children, former children and their families. The walkers and wheelchairs used by most of the patients at the Arthritis Foundation's Juvenile Arthritis meetings 20 years ago are now essentially nonexistent. Today's meetings suffer from the kids being told to stop running in the hallways, and my subspecialty is considering how do we define a cure for these previously incurable crippling rheumatic diseases. What a nice problem!

Biosimilars have the potential to further these advances through increased patient access and reduced costs for these life-changing medicines. While it is easy to assume that biosimilars are the biologic equivalent of generics and the past will be repeated, it is not that simple. Biosimilars are not generics because they are not exact copies of the originator molecule; in fact, exact copies cannot be made. Biologic medications are large, complex molecules made by living cells, using proprietary manufacturing processes that cannot be exactly replicated. Therefore, only similar, but not identical copies are possible. Differences will always exist between the medications, and, regardless of how small, these variations could have a significant clinical impact. For example, they may hasten the development of unwanted immune responses resulting in reduced efficacy or allergic reactions. These as yet unknown potential adverse effects makes addressing the issue of switching and substitution between biologic medications, be they originators or biosimilars, a complex and serious policy issue.

As you know, current Kansas law does not yet have a clear pathway regulating the substitution of a biologic medicine with a biosimilar. HB 2107 will update Kansas' Pharmacy Act to better allow the safe substitution of biologic medications when appropriate. Amending the Pharmacy Act is necessary to ensure patient safety and promote the availability and use of biosimilars to all of your citizens. On behalf of ASBM and all of its members, I strongly endorse HB 2107 and encourage you to pass it.

I would like to point out just a few of its important patient protections:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the originator product without additional risks relative to staying on the originator product) may *ever* be substituted.

- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing on the prescription "dispense as written" or similar language.

- It ensures the patient or the patient's representative is informed of any substitution.

- Most importantly, HB 2107 requires that the pharmacist communicate to the prescriber within a reasonable time frame (5 business days) if the less expensive substituted interchangeable biosimilar is dispensed. The pharmacist will maintain these records for 5 years, thereby creating an easy and automatic means to track which medications were dispensed as this is absolutely critical to ensuring the safe and successful use of biosimilars.

HB 2107's language reflects the opinions of the majority of biologic prescribing physicians throughout the United States. In surveys conducted by ASBM of 376 US physicians, **over 4 out of 5** considered communication in the event of a biosimilar substitution as well as the authority to prevent a substitution by indicating 'dispense as written' on a prescription, **'very important' or 'critical'**. As noted in the supplemental information from the Kansas House Committee on Health and Human Services, the language in this bill is also supported by a number of patient and physician groups, pharmaceutical manufacturers and a national specialty pharmacy company

It is our view that HB 2107 appropriately reflects the importance of patient-pharmacist-physician communication and collaboration when biosimilar substitution is a possibility. Further, it maintains the patient-physician relationship and decision-making at the core of these important treatment decisions while also not placing an undue or onerous burden upon the pharmacist.

HB 2107 will provide valuable protections to Kansas' citizens while increasing their access to life-altering and life-saving biologic therapies. These are among the reasons lawmakers in **28 states and Puerto Rico have passed similar bills** in the past few years.

Thank you for the opportunity to testify before your committee today. I am happy to answer any of your questions.