SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Written Testimony of
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In support of
Kansas HB 2107
regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists

Chairman Hawkins, Vice-Chair Dove, and Members of the House Health and Human Services Committee,

Thank you for the opportunity to testify before your committee today.

My name is Philip Schneider, I am Professor and Associate Dean at the University of Arizona, College of Pharmacy at the new Phoenix Biomedical Campus. I am a past president of the American Society of Health-system Pharmacists (ASHP) which represents more than 43,000 pharmacists, and serve on the Board of the International Pharmaceutical Federation, which represents 3 million pharmacists globally.

I also serve as Chair of the Advisory Board for the Alliance for Safe Biologic Medicines (ASBM) a group of patients, physicians, pharmacists, manufacturers of both originator and biosimilar biologics, and others working toward the safe introduction and use of biosimilars. ASBM has been working on biosimilar issues at the state, federal and international level for 5 years.

Biologic medicines help patients with some of the most serious and chronic conditions like cancer, rheumatoid arthritis, diabetes, Crohn's disease, and MS. "Copies" of these medicines, called "biosimilars" are becoming available in the U.S. and they have the potential to new therapeutic options to these patients at lower cost.

Yet unlike generic versions of more simple chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its biosimilar can have a significant impact on a patient- including reduced efficacy or unwanted immune responses. For these reasons, regulators including the FDA and WHO have made it a priority to name these products distinguishably- so inadvertent substitution is less likely to occur and any problems can be traced to the correct product.

With biosimilars, it is critical that everyone- physician, pharmacist, patient, and regulator- knows which medicine the patient actually received at the pharmacy.

What HB 2107 will do:

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- Current Kansas law has no clear pathway for substitution of biosimilar drug products. Therefore, pharmacists would be required to obtain advanced approval from the prescriber before they are allowed to substitute an interchangeable biologic for a brand name biologic. **This legislation will remove this requirement.**

- It will allow Kansas pharmacists the ability to dispense safe and less expensive biologic medications to patients, by allowing substitution of an **interchangeable** biologic for a prescribed brand name biologic.

HB 2107 protects patients:

- It assures that only FDA-approved "interchangeable" biologic products may be substituted without prior prescriber consent. (These are biosimilars which have been shown to produce the same effects as the original biologic, with no additional risks in the event a patient is switched.) This is similar to substitution requirements of generic substitution.

- Physicians will retain the authority to indicate "Dispense as Written" or DAW. This is identical to the authority they have with generic substitution.

- Because biologic products differ from generics in complexity and are not identical chemical products, the legislation ensures there will be **clear and timely communication** between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. Pharmacists will have up to 5 business days to relay information on which medication is dispensed, so that all providers will have an accurate patient medical record.

- **Having an accurate patient record** allows providers to assess the patient's response to a particular treatment, including proper attribution of any adverse events to the correct product, and help us make informed treatment decisions.

- Maintaining these records for 5 years will aid all of us in post-market surveillance of these medicines, and learning more about how they work.

Why support this legislation:

- **It will establish a clear substitution process** by allowing pharmacists to dispense an FDA approved interchangeable biologic without first seeking approval.

- It will increase access to lower cost medicines for patients.

- A large coalition (of branded & generic manufacturers and associations, many provider & patient groups, along with the largest pharmacy benefit manger and some health insurers) agree on the language in this legislation.

- It recognizes the growing use of interoperable electronic health records and electronic prescribing records, allowing such systems to be used by a patient's health care team to communicate regarding a patient's medication history.

- **Legislation to allow pharmacist substitution of biologic drugs has now passed in 26 states, plus Puerto Rico.**

In summary, ASBM supports this bill because it removes barriers to lower cost medicines and increases treatment options, while recognizing the need for transparency and communication between healthcare providers to ensure patient safety when using these promising new medicines.

Thank you for the opportunity to comment on this important legislation.

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