800 SW Jackson St., Suite 1414
Topeka, KS 66612
Alexandra Blasi, Executive Secretary

Kansas
Board of Pharmacy

phone: 785-296-4056
fax: 785-296-8420
pharmacy@ks.gov
www.kansas.gov/pharmacy
Sam Brownback, Governor

Testimony concerning HB 2071
Senate Committee on Public Health and Welfare
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
March 16, 2017

Madam Chair and Members of the Committee:

The Kansas State Board of Pharmacy testifies as an opponent of HB 2107. The Board has carefully reviewed these amendments and additions over the past year and generally supports incorporating biological products and the laws governing biosimilar and interchangeable products in Kansas. However, the Board cannot support some of the language proposed in HB 2107.

According to the FDA, a generic drug is bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Even though generic drugs are chemically identical, they are often utilized due to their price tag. This is the easiest comparison for a biological product, which is made from living organisms, such as proteins, instead of chemical compounding or synthesis. According to the FDA, there are two new types of biological products, known as biosimilars and interchangeable products. Biosimilars are FDA-approved biological products that are highly similar to another FDA-approved biological product, and have no clinically meaningful difference. An interchangeable biological product, in addition to meeting the biosimilarity standard, is expected to produce the same clinical result in a patient.

The Board opposes HB 2107 primarily because of the requirement that pharmacists report the substitution to the prescriber. Kansas already has a model for substituting prescription drugs deemed equivalent by the FDA and it has worked well for many years. Unless a prescriber expressly prohibits it, a Kansas pharmacist may exercise an exchange as long as the patient is informed and a record is kept in the pharmacy for five years. The requirements proposed for exchange of a biological product, however, require patient notification, a pharmacy record, and the additional step of reporting the exchange to the prescriber within five business days (see page 19, new subsection (h)). This extra step may seem inconsequential, but the Board of Pharmacy believes it places a significant and unnecessary burden on pharmacists. First, it makes the rules for exchange inconsistent for pharmaceutical drugs and biological products. Second, it imposes a duty to communicate back to the prescriber, which takes time and attention away from patient-centered practice and otherwise seems to lack purpose. Third, it creates a redundancy in record-keeping and communication. And last, no reasons have been provided to the Board of Pharmacy concerning what is achieved by this extra requirement.

It may be argued that there aren't currently many opportunities for exchange of biological products and so this burden would be minimal. While that may be true right now, the pharmacy community anticipates this is just the beginning of the biosimilars and interchangeables that will be available in coming years. Imagine if a similar requirement existed for generic substitutions, which are done by the thousands at a pharmacy each day – some exchanges are even required for a patient to receive full

insurance coverage or benefits. The number of emails, faxes, and phone calls to the prescribers would be overwhelming for both the pharmacies sending and the prescribers receiving such communications.

It has also been suggested that this presumption of communication via an interoperable electronic medical records system minimizes the impact of the reporting requirement. This is certainly a model that would be applicable in a hospital health system or, perhaps, a major metropolitan pharmacy, but it is not the model used in the rural or community pharmacy setting. Therefore, the impact would most heavily be felt in independent pharmacies that do not maintain integrated electronic records systems, creating quite a disparity between pharmacies.

For the aforementioned reasons, the Board of Pharmacy opposes the adoption of HB 2107. If the reporting requirement was removed, the Board would support the bill.