SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

January 23, 2017

Kansas House of Representatives
Health and Human Services Committee
Kansas State Capitol

Dear Members of the House Health and Human Services Committee,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to urge you to **support House Bill 2107 (HB 2107)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, researchers and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a retired pediatric rheumatologist and a former president of the American Society of Health-system Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. "Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of 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 attempted copy can have a significant impact on a patient, including reduced efficacy or unwanted immune responses.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 2107 and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in eleven countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Canada, Europe, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians found that 80% of those surveyed called communication in the event of a biosimilar substitution "very important" or "critical".**

- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating "do not substitute" or "dispense as written" on a prescription "very important" or "critical".**

These results are consistent with those of physicians around the world, including those surveyed in Canada and Europe, where biosimilars are currently in clinical use. All ASBM surveys are available on our website at www.safebiologics.org.

It is our view that **HB 2107 appropriately reflects the importance of pharmacist-physician communication** and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) 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".

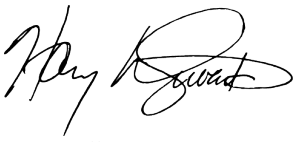
- It provides that the pharmacist inform the patient or the patient's representative that a substitution has occurred.

- Finally, HB 2107 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

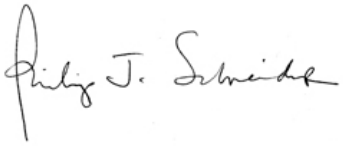
For these reasons, lawmakers in **26 states and Puerto Rico have passed similar bills** in the past few years. HB 2107 will extend these valuable protections to Kansas's patients while increasing their access to biologic therapies.

Thank you in advance for taking the necessary steps to keep patient safety a priority in Kansas by supporting House Bill 2107.

Sincerely,



Harry Gewanter, MD
Chairman, The Alliance for Safe Biologic Medicines



Philip J. Schneider, MS, FASHP
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