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Testimony concerning SB 51
House Committee on Health and Human Services
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
March 8, 2017

Chairman Hawkins and Members of the Committee:

The Kansas State Board of Pharmacy is pleased to testify as a proponent of SB 51. The amendments proposed with appropriately expand the Board's authority to schedule, on an emergency basis, dangerous drugs any time the legislature is not available to make such changes to the Kansas Uniform Controlled Substances Act.

Pursuant to K.S.A. 65-4102(e), the Board is required to initiate emergency scheduling proceedings when two sets of circumstances occur. The first set of circumstances requires an attorney notify the Board of Pharmacy of initiation of a prosecution with respect to a controlled substance analog. Though the ADA will cover this matter in greater detail, the difficulty of initiating a prosecution for possession of a substance that is not yet unlawful is notable. It is only after receiving this notice that the Board of Pharmacy is able to contemplate temporarily adding a substance to the Kansas drug schedules. For this reason, SB 51 amends subsection (e) to allow the Board of Pharmacy to initiate emergency scheduling proceedings upon a finding that the substance presents an imminent hazard to the public safety. Such a finding shall be based on the Board's consideration of whether the substance has been federally scheduled on a temporary basis, the history and current pattern of abuse, the scope, duration, and significance of abuse, the risk to the public health, and the clandestine importation, manufacture, or distribution of the substance. This evaluation is already outlined in K.S.A. 65-4102 and remains unchanged in this bill.

The second set of circumstances required to initiate emergency scheduling proceedings mandates the substance in question meet the criteria outlined in K.S.A. 21-5701 and K.S.A. 65-4101 under the definition of a controlled substance analog. Currently, a controlled substance analog means a substance that is intended for human consumption and:

1. The chemical structure is substantially similar to a controlled substance already scheduled in Kansas;
2. The substance has a stimulant, depressant, or hallucinogenic effect on the central nervous system similar to a controlled substance already scheduled in Kansas; or
3. With respect to a particular individual, the individual represents or intends the substance to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to a controlled substance already scheduled in Kansas.

The definition's three listed criteria are only separated by the word "or" between the last two criteria. Unfortunately, a Kansas appellate court has interpreted the first criterion to be conjunctive, meaning that multiple criteria must be present to determine that the substance in question is a controlled substance

analog. This is a high bar and one that even the lethal drug U-47700 did not meet last year. Furthermore, the court's interpretation is not believed to be the original intent of the statutory language. Therefore, SB 51 amends the statute to allow greater flexibility, such that the substance may meet any of the three criteria in order to be considered a controlled substance analog.

The controlled substance analog criteria also require that the substance be substantially similar to a controlled substance already scheduled in Kansas. This presents a challenge for new drugs, drugs that have emerged after being hidden in a drawer for decades, or drugs that are only substantially similar to controlled substances recently included in the federal schedules and not yet scheduled in Kansas. The issue encountered with U-47700 was that it is not substantially similar in chemical structure to any substance currently controlled in Kansas, though it was substantially similar to a federally scheduled controlled substance and was, itself, temporarily scheduled in Spring 2016. As a result, criminal charges could not be filed under K.S.A. 21-5701, and there was no mechanism to invoke the Board of Pharmacy's ability to consider emergency scheduling of the substance. To avoid this issue in the future, SB 51 expands K.S.A. 65-4102(e) to allow the Board of Pharmacy to consider controlled substance analogs or any new drug for emergency scheduling. New drugs are defined by K.S.A. 65-656 as:

1. Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or
2. Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Last, SB 51 amends the length of scheduling from one year to July 1 of the following calendar year. This change is made to accommodate the Kansas legislative session and tendency for bills to become effective upon publication in the statute book on July 1. This does not necessarily extend the timeline; it could mean as many as 16 months or as little as seven months.

Though these are material changes to the current laws governing emergency scheduling, the Board of Pharmacy believes they are imperative to protect the public from dangerous and lethal substances that may emerge at a time that the legislature is not in session and unable to consider permanent scheduling. This expanded authority still remains narrow in scope, is tailored to a specific purpose, and is not without checks and balances. Any emergency scheduling is only temporary and would have to be reviewed by the legislature during the next session.