

Testimony concerning S Sub for HB 2262
Senate Committee on Public Health and Welfare
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
February 1, 2022

Chairman Hilderbrand and Members of the Committee:

Last year, the Kansas State Board of Pharmacy was pleased to testify as a proponent of SB 298. The Board appreciates this Committee's willingness to work the bill, place its contents in Sen. Sub. for HB 2262, and recommend it favorably for passage. Pursuant to K.S.A. 65-4102(b), the Board is required to submit to the House and Senate an annual report on amendments to the Act which it delivered on January 24, 2022. A copy was also provided to the Chair.

Each year, the Board collaborates with the Kansas Bureau of Investigation (KBI), as well as pharmacy and law enforcement stakeholders to present vital updates to the Kansas Uniform Controlled Substances Act. Sen. Sub. for HB 2262 contains updates that protect Kansas citizens, and the Board stands by its testimony from last year. Recently, we discussed the opportunity to make an additional necessary revision to the bill, which the Board brings to your attention.

To provide some historical context, the Board wishes to highlight changes contained in Sen. Sub for HB 2262 specific to the FDA-approved drug Epidiolex, of which the main active ingredient is cannabidiol. Epidiolex is used to treat Dravet and Lennox-Gastaut Syndromes, which are debilitating seizure disorders affecting children. In 2017, with the knowledge that Epidiolex was undergoing the U.S. Food and Drug Administration's drug-approval process, Kansas proactively placed this drug in the Act under Schedule IV so that it would be able to be prescribed to Kansas patients immediately upon FDA approval (see KSA 65-4111(f)(3)). After the FDA approved the drug, it was placed in Schedule V of the Federal Controlled Substances list. More recently, the FDA has de-scheduled this drug entirely. It is no longer considered a federally controlled substance and may be prescribed under regular conditions, similar to antibiotics or other prescription medications. Kansas seeks to mirror this de-scheduling; thus, Sen. Sub. for HB 2262 updates the Act to remove Epidiolex. The manufacturer of Epidiolex supports this approach.

In recent months, the Board has become aware of at least one medication in the FDA drug-approval process composed of main active ingredients tetrahydrocannabinol and cannabidiol. This medication is being evaluated for the treatment of muscle spasticity in Multiple Sclerosis patients, and any approval would likely occur between the 2022 and 2023 legislative sessions. Consequently, if/when approved, the pending FDA prescription drug application would require amendments to the Kansas Uniform Controlled Substances Act before the medication may be lawfully prescribed to Kansas patients. Unless changes are made to the Act prospectively, Kansas patients will face a delay in their ability to access the prescription drug(s) necessary for disease management.

To ensure Kansas patients have timely access to this and other cannabis-based, FDA-approved medications in the future, the Board recommends proactively amending the Act to exempt all FDA-approved drug products from the definition of marijuana in K.S.A. 21-5701 and K.S.A. 65-4101. Similar to class scheduling approaches which have been incorporated into the Act, this one-size-fits-all approach helps ensure accessibility to FDA-approved medications as they become available. It is imperative that these amendments not be specific to any brand-name drug or pharmaceutical company. The Board feels this is paramount to maintaining regulatory neutrality and ensuring all pharmaceutical manufacturers are afforded the same opportunities. Such changes would not negatively impact the Act and the provision would not be triggered unless and until any such medication was approved by the FDA.

Respectfully submitted.