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 SB 298
Senate Committee on Public Health and Welfare
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
March 25, 2021

Chairman Hilderbrand and Members of the Committee:

The Kansas State Board of Pharmacy is pleased to testify as a proponent of SB 298. These amendments include vital updates to the Kansas Uniform Controlled Substances Act to protect Kansas citizens. Timely passage of these amendments are paramount to public safety. Therefore, the Board respectfully requests that the contents of SB 298 not be unnecessarily entangled with other matters.

The Kansas State Board of Pharmacy (Board) is created by statute and is comprised of seven members, each of whom is appointed by the Governor. Of the seven, six are licensed pharmacists and one is a member of the general public. Pursuant to K.S.A. 65-4102(b), the Board is required to submit to the Speaker of the House of Representatives and the President of the Senate a report on substances proposed by the Board for scheduling, rescheduling or deletion by the legislature with respect to any one of the schedules as set forth in the Kansas Uniform Controlled Substances Act, K.S.A. 65-4101 et seq. The Board submitted the aforementioned letter on February 11, 2021. In its determination, the Board shall consider the following:

(1) The actual or relative potential for abuse;
(2) The scientific evidence of its pharmacological effect, if known;
(3) The state of current scientific knowledge regarding the substance;
(4) The history and current pattern of abuse;
(5) The scope, duration and significance of abuse;
(6) The risk to the public health;
(7) The potential of the substance to produce psychological or physiological dependence liability; and
(8) Whether the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act.

The Drug Enforcement Administration (DEA) also issues their rulings based on information provided by the DEA's Deputy Administrator and the Department of Health and Human Services using the same factors and criteria that the state uses.

The Board staff has an ongoing relationship with the Kansas Bureau of Investigation (KBI) and collaborates with them to make necessary recommendations for updates to the Act. Earlier this year, we began a dialogue and have conducted a comparison of the controlled substances listed in Schedules I-V of the Federal Controlled Substances to protect the public health and safety of Kansans. This bill is the result of that work.

Congress created five schedules or classifications with varying qualifications for a substance to be included in each. The Drug Enforcement Agency ("DEA") and the Food and Drug Administration ("FDA") make recommendations after considering various factors that indicate the drug should have more restrictions.

- Schedule I are those drugs that have a high potential for abuse and have no accepted medical use in treatment in the United States.
- Schedule II substances have a high potential for abuse but have an accepted medical use in the United States or a currently accepted medical use with severe restrictions. Abuse of the drug may lead to severe psychological or physical dependence.
- Schedule III substances have less potential for abuse than drugs in Schedule I or II and they have an accepted medical use in treatment in the United States. Abuse may lead to moderate or low physical dependence or high psychological dependence.
- Schedule IV substances have a low potential for abuse relative to the drugs in Schedule III. The substances have a currently accepted medical use in treatment in the United States. Abuse may lead to limited physical dependence or psychological dependence relative to drugs or substances in Schedule III.
- Schedule V substances have a low potential for abuse relative to the drugs in Schedule IV. The drug or substance has a currently accepted medical use in treatment in the United States. Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or substances in Schedule IV.

The Board recommends that the following drugs be added to Schedule I because they present and imminent and significant risk to the health and safety of the public: crotonyl fentanyl; isotonitazene; brorphine; and 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1 H-pyrrolo[2,3-b]pyridine-3-carboxamide. Some amendments are proposed to the spelling and substance numbers previously contained in the Act. At KBI's recommendation, the Board also proposes some amendments from "ring" to "group" in certain cannabinoid classes, and the addition of a single "syncan" class. KBI can provide additional information regarding these chemical updates.

The Board recommends the following substances be added to Schedule II:

Noroxymorphone, an opioid metabolite of oxymorphone and oxycodone manufactured as an intermediate in the production of narcotic antagonists such as naltrexone, https://www.federalregister.gov/documents/2019/08/16/2019-17623/listing-of-noroxymorphone-in-the-code-of-federal-regulations-and-assignment-of-a-controlled;

Oliceridine, an intravenous opioid medication for severe, acute pain, https://www.federalregister.gov/documents/2020/10/30/2020-22762/schedules-of-controlled-substances-placement-of-oliceridine-in-schedule-ii; and

Norfentanyl, an opioid analgesic.

The Board recommends the following substances be added to Schedule IV:

Remimazolam, a short-acting sedation medication, https://www.federalregister.gov/documents/2020/10/06/2020-19313/schedules-of-controlled-

substances-placement-of-remimazolam-in-schedule-iv;

Lemborexant, an insomnia medication approved in December 2019, https://www.federalregister.gov/documents/2020/04/07/2020-07089/schedules-of-controlled-substances-placement-of-lemborexant-in-schedule-iv;

Brexanolone, used to treat depression including postpartum depression, https://www.federalregister.gov/documents/2020/01/24/2020-00669/schedules-of-controlled-substances-placement-of-brexanolone-in-schedule-iv; and

Solriamfetol, a medication for treatment of sleepiness due to narcolepsy or sleep apnea, https://www.federalregister.gov/documents/2020/01/07/2019-27955/schedules-of-controlled-substances-placement-of-solriamfetol-in-schedule-iv.

The Board recommends the following substances be added to Schedule V:

Cenobamate, a medication for treatment of adult seizures, https://www.federalregister.gov/documents/2020/08/20/2020-17357/schedules-of-controlled-substances-placement-of-cenobamate-in-schedule-v;

Lasmiditan, used to treat migraines without aura, https://www.federalregister.gov/documents/2020/01/31/2020-01957/schedules-of-controlled-substances-placement-of-lasmiditan-in-schedule-v;

The Board recommends updating scheduling for the FDA-approved drug Epidiolex, of which the main active ingredient is cannabidiol. Kansas proactively placed this drug in Schedule IV so that it would be able to be prescribed in Kansas immediately upon FDA approval (see KSA 65-4111(f)(3)). However, after the FDA approved the drug, it was placed in Schedule V of the Federal Controlled Substances list. More recently, the FDA has descheduled this drug entirely. It is no longer considered a federally controlled substance and is able to be prescribed under regular conditions, similar to antibiotics or other routine prescription medications. Kansas seeks to mirror this de-scheduling. The manufacturer of Epidiolex has consulted with the Board on this matter and is supportive of this approach.

Finally, there was one minor editing glitch with the draft of SB 298 which the Board hopes to offer a friendly amendment to correct. On page 10, Schedule I, KSA 65-4105(h)*(4)*, line 12-13 should be spelled naphthylmethylindene.

All recommendations are consistent with the Federal Controlled Substance Act.

Respectfully submitted.