STATE OF KANSAS

BOARD OF PHARMACY
800 S.W. JACKSON ST., SUITE 1414
TOPEKA, KS 66612

PHONE: (785) 296-4056
FAX: (785) 296-8420
pharmacy@ks.gov
www. pharmacy.ks.gov

GOVERNOR JEFF COLYER, M.D.
ALEXANDRA BLASI, J.D., M.B.A., EXECUTIVE SECRETARY

Testimony concerning SB 282
House Committee on Health and Human Services
March 8, 2018

Chairman Hawkins and Members of the Committee:

The Kansas State Board of Pharmacy is pleased to testify as a proponent of SB 282. These amendments include vital updates to the Kansas Uniform Controlled Substances Act to protect Kansas citizens. The Board strongly agrees that timely passage is paramount to public safety and respectfully requests that the contents of SB 282 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 the week of January 22, 2018. 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 meets regularly with them to discuss drugs of concern and make necessary recommendations for updates to the Act. In October, we began the dialogue and have conducted a comparison of the controlled substances listed in Schedules I-V of the Federal Controlled Substances in addition to data from other states and the KBI forensic science lab in order to protect the public health and safety of Kansans. This bill is the result

of that work, and the Board fully supports the changes proposed in SB 282 and agrees with the KBI's testimony.

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 the following substances be added to Schedule II:

ANPP, an immediate precursor to fentanyl; and

Dronabinol in an oral solution in a drug product approved for marketing by the FDA, which was federally scheduled on March 23, 2017. The rule and explanation can be found at: https://www.gpo.gov/fdsys/pkg/FR-2017-03-23/pdf/2017-05809.pdf.

The Board also recommends updating the list of anabolic steroids in Schedule III to mirror the federal schedules:

(1) 3β,17-dihydroxy-5a-androstane
(2) 3α,17β-dihydroxy-5a-androstane
(3) 5α-androstan-3,17-dione
(4) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene)
(5) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene)
(6) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene)
(7) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene)
(8) 1-androstenedione ([5α]-androst-1-en-3,17-dione)
(9) 4-androstenedione (androst-4-en-3,17-dione)
(10) 5-androstenedione (androst-5-en-3,17-dione)
(11) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)

(12) boldenone (17β-hydroxyandrost-1,4-diene-3-one)
(13) boldione (androsta-1,4-diene-3,17-dione)
(14) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)
(15) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one)
(16) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one)
(17) desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. 'madol')
(18) Δ1-dihydrotestosterone (a.k.a.'1-testosterone') (17β-hydroxy-5α-androst-1-en-3-one)
(19) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one)
(20) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one)
(21) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene)
(22) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one)
(23) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one)
(24) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan)
(25) 13β-ethyl-17β-hydroxygon-4-en-3-one
(26) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one)
(27) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one)
(28) mestanolone (17α-methyl-17β-hydroxy-5-androstan-3-one)
(29) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one)
(30) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one)
(31) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene)
(32) methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one)
(33) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one)
(34) 17α-methyl-3β,17β-dihydroxy-5a-androstane
(35) 17α-methyl-3α,17β-dihydroxy-5a-androstane
(36) 17α-methyl-3β,17β-dihydroxyandrost-4-ene
(37) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one)
(38) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one)
(39) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one)
(40) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one)
(41) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one)
(42) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. '17-α-methyl-1-testosterone')
(43) nandrolone (17β-hydroxyestr-4-en-3-one)
(44) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene)
(45) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene)
(46) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene)
(47) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene)
(48) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)
(49) 19-nor-4-androstenedione (estr-4-en-3,17-dione)
(50) 19-nor-5-androstenedione (estr-5-en-3,17-dione)
(51) norbolethone (13β, 17α-diethyl-17β-hydroxygon-4-en-3-one)
(52) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one)
(53) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one)
(54) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one)
(55) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one)

(56) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one)
(57) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one)
(58) prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole)
(59) stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole)
(60) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one)
(61) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
(62) testosterone (17β-hydroxyandrost-4-en-3-one)
(63) tetrahydrogestrinone (13β, 17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one)
(64) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one)

The Board recommends that the following drugs be added to Schedule I because they present an imminent and significant risk to the health and safety of the public:

> acryl fentanyl, cyclopentyl fentanyl, cyclopropyl fentanyl, isobutyryl fentanyl, methoxyacetyl fentanyl, ocfentanil, ortho-fluorofentanyl, para-chloroisobutyryl fentanyl, para-fluorobutyryl fentanyl, para-methoxybutyryl fentanyl, tetrahydrofuranyl fentanyl, valeryl fentanyl, MT-45, mitragynine, and 7-hydroxymitragynine.

Many of the proposed changes have already been temporarily or permanently added to the federal schedules. The Board also recommends updating the cannabinoid classes of drugs to include a new indole-3-carboxamide synthetic cannabinoid class, cyanoalkyl substitution in all classes, and cyanoalkyl and an additional benzyl substitution in the indazole-3-carbaxamide class.

After the Committee's informational hearing on March 5, 2018, the Board has also included some information specific to mitragynine and 7-hydroxymitragynine (Kratom) and the need for inclusion in Schedule I. According to the 2017 DEA Resource Guide, consumption of Kratom leaves produces stimulant effects in low doses and sedative effects similar to morphine in high doses, can lead to psychotic symptoms, and psychological as well as physiological dependence. The National Institutes of Health indicates that Kratom leaves have psychoactive alkaloids that produce opioid-like activity in the brain and has no medicinal value. The United Nations Office on Drugs and Crime included Kratom in its Early Warning on New Pscyhoactive Substances (plant-based) in 2013 which are defined as "substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat" (https://www.unodc.org/LSS/Page/NPS). Chronic use of Kratom may be associated with acute liver injury or hepatotoxicity, while overdoses can cause seizures, coma and death (https://livertox.nih.gov/Kratom.htm). While the internet says the LD50 of Kratom is 5g/kg, it is difficult to locate any peer-reviewed medical study that supports this finding.

In September 2016, the Board received correspondence from New Mexico regarding six poisonings from Kratom which resulted in four hospitalizations for moderate to major symptoms. Officials identified the substance as a threat and further indicated a high likelihood of Kratom being combined with other chemicals and substances with an even higher likelihood of dependence and abuse. Unfortunately, it is nearly impossible to provide a comprehensive report on poisonings related to this substance because it is not widely tested. However, the public health risk is significant because of the lack of regulation of the substance, the misleading information and consumer marketing associated with consuming a substance not intended for medical use, and the frequency with which this substance is

combined or mixed with other illicit and controlled substances. It is concerning and dangerous when a substance can only be legally imported by labeling it “not for human consumption” and yet it is held-out by advocates as safe for human consumption.

On February 6, 2018, the FDA issued another statement on the agency’s recent scientific research and evidence on the presence of opioid compounds in Kratom and underscoring the potential for abuse. FDA scientists found Kratom shares the most structural similarities with controlled substance opioid analgesics like morphine, and is known to activate opioid receptors in the brain. In fact, the FDA now considers the compounds found in Kratom to be opioids. This is the same class of drugs that have caused a national health crisis which was recognized by Governor Colyer, M.D., last week in his Executive Order. But unlike other controlled opioids, Kratom has not been reviewed or tested for safety or effectiveness. To date, there is no evidence of any medical use – an essential qualification for placing a substance in Schedule I of the Kansas Controlled Substances Act.
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm

It is also important to note that the Board of Pharmacy has statutory authority to schedule, on an emergency basis, certain new drugs or analogs of existing controlled substances which present an imminent hazard to the public safety until such time as the legislature reconvenes and considers the need to permanently schedule such substances. If the legislature chooses to remove mitragynine and 7-hydroxymitragynine from SB 282, the Board would not have authority to emergency schedule this substance should the need arise. The Board has always worked with the KBI to provide a robust and proactive approach to scheduling controlled substances in Kansas, and failure to pass SB 282 in its current form may pose a danger to Kansas citizens that cannot be remedied until the next legislative session.

Respectfully submitted.