

phone: 785-296-4056 fax: 785-296-8420 pharmacy@ks.gov www.kansas.gov/pharmacy

Board of Pharmacy Sam Brownback, Governor

Alexandra Blasi, Executive Secretary

Testimony concerning SB 52
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 52. These amendments include vital updates to the Kansas Uniform Controlled Substances Act to protect Kansas citizens.

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 earlier this week. 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 August, we began the dialogue and have conducted a comparison of the controlled substances listed in Schedules I-V of the Federal Controlled Substances, and also propose minor modifications to ensure continued compliance and enforcement of the Kansas Controlled Substances Act, as well as 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 52 and agrees with the KBI's recommendations and 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 that the following drugs be added to Schedule I because they present significant risk to the health and safety of the public:

AH-7921 (3.4-dichloro-N-[(1-dimethylaminocyclohexylmethyl]benzamide);

Beta-hydroxythiofentanyl (N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide);

Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylbutyramide);

Furanyl fentanyl N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide;

O-desmethyltramadol Some trade or other names: 2-((dimethylamino)methyl-1-(3-hydroxyphenyl)cyclohexanol; 3-(2-((dimethylamino)methyl)-1-hydroxycyclohexyl)phenol;

U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-Nmethylbenzamide); and

Etizolam Some trade or other names: (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine).

The bulk of the proposed changes have already been permanently added to the federal schedules.

The Board recommends adding Thiafentanil to Schedule II, which was added to the federal schedules effective August 26, 2016. The rule and explanation can be found at: https://www.federalregister.gov/documents/2016/08/26/2016-20463/schedules-of-controlled-substances-placement-of-thiafentanil-into-schedule-ii.

The Board also recommends adding Brivaracetam to schedule V, a drug that was approved by the FDA last February and added to the federal schedules effective May 12, 2016. The brand name of this drug is Briviact® and is indicated for treatment of partial-onset seizures in patients with epilepsy. The addition was published in the *Federal Register* on November 12, 2015. The Board is making the aforementioned requests so that the state schedule mirrors the federal regulation.