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Senate Bill No 2059 – Controlled Substances Rescheduling

House Judiciary Committee – Room 327B
11:00 AM - Wednesday – March 3rd, 2021

Chairman Klemin, members of the House Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today.

Senate Bill 2059 is the biennial bill introduced by State Board of Pharmacy to bring the Controlled Substances Act up-to-date with what the Food and Drug Administration [FDA] and Drug Enforcement Administration [DEA] have done over the past two years. This bill also revises the definition of marijuana to ensure future FDA approved drugs are exempt from the definition delaying their release to our state, adds to the list of synthetic schedule I drugs and adds DEA Schedule II-V drugs be consistent with state law in North Dakota.

The drafting of this bill, specifically Schedule I controlled substances, was done in conjunction with the ND Attorney General's Office and their State Crime Lab. A representative of the Crime Lab is here and can explain much of the chemistry and reasons for the changes in Schedule I compounds. Our intension for these changes in Schedule I compounds is to be proactive to ensure we have future chemical modifications that could be made to the substances identified as controlled substances. This bill is very lengthy and with the amendments, we feel, as comprehensive as possible with the information that we have at this time.

I would like to highlight each provision of the bill to ensure you have an understanding of the changes we have proposed for your considerations.

On page 1, line 8 continuing to page 2, line 3 represents updates to the definition of Marijuana in the North Dakota Century Code [NDCC]. The Senate modified the structure of the definition to be clearer on what Marijuana is and what it does not include. This is a consistent structure to the Federal law definition. The only substantive changes made were the reference to the specific chapter [4.1-18.1] where Hemp is defined in North Dakota's Century Code (Page 2, line 1) as well as language providing an exemption for a prescription drugs approved by the Food and Drug Administration [FDA] from the definition of Marijuana (Page 2, line 2-3). The reason for this language is to prevent any delays in any FDA approved Marijuana derived drugs that would be coming to market from being considered Schedule I compounds. Currently, we have added specific language in each specific schedule to address these compounds, but in the future, we

anticipate more FDA approved Marijuana derived prescription medications being brought to market.

Starting on Page 2 – line 25 is the addition of an opiate substance, Brorphine, continuing on Page 3 – line 10 is another opiate, Isotonitazene, and on Page 4 line 6 another opiate, Zipeprol, all of which were added to match the DEA Schedule I compounds in the past two years.

On page 6, lines 5-14 are additional specific Fentanyl compounds that the DEA has identified as being Schedule I compounds. As you may recall, these Fentanyl compounds have been increasingly tied to numerous overdose deaths, with the most commonly publicized being Furanyl Fentanyl in the State of North Dakota.

On page 8, line 14 is an adjustment to the reference to “hemp” to the specific chapter in the ND Century Code.

On page 12 lines 7-11 is a technical correction in a compound considered an indole carboxamide. The reason for this change is to keep the compound name as well as the other known names to be consistent with the DEA’s Scheduling action. This is an example of substances that we were ahead of the DEA in scheduling.

On page 13 lines 10-17 are additional indole carboxamide compounds that have been added by the DEA since the scheduling bill in the last legislative session.

On page 20 lines 22-27 are additional novel benzodiazepine compounds that we have recommended be added to Schedule I compounds. These compounds have not been scheduled by the DEA as of yet. However, in discussions with the ND Crime Lab these novel compounds have been identified as drugs of deep concern across the nation, which we anticipate being scheduled by DEA. Of note, it is important to realize that benzodiazepines are generally approved by the FDA and DEA for human use, which most commonly includes medication used to treat anxiety. However, these new compounds have no medical use. I understand that Char Rittenbach of the Crime Lab will be providing testimony in greater detail on these compounds.

On page 22 lines 22-28 are additional substituted cathinones compounds identified by the DEA as being Schedule I compounds.

On page 23 lines 20-22 is language to mirror specific exemptions to the Federal Law for Schedule II compounds classified under opium and opiates. Some of these are listed in other schedules while some, like naloxone, are not scheduled.

Page 24 line 2 is an additional opium derived compound, Noroxymorphone, that is medically approved by the FDA and DEA as a Schedule II substance.

On page 25, lines 17-18 is an additional opiate medication, Oliceridine, that the DEA added as a Schedule II compound.

On page 27, lines 2-4 represents a change to add to the precursors of fentanyl, a new drug, Norfentanyl which is an approved Schedule II drug.

On page 27, line 30, onto page 28, line 26, and lastly on page 29, line 18, are all additional depressants listed in Schedule IV compounds that are medically approved for human use by the FDA and DEA.

On page 30 line 14 is an additional stimulant compound, Solriamfetol, which was placed in Schedule IV.

On page 32 lines 3-15 represents changes in the Depressant section of Schedule V compounds. You will note that two additional compounds that have been added on lines 3 and 8 Cenobamate and Lasmiditan, and the removal of lines 11-15 of an approved cannabidiol drug. That cannabidiol drug is Epidiolex that was a schedule V drug, which the DEA unscheduled. This action likely is because of the low THC level (0.1%) that was in this specific compound which they felt was not a drug of abuse.

As is customary with previous years, on line 21 of Page 32 we respectfully ask for an emergency measure to be attached to this bill that if enacted would make these changes occur as quickly as possible.

I have distributed a document that outlines two proposed amendments. The first is a spelling correction. The second corrects the below omission made in the amendments in the Senate.

On page 23, under line 6 add: (k) 1-(4-methoxyphenyl)-N-methylpropan-2-amine (also known as paramethoxymethamphetamine and PMMA).

After submitting the legislative bill, we noticed this compound should be listed as a Schedule I Stimulant. The Senate removed the reference in a different section but the amendments did not add it back in the correct section. This was a simple error and was not caught in time before the bill was released to the Senate floor. We would appreciate this committee's consideration of this amendment.

I appreciate your attention to this lengthy and complicated bill draft and testimony. I will be happy to answer any questions you may have on this important legislation.