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Bill No 2093 – Controlled Substances Rescheduling

Senate Judiciary Committee – Peace Garden Room
9:00 AM - Wednesday – January 11th, 2023

Chairman Larson, Members of the Senate 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 2093 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 adds to the list of synthetic schedule I drugs.

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 intention 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 have included the list of Scheduling Actions from the DEA in chronological order.

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 2 line 18, represents an alternative name for the drug Isonitazene which is a schedule I Opiate substance.

On Page 3 lines 16 - 29 represents additional opiate compounds in which the DEA has scheduled during the past two-years.

On Page 5 line 30 and continuing to page 6 line 7, are additional alternative names for currently scheduled fentanyl derivatives.

On Page 6 lines 10-28, are additional fentanyl derivatives scheduled by the DEA. The represent more fentanyl compounds identified in drug seizures. As you may recall, these Fentanyl compounds have been increasingly tied to numerous overdose deaths.

On Page 9 line 14 and continuing through page 10 line 8, is a new class of cannabinoids referred to as indole acetamides. These compounds have not been scheduled by the DEA however have been recognized as a novel group of drugs which circumvent existing scheduled substances in states. The proposed language, that was compiled by the experts at the ND State Crime Lab, is drafted to look to capture any modifications that could potentially be made. Again, this is our best attempt to be proactive in future modifications to the core chemical structure as well as listing the specific substances that have been identified.

On Page 14 line 27 and continuing to page 15 lines 1-17, are changes to the Indole Carboxamides which are synthetic cannabinoids. Some of these changes are consistent with the DEA changes and others are emerging compounds yet to be scheduled by the DEA.

On Page 18 lines 9-22, are additional synthetic cannabinoids which are being proposed to be added based on these substances emerging in other states.

On Page 23 lines 10 and 11, are two drugs which are considered depressants, Bromazolam and Deschloroetizolam, both of which the DEA has placed in schedule I given their abuse and no medical use.

On Page 25 lines 6-20, are additional names for currently scheduled substituted cathinones compounds based on the DEA's scheduling actions

Lastly for Schedule I changes during the past two-years, on page 26 lines 1-6 are additional stimulant compounds scheduled by the DEA

Moving into page 27 line 13 is a new drug, daridorexant, which is a schedule IV medication marketed under the brand name Quviviq, which is approved for the treatment of insomnia

On Page 29 line 17, is a new drug, serdexmethylphenidate, a schedule IV stimulant which is approved for the treatment of ADHD.

On Page 30 line 26, is a new schedule V substance, ganaxolone, which is a narcotic medication which is indicated to treat Seizures. The brand name is Ztalmy.

As is customary with previous years, on Page 31 Line 21, we respectfully ask for an emergency measure be attached to this bill that if enacted would make these changes occur as quickly as possible.

I have distributed a document that outlines proposed amendments/ corrections to this legislation that includes additional compounds that became scheduled after we submitted this draft to the legislative council. The amendments also include a few typographical errors made in the drafting that we are asking to be corrected.

I do 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.

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	FINAL ORDER				
	PROPOSAL PUBLICATION DATE	PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
N-(4-METHOXYPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-METHOXYBUTYRYL FENTANYL)		11-25-20	85 FR 75231	11/25/2020	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLPENTANAMIDE (VALERYL FENTANYL)		11-25-20	85 FR 75231	11/25/2020	I
1-(1-(1-(4-BROMOPHENYL)ETHYL)PIPERIDIN-4-YL)-1,3-DIHYDRO-2H-BENZO[D]IMIDAZOL-2-ONE (BRORPHINE)*		03-01-21	86 FR 11862	3/1/2021	I
METHYL 2-(1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE ** (5F-MDMB-PICA)		03-31-21	86 FR 16669	4/16/2021	I
N-(ADAMANTAN-1-YL)-1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDE ** (FUB-AKB48; FUB-APINACA)		03-31-21	86 FR 16669	4/16/2021	I
1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1H-INDAZOLE-3-CARBOXAMIDE ** (5F-CUMYL-PINACA; SGT-25)		03-31-21	86 FR 16669	4/16/2021	I
(1-(4-FLUOROBENZYL)-1H-INDOL-3-YL)(2,2,3,3-TETRAMETHYLCYCLOPROPYL)METHANONE ** (FUB-144)		03-31-21	86 FR 16669	4/16/2021	I
ETHYL 2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE ** (5F-EDMB-PINACA)		03-31-21	86 FR 16669	4/16/2021	I
SAMIDORPHAN		04-19-21	86 FR 20284	4/19/2021	II -> 0
THIOFURANYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
PHENYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
PARA-METHYLFENTANYL		04-27-21	86 FR 22113	4/27/2021	I
2'-FLUORO ORTHO-FLUOROFENTANYL		04-27-21	86 FR 22113	4/27/2021	I
BETA-METHYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
BETA'-PHENYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
ORTHO-METHYL METHOXYACETYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
ORTHO-METHYL ACETYLFENTANYL		04-27-21	86 FR 22113	4/27/2021	I
ORTHO-FLUOROBUTYRYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
4'-METHYL ACETYL FENTANYL		04-27-21	86 FR 22113	4/27/2021	I
FENTANYL CARBAMATE		05-04-21	86 FR 23602	5/4/2021	I
ORTHO-FLUOROACRYL FENTANYL		05-04-21	86 FR 23602	5/4/2021	I
ORTHO-FLUOROISOBUTYRYL FENTANYL		05-04-21	86 FR 23602	5/4/2021	I
PARA-FLUORO FURANYL FENTANYL		05-04-21	86 FR 23602	5/4/2021	I
SERDEXMETHYLPHENIDATE		05-07-21	86 FR 24487	5/7/2021	IV
METHYL 2-(1-(CYCLOHEXYLMETHYL)-1 H-INDOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (MMB-CHMICA, AMB-CHMICA)		06-10-21	86 FR 30775	6/10/2021	I
1-(4-CYANOBUTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-INDAZOLE-3-CARBOXAMIDE (4-CN-CUMYL-BUTINACA)		06-10-21	86 FR 30775	6/10/2021	I
NAPHTHALEN-1-YL 1-(5-FLUOROPENTYL)-1 H-INDOLE-3-CARBOXYLATE (NM2201; CBL2201)		06-10-21	86 FR 30775	6/10/2021	I
1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-PYRROLO[2,3-B]PYRIDINE-3-CARBOXAMIDE(5FCUMYL-P7AICA)		06-10-21	86 FR 30775	6/10/2021	I

FINAL ORDER

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1 H-INDAZOLE-3-CARBOXAMIDE (5F-AB-PINACA)		06-10-21	86 FR 30775	6/10/2021	I
1-(1,3-BENZODIOXOL-5-YL)-2-(ETHYLAMINO)-PENTAN-1-ONE (N-ETHYLPENTYLONE, EPHYLONE)		06-14-21	86 FR 31427	6/14/2021	I
ALPHA-PYRROLIDINOHEPTAPHENONE** (PV8)		07-18-21	86 FR 37672	7/18/2021	I
4'-CHLORO-ALPHA-PYRROLIDINOVALEROPHENONE ** (4-CHLORO-A-PVP)		07-18-21	86 FR 37672	7/18/2021	I
ALPHA-PYRROLIDINOHEXANOPHENONE ** (A-PHP)		07-18-21	86 FR 37672	7/18/2021	I
4'-METHYL-ALPHA-PYRROLIDINOHEXIOPHENONE** (MPHP)		07-18-21	86 FR 37672	7/18/2021	I
N-ETHYLHEXEDRONE **		07-18-21	86 FR 37672	7/18/2021	I
4-METHYL-ALPHA-ETHYLAMINOPENTIOPHENONE ** (4-MEAP)		07-18-21	86 FR 37672	7/18/2021	I
PARA-METHOXYMETHAMPHETAMINE (PMMA), 1-(4-METHOXYPHENYL)-N-METHYLPROPAN-2-AMINE	05-15-20	06-25-21	86 FR 33508	7/26/2021	I
4,4'-DIMETHYLAMINOREX (4,4'-DMAR; 4,5-DIHYDRO-4-METHYL-5-(4-METHYLPHENYL)-2-OXAZOLAMINE)	04-07-20	08-12-21	86 FR 44270	9/13/2021	I
ISOTONITAZENE (N,N-DIETHYL-2-(2-(4-ISOPROPOXYBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE)		11-04-21	86 FR 60761	12/6/2021	I
5-METHOXY-N-METHYL-N-ISOPROPYLTRYPTAMINE (5-MeO-MIPT)	01-14-22	01-14-22	87 FR 2376		I
4-HYDROXY-N,N-DIISOPROPYLTRYPTAMINE (4-OH-DIPT)	01-14-22	01-14-22	87 FR 2376		I
5-METHOXY-N,N-DIETHYLTRYPTAMINE (MeO-DET)	01-14-22	01-14-22	87 FR 2376		I
5-METHOXY-ALPHA-METHYLTRYPTAMINE (5-MeO-AMT)	01-14-22	01-14-22	87 FR 2376		I
N,N-DIISOPROPYLTRYPTAMINE (DIPT)	01-14-22	01-14-22	87 FR 2376		I
DARIDOREXANT (QUVIVIQ)		04-07-22	87 FR 20313	4/7/2022	IV
METHYL 2-(1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (5F-MDMB-PICA)		04-07-22	87 FR 20318	4/7/2022	I
N-(ADAMANTAN-1-YL)-1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDE (FUB-AKB48; FUB-APINACA)		04-07-22	87 FR 20318	4/7/2022	I
1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1H-INDAZOLE-3-CARBOXAMIDE (5F-CUMYL-PINACA; SGT-25)		04-07-22	87 FR 20318	4/7/2022	I
(1-(4-FLUOROBENZYL)-1H-INDOL-3-YL)(2,2,3,3-TETRAMETHYLCYCLOPROPYL)METHANONE (FUB-144)		04-07-22	87 FR 20318	4/7/2022	I
ETHYL 2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (5F-EDMB-PINACA)		04-07-22	87 FR 20318	4/7/2022	I
2,5-DIMETHOXY-4-iodoamphetamine (DOI)	04-11-22	04-11-22	87 FR 21069		I
2,5-DIMETHOXY-4-CHLOROAMPHETAMINE (DOC)	04-11-22	04-11-22	87 FR 21069		I
N,N-DIETHYL-2-(5-NITRO-2-(4-PROPOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (PROTONITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
N,N-DIETHYL-2-(2-(4-FLUOROBENZYL)-5-NITRO-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (FLUNITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
N,N-DIETHYL-2-(2-(4-METHOXYBENZYL)-1H-BENZIMIDAZOL-1-YL)ETHAN-1-AMINE (METODESNITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I

Scheduling Actions - Chronological Order

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N,N-DIETHYL-2-(2-(4-METHOXYBENZYL)-5-NITRO-1HBENZIMIDAZOL-1-YL)ETHAN-1-AMINE (METONITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
2-(4-ETHOXYBENZYL)-5-NITRO-1-(2-(PYRROLIDIN-1-YL)ETHYL)1HBENZIMIDAZOLE (N-PYRROLIDINO ETONITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
2-(2-(4-BUTOXYBENZYL)-5-NITRO-1HBENZIMIDAZOL-1-YL)-N,N-DIETHYLETHAN-1- AMINE (BUTONITAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
2-(2-(4-ETHOXYBENZYL)-1HBENZIMIDAZOL-1-YL)-N,N-DIETHYLETHAN-1- AMINE (ETODESNITAZENE; ETAZENE)*		04-12-22	87 FR 21556	4/12/2022	I
3-ALPHA-HYDROXY-3-BETA-METHYL-5-ALPHA-PREGNAN-20-ONE (GANAXOLONE)		06-01-22	87 FR 32991	6/1/2022	V
4'-METHYL-ALPHA-PYRROLIDINOHEXIOPHENONE (MPHP)		06-01-22	87 FR 32996	6/1/2022	I
ALPHA-PYRROLIDINOHEPTAPHENONE (PV8)		06-01-22	87 FR 32996	6/1/2022	I
4'-CHLORO-ALPHA-PYRROLIDINOVALEROPHENONE (4-CHLORO-A-PVP)		06-01-22	87 FR 32996	6/1/2022	I
N-ETHYLHEXEDRONE		06-01-22	87 FR 32996	6/1/2022	I
ALPHA-PYRROLIDINOHEXANOPHENONE (A-PHP)		06-01-22	87 FR 32996	6/1/2022	I
4-METHYL-ALPHA-ETHYLAMINOPENTIOPHENONE (4-MEAP)		06-01-22	87 FR 32996	6/1/2022	I
METHOXETAMINE	12-07-21	06-07-22	87 FR 34166	7/6/2022	I
N,N-DIISOPROPYLTRYPTAMINE (DIPT)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
5-METHOXY-N,N-DIETHYLTRYPTAMINE (MeO-DET)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
5-METHOXY-N-METHYL-N-ISOPROPYLTRYPTAMINE (5-MeO-MIPT)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
5-METHOXY-ALPHA-METHYLTRYPTAMINE (5-MeO-AMT)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
4-HYDROXY-N,N-DIISOPROPYLTRYPTAMINE (4-OH-DiPT)	01-14-22	07-27-22	87 FR 45076		I Withdrew 2022 proposed rule
2,5-DIMETHOXY-4-iodoamphetamine (DOI)	04-11-22	08-29-22	87 FR 52712		I Withdrew 2022 proposed rule
2,5-DIMETHOXY-4-CHLOROAMPHETAMINE (DOC)	04-11-22	08-29-22	87 FR 52712		I Withdrew 2022 proposed rule
AMINEPTINE (7-[(10,11-DIHYDRO-5H-DIBENZO[A,D]CYCLOHEPTEN-5-YL)AMINO]HEPTANOIC ACID)	07-22-22	11-17-22	87 FR 68895	12/19/2022	I

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ZIPEPROL (1-METHOXY-3-[4-(2-METHOXY-2-PHENYLETHYL)PIPERAZIN-1-YL]-1-PHENYLPROPAN-2-OL)	05-14-20	11-21-22	87 FR 70717	12/21/2022	I
MESOCARB (N-PHENYL-N'-(3-(1-PHENYLPROPAN-2-YL)-1,2,3-OXADIAZOL-3-IUM-5-YL)CARBAMIMIDATE)	08-11-2021	11-22-22	87 FR 71247	12/22/2022	I
METHIOPROPAMINE (N-METHYL-1-(THIOPHEN-2-YL)PROPANE-2-AMINE)	09-02-21	12-09-22	87 FR 75470	1/9/2023	I