Minutes of the June 29, 2022, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Wednesday, June 29, 2022, at 10:00 a.m. in the Boardroom (#3420) at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance virtually:

Robert Bolchoz, Chairman
J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, Vice-Chairwoman, 2nd District
Charles M. Joye, II, P.E., 3rd District
Robert Morgan, MD, 4th District
Morris E. Brown, III, MD, 6th District
Jim P. Creel, Jr., 7th District

Not in attendance:
Richard V. Lee, Jr., 5th District

Also, in attendance were Dr. Edward Simmer, Director; W. Marshall Taylor, General Counsel; M. Denise Crawford, Clerk; Department staff; and members of the public. The meeting was also available via Livestream. (Attachment 0-2)

Chairman Bolchoz called the meeting to order and stated notice of this meeting had been provided to all persons, organizations, and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Minutes of May 5, 2022 meeting (Attachment 1-1)

Mr. Kinney moved, seconded by Dr. Brown, to approve the minutes as presented. The Board voted and Motion carried.

Item 2: Agency Affairs

Dr. Edward Simmer, Director, updated the Board on

- Agency's discouragement of wild animals as pets
- Annual abortion report and availability
- Monkeypox update
- COVID Vaccine for 6 months to 5 years of age
- Hurricane preparedness and response

Scott Jailette, Director of Legislative Affairs, provided an overview of the Legislative session.

Darbi MacPhail, Chief Financial and Operations Officer, provided a budget update.

Dr. Simmer presented Employee Appreciation Coins to Darbi MacPhail, Scott Jailette, and the Legislative Services Team for their work during the legislative session.

Item 3: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 3-1)

Ms. Kim McLeod, Senior Consultant, Healthcare Quality, stated that for this reporting period, one (1) Administrative Order and seven (7) Consent Orders with assessed civil penalties totaling $33,300.00 were issued.

After discussion, ***the Board accepted this item as information.***

Item 4: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 4-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, seventy-five (75) Consent Orders with assessed civil penalties totaling $375,346.09 and sixteen (16) Administrative Orders with assessed civil penalties totaling $89,905.00 were issued.

After discussion, ***the Board accepted this item as information.***

Item 5: Request for Placement of Ganaxolone into Schedule V for Controlled Substances in South Carolina (Attachment 5-1)

Ms. Chelsea Townsend, Program Manager II, Bureau of Drug Control, Healthcare Quality, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule V substances are listed in Section 44-53-270 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

On March 18, 2022, the United States Food and Drug Administration ("FDA") approved a new drug application ("NDA") for ZTALMY, an oral suspension of ganaxolone, for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in patients two years of age and older. The

Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place ganaxolone and its salts in schedule V of the Controlled Substances Act ("CSA").

In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing ganaxolone, including its salts in schedule V of the CSA. This rule has an effective date of June 1, 2022, *Federal Register*, Volume 87, Number 105, pages 32991-32996; *https://www.govinfo.gov/content/pkg/FR-2022-06-01/pdf/2022-11735.pdf.*

Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one) is a new molecular entity with central nervous system activity. Ganaxolone is a neuroactive positive allosteric modulator of gammaaminobutyric acid type-A receptors and an inhibitory neurosteroidal substance that shares structural features and a pharmacological mechanism of action with progesterone and schedule IV depressants alfaxalone and brexanolone.

On March 14, 2022, DEA received, from HHS, a scientific and medical evaluation entitled "Basis for the Recommendation to Control Ganaxolone and its Salts in Schedule V of the Controlled Substances Act" and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of ganaxolone, along with HHS's recommendation to control ganaxolone and its salts under schedule V of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that ganaxolone meets the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA. Pursuant to subsection 811(j), and based on HHS' scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule ganaxolone as a schedule V controlled substance under the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA ("Administrator"), pursuant to 21 U.S.C. 812(b)(4), finds that: 1) Ganaxolone has a low potential for abuse relative to the drugs or other substances in schedule IV. 2) Ganaxolone has a currently accepted medical use in treatment in the United States. 3) Abuse of ganaxolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

The Department recommended placement of ganaxolone and its salts in schedule V and the amendment of Section 44-53-270 of the South Carolina Controlled Substances Act to include:

( ) Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one)

After discussion, **Mr. Kinney moved, seconded by Mr. Creel, to designate Ganaxolone and the additional substances named in the DEA Notice published in the Federal Register on June 1, 2022 and amend Section 44-53-270 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.**

Item 6: Request for Placement of Methoxetamine into Schedule I for Controlled Substances in South Carolina (Attachment 6-1)

Ms. Chelsea Townsend, Program Manager II, Bureau of Drug Control, Healthcare Quality, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

On June 6, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act ("CSA") to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle, methoxetamine. This final rule was published on June 6, 2022, with an effective date of July 6, 2022, *Federal Register*, Volume 87, Number 108, pages 34166-34169; *https://www.govinfo.gov/content/pkg/FR-2022-06-06/pdf/2022-11933.pdf.*

Methoxetamine, also known as 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one or 2-(3-methoxyphenyl)-2-(N-ethylamino)cyclohexanone or MXE, belongs to the arylcyclohexylamine class of drugs with dissociative anesthetic and hallucinogenic properties, similar to phencyclidine (PCP), a schedule II controlled substance, and

ketamine, a schedule III controlled substance. Methoxetamine has no approved medical use in the United States. In March 2016, the Commission on Narcotic Drugs ("CND") voted to place methoxetamine in Schedule II of the 1971 Convention (CND Dec/59/6) during its 59th Session due to its dependence and abuse potential.

On April 14, 2018, in accordance with 21 U.S.C. 811(b), and in response to DEA's December 30, 2014, request and April 14, 2017, submission of additional data, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and scheduling recommendation for methoxetamine. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I.

After consideration of the public comment, scientific and medical evaluation, and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of methoxetamine. DEA is permanently scheduling methoxetamine as a controlled substance under the CSA.

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

1) Methoxetamine has a high potential for abuse that is comparable to other scheduled substances such as the ethylamine analog of phencyclidine (PCE; schedule I), the thiophene analog of phencyclidine (TCP; schedule I), phencyclidine (PCP; schedule II), and ketamine (schedule III).

2) Methoxetamine has no currently accepted medical use in treatment in the United States.

3) There is a lack of accepted safety for use of methoxetamine under medical supervision. Because methoxetamine has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of methoxetamine under medical supervision.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommended placement of Methoxetamine in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is

possible within the specific chemical designation, to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE)

After discussion, **Mr. Creel moved, seconded by Mr. Joye, to designate Methoxetamine and the additional substances named in the DEA Notice published in the Federal Register on June 6, 2022 and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.**

Being no further business, Chairman Bolchoz adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,

Charles M. Joye, II, P.E., 3rd District, Secretary

Minutes approved this 11th day of August 2022.

ATTEST:

Robert Bolchoz, Chairman

Attachments

0-1 Agenda
1-1 Minutes of June 29, 2022 meeting
3-1 Administrative Orders and Consent Orders issued by Healthcare Quality
4-1 Administrative Orders and Consent Orders issued by Environmental Affairs
5-1 Request for Placement of Ganaxolone into Schedule V for Controlled Substances in South Carolina
6-1 Request for Placement of Methoxetamine into Schedule I for Controlled Substances in South Carolina