Minutes of the January 5, 2023, meeting of the
South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, January 5, 2023, 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:

Seema Shrivastava-Patel, Vice-Chairwoman, 2nd District
J.B. (Sonny) Kinney, 1st District
Richard V. Lee, Jr., 5th District
Morris E. Brown, III, MD, 6th District

In attendance virtually:
Jim P. Creel, Jr., 7th District

Not in attendance:
Charles M. Joye, II, P.E., 3rd District
Robert Morgan, MD, 4th District

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

Vice Chairwoman Shrivastava-Patel 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 December 8, 2022 meeting (Attachment 1-1)

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

Item 2: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 2-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, three (3) Consent Orders with assessed monetary penalties totaling $13,500.00 were issued.

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

Item 3: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 3-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, seventy-six (76) Consent Orders with assessed civil penalties totaling $142,780.00 and four (4) Administrative Orders with assessed civil penalties totaling $27,380.00 were issued.

Ms. Sproles also provided the current compliance rate for orders issued by Environmental Affairs over the last twelve (12) months as requested by the Board at the December meeting. (Attachment 3-2)

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

Item 4: Appointment of Pamela Bailey, DO, MPH to the Hospital Infections Disclosure Act (HIDA) Advisory Committee (Attachment 4-1)

Dr. Abdoulaye Diedhiou, DADE Division Director, Bureau of Communicable Disease Prevention and Control, presented this item to the Board.

The Hospital Infections Disclosure Act (HIDA) Advisory Committee is a multi-disciplinary group that advises DHEC on reportable healthcare conditions in the state and public reports that provide healthcare-associated infection information to the public. Department staff requested the appointment of Dr. Pamela Bailey to a vacant position. A copy of Dr. Bailey's resume was provided to the Board for review. (Attachment 4-2)

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, to approve the appointment of Dr. Pamela Bailey to the Hospital Infections Disclosure Act Advisory Committee. The Board voted and Motion carried.**

Item 5: Appointment of Dr. Kayla Antosz to the Hospital Infections Disclosure Act (HIDA) Advisory Committee (Attachment 5-1)

Dr. Abdoulaye Diedhiou, DADE Division Director, Bureau of Communicable Disease Prevention and Control, presented this item to the Board.

The Hospital Infections Disclosure Act (HIDA) Advisory Committee is a multi-disciplinary group that advises DHEC on reportable healthcare conditions in the state and public reports that provide healthcare-associated infection information to the public. Department staff requested the appointment of Dr. Kayla Antosz to a vacant position. A copy of Dr. Antosz's resume was provided to the Board for review. (Attachment 5-2)

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, to approve the appointment of Dr. Kayla Antosz to the Hospital Infections Disclosure Act Advisory Committee. The Board voted and Motion carried.**

Item 6: Appointment of Jerry Alewine, Ed.D., RRT, RCP to the Hospital Infections Disclosure Act (HIDA) Advisory Committee as a replacement for Robert Rife representing the South Carolina Society for Respiratory Care (Attachment 6-1)

Dr. Abdoulaye Diedhiou, DADE Division Director, Bureau of Communicable Disease Prevention and Control, presented this item to the Board.

The Hospital Infections Disclosure Act (HIDA) Advisory Committee is a multi-disciplinary group that advises DHEC on reportable healthcare conditions in the state and public reports that provide healthcare-associated infection information to the public. Department staff requested the appointment of Jerry Alewine as a replacement for Robert Rife representing the South Carolina Society for Respiratory Care. A copy of Dr. Alewine's resume was provided to the Board for review. (Attachment 6-2)

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, to approve the appointment of Dr. Jerry Alewine as a replacement for Robert Rife representing the South Carolina Society for Respiratory Care to the Hospital Infections Disclosure Act Advisory Committee. The Board voted and Motion carried.**

Item 7: Placement of Methiopropamine in Schedule I for Controlled Substances in South Carolina (Attachment 7-1)

Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), 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 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 December 9, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing methiopropamine (chemical name: N-methyl-1- (thiophen-2-yl)propan-2-amine), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act ("CSA"). This action is being taken 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, import, export, engage in research, conduct instructional activities or chemical analysis with,

or possess), or propose to handle methiopropamine. This final rule has an effective date of January 9, 2023, *Federal Register* 87, Number 236, pages 75470-75473; *https://www.govinfo.gov/content/pkg/ FR-2022-12-09/pdf/2022-26805.pdf.*

Methiopropamine (chemical name: N-methyl-1-(thiophen-2-yl)propan-2-amine) is a central nervous system ("CNS") stimulant and is structurally related to the schedule II stimulants methamphetamine and amphetamine. Methiopropamine is not approved by the Food and Drug Administration for use in the United States. On March 16, 2017, the Commission on Narcotic Drugs voted to place N-methyl-1-(thiophen-2- yl)propan-2-amine (methiopropamine) in Schedule II of the 1971 Convention.

On August 27, 2020, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's November 20, 2018 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for methiopropamine. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA found substantial evidence of potential for abuse of methiopropamine. As such, DEA is permanently scheduling methiopropamine 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 outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), found that:

1) Methiopropamine has a high potential for abuse. Methiopropamine, similar to the schedule II stimulants amphetamine and methamphetamine, is a CNS stimulant with a high potential for abuse.

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

3) There is a lack of accepted safety for use of methiopropamine under medical supervision.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing methiopropamine in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers in 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:

( ) Methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2-amine)

After discussion, **Dr. Brown moved, seconded by Mr. Kinney, for the placement of Methiopropamine and the additional substances named in the DEA notice published in the Federal Register on December 9, 2022 and to amend Section 44-53-190 of the South Carolina Controlled Substances Act for consistency with Federal scheduling. The Board voted and the motion carried.**

Item 8: Removal of Fenfluramine from Schedule IV for Controlled Substances in South Carolina
(Attachment 8-1)

Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances 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 December 23, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule removing fenfluramine (chemical name: N-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts is possible, from the schedules of the Controlled Substances Act ("CSA"). Prior to the effective date of this rule, fenfluramine was a schedule IV controlled substance. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, engage in research, import, export, conduct instructional activities or chemical analysis with, or possess) or propose to handle fenfluramine. This final rule has an effective date of December 23, 2022, *Federal Register* 87, Number 246, pages 78857-78859; *https://www.govinfo.gov/content/pkg/ FR-2022-12-23/pdf/2022-27400.pdf.*

Fenfluramine (chemical name: N-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of such isomers, has been controlled under 21 CFR 1308.14(d) as a schedule IV substance of the CSA since June 15, 1973. On September 25, 2019, Zogenix, Inc. (Zogenix; the Sponsor) submitted to the Food and Drug Administration ("FDA") a New Drug Application ("NDA") for Fintepla (fenfluramine), for the treatment of seizures associated with Dravet syndrome in patients two years of age and older. FDA approved the NDA on June 25, 2020, with the labelling listing fenfluramine as a schedule IV controlled substance. On October 18, 2018, Zogenix submitted to DEA a petition requesting that fenfluramine be removed from schedule IV of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and DEA accepted the petition for filing on November 13, 2018.

Based on FDA's scientific and medical review of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, the Department of Health and Human Services ("HHS") recommended that fenfluramine and its salts be removed from all schedules of the CSA. Pursuant to 21 U.S.C. 811(b), the recommendations of HHS shall be binding on DEA as to such scientific and medical matters and if the Secretary recommends that a drug or other substance not be controlled, DEA shall not control the drug or other substances. After careful review of all relevant data including HHS' scientific and medical evaluation and scheduling recommendation, DEA is therefore promulgating this final rule to remove fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from control under the CSA.

The Department recommended the removal of fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from Schedule IV for controlled substances in Section 44-53-250 of the South Carolina Controlled Substances Act.

After discussion, **Dr. Brown moved, seconded by Mr. Lee, for the removal of Fenfluramine and the additional substances named in the DEA notice published in the Federal Register on December 23, 2022 and to amend Section 44-53-250 of the South Carolina Controlled Substances Act for consistency with Federal scheduling. The Board voted and the motion carried.**

Item 9: Food Access in South Carolina

Ms. Keisha Long, Environmental Justice Coordinator, Environmental Affairs, presented this item to the Board. Ms. Long introduced Ms. Leslie Hossfeld from Clemson University to demonstrate the food access map. (Attachment 9-1)

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

Item 10. Agency Affairs

Dr. Edward Simmer, Director, updated the Board on:

- 2023 DHEC Priorities
- DHEC's role in the Opioid Center for Excellence
- Overdose kits
- COVID 19
- RSV
- Flu

Dr. Simmer expressed appreciation to Department staff that worked over the holidays.

Dr. Simmer presented Employee Appreciation Coins to Department employee Keisha Long and Brooke Brittain of Clemson University for their work on the Food Access program.

Being no further business, Vice Chairwoman Shrivastava-Patel 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 9th day of March 2023.

ATTEST:

Seema Shrivastava-Patel, 2nd District
Vice-Chair

Attachments

0-1 Agenda
0-2 Sign in Sheet
1-1 Minutes of December 8, 2022 meeting
2-1 Administrative Orders and Consent Orders issued by Healthcare Quality
3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
3-2 Current Compliance Rates for orders issued by Environmental Affairs
4-1 Appointment of Pamela Bailey, DO, MPH to the Hospital Infections Disclosure Act (HIDA) Advisory Committee
4-2 Dr. Bailey's resume
5-1 Appointment of Dr. Kayla Antosz to the Hospital Infections Disclosure Act (HIDA) Advisory Committee
5-2 Dr. Kayla Antosz's Resume
6-1 Appointment of Jerry Alewine, Ed.D., RRT, RCP to the Hospital Infections Disclosure Act (HIDA) Advisory Committee as a replacement for Robert Rife representing the South Carolina Society for Respiratory Care
6-2 Dr. Alewine's Resume
7-1 Placement of Methiopropamine in Schedule I for Controlled Substances in South Carolina
7-2 Board Order for placement of Methiopropamine
8-1 Removal of Fenfluramine from Schedule IV for Controlled Substances in South Carolina
8-2 Board Order for placement of Fenfluramine
9-1 Food Access in South Carolina