



Mark R. Elam, Chairman
Jim P. Creel, Jr., Vice-Chairman
Charles M. Joye, II, P.E., Secretary
J.B. (Sonny) Kinney

Board:
Seema Shrivastava-Patel
Richard V. Lee, Jr.
Alex A. Singleton
Robert R. Morgan, Jr., MD, MBA

Minutes of the March 11, 2021, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, March 11, 2021, at 11:00 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:

Mark Elam, Chairman
J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, 2nd District
Richard V. Lee, Jr., 5th District

In attendance virtually
Jim P. Creel, Jr., Vice-Chairman
Charles M. Joye, II, P.E., 3rd District
Robert Morgan, MD, 4th District
Alex A. Singleton, 6th District

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

Chairman Elam 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 February 11, 2021 meeting (Attachment 1-1)

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

Item 4: Agency Affairs

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

- the future of Public Health in South Carolina;
- the plan for updating the agency strategic plan;
- current open positions;
- Public Health Accreditation;
- the state's public health preparedness;
- the agency's hurricane preparedness plan with the state's hospitals;
- the Midwives regulation that was previously before the board was pulled to provide more data;
- the hurricane preparedness in Charleston County;
- the hurricane preparedness for the dams in South Carolina;
- the COVID 19 vaccine transition to phase 1B;
- the COVID 19 vaccine programs in Sumter County and Oconee County;
- the COVID 19 vaccine pilot for vaccinating homebound people in Jasper County;
- new guidance on COVID 19 for Long Term Care facilities;
- recognition for Will Britt and his service to the agency's COVID 19 response and his transition back to his agency position;

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

Director Simmer introduced Nick Davidson to provide information on the agency's Public Health Accreditation. Mr. Davidson recognized Harley Davis and Ms. Davis provided an overview of the process and the award.

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

Item 3: Determination of implementation of COVID-19 vaccine allocation plan

Nick Davidson, Senior Deputy for Public Health, presented this matter to the board.

Mr. Davidson provided an update on the COVID-19 vaccine distribution plan including information on vaccinations in the DHEC regions as instructed at the February 11, 2021 board meeting. (Attachment 3-1) In addition, Mr. Keith Frost provided information on the vaccination sites throughout the state.

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

Item 4: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 4-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, five (5) Consent Orders with assessed civil penalties totaling \$21,600.00, sixty-five (65) Notices of Violation and Civil Penalty totaling \$18,850.00 in assessed civil penalties, and no Administrative Orders were issued.

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

Item 5: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 6-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, twenty-four (24) Consent Orders with assessed civil penalties totaling \$80,297.00 and thirteen (13) Administrative Order with assessed civil penalties totaling \$43,400.00 have been issued.

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

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

Ms. Christie Frick, Director, Prescription Monitoring Program, 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 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.

South Carolina Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless

overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one (commonly known as bromphine), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. This action is based on a finding by the Acting Administrator that the placement of bromphine in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed 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 bromphine. This temporary order will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). The federal order to schedule bromphine became effective March 1, 2021, *Federal Register*, Volume 88, Number 38, pages 11862-11867; <https://www.govinfo.gov/content/pkg/FR-2021-03-01/pdf/2021-04242.pdf>.

In accordance with 21 U.S.C. 811(h)(3) and based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of bromphine pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for bromphine in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for bromphine indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated September 22, 2020, notified the Assistant Secretary of DEA's intention to temporarily place bromphine in schedule I. DEA subsequently published a notice of intent on December 3, 2020.

The availability of synthetic opioids on the illicit drug market continues to pose an imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the increased popularity of these substances have posed serious health concerns in recent years. The presence of new synthetic opioids with no approved medical use exacerbates the unprecedented opioid epidemic in the United States continues to experience. The trafficking and abuse of new synthetic opioids are deadly new trends. The identification of bromphine on the illicit drug market has been reported in the United States, Canada, Belgium, and Sweden. Data obtained from preclinical pharmacology studies show that bromphine has a pharmacological profile similar to that of other potent opioids such as morphine and fentanyl, schedule II controlled substances. Because of the pharmacological similarities between bromphine and other potent opioids, the use of bromphine presents a high risk of abuse and may negatively affect users and their communities. The positive identification of this substance in law enforcement seizures and post-mortem toxicology reports is a serious concern to the public safety. The abuse of bromphine has been associated with at least seven fatalities between June and July 2020 in the United States. Thus, bromphine poses an imminent hazard to public safety.

Bromphine is part of a structural class of compounds known as substituted piperidine benzimidazolones. The general synthesis of bromphine was first reported in the literature in 2018. Bromphine is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. The Assistant Secretary, by a letter to DEA dated October 27, 2020, stated that there are no FDA-approved new drug applications ("NDAs") or investigational new drug applications ("INDs" for bromphine in the United States. Hence, DEA notes there is no legitimate channel for bromphine as a marketed drug product. The appearance of bromphine on the illicit drug market is similar to other designer drugs trafficked for their psychoactive effects. Since 2014, numerous synthetic opioids structurally related to fentanyl and several synthetic opioids from other structural classes have begun to emerge on the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in June 2019, bromphine emerged in the United States illicit, synthetic drug market as evidenced by bromphine's identification in drug seizures. Authorities Between July and September 2019, bromphine was first reported in drug casework in Canada and was first reported in police seizures in Sweden in March 2020. Bromphine has been encountered by United States law enforcement in powder form. In the United States, bromphine has been identified as a single substance and in combination with other substances. Between June 2019 and August 2020, there are twenty reports of bromphine in the National Forensic Laboratory Information System ("NFLIS") from three different states (see Scope, Duration, and Significance of Abuse). In several NFLIS encounters, bromphine was found in combination with heroin (a schedule I substance) and fentanyl (a schedule II substance). In reports from the Northeastern Illinois Regional Crime Laboratory, suspected heroin/fentanyl powders were analyzed and found to be bromphine in combination with flualprazolam, a non-scheduled benzodiazepine, and diphenhydramine, an over-the-counter antihistamine. Post-mortem toxicology samples collected and submitted to National Medical Services ("NMS") Laboratory in June and July 2020 verified the identification of bromphine. Bromphine was first

reported by the Center for Forensic Science Research and Education (“CFSRE”) – Novel Psychoactive Substance (“NPS”) Discovery Program (under the novel psychoactive substances discovery program, in collaboration with NMS Labs) in July 2020. In seven post-mortem toxicology reports in June and July 2020, bromphine was found in combination with fentanyl, flualprazolam, and heroin. Evidence suggests that individuals are using bromphine as a replacement to heroin or other opioids, either knowingly or unknowingly.

Bromphine has been described as a potent synthetic opioid, and evidence suggests it is being abused for its opioidergic effects. According to a recent publication by CFSRE - NPS Discovery Program, bromphine has been positively identified in seven death investigation cases spanning between June and July 2020. These cases occurred in three states, Illinois with three (3) deaths, Minnesota with three (3) deaths, and Arizona with one (1) death. Most of the decedents were male. The decedents’ ages ranged between their 40’s and 60’s with an average age of 52 years. Other substances identified in postmortem blood specimens obtained from these decedents include flualprazolam, a nonscheduled benzodiazepine (n = 5), fentanyl, a schedule II substance (n = 7), and heroin, a schedule I substance (n = 4). The appearance of benzodiazepines and other opioids is common with polysubstance abuse. NFLIS registered 20 reports of bromphine from Ohio (4 reports), Pennsylvania (1 report), and Wisconsin (15 reports) in 2019 and 2020. NFLIS was queried on August 18, 2020, for bromphine. Due to the rapid appearance of the drug, bromphine is most likely under reported as forensic laboratories secure reference standards for the confirmative identification and reporting of this substance. The population likely to abuse bromphine appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in samples obtained from bromphine seizures and post-mortem toxicology reports. Because abusers of bromphine are likely to obtain it through unregulated sources, the identity, purity, and quantity of bromphine are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well-characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH), as of 2019, an estimated 10.1 million people aged 12 years or older misused opioids in the past year, including 9.7 million prescription pain reliever misusers and 745,000 heroin users. In 2019, an estimated 1.6 million people had an opioid use disorder, which included 1.4 million people with a prescription pain reliever use disorder and 438,000 people with heroin use disorder. In 2018, an estimated 10.3 million people aged 12 years or older misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2 million people had an opioid use disorder, which included 1.7 million people with a prescription pain reliever use disorder and 500,000 people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing bromphine. Individuals who initiate use (i.e., use a drug for the first time) of bromphine are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.). Law enforcement reports demonstrate that bromphine is being illicitly distributed and abused.

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that bromphine exhibits a pharmacological profile similar to that of other mu-opioid receptor agonists. Data from in vitro studies showed that bromphine binds to and activates the mu-opioid receptors. In the [S]GTP γ S cell-based receptor assay, bromphine, similar to fentanyl, acted as a mu-opioid receptor agonist. Bromphine's activation of the mu-opioid receptor was also shown to involve recruitment of beta-arrestin-2, a regulatory protein whose interaction with the mu-opioid receptor has been implicated in the adverse effects of mu-opioid receptor activation. Bromphine binds to and activates the mu-opioid receptor and has efficacy on scale with fentanyl in in vitro studies. It is well established that substances that act as mu-opioid receptor agonists have a high potential for addiction and can induce dose-dependent respiratory depression. As with any mu-opioid receptor agonist, the potential health and safety risks for users of bromphine are high. The public health risks associated to the abuse of heroin and other μ -opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention ("CDC"), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. A CDC report shows that, from 2013 to 2018, opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose deaths for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths. In the United States, the abuse of opioid analgesics has resulted in large numbers of treatment admissions, emergency department visits, and fatal overdoses. The introduction of potent synthetic opioids such as bromphine into the illicit market may serve as a portal to problematic opioid use for those seeking these powerful opioids. Bromphine has been co-identified with other substances in seven post-mortem toxicology cases in June and July 2020. These substances include other opioids such as fentanyl and heroin, and other substance classes such as benzodiazepines. These deaths occurred in three states: Illinois, Arizona, and Minnesota. Information gathered from case history findings shows that bromphine use is similar to that of classic opioid agonists. As documented by toxicology reports, poly-substance abuse remains common in fatalities associated with the abuse of bromphine.

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one (commonly known as bromphine), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act .

The Department recommended placing this substance in Schedule I in the same manner as the federal Drug Enforcement Administration and based on the finding by the Acting Administrator that the placement of bromphine in schedule I of the

Controlled Substances Act is necessary to avoid an imminent hazard to the public safety.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended the addition of bromphine 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

() Bromphine 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one, its isomers, esters, ethers, salts and salts of isomers, esters and ethers

After discussion, **Mr. Lee moved, seconded by Ms. Shrivastava-Patel, to designate the additional substances named in the DEA Notice published in the Federal Register on March 1, 2021 and amend Section 44-53-190(B) of the South Carolina Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.**

Item 7: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-34, Raw Milk for Human Consumption, and Regulation 61-34.1, Pasteurized Milk and Milk Products, Document No. 5033 (Attachment 7-1)

A Public Hearing was conducted concerning the Regulation. Ms. Sandra Craig, Director, Division of Food and Lead Risk Assessments, presented this item to the Board.

The Bureau of Environmental Health Services ("Bureau") proposed the Notice of Final Regulation amending R.61-34, *Raw Milk for Human Consumption*, and R.61-34.1, *Pasteurized Milk and Milk Products*. Legal authority resides in S.C. Code Sections 44-1-140 and 44-1-150, which allow the Department of Health and Environmental Control ("Department") to promulgate regulations for the production, storing, labeling, transportation, and selling of milk and milk products, filled milk and filled milk products, imitation milk and imitation milk products, synthetic milk and synthetic milk products, milk derivatives, and any other products made in semblance of milk or milk products. Furthermore, S.C. Code Section 44-1-150 allows for the enforcement of these regulations. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

Pursuant to R.61-34, *Raw Milk for Human Consumption*, the Department provides sanitation oversight for the production and sale of raw milk that has not been

pasteurized for food safety in South Carolina. The Bureau is amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream, buttermilk, and kefir, and adding additional consumer advisory changes that are needed for products that receive further processing or become necessary as a byproduct of further processing. The revisions also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance ("PMO").

Pursuant to R.61-34.1, *Pasteurized Milk and Milk Products*, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Bureau is amending R.61-34.1 to adopt requirements of the 2019 PMO. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO will enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Bureau further provides clarification of requirements for potable water sources.

The Bureau is also revising R.61-34 and R.61-34.1 for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. The amendments to both regulations also include updates to administrative and enforcement provisions.

The Department had a Notice of Drafting published in the March 27, 2020, *State Register*.

Department staff conducted an internal review of the proposed amendments on December 3, 2020.

The Bureau conducted two separate stakeholder engagement meetings on December 7, 2020. The first meeting for R.61-34.1 had five (5) stakeholders in attendance, and the second meeting for R.61-34 had twenty-one (21) stakeholders in attendance. Comments made in these meetings included support for the amendments, suggestions for terminology, and discussion of the scope of raw milk products addressed in R.61-34. The Bureau considered these comments and, where appropriate, incorporated them into the proposed regulations.

Upon receiving approval during the January 7, 2021, Board meeting, the Bureau had a Notice of Proposed Regulation published in the January 22, 2021, *State Register*. The Department received public comments from five people by the February 22, 2021, close of the public comment period. A summary of the public comments received, and Department responses were provided to the Board.

The Bureau conducted two additional, separate stakeholder engagement meetings on February 12, 2021, following publication of the Notice of Proposed Regulation. The first meeting for R.61-34.1 had nine (9) stakeholders in attendance, and the second meeting for R.61-34 had fourteen (14) stakeholders in attendance. Comments made

in these meetings included several requests to add kefir as an allowed raw milk product under R.61-34.

After consideration of all timely received comments, staff made substantive changes to the R.61-34 regulatory text of the Notice of Proposed Regulation approved by the Board in the January 7, 2021, Board meeting and published in the January 22, 2021, *State Register*. Descriptions of the changes were provided to the Board.

Stakeholders have continued to express appreciation for the Department's industry engagement and support for these revisions.

The Bureau of Environmental Health Services requested the Board to find need and reasonableness of the amendment of Regulation 61-34, *Raw Milk for Human Consumption*, and Regulation 61-34.1, *Pasteurized Milk and Milk Products*, for submission to the General Assembly.

Board Counsel, W. Marshall Taylor, opened the meeting up for public comments on this matter, but no one wished to speak. (Attachment 7-2) No comments were received, and the public hearing was closed.

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, that based on the public hearing and documents provided, moved to find for the need and reasonableness of the proposed amendment of Regulation 61-34.1, *Pasteurized Milk and Milk Products*, Document 5033, and grant approval for submission to the General Assembly for review. The Board voted and Motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 7-3)

Being no further business, Chairman Elam adjourned the meeting.

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

Respectfully submitted,



Charles M. Joye, II, PE

Minutes approved this 8th day of April 2021.

ATTEST:



Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Minutes of March 11, 2021 meeting
- 3-1 Determination of implementation of COVID-19 vaccine allocation plan
- 3-2 Vaccine allocation PowerPoint
- 4-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 5-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 6-1 Request for Placement of Brophine into Schedule 1 for Controlled Substances in South Carolina
- 7-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-34, *Raw Milk for Human Consumption*, and Regulation 61-34.1, *Pasteurized Milk and Milk Products*, Document No. 5033
- 7-2 Public Hearing Sign Up Sheet
- 7-3 Verbatim transcript of public hearing