AGENDA
CONNECTICUT MEDICAL EXAMINING BOARD
Tuesday, March 21, 2023 at 1:30 PM

Department of Public Health
410 Capitol Avenue, Hartford Connecticut

CALL TO ORDER

I. APPROVAL OF MINUTES
November 15, 2022, December 20, 2022, January 17, 2023 and February 22, 2023

II. OPEN FORUM

III. UPDATES
A. Chair Updates
B DPH Updates

IV. NEW BUSINESS

V. PROPOSED MEMORANDUM OF DECISION
Michael Smith, M.D. - Petition No. 2021-101

VI. OFFICE OF LEGAL COMPLIANCE
None

ADJOURN

Connecticut Medical Examining Board via Microsoft Teams

Microsoft Teams meeting

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CONNECTICUT MEDICAL EXAMINING BOARD
MINUTES of November 15, 2022

The Connecticut Medical Examining Board held a meeting on Tuesday, November 15, 2022 via Microsoft TEAMS

BOARD MEMBERS PRESENT:	Kathryn Emmett, Esq., Chairperson Raymond Andrews, Jr., Esq. Allyson Duffy, MD Marie C. Eugene, DO Robert Green, MD Michele Jacklin Joseph Kaliko, Esq. William C. Kohlhepp, DHSc, PA-C Shawn London, MD Edward McAnaney, Esq. Daniel Rissi, MD Harold Sauer. MD David Schwindt, MD Andrew Yuan, DO Peter Zeman, MD
BOARD MEMBERS ABSENT:	Marilyn Katz, MD C. Steven Wolf, MD

Ms. Emmett called the meeting to order at 1:30 p.m.

I. MINUTES

The draft minutes of the August 16, 2022 meeting were reviewed and approved on a motion by Dr. Kohlhepp, seconded by Attorney McAnaney. Minutes unanimously approved

The draft minutes of September 20, 2022 meeting were reviewed and approved on a motion by Attorney McAnaney, seconded by Dr. Yuan. Minutes were approved by all Board members, with Michele Jacklin abstaining.

II. OPEN FORUM

None

III. UPDATES

A. Chair Updates

Chair Emmett notes the retirement of Mr. Kardys.

Reports the Ethics Board indicated that Dr. Wolf may participate on the Board but must recuse on matters involving the Department of Consumer Protection

Department of Public Health

None

IV. NEW BUSINESS

None

V. OFFICE OF LEGAL COMPLIANCE

A. Daniel Chen, Resident Physician – Petition No. 2022-196

Staff Attorney Linda Fazzina, Department of Public Health, presented the Consent Order this matter. Respondent was represented by Attorney Gretchen Randell.
Dr. Green made a motion, seconded by Attorney McAnaney to approve the Consent Order as presented. Following discussion, the Consent Order which imposes a reprimand was approved unanimously, with the exception that Doctor Katz recused from the voting.

B. Philip A. Mongulluzzo, Jr, M.D. – Petition No. 2020-547

Staff Attorney Linda Fazzina, Department of Public Health, presented a Consent Order in this matter. Respondent was not present. Respondent was represented by Attorney Richard Brown. Attorney McAnaney made a motion, seconded by Dr. Kohlhepp to approve the Consent Order as presented which imposes a reprimand, probation for a period of two years, and a $10,000.00 civil penalty. The motion passed unanimously.

VI. ADJOURNMENT

As there was no further business, the meeting was adjourned at 2:51 p.m. on a motion by Dr. Green.

Respectfully submitted,
Kathryn Emmett, Esq., Chairperson

The following minutes are draft minutes which are subject to revision and which have not yet been adopted by the Board.

CONNECTICUT MEDICAL EXAMINING BOARD
MINUTES of December 20, 2022

The Connecticut Medical Examining Board held a meeting on Tuesday, December 20, 2022, via Microsoft TEAMS

BOARD MEMBERS PRESENT:	Kathryn Emmett, Esq., Chairperson Raymond Andrews, Jr., Esq. Allyson Duffy, MD Robert Green, MD Michele Jacklin Joseph Kaliko, Esq. William C. Kohlhepp, DHSc, PA-C Marilyn Katz, MD Daniel Rissi, MD Harold Sauer. MD David Schwindt, MD Marie C. Eugene, DO C. Steven Wolf, MD Andrew Yuan, DO Peter Zeman, MD
BOARD MEMBERS ABSENT:	Edward McAnaney, Esq. Shawn London, MD

Ms. Emmett called the meeting to order at 1:33 p.m.

I. MINUTES

None

II. OPEN FORUM

Dr. Kohlhepp discussed a recent article in the Federation of State Medical Board regarding the approval of the PA Compact model licensure agreement.

III. UPDATES

A. Chair Updates

Chair Emmett discussed confidential information contained within the Department of Public Health Investigative Reports.

Department of Public Health

Christian Andresen, Section Chief, Department of Public Health, Practitioner Licensing and Investigations reported updated the Board regarding Connecticut Compact agreement becoming part of the Interstate Medical Licensure Compact effective October 1, 2022.

IV. NEW BUSINESS

None

V. OFFICE OF LEGAL COMPLIANCE

A. Robert W. Behrends, M.D. - Petition No. 2020-548

Staff Attorney Linda Fazzina, Department of Public Health, presented a Consent Order in this matter. Respondent was present and was represented by Attorney Mary Alice Leonhardt. Dr. Green made a motion, seconded by Dr. Rissi, to approve the Consent Order as presented. Following discussion, the motion passed. Dr. Green, Ms. Jacklin, Attorney Kaliko were opposed to approval. Attorney Andrews, Dr. Duffy, Mr. Kohlhepp, Dr. Katz, Dr. Rissi, Dr. Sauer, Dr. Schwindt, Dr. Eugene, Dr. Yuan, Dr. Zeman, Ms. Emmett were in approval of the Consent Order which imposes a reprimand. The motion to approve passed with all in favor except Dr. Wolf who recused himself from this petition.

B. Enrique J. Tello Silva, M.D. - Petition No. 2019-97

Staff Attorney Craig Sullivan, Department of Public Health, presented Consent Order in this matter. Respondent was not present. Respondent was represented by Attorney Budge. A motion to approve the Consent Order was made by Mr. Kohlhepp and seconded by Dr. Rissi. Following discussion, the motion passed with all in favor with Dr. Green recused himself from this petition. The Consent Order imposes coursework in patient communication and management of patients on lithium and a $5,000.00 civil penalty.

C. Sheikh Ahmed, M.D. – Petition Nos. 2017-184, 2018-1333

Staff Attorney Joelle Newton, Department of Public Health, presented a Withdrawal of Charges in this matter. Respondent was not present. Respondent was not represented by counsel. Dr. Wolf made a motion, seconded by Dr. Yuan to approve the Withdrawal of Charges. The motion passed unanimously based on the understanding Respondent voluntarily surrenders his medical license.

VII. 120 DAY EXTENSIONS

Michael Smith, M.D. – Petition No. 2021-101
Wayne Franco, M.D. – Petition No. 2018-1345

Attorney Kaliko made a motion, seconded by Dr. Green to approve 120 days extension on Michael Smith, M.D., Petition No. 2021-101 and Wayne Franco, M.D., Petition No. 2018-1345. The motion to approve passed with all in favor except Dr. Wolf who recused himself from these petitions.

VI. ADJOURNMENT

As there was no further business, the meeting was adjourned at 2:19 p.m. on a motion by Mr. Kaliko, seconded by Dr. Green.

Respectfully submitted,
Kathryn Emmett, Esq., Chairperson

The following minutes are draft minutes which are subject to revision and which have not yet been adopted by the Board.

CONNECTICUT MEDICAL EXAMINING BOARD
MINUTES of January 17, 2023

The Connecticut Medical Examining Board held a meeting on Tuesday, January 17, 2023 via Microsoft TEAMS

BOARD MEMBERS PRESENT:	Kathryn Emmett, Esq., Chairperson Raymond Andrews, Jr., Esq. Allyson Duffy, MD Marie C. Eugene, DO Robert Green, MD Michele Jacklin Joseph Kaliko, Esq. Marilyn Katz, MD William C. Kohlhepp, DHSc, PA-C Shawn London, MD Daniel Rissi, MD David Schwindt, MD C. Steven Wolf, MD Andrew Yuan, DO Peter Zeman, MD
BOARD MEMBERS ABSENT:	Edward McAnaney, Esq. Harold Sauer. MD

Ms. Emmett called the meeting to order at 1:36 p.m.

I. MINUTES

None

II. OPEN FORUM

None

III. UPDATES

A. Chair Updates

Chair Emmett repeated the Department of Public Health policy of including the investigative report with Consent Orders presented before the Board.

Department of Public Health

None

IV. NEW BUSINESS

None

V. OFFICE OF LEGAL COMPLIANCE

A. Desiree A. Clarke, MD – Partition No. 2020-292

Staff Attorney Aden Baume ~~Staff Attorney~~, Department of Public Health, presented the Consent Order in this matter. Respondent was not present. Respondent was represented by Attorney Eric Niederer. Dr. Green made a motion, seconded by Dr. Zeman to approve the Consent Order as presented. Following discussion, the Consent Order which imposes ~~a reprimand,~~ probation for a period of 1 year, and a reprimand passed with all in favor, except Attorney Kaliko who was opposed.

B. Helen Ede, M.D. - Petition No. 2020-103

Staff Attorney Linda Fazzina, Department of Public Health, presented a Consent Order in this matter. Respondent was not present. Respondent represented by Attorney Melinda Monson. Dr. Green made a motion, seconded by Dr. Rissi to approve the Consent Order as presented. Following discussion, the Consent Order which imposes a reprimand, probation for a period of one year, and a $5,000.00 civil penalty passed with all in favor, except Dr. Green, Ms. Jacklin, Attorney Kaliko who were opposed. Dr. Wolf recused due to association with the Department of Consumer Protection.

C. Adarsh A. Jha, M.D. Petition No. 2019-1332

Staff Attorney Linda Fazzina, Department of Public Health, presented a Consent Order in this matter. Respondent was not present. Respondent was represented by Attorney Edward Mayer. Mr. Kohlhepp, made a motion, seconded by Dr. Zeman to approve the Consent Order as presented. Following discussion, the Consent Order which imposes a $5,000.00 civil penalty and a permanent restriction requiring respondent to have a female chaperone present during the examination of a female patient passed with all in favor, except Dr. Duffy, Dr. Green, Ms. Jacklin who were opposed. Attorney Kaliko lost TEAMS connection and did not vote.

VI. ADJOURNMENT

As there was no further business, the meeting was adjourned at 2:51 p.m. on a motion by Dr. Wolf.

Respectfully submitted,
Kathryn Emmett, Esq., Chairperson

The following minutes are draft minutes which are subject to revision and which have not yet been adopted by the Board.

CONNECTICUT MEDICAL EXAMINING BOARD
MINUTES of February 22, 2023

The Connecticut Medical Examining Board held a meeting on Tuesday, February 22, 2023 via Microsoft TEAMS

BOARD MEMBERS PRESENT:	Kathryn Emmett, Esq., Chairperson Allyson Duffy, MD Robert Green, MD Michele Jacklin Marilyn Katz, MD William C. Kohlhepp, DHSc, PA-C Keat Jin Lee, MD Shawn London, MD Edward McAnaney, Esq. Daniel Rissi, MD Harold Sauer. MD David Schwindt, MD Andrew Yuan, DO Peter Zeman, MD
BOARD MEMBERS ABSENT:	Raymond Andrews, Jr., Esq. Marie C. Eugene, DO Joseph Kaliko, Esq C. Steven Wolf, MD

Ms. Emmett called the meeting to order at 1:32 p.m.

I. MINUTES

Dr. Zeman made a motion, seconded by Dr. Yuan to approve placing draft minutes of November 15, 2022, December 20, 2022, and January 17, 2023, on the Agenda. After a discussion Dr. Zeman made a motion, to withdraw placing draft minutes on the Agenda which was tabled until March 21, 2023 meeting.

II. OPEN FORUM

None

III. UPDATES

A. Chair Updates

Chair Emmett welcomed Keat Jin Lee, MD as a Board member.

Department of Public Health

None

IV. NEW BUSINESS

A. Board of Electrology Declaratory Ruling concerning hair removal on a nevus

Discussion regarding options specified by Connecticut General Statutes. Dr. Katz made a motion, seconded by Dr. Yuan to proceed with a hearing regarding the Declaratory Ruling concerning hair removal on a nevus. The motion passed unanimously.
Dr. Lee made a motion, seconded by Mr. Kohlhepp to assign a panel to hear Declaratory Ruling. The motion passed unanimously.

B. Review of License Application Catherine Brophy, M.D.
Celeste Dowdell, License and Application Analyst, Department of Public Health presented an application for Connecticut physician licensure. Attorney McAnaney made a motion, seconded by Dr. Lee to recommend approval of the application as presented. Following a discussion, the Application for physician licensure the motion passed unanimously.

IV. OFFICE OF LEGAL COMPLIANCE

A. Farhaad R. Riyaz, MD - Petition No. 2022-206
Staff Attorney Craig Sullivan, Department of Public Health, presented the Consent Order in this matter. Respondent was present. Respondent was not represented by counsel. Mr. Kohlhepp made a motion, seconded by Dr. Rissi to approve the Consent Order as presented. Following discussion, the Consent Order imposes a reprimand, a civil penalty of $3,000.00 dollars, and probation for a period of 2 years. The motion passed unanimously.

B. Derek Shia, MD – Petition No. 2022-419
Staff Attorney Aden Baume, Department of Public Health, presented the Consent Order in this matter. Respondent and his attorney were not present. Dr. Rissi made a motion, seconded by Ms. Jacklin to approve the Consent Order as presented. Following discussion, the Consent Order imposes a reprimand and civil penalty of $25,000.00 dollars. The motion passed unanimously.

C. Noah Starkey, MD - Petition 2021-74
Staff Attorney Craig Sullivan, Department of Public Health, presented the Consent Order in this matter. Attorney Eric Stockman was present for respondent. Dr. Rissi made a motion, seconded by Dr. Katz to approve the Consent Order as presented. Following discussion, the Consent Order imposes a civil penalty of $5, 00.00 dollars and probation for a period of 1 year. The motion passed with all in favor except Dr. Green and Ms. Jacklin who were opposed, Dr. Lee who abstained and Dr. Eugene who was present but did not vote due to TEAMS connection.

VI. ADJOURNMENT

As there was no further business, the meeting was adjourned at 2:51 p.m. on a motion by Dr. Lee.

Respectfully submitted,
Kathryn Emmett, Esq., Chairperson

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

CONNECTICUT MEDICAL EXAMINING BOARD

February 10, 2023

Michael Kurs
Pullman & Comley, LLC
90 State House Square
Hartford, CT 06103

VIA EMAIL (mkurs@pullcom.com**)**

Barbara Cass, RN, Bureau Chief
Healthcare Quality &Safety Branch
Department of Public Health
410 Capitol Avenue, MS #12HSR
PO Box 340308
Hartford, CT 06134-0308

VIA EMAIL ONLY

RE: Michael Smith, MD - Petition No. 2021-101

PROPOSED MEMORANDUM OF DECISION

Attached is the proposed Memorandum of Decision in the above referenced matter. Pursuant to § 4-179 of the Connecticut General Statutes, both parties will be afforded the opportunity to present oral argument before the Connecticut Medical Examining Board. The Board will consider this proposed Memorandum of Decision at its meeting scheduled for **March 21, 2023 at 1:30 p.m.**

If you wish to exercise this opportunity to present oral argument, please notify this office no later than **March 1, 2023**. The time allowed for argument is not to exceed ten (10) minutes for each party. There will not be a court stenographer present for these proceedings.

Any briefs or exceptions must be filed no later than **March 7, 2023**.

FOR: **CONNECTICUT MEDICAL EXAMINING BOARD**

BY: /s/ *Dianne Bertucio*
Dianne Bertucio, Interim Administrative Hearings Specialist
Department of Public Health
410 Capitol Avenue, MS #13PHO
Hartford, CT 06106
Tel. (860) 509-7648 FAX (860) 707-1904

c: Elizabeth Bannon, Assistant Attorney General
Christian Andresen, Section Chief, Practitioner Licensing and Investigations, DPH
Aden Baume, Staff Attorney, DPH

STATE OF CONNECTICUT
CONNECTICUT MEDICAL EXAMINING BOARD

Michael Smith, M.D. Petition No. 2021-101
License No. 033417

MEMORANDUM OF DECISION

Procedural Background

On January 18, 2022, the Department of Public Health ("Department") issued a Statement of Charges ("Charges") to the Connecticut Medical Examining Board ("Board") against license number 033417 of Michael Smith, M.D. ("Respondent"). Board ("Bd.") Exhibit ("Ex.") 1. The Charges allege that Respondent failed to meet the standard of care, subjecting his license to disciplinary action pursuant to Conn. Gen. Stat. §§ 19a-17 and 20-13c.

On March 31, 2022, a Notice of Hearing was sent to the parties, scheduling the hearing for June 10, 2022. Bd. Ex. 2.

The hearing was held on June 10, 2022, before a duly authorized panel of the Board ("Panel") comprised of Marilyn Anne Katz, M.D. and Edward G. McAnaney, Esq.[1]

The Panel conducted the hearing in accordance with Chapter 54 of the Statutes, the Uniform Administrative Procedure Act, and § 19a-9-1 et seq. of the Regulations of Connecticut State Agencies ("Regulations"). Attorney Aden Baume represented the Department; Attorney Michael Kurs represented Respondent. Both parties were afforded the opportunity to present witnesses and evidence, examine and cross-examine witnesses, and provide argument on all issues.

All Panel members involved in this Memorandum of Decision ("Decision") attest that they have heard the case and/or read the record in its entirety. The Board reviewed the Panel's proposed final decision in accordance with the provisions of Conn. Gen. Stat. § 4-179.

In rendering its Decision, the Board considered whether Respondent poses a threat, in the practice of medicine, to the health and safety of any person. The Board's decision is based entirely on the record and the specialized professional knowledge of the Panel in evaluating the evidence. *See* Conn. Gen. Stat. § 4-178; *Pet v. Dep't of Health Services*, 228 Conn. 651, 666 (1994). To the

[1] Robert Green, M.D., a member of the panel, was not present for the hearing due to an unforeseen scheduling conflict. He was provided a copy of the record and the transcript prior to the fact finding. Tr., pp. 27, 40.

extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.,* 605 F. Supp. 816 (Md. Tenn. 1985).

Allegations

1. In paragraph 1 of the Charges, the Department alleges that Respondent of Norwalk, Connecticut, is, and has been at all times referenced in the Charges, the holder of Connecticut physician and surgeon license number 033417.

2. In paragraph 2 of the Charges, the Department alleges Respondent provided care to Patient 1 on or about December 22, 2020. Respondent's care for Patient 1 failed to meet the standard of care in that Tranexamic acid ("TXA") was administered instead of Bupivacaine 0.5%.

3. In paragraph 3 of the Charges, the Department alleges that the above-described facts constitute grounds for disciplinary action pursuant to § 20-13c(4) of the Statutes.

Findings of Fact

1. Respondent is from Norwalk, Connecticut and has been at all times referenced in the Charges, the holder of Connecticut physician and surgeon license number 033417. Tr., pp. 8, 14.

2. Respondent provided care to Patient 1 on or about December 22, 2020. Tr., pp. 8, 14; Department ("Dept.") Ex. 1, pp. 2-4, Dept. Ex. 2, pp. 6-64 (sealed).

3. Patient 1 was to receive 2cc of Bupivacaine .5% [2] spinal anesthesia in preparation for a knee surgery. Dept. Ex. 1, pp. 2-3; Dept. Ex. 2, pp. 2, 13, 19 (sealed).

4. Respondent used sterile 4x4 gauze, which hid the name of the vial content, to pick up the medication vial prior to drawing the medication and administering it. Dept. Ex. 1, pp. 2-3; Ex. 2, pp. 2-3 (sealed).

5. On December 22, 2020, Respondent administered TXA instead of Bupivacaine 0.5% to Patient 1. Tr., pp. 8, 14; Dept. Ex. 1, pp. 1-4; Dept. Ex. 2, pp. 2-3, 19-20, 61, 83 (sealed).

6. Respondent's care for Patient 1 on December 22, 2020, failed to meet the standard of care. Tr., pp. 8, 14; Dept. Ex. 1; Dept. Ex. 2 (sealed).

Discussion and Conclusions of Law

Conn. Gen. Stat. § 20-13c provides, in pertinent part, that:

The board is authorized to restrict, suspend or revoke the license or limit the right to practice of a physician or take any other action in accordance with section 19a-17,

[2] Bupivacaine is interchangeably identified in the record as Marcaine, which is one of several brand names for the drug bupivacaine. Mayo Clinic, Bupivacaine (Injection Route), https://www.mayoclinic.org/drugs-supplements/bupivacaine-injection-route/description/drg-20406723 (last visited Dec. 27, 2022)

> for any of the following reasons: . . . (4) illegal, incompetent or negligent conduct in the practice of medicine. . . .

The Department bears the burden of proof by a preponderance of the evidence in this matter. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727, 739-40 (2013).

Respondent does not contest any of the allegations of the Charges, and a preponderance of the evidence establishes that Respondent is from Norwalk, Connecticut and the holder of Connecticut physician and surgeon license number 033417. Tr., pp. 8, 14. The preponderance of the evidence also establishes that on December 22, 2020, when the Respondent provided care to Patient 1, he administered TXA instead of Bupivacaine 0.5%. Tr., pp. 8, 14; Dept. Ex. 1, pp. 1-4; Dept. Ex. 2, pp. 13, 19-20, 61 (sealed). Therefore, the Department sustained its burden of proof.

In this case, in preparation for a knee surgery, Patient 1 was to receive 2cc of Bupivacaine .5% spinal anesthesia. Finding of Fact ("FF.") 3. On December 22, 2020, at the time the spinal anesthesia was to be administered to Patient 1, Respondent picked up a vial of TXA with sterile gauze that hid the name of the vial content and administered the 2cc of TXA instead of spinal anesthesia. FF. 4, 5. Subsequent to documenting the TXA injection in Patient 1's anesthesia record, and observing the vial of Bupivacaine on the anesthesia cart, Respondent realized the TXA was erroneously injected, and that Patient 1 was prescribed to receive 2cc of Bupivacaine .5% via spinal anesthesia. Dept. Ex. 1, pp. 2-3; Dept. Ex. 2 (sealed). Respondent then administered the 2cc of Bupivacaine .5% to Patient 1. *Id.*

While Respondent does not dispute that he erred in his administration of spinal anesthesia to Patient 1 on December 22, 2020, he argues that in his almost 40-year career he has never been in this situation before, and notes that just weeks prior, the Federal Drug Administration ("FDA") issued an alert to the medical community regarding injection errors due to the similarity of labeling for TXA and Bupivacaine. Tr., pp. 23, 29; Respondent ("Resp.") Ex. C. Respondent completed several educational courses, and his hospital implemented new policies and protocols to eliminate the risk of such errors. Tr., pp. 17, 23-25; Dept. Ex. 1, pp. 2-4 ; Dept. Ex. 3, pp. 4-17. Respondent contends that because of the measures he and the hospital have taken to ensure the safety of patients and based on precedent established in the *DPH v. Sygall*[3] matter, he should not be subject to disciplinary action. Tr., pp. 36-37, 39; Resp. Ex. B.

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[3] *Dep't of Public Health v. Sygall*, Connecticut Medical Examining Board Memorandum of Decision, Petition No. 2010-5766 (May 21, 2013).

The Board acknowledges the prompt steps taken by Respondent to eliminate future risks to patients by educating himself through coursework (Dept. Ex. 1, p. 4; Dept. Ex. 3, pp. 4-17), and the implementation of new policies and protocols in his hospital. Ex. 1, p. 4; Ex. 2, pp. 3, 95-103 (sealed). However, as correctly argued by the Department, a distinguishing factor in *Sygall* is that the intervening actions of another person contributed to Dr. Sygall's violation. Whereas, in Respondent's case, the misadministration of TXA instead of Bupivacaine to Patient 1 on December 22, 2020, was the direct result of Respondent's negligent conduct in violation of § 20-13c(4) of the Statutes.

Conclusion

In conclusion, the Department sustained its burden of proof with regard to all of the allegations in the Charges. Accordingly, the Board concludes that there is an adequate basis upon which to impose discipline on Respondent's license pursuant to §§ 19a-17 and 20-13c(4) of the Statutes, warranting the following Order.

Order

Based upon the record in this case, the above findings of fact and the conclusions of law, and pursuant to the authority vested in it by Conn. Gen. Stat. §§ 19a-17 and 20-13c, the Board finds, with respect to license number 033417 held by Michael Smith, M.D., that the violation alleged and proven in Petition No. 2021-101 warrants the disciplinary action imposed by this Order:

1. Respondent's license number 033417 to practice as a physician and surgeon in the State of Connecticut is hereby REPRIMANDED.
2. Respondent's license is hereby assessed a civil penalty in the amount of ten thousand dollars ($10,000.00).
3. Respondent shall pay the civil penalty described above by certified or cashier's check payable to "Treasurer, State of Connecticut." The check shall reference the Petition Number on the face of the check and shall be payable within thirty (30) days of the effective date of this decision.
4. All correspondence related to this Memorandum of Decision must be mailed to:

License Monitoring Unit
Department of Public Health
Division of Health Systems Regulations
410 Capitol Avenue, MS#12HSR
P.O. Box 340308
Hartford, CT 06134-0308

5. Respondent shall comply with all state and federal statutes and regulations applicable to his license.
6. Respondent shall pay all costs necessary to comply with this Decision.
7. Legal notice shall be sufficient if sent to Respondent's last known address of record reported to the Office of Practitioner Licensing and Certification of the Healthcare Systems Branch of the Department.
8. This Memorandum of Decision has no bearing on any criminal liability without the written consent of the Director of the Medicaid Fraud Control Unit or the Bureau Chief of the Division of Criminal Justice's Statewide Prosecution Bureau.
9. This Decision is effective upon signature of the Board.
10. This Memorandum of Decision is a public document.

Connecticut Medical Examining Board

_____
Kathryn Emmett, Esq., Chairperson

January _____, 2023

STATE OF CONNECTICUT
CONNECTICUT MEDICAL EXAMINING BOARD

MICHAEL SMITH, MD

PETITION NO. 2021-101 March 7, 2023

Respondent's Brief In Support of Imposition of Lesser Discipline or Alternatively No Discipline

I.

This brief addresses whether the "precedent" established in *Department of Public Health v. Sygall*, should apply to this case. See *Sygall*, Connecticut Medical Examining Board Memorandum of Decision, Petition No. 2010-5766 (May 21, 2013), a copy of which accompanies this brief. The Proposed Decision in the matter before the Medical Board distinguishes *Sygall* on the basis that "the intervening actions of another person contributed to Dr. Sygall's violation" -- implying no intervening actions of others contributed to Respondent's error. *See* Proposed Decision, p.4. The Board in *Sygall* actually concluded that Dr. Sygall's error "was mainly a result of anchoring and a flawed protocol system." *Sygall*, p. 6. The decision found that Dr. Sygall's actions "ultimately led to the incident" but that "there was a systemic flaw in the equipment set-up." *Id.* Systemic flaws in protocols in Respondent's case occurred in addition to Respondent's error and a drug not normally on the anesthesia cart unexpectedly being there. Department Exhibit 2, p. 112. *Sygall* should have been considered to apply.

II.

The systematic flaws that occurred in Respondent's case include: (1) the since discontinued use of very similar vials, one containing the drug administered in error, Tranexamic acid ("TXA"); (2) the since discontinued use of an automated dispensing system by operating room staff to obtain the vial of the inadvertently administered drug placed on the anesthesia cart; and (3) the lack of

implementation of protocol changes prior to the incorrect drug administration despite a federal Food and Drug Administration alert weeks before. The Department's own investigation, in fact, observed: "look-alike medication vials contributed to the respondent picking up the incorrect medication." *See* Department's Hearing Exhibit 1, Investigative Report, Complaint Analysis, A. 4, p. 2. The vial of TXA was not normally on the cart. Department's Exhibit 2, Page 112 of 115.

Respondent is a highly regarded anesthesiologist within his group and hospital. *See* Investigative Report, Department Exhibit 1, Statement of Facts Related to Allegations, C 3, p. 4. On December 22, 2020, after prepping a patient for spinal anesthesia pre-knee surgery and putting on his sterile gloves, respondent realized he had not opened the anesthesia to be administered. He used sterile gauze that covered the name of the vial's content that he picked up asking the assisting nurse to open the vial. The vial that was opened contained TXA instead of Bupivacaine. The nurse opened the vial and placed it on the table. Respondent drew and administered the TXA. Respondent immediately realized that the Bupivacaine was still on top of the anesthesia cart. *See* Department Exhibit 1, Investigative Report, Statement of Facts Related to Allegations, C. 1.

The charges make no other allegations of misconduct.

TXA has since been removed from the automated medication system. Pre-mixed bags of TXA for IV administration are now used instead of TXA extracted from vials. As an interim measure the circulator nurse was assigned to hold the TXA until the anesthesiologist asked for it. Department Exhibit 1, Investigative Report, Statement of Facts Related to Allegations, C. 3.

The proposed decision should have at least considered whether the systemic protocol shortcomings that contributed to respondent's error warrant lesser discipline be imposed by the Board, if the Board decides to discipline respondent at all. For instance, the Board should consider whether there were sufficient systemic contributing factors that no reprimand is warranted instead of adopting the decision as proposed.

III.

The Manual of Penalty Guidelines for Licensed Physicians and Surgeons were designed to promote consistency in sanctions imposed by the Medical Board. Application of the *Sygall* decision to the discipline decision here would promote the consistency appropriate to the discipline process.

MICHAEL SMITH, MD

By: /s/ Michael Kurs

Michael A. Kurs (#307465)
Pullman & Comley, LLC
90 State House Square
Hartford, CT 06103
Tel: 860-424-4331
Fax: 860-424-4370
mkurs@pullcom.com
His Attorneys

CERTIFICATION

I hereby certify that on March 7, the foregoing shall be immediately sent by e-mail, to the following:

Public Hearing Office phho.DPH@ct.gov (for filing)

Aden Baume Aden.Baume@ct.gov

Elizabeth Bannon Elizabeth.Bannon@ct.gov

Alina Bricklin-Goldstein Alina.Bricklin-Goldstein@ct.gov

Dianne Bertucio Dianne.Bertucio@ct.gov

/s/*Michael Kurs*
Michael A. Kurs
Commissioner of Superior Court

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

PUBLIC HEALTH HEARING OFFICE

May 22, 2013

James Rosenblum, Esq.
Rosenblum Newfield, LLC
1 Landmark Square
Stamford, CT 06901

Certified Mail RRR #91-7199-9991-7032-2704-2210

Matthew Antonetti, Principal Attorney
Department of Public Health
410 Capitol Avenue, MS #12LEG
PO Box 340308
Hartford, CT 06134-0308

Via EMAIL

RE: Paul Sygall, MD - Petition No. 2010-5766

Dear Attorney Rosenblum and Attorney Antonetti:

Enclosed please find a copy of the Memorandum of Decision issued by the **Connecticut Medical Examining Board** in the above-referenced matter.

Sincerely,

Jeffrey A. Kardys
Administrative Hearings Specialist/Board Liaison
Public Health Hearing Office

c: Jewel Mullen, MD, MPH, MPA, Commissioner, Department of Public Health
Tanya DeMattia, Assistant Attorney General
Wendy Furniss, Branch Chief, Healthcare Systems
Jennifer Filippone, Section Chief, Practitioner Licensing and Investigations
Lynn A. Rioux, Paralegal Specialist II, Office of the Attorney General

Phone: ***860-509-7648*** ***FAX 860-509-7553***
Telephone Device for the Deaf: (860) 509-7191
410 Capitol Avenue - MS # 13 PHO
P.O. Box 340308 Hartford, CT 06134

STATE OF CONNECTICUT
CONNECTICUT MEDICAL EXAMINING BOARD

Paul Sygall, M.D. **Petition No. 2010-5766**
License No.: 039155

MEMORANDUM OF DECISION

I. BACKGROUND

On December 23, 2011, the Department of Public Health ("Department") presented a Statement of Charges ("Charges") to the Connecticut Medical Examining Board ("Board") naming Paul Sygall, M.D., who holds Connecticut medical license number 039155, as Respondent ("Respondent"). Board Exh. 1. The Charges allege that Respondent's license is subject to disciplinary action under Connecticut General Statutes ("Statutes") § 20-13c, including, but not limited to, § 20-13c (4). Board Exh. 1.

On February 14, 2012, the Department sent the Charges and a Notice of Hearing regarding the Charges to Respondent, by certified mail, return receipt requested. Board Exh. 3.

The Notice of Hearing directed Respondent to appear before a duly authorized panel ("Panel") of the Board on April 17, 2012, for a formal hearing regarding the Charges. Board Exh. 3. The Panel consisted of Henry Jacobs, MD, Patricia Loving, PA., and Raymond Andrews, Jr., Esq. (the "Panel"). Board Exh. 3.

Respondent filed an Answer dated February 19, 2012. Board Exh. 2.

On April 17, 2012, the Board, through its duly authorized Panel held an administrative hearing, in accordance with § 4-166, et seq. of the Statutes, to adjudicate Respondent's case. During the hearing, Respondent was represented by Attorney James Rosenblum, and the Department was represented by Attorney Diane Wilan. Both parties were afforded the opportunity to present witnesses and evidence, examine and cross-examination witnesses, and provide argument on all issues. All Panel members involved in this decision received copies of the entire record and attest that they either heard the case or read the record in its entirety. The Board reviewed the Panel's proposed final decision in accordance with the provisions of § 4-179 of the Statutes.

In rendering the final decision, the Board considered whether Respondent poses a threat, in the practice of medicine, to the health and safety of any person. The Board's decision is based

entirely on the record and the specialized professional knowledge of the Panel in evaluating the evidence. See Conn. Gen. Stat. § 4 – 178; Pet v. Department of Health Services, 228 Conn. 651, 666 (1994). To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. SAS Inst., Inc., v. S & H Computer Systems, Inc., 605 F.Supp. 816 (Md. Tenn. 1985).

II. ALLEGATIONS

1. Department alleges that Respondent "is, and has been, at all times referenced in the [Charges], the holder of Connecticut medicine and surgery license number 039155." Charges, ¶ 1; Board Exh. 1.

2. Department alleges that "[o]n or about March 1, 2010, [R]espondent administered a nerve block anesthetic to the wrong surgical site of patient J.H. during a right wrist arthroscopy, in that [R]espondent administered a nerve block to patient J.H.'s left superclavicular area instead of the right" Charges, ¶ 2; Board Exh. 1.

3. Department alleges that "the above-described facts constitute grounds for disciplinary action pursuant to the [Statutes], § 20-13c, including but not limited to § 20-13c(4) of the Statutes." Charges, ¶ 3; Board Exh. 1.

III. FINDINGS OF FACT

1. Respondent is and has been, at all times referenced in the Charges, the holder of Connecticut medicine and surgery license number 039155. Respondent is an anesthesiologist. Board Exhs. 1, 2; Dept. Exh. 1, p. 22 (sealed); Hearing Tr., pp. 45-47

2. On March 1, 2010, J.H. was a patient at Greenwich Hospital who was scheduled to undergo a right wrist arthroscopy, which required Respondent to administer a nerve block anesthetic to the right superclavicular area. Dept. Exh. 1, pp. 9-37, 107-137 (sealed); Hearing Tr., pp. 50-53.

3. On March 1, 2010, Greenwich Hospital adhered to a universal protocol requiring physicians to take the "Time Out" to correctly identify the patient, the procedure to be done on the patient, and the correct side and site. Dept. Exh. 1, pp. 42, 45-48; Resp. Exh. A; Hearing Tr., p. 51.

4. In practice, the anesthesiologist sets up on the side of the patient opposite to the nurse and the ultrasound. The purpose of this set-up is to allow the anesthesiologist to more easily see the image and to allow the nurse to see what the anesthesiologist is doing. Hearing Tr., p. 50.

5. On March 1, 2010, Respondent met with J.H. in the ambulatory room to obtain anesthesia consent. After obtaining consent, Respondent followed the appropriate

universal "Time Out" protocol, and as required under the protocol, identified J.H., the procedure to be done on J.H., and the correct side and site. J.H. was then moved into the block room. Dept. Exh. 1, p. 13 (sealed); Resp. Exh. A; Hearing Tr., pp. 51, 52.

6. On March 1, 2010, while in the block room, one of Respondent's sterile gloves tore requiring him to leave the room and get a new one. While Respondent was out of the room, the nurse changed sides and moved the ultrasound with her. The nurse set up on the right side of the patient, and upon his return, Respondent complied with universal practice and went to the side opposite the nurse and the ultrasound. Hearing Tr., pp. 50-53.

7. On or about March 1, 2010, J.H. was scheduled to undergo a right wrist arthroscopy, and was prescribed a nerve block anesthetic to the right superclavicular area. Respondent administered a nerve block anesthetic to J.H's left superclavicular area. Board Exh. 2; Dept. Exh. 1, pp. 15 (sealed), 84, 87, 92, 93, 96, 97, 102, 103; Hearing Tr., pp. 50-53.

8. Immediately following the administration of the nerve block anesthetic to J.H's left superclavicular area, Respondent informed J.H. of his error and spoke to the surgeon and J.H.'s husband. Respondent kept J.H. overnight for observation as a precautionary measure. Hearing Tr., pp. 54-57.

IV. DISCUSSION

The Board has jurisdiction over this matter. The "[B]oard is authorized to restrict, suspend, or revoke the license or limit the right to practice of a physician or take any other action in accordance with section 19a-17, for . . . illegal, incompetent or negligent conduct in the practice of medicine." § 20-13c (4) of the Statutes. "[Boards] may conduct hearings on any matter within their statutory jurisdiction. Such hearings shall be conducted in accordance with Chapter 54 and the regulations established by the Commissioner of Public Health." § 19a-10 of the Statutes. Respondent is a licensed physician and the Department has alleged that he has engaged in illegal, incompetent or negligent conduct; thus, the Board has jurisdiction over this matter. Board Exhs. 1, 2.

In this administrative proceeding, the Department bears the burden of proving its case by a preponderance of the evidence. Herman & MacLean v. Huddleston, 459 U.S. 375, 389-90 (1983); Goldstar Medical Services, Inc., et al. v. Department of Social Services, 288 Conn. 790, 821 (2008). [1]

[1] The Board is aware that the Connecticut Supreme Court is reviewing the issue of whether the standard of proof in cases before the Board involving physicians should be the preponderance of evidence standard or the clear and

As discussed below, the Board finds that the Department met its burden of proof with respect to allegations 1 and 2 of the Charges.

Allegation 1 is not in dispute. Respondent admits that he holds a Connecticut license (no. 039155) to practice medicine and surgery. Board Exh. 2.

With respect to allegation 2, Respondent admits that on March 1, 2010, he incorrectly administered a nerve block to J.H.'s left superclavicular side, when he was supposed to administer the nerve block to the J.H.'s right superclavicular side. Board Exh. 2; Hearing Tr., pp. 50-53.The Department, therefore, met its burden of proof as it is undisputed that Respondent administered a nerve block to J.H. on the wrong side. The Board must determine the appropriate remedy.

Respondent contends that "an adverse result, by itself does not constitute grounds for disciplinary action", and asserts that any discipline of his license would go against the principles of a "Just Culture". Board Exh. 2. According to Respondent's expert, Kenneth Sands, MD, a Just Culture is not punitive but instead questions whether the individual made the best human effort to perform as expected or whether the system failed the individual through inadequate training, preparation, or system support. Hearing Tr., p. 105.

It is not disputed that Respondent adhered to the universal protocol of "Time Out" in effect on March 1, 2010 at Greenwich Hospital. The universal protocol at Greenwich Hospital tracked the Joint Commission-approved protocol that was in place nationally, and contained imperfections that Respondent's mistake brought to light. Hearing Tr., pp. 108, 117. In following the universal protocol, Respondent verified J.H.'s name, the procedure, the correct side and site. Dept. Exh. 1, pp. 39, 40. Upon his return to the block room after replacing a ripped glove, Respondent failed to re-engage the Time Out protocol, but according to Greenwich Hospital's protocol at that time, was not required to do so. Board Exh. 2; Resp. Exh. A; Dept. Exh. 1. pp. 39-42; Hearing Tr., pp. 69, 70. Respondent did not mark the procedural site on J.H. on which he was to administer the block, as the marking of a site at Greenwich Hospital at that time was the required practice of surgeons and not allowed by a proceduralist (Hearing Tr., p.

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convincing standard (Charles Ray Jones, M.D. v. Connecticut Medical Examining Board, S.C. 18843). In this particular case involving Respondent, the Board finds that even if the standard of proof was clear and convincing evidence, the Department met its burden with respect to the allegations in paragraphs 1through 3 of the Charges.

59), such as Respondent. Hearing Tr. pp. 58-60. Respondent was in compliance with the universal protocol in place at the time of the error.

Another factor that was key to Respondent's error, as opined by Dr. Sands, was that conventionally in the peri-operative field the ultrasound is positioned opposite the procedure site. Resp. Exh. A. He explained that Respondent engaged a process known as "anchoring," in which after administering several thousands of blocks in his career, he was fixed with interpreting the location of the procedure site in reference to the position of the ultrasound machine. Resp. Exh. A. It is standard practice in situations requiring actions to be taken precisely, accurately and very quickly, for practitioners to adopt the practice of anchoring and react instinctively to practiced visual cues to position themselves accurately and replicate actions without confusion, uncertainty or delay. Hearing Tr., p. 23. Anchoring standardizes actions and eliminates the need for potentially distracting midstream decisions where possible. The technique, although imperfect as revealed by this case, greatly facilitates, and is reasonably relied upon, for prompt and precise repetitive actions. Resp. Exh. A; Hearing Tr., pp. 61, 62. In this case, the location of the ultrasound machine and nurse were the anchor which indicated to Respondent where to position himself. Hearing Tr., p. 112.

Respondent has performed over 10,000 procedures and recalls that for every single procedure he did that involved laterality, the nurse and the ultrasound were always positioned on the side opposite to him. Hearing Tr., p. 62. This claim was further supported by Thomas Bladek, an anesthesiologist from St. Vincent's Hospital, who testified that the nurse and the ultrasound machine are "cues" and that "anesthesia has standardization because during critical times . . . you rely on your natural instinct to do what you've done repetitively to be in a position where you're automatically performing that task because it's been set up for you in that setting." Hearing Tr., pp. 76, 77. Dr. Bladek further testified that changing the position of the ultrasound machine and the position of a person can be disorienting to an anesthesiologist. Hearing Tr., pp. 76, 77. Although standardization and anchoring are utilized in anesthesiology, Respondent's anchoring and his expectation that the standardized set-up of the block room was in place contributed to his administration of the block to the wrong side when the set-up was altered.

The Board also considered the actions that Respondent took subsequent to his discovery that he had administered the anesthetic block to the wrong side. Respondent immediately informed J.H. and the surgeon, and apologized to J.H. Hearing Tr., pp. 55, 56. He took

precautionary measures and kept J.H. overnight in hospital for observation. He was an integral part of revising Greenwich Hospital's Time Out protocols. Hearing Tr., pp. 56, 57. Today, Greenwich Hospital has in place a model Time Out protocol, which is required to occur immediately prior to the insertion of a needle or catheter. It must be repeated by the nurse and physician if the attending physician leaves the patient's bedside for any reason. Dept. Exh. 1, pp. 87, 89; Hearing Tr., pp. 58, 59. Additionally, Greenwich Hospital now requires proceduralists to mark the site, and requires greater specificity as to time and dates relating to each procedure. Hearing Tr., p. 58-60. These actions significantly diminish the likelihood of a wrong site procedure occurring again, and elevates safety in the practice of medicine.

The Board believes Respondent's unfortunate error on March 1, 2010, was mainly a result of anchoring and a flawed protocol system. Respondent was responsible for administering a block to the wrong site. His actions ultimately led to the incident, but there was a systemic flaw in the equipment set-up, and we find there is a difference. For the imposition of a sanction by the Board, an act or omission is necessary, but not in and of itself sufficient justification. Though not specifically applied in this matter, the Board acknowledges that the principle of a Just Culture is befitting circumstances such as this and finds that there is a difference between individual responsibility for an action and culpability for it going wrong.

Respondent has maintained a stellar professional record and was found credible in his testimony. Hearing Tr., pp. 47, 49. Despite what appears to be an isolated incident, the Board weighed the totality of the circumstances that led to Respondent's error, as well as the immediacy and thoroughness with which the systemic deficiencies were addressed with Respondent's assistance. Dept. Exh. 1, pp. 87, 89; Hearing Tr., pp. 58, 59. As such, the Board finds that Respondent does not pose a threat to public health and safety, and that disciplinary action is not warranted.

ORDER

Based upon the record in this case, the above findings of fact and the conclusions of law, and pursuant to the authority vested in it by §§ 19a-17 and 20-13c of the Statutes, the Board finds that the ~~misconduct~~ error alleged is proven, but does not warrant any disciplinary action against the license of Paul Sygall, MD, under this Order.

MAY 21, 2013
Date

Anne C. Doremus
By: Anne C. Doremus, Chairperson

CERTIFICATION

I hereby certify that, pursuant to Connecticut General Statutes § 4-180(c), a copy of the foregoing Memorandum of Decision was sent this 22nd day of May 2013, by certified mail, return receipt requested to:

James Rosenblum, Esq.
Rosenblum Newfield, LLC
1 Landmark Square
Stamford, CT 06901

Certified Mail RRR #91-7199-9991-7032-2704-2210

and via email to:

Matthew Antonetti, Principal Attorney
Legal Office
Department of Public Health
410 Capitol Avenue, MS #12LEG
Hartford, CT 06134-0308

Jeffrey A. Kardys
Administrative Hearings Specialist/Board Liaison
Department of Public Health
Public Health Hearing Office

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
HEALTHCARE QUALITY AND SAFETY BRANCH

In re: Michael Smith, M.D. Petition No. 2021-101

Department's Opposition to Imposition of Lesser Discipline or Alternatively No discipline

On March 8, 2023, respondent filed a brief entitled "Respondent's Brief In Support of Imposition of Lesser Discipline or Alternatively No Discipline" in which respondent argues that the "precedent" established in *Department of Public Health v. Sygall,* Connecticut Medical Examining Board Memorandum of Decision, Petition No. 2010-5766 (May 21, 2013) should apply to this case. The Proposed Decision in the matter before the Medical Board distinguishes *Sygall* on the basis that "the intervening actions of another person contributed to Dr. Sygall's violation whereas, in Respondent's case, the misadministration of Tranexamic acid ("TXA") instead of Bupivacaine to Patient 1 on December 22, 2020 was the direct result of Respondent's negligent conduct…" *See* Proposed Decision, p.4. Respondent argues that because systemic flaws in protocols in Respondent's case occurred in addition to Respondent's error, and because a drug not normally on the anesthesia cart was unexpectedly there, that there was sufficient systemic flaws and intervening acts to support lesser or no discipline than the Proposed Decision imposes, and that the Proposed Decision fails to consider such systemic flaws. The Department argues that despite these arguments, the Proposed Decision should still be adopted by the Connecticut Medical Examining Board for the following reasons.

Tranexamic Acid Was Then Typically on The Medication Cart.

Respondent argues that because a drug not normally on the anesthesia cart was unexpectedly there, this is an intervening act and that *Sygall* should have been considered to apply. In support of this argument, Respondent cites Department Exhibit 2, p. 112. However, Department Exhibit 2, page 112 clearly indicates that TXA was then typically on the anesthesia cart. The exhibit documents the questions that a facility surveyor posed to Respondent following the incident, and includes the question "Normally isn't TXA on cart" with the answer "yes". Department Exhibit 2, p. 112. The only interpretation of this question and answer is to establish that TXA was then normally on the anesthesia cart. Because TXA was then normally on the anesthesia cart, it's presence should not be considered an intervening act.

The Proposed Decision Already Considers Any Systemic Flaws and Intervening Acts.

Respondent argues in part that because systemic flaws in protocols in Respondent's case occurred in addition to Respondent's error, that there was sufficient mitigating circumstances to support lesser or no discipline than the Proposed Decision imposes, and that the Proposed Decision fails to consider such systemic flaws. Respondent then proposed the systemic flaws as (1) the use of very similar vials, (2) the since discontinued use of an automated dispensing system, and (3) the lack of a proactive response to a Federal Drug Administration ("DEA") alert issued shortly before the mistake occurred.

However, the Proposed Decision already considered any and all intervening acts. The

Proposed Decision identifies the DEA's issued alert to the medical community as well as the similarity of the labeling and the hospital's policies and protocols. *See* Proposed Decision, p.3. After identifying these issues, the Proposed Decision finds that "the misadministration of TXA instead of Bupivacaine to Patient 1 on December 22, 2020 was the direct result of Respondent's negligent conduct…" *See* Proposed Decision, p.4. By identifying the cause, the Proposed Decision excludes the other potential causes and alleged intervening acts.

There Were No Systemic Flaws That Contributed to Respondent's Conduct.

Respondent proposed three systemic flaws as being (1) the use of very similar vials, (2) the since discontinued use of an automated dispensing system, and (3) the lack of a proactive response to a DEA alert issued shortly before the mistake occurred. As it pertains to the similar labeling between vials, Respondent acknowledged that in his almost forty-year career, he has never been in this situation before. *See* Proposed Decision, p.3. That is, the vials were distinguishable enough at all other points in his career for this to have not happened in other instances. Additionally, two vials labeled with the same color is not a systemic flaw, as there are only so many colors available that are distinguishable while the number of medications are too numerous to count. It is not possible to make all medications containers uniquely visually dissimilar.

As it pertains to the discontinued use of an automated dispensing system, this system only came into use after this incident occurred and so it's discontinuance cannot have contributed to the error. On top of this, the manner in which the vial came to be on the cart is unrelated to

the later actions of the Respondent once it was there. His error was in failing to read the label; how that label came to be on the cart has no relevance to what he did with it when it was there.

The lack of any implementation of protocol changes by the facility following a DEA alert is also not a systemic flaw. The DEA alert in question alerts "health care professionals", not facilities, of the risk of inadvertent intrathecal administration of TXA, and recommends, among other actions, that such professionals check the container label to ensure the correct product is selected and administered, and that they ensure the labels are visible. *See* Respondent's Exhibit C p. 1. Neither of these actions Respondent undertook when he covered the label with sterile gauze and when he failed to read the label, and neither of these actions are under the direct control of the facility administration.

Even If There Were Systemic Flaws, *Sygall* is Still Distinguishable.

In *Sygall,* a nurse set up equipment and positioned herself incorrectly after a time-out procedure, which cued Dr. Sygall to approach the incorrect side. *Sygall* p 5. It was a mistake of another that impelled the mistake of Dr. Sygall. This is different from the Respondent's case because in Respondent's case there was no intervening act by a third party. There was no cue upon which Respondent relied. It was Respondent who picked up the wrong vial, who then failed to read the label, who then injected its contents into a patient. Even if there were indeed systemic flaws in Respondent's case, *Sygall* is still distinguishable. The lack of intervening acts supersedes any perceived similarities.

Therefore, because the TXA medication was then typically on the medication cart, because the Proposed Decision already considered the possibility of any systemic flaws and intervening acts, because there were no systemic flaws or intervening acts that contributed to Respondent's negligence, and because even if there were systemic flaws, *Sygall* is still distinguishable, the Proposed Decision should still be adopted by the Connecticut Medical Examining Board as written.

Respectfully submitted,

THE DEPARTMENT OF PUBLIC HEALTH

Aden T. Baume
Aden T. Baume, Staff Attorney
Office of Legal Compliance

CERTIFICATION

I certify that on this 8th day of March, 2023, a copy of the foregoing was sent by email to Attorney Michael Kurs (mkurs@pullcom.com) and to Jennifer Zakrzewski (jennifer.zakrzewski@ct.gov), Administrative Hearings Specialist in the Department's Public Health Hearing Office.

Aden T. Baume
Aden T. Baume, Staff Attorney
Office of Legal Compliance