### State Board of Pharmacy April 30, 2024

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# BOARD MEMBERS:

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47 48 49 Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson

Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs Eric Esterbrook, R.Ph., Vice Chairperson Janet Getzey Hart, R.Ph., Secretary John R. Slagle, R.Ph. Tyler Ritchie, Esquire, Deputy Attorney General, Office of Attorney General Theresa M. Talbott, R.Ph.

## BUREAU PERSONNEL:

Carole Clarke Smith, Esquire, Senior Board Counsel Ariel O'Malley, Esquire, Board Counsel Tyesha C. Miley, Esquire, Board Counsel Ray J. Michalowski, Esquire, Senior Board Prosecutor Nathan C. Giunta, Esquire, Board Prosecution Liaison Glenn P. Masser, Esquire, Board Prosecutor Ashley P. Murphy, Esquire, Board Prosecutor Christina Townley, Interim Board Administrator Marc Farrell, Esquire, Regulatory Counsel, Office of Chief Counsel, Department of State Jessica Zukoski, Senior Legal Analyst, Department of State

#### ALSO PRESENT:

Partnerships Leader, Walgreens Alan Portnoy, Director of Inpatient Pharmacy, Tower Health Joseph Millward, Pharmacy Quality and Accreditation, PANTHERx Rare Pharmacy Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State Cory Ulisse, PharmD, Pharmacy Clinician Services Katherine Medei, Area Healthcare Supervisor NJ/PA,

James Reed, Health Outcomes Supervisor/Strategic

Walgreens Grace Sesi, Executive Director, Regulatory Affairs at CVS Health/Chairperson, Michigan Board of Pharmacy Jacquelyn Sassaman, Pentec Health

# State Board of Pharmacy April 30, 2024

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#### ALSO PRESENT: (cont.)

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Christopher Miller, Pharm.D., Giant Eagle Angela Morelli, PharmD, BCPS, BCIDP, Allegheny Health Network

Timothy Kaylor, Regional Pharmacy Manager, The GIANT Company

Susan DelMonico, R.Ph., JD

13 | Heather Wilson

Geoffrey Christ, Senior Pharmacy Compliance Manager, Chewy Pharmacy

Joshua Finger, Pharm.D., Enclara Pharmacia

Laura Lenart, Pharm.D., Pharmacist Supervisor, Vetsource

David Klinger, RPh, Director of Pharmacy, Geisinger Medical Center

Charlotte Harris, Pharmacy Intern, Duquesne University Misha Patel, M.D., Curriculum Education Assistant, Geisinger Commonwealth School of Medicine

Rhonda Thomas, PharmD, MBA, BSPS, BCSCP, Director of Pharmacy, Lehigh Valley Health Network

Matthew Roesch, R.Ph., Pharmacist-in-Charge, Vetsource Pharmacy

Meghan Dixon, PharmD, RPh, Clinical Pharmacy Specialist, The GIANT Company

Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health Victoria Elliott, RPh, MBA, CAE, Chief Executive

Officer, Pennsylvania Pharmacists Association

34 Valerie Pentland, PharmD, ConnectiveRx

Judy Kutchman, R.Ph., AllianceRx Walgreens Prime

Sean Marks, Pharmacy Technician, Kerr Drug

37 Edward Foote, Pharm.D., FCCP, BCPS, Dean,

Philadelphia College of Pharmacy at the University of Sciences

Patrick Lavella, R.Ph., President, Pennsylvania Pharmacist Association

Tiffany Booher, MA, LPC, CAADC, CIP, CCSM, Director, Peer Assistance Monitoring Programs; Program Director, Physicians' Health Program, Pennsylvania Medical Society

Medical Society
Larry Jones, Executive Director, Pennsylvania
Society of Health-System Pharmacists

Jill Rebuck, Pennsylvania Society of Health-System
Pharmacists

Jessica Adams

1

2 State Board of Pharmacy

April 30, 2024

\* \* \*

5 | [Pursuant to Section 708(a)(5) of the Sunshine Act,

6 at 9:00 a.m., the Board entered into Executive

7 | Session with Ariel E. O'Malley, Esquire, Board

8 | Counsel, for the purpose of conducting quasi-judicial

9 deliberations and to receive the advice of Board

10 Counsel. The Board returned to open session at

11 10:30 a.m.]

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13 The regularly scheduled meeting of the State

14 Board of Pharmacy was held on Tuesday, April 30,

15 2024. Christine Roussel, Pharm.D., BCOP, BCSCP,

16 Chairperson, called the meeting to order at

17 10:30 a.m.

18

19 Introduction of the Board Members

20 [Chair Roussel requested an introduction of Board

21 members. She also reminded everyone to turn off

22 their cell phones.

23 Chair Roussel also noted the meeting was being

24 recorded, and those who continued to participate were

25 giving their consent to be recorded.]

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                               * * *
1
2
   Introduction of Attendees
3
   [Christina Townley, Board Administrator, provided an
   introduction of attendees.]
4
                               * * *
5
6
   Approval of the Agenda
7
   CHAIRPERSON ROUSSEL:
8
                 Do I have a motion related to the agenda?
9
   MS. TALBOTT:
10
                 I'll make a motion that we approve the
11
                 agenda as presented.
12
   CHAIRPERSON ROUSSEL:
13
                 Second?
14
   MR. RITCHIE:
15
                 Second.
16
   CHAIRPERSON ROUSSEL:
17
                 Call the vote.
18
19
                 Esterbrook, aye; Slagle, aye; Ritchie,
20
                 aye; Talbott, aye; Claggett, aye; Hart,
21
                 aye.
22
   [The motion carried. Christine Roussel did not vote
23
   on the motion.]
24
25
   Approval of Minutes
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1
   CHAIRPERSON ROUSSEL:
2
                 Do we have a motion or corrections,
3
                 anything related to the meeting minutes
 4
                 from March 19, 2024?
5
   MR. ESTERBROOK:
6
                 Motion to approve the minutes.
7
   MS. TALBOTT:
8
                 Second.
9
   CHAIRPERSON ROUSSEL:
10
                 Let's call the vote. No amendments.
11
                 Motion to approve as is.
12
13
                 Esterbrook, aye; Slagle, aye; Ritchie,
14
                 aye; Talbott, aye; Claggett, aye;
15
                 Roussel, aye; Hart, aye.
16
   [The motion carried unanimously.]
17
18
   [Chair Roussel noted the Board of Pharmacy met in
19
   Executive Session to seek legal advice and conduct
20
   quasi-judicial deliberations.]
                              * * *
21
   Report of Board Prosecution
22
23
   [Glenn P. Masser, Esquire, Board Prosecutor,
24
   presented the Consent Agreement for Case No. 22-54-
25
   006636.
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1
        Chair Roussel thanked Mr. Masser for protecting
2
   the business of the Commonwealth and being a strong
3
   supporter of their profession.
        Mr. Masser informed Board members that he is
 4
5
   going to the Department of Environmental Protection
   and thanked the Board for everything over the years.]
6
                              * * *
7
8
   [Nathan C. Giunta, Esquire, Board Prosecution
   Liaison, presented the Consent Agreement for Case No.
10
   22-54-009969.1
                              * * *
11
12
   [Janet Getzey Hart, R.Ph., Secretary, exited the
   meeting for recusal purposes at 10:39 a.m.]
13
                              * * *
14
15
   [Nathan C. Giunta, Esquire, Board Prosecution
16
   Liaison, presented the Consent Agreement for Case No.
17
   23-54-014033.1
                              * * *
18
19
   [Janet Getzey Hart, R.Ph., Secretary, reentered the
20
   meeting at 10:41 a.m.]
                              * * *
21
22
   [Ray J. Michalowski, Esquire, Senior Board
23
   Prosecutor, presented the Consent Agreement for Case
   No. 24-54-003048.
24
25
        Chair Roussel referred to prior Board discussion
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regarding the Board receiving the updated copy of the inspection form being used for sterile compounding inspections and refreshing it because of the new United States Pharmacopeia (USP) standards that went into effect November 1, 2023.

Mr. Michalowski informed Board members that the form could be obtained through Board Counsel. He explained that directed inspections are the prosecution division's responsibility but routine inspections are the Board's purview.

Mr. Michalowski could share the results, but the results are the same as their pharmacy and just the resulting checklist. He stated there are also checklists, where behind each one of those questions are other questions that have to be answered, and the final answer will be yes, no, or N/A depending on the answer.

Mr. Michalowski works with the inspectors, but this would have to go through the Bureau of Enforcement and Investigation (BEI) because the inspectors handle all of the inspections and would be able to share those checklists.

Mr. Michalowski stated there were not many pharmacies anymore with the surveys from the Department of Health, because all of the hospital

systems are merging with smaller hospitals. He
mentioned 10 to 12 used to be received per month, but
now almost all are exempt from inspection or survey
by the Department of Health because the hospitals are
accredited.

Mr. Michalowski explained that all of their facilities have to be accredited if they want their entire system accredited and is handled at a higher standard. He now receives only one a month from one or two very small hospitals throughout the state.

Mr. Michalowski mentioned that it is a legislative issue, but something the Board may want to revisit because the questionnaires are also rather out of date. He noted the Pennsylvania Society of Health-System Pharmacists (PSHP) offered to assist with those forms. He stated the forms are generated by the Department of Health, noting a pharmacist does that survey. He believed the system should be modernized, not just on their side of inspections but also on the hospital side.

Chair Roussel asked whether the inspectors should be inspecting the hospitals.

Mr. Michalowski explained that it was out of their power because it is at the legislative level. He noted that the other hospitals are inspected by

the Joint Commission on Accreditation of Healthcare
Organizations (JCAHO) or another accrediting agency
and are being inspected at a much higher level than
the few being inspected by the Department of Health
(DOH).

Mr. Michalowski commented that it would make more sense that anybody who does not qualify for accreditation should fall back into the Board of Pharmacy to make sure those individuals are getting the same level of attention to detail and standards that are equal to those in retail and other pharmacy community.

Chair Roussel commented that accreditation bodies do considerate gestures that definitely are outside the scope of the Board of Pharmacy in terms of quality but are not looking for the same specific things as state inspectors regarding state laws. She believed there was some value in having Board of Pharmacy inspectors for their state.

Mr. Michalowski explained that the ones done by the Department of Health are uploaded into the Pennsylvania Licensing System (PALS) State Board of Pharmacy records. He noted the Board does not receive a copy when the inspection is done by an accrediting agency because the Department of Health

signs off and approves it.

Chair Roussel noted it to be interesting that The Joint Commission, when they have pharmacy citations, have medication management standards, but if it is physical things, such as something under the Food and Drug Administration (FDA) and sanitary conditions for compounding, they will actually show up under infection control and not under the pharmacy.

Chair Roussel mentioned that a lot of the physical things that would otherwise be picked up by an inspector would be infection control issues and would not be seen under the pharmacy inspection. She noted it makes it a little more difficult to tease out and find it, noting most of the medication management citations are related to processes for orders to make sure orders are clear, along with other things that would not be Board of Pharmacy stuff.

Mr. Michalowski referred to prior discussion concerning ways to handle compounding cases. He noted the the Department of Health always asks for a letter of corrective action and prosecution often asks for mitigation.

Mr. Michalowski discussed prosecution possibly asking individuals to submit something like that,

especially in some of their practice cases. He
mentioned not having the form but noted hospitals and
pharmacies are used to doing that. He noted maybe
discussing the matter further as a group as public
guidance, where individuals could be held accountable

Mr. Michalowski stated the change could be done informally, noting they are already getting the letter of mitigation in some cases but believed consistency is important.]

11 \*\*\*

again.

Report of Board Counsel - Regulatory Report

[Ariel E. O'Malley, Esquire, Board Counsel, had

nothing new to report but informed Board members that

the Independent Regulatory Review Commission (IRRC)

comments are due back sometime this week for the

pharmacy technician regulation.

Ms. O'Malley noted she will be preparing comments and proposed responses for all of the comments received from the public and IRRC and any suggested amendments to the annex for the next Board meeting.]

\* \* \*

Report of Board Counsel - Legislative Report

[Ariel E. O'Malley, Esquire, Board Counsel, informed

Board members that House Bill 1295 has passed and is

now Act 5 of 2024. She stated it allows for the submission of written impact statements to be used in Board hearings and also sets up the procedure of how hearings are already being conducted.

Ms. O'Malley referred to House Bill 1993, which would amend the Pharmacy Audit Integrity and Transparency Act, also known as the Community Pharmacy Protection Act, which was introduced and referred to Health and Human Services on April 3, 2024.

Mr. Slagle commented that over 200 pharmacies have gone out of business in the last six months and it is becoming an issue. He noted 11 Mainline Pharmacies closed, and people cannot afford to drive over 100 miles to get a \$5 prescription. He mentioned that he is trying to get people to back House Bill 1993 to get through the legislative process.

Ms. O'Malley explained that House Bill 1993 kind of prohibits some of the practices that are going on with pharmacy benefit managers (PBMs) and sets up a practice with the Insurance Department to develop a process for hearing and resolving pharmacy complaints against PBMs. She mentioned that House Bill 1993 has a lot of similarities to Senate Bill 1000, which have

- both been introduced. She mentioned there have been
  a lot of complaints with some of the smaller
  pharmacies being pushed out of the market and is
  hoping that something will happen with the regulation
  of PBMs to make some adjustments.
  - Chair Roussel commented that patients need to find care elsewhere when pharmacies close and noted the importance of relationships between pharmacists and patients.

- Victoria Elliott, RPh, MBA, CAE, Chief Executive Officer, Pennsylvania Pharmacists Association, sent a message noting Mainline Pharmacy closed 9 of 11 pharmacies, along with sending a website and some links. She also provided a link for more information regarding House Bill 1993 and companion Senate Bill 1000.
- Ms. O'Malley noted House Bill 2178 was also introduced on April 3 requiring each person applying for a license to complete training regarding implicit bias and cultural competence in accordance with continuing education requirements.
- Chair Roussel commented that the training would be for everyone and is part of the continuing education (CE). She mentioned that all will soon have to have the required training and not any

options, noting one third of continuing education will be mandated.

Chair Roussel mentioned that it might be a nice time for professional organizations to remind people to get the child abuse CE done because sometimes there is a lack of certain child abuse vendors.

7 Ms. Talbott suggested including the reminder in 8 the newsletter.

Ms. O'Malley informed Board members that she is taking a position with the Department of General Services and this would be her last meeting.

Chair Roussel thanked Ms. O'Malley for all of her help with the first half of the regulations.

14

15 Report of Board Chair

16 | [Christine Roussel, Pharm.D., BCOP, BCSCP,

17 | Chairperson, acknowledged this was Ms. Talbott's last

18 official meeting and noted her to be the most amazing

19 representative concerning regulations outside of

20 their state and bringing perspectives from all over.

21 She welcomed Ms. Talbott to continue to attend the

22 meetings.

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23 Chair Roussel stated there was a beautiful letter 24 submitted on behalf of the Board to get Ms. Talbott 25 the National Association of Boards of Pharmacy's (NABP) Honorary President Award.

Chair Roussel announced that Board members would be attending NABP's Annual Meeting next month. She noted their goals are to network with colleagues and learn about best practices in other states to do their best job to protect public health. She encouraged everyone to feel free to talk to the Board about matters for the Board to inquire about that other states do and offer ways that they can improve.

Chair Roussel welcomed everyone to provide any recommendations for the newsletter. She noted Ms. Talbott and Ms. Townley will be meeting to work on the newsletter. She mentioned that some of the Board's ideas were updates for controlled substances and the new compounding regulation, along with maybe mentioning the applicable federal regulations related to compounding.]

\* \* \*

[Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs, informed Board members that licensees will be able to print their own license on May 31 from their own dashboard. He noted the staff will still print and mail licenses to licensees who apply while still in PALS.]

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   Report of Board Administrator - No Report
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   Report of Board Members - No Report
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   MOTIONS
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   CHAIRPERSON ROUSSEL:
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                At this point, I would like to announce
                 that the Board had met in Executive
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9
                Session to receive legal advice and
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                engage in quasi-judicial deliberations.
                     At this time, I welcome any motions
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12
                 related to the agenda items for today.
13
   MR. ESTERBROOK:
14
                Motion to approve the Consent Agreement
15
                for Case No. 22-54-006636.
   MR. RITCHIE:
16
17
                Second.
18
   CHAIRPERSON ROUSSEL:
19
                Any discussion? Let's call the vote.
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21
                Esterbrook, aye; Slagle, aye; Ritchie,
22
                aye; Talbott, aye; Claggett, aye;
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                Roussel, aye; Hart, aye.
24
   [The motion carried unanimously. The Respondent's
25
   name is Sofie Co.]
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19 \* \* \* 1 2 MR. ESTERBROOK: 3 I make a motion to approve the Consent 4 Agreement for Case No. 23-54-014033. MR. RITCHIE: 5 6 Second. 7 CHAIRPERSON ROUSSEL: 8 Any discussion? No discussion. We will 9 call the vote. 10 11 Esterbrook, aye; Slagle, aye; Ritchie, 12 aye; Talbott, aye; Claggett, aye; 13 Roussel, aye; Hart, recuse. [The motion carried. Janet Getzey Hart recused 14 15 herself from deliberations and voting on the motion. 16 The Respondent's name is Susan Gayle Olevnik, R.Ph.] 17 18 MR. ESTERBROOK: 19 I make a motion to approve the Consent 20 Agreement for Case No. 22-54-009969. 21 MR. RITCHIE: 22 Second. 23 CHAIRPERSON ROUSSEL: 24 Any discussion? We shall call the vote. 25

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1
                 Esterbrook, aye; Slagle, aye; Ritchie,
2
                 aye; Talbott, aye; Claggett, aye;
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                 Roussel, aye; Hart, aye.
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   [The motion carried unanimously. The Respondent's
5
   name is Castleton Pharmacy Corp.]
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6
7
   MR. ESTERBROOK:
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                 I make a motion to approve the Consent
9
                 Agreement for Case No. 24-54-003048.
10
   MR. RITCHIE:
11
                 Second.
12
   CHAIRPERSON ROUSSEL:
13
                 Any discussion? We will call the vote.
14
15
                 Esterbrook, aye; Slagle, aye; Ritchie,
16
                 aye; Talbott, aye; Claggett, aye;
17
                 Roussel, aye; Hart, aye.
18
    [The motion carried unanimously.]
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19
20
   MR. ESTERBROOK:
21
                 I have a motion to have Board Counsel
22
                 draft an Adjudication as discussed in
23
                 Executive Session for Ihsanullah Maaf
                 Case No. 23-54-016668.
24
25
   MR. RITCHIE:
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21 Second. 1 2 CHAIRPERSON ROUSSEL: 3 Any discussion? We will call the vote. 4 5 Esterbrook, aye; Slagle, aye; Ritchie, 6 aye; Talbott, aye; Claggett, aye; 7 Roussel, aye; Hart, aye. [The motion carried unanimously.] 8 9 10 MR. ESTERBROOK: 11 I have a motion in the matter of Brandon 12 Kipp Pope. I make a motion to grant 13 settlement authority to Board Counsel as 14 discussed in Executive Session. 15 MR. RITCHIE: 16 Second. CHAIRPERSON ROUSSEL: 17 18 Any discussion? 19 20 Esterbrook, aye; Slagle, aye; Ritchie, 21 aye; Talbott, aye; Claggett, aye; 22 Roussel, aye; Hart, aye. 23 [The motion carried unanimously.] 24 25 Review of Applications

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22
   MR. ESTERBROOK:
1
2
                 I have a motion to grant the Pharmacist
3
                 by Exam Application upon completion of
 4
                 the review course for Aliya Naz.
5
   MR. RITCHIE:
                 Second.
6
7
   CHAIRPERSON ROUSSEL:
8
                 Any discussion? We will call the vote.
9
10
                 Esterbrook, aye; Slagle, aye; Ritchie,
11
                 aye; Talbott, aye; Claggett, aye;
12
                 Roussel, aye; Hart, aye.
13
    [The motion carried unanimously.]
                              * * *
14
15
   MR. ESTERBROOK:
16
                 I have a motion to deny a request for
17
                 acceptance of Authorization to Administer
18
                 Injectables training of Crista Michelle
19
                 Drayton.
20
   MR. RITCHIE:
21
                 Second.
22
   CHAIRPERSON ROUSSEL:
23
                 Any discussion?
                                   We will call the vote.
24
25
                 Esterbrook, aye; Slagle, aye; Ritchie,
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23 1 aye; Talbott, aye; Claggett, aye; 2 Roussel, aye; Hart, aye. 3 [The motion carried unanimously.] 4 5 MR. ESTERBROOK: 6 I have a motion to accept the request for 7 acceptance of Authorization to Administer 8 Injectables training of Nirnay Patel. 9 MR. RITCHIE: 10 Second. 11 CHAIRPERSON ROUSSEL: 12 Any discussion? Call the vote. 13 14 Esterbrook, aye; Slagle, aye; Ritchie, 15 aye; Talbott, aye; Claggett, aye; 16 Roussel, aye; Hart, aye. [The motion carried unanimously.] 17 \* \* \* 18 MR. ESTERBROOK: 19 20 I have a motion to provisionally deny the 21 Application for New Solutions Functional 22 Wellness Pharmacy - Nonresident Pharmacy. 23 MR. RITCHIE: 24 Second. 25 CHAIRPERSON ROUSSEL:

\* \* \*

Any discussion? Call the vote.

2

3 Esterbrook, aye; Slagle, aye; Ritchie,

4 aye; Talbott, aye; Claggett, aye;

5 Roussel, aye; Hart, aye.

Old Business - Newsletter Articles

6 [The motion carried unanimously.]

7

8

9 [Christine Roussel, Pharm.D., BCOP, BCSCP,

10 Chairperson, mentioned that the Board already

11 discussed the newsletter.]

12 \*\*\*

13 Upcoming Meeting Dates

14 [Christine Roussel, Pharm.D., BCOP, BCSCP,

15 Chairperson, noted the next State Board of Pharmacy

\* \* \*

16 Meeting is scheduled for June 18, 2024.]

17

18 Public Comment

19 [Ariel E. O'Malley, Esquire, Board Counsel, thanked

20 Mr. Esterbrook for attending the Pennsylvania

21 | Pharmacists Association Pharmacy Legislative Day and

22 | speaking with students.

Chair Roussel also thanked Ms. O'Malley for

24 working so hard for the Board and wished her luck on

25 her next initiative.

1 Ms. Talbott thanked everyone and noted being 2 blessed to have had an impact on the profession.

3 Larry Jones, Executive Director, Pennsylvania 4 Society of Health-System Pharmacists, thanked Ms.

5 Talbott for her approach to getting things done. He

6 also wished Ms. O'Malley good luck and thanked Mr.

7 Masser and Ms. Clarke Smith on behalf of PSHP.

Chair Roussel asked whether the October 22 Board meeting at the Philadelphia College of Pharmacy has been finalized.

11 Ms. Townley noted they are still working on 12 having that meeting in Philadelphia.]

13

14 | Adjournment

8

10

24

15 CHAIRPERSON ROUSSEL:

Does anybody want to make a motion to

17 adjourn?

18 MR. ESTERBROOK:

Motion to close.

20 MR. RITCHIE:

21 Second.

22 CHAIR ROUSSEL:

23 All in favor? Meeting is adjourned.

\* \*

25 [There being no further business, the State Board of

Pharmacy Meeting adjourned at 11:11 a.m.] CERTIFICATE I hereby certify that the foregoing summary minutes of the State Board of Pharmacy meeting, was reduced to writing by me or under my supervision, and that the minutes accurately summarize the substance of the State Board of Pharmacy meeting. Autumn Karper, Minute Clerk Sargent's Court Reporting Service, Inc. 

		27
123456789011231456789012322222222333333333333333333333333333		27 STATE BOARD OF PHARMACY REFERENCE INDEX
		April 30, 2024
	TIME	AGENDA
	9:00 10:30	Executive Session Return to Open Session
	10:30	Official Call to Order
	10:30	Introduction of Board Members/Attendees
	10:33	Approval of Agenda
	10:34	Approval of Minutes
	10:35	Report of Board Prosecution
	10:50	Report of Board Counsel
	10:58	Report of Board Chairperson
	11:01	Report of Acting Commissioner
	11:03	Motions
	11:06	Review of Applications
	11:08	Upcoming Meeting Dates
	11:08	Public Comment
	11:11	Adjournment
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40 41		
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