# State Board of Pharmacy

## June 4, 2019

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### BOARD MEMBERS:

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10 11 Robert B. Frankil, R.Ph., Vice Chairman 12 13

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Gayle A. Cotchen, Pharm.D./MBA, R.Ph. Patrick M. Greene, Esquire, Office of Attorney General

Kalonji Johnson, Acting Commissioner, Bureau of Professional and Occupational Affairs

Terry M. Talbott, R.Ph., Chairperson

Janet Getzey Hart, R.Ph., Secretary

# BUREAU PERSONNEL:

Kerry E. Maloney, Esquire, Board Counsel Ray Michalowski, Esquire, Board Prosecution Liaison Monty J. Batson, Esquire, Board Prosecutor J. Karl Geschwindt, Esquire, Board Prosecutor Alissa Harrison, Esquire, Board Prosecutor Tara J. Smith, Esquire, Board Prosecutor Angela B. Lucci, Esquire, Board Prosecutor Caroline A. Bailey, Esquire, Board Prosecutor Glenn P. Masser, Esquire, Board Prosecutor Steven A. Mimm, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Executive Secretary

### ALSO PRESENT:

Patricia A. Epple, CAE, Pennsylvania Pharmacists Association Carl Harting, CVS Health Bill Maguire, Pharmacy Consultant, Omnicell

Lauren Paul, CVS Health

Frank Trollo, Central Admixture Pharmacy Services James Reed, Area Healthcare Supervisor, Walgreens David Klinger, System Director, Operations &

Compliance, Geisinger Health System John Loxterman, Enclara Pharmacia

Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists

Jacquelyn Sassaman, Pentec Health Jenna L. McCarthy, Malady & Wooten

# State Board of Pharmacy

June 4, 2019

ALSO PRESENT: (cont.)

Teresa Moore, Secundum Artem Reaching Pharmacists with Help Nurse Peer Assistance Program Robert Grobinski, Cardinal Health

Christine Roussel, Pharm.D., BCOP, Pennsylvania Society of Health-System Pharmacists, Doylestown Hospital

 Gregory Smith, Director of Pharmacy, Central Admixture Pharmacy Services

 Lawrence Carey, Pennsylvania Society of Health-System Pharmacists

Andrew C. Harvan, Esquire, Pennsylvania Medical Society

John Sisto, Express Scripts, Incorporated Tiffany Walter, Western New England University

Sargent's Court Reporting Service, Inc. (814) 536-8908

\* \* \* 1 2 State Board of Pharmacy 3 June 4, 2019 \* \* \* 4 5 The regularly scheduled meeting of the State 6 Board of Pharmacy was held on Tuesday, June 4, 2019. Terry Talbott, R.Ph., Chairperson, called the meeting to order at 8:59 a.m. Kalonji Johnson, Acting Commissioner, Bureau of Professional and Occupational 10 Affairs, was not present at the commencement of the 11 meeting. 12 The Pledge of Allegiance was recited. \* \* \* 13 14 Introduction of Board Members, Board Staff, and 15 Audience [Chairperson Talbott requested the introduction of 16 17 Board Members, Board staff, and audience members.] \* \* \* 18 [Kalonji Johnson, Acting Commissioner, Bureau of 19 20 Professional and Occupational Affairs, entered the 21 meeting at 9:00 a.m.] \* \* \* 22 23 [Chairperson Talbott requested that all cell phones be 2.4 turned off. 25 \* \* \*

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   Evacuation Announcement
1
   [Melanie Zimmerman, R.Ph., Executive Secretary,
2
3
   reviewed the emergency evacuation procedures for One
4
   Penn Center.]
                              * * *
5
6
   Approval of Agenda
   CHAIRPERSON TALBOTT:
                 I ask for a motion to approve the agenda.
9
                 Are there any additions to the agenda?
10
   DR. COTCHEN:
11
                 So moved.
12
   CHAIRPERSON TALBOTT:
13
                 Okay. Second?
   MS. HART:
14
15
                 Second.
16
   CHAIRPERSON TALBOTT:
17
                 Any discussion on the agenda? Motion to
18
                 approve? All in favor? Any opposed?
19
   [The motion carried unanimously.]
                              * * *
20
21
   Approval of minutes of the April 16, 2019 meeting
22
   CHAIRPERSON TALBOTT:
2.3
                 We will move on to the minutes from
24
                 April.
25
   DR. COTCHEN:
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6
1
                 I move that we approve the minutes from
2
                 April.
   CHAIRPERSON TALBOTT:
3
 4
                 Thank you.
5
   MS. HART:
6
                 Second.
7
   CHAIRPERSON TALBOTT:
8
                 Any discussion on the minutes? All in
9
                 favor?
                        Any opposed?
10
   [The motion carried unanimously.]
                              * * *
11
12
   Report of Prosecutorial Division
13
   [Monty J. Batson, Esquire, Board Prosecutor, presented
14
   the Consent Agreement for File No. 15-54-07398.]
15
16
   [J. Karl Geschwindt, Esquire, Board Prosecutor,
17
   presented the Consent Agreement for File No. 18-54-
18
   005617.1
                              * * *
19
   [Alissa Harrison, Esquire, Board Prosecutor, presented
20
   the Consent Agreements for File No. 16-54-08283, 17-
21
22
   54-03637, 14-54-04260, 17-54-11569, 17-54-07163, 16-
23
   54-14929, 17-54-11568 & 17-54-08037.]
2.4
25
   [Tara J. Smith, Esquire, Board Prosecutor, presented
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1 the Consent Agreement for File No. 18-54-012188.]

\*

[Ray Michalowski, Esquire, Board Prosecution Liaison, on behalf of Heather J. McCarthy, presented the Consent Agreement for VRP File No. 19-54-003471.

Mr. Michalowski addressed reorganization of prosecution teams. He noted five groups, where the Pharmacy Board was moved back to his team which includes the boards with inspection authority.

Caroline Bailey, Glenn Masser, Steve Mann and Angela

Lucci will be prosecutors for the Pharmacy Board.

Dr. Cotchen questioned whether licensees will be able to see what the inspection form will look like because of the new regulations and the United States Pharmacopeia (USP) revising the general chapters.

Mr. Michalowski explained that Board of
Pharmacy's compounding regulations are out for final
approval but are not in effect yet. He noted that the
Bureau of Enforcement and Investigation will be
developing the inspection forms. Mr. Michalowski
also mentioned that he will be speaking with Jaime
Black, who is an attorney for the Department of
Health, about the surveys for hospital pharmacies
regarding updating hospital inspection forms.]

\* \* \*

- 1 Report of Board Counsel
- 2 [Kerry E. Maloney, Esquire, Board Counsel, stated the
- 3 compounding regulation was approved by the Independent
- 4 Regulatory Review Commission (IRRC) and submitted to
- 5 the Office of Attorney General for review. The
- 6 regulation will go back to the Office of General
- 7 | Counsel (OGC) for publication and will go into effect
- 8 once published in the Pennsylvania Bulletin.
- 9 Mr. Maloney stated the General Revisions had not
- 10 been published for exposure yet but is expecting those
- 11 to be sent out to stakeholders for comments within a
- 12 week.
- Dr. Cotchen expressed her concern that new
- 14 inspection questions related to the compounding
- 15 regulations have not been provided to licensees.
- 16 Mr. Maloney noted that BEI has not finalized a
- 17 | new inspection form based on the pending compounding
- 18 regulations. He stated the public would be made aware
- 19 of the inspection questions once they are determined.
- 20 Chairperson Talbott suggested placing the
- 21 questions on the Board's website and having Pat Epple
- 22 and Steve Sheaffer send an email blast to their
- 23 | associations' members.]
- 2.4
- 25 Report of Board Chairperson

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1 [Terry M. Talbott, R.Ph., Chairperson, commented that
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- 2 | she and Janet Hart attended the National Association
- 3 of Boards of Pharmacy's (NABP's) Annual Meeting in
- 4 Minneapolis. Ms. Talbott reviewed NABP's election
- 5 results.
- 6 Ms. Talbott noted discussion concerning artificial
- 7 | intelligence and how to use technology so pharmacists
- 8 can have a more personal touch with patients instead
- 9 of handling nonclinical work, noting that regulations
- 10 could allow for such things.
- 11 Ms. Hart noted that it was the first time a
- 12 certified pharmacy technician ran for a position on
- 13 the NABP Executive Committee.
- 14 Ms. Hart provided information regarding 12
- 15 resolutions discussed at the meeting.
- 16 \*\*\*
- 17 Report of Probable Cause Screening Committee No
- 18 Report
- 19 \*\*\*
- 20 Report of Acting Commissioner
- 21 [Kalonji Johnson, Acting Commissioner, Bureau of
- 22 | Professional and Occupational Affairs, noted his
- 23 recent approval of articles for the newsletter. The
- 24 newsletter should be sent out shortly.
- 25 Acting Commissioner Johnson commented that the

Senate Professional Licensure Committee would soon be meeting and sending to the floor several bills that include the endorsement bill, where boards would be required to endorse candidates for licensure for those

applicants from other states absent of discipline on

6 their license or criminal conviction.

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2.0

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Acting Commissioner Johnson addressed Board Member vacancies and will be speaking with Steve Latanishen later today in terms of new member nominations.

Mr. Maloney noted that House Bill 770 regarding pharmacy technicians is sitting in the Senate Committee on Consumer Protection and Professional Licensure and has not moved.

Mr. Maloney explained HB 1172 regarding license endorsement is for individuals in good standing and who have no discipline in another state who would seek licensure in Pennsylvania.

Chairperson Talbott mentioned a bill percolating in New York that would allow reciprocity for immunization authority.]

22 \*\*\*

23 Report of Executive Secretary

24 [Melanie Zimmerman, R.Ph., Executive Secretary, had no

25 report and noted that the applications would be

1 discussed during executive session.]

2

3 New Business - Pennsylvania Pharmacists Association

4 MPJE Prep & Review

5 | [Melanie Zimmerman, R.Ph., Executive Secretary, noted

6 | an applicant's request for the Board to consider the

7 | Pennsylvania Pharmacists Association Multistate

8 | Pharmacy Jurisprudence Examination (MPJE) Prep &

9 Review as an option when an applicant fails the PA

10 MPJE three or more times. Discussion will be held

11 during executive session.

12 Ms. Zimmerman referred to the invitation to

13 provide a presentation at the Pennsylvania Pharmacists

14 Association's 2019 Annual Conference on September 21,

15 2019 at Seven Springs.]

16

17 MS. HART:

I make a motion to approve Gayle, Kerry,

and a BEI representative to attend to

give a presentation.

21 CHAIRPERSON TALBOTT:

22 (BEI representative) To be named.

23 MR. FRANKIL:

I will second that motion.

25 CHAIRPERSON TALBOTT:

12 Any other discussion? All in favor? 1 Any 2 opposed? 3 [The motion carried unanimously.] \* \* \* 4 5 New Business - (cont.) 6 [Melanie Zimmerman, R.Ph., Executive Secretary, referred to the NABP Interactive Compliance Officer and Legal Counsel Forum December 4-5, 2019. Ms. Zimmerman was asked to attend the Interactive 10 Executive Officer Forum October 1-2, 2019. 11 Mr. Maloney was asked to attend the Interactive Compliance Officer and Legal Counsel Forum December 4-12 5, 2019. 13 \* \* \* 14 15 CHAIRPERSON TALBOTT: 16 We would need a motion to send both of 17 those. DR. COTCHEN: 18 19 So moved. 20 CHAIRPERSON TALBOTT: 21 The motion is to send Melanie if she is 22 approved in October and Kerry in 23 December. 2.4 MR. JOHNSON: 25 Second.

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13
1
   CHAIRPERSON TALBOTT:
2
                 Any other discussion? All in favor?
3
                 opposed?
4
    [The motion carried unanimously.]
                               * * *
5
   New Business - (cont.)
6
   [Melanie Zimmerman, R.Ph., Executive Secretary,
   referred to the 2019 Tri-Regulator Symposium September
   26-27, 2019 in Frisco, Texas.]
                               * * *
10
11
   DR. COTCHEN:
12
                 I make a motion that we send Janet to the
13
                 Tri-Regulator Symposium in Texas.
14
   MR. JOHNSON:
15
                 Second.
16
   CHAIRPERSON TALBOTT:
17
                 Any other discussion? All in favor?
                                                         Any
18
                 opposed?
19
   [The motion carried unanimously.]
20
                               * * *
21
   New Business - (cont.)
22
   [Melanie Zimmerman, R.Ph., Executive Secretary,
23
   referred to the NABP/AACP District 1 & 2 meeting to be
24
   held September 19-21, 2019 in Burlington, VT.
25
        Chairperson Talbott requested approval for
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14
   staying at the hotel due to the distance of other
1
2
   hotels.
3
        Chairperson Talbott will be attending the meeting
4
   through her job. Ms. Hart volunteered to attend the
5
   meeting on behalf of the Board.]
                              * * *
6
7
   DR. COTCHEN:
                I make a motion that we send Janet as the
9
                delegate to the District 1 & 2 meeting
                and Terry will be the alternate.
10
11
   MR. FRANKIL:
12
                I second.
   CHAIRPERSON TALBOTT:
1.3
14
                Any other discussion?
                                        All in favor?
15
   [The motion carried unanimously.]
16
17
   Old Business - Pharmacist Workload and Patient Safety
18
      Concerns
19
   [Robert B. Frankil, R.Ph., Vice Chairman, addressed
20
   earlier complaints from pharmacists concerning
21
   workload and how this relates to public safety.
2.2
   Frankil referred to The Pharmacist Activist newsletter
23
   by Dr. Dan Hussar, specifically looking at some of the
24
   chain pharmacies and their demands on performance and
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workload. He stated this is a concern of the

1 independent pharmacy world as well.

2.1

Mr. Frankil noted that many states have something that addresses this in the regulations, such as ratios for technicians to pharmacists, noting that Pennsylvania does not have a real definition of technician because a law granting authority to the Board to register pharmacy technicians has not been passed.

Chairperson Talbott commented that one of the NABP resolutions that passed was a study to look at workload and suggested a subcommittee, noting that she does not want to duplicate efforts going on at a national level.

Mr. Maloney provided an overview of the regulation process and suggested a separate bill or maybe plugging it into the pharm tech bill regulations if the pharmacy technician bill passes.

Mr. Frankil referred to the NABP study and the pharm tech bill and suggested responding to licensees as a Board to let them know this issue is being discussed.

Mr. Maloney mentioned obtaining information from the NABP study, research data collected from other states as far as pharmacist to pharmacy technician ratios, and inviting comments for the July meeting.

Ms. Hart suggested waiting to look at what other states have been doing with technicians. She mentioned that there are other things to consider because states that have had ratios in the past have done away with them and moved to different areas.]

\* \* \*

7 Old Business (cont.)

[Melanie Zimmerman, R.Ph., Executive Secretary, noted the need for discussion of the July 16, 2019 Board meeting date. The Board decided to change the date to July 24, 2019.

Mr. Maloney thanked Gayle for her presentation at the Pennsylvania Society of Health-System Pharmacists (PSHP) compounding seminar.

Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists, noted appreciation of the large number of Bureau staff in attendance.

Mr. Sheaffer received questions about pharmacy applications and whether or not they will be changed to reflect the requirements of USP.

Mr. Maloney commented that the Board will need to look at amending the applications once the pending compounding regulations are finalized.

Dr. Cotchen commented that hospitals are surveyed by Joint Commission or whoever is doing accreditation

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of the hospital. She stated pharmacy businesses in the
1
2
   community were doing sterile compounding and get
3
   inspected by BEI, noting the importance of making sure
4
   the public is protected from unsafe practices. She
5
   also stated the Board and BEI want to make sure they
6
   accomplish what needs to be done, including training
   of the inspectors.
                              * * *
   [Kalonji Johnson, Acting Commissioner, Bureau of
10
   Professional and Occupational Affairs, exited the
11
   meeting at 10:13 a.m.]
                              * * *
12
13
   [Pursuant to Section 708(a)(5) of the Sunshine Act, at
   10:13 a.m., the Board entered into Executive Session
14
15
   with Kerry E. Maloney, Esquire, Board Counsel, to
16
   receive legal advice and engage in quasi-judicial
17
   deliberations. The Board returned to open session at
18
   10:59 a.m.]
                              * * *
19
20
   MOTIONS
21
   CHAIRPERSON TALBOTT:
2.2
                The Board of Pharmacy met in executive
2.3
                 session to discuss and review consent
2.4
                 orders and other legal documents.
25
                     Are there any motions regarding these
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18 discussions? 1 2 DR. COTCHEN: 3 Madam Chairperson, I move that we approve 4 the Consent Agreement for File No. 15-54-5 07398. 6 MR. FRANKIL: 7 Second. 8 CHAIRPERSON TALBOTT: 9 Any discussion? Call the vote. 10 Frankil, aye; Greene, aye; Talbott, aye; 11 12 Cotchen, aye; Hart, aye. 13 [The motion carried unanimously. The Respondent's 14 name is Joseph G. Yost, R.Ph.] \* \* \* 15 16 DR. COTCHEN: 17 I move that we approve the Consent 18 Agreement for File No. 18-54-005617. 19 MR. FRANKIL: 20 Second. 21 CHAIRPERSON TALBOTT: 22 Any discussion? Call the vote. 2.3 2.4 Frankil, aye; Greene, aye; Talbott, aye; 25 Cotchen, aye; Hart, aye.

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19
   [The motion carried unanimously. The respondent is
1
2
   Talon Compounding Pharmacy.]
3
   DR. COTCHEN:
4
5
                 I move that we reject the Consent
                 Agreements as too lenient for File Nos.
6
                 16-54-08283, 17-54-03637, 14-54-04260,
8
                 17-54-11569, 17-54-07163, 16-54-14929,
9
                 17-54-11568 & 17-54-08037.
10
   MR. FRANKIL:
11
                 Second.
12
   CHAIRPERSON TALBOTT:
13
                 Any discussion? Call the vote.
14
15
                 Frankil, aye; Greene, aye; Talbott, aye;
16
                 Cotchen, aye; Hart, aye.
17
   [The motion carried unanimously.]
                               * * *
18
19
   DR. COTCHEN:
20
                 I move that we approve the Consent
21
                 Agreement for File No. 19-54-003471.
22
   MR. FRANKIL:
2.3
                 Second.
2.4
   CHAIRPERSON TALBOTT:
25
                 Any discussion? Call the vote.
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20
1
2
                 Frankil, aye; Greene, aye; Talbott, aye;
3
                 Cotchen, aye; Hart, aye.
4
    [The motion carried unanimously.]
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5
6
   DR. COTCHEN:
                 I move that we reject the Consent
8
                 Agreement as too lenient for File No. 18-
9
                 54-012188.
10
   MR. FRANKIL:
11
                 Second.
12
   CHAIRPERSON TALBOTT:
13
                 Any further discussion? Call the vote.
14
15
                 Frankil, aye; Greene, aye; Talbott, aye;
16
                 Cotchen, aye; Hart, aye.
17
   [The motion carried unanimously.]
                               * * *
18
   DR. COTCHEN:
19
20
                 I move that we approve the final
21
                 Adjudication and Order in the case of
22
                 Mitesh M. Patel, R.Ph., Case No. 13-54-
23
                 08175.
2.4
   MR. FRANKIL:
25
                 Second.
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21
1
   CHAIRPERSON TALBOTT:
2
                 Any discussion? Call the vote.
3
 4
                 Frankil, aye; Greene, recuse; Talbott,
5
                 aye; Cotchen, aye; Hart, aye.
6
   [The motion carried. Mr. Greene recused himself from
   deliberations and voting on the motion.]
9
   DR. COTCHEN:
10
                 I move that we provisionally deny the
11
                 Nonresident Pharmacy Application
12
                 submitted by ZooPharm, Inc.
13
   MR. FRANKIL:
14
                 Second.
15
   CHAIRPERSON TALBOTT:
16
                 Any discussion? Call the vote.
17
18
                 Frankil, aye; Greene, aye; Talbott, aye;
19
                 Cotchen, aye; Hart, aye.
20
   [The motion carried unanimously.]
21
                               * * *
22
   Adjournment
2.3
   DR. COTCHEN:
24
                 I move that we adjourn the meeting.
25
   CHAIRPERSON TALBOTT:
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22
 1
                 All in favor?
 2
    [The motion carried unanimously.]
 3
 4
    [There being no further business, the State Board of
   Pharmacy Meeting adjourned at 11:03 a.m. A regulation
 5
 6
   work session was held after the meeting.]
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### 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.

 Seth R. Baier,

Minute Clerk

Sargent's Court Reporting Service, Inc.