State Board of Pharmacy

October 3, 2017

Janet Getzey Hart, R.Ph., Chairperson

Kishor S. Mehta, Public Member - Absent

BOARD MEMBERS:

General

7 9

Ian Harlow, Commissioner of Professional and Occupational Affairs - Absent 10 Terry Talbott, R.Ph., Vice Chairperson Robert Frankil, R.Ph., Secretary

11 12 Gayle Cotchen, Pharm.D., R.Ph. 13 Patrick M. Greene, Esquire, Office of Attorney

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BUREAU PERSONNEL:

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James Rajnath, Walmart

Jill Schachte, CVS Health

John Loxterman, Enclara Pharmacia

Theresa Rossetti, CVS Health

Jim Reed, Walgreens

Mark Zilner, R.Ph.

Kerry Maloney, Esquire, Board Counsel Neil P. McConnell, Esquire, Board Counsel Ray Michalowski, Esquire, Board Prosecution Liaison Keith Bashore, Esquire, Board Prosecutor Monty Batson, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Executive Secretary

Janelle Hawthorne, Intern, Department of State, Counsel Division

Joseph McHale, Esquire, Counsel for Respondent

Rachael G. Pontikes, Esquire, Counsel for Respondent Christine Roussel, Pennsylvania Society of Health-System Pharmacists (PSHP), Doylestown Hospital Megan Doran, Pennsylvania Society of Health-System Pharmacists (PSHP) Makindree Nicolosi, Pennsylvania Society of Health-System Pharmacists (PSHP) Andrew Lee, Pennsylvania Society of Health-System Pharmacists (PSHP) Carl Harting, CVS Health

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State Board of Pharmacy

<u>October 3, 2017</u>

ALSO PRESENT: (Continued)

Leigh Shirley, Giant

Robert Grobinsici, Cardinal Health

John Sisto, ESI

Vince Lacroce, Pennsylvania Society of Health-System Pharmacists (PSHP)

Claudia Cho, Penn State Hershey Medical Center Ellie Tomaszewski, University of Pittsburgh

Samirkumar Patel, Temple University School of Pharmacy Andrew Harvan, Pennsylvania Medical Society (PaMED)

Greg Smith, Central Admixture Pharmacy

Rhonda Thomas, Pennsylvania Society of Health-System Pharmacists (PSHP)

Rachel Constant, Wilkes University Pharmacy Student Rebecca Mitchell

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* * * 1 2 State Board of Pharmacy 3 October 3, 2017 * * * 4 5 The regularly scheduled meeting of the State 6 Board of Pharmacy was held on Tuesday, October 3, 7 2017. Janet Getzey Hart, R.Ph., Chairperson, called the meeting to order at 9:01 a.m. The Pledge of 10 Allegiance was recited. A quorum was noted to be 11 present. * * * 12 Introductions 13 14 {Chairperson Hart requested the introduction of Board 15 Members, Board staff, and audience members in 16 attendance.1 * * * 17 Evacuation Announcement 18 19 [Melanie Zimmerman, R.Ph., Executive Secretary, 20 reviewed the emergency evacuation procedures for One 21 Penn Center.] * * * 22 23 Approval of Agenda CHAIRPERSON HART: 2.4 25 Do I have a motion to approve the

5 agenda? 1 2 DR. COTCHEN: 3 So moved. 4 MS. TALBOTT: 5 Second. 6 CHAIRPERSON HART: Any discussion? All in favor? Opposed? [The motion carried unanimously]. 9 10 Approval of Minutes of the May 31, 2017 meeting and 11 July 11, 2017 meeting 12 CHAIRPERSON HART: 13 We have approval of two Minutes. The 14 first one would be May 31, 2017. I had 15 one minor name spelling change, which I 16 gave to Melanie. But other than that, 17 from my perspective, I read them as fine, but I don't know if you all had a 18 chance to look at them or not. 19 20 DR. COTCHEN: 2.1 I move that we approve the May and July 22 Minutes as written with the changes that 2.3 you submitted. 2.4 MS. TALBOTT: 25 Second.

CHAIRPERSON HART:

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2 Any discussion? All in favor? Opposed?

3 [The motion carried unanimously].

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5 Report of Prosecutorial Division

6 | [Keith Bashore, Esquire, Board Prosecutor, presented a

7 | Consent Agreement for File No. 17-54-01094.]

* * *

9 | [Ray Michalowski, Esquire, Board Prosecution Liaison,

10 discussed legal referrals from the Board following

11 | this year's pharmacy renewal cycle. Some pharmacies

12 are reporting information that is already known to the

13 Board.

14 Mr. Michalowski discussed the PALS system and the

15 reporting of a criminal conviction or disciplinary

16 action.

17 He also noted complaints from pharmacies and

18 doctors are being reviewed in relation to the

19 | Prescription Drug Monitoring Program.

20 Chairperson Hart mentioned the delay for the

21 | implementation of the United States Pharmacopeia (USP)

22 | 800 until 2019, which relates to the way pharmacies

23 compound and dispense prescriptions. Mr. Michalowski

24 noted that the pharmacy inspectors are evaluating

25 | pharmacies for proper equipment and he is waiting for

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the Food and Drug Administration to schedule the yearly meeting with BPOA staff.
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4 Report of Board Counsel

5 | [Kerry Maloney, Esquire, Board Counsel, noted matters

6 | for the Board's deliberation during Executive Session,

7 | including one hearing.

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He noted the revisions to the Compounding
Regulations will be presented during the Board's next
meeting.

Mr. Maloney noted his attendance at a meeting with the Government Pharmaceutical Practice Group that involved Chief Counsel of the major agencies associated with pharmacy, health, and aging. He noted a presentation by Tom Snedden from the Programs of All-Inclusive Care for the Elderly (PACE). Mr. Snedden was invited to present at a future Board meeting.

Mr. Maloney noted the travel ban in effect is expected to clear once the budget is approved. Mr. Maloney submitted a travel request to attend the American Society for Pharmacy Law Conference.

Chairperson Hart discussed providing Board approval for Mr. Maloney to attend the NABP Board Counsel meeting being held November 29 and 30, 2017, in Chicago, pending the outcome of the budget approval

8 and the travel ban.] 1 DR. COTCHEN: 2 3 I move that we send Kerry to the NABP meeting for general counsel later this 4 5 year. 6 CHAIRPERSON HART: I believe I have a motion. Was there a 8 second? 9 MR. ZILNER: 10 Second. 11 CHAIRPERSON HART: 12 Any discussion? All in favor? Opposed? 13 [The motion carried unanimously.] * * * 14 15 Discussion 16 [Chairperson Hart discussed the travel ban placing the 17 Board at a disadvantage; Board Members are limited in 18 their ability to participate in different events and 19 are unable to accept funding from NABP. 20 Mr. Frankil agreed with the Chairperson's 21 comments. He further noted that the Board was 22 prevented from networking with others around the 23 country (due to staying off site from the meeting 2.4 location) and thus serving the Commonwealth better. 25 Mr. Maloney stated the Board should consider that

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funding may come out of Board funds as long as the
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   reason related to Board membership and would enhance
3
   the ability of Board Members to perform their jobs as
4
   Board Members. Limitations of state travel policies
5
   were noted.
6
        Chairperson Hart referred Board members to the
7
   recusal guidelines for further review.]
   Report of Board Chairperson
10
   [Chairperson Hart noted her attendance at a recent
11
   NABP Task Force on Long-Term Care meeting. She noted
12
   several comments and changes to the NABP Practice Act
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Chairperson Hart and Ms. Talbott attended the NABP/AACP Districts 1 & 2 meeting in Groton,

Connecticut. She mentioned that five resolutions introduced by District 1 were not supported by District 2, which remained neutral. Chairperson Hart briefly discussed the resolutions.

that will be addressed at an upcoming task force

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conference call.

Terry Talbott commented on a presentation regarding social status impacting one's health and a presentation from the Advisory Committee on Examinations regarding the new North American Pharmacists Licensure Examination (NAPLEX).]

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2 Report of Probable Cause Screening Committee

3 | [Patrick M. Greene, Esquire, Office of Attorney

4 General, provided an explanation of the Probable Cause

5 | Screening Committee's role and its process for

6 reviewing petitions to the students in the audience.

7 Mr. Greene then explained his recusal from the matters

8 that come before the Board.

* * *

10 Report of Commissioner - No Report

11

12 Report of Executive Secretary

13 [Melanie Zimmerman, R.Ph., Executive Secretary, stated

14 articles must be received by the end of November for

15 publication in the newsletter in January.

16 Ms. Talbott stated information regarding the

17 opioid education requirement for pharmacists should be

18 | in the newsletter as well as an article by Mr. Tom

19 | Snedden. Board Counsel Maloney will contact Mr.

20 | Snedden regarding the provision of an article.

21 Mr. Frankil offered to write an article on the

22 opioid CE issue and will include in that article

23 information regarding patient safety and child abuse

24 | continuing education.]

25 ***

- 1 | Applications
- 2 [Chairperson Hart noted applications for discussion
- 3 during Executive Session.
- 4
- 5 New Business
- 6 | Opioid Continuing Education for Pharmacists
- 7 [Chairperson Hart noted confusion regarding opioid
- 8 | continuing education for pharmacists.
- 9 Ms. Zimmerman explained the Board will accept any
- 10 | ACPE-approved provider who offers pharmacist
- 11 continuing education programs covering the required
- 12 opioid topics given that the Board already accepts
- 13 Accreditation Council for Pharmacy Education-approved
- 14 (ACPE-approved) pharmacist continuing education.
- 15 She noted that for pharmacist license renewal,
- 16 two hours of CE needs to be in pain management or the
- 17 | identification of addiction or in the practices of
- 18 prescribing or dispensing of opioids.
- 19 A total of four hours of opioid continuing
- 20 education is required for initial licensure consisting
- 21 of two hours in pain management or the identification
- 22 of addiction and 2 hours in the practices of
- 23 prescribing or dispensing of opioids.]
- 24 **
- 25 ACPE Site Visit to Jefferson School of Pharmacy

1 [The Board discussed representation to the ACPE Site

2 Visit at Jefferson School of Pharmacy November 7-9,

- 3 2017.
- 4 Mr. Frankil volunteered to attend the meeting.
- 5 | Chairperson Hart offered to attend should Mr. Frankil
- 6 be unavailable.
- 7 DR. COTCHEN:
- 8 I move that we send Rob to the ACPE Site
- 9 Visit to Jefferson School of Pharmacy
- in November of this year, and that
- Janet would be the alternate if Rob was
- 12 unable to participate.
- 13 MS. TALBOTT:
- I will second that motion.
- 15 CHAIRPERSON HART:
- Any additional discussion? All in
- favor? Opposed?
- 18 [The motion carried unanimously.]
- 19 ***
- 20 Old Business
- 21 2017 Intergovernmental Working Meeting on Pharmacy
- 22 Compounding
- 23 [Chairperson Hart referred to the agenda for
- 24 attachments regarding the 2017 Intergovernmental
- 25 Working Meeting on Pharmacy Compounding attended by

Dr. Cotchen.

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Dr. Cotchen discussed the proposed guidance provided by the Food and Drug Administration and recommended this information be reviewed by those who perform pharmacy compounding.

She reviewed additional matters, such as insanitary conditions and outsourcing, advisories versus enforcement actions, balancing federal and state oversight, state referral letters and state transfer letters, animal drug compounding and special issues, including matters regarding hospitals, complex compounding, and radiopharmaceuticals.]

13

14 For the Board's Information

15 [Chairperson Hart referred Board Members to

16 information included in the agenda relating to the

17 | Tri-Regulator Collaborative, United States

18 | Pharmacopeia (USP) Questions and Answers, and State

19 and Federal Occupational Licensing Reform.]

20 ***

21 Public Session

22 | [Terry Talbott, R.Ph., Vice Chairperson, clarified a

23 question regarding whether or not vaccines could be

24 administered by a student. Ms. Talbott stated

25 | registered Pennsylvania pharmacy interns would be

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able to perform immunizations once the Board
1
2
    Regulations are finalized and the interns apply for
3
    and are issued the required authorization, but
 4
    currently interns can only assist individuals with
5
    completing their paperwork.]
                              * * *
6
   [The Board recessed from 9:44 a.m. until 10:00 a.m.]
   [A Formal Hearing was held from 10:00 a.m. until 10:34
10
   a.m. In the Matter of the Application for the
11
   Nonresident Pharmacy Registration of US Compounding,
12
   Inc.; File No. 17-54-09671, Docket No. 1623-54-17.]
                              * * *
1.3
14
   [Pursuant to Section 708(a)(5) of the Sunshine Act, at
15
   10:34 a.m., the Board entered into Executive Session
   with Kerry Maloney, Esquire, Board Counsel, and Neil
16
17
   P. McConnell, Esquire, Board Counsel, to receive legal
18
   advice and for the purpose of conducting quasi-
   judicial deliberations. The Board returned to open
19
2.0
   session at 11:28 a.m.]
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22
   MOTIONS
2.3
   CHAIRPERSON HART:
2.4
                  The Board of Pharmacy met in Executive
25
                  Session to discuss and review consent
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                  orders and other legal documents.
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                                                       Are
2
                  there any motions regarding this
3
                  discussion?
4
   DR. COTCHEN:
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                  Madam Chairwoman, I move that we
6
                  approve the Consent Agreement for File
7
                  No. 17-54-08627.
   MS. TALBOTT:
9
                  Second.
10
   CHAIRPERSON HART:
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                  Any discussion? Call for a vote.
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                  Frankil, aye; Greene, aye; Zilner, aye;
                  Hart, aye; Cotchen, aye; Talbott, aye.
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   [The motion carried unanimously.]
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   DR. COTCHEN:
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                  I move that we approve the Consent
19
                  Agreement for File No. 17-54-01094,
20
                  Enclara Pharmacia, Incorporated.
21
   MS. TALBOTT:
22
                  Second.
2.3
   CHAIRPERSON HART:
2.4
                  Call for discussion? Call for a vote.
25
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16 Frankil, aye; Greene, aye; Zilner, aye; 1 2 Hart, aye; Cotchen, aye; Talbott, aye. 3 [The motion carried unanimously.] * * * 4 5 DR. COTCHEN: 6 In the matter of US Compounding, 7 Incorporated, File No. 17-54-09671, I motion that we direct Board Counsel to 9 draft an Adjudication and Order 10 consistent with discussion in Executive 11 Session. 12 MS. TALBOTT: Second. 13 14 CHAIRPERSON HART: 15 Call for discussion? Call for a vote. 16 17 Frankil, aye; Greene, aye; Zilner, aye; 18 Hart, aye; Cotchen, aye; Talbott, aye. 19 [The motion carried unanimously.] * * * 20 21 MR. MALONEY: 22 In File No. 16-54-01184, I look for a 2.3 motion to revise the proposed 2.4 Adjudication and Order to be consistent with our discussion in Executive 25

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17
                  Session.
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2
   DR. COTCHEN:
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                  So moved.
4
   MS. TALBOTT:
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                  Second.
6
   CHAIRPERSON HART:
                  Call for discussion? Call for a vote.
8
9
                  Frankil, aye; Greene, aye; Zilner, aye;
10
                  Hart, recused; Cotchen, aye; Talbott,
11
                  aye.
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   [The motion carried. Janet Hart recused from
13
   deliberations and voting on the motion. Executive
14
   Secretary Zimmerman left the Board Room while the
15
   Board deliberated on this matter.
16
17
   MR. MALONEY:
18
                  In File No. 17-54-05554, Michael G.
19
                  Kenney, Pharm.D., I look for a motion to
20
                  grant the request to reopen the record
21
                  for a limited time and purpose.
22
   DR. COTCHEN:
23
                  So moved.
2.4
   MS. TALBOTT:
25
                  Second.
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18 1 CHAIRPERSON HART: Open for discussion? Call for a vote. 2 3 Frankil, aye; Greene, aye; Zilner, aye; 4 5 Hart, aye; Cotchen, aye; Talbott, aye. 6 [The motion carried unanimously.] * * * 8 DR. COTCHEN: I move that we deny the Application for 10 Nontraditional Internship Preceptor 11 Approval submitted by Joseph Weidman. 12 MS. TALBOTT: Second. 13 14 CHAIRPERSON HART: 15 Discussion? Call for a vote. 16 17 Frankil, aye; Greene, aye; Zilner, aye; 18 Hart, aye; Cotchen, aye; Talbott, aye. 19 [The motion carried unanimously.] * * * 20 21 DR. COTCHEN: 22 I move that we approve the Application 2.3 for Reduced Intern Hours as a Graduate 2.4 of a Foreign Pharmacy School submitted 25 by Tapan Patel, reducing the intern

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                  hours to 1000.
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   MS. TALBOTT:
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                  Second.
   CHAIRPERSON HART:
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                  Discussion? Call for a vote.
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                  Frankil, aye; Greene, aye; Zilner, aye;
8
                  Hart, aye; Cotchen, aye; Talbott, aye.
   [The motion carried unanimously.]
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11
   DR. COTCHEN:
12
                  I move that we approve the application
13
                   submitted by Alesha Heil for Reciprocal
14
                   Licensure Application.
15
   MS. TALBOTT:
16
                  Second.
17
   CHAIRPERSON HART:
                  Discussion? Call for a vote.
18
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20
                  Frankil, aye; Greene, aye; Zilner, aye;
21
                  Hart, aye; Cotchen, aye; Talbott, aye.
22
   [The motion carried unanimously.]
23
2.4
   DR. COTCHEN:
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                  I move that we provisionally deny the
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1
                   Reciprocal Licensure Application
2
                   submitted by Cory Pazcoguin.
3
   MS. TALBOTT:
                   Second.
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5
   CHAIRPERSON HART:
                  Call for discussion? Call for a vote.
6
8
                  Frankil, aye; Greene, aye; Zilner, aye;
9
                  Hart, aye; Cotchen, aye; Talbott, aye.
10
   [The motion carried unanimously.]
                               * * *
11
12
   Adjournment
13
   DR. COTCHEN:
14
                   I motion that we adjourn.
15
   MS. TALBOTT:
16
                  Second.
17
   CHAIRPERSON HART:
18
                  So be it.
19
   [The motion carried unanimously.]
                               * * *
20
21
   [There being no further business, the State Board of
22
   Pharmacy meeting adjourned at 11:33 a.m.]
23
                               * * *
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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.

Dana Marie Ross,

Minute Clerk

Sargent's Court Reporting
Service, Inc.

			22
1 2 3		STATE BOARD OF PHARMACY REFERENCE INDEX	
4 5		October 3, 2017	
6 7 8	TIME	AGENDA	
9 10	9:01	Official Call to Order	
10 11 12	9:01	Pledge of Allegiance	
13 14 15	9:03	Introduction of Board Members, Board Staff, and Audience Members	
16 17	9:03	Evacuation Announcement	
18 19	9:04	Approval of Agenda/Minutes	
20	9:05	Report of Prosecutorial Division	
21 22	9:09	Report of Board Counsel	
23 24	9:15	Discussion	
2526	9:19	Report of Board Chairperson	
27 28 29 30	9:23	Report of Probable Cause Screening Committee	
31 32	9:25	Report of Executive Secretary	
32 33 34	9:27	New Business	
35 36	9:33	Old Business	
37	9:41	For the Board's Information	
38 39	9:42	Public Session	
40 41 42 43	9:44 10:00	Recess Return to Open Session	
44 45 46 47 48 49	10:00 10:34	Formal Hearing - <u>US Compounding,</u> <u>Incorporated</u>	

		23
	STATE BOARD OF PHARMACY REFERENCE INDEX (CONTINUED)	
	October 3, 2017	
TIME	AGENDA	
10:34 11:28	Executive Session Return to Open Session	
11:29	Motions	
11:33	Adjournment	