State Board of Pharmacy June 16, 2020

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BOARD MEMBERS:

Terry M. Talbott, R.Ph., Chairperson K. Kalonji Johnson, Commissioner, Bureau of Professional and Occupational Affairs Robert B. Frankil, R.Ph., Vice Chairman Patrick M. Greene, Esquire, Office of Attorney General

12 General
13 Thomas P.

Thomas P. Carey, Ed.D. - Absent

14 15

BUREAU PERSONNEL:

16 17

Juan A. Ruiz, Esquire, Board Counsel
Ray Michalowski, Esquire, Board Prosecution Liaison
Caroline A. Bailey, Esquire, Board Prosecutor
Angela B. Lucci, Esquire, Board Prosecutor
Alice Glasser, Esquire, Board Prosecutor
Elliott Zucker, Intern, Department of State

Carole Clarke Smith, Esquire, Senior Counsel in Charge Melanie Zimmerman, R.Ph., Executive Secretary

26 Theodore Stauffer, Executive

Secretary, Bureau of Professional and Occupational Affairs Marc Farrell, Deputy Policy Director, Department of

State
Carolyn DeLaurentis Esq. Deputy Chief Counsel

Carolyn DeLaurentis, Esq., Deputy Chief Counsel Nicole VanOrder, Esq., Senior Counsel in Charge

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ALSO PRESENT:

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Christine Roussel, Pharm.D., BCOP, Pennsylvania Society of Health-System Pharmacists, Doylestown Hospital Kerry E. Maloney, Esquire, Post & Shell

Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists Jenna L. McCarthy, Malady & Wooten

James Reed, Area Healthcare Supervisor, Walgreens Andrew Felter, Manager of Pharmacy Compliance and Regulatory Relations, Wegmans Food Markets

Barbara Knightly, Executive Vice President of Regulatory Affairs and Quality Operations, Pentec Health & International Academy of Compounding

Pharmacists
Carl Harting, CVS Health

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ALSO PRESENT: (Continued)

Christine Renfer, CVS Health David Klinger, System Director, Operations & Compliance, Geisinger Health System Heather Coy, AllianceRx Walgreens Prime Jennifer Welch, ACME/Sav-on Pharmacy Joel Jose, Student, Doylestown Hospital John Loxterman, Enclara Pharmacia

Judy Kutchman, AllianceRx Walgreens Prime

Lauren Miller, Doylestown Hospital

Lisa Scannapieco, Director of Pharmacy Education and Clinical Integration, Pentec Health

Patricia A. Epple, CEO, Pennsylvania Pharmacists Association

Rachel Schwartz, Central Admixture Pharmacy Services Rhonda Thomas, Pennsylvania Society of Health-System Pharmacists, Lehigh Valley Hospītal

Timothy Kaylor, Giant/Martin's Pharmacy

Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation

Janet Getzey Hart, Rite Aid

4 * * * 1 2 State Board of Pharmacy 3 June 16, 2020 * * * 4 5 The regularly scheduled meeting of the State 6 Board of Pharmacy was held on Tuesday, June 16, 2020. 7 Terry M. Talbott, R.Ph., Chairperson, called the meeting to order at 9:05 a.m. 10 [Chairperson Talbott requested Board members announce 11 themselves. * * * 12 13 [Chairperson Talbott announced Janet Getzey Hart was 14 reconfirmed as a Board Member but paperwork has not 15 been completed.] * * * 16 17 [Melanie Zimmerman, R.Ph., Executive Secretary, 18 further explained that the Board office has not 19 received official notice that Janet Getzey Hart has 20 been reappointed, and Ms. Hart will need to be sworn 21 in again before she can engage in Board Member 22 duties.] 2.3 * * * 24 [Chairperson Talbott also announced Christine Roussel 25 has been confirmed as a new Board Member but not yet

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   fully appointed at this time.]
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   [Chairperson Talbott sought an introduction of Board
   staff and audience members.]
                               * * *
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   Approval of Agenda
   CHAIRPERSON TALBOTT:
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                 Do I have a motion to accept the agenda
9
                 as presented?
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   MR. FRANKIL:
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                 So moved.
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   CHAIRPERSON TALBOTT:
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                 Second?
   MR. GREENE:
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                 Second.
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   CHAIRPERSON TALBOTT:
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                 Any discussion? All in favor?
18
                 opposed?
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   [The motion carried unanimously.]
                               * * *
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21
   Approval of minutes of the May 5, 2020 meeting
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   CHAIRPERSON TALBOTT:
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                 Next, we will move on to approval of the
24
                 minutes from the May 5 meeting. Do I
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                 have a motion to accept?
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6 MR. FRANKIL: 1 2 I make that motion. 3 CHAIRPERSON TALBOTT: Second? 4 MR. GREENE: 5 6 Second. 7 CHAIRPERSON TALBOTT: Any corrections to the minutes or any 9 amendments? Any discussion? 10 I have a motion and a second. All in 11 favor of approving the minutes as 12 Any opposed? written? 13 [The motion carried unanimously.] 14 15 Report of Prosecutorial Division 16 [Caroline A. Bailey, Esquire, Board Prosecutor, 17 presented the Consent Agreement for Case No. 19-54-18 002138. 19 Mr. Michalowski noted more charges are being 20 filed now that everybody is in phase green or yellow, 21 along with consent agreements being worked out behind 22 the scenes. He mentioned pharmacy inspectors are back 23 to doing full inspections and working on integrating 24 compounding into the Board checklist for pharmacy 25 inspections.

Mr. Michalowski mentioned that in the past, they simply used the one question of whether or not the pharmacy were properly equipped, compounding or general, incorporating the two USP standards. He commented that now that there is regulatory authority to make those more significant on the inspection question, it will lead to updating the inspection form.

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Mr. Michalowski addressed hospital pharmacies, noting that most are being certified by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other certifying agencies that the Department of Health accepts in lieu of conducting their own inspections. Because the Department of Health now does so few inspections of hospital pharmacies, BEI will start conducting those hospital pharmacy inspections where an accrediting agency is not certifying the hospital pharmacy.

Ms. Hart addressed the amount of damages from civil unrest to pharmacies that has been happening throughout the Commonwealth.

Mr. Frankil stated over 50 independent pharmacies in the Philadelphia area were damaged on some level. He mentioned a relief fund that was created, which will be filtered through the Pennsylvania Pharmacists

Ω

Association (PPA) with the help of the Philadelphia
Association of Retail Druggists (PARD) and Value Drug,
to offer financial help.

Ms. Zimmerman reviewed the procedure and policy with regard to pharmacies reporting damage. The Board office seeks information on damage and how long it would take for completion of repairs. She stated individuals would need to provide a Drug Enforcement Administration (DEA) Form 106, a Theft/Loss Reporting Form to the Board per standard procedure.

Ms. Zimmerman stated, once the pharmacy has made all of the repairs, an inspector will confirm that the pharmacy is in good working order and repair. She also mentioned that applications will be expedited for those who need to remodel or move to a new location in order to provide services more quickly.

Ms. Hart also noted Form 41 for destruction because there may not be a Form 106.]

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20 Report of Board Counsel

21 [Juan A. Ruiz, Esquire, Board Counsel, noted four 22 final adjudications and orders for discussion during

23 executive session.

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Mr. Ruiz referred to the Distributions of
Compounded Drug Products Memorandum of Understanding

a

1 (MOU) with the Food and Drug Administration (FDA) for 2 the Board's review.

Mr. Ruiz stated the FDA alleviated some of his concerns and believes this could be moved forward. He also noted discussions on the National Association of Boards of Pharmacy (NABP) conference calls, noting about 45 states were expected to sign it.

Mr. Ruiz referred to the Licensure by Endorsement under Act 41 exposure draft, noting it will be sent to stakeholders for comment before moving forward. He mentioned the Board's prior concerns with individuals having to take the North American Pharmacists
Licensure Examination (NAPLEX) and the Multistate
Pharmacy Jurisprudence Exam (MPJE), noting the removal of the reference to these exams after discussion with regulatory counsel. The requirements still will go to substantial equivalency for licensure.

Mr. Ruiz stated anything else that was discussed is in there and requested the Board's approval to send this out as an exposure draft.]

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22 MR. FRANKIL:

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I make a motion to approve that exposure draft.

25 CHAIRPERSON TALBOTT:

10 Do I have a second? 1 2 MR. GREENE: 3 Second. CHAIRPERSON TALBOTT: 4 5 Any other discussions? 6 MR. FRANKIL: Noted the committee to address any Act 41 requests is himself and Terry Talbott. 8 9 10 CHAIRPERSON TALBOTT: 11 All in favor of sending Juan's draft 12 after he fixes typos in his exposure 13 draft, please say aye. Any opposed? 14 [The motion carried unanimously.] 15 16 Report of Board Chairperson 17 [Terry M. Talbott, R.Ph., Chairperson, welcomed Ms. 18 Getzey Hart back and officially welcomed Christine 19 Roussel, who has been instrumental in helping with 20 regulations. She also announced John Slagle, owner of 21 The Medicine Shoppe Pharmacy in Clarion, has been 22 nominated but not yet confirmed. She also mentioned 23 the importance of having Mr. Frankil reappointed. 24 Chairperson Talbott provided a brief report of 25 her virtual attendance at the National Association of

Boards of Pharmacy Meeting on May 14. She informed the Board that all of the reports normally given orally are available on the NABP website under publications.

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Chairperson Talbott noted some states use the FDA Form 483 as a basis for discipline, where if the FDA finds something wrong, the Board automatically disciplines the pharmacy. She commented that boards should not use that as the sole disciplinary fact finding and should validate that information prior to the resolution of a complaint.

Chairperson Talbott addressed the resolution that created a task force on medication reuse, noting Pennsylvania has this for cancer drugs but not a lot of pharmacies take part in it.

Chairperson Talbott discussed a resolution directing NABP to see if they could incorporate various criminal background checks required by different boards in the NABP profile, where NABP would be given authorization to run the background check.

NABP is going to look into that in an effort to streamline the process and will provide a report from that investigation.

Chairperson Talbott mentioned a resolution to encourage patient-specific biologics to be shipped to

the practitioner for administration so that chain of custody is protected and the storage is adequate.

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Chairperson Talbott announced Tim Fensky from Massachusetts is now president of NABP and Caroline Juran, who is the executive director of the Virginia Board of Pharmacy, is president-elect. She also announced Lemrey "Al" Carter as the new executive director/secretary with the retirement of Carmen Catizone.

Chairperson Talbott requested approval for someone to attend the National Association of Boards of Pharmacy District Meeting September 9-11, 2020, in Annapolis, MD.

Commissioner Johnson provided information regarding the travel policy, where the administration is still strongly encouraging the use of virtual platforms but identifying a delegate if that policy changes.

Chairperson Talbott noted that she will be attending the meeting through her job and questioned whether a delegate would be able to represent the state if the state does not pay.

Commissioner Johnson will discuss the issue with $\mbox{Mr. Ruiz.}\mbox{]}$

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1 MR. FRANKIL:

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I make a motion to have Janet Hart be our delegate and Terry Talbott be the alternate.

5 MR. JOHNSON:

6 Second.

7 CHAIRPERSON TALBOTT:

Any other discussions?

9 [Ms. Zimmerman noted receiving a survey concerning
10 meetings and answered that the Board would prefer
11 virtual meetings because out-of-state travel is

12 prohibited at the moment based on the Commonwealth's

13 policy regarding travel.]

14 CHAIRPERSON TALBOTT:

We still have a motion on the table.

Regardless, we are going to need the

delegate, whether it is virtual or not

18 virtual.

Janet will be the delegate. I will be the alternate. We will go if we can.

If we cannot, we would not.

22 All in favor? Any opposed?

23 [The motion carried unanimously.]

24 **

25 Report of Probable Cause Screening Committee - No

1 Report

2 ***

- 3 Report of Commissioner
- 4 [K. Kalonji Johnson, Commissioner, Bureau of
- 5 | Professional and Occupational Affairs, welcomed the
- 6 new Board members and returning Board members. He
- 7 thanked the Legislature for moving on these
- 8 nominations. He informed the Board that the
- 9 Department of State is working to ensure all vacant
- 10 positions are filled.
- 11 Commissioner Johnson acknowledged the exemplary
- 12 work Ms. Zimmerman and Mr. Ruiz have been doing
- 13 throughout the year.
- 14 Chairperson Talbott also thanked Ms. Zimmerman
- 15 and Mr. Ruiz for everything they are doing for the
- 16 profession and the public.
- 17 Mr. Frankil also commended Ms. Zimmerman after
- 18 being contacted by a family whose child had trouble
- 19 | getting licensed and specifically complimented
- 20 Ms. Zimmerman.]
- 21 ***
- 22 Report of Executive Secretary
- 23 [Melanie Zimmerman, R.Ph., Executive Secretary,
- 24 informed the Board that staff continues to work from
- 25 | home and process applications.]

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- 2 New Business
- 3 | [Melanie Zimmerman, R.Ph., Executive Secretary,
- 4 informed the Board that NABP is adjusting their policy
- 5 requiring a transcript before releasing test scores,
- 6 where they will be releasing test scores but still
- 7 | want transcripts by July 31.
- 8 Ms. Zimmerman noted the invitation from the
- 9 Pennsylvania Society of Health-System Pharmacists
- 10 (PSHP) for the Board chairperson to speak on emergency
- 11 preparedness.
- 12 Chairperson Talbott announced the Ambulatory Care
- 13 Summit that was scheduled for May will now be held in
- 14 the spring of 2021. She also announced the
- 15 Pennsylvania Society of Health-System Pharmacists is
- 16 having an Emergency Preparedness Management Virtual
- 17 | Summit on September 11. She noted the request of a
- 18 30-minute discussion regarding emergency waivers, etc.
- 19 | She requested Commissioner Johnson or Mr. Ruiz also
- 20 attend.]
- 21 ***
- 22 MR. FRANKIL:
- I make a motion we look into sending
- 24 Terry to the PSHP Meeting.
- 25 MR. JOHNSON:

1 Second.

2 CHAIRPERSON TALBOTT:

Any other discussion? All in favor? Any

4 opposed?

5 | [The motion carried unanimously.]

7 Old Business

8 [Melanie Zimmerman, R.Ph., Executive Secretary,

9 referred to the letter from a group of University of

10 Pittsburgh students who asked the Board to address

11 working conditions for pharmacists. She posted

12 | information received from NABP related to a study that

13 | had been proposed.

14 Commissioner Johnson suggested reaching out to

15 someone within the university to see what their level

16 of knowledge is with regard to the request.

17 | Chairperson Talbott noted the July 21, 2020 Board

18 meeting date and suggested changing the date to August

19 18. She also noted concerns with having to possibly

20 work on the PA MPJE test question review

21 independently.

22 Ms. Zimmerman noted questions are available from

23 August 10 through September 11 with the original plan

24 to meet on September 1 as a group.

25 Mr. Ruiz cautioned the committee to ensure

1 everything is kept as confidential as possible as a

2 group and will look into the issue. He noted

3 answering questions separately is not an issue.

4 Mr. Frankil suggested using a Zoom-type format, 5 where all questions are done at a specific time and

6 questions discussed if there are any issues.

Ms. Zimmerman confirmed that August 11, August

8 | 18, August 24, and August 27 dates are available.

9 Chairperson Talbott noted canceling the July and

10 | September meetings and moving the meeting date to

11 August 18. She also noted the Board will further

discuss the issue concerning the test question review

13 during executive session.]

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15 MR. FRANKIL:

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I make the motion to combine July and

September into one meeting on August 18.

18 MR. JOHNSON:

19 Second.

20 CHAIRPERSON TALBOTT:

21 Any other discussion? All in favor?

22 [The motion carried unanimously.]

23 ***

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

25 | 10:11 a.m., the Board entered into Executive Session

1 | with Juan A. Ruiz, Esquire, Board Counsel, to receive

- 2 | legal advice and engage in quasi-judicial
- 3 deliberations. Nicole VanOrder, Esq., handled the
- 4 presentation, questions and discussion related to the
- 5 | Final Adjudication and Order for John A. Kriak, R.Ph.,
- 6 | Case No. 19-54-013954 as Board Counsel Juan Ruiz
- 7 recused himself from this particular matter. The Board
- 8 | returned to open session at 11:03 a.m. Commissioner
- 9 Johnson exited the meeting during this time with
- 10 Theodore Stauffer serving as his replacement for the
- 11 | remainder of the meeting.]
- 12 ***
- 13 MOTIONS
- 14 CHAIRPERSON TALBOTT:
- The Board of Pharmacy met in executive
- 16 session.
- 17 Are there any motions following that
- 18 executive session?
- 19 MR. FRANKIL:
- I will make a motion to approve Consent
- 21 Agreement Case No. 19-54-002138.
- 22 CHAIRPERSON TALBOTT:
- We have a motion.
- 24 MR. STAUFFER:
- On behalf of Mr. Johnson, I'll second.

19 1 CHAIRPERSON TALBOTT: 2 Any discussion? Hearing none. Call the 3 vote. 4 5 Frankil, aye; Greene, recuse; Stauffer, 6 aye; Talbott, aye. 7 [The motion carried. Mr. Greene recused himself from deliberations and voting on the motion. The pharmacist's name is Gregory F. Claypool, R.Ph.] * * * 10 11 MR. GREENE: 12 For agenda Item No. 3, I make a motion that we adopt the final Adjudication and 1.3 Order in the matter of BPOA v. Donna 14 15 Horger, R.Ph., Case No. 17-54-10558. 16 MR. FRANKIL: 17 Second. 18 CHAIRPERSON TALBOTT: 19 Any discussion? Call the vote. 2.0 2.1 Frankil, aye; Greene, aye; Stauffer, aye; 22 Talbott, aye. 2.3 [The motion carried unanimously.] * * * 2.4 25 MR. GREENE:

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1
                 Talbott, aye.
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   [The motion carried unanimously.]
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   MR. GREENE:
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                 For agenda Item No. 6, I make a motion
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                 that we adopt the final Adjudication and
                 Order in the matter of BPOA v. Trevor B.
8
                 Strenchock, R.Ph., Case No. 17-54-07192.
9
   MR. FRANKIL:
10
                 Second.
11
   CHAIRPERSON TALBOTT:
12
                 Any further discussion? Call the vote.
13
14
                 Frankil, aye; Greene, aye; Stauffer, aye;
15
                 Talbott, aye.
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   [The motion carried unanimously.]
                               * * *
17
   Adjournment
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   CHAIRPERSON TALBOTT:
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                 I will entertain a motion for adjournment
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                 until August 18.
22
   MR. FRANKIL:
2.3
                 So moved.
2.4
   CHAIRPERSON TALBOTT:
25
                 Second?
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22 1 MR. GREENE: 2 Second. 3 CHAIRPERSON TALBOTT: All in favor? 4 5 [The motion carried unanimously.] * * * 6 7 [There being no further business, the State Board of Pharmacy Meeting adjourned at 11:07 a.m.] 10 11 CERTIFICATE 12 13 I hereby certify that the foregoing summary 14 minutes of the State Board of Pharmacy meeting, was 15 reduced to writing by me or under my supervision, and 16 that the minutes accurately summarize the substance of 17 the State Board of Pharmacy meeting. 18 19 20 21 Alicia R. Gascoigne 22 Minute Clerk 2.3 Sargent's Court Reporting 24 Service, Inc. 25 26

		23
1 2 3 4 5 6		STATE BOARD OF PHARMACY REFERENCE INDEX
5		June 16, 2020
7 8 9 10 11 11 11 11 11 11 11 11 11	TIME	AGENDA
	9:05	Official Call to Order
	9:05	Roll Call
	9:06	Introduction of Board Staff and Audience Members
	9:12	Approval of Agenda and Minutes
	9:14	Report of Prosecutorial Division
	9:25	Report of Board Counsel
	9:32	Report of Board Chairperson
	9:44	Report of Commissioner
	9:46	Report of Executive Secretary
	9:47	New Business
	9:54	Old Business
	10:11	Executive Session
	11:03	Return to Open Session
	11:03	Motions
	11:07	Adjournment
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42 43		
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