State Board of Pharmacy June 8, 2021

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BOARD MEMBERS:

Janet Getzey Hart, R.Ph., Chairperson Theodore Stauffer, Executive Secretary, Bureau of Professional and Occupational Affairs, on behalf of K. Kalonji Johnson, Commissioner Christine Roussel, Pharm.D., BCOP, BCSCP, Secretary Patrick M. Greene, Esquire, Office of Attorney General John R. Slagle, R.Ph. Terry M. Talbott, R.Ph.

15 16 17

BUREAU PERSONNEL:

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Juan A. Ruiz, Esquire, Board Counsel Ray Michalowski, Esquire, Senior Board Prosecution Liaison

Alice Glasser, Esquire, Board Prosecutor Angela B. Lucci, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Executive Secretary Marc Farrell, Deputy Director, Policy Office, Department of State

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Glenn P. Masser, Esquire, Board Prosecutor Thaddeus Cwiklinski, Legal Office Summer Intern

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ALSO PRESENT:

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Andrew C. Harvan, Esquire, Pennsylvania Medical Society

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

Christopher Miller, Pharm.D., Giant Eagle

Christine Renfer, Pharm.D., Director of Professional Practices & Pharmacist in Charge, CVS/Caremark Pharmacy

Heather Coy, AllianceRx Walgreens Prime Jacquelyn Sassaman, Pentec Health

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State Board of Pharmacy June 8, 2021

<u>ALSO PRESENT:</u> (Continued)

Jim Reed, Health Outcomes Supervisor/Strategic Partnerships Leader, Walgreens Judy Kutchman, AllianceRx Walgreens Prime Kerry E. Maloney, Esquire, Post & Shell Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists Laura Romeo, Pharmacist-in-Charge at ConnectiveRx, Careform Pharmacy Leigh Shirley, Director of Pharmacy Operations, Giant Food Stores Lisa Scannapieco, Director of Pharmacy Education and Clinical Integration, Pentec Health Matthew Roesch, R.Ph., Pharmacist-in-Charge, Vetsource Pharmacy Nicholas Nigro, Compliance Officer, Hopkinton Drug, Incorporated Nicole Kruczek, R.Ph., MPBA, CVS/Caremark Pharmacy Nicole Fidler, Malady & Wooten, on behalf of PA CVS Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists Tamara Walker, Emerus Holdings/Allegheny Health Network Neighborhood Hospitals Victoria Elliott, R.Ph., MBA, CAE, CEO, Pennsylvania Pharmacists Association Edward Foote, Pharm.D., FCCP, BCPS, Dean, Philadelphia College of Pharmacy at the University of Sciences Catherine Lutz, Pharmacy Inspector, Bureau of

Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State Derek Richmond

Enforcement and Investigation, Department of State

4 * * * 1 2 State Board of Pharmacy 3 June 8, 2021 * * * 4 5 [Pursuant to Section 708(a)(5) of the Sunshine Act, at 9:00 a.m., the Board entered into Executive Session 6 with Juan A. Ruiz, Esquire, Board Counsel, to receive legal advice and engage in quasi-judicial deliberations. The Board returned to open session at 10 10:30 a.m.1 * * * 11 12 [Theodore Stauffer, Executive Secretary, Bureau of 13 Professional and Occupational Affairs, noted the 14 meeting was being recorded, and those who remained on 15 the line were giving their consent to be recorded.] 16 17 The regularly scheduled meeting of the State 18 Board of Pharmacy was held on Tuesday, June 8, 2021. 19 Janet Getzey Hart, R.Ph., Chairperson, called the 20 meeting to order at 10:31 a.m. 21 * * * 22 Introduction of the Board Members/Audience 23 [Chairperson Hart requested Board Members and audience 2.4 introduce themselves. 25 * * *

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   Approval of Agenda
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   CHAIRPERSON HART:
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                 Do I have a motion to approve the agenda?
4
   DR. ROUSSEL:
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                 I'd like to make a motion to approve the
6
                 agenda.
7
   MS. TALBOTT:
                 Second.
9
   CHAIRPERSON HART:
10
                 Any call for discussion? Vote to approve
11
                 the agenda. All in favor, aye? Opposed?
12
                 Abstained?
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   [The motion carried unanimously.]
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                               * * *
15
   Approval of Minutes
16
   CHAIRPERSON HART:
                 The next item on the agenda will be
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18
                 approval of the minutes from the previous
19
                 meeting.
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   MS. TALBOTT:
21
                 I'll make that motion, Madam Chair, to
22
                 approve the minutes from the last
23
                 meeting.
2.4
   MR. GREENE:
25
                 Second.
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1 CHAIRPERSON HART:

- Call for a discussion? Call for a vote.
- All in favor, aye. Opposed? Abstained?
- 4 [The motion carried unanimously.]
- 5 ***
- 6 Report of Prosecutorial Division
- 7 | [Angela B. Lucci, Esquire, Board Prosecutor, presented
- 8 the Consent Agreement for Case Nos. 19-54-011961 & 19-
- 9 | 54-011964.1
- 10 ***
- 11 [Glenn P. Masser, Esquire, Board Prosecutor, presented
- 12 | the Consent Agreements for Case No. 20-54-000721, Case
- 13 No. 20-54-010231, Case No. 20-54-013766, and Case No.
- 14 21-54-000757.1
- 15 ***
- 16 | [Ray Michalowski, Esquire, Senior Board Prosecution
- 17 Liaison, presented the VRP Consent Agreements for Case
- 18 No. 20-54-014353 and Case No. 21-54-004072.1
- 19 ***
- 20 Mr. Michalowski stated Ms. Glasser, Ms. Bailey,
- 21 and Jessica Zukoski, were working closely with the
- 22 Department of Health's Prescription Drug Monitoring
- 23 | Program (PDMP) to get pharmacies in compliance with
- 24 timelines and working on pharmacy errors.
- Mr. Michalowski mentioned that the Department

receives quarterly reports from PDMP's compliance officer and works with them contacting pharmacies by email to get things corrected and then by mail, along with the Bureau of Enforcement and Investigation (BEI) if the mailed letter does not work.

Mr. Michalowski noted Ashley Bolton, the Director of the Office of Drug Surveillance and Misuse Prevention, and Jared Shinabery, the Deputy Secretary for Health Resources and Services, were working on changing their vendor to an in-house PDMP system and have been contacting him because PALS connects to their system and there are missing data elements. He informed the Board that senior prosecutors from prescribing boards and Mark Zogby would soon be meeting PDMP to discuss their new system. Mr. Michalowski indicated that he would ask the PDMP to provide a presentation to the Board in the future.]

19 Report of Board Counsel

[Juan A. Ruiz, Esquire, Board Counsel, noted one motion to enter default and deem facts admitted was discussed during Executive Session. Mr. Ruiz announced that the regulation work session scheduled for later in the day to discuss pharmacy technician regulations was canceled.

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Mr. Ruiz noted no new updates to report on the
Memorandum of Understanding (MOU). He provided some
information, where the National Association of Boards
of Pharmacy (NABP) sent a letter to the Food and Drug
Administration (FDA) on April 27 requesting delay in
enforcements of the section of the drug act so more
boards could come together to sign the MOU given all
the different issues independent boards have due to
different laws in different states.
    Mr. Ruiz stated pharmacy renewals were coming out
this year, where questions will be asked concerning
compounding to obtain information necessary for the
MOU, to at least start gathering that information to
be ready to participate if it is signed.
    Mr. Ruiz provided an update on immunization
regulations and hoped to get those moving and
delivered to the Office of General Counsel (OGC) and
Office of Budget and Policy for approval and
completion by early fall.]
                          * * *
Report of Board Chairperson - No Report
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23 Report of Probable Cause Committee

24 [Patrick M. Greene, Esquire, Office of Attorney

25 General, noted reviewing one Petition for Immediate

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1 | Temporary Suspension.]
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- 3 Report of Executive Secretary
- 4 | [Melanie Zimmerman, R.Ph., Executive Secretary,
- 5 | mentioned the Board office is preparing for the
- 6 upcoming pharmacy and nonresident pharmacy renewal.
- 7 | She also noted the addition of compounding questions
- 8 to help the Board determine any pharmacies that would
- 9 be involved with the FDA MOU.
- 10 Ms. Zimmerman stated pharmacies will be asked for
- 11 their National Provider Identifier (NPI) number to
- 12 help the Legal Office. She expected the renewal to be
- 13 released in early July, noting pharmacies should watch
- 14 for an email notice and check their spam account
- 15 because emails sometimes go to spam.
- 16 Ms. Zimmerman answered a question regarding
- 17 whether someone could go into the Pennsylvania
- 18 Licensing System (PALS) and renew if they do not see
- 19 anything by July 10. She explained that anyone can
- 20 login to their PALS account and, if the renewal is
- 21 available, the renewal tile will be active and there
- 22 | will be a renewal pin under the "Professional License
- 23 Details" banner.
- 24 Dr. Roussel encouraged Ms. Elliott to provide the
- 25 | information to Pennsylvania Pharmacists Association

(PPA) members, and Mr. Jones and Mr. Sheaffer could provide the information to Pennsylvania Society of Health-System Pharmacists (PSHP) members as well.]

5 New Business

[Juan A. Ruiz, Esquire, Board Counsel, addressed a request received from pharmacy students at Wilkes University Nesbitt School of Pharmacy advocating for continuing education concerning human trafficking.

* * *

Mr. Ruiz commented that the Board applauds their efforts, but the Board does not have the ability to mandate anyone to take that education. The Board also acknowledged that pharmacists are in a good position to recognize human trafficking and that there appear to be limited ACPE-approved pharmacist continuing education programs on this topic.

Mr. Ruiz recommended the students reach out to the Department of Human Services (DHS) given that knowledge of this subject would be beneficial to all mandatory reporters and DHS oversees the requirement for child abuse recognition and reporting continuing education. It was also suggested that the student group reach out to pharmacist associations such as PPA and PSHP to see if continuing education programs on this topic could be provided at some of their annual

1 | meetings/events.]

2 ***

3 Old Business

4 [Christine Roussel, Pharm.D., BCOP, BCSCP, Secretary,

5 addressed her attendance at the 117th Annual National

6 Association of Boards of Pharmacy Meeting on May 13-

7 | 14. She mentioned continuing education sessions and

8 noted resolutions were reviewed and passed. She

9 addressed the resolutions that were passed, noting

10 none of the resolutions passed were significantly

11 | controversial.

12 Dr. Roussel noted that she found amazing the

13 importation of drug presentation by a member of the

14 | Colorado government, where her job as a pharmacist is

15 to help Colorado import drugs directly from Canada

16 through their wholesalers. Dr. Roussel noted

17 discussion regarding a task force on workplace safety

18 and fatique and how that affects patient safety. She

19 addressed NABP convening a task force to look at "just

20 culture" and how it will be integrated into regulatory

21 structure for the boards of pharmacy as it relates to

22 | medication errors and what resources are available.

Dr. Roussel noted the NABP Districts 1 & 2

24 Meeting will be in September.

25 MS. TALBOTT:

All in

Christine mentioned the District 1 and 2 1 meeting. I know the agenda is going to 2 3 be posted soon and still unsure whether we can travel for the Commonwealth, but I 4 5 would like to make a motion that we send 6 you (Janet Getzey Hart) as the delegate and Christine as the alternate delegate to Annapolis to that meeting September 7-8 9 10. 10 MR. GREENE: 11 Second. 12 CHAIR HART: 13 Any discussion? Call for a vote. All in 14 favor, aye. Opposed? Abstained? 15 [The motion carried unanimously.] MS. TALBOTT: 16 17 Madam Chair, I will make a further motion 18 that since we were supposed to meet on 19 September 8 and conflicts with that 20 meeting, we could move the Board meeting 21 to Tuesday, August 31. 22 DR. ROUSSEL: 2.3 Second. 2.4 CHAIRPERSON HART:

Any discussion? Call for a vote.

25

favor? Opposed? 1 2 [The motion carried unanimously. Chairperson Hart 3 encouraged members in the audience to note the change 4 in the Board Meeting date.] * * * 5 6 Report of Commissioner - No Report [Theodore Stauffer, Executive Secretary, Bureau of Professional and Occupational Affairs, on behalf of K. Kalonji Johnson, Commissioner, had no official report 10 but informed everyone that, if they had concerns 11 regarding the current COVID-19 waivers, to contact 12 their local legislator . 13 Marc Farrell, Deputy Director, Policy Office, 14 Department of State, commented that the Department is 15 awaiting information from the legislature and was 16 doing its best to provide notice to folks and build a 17 grace period or transition time to adjust to 18 normalcy.] * * * 19 20 MOTIONS 2.1 CHAIRPERSON HART: The Board met in Executive Session to 2.2 2.3 discuss and review consent orders and 2.4 other legal documents. 25 Are there any motions regarding these

14 discussions? 1 2 MR. GREENE: 3 At agenda item 2, I make the motion that 4 we approve the Consent Agreement at Case Nos. 19-54-011961 & 19-54-011964. 5 6 MS. TALBOTT: 7 Second. CHAIRPERSON HART: 9 Any discussion? Call for a vote. 10 11 Stauffer, aye; Roussel, aye; Greene, aye; 12 Slagle, aye; Talbott, aye; Hart, aye. 13 [The motion carried unanimously. The Respondents are 14 Neighborhood Pharmacy & Brad Silver.] * * * 15 16 MR. GREENE: For agenda item 3, I make the motion that 17 18 we approve the Consent Agreement at Case No. 20-54-000721. 19 20 MS. TALBOTT: 21 Second. 22 CHAIRPERSON HART: 2.3 Call for a discussion? No discussion. 2.4 Call for a vote. 25

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                 Stauffer, aye; Roussel, aye; Greene, aye;
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                 Slagle, aye; Talbott, aye; Hart, aye.
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    [The motion carried unanimously. The Respondent's
   name is BET Pharm LLC.]
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6
   MR. GREENE:
                 At agenda item 4, I make the motion that
                 we approve the Consent Agreement at Case
8
9
                 No. 20-54-010231.
10
   MS. TALBOTT:
11
                 Second.
12
   CHAIRPERSON HART:
13
                 Any discussion? Call for a vote.
14
15
                 Stauffer, aye; Roussel, aye; Greene, aye;
16
                 Slagle, aye; Talbott, aye; Hart, aye.
17
   [The motion carried unanimously. The Respondent's
18
   name is Gregory Dale Malloy, R.Ph.]
                               * * *
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   DR. ROUSSEL:
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                 I'd like to make a motion to approve
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                 agenda item 5 at Case No. 20-54-013766.
2.3
   MS. TALBOTT:
24
                 Second.
25
   CHAIRPERSON HART:
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16 Any discussion? Call for a vote. 1 2 3 Stauffer, aye; Roussel, aye; Greene, 4 recuse; Slagle, aye; Talbott, aye; Hart, 5 aye. 6 [The motion carried. Mr. Greene recused himself from deliberations and voting on the motion. Respondent's name is Jeffrey W. Eshelman, R.Ph.] * * * 9 10 MR. GREENE: 11 I make a motion on agenda item 6 that we 12 approve the Consent Agreement at Case No. 21-54-000757. 13 14 DR. ROUSSEL: 15 Second. 16 CHAIRPERSON HART: 17 Any discussion? Call for a vote. 18 19 Stauffer, aye; Roussel, aye; Greene, aye; 20 Slagle, aye; Talbott, aye; Hart, aye. 21 [The motion carried unanimously. The Respondent's 22 name is Pacifico West Rx., Inc. DBA PureScience.] 23 * * * 2.4 MR. GREENE: 25 At agenda items 7 and 8, I move that we

17 approve the following VRP Consent 1 2 Agreements at Case No. 20-54-014353 and 3 Case No. 21-54-004072. 4 DR. ROUSSEL: 5 Second. 6 CHAIRPERSON HART: Any discussion? Call for a vote. 8 9 Stauffer, aye; Roussel, aye; Greene, aye; 10 Slagle, aye; Talbott, aye; Hart, aye. 11 [The motion carried unanimously.] * * * 12 13 MR. GREENE: 14 At agenda item 10 in the matter of Sunwon 15 So at Case No. 19-54-004115, I move that 16 we approve the Motion to Deem Facts Admitted and Enter Default and direct 17 Board Counsel to draft an Adjudication 18 and Order consistent with communications 19 20 and discussions in Executive Session. 21 DR. ROUSSEL: 22 Second. 2.3 CHAIRPERSON HART: 2.4 Any discussion? Call for a vote. 25

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18
                 Stauffer, aye; Roussel, aye; Greene, aye;
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2
                 Slagle, aye; Talbott, aye; Hart, aye.
3
    [The motion carried unanimously.]
 4
   MR. GREENE:
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6
                 At agenda item 11, I make a motion that
                 we provisionally deny the Nonresident
                 Pharmacy Application submitted by Florida
8
9
                 Discount Drugs, Inc.
   DR. ROUSSEL:
10
11
                 Second.
12
   CHAIRPERSON HART:
13
                 Any discussion? Call for a vote.
14
15
                 Stauffer, aye; Roussel, aye; Greene, aye;
16
                 Slagle, aye; Talbott, aye; Hart, aye.
17
   [The motion carried unanimously.]
                               * * *
18
19
   MR. GREENE:
20
                 At agenda item 12, I make the motion that
21
                 we provisionally deny the Nonresident
22
                 Pharmacy Application submitted by
23
                 Hopkinton Drug, Inc.
2.4
   DR. ROUSSEL:
25
                 Second.
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CHAIRPERSON HART:

2 Any discussion? Call for a vote.

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Stauffer, aye; Roussel, aye; Greene, aye;

5 Slagle, aye; Talbott, aye; Hart, aye.

6 [The motion carried unanimously.]

* * *

8 Public Comment

9 [Laura Romeo, Pharmacist-in-Charge at ConnectiveRx,

10 Careform Pharmacy, questioned when the Board would be

11 addressing pharmacy technicians.

Mr. Ruiz noted discussion concerning pharmacy

13 technicians is planned for the next Board meeting.
14 Larry Jones, Executive Director, Pennsylvania

15 Society of Health-System Pharmacists, questioned

16 whether there has been any kind of ranking of

17 importance for waivers that are at the top of the

18 priority list to move that PSHP can assist the Board

19 and Commissioner with possibly introducing legislation

20 or getting legislation introduced to make them more

21 permanent.

Mr. Ruiz had not personally been involved in or

23 made aware of such conversations.

Victoria Elliott, R.Ph., MBA, CAE, CEO,

25 Pennsylvania Pharmacists Association, put in a chat

1 that there is legislation being considered and to
2 reach out to fellow leadership.

2.0

Dr. Roussel encouraged Mr. Jones to perhaps work with Ms. Elliott and add PSHP to that push.

Edward Foote, Pharm.D., FCCP, BCPS, Dean of the Philadelphia College of Pharmacy at the University of Sciences, requested more information concerning the two-year expiration for injectables training.

Dr. Roussel commented that injectables training is still two years until the three-year period in the proposed regulations is final.

Christopher Miller, Pharm.D., Giant Eagle, questioned whether interns, who are currently registered through PALS, would be able to administer with that certificate if emergency orders for intern immunization administration would expire before the new regulations are published.

Mr. Ruiz commented that interns would be able to administer under the statute if registered with the Board.

Mr. Farrell stated the Public Readiness and Emergency Preparedness (PREP) Act would still be in force with many provisions regarding pharmacy when many pharmacy-related waivers with regard to vaccination go away on a state level.]

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 2
   Adjournment
 3
   CHAIRPERSON HART:
 4
                 Do we have a motion to adjourn?
   MS. TALBOTT:
 5
                 Madam Chair, I will make a motion to
 6
 7
                 adjourn.
   DR. ROUSSEL:
                 I will second that motion.
10
   CHAIRPERSON HART:
11
                 Any discussion? All in favor, aye?
12
    [The motion carried unanimously.]
13
                               * * *
14
    [There being no further business, the State Board of
15
   Pharmacy Meeting adjourned at 11:25 a.m.]
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$\begin{smallmatrix} 1&2&3&4&5&6&7&8&9&0&1&2&3&4&5&6&2&2&2&2&2&2&2&2&2&2&2&2&2&2&2&2&2&2$		STATE BOARD OF PHARMACY REFERENCE INDEX	
		June 8, 2021	
	TIME	AGENDA	
	9:00	Executive Session	
	10:30	Return to Open Session	
	10:31	Official Call to Order	
	10:31	Introduction of Board Members/Audience	<u></u>
	10:38	Approval of Minutes	
	10:38	Report of Prosecutorial Division	
	10:52	Report of Board Counsel	
	10:56	Report of Probable Cause Screening Committee	
	10:56	Report of Executive Secretary	
	10:58	New Business	
	11:01	Old Business	
	11:09	Motions	
	11:16	Public Comment	
	11:25	Adjournment	

