State Board of Pharmacy April 27, 2021

Janet Getzey Hart, R.Ph., Chairperson

K. Kalonji Johnson, Commissioner, Bureau of

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BOARD MEMBERS:

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Professional and Occupational Affairs 10 Christine Roussel, Pharm.D., BCOP, BCSCP, Secretary 11 Patrick M. Greene, Esquire, Office of Attorney 12 General

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BUREAU PERSONNEL:

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John R. Slagle, R.Ph.

Terry M. Talbott, R.Ph.

Juan A. Ruiz, Esquire, Board Counsel Carole Clarke Smith, Esquire, Senior Board Counsel Nicole Ehrhart, Esquire, Board Counsel Carolyn DeLaurentis, Deputy Chief Counsel, Prosecution Division

Ray Michalowski, Esquire, Senior Board Prosecution Liaison Alice Glasser, Esquire, Board Prosecutor

Caroline A. Bailey, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Executive Secretary Theodore Stauffer, Executive Secretary, Bureau of Professional and Occupational Affairs Andrew LaFratte, MPA, Executive Policy Specialist, Department of State

ALSO PRESENT:

Andrew C. Harvan, Esquire, Pennsylvania Medical Society

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 April 27, 2021

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ALSO PRESENT: (cont.)

Jen Smeltz, Republican Executive Director, Senate Consumer Protection & Professional Licensure Committee

Jenna McCarthy, Malady & Wooten, on behalf of PA CVS Jim Reed, Health Outcomes Supervisor/Strategic Partnerships Leader, Walgreens

Judy Kutchman, AllianceRx Walgreens Prime

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

Nicole Sidle, Republican Executive Director, House Professional Licensure Committee

Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists

Victoria Elliott, R.Ph., MBA, CAE, CEO, Pennsylvania Pharmacists Association

Catherine Lutz, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State

Steven Zahn, Pharmacy Inspector, Bureau of

Enforcement and Investigation, Department of State Ryan Burke

26 27 Barbara Knightly

28 Tamara Walker

29 Gail Groves Scott

30 Jason Anderson

31 Rubert Kistler

Lisa Scannapieco

33 Yousef Al

34 Selleca Huhn 35

Derek Richmond

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* * * 1 2 State Board of Pharmacy 3 April 27, 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 is being recorded, and those who remain on the 15 line are giving their consent to being recorded. 16 17 The regularly scheduled meeting of the State 18 Board of Pharmacy was held on Tuesday, April 27, 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 * * *

5 Approval of Minutes 1 2 CHAIRPERSON HART: 3 At this point, we move to the agenda and approval of the meeting minutes from 4 5 March 17. 6 MS. TALBOTT: I'll make a motion that we approve the 8 minutes from March 17. 9 DR. ROUSSEL:

I will second that motion.

11 CHAIRPERSON HART:

12 Any discussion on the motion? Vote on

the motion. All in favor, aye? Opposed?

14 [The motion carried unanimously.]

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16 Report of Prosecutorial Division

17 [Caroline A. Bailey, Esquire, Board Prosecutor,

18 presented the Consent Agreements for Case No. 18-54-

 $19 \mid 009040$, Case Nos. 20-54-004433 & 21-54-000053, and

20 Case No. 20-54-009805.1

21 ***

22 | [Ray Michalowski, Esquire, Senior Board Prosecution

23 Liaison, presented the VRP Consent Agreements for Case

 $24 \mid \text{No. } 21-54-000056$, Case No. 21-54-000184, Case No. 21-54-000184

 $25 \mid 54-000318$, and Case No. 21-54-000319.

Ms. Talbott questioned whether violations have increased or decreased.

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Mr. Michalowski provided an overview of COVID cases, noting a slowdown since the beginning of COVID with recent cases involving vaccination-related issues and masking. He noted all of the cases have been resolved by warning letters with the help of the Department of Health.

Mr. Michalowski addressed general cases, where many individuals receive reciprocal discipline during renewal years, especially with out-of-state nonresidents. He noted a fair number of in-state cases and people having more issues than any other time. He stated the Professional Health Monitoring Programs (PHMP) and other individuals are handling those well.

Mr. Michalowski also addressed complaints, noting those to be difficult to prove and end up being a warning letter. He mentioned cases where pharmacists may be dealing with a problem patient and get overly loud and cases involving opiate prescriptions and refills. He noted Mr. Frankil wrote an article for the newsletter last year on dealing with individuals in a professional manner.

Mr. Michalowski mentioned receiving a few

complaints regarding the vaccine but none that had any merit and mostly where people are jumping the line.

Mr. Michalowski noted renewals were last year for pharmacists, and there may be licensees who failed to report charges or convictions but these individuals will be caught. He commented that the only charge missed would be federal charges or out-of-state charges that were not reported.]

* * *

10 Report of Board Counsel

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[Juan A. Ruiz, Esquire, Board Counsel, noted the Board deliberated on two proposed adjudications and orders during Executive Session prior to the meeting.

Mr. Ruiz read a scam alert pertaining to licensees, where the Bureau of Professional and Occupational Affairs (BPOA) received reports of persons pretending to be from one of the health-related boards and contacting licensees regarding the status of their license. He noted scammers are threatening license suspension for failure to act and falsely claiming involvement with the Federal Bureau of Investigation (FBI) and the Drug Enforcement Administration (DEA).

Mr. Ruiz stated scammers are threatening license suspension for failure to provide personal

information. He provided reminders from the Bureau of
Professional and Occupational Affairs (BPOA)
concerning how BPOA truly operates.

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Mr. Ruiz mentioned that those who are the subject of an investigation or disciplinary action will receive notice by certified mail and/or personal service and provided with a contact name and phone number. He informed everyone to contact their local police department or the state police if they have been a victim of the scam. He noted the scam alert is posted on all of the boards' websites.

Mr. Ruiz provided an update regarding the Memorandum of Understanding (MOU). He addressed the Food and Drug Administration (FDA) small group meeting on April 7, 2021 discussing the MOU. He explained that the FDA needed information to fill in the blanks that are in the MOU right now for each state.

Mr. Ruiz stated the National Association of Boards of Pharmacy (NABP) was also there presenting information on their information-sharing network, regarding how it works and responsibilities if the information-sharing network is used going forward.

Mr. Ruiz explained that legislative changes may be needed to actually enter into the MOU, and many states are in the same situation as Pennsylvania. He

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1 noted the FDA will not alter the MOU in any way, shape
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- 2 or form. He mentioned New Hampshire is the only state
- 3 that has signed the MOU. North Carolina is amending
- 4 their laws and regulations to enter the MOU.
- 5 | California indicated it would be roughly two to three
- 6 years before it could enter into the MOU.
- 7 Mr. Ruiz will continue to examine what
- 8 | Pennsylvania needs to do to make this possible and
- 9 investigate avenues to enter into the MOU.]
- 10 ***
- 11 Report of Board Chair
- 12 | [Janet Getzey Hart, R.Ph., Chairperson, had nothing
- 13 new to report but requested Dr. Roussel provide an
- 14 update on Dr. Roussel's attendance at the virtual
- 15 Accreditation Council for Pharmacy Education (ACPE)
- 16 reaccreditation site visit at Duquesne University.
- 17 Dr. Roussel commented that many components of the
- 18 curriculum are evaluated, including an assessment of
- 19 the facilities which was accomplished as an extended
- 20 video of the campus, classrooms, and laboratory
- 21 facilities.
- 22 Dr. Roussel noted many subcommittee meetings
- 23 occurred during the three-day event, where members
- 24 from the team, including a dean representative from
- 25 another pharmacy school and different faculty from

other universities, came together to discuss student curriculum, integration with interdisciplinary education, and patient care.

Dr. Roussel felt confident that ACPE did a great job in ensuring the pharmacy colleges do a good job educating their students and was confident in the accreditation process.]

* * *

9 Report of Probable Cause Screening Committee
10 [Patrick M. Greene, Esquire, Office of Attorney
11 General, noted signing one Petition for Immediate
12 Temporary Suspension.]

14 Report of Commissioner

[K. Kalonji Johnson, Commissioner, Bureau of Professional and Occupational Affairs, addressed working with NABP with regard to a possible upgrade in the Pennsylvania Licensing System (PALS) to allow for an easier exchange of exam scores between that organization and the Board of Pharmacy. He reported challenges with regard to the cost needed to develop the application programming interface (API) and to integrate that into PALS. He noted earlier discussion related to potential financial grants and the legality

of that. He will continue to investigate the matter.

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Report of Executive Secretary Ms. Zimmerman reported currently being unable to engage in the data integration using the API method with NABP due to BPOA's priorities with other computer work. She is working on resolving the score import issues, so it can be done through the system, rather than manually.

Terry Talbott commented that NABP went to pass/fail results for the licensure exams and is also requiring a transcript be submitted for pharmacist applicants prior to allowing them to test. She noted schools being able to certify graduation and the Board office staff authorizing an Authorization to Test (ATT) letter even if the PA applicant had not provided their transcript to the Board because it was not mandated by our law.

Board Member Talbott mentioned NABP had a couple incidents where people actually signed up to take the North American Pharmacists Licensure Examination (NAPLEX) without having gone to pharmacy school but these individuals never took the test. She stated applicants must have their schools provide their transcript to NABP prior to the student receiving authorization to test regardless of state statute.

She also informed everyone that schools can

1 upload the information in bulk to NABP. The

- 2 | information will be uploaded into the applicant's
- 3 record at NABP, and once signed off, their ATT is
- 4 given. She stated colleges have been provided this
- 5 information by NABP, and she personally asked Janet
- 6 Astle at Duquesne University to make sure all the
- 7 deans in Pennsylvania know about it as well.]
- 8 ***
- 9 Approval of Agenda
- 10 | CHAIRPERSON HART:
- Do we have a motion to approve the
- 12 agenda?
- 13 MS. TALBOTT:
- I will make that motion.
- 15 DR. ROUSSEL:
- I will second that motion.
- 17 CHAIRPERSON HART:
- 18 Any discussion? Call for a vote. All in
- 19 favor, aye?
- 20 [The motion carried unanimously.]
- 21 ***
- 22 MOTIONS
- 23 CHAIRPERSON HART:
- The Board met in Executive Session prior
- to our public meeting to discuss and

13 review consent orders and other legal 1 2 documents. 3 Are there any motions regarding these discussions? 4 5 MR. GREENE: 6 On agenda item 2, I make the motion that 7 we approve the Consent Agreement at Case 8 No. 18-54-009040. 9 MS. TALBOTT: 10 Second. 11 CHAIRPERSON HART: 12 Any discussion? Call for a vote. 13 14 Talbott, aye; Roussel, aye; Greene, aye; 15 Johnson, aye; Slagle, aye; Hart, aye. 16 [The motion carried unanimously. The Respondent's 17 name is Family Pharmacy.] * * * 18 19 MR. GREENE: 20 On agenda item 3, I make the motion that 21 we approve the Consent Agreement at Case Nos. 20-54-004433 & 21-54-000053. 22 2.3 MS. TALBOTT: 24 Second. 25 CHAIRPERSON HART:

14 Any discussion? Call for a vote. 1 2 3 Talbott, aye; Roussel, aye; Greene, aye; 4 Slagle, aye; Johnson, aye; Hart, aye. 5 [The motion carried unanimously. The Respondent's 6 name is Ott and McHenry Pharmacy & Michael Alton 7 Dolan.] * * * 8 9 MR. GREENE: 10 On agenda item 4, I make the motion that 11 we approve the Consent Agreement at Case No. 20-54-009805. 12 MS. TALBOTT: 13 Second. 14 15 CHAIRPERSON HART: Call for discussion? Call for a vote. 16 17 18 Talbott, aye; Roussel, aye; Greene, aye; 19 Slagle, aye; Johnson, aye; Hart, aye. 20 [The motion carried unanimously. The Respondent's 21 name is Absolute Pharmacy, LLC.] * * * 22 2.3 MR. GREENE: 2.4 On agenda items 5, 6, 7, and 8, I make a 25 motion that we approve the VRP Consent

15 Agreements at Case No. 21-54-000056, Case 1 2 No. 21-54-000184, Case No. 21-54-000318, 3 and Case No. 21-54-000319. 4 MS. TALBOTT: 5 Second. 6 CHAIRPERSON HART: Any discussion? Call for a vote. 8 9 Talbott, aye; Roussel, aye; Greene, aye; 10 Slagle, aye; Johnson, aye; Hart, aye. 11 [The motion carried unanimously.] * * * 12 MR. GREENE: 13 14 On agenda item 9 in the matter of the 15 Petition for Reinstatement of Douglas J. 16 Clark, R.Ph., I make a motion we adopt 17 the hearing examiner's proposed 18 Adjudication but direct Board Counsel to 19 issue a corrected order. 20 MS. TALBOTT: 21 Second. 22 CHAIRPERSON HART: 2.3 Call for discussion? Call for a vote. 2.4 25 Talbott, aye; Roussel, aye; Greene, aye;

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16
                 Slagle, aye; Johnson, aye; Hart, aye.
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   [The motion carried unanimously.]
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   DR. ROUSSEL:
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                 For agenda item 10, I would like to make
6
                 a motion to approve the Adjudication
                 Order for Umesh Patel, R.Ph., Case No.
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                 20-54-009692.
9
   MR. SLAGLE:
10
                 I'll second that.
11
   CHAIRPERSON HART:
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                 Any discussion? Call for a vote.
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14
                 Talbott, recuse; Roussel, aye; Greene,
15
                 recuse; Slagle, aye; Johnson, aye; Hart,
16
                 aye.
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   [The motion carried. Ms. Talbott and Mr. Greene
18
   recused themselves from deliberations and voting on
19
   the motion.
                              * * *
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   MR. GREENE:
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22
                 On agenda item 12, I make a motion that
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                 we provisionally deny the Reciprocal
24
                 Licensure Application of Michael Joyce.
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   MS. TALBOTT:
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17 Second. 1 2 CHAIRPERSON HART: 3 Call for discussion? Call for a vote. 4 5 Talbott, aye; Roussel, aye; Greene, aye; 6 Slagle, aye; Johnson, aye; Hart, aye. [The motion carried unanimously.] 9 MR. GREENE: 10 On agenda item 13, I make a motion that 11 we provisionally deny the Reciprocal 12 Licensure Application of Purvi Trivedi. 13 MS. TALBOTT: 14 Second. 15 CHAIRPERSON HART: 16 Any discussion? Call for a vote. 17 18 Talbott, aye; Roussel, aye; Greene, aye; 19 Slagle, aye; Johnson, aye; Hart, aye. 20 [The motion carried unanimously.] * * * 21 22 MR. GREENE: 2.3 On agenda item 14, I make a motion that 2.4 we require the applicant, Emmanuil 25 Shamilov, to take the Pennsylvania

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Pharmacists Association MPJE Prep &
1
2
                Review course and successfully pass the
3
                Practice Exam before retaking the MPJE.
 4
   MS. TALBOTT:
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                Second.
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   CHAIRPERSON HART:
                Any discussion? Call for a vote.
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9
                Talbott, aye; Roussel, aye; Greene, aye;
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                Slagle, aye; Johnson, aye; Hart, aye.
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   [The motion carried unanimously.]
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   [Janet Getzey Hart, R.Ph., Chairperson, announced a
   work session following the Board meeting.]
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   Public Comment
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   [Juan A. Ruiz, Esquire, Board Counsel, addressed a
18
   question in chat requesting clarification of MOU.
19
   provided a definition of MOU as a Memorandum of
20
   Understanding with the FDA concerning 503A compounding
21
   pharmacies. He explained that Pennsylvania needed to
22
   enter into an MOU with the FDA in order for
23
   compounding pharmacies to dispense an inordinate
24
   amount of compounded prescriptions out of state.
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        Mr. Ruiz stated a restriction of only 5% of total
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compounding prescriptions could be sent out of state
1
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   if Pennsylvania did not enter into an MOU.
                                                 He noted
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   it to be a request from the FDA for Pennsylvania to
   share information concerning serious adverse events
5
   that happen concerning compounded medication.]
                              * * *
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7
   Adjournment
   CHAIRPERSON HART:
                Motion to close?
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   MS. TALBOTT:
11
                 I'll make the motion we adjourn and go to
12
                 our work session.
13
   MR. GREENE:
14
                 Second.
15
   CHAIRPERSON HART:
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                 Any discussion? All in favor, say aye.
17
                 Opposed.
18
   [The motion carried unanimously.]
                              * * *
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   [There being no further business, the State Board of
21
   Pharmacy Meeting adjourned at 11:10 a.m. A regulation
   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.

Derek Richmond,

Minute Clerk

Sargent's Court Reporting Service, Inc.

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		April 27, 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	:
	10:37	Approval of Minutes	
	10:37	Report of Prosecutorial Division	
	10:48	Report of Board Counsel	
	10:54	Report of Board Chairperson	
	10:55	Report of Probable Cause Screening Committee	
	10:56	Report of Commissioner	
	10:59	Report of Executive Secretary	
	11:01	Approval of Agenda	
	11:02	Motions	
	11:08	Public Comment	
	11:10	Adjournment	