State Board of Pharmacy January 19, 2021

BOARD MEMBERS:

K. Kalonji Johnson, Commissioner, Bureau of Professional and Occupational Affairs Robert B. Frankil, R.Ph., Vice Chairman

Janet Getzey Hart, R.Ph., Chairperson

Christine Roussel, Pharm.D., BCOP, BCSCP, Secretary Patrick M. Greene, Esquire, Office of Attorney General

13 | General 14 | John R. Slagle, R.Ph. 15 | Terry M. Talbott, R.Ph.

BUREAU PERSONNEL:

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

Glenn P. Masser, Esquire, Board Prosecutor Alice Glasser, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Executive Secretary

Carolyn DeLaurentis, Deputy Chief Counsel, Prosecution Division

Theodore Stauffer, Executive Secretary, Bureau of Professional and Occupational Affairs

Andrew LaFratte, MPA, Policy Fellow, Department of State

Marc Farrell, Deputy Policy Director, Department of State

ALSO PRESENT:

Alicia Palombo, Pharm.D., Pharmacy Regulatory Affairs Advisor at CVS Health

Andrew C. Harvan, Esquire, Pennsylvania Medical Society

Barbara Knightly, Executive Vice President of Regulatory Affairs and Quality Operations, Pentec Health

Kaitlyn Porta, Villa Maria Academy

1 State Board of Pharmacy 2 January 19, 2021 3 4 5 ALSO PRESENT: (Continued) 6 7 Diedra Kaan, Pharmacy Resident 8 Gail Scott, MPH, Health Policy Network, LLC 9 Grace Fisher, Regional Pharmacy Manager, Giant Food 10 Stores, LLC 11 Jayanth Panyam Ph.D., Dean and Professor of 12 Pharmaceutics, Temple University School of Pharmacy 13 Jen Smeltz, Republican Executive Director, Senate 14 Consumer Protection & Professional Licensure 15 Committee Jenna L. McCarthy, Malady & Wooten on behalf of CVS 16 17 Jerry J. Livingston, Democratic Executive Director, 18 Senate Consumer Protection & Professional Licensure 19 Committee 20 Kimberly Mehta, Pharm.D., MPH, Director of Medication 21 Safety and Regulatory, Allegheny Health Network 22 Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists 23 24 Lauren Paul, Pharm.D., CVS Health 25 Lisa Scannapieco, Director of Pharmacy Education and 26 Clinical Integration, Pentec Health Shannon Snell, Research Analyst, Democratic House 27 28 Professional Licensure Committee 29 Steven L. Sheaffer, Pharm.D., FASHP, Pennsylvania 30 Society of Health-System Pharmacists 31 Victoria Elliott, RPh, MBA, CAE, CEO, Pennsylvania 32 Pharmacists Association 33 John Sisto, Express Scripts 34 Jacquelyn Sassaman, Pentec Health 35 Steven Zahn, Pharmacy Inspector, Bureau of Enforcement 36 and Investigation, Department of State 37 Tim Black, Pharmacy Inspector, Bureau of Enforcement 38 and Investigation, Department of State 39 Derek Richmond 40 Margaret Durkin 41 42 43 44 45 46 47 48

* * * 1 2 State Board of Pharmacy 3 January 19, 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.l * * * 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 being recorded. 16 17 The regularly scheduled meeting of the State 18 Board of Pharmacy was held on Tuesday, January 19, 19 2021. Janet Getzey Hart, R.Ph., Chairperson, called 20 the meeting to order at 10:30 a.m. 21 * * * 22 Introduction of the Board Members/Audience 23 [Chairperson Hart requested Board members and Board 2.4 staff introduce themselves. * * * 25

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   Approval of Agenda
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   CHAIRPERSON HART:
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                 Is there a motion to approve the agenda
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                 as distributed?
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   MS. TALBOTT:
                 So moved.
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   CHAIRPERSON HART:
                 Do I have a second?
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   MR. FRANKIL:
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                 Second.
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   CHAIRPERSON HART:
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                 All in favor, aye?
   [The motion carried unanimously.]
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   Report of Prosecutorial Division
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   [Glenn P. Masser, Esquire, Board Prosecutor, presented
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   the Consent Agreements for Case No. 20-54-004558, Case
   No. 20-54-003926, and Case No. 20-54-012692.
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   [Ray Michalowski, Esquire, Senior Board Prosecution
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   Liaison, presented the VRP Consent Agreements for VRP
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   Case No. 20-54-006205, VRP Case No. 20-54-008856, and
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   VRP Case No. 20-54-011049.]
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   Introduction of Audience Members
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1 [Theodore Stauffer, Executive Secretary, Bureau of 2 Professional and Occupational Affairs, provided an 3 introduction of audience members.]

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Appointment - Carolyn A. DeLaurentis, Esquire, Deputy
Chief Counsel, Prosecution Division Presentation
[Carolyn A. DeLaurentis, Esquire, Deputy Chief
Counsel, Prosecution Division, provided highlights of
the prosecution division's work during the past year.
She commended staff for all of their hard work to make
teleworking successful.

Ms. DeLaurentis stated Board prosecutors made every effort to monitor the restrictions, waivers, policies, and new procedures specific to the practice in each profession regarding challenges imposed on licensees by the COVID-19 pandemic.

Ms. DeLaurentis noted the Pennsylvania Licensing System (PALS) to be a lifeline. She stated the Bureau of Enforcement and Investigation (BEI) worked closely with prosecution to continue investigations and figure out the best methods during statewide shutdowns and stay-at-home orders. She also noted the Professional Compliance Office continued opening cases and processing files, and legal assistants have been working a hybrid schedule to ensure mailings and

filings are completed.

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Ms. DeLaurentis commented that the Board, Board staff, and counsel all have adapted to virtual Board meetings and prosecution will continue to work with everyone to ensure efficient and effective presentation and resolution of cases. She mentioned 2020 was a year filled with challenges, but the prosecution division led by the incredible senior staff rose to the challenge and will continue to do so.

Ms. DeLaurentis informed the Board that 752 cases were opened in 2020 and 593 in 2019 with 611 files closed in 2020 for the State Board of Pharmacy. She noted 487 open files as of January 1, 2021. Ms. DeLaurentis addressed enforcement actions with 93 total cases that resulted in discipline in 2020 for the State Board of Pharmacy. She reported 200 warning letters, 20 fines, 46 Act 48 citations, 24 suspensions, 1 automatic suspension, 10 reprimands, 4 revocations, 2 voluntary surrenders, and 4 probation cases in 2020.

Ms. DeLaurentis discussed 2020 overall prosecution as a whole. She noted 44 immediate temporary suspensions in 2020. She mentioned 24 of the 1,223 opened COVID-19 cases are for the State

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1 Board of Pharmacy in 2020. She reported the total

2 number of open cases as of January 1 is 12,250 and the

3 total number of files opened overall in 2020 is

4 13,394, which is down from 2019 at 16,295. She noted

5 | 13,274 files were closed in 2020.

6 Chairperson Hart requested information concerning 7 the number one complaint.

Mr. Michalowski reported that a large number of complaints come from the boards themselves that are typically referrals from the Board office at the time of renewal, reciprocals, criminal matters, lapsed licenses, and continuing education.

Mr. Michalowski stated the Board of Pharmacy receives a lot of inspection reports concerning failed inspections and mentioned consumer reports complaining of bad service.

Ms. Talbott thanked Ms. DeLaurentis and her team for assisting the Board of Pharmacy in protecting the citizens of the commonwealth during the challenging year.]

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22 Report of Board Counsel

23 [Juan A. Ruiz, Esquire, Board Counsel, noted one

24 adjudication and order was discussed during executive

25 session.

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Mr. Ruiz referred to information for the Board's review regarding House Bill 145, which was introduced January 1 requiring labeling for opiates.

Mr. Ruiz referred to proposed rulemaking 16A-5429 regarding the administration of injectable medications, biologicals, and immunizations. He noted the Board proposed the regulation concerning the addition of an intern piece to the regulation scheme already in place.

Mr. Ruiz addressed comments received from the Pennsylvania Medical Society, where they noted being in favor of the regulation but questioned how primary care providers would become known, along with several notification questions.

Ms. Talbott stated the responsibility of notification falls with the pharmacist because they can operate independently, so the responsibility of notification goes back on to the supervising pharmacists and is already addressed in the regulations. She noted the part of the pharmacy intern to fulfill notification requirements would go back on the supervising pharmacist because they are directing the intern.

Mr. Ruiz addressed a comment from the National Association of Chain Drug Stores, where they talked

about the urgency of having this regulation in place due to the pandemic and the importance of having interns.

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Mr. Ruiz noted the Pennsylvania Society of Physician Assistants are in favor of the regulation.

Mr. Ruiz addressed comments from the Pennsylvania Osteopathic Medical Association expressing concerns regarding providers not receiving notifications when a patient received a shot. He reported that to be an enforcement issue.

Mr. Ruiz addressed the Independent Regulatory
Review Commission's (IRRC) question concerning
application renewal and reactivation procedures. He
mentioned that interns are different from regular
pharmacists because the pharmacy intern authorization
to administer injectables is not renewable and is only
good for 6 years. He noted IRCC questioned how the
Board ensures individuals are current with their
cardiopulmonary resuscitation (CPR) certification.

Mr. Frankil explained the process by having a license on the wall and a copy of the CPR certificate and end date. He noted it falls on the responsibility of the pharmacist in charge.

Ms. Talbott stated the intern certificate cannot be renewed after 6 years. She noted most of the

- schools are waiting for the regulations to be
 processed and final and are going to start training
 students so the education falls within that 3-year
 time period of when they could apply for their
 pharmacist license.
- Mr. Ruiz mentioned answering this through the
 preamble but suggested just stating, "While you have
 to have a current registration, the CPR certification
 also has to be current."
- Mr. Ruiz noted the second comment from IRRC concerning conditions for administration.

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- Ms. Talbott noted that could be fixed because it was not called the right name.
 - Mr. Ruiz suggested clarifying notification requirements in the preamble regarding IRRC's comment.
 - Mr. Ruiz addressed IRRC's comment questioning whether or not the insurance that the pharmacist has covers the negligent supervision by a pharmacist that is supervising a pharmacist intern who has authorization to inject.
 - Mr. Ruiz commented that pharmacy interns are not required to maintain professional liability insurance but questioned whether there is any insurance coverage if the pharmacist's supervision is proper but the pharmacy intern is negligent in administering the

injection.

Mr. Frankil stated a pharmacy also has liability
insurance, and there should be language in the policy
covering all employees. He commented that the
responsibility falls back on the supervising

6 pharmacist, which should also be covered under the
7 pharmacy in the language that covers all professional

8 responsibilities.

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Mr. Ruiz suggested clarifying that there is adequate protection given the supervising pharmacist has insurance for injectables plus the pharmacy itself has liability insurance in the preamble as opposed to changing the regulation.

Mr. Ruiz will add a few words to the preamble regarding CPR certification and provide a draft for the Board's review and approval for final rulemaking.

Mr. Ruiz informed the Board of a work session after the next meeting to discuss the pharmacy technician bill.]

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21 Report of Board Chairperson - No Report

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23 Report of Probable Cause Screening Committee - No 24 Report

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13 Report of Commissioner - No Report 1 2 3 Report of Executive Secretary - No Report * * * 4 5 MOTIONS 6 [Commissioner Johnson stepped away from the meeting during the motions] 8 9 CHAIRPERSON HART: 10 The Board of Pharmacy met in executive session to discuss and review consent 11 12 orders and other legal documents. Are 13 there any motions regarding these discussions? 14 15 MR. GREENE: 16 I have a motion at agenda Item No. 1. make a motion that we approve the Consent 17 18 Agreement at Case No. 20-54-004558. 19 MR. FRANKIL: 20 Second. 21 CHAIRPERSON HART: 22 Any call for discussion? Call for a 2.3 vote. 2.4 25 Hart, aye; Frankil, aye; Roussel, aye;

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                 Slagle, aye; Talbott, aye; Greene, aye.
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   [The motion carried unanimously. The Respondent's
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   name is Schrafts 2.0 LLC.]
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   MR. FRANKIL:
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                 I make the motion on agenda Item No. 2.
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                 We approve the Consent Agreement for Case
                 No. 20-54-003926.
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   MS. TALBOTT:
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                 Second.
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   CHAIRPERSON HART:
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                 Any discussion? Call for a vote.
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                 Hart, aye; Frankil, aye; Roussel, aye;
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                 Talbott, aye; Slagle, aye; Greene,
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                 recuse.
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   [The motion carried. The Respondent's name is Thomas
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   John O'Donnell, R.Ph. Mr. Greene recused himself from
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   deliberations and voting on the motion.]
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   MR. FRANKIL:
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                 I make the motion that we approve agenda
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                 Item No. 3, the Consent Agreement for
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                 Case No. 20-54-012692.
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   MS. TALBOTT:
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15 Second. 1 2 CHAIRPERSON HART: 3 Any discussion? Call for a vote. 4 5 Hart, aye; Frankil, aye; Roussel, aye; 6 Talbott, aye; Slagle, aye; Greene, 7 recuse. [The motion carried. The Respondent's name is Gerald S. Effland, Jr., R.Ph. Mr. Greene recused himself 10 from deliberations and voting on the motion.] * * * 11 12 MR. GREENE: At agenda items 4, 5, and 6, I make the 13 14 motion that we approve the following VRP 15 Consent Agreements: Case No. 20-54-006205, Case No. 20-54-008856, Case No. 16 17 20-54-011049. 18 CHAIRPERSON HART: 19 Do I have a second? 20 MR. FRANKIL: 21 Second. 22 CHAIRPERSON HART: 2.3 Any discussion? Call for a vote. 2.4 25 Hart, aye; Frankil, aye; Roussel, aye;

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Talbott, aye; Slagle, aye; Greene, aye.
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   [The motion carried unanimously.]
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   MR. FRANKIL:
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                 I make a motion that we approve agenda
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                 Item No. 8, the Final Adjudication and
                 Order for Andrew Freeman, Jr., R.Ph. at
                 Case No. 19-54-002334.
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   MS. TALBOTT:
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                 Second.
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   CHAIRPERSON HART:
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                 Any discussion? Call for a vote.
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                 Hart, aye; Frankil, aye; Roussel, aye;
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                 Talbott, aye; Slagle, aye; Greene,
16
                 recuse.
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   [The motion carried. Mr. Greene recused himself from
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   deliberations and voting on the motion.]
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   New Business
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   [Janet Getzey Hart, R.Ph., Chairperson, noted proposed
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   2022 meeting dates.
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        Ms. Talbott suggested moving August 9 to August
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   16, 2021, and September 20 to September 27, 2021,
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   because the window for the law review questions is
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1 around August 11 through September 9, 2021.

2 Ms. Zimmerman will submit those dates to the

3 | Commissioner's Office and post them online.

4 Ms. Zimmerman noted the Multistate Pharmacy

5 Jurisprudence Exam (MPJE) Item Development Workshop

6 March 1-26, 2021. She also noted Rich Smiga is

7 | willing to write test questions.]

* * *

9 MR. FRANKIL:

10 I'll make the motion to have Rich Smiga

do the questions.

12 MS. TALBOTT:

13 Second.

14 | CHAIRPERSON HART:

Call for discussion? All in favor, aye?

16 [The motion carried unanimously.]

17

18 New Business - 117th Annual National Association of

19 | Boards of Pharmacy (NABP) Meeting

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

21 mentioned the Board wanted to discuss the 117th NABP

22 | Annual Meeting scheduled for May 13-14, 2021, after

23 they receive information regarding the registration

24 fee and confirmation on how many people could attend.

25 Ms. Zimmerman noted the NABP Interactive Member

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   Forum on January 27, 2021, and will inquire as to
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   whether Dr. Roussel is still able to register.]
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   MS. TALBOTT:
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                I'll make the motion that we send
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                Christine Roussel to both the NABP
                Interactive Forum and be the
                representative to the Duquesne University
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9
                ACPE recertification process in April.
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   MR. FRANKIL:
                I'll second that.
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   CHAIRPERSON HART:
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                Any discussion? All in favor, aye?
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   [The motion carried unanimously.]
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   [Commissioner Johnson returned to the meeting during
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   this discussion.
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        Terry M. Talbott, R.Ph., reported receiving an
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   email that Dr. Levine has been nominated to go to
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   Washington to serve as the Assistant Health Secretary.
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    Ms. Talbott expressed concern regarding the naloxone
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   standing order and suggested Commissioner Johnson or
2.3
   Mr. Ruiz take that to the Department of Health to get
24
   the statewide standing order updated prior to Dr.
25
   Levine's departure to avoid a gap in care.
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- 1 Mr. Ruiz will follow up with the Board after he 2 receives information concerning the naloxone standing 3 order.
- Mr. Frankil noted also receiving an email from a concerned pharmacist recommending phases of immunization for COVID be moved along faster. He mentioned that the pharmacist has hundreds of vaccine doses but cannot administer those.
- 9 Mr. Frankil reported that Pennsylvania is still 10 in Phase 1a and questioned whether the Board has any 11 influence on the Department of Health (DOH) to move 12 these phases along faster.
- Commissioner Johnson will provide the information
 to the Department of Health but also encouraged
 stakeholders to also reach out directly to the
 Department of Health for greater influence.
- 17
- 18 | Adjournment
- 19 CHAIRPERSON HART:
- Do we have a motion to adjourn?
- 21 MS. TALBOTT:
- I make a motion to adjourn.
- 23 MR. FRANKIL:
- 24 Second.
- 25 CHAIRPERSON HART:

1 Any discussion? All in favor, aye? 2 [The motion carried unanimously.] 3 4 [There being no further business, the State Board of 5 Pharmacy Meeting adjourned at 11:41 a.m.] * * * 6 8 CERTIFICATE 9 10 I hereby certify that the foregoing summary 11 minutes of the State Board of Pharmacy meeting, was 12 reduced to writing by me or under my supervision, and 13 that the minutes accurately summarize the substance of 14 the State Board of Pharmacy meeting. 15 16 17 18 Derek Richmond, 19 Minute Clerk 20 Sargent's Court Reporting 21 Service, Inc. 22 2.3 2.4 25

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		January 19, 2021	
	TIME	AGENDA	
	9:00	Executive Session	
	10:30	Return to Open Session	
	10:30	Official Call to Order	
	10:31	Introduction of Board Members	
	10:32	Approval of Agenda	
	10:33	Report of Prosecutorial Division	
	10:35	Introduction of Audience Members	
	10:45	Appointment - Carolyn A. DeLaurentis, Esquire, Deputy Chief Counsel, Prosecution Division Presentation	
	11:01	Report of Board Counsel	
	11:24	Motions	
	11:29	New Business	
	11:41	Adjournment	