State Board of Pharmacy July 29, 2021

Janet Getzey Hart, R.Ph., Chairperson

John R. Slagle, R.Ph. - Absent

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 General

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48 49 50 BUREAU PERSONNEL:

Terry M. Talbott, R.Ph.

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

Liaison Alice Glasser, Esquire, Board Prosecutor Timothy A. Fritsch, Esquire, Board Prosecutor

Melanie Zimmerman, R.Ph., Executive Secretary Marc Farrell, Deputy Policy Director, Department of State

Thaddeus Cwiklinski, Legal Extern, Office of General Counsel, Department of State

ALSO PRESENT:

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

Christopher Miller, Pharm.D., Giant Eagle David Klinger, System Director, Operations & Compliance, Geisinger Health System

Grace Fisher, Regional Pharmacy Manager, Giant Food Stores, LLC

Hallie Fromm

Heather Coy, AllianceRx Walgreens Prime

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

State Board of Pharmacy July 29, 2021

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ALSO PRESENT: (cont.)

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38 39 Jennifer Welch, ACME/Sav-on Pharmacy Jenna McCarthy, Malady & Wooten, on behalf of PA CVS

Judy Kutchman, AllianceRx Walgreens Prime Kate Nelms, Pharm.D., Walgreens Boots Alliance

Kate Nelms, Pharm.D., Walgreens Boots Alliance Kimberly Mehta, Pharm.D., MPH, Director of Medication

Safety and Regulatory, Allegheny Health Network

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

Laura Romeo, Pharmacist-in-Charge at ConnectiveRx, Careform Pharmacy

Martin Farrell, R.Ph., Manager, Sterile Pharmacy

Matthew Roesch, R.Ph., Pharmacist-in-Charge, Vetsource Pharmacy

Megon McCall, Senior Manager and Pharmacist-in-Charge, CVS Specialty

Nicole Fidler, Malady & Wooten, on behalf of PA CVS

Nicole Pillarella, Jefferson College of Pharmacy

Nicole Sidle, Republican Executive Director, House Professional Licensure Committee

Robert B. Frankil, R.Ph., President, BucksMont Pharmacists Association

Ron Raymond

Ryan Burke, Pharm.D., Director of Professional Affairs, Pharmacy Technician Certification Board Steve Sheaffer, Pharm.D., Pennsylvania Society of Health-System Pharmacists

Tejal Patel, Pharm.D., Walgreens Boots Alliance Timothy Black, R.Ph.

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

Catherine Lutz, Pharmacy Inspector, Bureau of

Enforcement and Investigation, Department of State Jennifer Winters

Margaret Barca

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* * * 1 2 State Board of Pharmacy 3 July 29, 2021 * * * 4 5 [Pursuant to Section 708(a)(5) of the Sunshine Act, at 6 9:00 a.m., the Board entered into Executive Session 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 The regularly scheduled meeting of the State 13 Board of Pharmacy was held on Thursday, July 29, 2021. 14 Janet Getzey Hart, R.Ph., Chairperson, called the 15 meeting to order at 10:30 a.m. 16 17 Introduction of the Board Members 18 [Chairperson Hart requested an introduction of Board 19 members.1 20 * * * 21 Introduction of Attendees 22 [Melanie Zimmerman, R.Ph., Executive Secretary, 23 provided an introduction of those in attendance.] * * * 24 25 Approval of Agenda

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   CHAIRPERSON HART:
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                 Do I have a motion to approve the agenda?
3
   DR. ROUSSEL:
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                 I'll make a motion to approve the agenda
5
                 today.
6
   MS. TALBOTT:
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                 Second.
   CHAIRPERSON HART:
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                 Call for a vote. All in favor, aye?
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                 Opposed?
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   [The motion carried unanimously.]
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   Approval of Minutes
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   CHAIRPERSON HART:
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                 Approval of the minutes from June 8.
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                 I have a motion to approve the minutes,
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                 or are there any changes?
   DR. ROUSSEL:
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19
                 I make a motion to approve the minutes.
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   CHAIRPERSON HART:
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                 Do I have a second?
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   MS. TALBOTT:
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                 Second.
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   CHAIRPERSON HART:
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                 Call for a vote. All in favor, aye?
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1 [The motion carried unanimously.]

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3 | [Janet Getzey Hart, R.Ph., Chairperson, informed

4 everyone that the Board of Pharmacy met in Executive

5 | Session earlier today to receive legal advice and

6 engage in quasi-judicial deliberations.]

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- 8 Report of Prosecutorial Division
- 9 [Alice Glasser, Esquire, Board Prosecutor, presented
- 10 the Consent Agreements for Case No. 20-54-002066 and
- 11 | Case No. 21-54-002091.]

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- 13 [Ray Michalowski, Esquire, Senior Board Prosecution
- 14 Liaison, presented the VRP Consent Agreement for Case
- 15 No. 21-54-008044.
- Mr. Michalowski introduced Timothy Fritsch as a
- 17 | new Board prosecutor for the Board of Pharmacy.
- 18 Mr. Fritsch commented that he looked forward to
- 19 learning more about the pharmacy profession.
- 20 Mr. Fritsch presented the Consent Agreement for
- 21 Case No. 21-54-005130.
- 22 Chairperson Hart welcomed Mr. Fritsch to the
- 23 Board.]
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25 Report of Board Counsel

- 1 [Juan A. Ruiz, Esquire, Board Counsel, noted two Final
- 2 | Adjudications and Orders were discussed during
- 3 Executive Session. He also informed everyone of a
- 4 regulatory work session to discuss pharmacy technician
- 5 regulations following the meeting.]
 - * * *
- 7 Report of Board Chairperson

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- 8 | [Janet Getzey Hart, R.Ph., Chairperson, announced she
- 9 has been appointed to a National Association of Boards
- 10 of Pharmacy (NABP) Task Force on Law
- 11 Enforcement/Legislation. Ms. Talbott also
- 12 announced she was appointed to the Model State
- 13 | Pharmacy Act and Model Rules Task Force to review
- 14 regulations. She mentioned the task force had their
- 15 | first meeting, noting the next meeting will be
- 16 sometime in October or November.
- 17 Ms. Talbott stated she is chair of the NABP
- 18 Advisory Committee on Examinations. She commented
- 19 that the committee is having a subcommittee with a
- 20 member from the NAPLEX Review Committee, Multistate
- 21 Pharmacy Jurisprudence Examination (MPJE) Review
- 22 | Committee, and Foreign Pharmacy Graduate Equivalency
- 23 Examination (FPGEE) Review Committee to address and
- 24 standardize committee structure because there is no
- 25 consistent term limit or guidelines for the

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   committees.
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   Report of Probable Cause Committee - No Report
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   Report of Commissioner
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   [K. Kalonji Johnson, Commissioner, Bureau of
   Professional and Occupational Affairs, addressed
   physical presence requirements, noting waivers as a
   result of the emergency declaration will expire on
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   September 30, 2021, including the suspension of the
11
   virtual platform.
12
        Commissioner Johnson mentioned that the Board of
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   Pharmacy does have a physical presence requirement
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   within the Practice Act. He advised everyone that
15
   they will be returning to physical presence meetings
16
   at the Penn Center location on October 1, 2021,
17
   provided the General Assembly does not extend the
18
   waiver of the physical presence requirement.
19
        Commissioner Johnson informed the Board that
20
   suspensions on travel have been lifted, and the
   department is allowing physical travel for regional
21
   and national conferences. He strongly encouraged
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   virtual attendance because of health and safety
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concerns. He mentioned all requests are still subject

to the Governor's Office approval and asked Board

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1 members to submit requests as soon as possible to 2 address any concerns.

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Report of Prosecutorial Division (Continued)

[Ray Michalowski, Esquire, Senior Board Prosecution

Liaison, on behalf of Glenn P. Masser, Esquire, Board

Prosecutor, presented the Consent Agreements for Case

No. 16-54-08283 & 17-54-03637, Case No. 21-54-004970,

Case No. 20-54-014113, and Case No. 21-54-001227.

Ms. Talbott requested information regarding whether there has been a change in the number of violations compared to past years.

Mr. Michalowski offered to provide those numbers with the assistance of Mr. Fritsch at the next Board meeting. He stated that prosecution has been busy working with the Prescription Drug Monitoring Program (PDMP) to bring pharmacies into compliance and working closely with the Department of Health. He stated Ms. Bailey and Ms. Glasser were doing the heavy lifting on that, along with their law clerk. He noted receiving a fair amount of inspection issues because of inspection delays during COVID-19.

Mr. Michalowski reported there are some new types of issues such as mini-hospitals. There may be a need for the Legislature to take action or the Board

Regulations to be amended to allow for disciplinary action for noncompliance with the PDMP.. Board Counsel Ruiz noted that a work session will be held on August 31, 2021 to review the General Revisions.

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Ms. Talbott recommended breaking up the big package into small packages that are noncontroversial, so they do not have to start with the 35-page package where most of the work has been completed.

Mr. Michalowski mentioned a request from PDMP, where the Board still does not have a reference in the act or regulations on using the PDMP. He noted that he has to hire an expert at the Board's cost if someone is charged to show that what they have done falls below the standard of care and suggested putting something in the section on review to show very simple and direct requirements and penalties.

Mr. Michalowski stated the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) empowers prescribing boards to take action for failure to comply with ABC-MAP, noting that none of the boards were granted the ability to take action for violations in a legislative way.

Mr. Michalowski mentioned that he would like the Board of Pharmacy to be the first Board to have something in the regulations that allows them to take

those kind of actions. He noted that at the present time prosecution works with them on compliance, but a case would be just under general nonconformance if it is brought before the Board.

Ms. Talbott questioned whether the Board could do that because the statute requires due diligence on the pharmacist to check, but it was not mandatory. She commented that she did not think the Board could just put a blanket requirement in the regulations because it is not in the statute.

Mr. Michalowski reported many issues at the Department of Health concern physicians not performing the mandated lookups, but he is talking about pharmacies and pharmacists reporting errors and late reporting, where the PDMP does not work if the data is not entered. He reported 99 percent of issues deal with data entry, where it has not been done at all, late, or incorrectly.

Mr. Michalowski suggested just referring to the ABC-MAP Act, where compliance is mandatory, and whatever legislature adds or detracts later from the ABC-MAP would be covered. He reported very few complaints, if any, noting other cases, where a pharmacy was clearly supplying tons of opiates, would already be dealing with law enforcement.

Mr. Ruiz believed he had the revisions that were sent to him and will add it to the next agenda for discussion regarding any changes the Board wishes to make at the regulation work session.

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Ms. Talbott suggested Mr. Ruiz send the file to Board members for review before the work session.

Mr. Michalowski again suggested just referring to the ABC-MAP Act, where compliance is mandatory, and whatever legislature adds or detracts later from the ABC-MAP would be covered.

Mr. Michalowski reported a decline in hospital pharmacies being inspected by the Department of Health due to large hospital systems buying all of the small ones. He mentioned not receiving many of these inspection reports because the Department of Health will then defer to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or those accredited by a national accrediting organization.

Mr. Michalowski believed it would take a legislative change to move inspections from the Department of Health to BEI's inspectors but thinks there are so few that BEI's inspectors could handle those. He noted the DOH hospital pharmacy surveys would need to be updated to include some of the

standards regarding compounding.

Mr. Michalowski commented that having inspections by a pharmacist rather than a nurse and inspections rather than surveys for the last few remaining hospitals would be appropriate and could be handled by the BEI staff.

Chairperson Hart questioned whether Mr.

Michalowski had any new information concerning a PDMP vendor change in Pennsylvania.

Mr. Michalowski mentioned prosecution has been working closely with the compliance specialist, Andrea Jenkins, from Drug Surveillance and Misuse Prevention. He noted they are switching from their current vendor to an in-house created system. He offered to invite Andrea Jenkins to speak with the Board as far as what is coming up and how the switchover will occur.

Chairperson Hart had voiced her concerns of not wanting the changes to occur during COVID because pharmacists were providing vaccinations and tests and going to a new vendor would be too much.

Mr. Michalowski commented that an off-the-shelf system was bought. He mentioned that there are concerns because pharmacies will have to adapt, and third-party vendors have to convert from the pharmacy's computer system to the PDMP system.

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Mr. Michalowski stated that prosecution
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2
   recognizes changes can be difficult and has been
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   lenient with pharmacies and pharmacists with change of
   pharmacist managers and delayed license renewals.
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   also noted utilizing warning letters, recognizing
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   stressors pharmacies and pharmacists are undergoing.]
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   Report of Executive Secretary
   [Melanie Zimmerman, R.Ph., Executive Secretary,
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   reported pharmacy renewals opened 3 to 4 weeks ago and
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   about 36 percent of Pennsylvania pharmacies and
   nonresident pharmacies have renewed at this point.]
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   Applications
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   [Melanie Zimmerman, R.Ph., Executive Secretary, noted
   the application was discussed during Executive
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   Session, and the Board will be placing their decision
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   on record.1
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   New Business
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   [Melanie Zimmerman, R.Ph., Executive Secretary, noted
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- 22 the request for the pharmacy law update at the
- 23 Duquesne Alumni Conference was discussed during
- 24 Executive Session, and the Board will be placing the
- 25 decision on record.]

* * * 1 2 Old Business 3 [Melanie Zimmerman, R.Ph., Executive Secretary, 4 announced the Board will be holding a private work 5 session at the next Board meeting to discuss the 2021 6 MPJE state-specific review and pre-test item selection. Chairperson Hart commented that there is no ability to perform a batch renewal on a pharmacy 10 permit like they do with the Drug Enforcement 11 Administration and questioned whether there has been any consideration of updating PALS for batch renewals. 12 13 Ms. Zimmerman explained that each pharmacy record is an individual record with no way of tying them 14 15 together based on ownership or name and the ability to perform batch renewals would be a question for the 16 17 system programmers. 18 Ms. Zimmerman noted that they are still working on getting all of the pharmacy applications online 19 20 because a lot of the facility applications are still 21 paper applications. She noted information technology 22 (IT) work has to be prioritized but will broach with 2.3 IT the subject of batch renewals.]

MOTIONS

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16 1 CHAIRPERSON HART: 2 The Pharmacy Law Update Education 3 Duquesne Alumni Conference. I believe we need a motion to allow that to occur and 4 5 who might attend. DR. ROUSSEL: 6 I make a motion for Terry Talbott to 8 attend and provide that education. 9 MR. GREENE: 10 Second. 11 CHAIRPERSON HART: 12 Call for a vote. All in favor? Opposed? 13 [The motion carried unanimously. * * * 14 15 CHAIRPERSON HART: If Terry cannot attend, Christine and/or 16 17 I will attend. Do I have that motion? 18 19 MR. GREENE: 20 So moved. 21 DR. ROUSSEL: 22 Second. 2.3 CHAIRPERSON HART: 24 Call for a vote. All in favor, aye? 25 Opposed?

17 [The motion carried unanimously.] 1 2 3 CHAIRPERSON HART: The Board of Pharmacy met in Executive 4 5 Session to discuss and review consent 6 orders and other legal documents. 7 Are there any motions regarding these 8 discussions? 9 MR. GREENE: 10 At agenda item 2, I make a motion that we 11 approve the Consent Agreement at Case Nos. 16-54-08283 & 17-54-03637. 12 DR. ROUSSEL: 13 I second the motion. 14 15 CHAIRPERSON HART: Call for discussion. Call for a vote. 16 17 18 Talbott, aye; Roussel, aye; Greene, aye; 19 Johnson, aye; Hart, aye. 20 [The motion carried unanimously. The Respondent's 21 name is Kofi Dei Gbomita, R.Ph.] * * * 22 2.3 MR. GREENE: At agenda item 3, I make a motion that we 2.4 25 approve the Consent Agreement at Case No.

18 21-54-004970. 1 2 DR. ROUSSEL: 3 I would like to second. 4 CHAIRPERSON HART: 5 Call for discussion. Call for a vote. 6 Talbott, aye; Roussel, aye; Greene, aye; 8 Johnson, aye; Hart, aye. [The motion carried unanimously. The Respondent's 10 name is Specialty Rx Inc Pharmacy.] * * * 11 12 MR. GREENE: At agenda item 4, I make a motion that we 13 14 approve the Consent Agreement at Case No. 15 20-54-014113. 16 DR. ROUSSEL: 17 Second. CHAIRPERSON HART: 18 19 Call for discussion. No discussion. 20 Call for a vote. 2.1 22 Talbott, aye; Roussel, aye; Greene, aye; 2.3 Johnson, aye; Hart, aye. 24 [The motion carried unanimously. The Respondent's 25 name is Waschko's Pharmacy, Inc. t/d/b/a Waschkos

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   Pharmacy.]
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   MR. GREENE:
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                 At agenda item 5, I make a motion that we
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                 approve the Consent Agreement at Case No.
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                 21-54-001227.
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   DR. ROUSSEL:
                 I'd like to second.
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   CHAIRPERSON HART:
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                 Call for discussion. Call for a vote.
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                 Talbott, aye; Roussel, aye; Greene, aye;
                 Johnson, aye; Hart, aye.
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   [The motion carried unanimously. The Respondent's
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   name is Rita Ka-Man Jew, R.Ph.]
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   MR. GREENE:
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                 At agenda item 6, I make a motion that we
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                 approve the Consent Agreement at Case No.
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                 20-54-002066.
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   DR. ROUSSEL:
                 I'd like to second.
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2.3
   CHAIRPERSON HART:
2.4
                 Call for discussion. No discussion.
25
                 Call for a vote.
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20 1 2 Talbott, aye; Roussel, aye; Greene, aye; 3 Johnson, aye; Hart, aye. 4 [The motion carried unanimously. The Respondent's 5 name is Todd Michael Whitehead, R.Ph.] * * * 6 7 MR. GREENE: At agenda item 7, I make a motion that we 9 approve the Consent Agreement at Case No. 10 21-54-002091. 11 DR. ROUSSEL: 12 Second. 13 CHAIRPERSON HART: 14 Call for discussion. No discussion. 15 Call for a vote. 16 17 Talbott, aye; Roussel, aye; Greene, aye; 18 Johnson, aye; Hart, aye. 19 [The motion carried unanimously. The Respondent's 20 name is Specialty Veterinary Pharmacy.] * * * 21 22 MR. GREENE: 2.3 At agenda item 8, I make a motion that we 2.4 approve the VRP Consent Agreement at Case 25 No. 21-54-008044.

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   DR. ROUSSEL:
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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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                 Talbott, aye; Roussel, aye; Greene, aye;
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                 Johnson, aye; Hart, aye.
   [The motion carried unanimously.]
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   MR. GREENE:
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                 At agenda item 9, I make a motion that we
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                 approve the Consent Agreement at Case No.
                 21-54-005130.
13
   DR. ROUSSEL:
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15
                 Second.
16
   CHAIRPERSON HART:
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                 Call for discussion. No discussion.
                 Call for a vote.
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                 Talbott, aye; Roussel, aye; Greene, aye;
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                 Johnson, aye; Hart, aye.
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   [The motion carried unanimously. The Respondent's
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   name is Keystone Pharmacy.]
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   MR. GREENE:
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22 At agenda item 10, I make a motion that 1 2 we adopt the Final Adjudication and Order 3 in the matter of Peter Antinopoulos, 4 R.Ph. 5 DR. ROUSSEL: 6 Second. 7 CHAIRPERSON HART: Call for discussion. Call for a vote. 9 10 Talbott, aye; Roussel, aye; Greene, aye; 11 Johnson, aye; Hart, aye. 12 [The motion carried unanimously.] * * * 13 MR. GREENE: 14 15 At agenda item 11, I make a motion that 16 we adopt the Final Adjudication and 17 Order in the matter of Jacient Bray, 18 R.Ph. 19 DR. ROUSSEL: 20 Second. 21 CHAIRPERSON HART: 22 Any discussion? Call for a vote. 2.3 24 Talbott, aye; Roussel, aye; Greene, aye; 25 Johnson, aye; Hart, aye.

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   [The motion carried unanimously.]
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   MR. GREENE:
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                 At agenda item 13, I make a motion that
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                 we approve the Reciprocal Licensure
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                 Application Reevaluation of Purvi
7
                 Trivedi.
   DR. ROUSSEL:
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                 Second.
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   CHAIRPERSON HART:
11
                 Any discussion? Call for a vote.
12
13
                 Talbott, aye; Roussel, aye; Greene, aye;
14
                 Johnson, aye; Hart, aye.
15
   [The motion carried unanimously.]
16
   [Janet Getzey Hart, R.Ph., Chairperson, requested
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18
   people participate in the regulation work session to
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   discuss pharmacy technicians following the Board
20
   meeting.]
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22
   Adjournment
2.3
   CHAIRPERSON HART:
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                 Can we make a motion to close the
25
                 meeting?
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   MS. TALBOTT:
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                 I make a motion that we close the meeting
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                 and move to the workshop.
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   DR. ROUSSEL:
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                 I second that.
6
   CHAIRPERSON HART:
                 All in favor, aye?
   [The motion carried unanimously.]
9
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   [There being no further business, the State Board of
11
   Pharmacy Meeting adjourned at 11:29 a.m. A regulation
   work session was held from 11:30 a.m. to 1:17 p.m.]
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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.

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Derek Richmond,

Minute Clerk

Sargent's Court Reporting
Service, Inc.