## State Board of Pharmacy November 1, 2022

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## BOARD MEMBERS:

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### 18 BUREAU PERSONNEL:

Chairperson

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48 49 Patrick M. Greene, Esquire, Office of Attorney General, Secretary John R. Slagle, R.Ph. Terry M. Talbott, R.Ph.

Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs

Christine Roussel, Pharm.D., BCOP, BCSCP, Vice

Janet Getzey Hart, R.Ph., Chairperson

Carole Clarke Smith, Esquire, Senior Board Counsel Ariel O'Malley, Esquire, Board Counsel Carolyn DeLaurentis, Deputy Chief Counsel, Prosecution Division

Ray Michalowski, Esquire, Senior Board Prosecution Liaison

Glenn P. Masser, Esquire, Board Prosecutor Alice Glasser, Esquire, Board Prosecutor Ashley Murphy, Esquire, Board Prosecutor Caroline A. Bailey, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Board Administrator Marc Farrell, Deputy Policy Director, Department of State

Nicole VanOrder, Esquire, Prosecuting Attorney Jane Michetti, Legal Intern

## ALSO PRESENT:

Mary Tran, Pharm.D., Executive Fellow, Pennsylvania Pharmacists Association

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

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

Timothy Black, R.Ph., Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State Jacquelyn Sassaman, Pentec Health

Jenna McCarthy, Associate, Malady & Wooten Judy Kutchman, AllianceRx Walgreens Prime

# State Board of Pharmacy November 1, 2022

ALSO PRESENT: (cont.)

Kimberly Mehta, Pharm.D., MPH, Director of Medication
 Safety and Regulatory, Allegheny Health Network
Nicole Sidle, Republican Executive Director, House
 Professional Licensure Committee
Jeffrey Dietrich, Pharmacy Manager, Cardinal Health
William Johnson
David Klinger, System Director, Operations
 & Compliance, Geisinger Health System
Christopher Miller, Pharm.D., Giant Eagle
Cheryl McChesney, Pharm.D., Genoa Healthcare
Laura Romeo, Pharmacist-in-Charge at ConnectiveRx,
 Careform Pharmacy

Christina Swiger, Pharmacy Intern Derek Richmond

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

Alexis Jeschonnek

5 | Vinay Arora 6 | Charlotte Harris

Eric Esterbrook, R.Ph.

8 Joshua Finger
9 Jennifer Raibley
0 Matt Roesch,
1 Alicia Palombo

31 | Alicia Palombo 32 | Misha Patel

3 Raymond Vellky
4 Jennifer Smeltz
5 Jessica Zukoski

4 \* \* \* 1 2 State Board of Pharmacy 3 November 1, 2022 \* \* \* 4 5 [Pursuant to Section 708(a)(5) of the Sunshine Act, 6 at 9:30 a.m., the Board entered into Executive 7 Session with Ariel E. O'Malley, Esquire, Board Counsel, for the purpose of conducting quasi-judicial deliberations and to receive the advice of Board 10 Counsel. The Board returned to open session at 10:30 11 a.m.] \* \* \* 12 13 The regularly scheduled meeting of the State Board of 14 Pharmacy was held on Tuesday, November 1, 2022. 15 Janet Getzey Hart, R.Ph., Chairperson, called the 16 meeting to order at 10:36 a.m. \* \* \* 17 18 Pledge of Allegiance 19 [The Pledge of Allegiance was recited.] \* \* \* 20 21 Introduction of the Board Members/Audience 22 [Janet Getzey Hart, R.Ph., Chairperson, requested an 23 introduction of Board members, Board staff and the 24 audience.1 \* \* \* 25

5 [Ariel E. O'Malley, Esquire, Board Counsel, 1 2 reminded everyone that the meeting was being 3 recorded, and those who continued to participate were 4 giving their consent to be recorded.] 5 6 Approval of Agenda 7 CHAIRPERSON HART: 8 At this point, I would seek a motion to 9 approve the agenda as posted and 10 distributed. 11 DR. ROUSSEL: 12 I'd like to make a motion to approve the 13 agenda. 14 MS. TALBOTT: 15 Second. CHAIRPERSON HART: 16 Any discussion? Call for a vote. 17 18 19 Roussel, aye; Hart, aye; Claggett, aye; 20 Slagle, aye; Greene, aye; Talbott, aye. 21 [The motion carried unanimously.] 22 23 Approval of Minutes

24 [Janet Getzey Hart, R.Ph., Chairperson, noted the

25 approval of minutes would be postponed until the next

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   agenda.]
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   [Janet Getzey Hart, R.Ph., Chairperson, noted the
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   Board of Pharmacy met in Executive Session to receive
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   legal advice and engage in quasi-judicial
6
   deliberations.1
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                              * * *
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   Evacuation Announcement
   [Melanie Zimmerman, R.Ph., Board Administrator,
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   reviewed the emergency evacuation procedures for One
   Penn Center.]
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   Report of Board Prosecution
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   [Caroline A. Bailey, Esquire, Board Prosecutor,
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   presented the Consent Agreements for Case Nos. 22-54-
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   005324 \& 22-54-005326 and Case Nos. 20-54-007700, 20-
   54-007701 & 20-54-007702.1
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19
   [Alice Glasser, Esquire, Board Prosecutor, presented
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   the Consent Agreement for Case No. 21-54-018999.]
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   [Glenn P. Masser, Esquire, Board Prosecutor,
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   presented the Consent Agreements for Case No. 22-54-
   007280 and Case Nos. 21-54-014350 \& 21-54-014351.1
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- 1 Report of Board Counsel
- 2 | [Ariel E. O'Malley, Esquire, Board Counsel, referred
- 3 to the pharmacy technician annex that the Board has
- 4 been working on at their workgroup sessions for
- 5 several months. She stated the biggest change and
- 6 addition would be regarding the fees.
- 7 Ms. O'Malley addressed the fee reports, noting
- 8 the application fee for pharmacy technician
- 9 registration at \$135. She noted the trainee
- 10 registration could not be more than half of what the
- 11 pharmacy technician registration could be in the act.
- 12 | She noted that took it down to \$67.50 and would go
- 13 toward their technician registration if they become a
- 14 pharmacy technician while their training registration
- 15 is still in place.
- 16 Ms. O'Malley mentioned that \$135 was not the fee
- 17 the Board wanted or had seen in other states. She
- 18 | noted requesting to look at all of the applications
- 19 and application fees, noting the request is in place
- 20 and is hoping to be able to reevaluate other
- 21 applications and bring that down for pharmacy
- 22 technicians.
- Ms. O'Malley noted the Board expressed the
- 24 starting salaries for pharmacy technicians is \$15 an
- 25 hour and the math does not work out and is not fair

or justifiable. She noted that math is not going to
work with the Regulatory Analysis Form (RAF) with the
regulatory package either. She noted the need to
look at all of the application fees and have a
discussion with the Bureau of Finance and Operations
(BFO).

Ms. O'Malley commented that the Board has not had a fee increase in a while and some of the other fees may go up after all of the application fees are reviewed. She informed Board members that she would be doing another regulatory package and would be able to bring the pharmacy technician down and do another fee package in conjunction with this package to reevaluate all of the fees. She noted that she would need to do an entire fee regulation along with the pharmacy technician package.

Dr. Roussel informed Ms. O'Malley of questions around the pharmacy technician education requirements and believed there are more questions as to what is in there right now and wording issues.

Ms. O'Malley informed Board members that it is better to address any questions or alterations of the language as much of that as possible now before it goes in as proposed.

25 Larry Jones, Executive Director, Pennsylvania

Society of Health-System Pharmacists, questioned the reserved section on page 4, Section 27.12(d)(2)(v).

Ms. Talbott explained that the section was taken out because they capture that in Section 27.12(d)(2)(vii) - assist the pharmacist in the compounding of drug products.

Mr. Jones referred to Section 27.12a(a)(7), where it talks about compounding and dispensing. He stated the technician does not choose products and asked why the section is in the technician regulation.

Ms. O'Malley stated the legislation decided it was going to have disciplinary sections in the act that apply to the pharmacy technician and cross-referenced them, so they were copied and pasted into there. She offered to remove the specific language if it does not apply to pharmacy technicians.

Ms. O'Malley further explained that when the General Assembly wrote the language, they cross-referenced in the disciplinary section what applied to the pharmacy technicians and trainees but did not specifically put the language in the act, so it was copied and pasted into the regulations so pharmacy technicians would know.

Ms. Talbott agreed the last sentence that starts

- with "this restrictive clause" could be taken out but not all of Section 27.12a(a)(7).
- 3 Mr. Jones referred to Section 27.702(b)(2), 4 noting the American Society for Health-System
- 5 | Pharmacists (ASHP) and the Accreditation Council for
- 6 | Pharmacy Education (ACPE) are not separate programs.
- 7 He mentioned that ASHP utilized ACPE for the 8 programs.
- 9 Ms. Talbott asked whether it would be appropriate
  10 to have it read: ... a program that holds current
  11 accreditation from ACPE (and strike ASHP because
  12 every program that ASHP uses is already accredited by
  13 ACPE).
- Ms. O'Malley confirmed the Board wanted to remove
  ASHP, where it would now only read, any program
  accredited by ACPE.

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- Mr. Jones referred to Section 27.702(b)(3), noting PTCB is not a recognized training program and is a certificate program and approves other training programs, of which there are 3,500.
- Ms. Talbott read the paragraph: Nationally recognized pharmacy technician training programs including, but not limited to, those recognized by the Pharmacy Technician Certification Board (PTCB) and National Healthcareer Association for admission

1 to their respective certification exams. She stated

2 | they are not saying PTCB and the National

3 | Healthcareer Association are training programs and

4 are just saying those training programs that are

5 nationally recognized and these two organizations as

6 examples of organizations that would recognize a

7 training program.

Mr. Jones asked whether schools licensed by the State Board of Private Licensed Schools are approved by the ACPE pharmacy standards because when the Board licenses pharmacists, the pharmacist applicants have to have graduated from an accredited school of pharmacy. He asked who is validating the Pennsylvania State Board Private Licensed Schools pharmacy content.

Ms. Talbott explained that they would fall in the bucket of employers, and their program would have to file everything that was under § 27.702(a). She noted Mr. Jones is saying that ACPE does not do it, but she thinks they would have to put them under that because they were saying they train people to take the PTCB exam. She noted their state-approved programs do not issue a state certificate.

Dr. Roussel referred to the language in Section 27.702(b)(3), where it says PTCB-approved training

program to allow them to sit for the certificate and asked whether just being allowed to sit for the certificate would qualify as opposed to the certificate.

- Dr. Roussel noted that each of the training programs approved by PTCB is reasonable but if someone actually certified by PTCB would count as well. She asked whether it should be tweaked or is acceptable.
- Theresa Talbott believes somebody would meet that section if they had their PTCB certificate.
- Dr. Roussel expressed concern regarding the language, where if someone has the certificate, then it just waives the training but does not say that.
- Victoria Elliott, R.Ph., MBA, CAE, CEO,
  Pennsylvania Pharmacists Association, requested more
  information regarding who would be making sure the
  organizations that have been approved still meet all
  of the criteria.
- Ms. Zimmerman commented that it would likely be an education verification form, where the applicant is going to have to apply for the registration and forward the education verification form to the training provider. The training provider would have to verify that standards were met.

Mr. Jones commented that he does not see competency listed anywhere nor the one caveat that says topics should be covered to be sure the employee can function in the job that is there, noting there are others than what is listed in Section 27.702(a).

There was discussion regarding amending Section 27.702(c) and adding Section 27.702(d) to address competency. Ms. Zimmerman suggested amending Section 27.702(a) to require a minimum level of testing of competency.

The Board was in agreement to make this change. Mr.

Jones requested information regarding the technician and employer responsibilities when a new technician is hired.

Ms. Talbott explained that the onus would be on the employer to develop the pharmacy technician protocol and confirm the validation when an inspector would come in that someone is nationally certified and was provided any training that meets the act.

Ms. O'Malley informed Board members that she would do an exposure draft with the changes if they are fine with the revisions.]

23 MS. O'MALLEY:

You need to make a motion to send out an exposure draft.

1 MS. TALBOTT:

I make a motion that we send out an

3 exposure draft for the pharmacy tech reg.

4 DR. ROUSSEL:

5 I second that.

6 CHAIRPERSON HART:

7 Call for a vote.

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9 Roussel, aye; Hart, aye; Claggett, aye;

10 Slagle, aye; Greene, aye; Talbott, aye.

11 [The motion carried unanimously.]

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13 [Ariel E. O'Malley, Esquire, Board Counsel, informed

14 Board members she is also working on getting the

15 proposal to final-omitted for Act 80 regarding the

16 ability to administer COVID vaccinations down to age

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19 Report of Board Chairperson

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

21 everyone that she attended the National Association

22 of Boards of Pharmacy (NABP) / American Association of

23 Colleges of Pharmacy (AACP) District 1 and District 2

24 Meeting in Rhode Island, along with Dr. Roussel and

25 Ms. Talbott.

Chairperson Hart noted discussion regarding the Multistate Pharmacy Jurisprudence Examination (MPJE) and whether it should be eliminated. She stated ACPE was in favor of eliminating it and some states allow students to take it up to 12 times. She also mentioned there would possibly be a task force to have everybody at the table for further discussion.

Chairperson Hart noted the 2025 National
Association of Boards of Pharmacy/AACP District 1 and
District 2 Meeting will be held in Delaware. She
noted there are no pharmacy schools in Delaware and
the American Association of Colleges of Pharmacy
offered to work with the Delaware Board of Pharmacy
as far as some of the pharmacy schools in
Pennsylvania helping to host the meeting.

Chairperson Hart noted the National Association of Boards of Pharmacy/AACP District 1 and District 2 Meeting will be held in Atlantic City, NJ, September 20-22, 2023.

Chairperson Hart also noted some proposed resolutions from District 1 regarding point-of-care testing. District 2 did not vote on these and the. District 1 drafted resolution will be and these voted on at the next NABP Annual Meeting.

Chairperson Hart addressed her attendance at the

Tri-Regulator Symposium, which brings together the 1 2 nursing boards, medical boards, and pharmacy boards 3 in a collaborative atmosphere. She addressed a major 4 topic concerning telehealth and how telehealth is going to continue. She noted mental health is a hot 5 6 topic with telehealth and there are perhaps going to

be some changes at a national level.

Chairperson Hart commented that there were a lot of good speakers from the Food and Drug Administration and different organizations and there is a potential for smaller groups to be meeting more often than every two years.

Chairperson Hart addressed other NABP activity, including a leadership and executive officer forum held in Chicago concerning what other boards are She reported COVID, remote work and technicians immunizing was the big topic that came out of that.]

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20 Report of Acting Commissioner

[Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs, provided an 23 update regarding new Board Member Eric Esterbrook, 24 noting paperwork has not yet been received for 25 processing, and he has not been sworn in.

Ms. Talbott thanked Acting Commissioner Claggett 1 2 for shepherding that process.] 3 4 Report of Board Administrator 5 [Melanie Zimmerman, R.Ph., Board Administrator, addressed renewals. She informed Board members that 6 7 the renewal period ended yesterday, but the system allows collection of any child abuse continuing education (CE) for another week. She explained that 10 somebody who submitted an application by yesterday and if their child abuse CE comes in within the next 11 12 seven days, the licensee would still have their 13 license renewal processed. 14 Ms. Zimmerman reported about 7.6 percent of 15 authorizations to administer did not renew and 6 16 percent of pharmacists did not renew. She noted traditionally losing about 1,000 pharmacists every 17 18 renewal period and 6 percent is about 1,500, which is 19 more than normal. 20 Dr. Roussel thanked Ms. Zimmerman and Acting 21 Commissioner Claggett for extending the renewal 22 period.] 23 24 Report of Board Members 25 [Christine Roussel, Pharm.D., BCOP, BCSCP, Vice

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   Chairperson, noted she would be attending and logging
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   into the FDA Intergovernmental Work Group on
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   Compounding meeting.
 4
        Dr. Roussel noted the United States Pharmacopeia
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   (USP) should be updating the revised edition of the
   proposed USP 797 and 795 for sterile and nonsterile
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7
   compounding today.]
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                              * * *
9
   MOTIONS
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   CHAIRPERSON HART:
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                 The Board of Pharmacy met in Executive
                 Session to discuss and review consent
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                 orders and other legal documents.
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                     Are there any motions regarding
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                 these discussions?
   MR. GREENE:
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                 At agenda item 1, I make a motion that we
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                 reject as too lenient the Consent
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                 Agreement at Case Nos. 22-54-005324 and
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                 22-54-005326.
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   DR. ROUSSEL:
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                 Second.
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   CHAIRPERSON HART:
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                 Any discussion?
                                  No discussion. Call for
25
                 a vote.
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19 1 2 Roussel, aye; Hart, aye; Claggett, aye; 3 Slagle, aye; Greene, aye; Talbott, aye. 4 [The motion carried unanimously.] \* \* \* 5 6 MR. GREENE: 7 At agenda item 2, I make a motion that we 8 reject as drafted the Consent Agreement 9 at Case Nos. 20-54-007700, 20-54-007701, 10 and 20-54-007702. DR. ROUSSEL: 11 Second. 12 13 CHAIRPERSON HART: 14 Any discussion? No discussion. Call for 15 a vote. 16 17 Roussel, aye; Hart, aye; Claggett, aye; 18 Slagle, aye; Greene, aye; Talbott, aye. 19 [The motion carried unanimously.] \* \* \* 20 21 MR. GREENE: 22 At agenda item 3, I make a motion that we 23 approve the Consent Agreement at Case No. 21-54-018999. 24 25 DR. ROUSSEL:

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                 I second the motion to accept.
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   CHAIRPERSON HART:
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                 Any discussion? Call for a vote.
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                 Roussel, aye; Hart, aye; Claggett, aye;
                 Slagle, aye; Greene, aye; Talbott, aye.
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   [The motion carried unanimously. The Respondent's
   name is Mitchell Spivack, R.Ph.]
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   MR. GREENE:
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                 At agenda item 4, I make a motion that we
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                 approve the Consent Agreement at Case No.
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                 22-54-007280.
14
   DR. ROUSSEL:
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                 Second.
   CHAIRPERSON HART:
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17
                 Any discussion? Call for a vote.
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                 Roussel, aye; Hart, aye; Claggett, aye;
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                 Slagle, aye; Greene, aye; Talbott, aye.
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   [The motion carried unanimously. The Respondent's
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   name is Angela Frances D'Alessandro.]
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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
                Nos. 21-54-014350 & 21-54-014351.
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   DR. ROUSSEL:
4
                Second.
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   CHAIRPERSON HART:
                Any discussion? Call for a vote.
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                Roussel, aye; Hart, aye; Claggett, aye;
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                Slagle, aye; Greene, aye; Talbott,
10
                recuse.
   [The motion carried. Terry Talbott recused herself
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12
   from deliberations and voting on the motion. The
13
   Respondents are Pennsylvania CVS Pharmacy, LLC
14
   t/d/b/a CVS Pharmacy #2951 and Lily Moy-Maldonado.]
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                              * * *
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   MR. GREENE:
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                At agenda item 7, in the Matter of the
18
                Petition for Reinstatement of Peter
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                Grujich, I make a motion that we direct
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                Board Counsel to draft an Adjudication
                and Order consistent with discussions in
21
22
                Executive Session.
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   DR. ROUSSEL:
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                Second.
   CHAIRPERSON HART:
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1
                 Any discussion? Call for a vote.
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                 Roussel, aye; Hart, aye; Claggett, aye;
 4
                 Slagle, aye; Greene, aye; Talbott, aye.
5
   [The motion carried unanimously.]
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   Discussion Item
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   MR. GREENE:
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                 At agenda item 9, I make a motion that we
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                 grant the Applicant, Sabah Daoud's
11
                 Request for an Extension for the
                 Authorization to Test.
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   DR. ROUSSEL:
14
                 Second.
15
   CHAIRPERSON HART:
16
                 Any discussion? Call for a vote.
17
18
                 Roussel, aye; Hart, aye; Claggett, aye;
19
                 Slagle, aye; Greene, aye; Talbott, aye.
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   [The motion carried unanimously. The extension was
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   granted to 12/31/2022 based on applicant's special
22
   circumstances.]
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24
   Adjournment
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   MS. TALBOTT:
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23 1 I make a motion that we adjourn. 2 DR. ROUSSEL: 3 I second the motion. 4 CHAIRPERSON HART: 5 Meeting adjourned. \* \* \* 6 7 [There being no further business, the State Board of Pharmacy Meeting adjourned at 11:40 a.m.] 9 10 11 CERTIFICATE 12 13 I hereby certify that the foregoing summary 14 minutes of the State Board of Pharmacy meeting, was 15 reduced to writing by me or under my supervision, and 16 that the minutes accurately summarize the substance 17 of the State Board of Pharmacy meeting. 18 19 20 21 Derek Richmond, 22 Minute Clerk 23 Sargent's Court Reporting 24 Service, Inc. 25