State Board of Pharmacy December 6, 2022

3 45 BOARD MEMBERS:

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Janet Getzey Hart, R.Ph., Chairperson Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs 9 Christine Roussel, Pharm.D., BCOP, BCSCP, Vice 10 Chairperson 11 Patrick M. Greene, Esquire, Office of Attorney 12 General, Secretary

13 John R. Slagle, R.Ph. 14 Terry M. Talbott, R.Ph. Eric Esterbrook, R.Ph. 15

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BUREAU PERSONNEL:

19 20 Carole Clarke Smith, Esquire, Senior Board Counsel 21 Ariel O'Malley, Esquire, Board Counsel 22 Carolyn DeLaurentis, Deputy Chief Counsel, 23 Prosecution Division 24 Ray Michalowski, Esquire, Senior Board Prosecution 25 Liaison 26 Glenn P. Masser, Esquire, Board Prosecutor 27 Caroline A. Bailey, Esquire, Board Prosecutor Alice Glasser, Esquire, Board Prosecutor 28

Ashley P. Murphy, Esquire, Board Prosecutor Jared Hinsey, Esquire, Department of State Nicole L. Van Order, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Board Administrator Marc Farrell, Deputy Policy Director, Department of State

Andrew LaFratte, MPA, Executive Policy Specialist, Department of State Jessica Zukoski, Senior Legal Analyst, Prosecution

Division

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ALSO PRESENT:

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Danie Bendesky, Director of Intergovernmental Affairs, Department of State Amanda Richards, Acting Fiscal Chief, Bureau of Finance and Operations, Department of State Michelle Witmer, Fiscal Management Specialist 1, Bureau of Finance and Operations, Department of State

State Board of Pharmacy December 6, 2022

ALSO PRESENT: (Cont.)

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4 5 6 Catherine Lutz, Pharmacy Inspector, Bureau of 7 Enforcement and Investigation, Department of State 8 Timothy Black, R.Ph., Pharmacy Inspector, Bureau of 9 Enforcement and Investigation, Department of State 10 Steven Zahn, Pharmacy Inspector, Bureau of 11 Enforcement and Investigation, Department of State 12 Victoria Elliott, R.Ph., MBA, CAE, CEO, Pennsylvania 13 Pharmacists Association 14 Larry Jones, Executive Director, Pennsylvania 15 Society of Health-System Pharmacists 16 Jessica Adams, Director of Regulatory Affairs, 17 Cardinal Health 18 Jacquelyn Sassaman, Pentec Health 19 Jenna McCarthy, Associate, Malady & Wooten 20 Judy Kutchman, AllianceRx Walgreens Prime 21 Joshua Finger, Pharm.D., Enclara Pharmacia 22 Nicole Kruczek, R.Ph., MPBA, CVS/Caremark Pharmacy 23 Matthew Roesch, R.Ph., Pharmacist-in-Charge, 24 Vetsource Pharmacy 25 Nicole Sidle, Republican Executive Director, House 26 Professional Licensure Committee David Klinger, System Director, Operations 27 28 & Compliance, Geisinger Health System 29 Laura Romeo, Pharmacist-in-Charge at ConnectiveRx, 30 Careform Pharmacy 31 Timothy Kaylor, Regional Pharmacy Manager, The GIANT 32 Company 33 Misha Patel, M.D., Curriculum Education Assistant, 34 Geisinger Commonwealth School of Medicine 35 Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health 36 Thomas E. Brenner, Esquire, Caldwell & Kerns, P.C. 37 Alice Palombo 38 Raymond Vellky 39 Mary Tran 40 Gino Cordisco 41 Caroline Cordisco

> Sargent's Court Reporting Service, Inc. (814) 536-8908

4 * * * 1 2 State Board of Pharmacy 3 December 6, 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 14 Board of Pharmacy was held on Tuesday, December 6, 15 2022. Janet Getzey Hart, R.Ph., Chairperson, called 16 the meeting to order at 10:33 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

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[Ariel E. O'Malley, Esquire, Board Counsel, informed
1
2
   everyone that the meeting was being recorded, and
3
   those who continued to participate were giving their
4
   consent to be recorded.]
5
                               * * *
6
   Approval of Agenda
7
   CHAIRPERSON HART:
8
                 Approval of the agenda.
9
   MS. TALBOTT:
10
                 I move that we approve the agenda as
11
                 presented.
   MR. GREENE:
12
13
                 Second.
14
   CHAIRPERSON HART:
15
                 Any discussion? Call for a vote.
16
17
                 Greene, aye; Hart, aye; Claggett, aye;
18
                 Talbott, aye; Esterbrook, aye; Roussel,
19
                 aye; Slagle, aye.
20
    [The motion carried unanimously.]
                               * * *
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22
   Approval of Minutes
23
   CHAIRPERSON HART:
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                 I do believe as part of the agenda we
25
                 have approval of minutes from the
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1
                September 27 meeting.
                                        Any discussion on
2
                the minutes, changes?
3
   MS. TALBOTT:
 4
                I will make a motion that we approve the
5
                minutes as presented.
6
   MR. GREENE:
7
                Second.
8
   CHAIRPERSON HART:
                Call for discussion? Call for a vote.
9
10
11
                Greene, aye; Hart, aye; Claggett, aye;
12
                Talbott, aye; Esterbrook, recuse;
13
                Roussel, aye; Slagle, aye.
14
   [The motion carried. Eric Esterbrook recused himself
15
   from deliberations and voting on the motion.]
16
17
   Report of Board Prosecution
18
   [Caroline A. Bailey, Esquire, Board Prosecutor,
19
   presented the Consent Agreements for Case No. 20-54-
20
   004605, Case Nos. 21-54-012692 \& 21-54-017778, and
21
   Case Nos. 20-54-007700, 20-54-007701 & 20-54-007702.
22
23
   [Glenn P. Masser, Esquire, Board Prosecutor,
24
   presented the Consent Agreement for Case Nos. 21-54-
25
   019186 & 21-54-014771.]
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2 [Ray Michalowski, Esquire, Senior Board Prosecutor, 3 presented the Consent Agreements for Case No. 22-54-

4 016287 and Case No. 22-54-016621.

Mr. Michalowski provided an update regarding the prosecution division and informed Board members that Alice Glasser would be the Board liaison going forward but that he would be there whenever Ms.

Glasser was not available.

Ms. Talbott asked whether the Board could receive a case update for January, and Mr. Michalowski offered to provide the update.]

13

14 [A Formal Hearing was held from 10:53 a.m. until

15 11:29 a.m. in the <u>Matter of the Petition for</u>

16 Reinstatement of Gino S. Cordisco, R.Ph., Case No.

17 22-54-016270.]

18

19 Appointment - Bureau of Finance and Operations

20 Annual Budget Presentation

21 [Amanda Richards, Acting Chief of Fiscal Management,

22 Bureau of Finance and Operations, Department of

23 State, referred to licensee population over the past

24 seven years, along with the last four budget periods

25 broken out by license class. She noted the Board had

1 40,329 licensees which is a decrease from last year 2 of 682 licensees. She reported an increase of 3 another 41 licensees as of this morning for a total 4 of 40,370 licensees.

Ms. Richards noted the revenue for FY20-21 and FY21-22, as well as the biennial total. She noted 95 percent of revenue comes from renewals and applications. She stated that revenue is received from other categories but is not consistent and cannot be used as a main source of revenue.

Ms. Richards stated that expenses are broken down into administrative costs and legal costs and hit the Board through direct charges, timesheet-based charges, and license population charges. She reported on the expenses in FY20-21, FY21-22, and as of November 23, 2022. She noted the budget was more than adequate to cover the fiscal year.

Ms. Richards addressed revenue and expenses showing a projected balance at the end of FY22-23. She mentioned the revenue showed a decrease in FY24-25 and FY25-26 and did take into account the anticipated first-time applications for pharmacy technicians and pharmacy technician trainees but that it is not enough to increase revenue because expenses are starting to exceed revenue.

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1
       Ms. Richards noted a fee package is already in
2
   progress but asked Board members to provide a renewal
3
   fee amount for pharmacy technicians to be able to
4
   proceed.
5
       Ms. Talbott requested more time for Board
6
   discussion concerning the renewal fee.
7
       Ms. Richards informed Board members that she would
8
   return to present the fee package at the end of this
   year or beginning of next year.]
10
   Report of Board Counsel - Regulatory Report
11
12
   [Ariel E. O'Malley, Esquire, Board Counsel, noted the
13
   Act 53 document regarding consideration of criminal
14
   convictions is for the Board's review and informed
15
   Board members that it was published as proposed in
16
   the Pennsylvania Bulletin on November 19 and
   available for public comment.
17
18
        Ms. O'Malley reminded Board members that there is
19
   a regulatory work session directly following the
20
   Board meeting.
21
        She also directed the Board to the recusal
22
   quidelines.]
23
24
   Report of Board Chairperson - No Report
                              * * *
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1 Report of Acting Commissioner - No Report
2 ***

3 Report of Board Administrator - No Report

* * *

5 Report of Board Members

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

7 | Chairperson, addressed her attendance as the

8 Pennsylvania representative at the Food and Drug

9 Administration (FDA) Intergovernmental Working

10 Meeting on Compounding. She noted receiving

11 education and updates from the FDA with significant

12 | focus on insanitary conditions in 503As and 503Bs and

13 mentioned an in-depth discussion of infusion clinics

14 | that are not regulated.

Dr. Roussel informed everyone that she is the Board of Pharmacy representative to the Medical Marijuana Advisory Board. She noted the Medical Marijuana Advisory Board meets every two months and there have been petitions to evaluate the limits for microbial contamination and fungal and yeast contamination of products. She informed Board members that the United States Pharmacopeia has published a cannabis monograph addressing those

levels of contamination, which would be a federal

standard. She reported that would be open for

11 comment until the end of December 2022.] 1 2 3 MOTIONS 4 CHAIRPERSON HART: 5 The Board met in Executive Session to discuss and review consent orders. 6 7 Are there any motions regarding those discussion? 8 9 MR. GREENE: 10 At agenda item 4, I make a motion that we 11 approve the Consent Agreement at Case No. 20-54-004605. 12 13 MS. TALBOTT: 14 Second. 15 CHAIRPERSON HART: 16 Any discussion? Call for a vote. 17 18 Greene, aye; Hart, aye; Claggett, aye; 19 Talbott, aye; Esterbrook, aye; Roussel, 20 aye; Slagle, aye. 21 [The motion carried unanimously. The Respondent's 22 name is John Timothy Bianco, R.Ph.] 23 * * * 24 MR. GREENE: 25 At agenda item 5, I make a motion that we

12 1 approve the Consent Agreement at Case Nos. 21-54-016292 & 21-54-017778. 2 3 MS. TALBOTT: 4 Second. 5 CHAIRPERSON HART: Any discussion? Call for a vote. 6 7 Greene, aye; Hart, aye; Claggett, aye; 9 Talbott, aye; Esterbrook, aye; Roussel, 10 aye; Slagle, aye. [The motion carried unanimously. The Respondent's 11 12 name is Aids Healthcare Foundation d/b/a AHF 13 Pharmacy.] * * * 14 15 MR. GREENE: 16 At agenda item 6, I make a motion that we 17 approve the Consent Agreement at Case 18 Nos. 20-54-007700, 20-54-007701 & 20-54-007702. 19 20 MS. TALBOTT: 21 Second. CHAIRPERSON HART: 22 23 Any discussion? Call for a vote. 24 25 Greene, aye; Hart, aye; Claggett, aye;

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13
1
                 Talbott, aye; Esterbrook, aye; Roussel,
2
                 aye; Slagle, aye.
3
   [The motion carried unanimously. The Respondents'
4
   names are Savage Family Pharmacy, Rodger William
5
   Savage & Thomas Anthony Gossert.]
                              * * *
6
7
   MR. GREENE:
8
                At agenda item 7, I make a motion that we
9
                 approve the Consent Agreement at Case
10
                Nos. 21-54-019186 & 21-54-014771.
11
   MS. TALBOTT:
                 Second.
12
13
   CHAIRPERSON HART:
14
                Any discussion? Call for a vote.
15
16
                Greene, aye; Hart, recuse; Claggett, aye;
17
                 Talbott, aye; Esterbrook, aye; Roussel,
18
                aye; Slagle, aye.
19
   [The motion carried. Janet Getzey Hart recused
20
   herself from deliberations and voting on the motion.
21
    The Respondent's name is Raymond James Ancypowic.]
22
23
   MR. GREENE:
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                At agenda items 8 and 9, I make a motion
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                that we approve the following VRP Consent
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14 1 Agreements at Case Nos. 22-54-016621 & 22-54-016287. 2 3 MS. TALBOTT: 4 Second. 5 CHAIRPERSON HART: Any discussion? Call for a vote. 6 7 Greene, aye; Hart, aye; Claggett, aye; 9 Talbott, aye; Esterbrook, aye; Roussel, 10 aye; Slagle, aye. 11 [The motion carried unanimously.] 12 13 MR. GREENE: 14 At agenda item 12 in the Matter of BPOA 15 v. Zilpa Odera, Case No. 22-54-008333, I 16 make a motion that we delegate the matter 17 to a hearing examiner to conduct a 18 hearing and prepare a Proposed 19 Adjudication. 20 DR. ROUSSEL: 21 Second. CHAIRPERSON HART: 22 23 Any discussion? Call for a vote. 24 25 Greene, aye; Hart, aye; Claggett, aye;

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15
1
                 Talbott, recuse; Esterbrook, aye;
                 Roussel, aye; Slagle, aye.
2
3
   [The motion carried. Terry Talbott recused herself
4
   from deliberations and voting on the motion.]
5
   MR. GREENE:
6
7
                 At agenda item 13 in the Matter of BPOA
8
                 v. Pharmacy Services American Inc t/d/b/a
9
                 Pharmacy Services America, Case No. 21-
10
                 54-016509, I make a motion that we Enter
11
                 Default Judgment and instruct Board
                 Counsel to draft a Final Adjudication and
12
13
                 Order consistent with discussions in
14
                 Executive Session.
15
   MS. TALBOTT:
16
                 Second.
17
   CHAIRPERSON HART:
18
                 Any discussion? Call for a vote.
19
20
                 Greene, aye; Hart, aye; Claggett, aye;
21
                 Talbott, aye; Esterbrook, aye; Roussel,
22
                 aye; Slagle, aye.
23
   [The motion carried unanimously.]
                              * * *
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25
   MR. GREENE:
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1
                 At agenda item 15, I make a motion that
                 we approve the Application of Erjona
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3
                 Magellari for a reduction of intern hours
 4
                 for a graduate of a foreign college from
5
                 1,500 to 1,000 hours.
6
   MS. TALBOTT:
7
                 Second.
8
   CHAIRPERSON HART:
9
                 Any discussion? Call for a vote.
10
11
                 Greene, aye; Hart, aye; Claggett, aye;
12
                 Talbott, aye; Esterbrook, aye; Roussel,
13
                 aye; Slagle, aye.
14
   [The motion carried unanimously.]
15
16
   Upcoming Meeting Dates - Change
   MS. TALBOTT:
17
18
                 We have a conflict of the August 2023
                 Board meeting. I will make a motion that
19
20
                 we move the August meeting to August 29,
21
                 2023, as opposed to August 22, 2023.
22
   MR. ESTERBROOK:
23
                 Second.
24
   CHAIRPERSON HART:
25
                 Any discussion? Call for a vote.
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17
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2
                 Greene, aye; Hart, aye; Claggett, aye;
3
                 Talbott, aye; Esterbrook, aye; Roussel,
 4
                 aye; Slagle, aye.
5
    [The motion carried unanimously.]
                               * * *
6
7
   Discussion Items - Election of Officers
8
   DR. ROUSSEL:
9
                 I would like to make a motion to nominate
10
                 Terry Talbott to be the Chair for the
11
                 2023 year.
   MR. ESTERBROOK:
12
13
                 I'll second that.
14
   CHAIRPERSON HART:
15
                 Any discussion? Call for a vote.
16
17
                 Greene, aye; Hart, aye; Claggett, aye;
18
                 Talbott, aye; Esterbrook, aye; Roussel,
19
                 aye; Slagle, aye.
20
    [The motion carried unanimously.]
                               * * *
21
22
   MS. TALBOTT:
23
                 I make a motion that Christine Roussel be
24
                 our Vice Chair for the year.
25
   MR. ESTERBROOK:
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18
                 Second.
1
2
   CHAIRPERSON HART:
3
                 Any discussion? Call for a vote.
 4
5
                 Greene, aye; Hart, aye; Claggett, aye;
 6
                 Talbott, aye; Esterbrook, aye; Roussel,
7
                 aye; Slagle, aye.
   [The motion carried unanimously.]
8
9
10
   MS. TALBOTT:
11
                 I would also make a motion that Eric
12
                 Esterbrook be our secretary for the year.
13
   MR. GREENE:
14
                 Second.
15
   CHAIRPERSON HART:
16
                 Any discussion? Call for a vote.
17
18
                 Greene, aye; Hart, aye; Claggett, aye;
19
                 Talbott, aye; Esterbrook, aye; Roussel,
20
                 aye; Slagle, aye.
21
   [The motion carried unanimously.]
22
23
   MS. TALBOTT:
24
                 The Probable Cause Screening Committee,
25
                 Pat will be Chair, alternate will be
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Christine. 1 2 The Pharmacy Application Review 3 Committee will be Christine, John, and Eric with Janet as the alternate. 4 5 I'll stay on the CPR/Injectable 6 Training Program Approval Committee. 7 Janet will keep the Act 41 Committee. Christine will stay on the Medical 8 9 Marijuana Board. 10 The Regulations Committee will be myself as Chair, Eric, and Christine. 11 I move that those be the committees. 12 13 MR. GREENE: 14 Second. 15 CHAIRPERSON HART: 16 Any additional discussion? Call for a vote. 17 18 19 Greene, aye; Hart, aye; Claggett, aye; 20 Talbott, aye; Esterbrook, aye; Roussel, 21 aye; Slagle, aye. 22 [The motion carried unanimously.] 23 24 FYI Items 25 [Janet Getzey Hart, R.Ph., Chairperson, referred to

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Senate Bill 317 and asked whether the associations
1
2
   would be able to publish the bill on their website to
3
   notify pharmacists.
 4
        Ms. O'Malley commented that Senate Bill 317 is
   now known as Act 147 of 2022.
5
        Larry Jones, Executive Director, Pennsylvania
6
7
   Society of Health-System Pharmacists, offered to
   publish Act 147 on their website.
9
        The Board made no comments on the remaining FYI
10
  items.1
11
12
   Adjournment
13
   MS. TALBOTT:
14
                 I make a motion to adjourn.
15
   MR. GREENE:
16
                 Second.
17
18
   [There being no further business, the State Board of
19
   Pharmacy Meeting adjourned at 11:50 a.m.]
                              * * *
20
21
   [A State Board of Pharmacy Regulatory Work Session
22
   was held immediately following the regular Board
23
   meeting.]
                              * * *
24
25
26
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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.

Kathryn Witherow,

Minute Clerk

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