PENNSYLVANIA DEPARTMENT OF HEALTH

MEDICAL MARIJUANA ADVISORY BOARD

\* \* \* \* \* \* \* \*

IN RE: ADVISORY BOARD MEETING

\* \* \* \* \* \* \* \*

BEFORE: DR. DEBRA BOGEN, Secretary of Health, Chair

Matthew Eaton, Member

Christine Roussel, Member

Shalawn James, Member

Bhavini Patel, Member

John Adams, Member

William Goldfarb, M.D., Member

Dianna Briggs, Member

Geith Shahoud, M.D., Member

Chief David Splain, Member

HEARING: Wednesday, April 12, 2023

10:31 a.m.

LOCATION: Commonwealth Keystone Building

400 North Street

Harrisburg, PA 17120

WITNESSES: None

Reporter: Devin Nunemaker

Any reproduction of this transcript

is prohibited without authorization

by the certifying agency

		2
1	APPEARANCES	
2		
3	KATELYN MALTAIS, ESQUIRE	
4	PA Department of Health	
5	625 Forster Street, Room 912	
6	Harrisburg, PA 17120	
7	Counsel for <name></name>	
8		
9	ALSO PRESENT: LAURA MENCH, DIRECTOR, OFFICE OF	
10	MEDICAL MARIJUANA	
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

		3
1	INDEX	
2		
3	OPENING REMARKS	
4	By Chair 5 - 6	
5	ROLL CALL 6 - 8	
6	APPROVAL OF MINUTES 8	
7	DISCUSSION AMONG PARTIES 8 - 37	
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

			-
			4
1		EXHIBITS	
2			
3			Page
4	Number	Description	Offered
5		NONE OFFERED	
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

## PROCEEDINGS

\_\_\_\_\_

CHAIR: Wonderful. Good morning. Can you hear me okay. My voice is a bit hoarse, but I'm getting over a cold. So good morning, everyone. I'm excited to be here. Thank you for attending today's Medical Marijuana Advisory Board. Again, please be patient with us as we are using a new form. As I said, please be patient with us because we're using new technology. We wanted to conduct today's meetings we want to see how it goes. We're really making every effort to find a hybrid model that best fits the needs of both the board. So of all members of the board were found across the Commonwealth.

So regardless of whether you're in person or online, my goal is really to ensure that all members of the board are able to participate effectively. I also see the value of making sure the general public or anyone who wishes to tune in can do so, which is why we're sort of having this hybrid method. So there are people online who can hear and see what is going on, but can't actively participate.

So I'm excited by the opportunity to

chair the board and eager to see how we can work 2. together to help improve Pennsylvania's already successful medical marijuana program. Before we get too far along, I want to take a moment to introduce a new board member. Unfortunately, he cannot be here with us today, but Colonel Christopher Paris is replacing the previous commissioner, Colonel Evancheck.

- So Colonel Paris is a native of
  Lackawanna County. He was nominated by Governor
  Shapiro to serve as the Commissioner of the
  Pennsylvania State Police. His rare and broad range
  of expertise brings a unique perspective to the
  board's diverse structure that's paramount to the work
  that we do here. So I welcome Colonel Paris, I'm
  sorry, he's not here today. I also want to thank the
  previous Commissioner for his work, his many years of
  service to the board, and for laying the foundation
  for the work that we do here.
  - With that being the only major change in membership to announce this time I'd like to officially call this meeting to order. Again, this is the Medical Marijuana Advisory Board being held at 10:30 on April 12, 2023. We'll get started by taking roll call. So most of you are online. We haven't met

```
in person, and we'll have an opportunity for you all
1
   to introduce yourself in just a few minutes but right
2.
3
   now, I'm just going to take roll call. Christine
4
   Roussel?
5
                   MS. ROUSSEL: Good morning.
6
                   CHAIR:
                           And if I mispronounce your
7
   names, please feel free to correct me. I'll try to be
8
   a quick learner. Matthew Eaton?
9
                   MR. EATON:
                               Here.
10
                   CHAIR:
                           David Splain?
11
                   MR. SPLAIN:
                                 Here.
12
                   CHAIR:
                            John Adams?
13
                   MR. ADAMS: Here, here, John Adams is
14
   here.
15
                            Thank you.
                                        Doctor Shahoud?
                   CHAIR:
16
                   DOCTOR SHAHOUD:
                                     Here.
17
                   CHAIR:
                            Thank you.
                                        Bhavani Patel?
18
                   MS. PATEL:
                               Here.
                                        Daniel Cambic?
19
                            Thank you.
                   CHAIR:
                                                         Т
20
   don't think Doctor Cambic is here. Doctor Goldfarb?
21
                   DOCTOR GOLDFARB: Here.
22
                   CHAIR:
                            Shalawn James?
23
                   MS. JAMES:
                               Here.
2.4
                   CHAIR:
                            Thank you. And Diana Briggs?
25
                   MS. BRIGGS:
                                 Here.
```

```
CHAIR: Great, okay. So I want to ask legal counsel Ms. Maltais to confirm that we have a
```

- 3 quorum today.
- 4 MS. MALTAIS: Yes, I can confirm that 5 we have a quorum this morning.
- 6 CHAIR: Great. The next order of
- 7 business is to approve the previous meeting minutes.

I understand that we all set the meeting minutes for

- 9 the board last the last board meeting that was held
- 10 November 22, 2022, which I hope you had a chance to
- 11 review. At this time may I get a motion to approve
- 12 the minute meetings from November 22, 2023 board
- 13 meeting?
- 14 UNIDENTIFIED SPEAKER: Motion to
- 15 approve.
- 16 CHAIR: Great. Second.
- 17 MS. ROUSSEL: Roussel second the
- 18 motion.
- 19 CHAIR: All in favor to approve the
- 20 minutes, say aye.
- 21 ALL RESPOND AYE
- 22 CHAIR: Any opposed? All right. Any
- 23 abstentions? Okay, looks like the minutes for the
- 24 November meeting are approved.
- So before we move on to the agenda

items today, since this is my first meeting, most of
you are, and most times you're actually meeting me for
the first time, I was hoping we could take a minute to
introduce ourselves and share some background. So
I'll go around and I'll start.

6

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

2.4

25

For those of you who don't know me, I'm Doctor Deborah Bogen. I'm a pediatrician by training and by passion. I really made a career swerve in 2000 and went from academic medicine, where I did clinical research, primary care, patient care, and administrative medical education work, to really full time public health when I became the director of the Allegheny County Health Department. And I served until I moved here. And I'm truly honored to be nominated by Governor Shapiro to serve as the secretary. And I'm still in an acting role and don't know when that will change, but I'm currently going through the process, so I'm thrilled to be here with you all. I have learned a lot from our medical marijuana team over the last couple of months. That office is great.

So that's a little bit about myself so if it's okay with you, I'll just run down the same roster I went down for roll call and ask you each to introduce yourselves and to tell us a little bit about

- 1 yourselves, keeping it brief so we can keep our
- 2 | meeting on time. So Christine Roussel?
- MS. ROUSSEL: Hi. I am appointed by
- 4 the Board of Pharmacy to be part of the Medical
- 5 Marijuana Advisory Board. In my day job, I'm senior
- 6 executive director pharmacy laboratory medical
- 7 research at Doylestown Hospital. And then I also
- 8 | teach the Medical Cannabis Program for Philadelphia
- 9 College at St. Joe's.
- 10 CHAIR: Thank you, Matthew do you want
- 11 to go ahead?
- MR. EATON: Sure. I'm Matthew Eaton.
- 13 I am the designee for the Bureau of Professional and
- 14 Occupational Affairs, where we license we have 29
- 15 | licensing boards and commissions. I'm currently the
- 16 director of operations originally from Pittsburgh,
- 17 where I was an optician for seven years and came to
- 18 the state in 2018.
- 19 CHAIR: It's a small little
- 20 Pennsylvania world because Matthew was my optician for
- 21 many years which we discovered when we sat down
- 22 | together. It's great to see him.
- MR. EATON: Good to see you again,
- 24 Doctor Bogen.
- 25 CHAIR: That is the way the world

1 | works, right. David Splain?

MR. SPLAIN: I'm David Splain, I'm the
police chief in Nether Providence Township in Delaware
County. I'm also the president of the Pennsylvania
Police Chiefs Association.

6 <u>CHAIR:</u> Wonderful, thank you. John

7 Adams?

9

10

11

12

13

14

15

16

17

18

21

22

23

25

MR. ADAMS: Good morning. I am the District Attorney of Berks County. I've been a District Attorney for 16 years, and I was president of the District Attorneys Association when this board was organized and have been on the Medical Marijuana Board almost since, it's actually most of its life, I've been DA's representative.

CHAIR: Great. Well, it's great to have the experience of you all, many of you having served on this board a long time and I look forward to your institutional knowledge, which is essential.

19 Doctor Shahoud. I'm not sure you're unmated, we can't 20 hear you here.

DOCTOR SHAHOUD: Can you hear me?

CHAIR: Yes, we can hear you now.

DOCTOR SHAHOUD: Okay. This is Geith

24 | Shahoud I'm a child and adult psychiatrist ---

CHAIR: Wonderful, thank you. Bhavini

12 Patel? 1 2. MS. PATEL: Good morning, everyone. 3 My name is Bhavini as mentioned, I was appointed by 4 --- Costa, and my day job is in the Allegheny County Executive's Office where I serve as Community Outreach 5 6 Manager. 7 CHAIR: Great. And Doctor Goldfarb? 8 DOCTOR GOLDFARB: Good morning. 9 Goldfarb, retired physician and former chief medical 10 officer at Allegheny General Hospital and West Penn 11 Hospital. I've been on the board since inception. 12 Great, thanks. And Ms. James? CHAIR: 13 MS. JAMES: Good morning. My name is 14 Shalawn James. My day job is as a mental health and 15 housing advocate. I've been on the board since it's 16 inception and I'm really happy to be here. Thank you. 17 CHAIR: Great, thank you. And Ms. 18 Briggs? 19 MS. BRIGGS: 20 CHAIR: I think we lost your sound, 21 Diana. Yeah, we lost you shortly after you started. 22 Make sure --- yep, good. 23 Can you hear me now? MS. BRIGGS:

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

MS. BRIGGS: I was appointed by

Yes.

CHAIR:

2.4

Governor Wolf ---

1

18

19

20

21

22

23

24

25

2 CHAIR: Unfortunately, we're having
3 some technical challenges here. The connection seems
4 to be challenging. Can't really hear. It might be
5 where she's at. You want to try one more time to
6 introduce yourself we're having a hard time hearing
7 you. I'm so sorry.

8 MS. BRIGGS: Okay, --- and I'm a 9 founding member.

CHAIR: Diana, I don't know if you could maybe try to find a different location on your end, just because the way that it's going in and out makes me feel like it might be the connection or location.

UNIDENTIFIED SPEAKER: She needs her cell phone. If she dials in on her phone it will be better.

CHAIR: All right, well, hopefully

I'll get to meet you in person and hear your

introduction a little better. I just want to thank

you all for introducing yourselves and giving your

background. It's really quite a lovely, diverse group

of people with really diverse expertise so I'm excited

to work with you all over the coming years.

The next item on the agenda is the

Office of Medical Marijuana program update. It is really my great pleasure of handing things over to Lauren Mench, Director of the Office of Medical Marijuana, to provide the program update.

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MS. MENCH: Good morning. Thank you, Doctor Bogen, for the kind introduction. All of a sudden, it's seven months later from being hired as the Director office of Medical Marijuana. I'm not sure where the time went. The second in person board meeting. Since that time the final form regulations were published on March 4, along with what we hope served as a helpful, frequently asked question document. We continue to expand the Office of Medical Marijuana, filling holes and hiring additional staff while reorganizing to best suit the needs of the office for efficiency and productivity. And as you have heard at every board meeting and you will see in a moment, the program has consistently grown since its inception, and it is imperative that we adequately staff to continue to accommodate that growth.

We work to ensure that all processes and policies that were currently used in the office were clearly documented, allowing us to better prepared to easily teach and train new employees moving forward. At the last meeting, we promised to

- 1 publish updated Fillable compliance forms to be used
- 2 by the permittees, and we delivered on that promise.
- 3 | I attended the Cannabis Regulators Association meeting
- 4 | in December, shorthand is CANRA. I found it very
- 5 | valuable to network and collaborate with other
- 6 regulators in cannabis across the country and an
- 7 opportunity to speak about the issues we are all
- 8 | facing and the hurdles we have crossed. It's a great
- 9 resource for information and an excellent
- 10 | collaboration association.
- 11 There is certainly much more to do,
- 12 but overall, I am pleased with what we have
- 13 accomplished in a short amount of time and the
- 14 direction in which we are headed.
- Moving on to the program update this
- 16 month we have the seven year anniversary of the bill
- 17 | signing, which is very exciting, as well as an
- 18 upcoming research summit hosted by Penn State in
- 19 Hershey on April 17. That will be an exciting meeting
- 20 for everyone involved in research of medical marijuana
- 21 to gather and offer oral presentations of what they
- 22 | are working on, as well as poster displays and
- 23 presentations. It's an opportunity for the
- 24 researchers to meet in person, as well as pave the
- 25 road for collaboration efforts and expand the areas of

research.

1

10

2. As an update to the Medical Marijuana 3 Advisory, I'm sorry, Medical Marijuana Assistance 4 Pilot Program Pilot Phase Three in November, we began distributing \$50 monthly financial benefits to 5 patients registered in and who had selected PACE or 6 PACENET as their financial hardship program to reduce the fee of their medical marijuana identification card 8 9 and annual fee.

Do you want to advance that CHAIR: 11 slide? Thank you.

12 MS. MENCH: That slide that you're 13 looking at there is showing the implementation in the different phases. So we are still currently in phase 14 15 three with the rollout of the PACE and PACENET. Patients will be able to use their financial --- their 16 17 monthly financial benefit at any dispensary in 18 Pennsylvania to assist with the purchase of their medical marijuana for the remainder of the fiscal 19 20 year, which is June of 2023. The Office of Medical 21 Marijuana partnered with the Department of Aging's 22 PACE program provider Magellan Health to supply the 23 required infrastructure and to execute and manage the 24 benefit transactions. We continue to work in 25 conjunction with them and the call centers to

administer the program and to assist PACE enrollees
who will be eligible or may be eligible for MF.

3

4

5

6

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

To date, we have performed over 1100 transactions and distributed nearly \$65,000 to eligible patients, and we will continue to offer updates as we expand those expansion efforts move This next slide will show the program forward. I will read it to you just so the people in metrics. case there's people that are traveling, you can't see the slide. So there's almost 900,000 patients and caregivers registered, 425,000 rounding to make it easy active patient certifications, 1825 approved practitioners, 31 million patient dispensing events, 87.9 million products dispensed, 7.3 billion in sales, 2.9 billion by grower processors to dispensaries, and 4.4 billion by dispensaries. We have 173 operational dispensaries, and those numbers are as of March 30 of this year. Month to month dispensaries, I think I need the next slide. Month to month dispensary sales show continued trend on increased sales from the previous year of note, all the numbers are increased from last year. However, I believe it's July and October are basically even. Those were our flattest months for growth. The program continues to grow, but that increase continues to level out.

This next slide will show a similar 1 trend, but it's a combination of all years from 2020 2. 3 to March of 2023. The next slide shows the sales for 4 January, February, and March of 2020 to 2023, and clearly still growth, but again, it has slowed. 5 Patient purchase trends will be the next slide. 6 No 7 change here. It's the same story. Dry Leaf is the top seller, followed by Vapes concentrates, infused and The next slide will show you that Dry Leaf other. 10 retail and wholesale pricing. So that slide is 11 showing you that the prices have continued to decrease, with retail price per gram at an all time 12 13 low, and a wholesale price program reaching an all 14 time low in January, with only a slight increase to 15 date of \$0.29.

Does anyone have any questions?

CHAIR: Thank you. Are there any questions from the board for Ms. Mench? Thank you, Laura, for running the program so well. It's really a pleasure. We've all gotten to work with her, but she's pretty astonishing. All right, so hearing no questions, we will now move on to old business. On March 18, 2023, through the publication of the Pennsylvania Bulletin, the recommendation set forth by the board to add chronic hepatitis C as a qualifying

16

17

18

19

20

21

22

23

24

serious medical condition for medical marijuana usage 1 2. in the program was effectuated. I agree with the 3 recommendations that by adding chronic hepatitis C to the list of serious medical conditions for medical 4 marijuana usage, patients may get relief and help 5 alleviate complications of the disease and its 6 7 symptoms. To be clear, while medical marijuana alone cannot treat hepatitis C, there is research that 8 supports, when used to complement physician prescribed 9 10 medications, there is a higher likelihood of treatment 11 success for chronic hepatitis C. The addition of this new serious medical condition for the program serves 12 13 as a reminder for how important medical marijuana 14 research is for both patients and the medical 15 community.

Another item of old business that I wanted to close the loop on today is feedback received from the health contact form that is intended for the board. At the last board meeting, there was a discussion about how we could best use the health contact form submissions. From a review of the meeting minutes, it was decided that the patient and caregiver subcommittee would be tasked with reviewing the health contact form submissions and providing updates of the board at our meetings. All the board

16

17

18

19

20

21

22

23

2.4

members were provided with the health contact form submissions received since the November meeting in your packet. Going forward, the patient caregiver subcommittee will be provided with the feedback in advance of the meeting so that they have ample time to review and discuss them. At each board meeting, the committee will also receive, I mean, the board will receive a copy of the feedback in their packets and the patients and caregivers subcommittee will provide updates, offer feedback, and identify trends as appropriate and necessary.

2.

All right, onto new business. I'd like to discuss the board duties and current subcommittee structure to ensure we are maximizing our ability to achieve the best possible outcomes. My understanding is that when Act 44 passed in June of 2021, the board regained most, if not all, of their initial duties and responsibilities outlined in the original medical marijuana act. At that time, the previous acting secretary, Alison Dean, increased the frequency of the board meetings to every two months. At the November 2022 board meeting, the frequency of the board meetings was discussed again and the consensus was that every two months would be most efficient. Therefore, going forward, the board will

continue to meet every two months. Acting secretary 1 2. being also reestablished or reactivated, the board's 3 preexisting subcommittees and assigned each one with 4 specific tasks identified in the act. At this time, I do not intend to change that because I'm certain this 5 6 was done to assure the board was focusing on things 7 that they had the ability to change and make meaningful impact. My understanding is also that 8 Doctor Levine originally established the subcommittees 9 10 and assigned members. Her goal was to create a 11 diverse group of individuals on each subcommittee. So 12 as such, I thought it only appropriate to assign 13 Colonel Paris to the vacancy left by the previous commissioner on the patient and caregiver 14 15 subcommittee.

I can certainly see why it would beneficial for law enforcement to be represent on the patient and caregiver subcommittee. This allows for a different, yet extremely important perspective to be considered when making decisions that will impact the future of the program. I really want to make sure that subcommittees make up not only still makes sense today, but also aligns with what we accomplish moving forward. So as I am new to the board myself, I'd like to take a few minutes to ask for your thoughts and

16

17

18

19

20

21

22

23

2.4

1 feedback on how useful you feel the subcommittees are 2 and what you think could be improved.

3 In your packet today, you were 4 provided a list of the subcommittee and its members. So, as you can see on the slide, we currently have 5 6 four subcommittees, and they include the medical review subcommittee, which is assigned to modify the types of serious medical conditions for which someone 8 can be certified to participate in the medical 9 10 marijuana program. We have the patient and caregiver 11 subcommittee, which is responsible for ensuring patients have affordable access to their medical 12 13 marijuana. We have a regulatory review subcommittee, 14 which is responsible for what types of medical 15 professionals can certify patients to participate in We have the medical research 16 the program. 17 subcommittee, which is responsible for exploring what 18 forms to consider for patients to access in our 19 program.

As the board chair, I'm responsible for determining not only who chairs, but who is assigned each subcommittee. However, for your awareness, board members can always request to join additional subcommittees for which they want to partake. This can be done by reaching out to Holly

20

21

22

23

24

- 1 | Senior at any time we'll make sure I'm notified and
- 2 that appropriate action is taken. So I'd like to
- 3 pause now and ask if you have any thoughts or
- 4 questions or feedback regarding the structure of the
- 5 subcommittees or anything else related to the
- 6 responsibilities and how that's currently working.
- 7 Again, many of you have served on the board for a long
- 8 time. I'm new, and I'm really seeking your input at
- 9 this time.
- 10 UNIDENTIFIED SPEAKER: Really quickly,
- 11 before we move forward Secretary, Diana can you just
- 12 | confirm if could speak and we can hear you?
- MS. BRIGGS: ---
- 14 UNIDENTIFIED SPEAKER: You're still a
- 15 little shoddy. I just wanted to make sure weren't
- 16 missing you if you were trying to provide feedback.
- 17 | Sorry about the connection, Diana.
- 18 CHAIR: So you can just unmute
- 19 yourself and speak or raise your hand, and we can call
- 20 on you if you have comments or thoughts on the
- 21 | subcommittee structure or anything.
- 22 UNIDENTIFIED SPEAKER: Don't be shy,
- 23 board members.
- UNIDENTIFIED SPEAKER: I am.
- 25 <u>CHAIR:</u> You're a quiet group today.

All right, so as it relates to the subcommittees and 1 2. staying aligned with our agenda, we'll have some 3 subcommittee updates. As most of you are aware, it 4 was determined before my time that the best way to track progress and share information on an ongoing 5 6 basis would be to have each subcommittee provide an 7 update at each board meeting regarding their activities since previous board meeting. 8 So board members are also queried ahead of each board meeting 9 10 to determine if they have additional or specific 11 agenda items that they would like to include that they require deliberation. For those of you who may not be 12 13 aware, we are required to share the agenda for these 14 meetings no later than 24 hours in advance of the 15 meeting, and we must include all issues expected to be deliberated on and any planned official actions such 16 17 as votes on the agenda.

So, at this time, I'm going to ask each subcommittee chair to share an update. I will start with the medical review subcommittee. I'm aware that there's currently a vacancy for the chair position of this committee, and my goal is to get that filled in the very near future. While I can confirm there have not been any serious medical condition applications received for review, and therefore there

18

19

20

21

22

23

24

- 1 | weren't any that needed to be discussed or considered
- 2 | for this particular meeting, I don't want to assume
- 3 that others may not have something to share. So does
- 4 anyone from that subcommittee have anything to share
- 5 at this time? Again, quiet group. Next is the
- 6 patient and caregiver subcommittee, chaired by Ms.
- 7 James.
- 8 MS. JAMES: Good morning. Currently
- 9 we are really pleased with the progress that we have
- 10 made. --- are reviewing ---
- 11 CHAIR: Unfortunately, we are having,
- 12 as I said at the beginning, be patient with us. This
- 13 | is our --- we're trying to do a hybrid model, and
- 14 | clearly it's not working as effectively as we would
- 15 like. We're definitely having trouble hearing the
- 16 | folks online. Are they able to ---
- 17 MS. JAMES: Can you hear me?
- 18 CHAIR: Yeah, we can hear you, but it
- 19 comes in and out is the problem. We hear every couple
- 20 of words.
- MS. JAMES: Let me try to speak
- 22 slower.
- 23 CHAIR: Okay, that would work. Let's
- 24 try that.
- 25 MS. JAMES: The patient and caregiver

- 1 committee is pleased with the current progress that we
- 2 are making, and we've seen great change over the
- 3 | inception of ---, and we hope to continue to see
- 4 change and affordability for patients as we move
- 5 forward.
- 6 CHAIR: Speaking slower definitely
- 7 helped, so thank you.
- MS. JAMES: You're welcome.
- 9 CHAIR: Is there anything else you'd
- 10 like to add?
- 11 MS. JAMES: Not at this time. We will
- 12 be meeting within the next couple of weeks to review
- 13 the form and then have a full report ready for the
- 14 next meeting.
- 15 CHAIR: Thank you so much for chairing
- 16 that committee and for your report. Up next is a
- 17 | regulatory subcommittee chaired by Ms. Russell.
- 18 MS. ROUSSEL: Hello. Regulatory
- 19 | subcommittee does not have any formal recommendations
- 20 at this time. We have received a request from another
- 21 professional board related to the last certified
- 22 patients. We will be working on that and hopefully
- 23 bringing an update for the next meeting.
- 24 CHAIR: Wonderful. Thank you again
- 25 | for chairing that committee and look forward to your

- 1 report next time. And our last subcommittee is a
- 2 medical research subcommittee chaired by Ms. Patel. I
- 3 understand that the subcommittee has findings and
- 4 recommendations to share today regarding the research
- 5 initiative presentation from July of 2022. Ms. Patel,
- 6 before your update, if you can please explain what
- 7 | your subcommittee is covering today and why, for the
- 8 record, that would be great, and then you can give
- 9 your presentation. Thank you.
- 10 MS. PATEL: Thank you. So the medical
- 11 | research committee did meet, and we discussed
- 12 presentation that was provided by Organic Remedies,
- 13 and this team will actually be presenting some of the
- 14 | findings and questions that we had based on the July
- 15 28 board meeting.
- 16 UNIDENTIFIED SPEAKER: Christine,
- 17 | please remember to speak slowly when you're presenting
- 18 today just so that we can make sure we hear every
- 19 word. Thank you.
- 20 MS. PATEL: If we can start with the
- 21 first slide that details the request. At the Medical
- 22 | Marijuana Advisory Board meeting on July 28, a
- 23 presentation was made, which was a summary of medical
- 24 literature, the evaluation of the efficacy of a
- 25 proprietary process to sterilize extract the

1 contaminated cannabis product. Their goal was to show
2 that all these extractions will minimize contamination
3 with microbial elements, specifically around bacteria.

The request was to have the act or the committee recommend that the act be modified ---- regulation on the level of bacteria and fungus ---.

We can pop to the next slide. The subcommittee met twice and with a unanimous consensus that at this time we did not want to make a recommendation based on the regulation allowable quantities --- forming units of bacteria and only use ---. What we'd like to --- a little bit about regulation, how it's measured. Look at Pennsylvania in terms of other states. Look at that research and then what's on the horizon.

Firstly, next slide is perfect, when we talk about bacteria and fungus, we measure them in colony forming units.

And for anybody who is not a nerdy microbiologist it really is looking at viable cell effects and growth. So you think about Petri dish and where organisms start to grow and replicate. And that's how it's measured. It's measured per gram of cannabis. We'll say a gram of dried cannabis is about the size of a grape, a larger grape. And then also for perspective, I have a little bit of numbers on the

screen. Colony forming units are measured by how many 1 are allowed, so we allow --- 1000, 2000 all within 2. 3 that grape size piece of material. The larger the 4 number we allow, the more permissive or lenient regulations. Let's hop on to the next slide. 5 6 Pennsylvania regulations currently, if you look there's six organisms that are not allowed at all ---There is a full amount of molding --- that is 8 permissible currently listed about 10,000 --- colonies 9 10 from a unit gram of cannabis. And then bacteria can --- there are many types. We'll just focus on aerobic 11 There is also 10,000 colonies in the units 12 bacteria. 13 There are different things that we'll offer per gram. 14 you. 15 And now if we can pop to the next

And now if we can pop to the next slide, just see where Pennsylvania fits in with other states. So this is totally --- permissible per gram of cannabis. But you can see a lot of the states in the US have 2000 colony forming units per gram estimates. A couple of states that are more a --- a couple that are more restricted. In some states like California, it's not apples and oranges --- are the same way. Pennsylvania is definitely on par with other states. On the next slide is looking at aerobic bacteria. And aerobic bacteria Pennsylvania is also

16

17

18

19

20

21

22

23

24

similar. Again, some states are a little bit more 1 2. lenient, some are more specific and it --- some 3 states only allowing as little as 100 colony forming 4 units per gram of material. Pennsylvania is in that What was presented by the researchers with lower 5 6 processors was how they could start with the product --- and reduce it to almost nothing. The parent materials that they use, this is from what they 8 presented, I added some numbers in red to clarify 9 10 because the --- presented, the exponent and the graph 11 is block rhythmic so just to help visualize our threshold is 10,000. This manufacturing process 12 13 article --- yeast products that had over a million 14 homecoming units of yeast and mold per gram of 15 cannabis. And actually their literature dictated TNT means too numerous to tell. It's a significant burden 16 17 of mold that was used to remediate. And I'd just like 18 to remind people that mold and yeast produce things 19 called microtoxins, which could be toxic, and ---20 something called aflatoxins, which mold can produce carcinogenic chemicals as well. 21 22

Looking next slide, please. So in consideration of this --- their research, which we did across separate meetings, there are questions about reproducibility of results. Also, the company

23

24

```
presented information based on proprietary method that
1
2.
   was not necessarily available or replicated by all
3
   lower processors. We were concerned about the
4
   magnitude of the amount of bacteria and fungus in the
   base product. Looking at the other states,
5
   Pennsylvania is pretty consistent with the other
6
   states. And also when looking at laws from other
   states these states allow for remediation products.
8
   So some of them actually required what they're
9
10
   allowed. While it is not a cut and dried to amend the
11
   regulations to allow remediation, there would have to
12
   be a lot more details about what that topic would be
13
   and what board would handle providing approval for
   mediation of certain batches of cannabis and someone
14
15
   may produce that has significantly high bacteria or
            Next slide, please. What is important ---
16
17
   today is that there are current regulations that are
18
   actually standards that are being produced right now.
   US Pharmacopeia is something that physicians and
19
20
   pharmacists are very familiar with, basically putting
   drugs, cosmetic act, an FDA regulation in that act.
21
22
   US Pharmacopeia is a formulary service for our
23
                They're an organization that sets the
   government.
   standard for medicinal products as well as food
24
25
   products, depending on the situation ---.
                                               The USB has
```

1 produced a cannabis monograph. It convened an expert 2. panel working on this monograph for nine years and was 3 recently published for comment. The comment period 4 closed in May 2022. So we're kind of on the precipice of some national document creating safety standards 5 6 around cannabis. And there's a list of tests that 7 would apply to cannabis. Most people may not know, --- but pharmacy, there are limits on how much 8 bacteria, fungus given off drugs, the levels of heavy 9 10 metals, or pesticides that are allowed in that product 11 and so those are the similar standards that have been proposed for cannabis. Next slide, please. 12 While the 13 cannabis --- monograph, a lot of topics on it from 14 safe labeling related to the --- CBD ratio and also 15 even defining cannabis in terms of its variable ---. The most important thing with appreciating microbial 16 17 contamination limits is that elemental impurities.

Next slide please. So in consistent with USB you know on your --- table straight out of the document and then on your right I kind of paraphrased it a little bit maybe severe to digest, but microbial testing depending on what they're looking at, maybe the limit anywhere from 100,000 or less for the bacterial component and then final acceptance criteria for the non feral product. Again, as little as 100 --

18

19

20

21

22

23

24

1 --- units per gram for aerobic bacteria and --- colony
2 units. I think it's just perspective with regards to
3 where the regulation are going. Slides, please.

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

So with this, the Medical Research subcommittee diligently evaluated these over --meetings and they found that while they recognize that regulation is heterogeneous, Pennsylvania is pretty consistent with current regulations throughout other states. Board threshold for bacteria as well as total yeast present in cannabis chemistry. Considering the actions of the US Pharmacopeia with the Cannabis monograph in 2022, and like these comments will be finalized in 2023, at this time, we recommend not changing Pennsylvania regulations, opening the door to cannabis not --- reconsidering our threshold as it relates typically to patient safety. I'll be honest, I got criticism my bachelor's in oncology and Board Certified in oncology and really this is our first consideration patient ---. With that, that was the recommendation from the medical research subcommittee. Open for questions, if any.

CHAIR: Thank you so much for that presentation. Again, open for discussion. Are there any questions from the board on the presentation and the recommendation? Quiet group. Hearing no more

```
1 discussion or no discussion, does anyone want to make
```

2 | a motion to accept or reject their recommendation as

3 presented?

4 DOCTOR GOLDFARB: Goldfarb, motion to

5 approve.

6 CHAIR: Thank you. Do I have a

7 second?

MS. JAMES: Shalawn James, second.

9 CHAIR: I'm sorry, I didn't --- did

10 you get who that was.

11 UNIDENTIFIED SPEAKER: It was Shalawn

12 James.

23

2.4

13 CHAIR: Great. Thanks, Ms. James. All

14 | right, so we'll do a roll call is that right. All

15 right, so I'm going to take a roll call to see how

16 | we're voting on this. Do you want to reiterate what

17 | the motion is?

18 UNIDENTIFIED SPEAKER: The motion

19 | would be to approve the recommendation of the Medical

20 Research Subcommittee. So when Doctor Bogen calls

21 | your name it will be a yes to approve, a no to reject

22 and then if you wish to abstain you can abstain.

CHAIR: Christine Roussel?

MS. ROUSSEL: Yes.

25 CHAIR: Matthew Eaton?

	35		
1	MR. EATON: Yes.		
2	CHAIR: David Splain? David, you		
3	might be muted if you're trying to talk. We didn't		
4	hear your vote. I'm sorry. Okay, I'll come back to		
5	you. John Adams?		
6	MR. ADAMS: I support the		
7	recommendation of our committee.		
8	CHAIR: So that was a yes.		
9	MR. ADAMS: Yes.		
10	CHAIR: Thank you. Doctor Shahoud?		
11	DOCTOR SHAHOUD: Yes.		
12	CHAIR: Thank you. Ms. Patel?		
13	MS. PATEL: Yes.		
14	CHAIR: Doctor Goldfarb.		
15	DOCTOR GOLDFARB: Yes.		
16	<pre>CHAIR: Ms. James?</pre>		
17	MS. JAMES: Yes.		
18	CHAIR: I think you said yes. Okay,		
19	Ms. Briggs?		
20	UNIDENTIFIED SPEAKER: Diana is going		
21	to do a thumbs up or a thumbs down, Diana? Thanks		
22	Diana.		
23	CHAIR: Yes. And then Dave Splain?		
24	<u>UNIDENTIFIED SPEAKER:</u> Chief Splain,		
25	you might be muted on your end if you want to vote on		

1 | the record if you could speak now.

17

18

19

20

21

22

23

24

25

2. CHAIR: All right. Okay. So, as a reminder, per the board's report policy following the 3 4 approval of a recommendation the subcommittee is 5 responsible for proposing the recommendation as to 6 generate a written report to be presented at the next regularly scheduled public meeting. At the discretion of the Secretary, the Department of Health can 8 transmit a notice to the Legislative Reference Bureau, 10 also known as the LRB, setting forth the Secretary's 11 rationale for effectuating or declining any recommendation of the board within twelve months of 12 13 receipt of the report. And again, this motion was 14 approved. This process is the same as the one that we 15 used for the chronic hepatitis C addition as a serious medical condition. 16

At this time, I want to thank the subcommittee chairs or any of the designees that spoke today for sharing your updates. I'd like to open things up for additional discussion, but first, I want to note on the slide are the dates and times for the upcoming 2023 board meetings.

We'll also be sure to send those out to everyone after the meeting for your convenience. A notice in the Pennsylvania Bulletin will be

1 forthcoming. 2 Does any member of the board have any 3 questions or comments? Hearing no discussion or any 4 more questions, I want to thank everyone for 5 participating and for joining today. I look forward to 6 seeing what we can all accomplish together. May I have a motion to adjourn the meeting, please. 8 UNIDENTIFIED SPEAKER: Make a motion 9 to adjourn the meeting. MS. ROUSSEL: Roussel second. 10 11 All right. We are officially CHAIR: 12 Thank you so much. We will work on adjourned. 13 technology. 14 15 MEETING CONCLUDED AT 11:18 A.M. 16 17 18 19 20 21 22 23 24 25

## CERTIFICATE

I hereby certify that the foregoing

proceedings, hearing held before Secretary of Health,

Chair Bogen, was reported by me on April 12, 2023 and

that I, Devin Nunemaker, read this transcript and that

I attest that this transcript is a true and accurate

record of the proceeding.

Dated the 5 day of May, 2023.

Juin Meramoure

Court Reporter

Devin Nunemaker,