

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
MEDICAL MARIJUANA ADVISORY BOARD MEETING

* * * * *

BEFORE: DEBRA BOGEN, M.D., Chair
COL. CHRISTOPHER PARIS, Member
CHRISTINE ROUSSEL, Pharm.D., Member
MATTHEW EATON, Member
JOHN ADAMS, Member
GEITH SHAHOUD, Member
BHAVINI PATEL, Member
DANIEL KAMBIC, D.O., Member
MICHAEL LYNCH, Member
DIANA BRIGGS, Member
ROYCE ENGLER, Member

HEARING: Wednesday, January 24, 2024
10:31 a.m.

LOCATION: Capitol Media Center
State Capitol
Room 1E East Wing
Harrisburg, PA 17126

Reporter: Erin Badstuebner

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Eric Hauser
Mark June-Wells
David Vaillencourt
Lara Mentch

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SANDRA ADAMS, ESQUIRE
Assistant Counsel
PA Department of Health
625 Forster Street
Harrisburg, PA 17120
Counsel for the Department

ALSO PRESENT:

Charlina Daitouah, Esquire

I N D E X

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CHAIR: Good morning. As you all know, I like to start these meetings promptly, so not too bad. 10:31. I'm officially calling this meeting to order. This is the Medical Marijuana Advisory Board meeting being held at 10:30 in the morning on January 24th. And these meetings are broadcast live.

And so first, I will take a roll call. For your reference you were all provided with a board member list in your packet. And when I read your name, please acknowledge that you are present for the record.

CHAIR: Colonel Christopher Paris.
Christine Roussel.

MEMBER ROUSSEL: Present.

CHAIR: Chief Royce Engler.

MEMBER ENGLER: Present.

CHAIR: John Adams.

MEMBER ADAMS: Present.

CHAIR: Thank you.

Dr. Shahoud?

MEMBER SHAHOUD: Present.

CHAIR: Thank you.

1 Bhavini Patel?

2 MEMBER PATEL: Present.

3 CHAIR: Dr. Kambic?

4 Dr. Michael Lynch?

5 MEMBER LYNCH: Present

6 CHAIR: Diana Briggs?

7 MEMBER BRIGGS: Present.

8 CHAIR: Let me see if we have anyone
9 else join for me to retake the call?

10 I'm going to go back through. Colonel
11 Christopher Paris.

12 MEMBER ROUSSEL: He is on.

13 CHAIR: Oh, great. Thank you.

14 And then Dr. Kambic?

15 And with that can you confirm that we
16 have a quorum for today's meeting?

17 ATTORNEY ADAMS: Confirmed.

18 CHAIR: Great. Thank you so much.

19 Before proceeding with the rest of the
20 full agenda, I have a few announcements. First, Dr.
21 William Goldfarb, who was the minority leader of the
22 House of Representatives appointee, resigned from the
23 Board.

24 I want to thank Dr. Goldfarb for his
25 dedicated service and commitment to the Board and for

1 the Medical Review Subcommittee. We'll miss his
2 guidance. And we will work to find a - for the work
3 of the minority leader on drug replacement for him on
4 the Board.

5 We now have three vacancies on the
6 Board, as noted on the membership list posted on our
7 website and included in your electronic packages.

8 Today we have with us Sandra, Sandy,
9 Adams, assistant counsel to assist with today's board
10 meeting. We also have Charlina Daitouah, who's also
11 serving as a legal counsel to the Board, here with
12 us. As you know, all board meetings are held on
13 Wednesday in the same timeframe of 10:30 a.m. to
14 12:30 p.m. here in the Capitol media Center with a
15 virtual option.

16 Board Members, if any of the selected
17 dates that we set out for the rest of the year don't
18 work with your schedule, please let Ms. Reddy know.
19 She's in the back of the room. So - because we need
20 a quorum for these meetings.

21 Today's agenda reflects the items that
22 have been identified by the Board for discussion.

23 The next order of business is to
24 approve the minutes from the November 15th meeting.
25 I hope you've had a chance to review those minutes

1 that were distributed to you in advance. We've not
2 received any suggested changes, so at this time, if
3 there are no corrections to note, may I get a motion
4 to approve the meeting minutes as they are for the
5 November 15th board meeting?

6 MEMBER ROUSSEL: Roussel, I motion to
7 approve the minutes.

8 CHAIR: Thank you.

9 Second?

10 MEMBER EATER: Matthew Eaton. Second.

11 CHAIR: Great. All in favor of the
12 motion to approve the minutes, say aye.

13 AYES RESPOND

14 CHAIR: Is there anyone opposed? Are
15 there any abstentions? Looks like those minutes are
16 approved. Thank you. And those minutes will be
17 posted on the website later this week.

18 The next agenda item is an office of
19 Medical Marijuana Program update. I'm going to turn
20 things over to Laura Mentch, the Director of the
21 Office of Medical Marijuana, to provide the program
22 update.

23 As always, welcome, Laura. Thank you.

24 MS. MENTCH: Thank you, Dr. Bogen.

25 Good morning, everyone.

1 So we haven't met since November. In
2 December, I was lucky enough to attend the Cannabis
3 Regulators Association meeting, the CANNRA meeting.
4 There were at least 39 states represented, as well as
5 Canada and the FDA. Discussions included federal
6 policy, adverse event monitoring, trends in cannabis
7 and hemp, state reference labs, lab standards and
8 best practices, cannabinoid hemp regulation, and
9 rescheduling implications, among a lot of other
10 really fruitful topics.

11 This meeting is exceptionally valuable
12 in allowing regulators across the country to come
13 together to network and discuss topics, issues,
14 challenges and accomplishments in the cannabis space.

15 Next slide on December 14th, 2023,
16 Senate Bill 773 now Act 63 of 2023 was signed into
17 law by the Governor and will become effective in
18 April of 2024.

19 This legislation will allow medical
20 marijuana organizations that meet the criteria to
21 qualify as independent grower processor or
22 independent dispensary to apply for and be issued
23 either a dispensary permit or a grower processor
24 permit, increasing the number of vertically
25 integrated medical marijuana organizations currently

1 in Pennsylvania.

2 The office is currently analyzing the
3 legislation and preparing its operations to be
4 compliant with the legislation's effective date. In
5 preparation for the additional dispensary permits and
6 in keeping with the office's commitment to patient
7 access. The office has determined that there are 13
8 counties that are underserved by dispensary
9 facilities listed in alphabetical order on the next
10 slide, and encourages the independent grower
11 processors to consider these counties when choosing
12 potential dispensary locations in the application.

13 Next slide. These counties were
14 identified by calculating the average distance
15 traveled per order and the current population or
16 certification density per dispensary.

17 It should be noted that the criteria
18 and results change as the market matures and as more
19 dispensaries become operational and more patients are
20 enrolled.

21 Next slide. Moving on to program
22 metrics, this slide information is current. As of
23 January 12th, there were 436,018 active patient
24 certifications. 9,286 active carded caregivers.
25 1,920 approved practitioners \$400,587.09 going to

1 MMAP phase three qualifiers, 177 operational
2 dispensaries and 33 operational grower processors.
3 The next slide shows the dispensary sales by month
4 since January of 2020 to December of 2023. December
5 of 2023 was a very good sales month and every month
6 has been an increase in sales from the previous year,
7 with the exception of April of 2023, which had a
8 slight decrease over 2022. The next slide shows the
9 dry leaf retail and wholesale pricing details from
10 2023.

11 There was a bump in wholesale pricing
12 at the end of 2023 which has not affected retail
13 sales at the close of the year. The bump in price in
14 dry leaf wholesale price is still less than half of
15 the wholesale price from January of 2021.

16 That is all I have. Thank you, Dr.
17 Bogen.

18 CHAIR: Sure. With the holidays and
19 meeting in November. I appreciate your time.

20 DIRECTOR MENTCH: Thank you so much.
21 Thank you.

22 CHAIR: And I just want to announce
23 that Colonel Paris is present at the meeting as well
24 for our minutes.

25 MEMBER PARIS: Thank you, Doc.

1 CHAIR: Thanks for joining us. And we
2 don't have Dr. Kambic.

3 Is that correct still?

4 MEMBER ROUSSEL: No, he's on Zoom now.
5 Oh, he's on Zoom now. Okay.

6 CHAIR: So to correct the minutes, we
7 also have Dr. Kambic on. So we have a full board
8 present. Thank you very much.

9 So as we discussed at previous
10 meetings, each subcommittee chair will provide an
11 update at each board meeting regarding the activities
12 that have happened since the previous meeting. On
13 the agenda we included the main topic that the
14 subcommittee is addressing as part of each
15 subcommittee update.

16 So let's start with the Medical Review
17 Subcommittee. But before I begin, I'm pleased to
18 announce that Dr. Shahoud has agreed to chair this
19 subcommittee. Dr. Shahoud has been a very active
20 member of the Board, and I'm excited to have him
21 serving in this role.

22 At the September board meeting, we
23 announced that we have received a serious medical
24 condition for Chapter 27 research application. Some
25 of you may recall in July of 2022 that the Board

1 approved a policy that established a process for
2 accepting recommendations from academic clinical
3 research centers for a qualifying serious medical
4 condition to be added for Chapter 27 research
5 purposes only. We received an application from Penn
6 State College of Medicine for a moderate to severe
7 traumatic brain injury with chronic symptoms.

8 With that said, I will now turn that over
9 to the Medical Review Subcommittee for discussion on
10 the serious medical condition application regarding
11 traumatic brain injury.

12 Dr. Shahoud, I'm going to turn it over
13 to you. Thank you.

14 MEMBER SHAHOUD: Thank you. Hello.
15 The Medical Review Subcommittee was in receipt of a
16 serious medical condition Chapter 20 research
17 application from Penn State College of Medicine for
18 moderate to severe brain injury with chronic symptoms
19 in August 2023.

20 The subcommittee has met a few times
21 to review and discuss the application and has come to
22 a determination to recommend that this research
23 application be approved. This application is to
24 conduct clinical and preclinical studies to document
25 the potential value of cannabis in traumatic brain

1 injury.

2 Based on the merit of the application
3 and the subcommittee discussions, I would like to
4 make the motion to approve the serious medical
5 condition, Chapter 20 research application from Penn
6 State College of Medicine for moderate to severe
7 traumatic brain injury with chronic symptoms.

8 MEMBER LYNCH: This is Lynch. I'll
9 second the motion.

10 CHAIR: Thank you very much. I'm
11 going to do a roll call to make sure that we record
12 people's votes for this motion. So I'll start with
13 Colonel Paris.

14 MEMBER PARIS: Yes.

15 CHAIR: Christine Roussel?

16 MEMBER ROUSSEL: Roussel, aye.

17 CHAIR: Chief Engler?

18 MEMBER ENGLER: Yes.

19 CHAIR: Matthew Eaton?

20 MEMBER EATON: Yes.

21 CHAIR: John Adams?

22 MEMBER ADAMS: Yes.

23 CHAIR: Dr. Shahoud?

24 MEMBER SHAHOUD: Yes.

25 CHAIR: Bhavini Patel?

1 MEMBER PATEL: Yes.

2 CHAIR: Dr. Kambic?

3 MEMBER KAMBIC: Yes.

4 CHAIR: Dr. Lynch?

5 MEMBER LYNCH: Yes.

6 CHAIR: Diana Briggs?

7 MEMBER BRIGGS: Yes.

8 CHAIR: So it looks like we have a
9 unanimous approval for that motion. So this motion
10 is passed.

11 According to the policy regarding
12 qualifying medical conditions for Chapter 20 medical
13 marijuana research only, the next step is for the
14 Medical Review Subcommittee to submit a report
15 recommending that this application be approved for
16 research purposes only. If the report is approved,
17 then the report is distributed to the governor, the
18 Senate, the House of Representatives, the Secretary
19 of Health, and will be a public record under the
20 Right-to-Know Law.

21 I want to reiterate that this approval
22 does not mean that the condition is automatically
23 added as a serious medical condition. The Department
24 may or may not effectuate recommendations of that
25 with reason.

1 All right.

2 So our next is the patient - thank
3 you, Dr. Shahoud. Is there anything else from your
4 subcommittee before I move on?

5 MEMBER SHAHOUD: Yes, yes. There is a
6 new business -.

7 CHAIR: We're at old business now, so
8 I'm going to hold that for new business, if you don't
9 mind.

10 MEMBER SHAHOUD: All right. Sure.
11 Sure.

12 CHAIR: Great. Thank you.

13 The next is a patient and caregiver
14 subcommittee chaired by Diana Briggs.

15 MEMBER BRIGGS: Good morning. The
16 Patient Caregiver Subcommittee met earlier this
17 month, where we continue to discuss and educate
18 ourselves on extraction and decontamination methods
19 used in other states' medical marijuana programs.

20 I'd like to thank the teams from Insa
21 and Terrapin for sharing their time and expertise
22 with us on these different methods these last few
23 months. We ended our meeting with me sharing new
24 products.

25 Colonel Paris and Chief Engler have

1 expressed an interest in continued knowledge of all
2 the new products, especially after the troche
3 discussions. So I'd like to share that Cannabis
4 syrup is now going to be available in dispensaries
5 starting last week. I haven't seen them in the
6 Pittsburgh area yet, but I'm checking the menus
7 daily. Really nice. Interesting new product for
8 patients.

9 We continue to appreciate the growth
10 of our medical marijuana program and we look forward
11 to more positive progress this year. Thank you.

12 CHAIR: Thank you so much, Diana.

13 Our next is the Regulatory
14 Subcommittee chaired by Dr. Roussel.

15 MEMBER ROUSSEL: The committee was
16 active - Good morning.

17 The committee was active. We had
18 three meetings, one specifically related to do
19 business for nurse practitioners, which we'll discuss
20 later. But we did have a subcommittee meeting to
21 discuss, and then we held a stakeholder meeting
22 around medical marijuana regulations related to
23 healthcare facilities and institutions.

24 We had stakeholders from a variety of
25 different healthcare settings, including the school

1 nurse association, nursing home representatives,
2 hospital representatives, and we look forward to
3 getting representatives from mental health
4 facilities.

5 Anyone who's a stakeholder who's
6 interested can reach out to Siri and get involved.
7 We're going to be having another meeting next, and
8 the goals of our meeting were to understand the risks
9 and barriers of storing and administering medical
10 marijuana in facilities and institutional settings,
11 understanding the type of institutional policies for
12 medical marijuana management, both what different
13 institutions are using and what's available.

14 And then were considering state
15 regulation to help support patients and institutions
16 where continuation of medical marijuana care while in
17 the facility or institutional setting is appropriate.
18 So more to come on that activity, and we'll be having
19 another subcommittee meeting on that soon. And
20 that's the end of the report.

21 CHAIR: Thank you so very much. It's
22 great. Thank you.

23 And our last subcommittee report is
24 for the Medical Research Subcommittee, chaired by
25 Bhavini Patel, to also include discussions of Organic

1 Remedies presentation regarding the findings of the
2 research initiative.

3 I'm going to turn it over to you,
4 Bhavini. Thank you.

5 MEMBER PATEL: Thank you.

6 So at the November Medical Marijuana
7 Advisory Board meeting, the medical research
8 subcommittee reported that it had a few discussions
9 around the Organic Remedies presentation, including
10 discussions with Organic Remedies and with ASTM, the
11 American Society for Testing and Materials. After
12 those discussions, it was decided by the subcommittee
13 to extend an invitation to both organizations to come
14 to today's meeting and provide information on a
15 public platform. We will first hear a brief overview
16 of Organic Remedies research for ten minutes,
17 followed by a brief instruction introduction to ASTM
18 for ten minutes, then board members are welcome to
19 ask any questions or provide comments for the next
20 ten minutes.

21 CHAIR: So we'd like to go ahead and
22 begin our Organic Remedies presentation.

23 MR. HAUSER: Hey, good morning. My
24 name is Eric Hauser. I'm the president of Organic
25 Remedies. I'm here today with my research team.

1 It's comprised of folks from the Philadelphia College
2 of Osteopathic Medicine, which is our ACRC partner,
3 our testing lab, Green Analytics, and in-house
4 talent, our lab director, chief science officer, and
5 chief medical officer. So I'd like to start today by
6 thanking the Medical Marijuana Advisory Board for
7 allowing us to present our research. We've actually
8 presented our research several times now over the
9 past year, and we look forward to discussing our
10 conclusions based on that research. I want to add
11 that our research was peer-reviewed and published in
12 a scientific journal last year.

13 And for some of our viewers that
14 aren't in the science field, peer-review basically
15 means that third-party researchers basically tried to
16 poke holes in the research and just validated the
17 research as valid, having high levels of academic
18 rigor as well as procedures aligned with scientific
19 design, and that our conclusions were supported by
20 the research.

21 So on our team, we have five
22 researchers who have Ph.D.'s in their respective
23 fields. Mindy George Weinstein, Ph.D., from the
24 Philadelphia College of Osteopathic Medicine.
25 Mindy's their chief research officer. Brian Balin,

1 Ph.D., also from Philadelphia College of Osteopathic
2 Medicine. He's a microbiology researcher.

3 From Green Analytics we have Dan
4 Niesen, Ph.D., he's their lab director over there.
5 And then in-house, we have Mark June Wells, Ph.D.,
6 he's our chief science officer. And Fred Fochtman,
7 Ph.D., who is our chief medical officer.

8 Before we get into today's
9 presentation, I'd like to spend just a few minutes
10 reviewing Act 44 and how we got here today. So since
11 the inception of the medical marijuana program in
12 Pennsylvania, there's been a healthy debate
13 surrounding the use of solvent based extraction to
14 produce products that are both microbe free and safe
15 to consume for patients.

16 As Act 44 was being drafted, the
17 debate continued to go on, unresolved, in spite of
18 much evidence from other states showing that
19 solvent-based extraction was an acceptable practice
20 to produce clean and safe products for patients. In
21 order to resolve the debate, then Governor Wolf
22 requested that research be done locally here in the
23 State of Pennsylvania, under the direction of an
24 ACRC, in collaboration with their clinical
25 registering partner.

1 So we took on that challenge several
2 years ago, and the research then was to be presented
3 at this meeting to the Medical Marijuana Advisory
4 Board for review. So the only question being posed
5 here today is, does solvent based extraction result
6 in a clean, microfree, and safe product that meets
7 the regulatory requirements of Pennsylvania for
8 medical marijuana products? In our past
9 presentations, we feel that the Medical Marijuana
10 Advisory Board has not focused on the specific
11 research results and the expectations assigned to
12 them in Act 44.

13 To answer that question, as a follow
14 up to one of our presentations, we heard testimony
15 about microbial limits and not wanting to change
16 them. And this is something we've never requested or
17 asked for. So we feel that our research answers the
18 question posed by Act 44.

19 And we'd like to go into detail with
20 it with our Chief Science Officer Mark June Wells,
21 who will walk you through the slides hearing. Thank
22 you.

23 MR. JUNE WELLS: Thank you, Eric. And
24 personally and on behalf of my colleagues, thank you
25 for taking the time to listen to us today. I'm going

1 to try to move rapidly since we've been through this
2 presentation a number of times. But I will be
3 presenting our research that we conducted over a year
4 ago now to evaluate whether extracts that were
5 suitable for consumer use and were free of microbial
6 contamination. It could be manufactured from
7 materials that had significant contamination from
8 enterobacteria, aerobic bacteria and yeast and mold.

9

10 Next slide, please. So during this
11 presentation, I'm just quickly going to go over the
12 current state regulations, the impact of crop
13 destruction on the patient and business, the purposes
14 and goals of this study, and then I'll review quickly
15 our manufacturing processes, talk about the study
16 methodology, and then our findings.

17 Next slide, please. So most of you at
18 this meeting are probably aware of the state
19 regulations, and suffice to say that they are more
20 strict than other states in the union. And that is
21 perfectly reasonable, considering we were talking
22 about medical patients and the need to ensure that
23 they are getting safe products. I will also have you
24 note that when it comes to extracts, the limits of
25 the contaminants in those extracts are more strict

1 than those that are allowed in plant material. So
2 for us to explore this and meet the state
3 regulations, this process would have to have outcomes
4 that are more strict than the flour material that
5 would be put into that process. Also, I'll have you
6 note that material that does not pass what is called
7 harvest testing at this point is not to be utilized
8 in extraction.

9 So we set out to determine whether the
10 plant material that was contaminated could be used in
11 the extraction process and result in extracts that
12 were within or exceeding state limits.

13 Next slide, please. So what are the
14 ramifications of product destruction? Most
15 importantly, it's a higher cost to the patients, and
16 that can't be stated strongly enough, particularly
17 with inflation these days, everyone's finding that
18 they have to pinch pennies and have to figure out
19 more creative ways to make ends meet. So first and
20 foremost, the cost of products to patients is of
21 significant concern. Furthermore, employment
22 opportunities could be lost, and then, of course,
23 from a business side, a loss of revenue.

24 Next slide, please. So what are the
25 goals of this study? Well, first, we set out to

1 determine whether we could create extractive products
2 that were meeting Pennsylvania's state limits. When
3 we used cannabis material that was contaminated, we
4 wanted to determine whether there were critical steps
5 involved and whether that these extracting materials
6 could be used in the production of consumer products.

7 Next slide, please. Okay. Again,
8 just reiterating what Eric said. We are not looking
9 for a change in the regulatory framework at all in
10 regards to the limits that are currently present for
11 the state, whether it be flour or extracted products.
12 We are also not comparing our state limits to any
13 other state, and we are not promoting any form of
14 remediation. We are purely looking to see if we can
15 create extracted products that fall within state
16 limits and therefore are suitable for the use by the
17 medical marijuana patients of Pennsylvania.

18 Next slide, please. Okay. So I'm
19 going to quickly go through how our manufacturing
20 process works to give everybody a point of reference
21 when we're talking about the results of this study.
22 So we have two different manufacturing pipelines, a
23 hydrocarbon manufacturing pipeline and a
24 supercritical carbon dioxide manufacturing pipeline.

25

1 Next slide, please. Okay. So first
2 thing I'll draw your attention to are the asterisks,
3 which indicate where samples were taken during this
4 study. So during the hydrocarbon manufacturing
5 process, we start off with plant material. We then
6 go through an extraction process. We then go through
7 a winterization process, which is the removal of the
8 fatty acids and waxes from the extract. We then go
9 through a filtration process. We then go through a
10 clarification process which removes chlorophyll. We
11 then go through a sterilizing filtration process.

12 And just so everybody knows what that
13 means, the filtration sip size is 0.2 micron, which
14 is smaller than a bacterial cell. We then have to
15 recover our solvent and then purge off the remainder
16 of the solvent to meet state regulations.

17 Next slide, please. So again, please
18 note the asterisks. This is where samples were
19 collected from our carbon dioxide manufacturing
20 process. Again, we start off with plant material.
21 We go through an extraction process, again,
22 winterization to remove the fats and waxes, and then
23 a filtration process. Again, we remove the
24 chlorophyll during our clarification process, that
25 same sort of sterilizing filtration process. And

1 then we recover our solvent. We then go through a
2 decarboxylation process.

3 For anyone who doesn't know, the plant
4 does not make THC, it makes an acid version of THC.
5 We then have to turn that into Delta 9 THC. And then
6 we go through a cannabinoid distillation process,
7 which basically concentrates the cannabinoids to
8 about 99 percent.

9 Next slide, please. Okay. So just
10 quickly on our study methodology. Again, we have two
11 manufacturing pipelines. Each of those pipelines we
12 use replicates in the number of five for each test.
13 So for hydrocarbons we had 9.67 kilograms material
14 and in each replicate we used 1.93 kilograms. In the
15 supercritical food carbon dioxide process we have
16 12.98 kilograms, per replicate. We selected a
17 repeated measures analysis to utilize in analyzing
18 those data. We chose this because essentially
19 throughout the process we are sampling the same
20 sample over and over at different time points.

21 We also selected a two Ps HSD
22 significant difference post hoc analysis to determine
23 whether there were differences at each stage, each
24 sample - or each replicate that was tested for
25 potency using an HPLC, terpenes using a gas

1 chromatograph mass spec, mycotoxins using liquid
2 chromatography mass spec, and microbial communities
3 using a standard plating technique.

4 Additionally, each one of those tests
5 executed by the lab was done in replicates of five.
6 Next slide please. So what are our potential
7 hypotheses? One is the null hypothesis, which is
8 that essentially extraction does nothing and microbes
9 are still present in the extract that were present in
10 the plant material and potentially concentrated as
11 well.

12 Our second hypothesis is essentially a
13 linear reduction from step to step of the microbial
14 communities. And our third hypothesis is that there
15 is a critical step involved. One step that removes
16 microbial contamination.

17 Next slide, please. Excuse me. So
18 I'll give you the actual outcomes up front. And we
19 did find, most notably, that microbes were not
20 conveyed during the extraction process. We started
21 off with highly contaminated plant material and
22 resulted in extracts that had zero colony forming
23 units of any of the major groups that we tested for.
24 We also found out that there was a critical step
25 involved and that step was actually the extraction

1 step. There was no linear reduction from step to
2 step. And at the extraction step all of the
3 microbial contaminants were either deactivated or
4 removed. And what we also found is that that removal
5 was maintained through all steps subsequent to the
6 critical step, which was the extraction step.

7 Next slide, please. So now I'd like
8 to show you those results in graphical form. First
9 thing I'd like to note is that there were no
10 statistics possible on these data sets and the reason
11 for that is because we had no variants. We went from
12 contaminated plant material to extracts that had zero
13 microbial contamination at all, no colony forming
14 units whatsoever.

15 So these are three graphs from our
16 hydrocarbon manufacturing pipeline. We have total
17 yeast and mold by stage. And you can see that the
18 plant material was highly contaminated. We could not
19 even count the number of colony forming units.
20 Essentially, the whole plate was one huge unit. So
21 to deal with that, I put in a number of one million
22 colony formic units following extraction, zero. The
23 next step, zero. That pattern holds true also for
24 aerobic bacteria and total enterobacteria.

25 Next slide, please. This slide is

1 just there for people who prefer numbers over graphs.
2 I'm sure they'll make this presentation available to
3 anybody who's interested. And you can get a closer
4 look at this particular table here that shows the
5 same thing that the graphs did.

6 Next slide, please. So this is our
7 carbon dioxide manufacturing process. Again, we had
8 highly contaminated plant material that in subsequent
9 steps, showed zero microbial contamination, whether
10 it be yeast and mold, aerobic enterobacteria.

11 Next slide, please. This is a table
12 of those same data. At this point, I will also say
13 that we did test the mycotoxins just to ensure that
14 while we are either destroying or removing the
15 microbial contaminants, particularly the yeast and
16 molds, that they were not conveying some toxin to the
17 extract. Those data are not presented here, but
18 suffice to say that they were all zero. From one
19 step to the next, all steps showed zero.

20 Next slide, please. Okay. So just to
21 summarize, what did we find? Again, we found that
22 there was a critical step that removed the microbial
23 contaminants or stopped the control microbial
24 contaminants from making their way from the plant
25 material to the extract. That step was the

1 extraction step. Furthermore, we found that
2 sterility was maintained throughout all subsequent
3 steps. We would also conclude that these products
4 are suitable formulation into final product and
5 suitable for consumer use. And we would also
6 conclude that prior to extraction, that there may not
7 be a need to test as long as that plant material is
8 intended for extraction and not the final flower
9 product.

10 Next slide, please. Again, on behalf
11 of my colleagues and all of the participants in this
12 research, as well as my staff, we thank you for
13 taking the time to listen to us and thank you.
14 That's it.

15 CHAIR: Thank you. We're going to, I
16 think, move to the next presentation.

17 MR. VAILLENCOURT: Should I jump in?
18 Can you guys hear me okay?

19 MEMBER EATON: Yes, we can hear you.

20 MR. VAILLENCOURT: Okay. Awesome.

21 Good morning - it's still morning -
22 everybody. David Vaillencourt. It's really great to
23 be here. Thank you guys for all having me.

24 Just a bit about myself. I'm the
25 co-founder and board member for the S3 collective,

1 which is a 501(c)(3) nonprofit. I'm also the vice
2 chairman for ASTM International's Committee D37 on
3 Cannabis, which I know as CAM was referenced a bit
4 earlier. I've got a Master's degree in science, and
5 I've been working in the Cannabis industry for a
6 little over seven years now. Before that, I did a
7 lot of government contract work.

8 We'll see in the testing side, the
9 Department of Defense and Department of Interior, and
10 my mission and the S3 collective mission and focus,
11 working together with ASD and international on
12 standard development processes that bridge the gap
13 between science and data, standards and public
14 health, and then ultimately to policies to ensure
15 that marketplaces work and that products are safe. I
16 want to reiterate what Dr. Laura mentioned earlier
17 about CANNRA, which this photo at the front there is
18 myself and several other standards organization
19 members, including U.S. Pharmacopeia and AOAC,
20 discussing the importance of standards to protect
21 public health and safety and allow marketplaces to
22 operate at those two CANNRA external stakeholder
23 events ago. It's one of the amazing organizations
24 that's really working to solve some of these
25 challenging problems that we all have in common.

1 The problems that we're here
2 discussing, that I've brought up to discuss is not
3 unique or new. It's not new to Pennsylvania. The
4 lack of federal oversight has meant that nobody here,
5 from, whether it's the Governor's appointed office,
6 to lawmakers, to industry, has a playbook with simple
7 answers. So hopefully today I can help shed some
8 light on some recommendations that are rooted in best
9 practices.

10 If you want to move ahead to the next
11 slide. Just briefly, for this short presentation,
12 understanding the importance of what makes products
13 in the marketplace that are safe, affordable and
14 trusted is the ultimate goal here. I'll spend a
15 couple of minutes. Just what is ASTM International?
16 Why do we have an industry landscape? What is the
17 industry landscape of current microbial and bioburden
18 requirements look like? What's the history of public
19 health crises and regulations?

20 Why do we need regulations and
21 oversight of these things? And how does
22 decontamination kill steps? What are those words
23 even mean? Are there differences between those words
24 and some of the risks? And ultimately, what matters
25 here, some of the solutions.

1 So moving on to the next slide. ASTM,
2 as you may have known, may or may not know, it's
3 actually in your backyard in West Conshohocken,
4 Pennsylvania. They were established in 1898 because
5 railroads and train cars were literally falling off
6 tracks because the consistency and quality of steel
7 to lay the tracks was not defined. It's poorly
8 defined and varied considerably based on where it
9 came from.

10 Today, there's 147 committees spanning
11 with over 12,500 standards developed. ASTM D37 on
12 Cannabis is just one of those committees. We as a
13 committee, have about 700 volunteer members across
14 over 30 countries. And the development and delivery
15 of information is made uncomplicated and
16 straightforward. It's a common sense approach. It
17 has industry drivers, but it is balanced to ensure
18 that public health and safety is there, which the
19 level of consensus to attain, as some of it was
20 mentioned on the peer-review papers earlier, just for
21 context, I didn't think there was anything higher
22 than a peer-review process for the level of rigor.
23 And then I met the ASTM process around consensus.
24 These standards are used - they're set in contracts
25 used by government fairly often. And two standards

1 that I reference up here are ones that may be
2 relevant for this conversation for consideration.

3 The specification for medical use,
4 cannabis inflorescence, which defines the quality and
5 quality specifications of limits for things like
6 microbials, which is actually in line with a lot of
7 what I've seen in my brief review of State of
8 Pennsylvania, as well as lab method - test method
9 validation and method development best practices down
10 there. These are actually two standards of the 54
11 that I helped develop and put through the ASTM
12 process with government industry and public health
13 experts, reviewing to get a consensus.

14 If you go to the next slide. And just
15 for the sake of time, just very briefly, there's a
16 federal precedent for use of these standards. This
17 actually goes back to the 50s and long before,
18 honestly, things from the Defense Standardization Act
19 of, I believe, 1954, to the National Technology
20 Transfer Advancement Act has recognized the value of
21 these standards.

22 So again, just similar to the peer-
23 review process, our view - and it's pretty collective
24 is that if it's gone through the consensus process,
25 whether it's through something like ASTM

1 International, which is an accredited standard body,
2 ISO, that many folks are familiar with, ISO 1755 for
3 lab testing is a fairly global requirement, as well
4 as AOC U.S. Pharmacopeia, then it's ready for prime
5 time use by the marketplace.

6 I'll let you go to the next slide. So
7 just briefly, you know, I think a reminder of history
8 is always critical. Why the public health
9 regulations, The Jungle, which is a book around the
10 meat packing industry and some of the conditions
11 happening back in the early 1900s, really led to the
12 Pure Food and Drug Act in 1906, which established the
13 predecessor to what is now the FDA.

14 We've had major critical outbreaks in
15 the world with world health issues as we have grown
16 as a society that's necessitated common sense
17 oversight. And what's being talked about today is
18 we're no different in cannabis. Looking at this
19 slide here, we've got aspergillus just as a point
20 reference. There's over 20 states that aspergillus
21 is a mold that can produce and has been associated
22 with some many injuries and a few deaths by
23 inhalation through cannabis. So this is one pathogen
24 that is important to be testing for. And as you can
25 see, over 20 states have tested for that.

1 Pennsylvania is not one of them.

2 Next slide. Total yeast and mold.

3 Again, this is not a problem unique to Pennsylvania.

4 Nobody's come up with a consensus of what the number
5 should be. What is the pass fail number? And we've
6 got over 25 states that test for total yeast and
7 mold. But as you can see, while you're in line with
8 10,000, the majority, and that's actually the
9 recommendation of mold, that ASTM standard I cite,
10 and the U.S. Pharmacopeia's papers, it's not
11 harmonized across states.

12 Next slide. So just to look at a
13 broad - actually, can you go back to one slide,
14 please? There we go. Thank you. So again, building
15 on what is out there, what should best practices be?
16 Should decontamination be allowed or remediation, or
17 again, what are we going to call. I'll get to that
18 later.

19 The American herbal Pharmacopeia is
20 another relevant document that was commissioned.
21 They're a 501(c)(3), and they're one of the most
22 premier Pharmacopeias for non-traditional medicines
23 and non-standard dietary supplements. I want to just
24 quote one thing out of them in the Sarma, et al.
25 paper about Cannabis Inflorescence, which, again,

1 another peer reviewed paper that was produced by the
2 U.S. Pharmacopeia's cannabis expert panel.

3 Sarma, et al.'s paper states that
4 cannabis products should be held to microbial
5 specifications that help ensure practices using
6 cannabis production are indeed effective, and to
7 verify that cannabis for medical purposes held to a
8 high quality standard. They recognize that using
9 best sanitation practices, good production practices,
10 and good harvesting practices should help with
11 achieving acceptable microbial loads.

12 Looking at the American Herbal
13 Pharmacopoeia's publication, which came out almost
14 ten years ago but is still relevant, this was at the
15 request of the State of Washington, if my memory
16 serves me correctly, to develop this monograph, as
17 it's called, what they cited in page 45 of their
18 paper. There's a couple of things that I want to
19 quote out.

20 One is regarding - it's important to
21 note that microbial and fungal values do not
22 typically represent pass or fail criteria. Rather,
23 they are recommended levels when plants are produced
24 under normal circumstances. Herbs such as mints and
25 cannabis, which have a high concentration of

1 trichome, are prone to higher levels of mold than
2 crops with fewer trichomes. That's just a fact of
3 botany.

4 And they state further that as because
5 of this, we should consider that and recommended
6 limits may require adjustment over time as we collect
7 data and start to understand public health risks and
8 market opportunities and market inspirations. The
9 last sentence that they state, I wanted to say is
10 typical microbial and fungal limits may not be
11 appropriate for materials that are subjected to
12 processing, such as infusing, decocting, like using
13 water, extracting with heat, alcohol or other
14 processes that introduce microbial steps prior to
15 reduction, steps prior to consumption.

16 So again, I hope this kind of sets the
17 stage for where I'm going with the evidence around
18 some of the risks and, you know, what's reasonable.

19 Next slide. You know, just a broader
20 perspective. A couple images I threw on there's the
21 global or American Spice Trade Association, they have
22 developed a lot of recommendations, and there's
23 actually several World Health Organization and Food
24 and Ag Organization, FAO, which is a subsector of the
25 UN or established through the UN, has developed good

1 agricultural collection practices as well as
2 microbial reduction best practices for these
3 industries. So this is in line with other industry
4 best practices as well that supports our global food
5 and natural products marketplace, as well as just a
6 citation around sterilitic irradiation and use by the
7 FDA.

8 So moving on to the next slide, you
9 know, a couple of solutions here. One is looking at
10 - so one, I'm not aware of any state. I'm sure
11 there must be one. But I know of several states that
12 explicitly do allow this.

13 Colorado is home base for me, and
14 we've had this discussion, this very same discussion
15 many times for the last five years in bowl making,
16 which I have participated as a volunteer on. So I'm
17 not aware, again, at least in Colorado, Nevada and I
18 believe Michigan are the three that come to mind.
19 The top of mind, that explicitly allow what's being
20 discussed today around production being acceptable,
21 using production process like CO2 extraction or
22 ethanol extraction to remediate failed products or
23 products that would have otherwise failed microbial,
24 yeast and mold counts from end plant form or raw
25 material.

1 Ultimately, we know that flour and galicia
2 flour is the highest risk from a lung standpoint.
3 Sure, the physicians that are much more qualified
4 than me can reaffirm that. It's probably been
5 discussed here, but limits are different based on
6 other administration, say edibles, something that
7 you're ingesting not inhaling.

8 But how do we control this? The
9 citation at the bottom here is the standard practice
10 of requiring a hazard program. That's a hazard
11 analysis, critical control points. The standard was
12 developed for the cannabis industry. It was actually
13 recently approved in the State of Colorado. It
14 incorporated the reference in Colorado rules as part
15 of their reduced testing loan strategy. And in it,
16 this was actually developed by Pillsbury and NASA for
17 some context to ensure that essentially we don't have
18 astronauts getting stomachaches in space, because
19 that just does not sound fun for anybody.

20 So it provides a risk production
21 system that requires you to just look as an operator,
22 as a producer of any consumer product, and say, what
23 are the biological risks, aka microbiologicals, that
24 we're talking about here today? Chemical risks and
25 physical risks.

1 Identify those risks and then identify
2 how you're going to control them. And so that comes
3 into a definition straight from the State of
4 Colorado's regulations, the microbial control step,
5 which means a post-harvest batch process that is
6 intended to reduce the presence of microbial
7 contamination contaminants in a harvest batch for
8 production batch performed prior to testing
9 consistently on all harvest batches. So that's one
10 recommendation that I think you can use in addition
11 to the hassle system to allow folks to use extraction
12 processes or even other control steps, radiation x-
13 ray or other ones, which I'll talk about a standard,
14 I'll reference the standard of valid briefly in a
15 moment on that, to really allow for this type of
16 process to go through with safety and full risk.

17 Because what essentially, at a
18 simplistic level, much of what at least Organic
19 Remedies did, from what I heard this morning and had
20 reviewed prior to hear that, based on previous
21 discussions you have had, was essentially a
22 validation step of that critical control point, or
23 rather a microbial control stream. That said,
24 there's just a couple considerations there around
25 seasonality and replication of that information,

1 which I would say was obviously done since this is in
2 Pennsylvania and they had referenced another study
3 out of another state. So getting multiple locations,
4 multiple types of parts of the year is really part of
5 what builds that level of validation, which is the
6 same thing that pharmaceutical products have to go
7 through as well.

8 And then the last thing I just want to
9 mention that I didn't have time to be able to put on
10 this slide because it's still a work item. So it's
11 not in the standard yet, but it's actually going to
12 ballot this week. I'm actually at the committee meet
13 right now. It is a standard guide for techniques to
14 lower microbial load of post harvest inflorescence of
15 cannabis sativa L.

16 In other words, what are the
17 appropriate techniques that could be used to lower
18 the microbial load of cannabis flower products? And
19 by having that type of standard, then it makes it a
20 lot easier for industry operators as well as the
21 regulators and lawmakers to say here, the experts
22 have really figured this out.

23 If it's listed in this document, it's
24 worthy of consideration use. And if it's not on
25 there, then you have to go through the AFC consensus

1 process to get that approved. So with that, I think
2 I did okay on time, because I forgot to start my
3 stopwatch in the corner, but I'll go to the next
4 slide.

5 CHAIR: David, we do need you to wrap
6 up. Thank you.

7 MR. VAILLENCOURT: Thank you. Okay.
8 Yep. So thank you.

9 CHAIR: So thank you for those
10 presentations by both Organic Remedies and ASTM. The
11 floor is now open for discussion. Comments,
12 questions?

13 MEMBER ROUSSEL: Hi, I'm Christine
14 Roussel. So I'm a pharmacist, and I oversee a
15 laboratory and my health system. And I kind of had
16 some questions about the study and had the ability to
17 talk to Organic Remedies offline.

18 Some of the concerns I had about the
19 study were reproducibility of the results. It is a
20 proprietary method, which I think it's always
21 important when you look at research, is it
22 proprietary? Is it something that other
23 organizations could reproduce? But I think it's
24 important when we think about the research. Colony
25 forming unit of a microorganism is something viable,

1 something that can grow, something that can just
2 replicate. So when you look at something and you
3 measure their colony forming units at one point, if
4 you go back and measure them days later, that colony
5 forming units will increase.

6 You know, so I think it's important to
7 understand the potential of each one as we're talking
8 about viable, something viable that's going to grow
9 and replicate. When we look at studies like this,
10 also there's different microbial patterns and the
11 type of infections people get in different seasons.
12 We know there's viral season or flu in the winter,
13 but it's the same thing with microbes. One of the
14 things with this study was they looked at one grow
15 and then tested it.

16 And I think when you're looking at
17 different seasonality, just as we can feel inside our
18 house is dry, you have different microorganisms,
19 specifically fungus, that may be present in different
20 times of the year. So it is some concerns I have
21 with the reproducibility.

22 I think, in looking at this, some of
23 the questions I also have is if the starting material
24 was a piece of cannabis, that the whole entire plate
25 was one giant unit of mold, too numerous to count,

1 and well over a million pieces of growing mold, and
2 it was extracted to a product, I guess my first
3 question is, should we even be doing that? I mean, I
4 know sometimes we think of - I'm a pharmacist, so I
5 know my drugs are effective, so I know I could give
6 somebody a drug and it could have an effect. But the
7 question to me is sometimes, is it appropriate to be
8 doing that? And that's one of the questions I have.
9 Where does this fall with other standards, and where
10 does it fall in line with what's being done on a
11 federal level, both from U.S. Pharmacopeia, where it
12 seems that our microbial limits in Pennsylvania are
13 appropriate and consistent with other regulators?

14 So I have a couple more questions, but
15 I'd really like to hear, Dr. Mentch. I don't know if
16 you have the ability to kind of maybe give us some of
17 your insights. I know you go to CANNRA, so I know
18 this is a hot topic. I'm sure you're familiar with
19 USP and ASTM. I'm wondering if you can kind of give
20 us your perspective on some of the information being
21 a little bit more technical maybe than others.

22 DIRECTOR MENTCH: Did you have a
23 specific question?

24 MEMBER ROUSSEL: No, I guess two
25 things, one being with more insight than I think

1 maybe some of the other people on the committee, I'll
2 throw myself as well. What are your kind of thoughts
3 around the science? And then what are you seeing
4 with regulations in other states? I know one of the
5 things that we had asked was, for some example,
6 regulations from other states where they allowed
7 this. Other than some state names, no specific words
8 were provided.

9 So I'm not sure if you're familiar
10 with similar processes. And one of the things
11 specifically I think was of greatest level of concern
12 for me is when we look at the study findings, the
13 conclusion that there is little need for testing
14 prior to extraction manufacturing due to the
15 findings.

16 And I feel that even if you're doing
17 some type of method to reduce microbial burden, I
18 feel that good science is to test beforehand or even
19 have a quality process. I know ASTM mentioned HASEP,
20 which is where you test a fair amount of batches, and
21 once you have a consistent result, you can skip. And
22 you only test risk based in pharmaceuticals. It's
23 called skip batch technology about something where
24 that may play into still doing some upfront testing
25 for quality control.

1 I know I said a lot. I apologize for
2 calling you on the spot.

3 DIRECTOR MENTCH: First, I just wanted
4 to say we're really close to having standards.
5 CANNRA is a great. Again, I'll just go back to that,
6 great resource for what they're putting together,
7 pulling people together across - as he had noted
8 difference in the microbial allowances and trying to
9 find some consistency there across the United States
10 as it comes to cannabis.

11 In Pennsylvania, remediation is only
12 allowed for yeast and mold. I guess I can start
13 there. Just like kind of like a ground setting.
14 It's only allowed for yeast and mold. It can only be
15 converted into toxins. And I can only imagine this
16 because as you stated, your biggest risk is inhalable
17 products and that we contaminate it and directly into
18 the lung. So it was developed so that topical is a
19 safe remediation.

20 The permittees are required to do
21 compliance testing at Harvest and lot, so that kind
22 of touches on where we were talking recommendation on
23 whether or not there should be any testing
24 whatsoever. Can you hear that? I can't get closer.

25 Can you hear me? Thank you. Did

1 everyone hear up until that point? Sorry. Okay.

2 Remediation is allowed for yeast and
3 mold, but it can only be converted only for yeast and
4 mold. It can only be converted into topicals. And
5 as it was stated during the presentation, your
6 biggest risk is of course, having something
7 remediated. If it was contaminated and remediated
8 into inhaled product, directly into the lungs, as you
9 showed with that aspergillosis, those things can be
10 very deadly.

11 Permittees are required to do
12 compliance testing at Harvest Lot, and may do
13 research and development testing to better guide how
14 to grow their plants and just better business
15 practice. They can't use research and development to
16 remediate product outside of that use. And research
17 and development testing is not a mechanism that would
18 allow permittees to remediate. Remediation is for
19 any other purpose would be non-compliant.

20 Of course, along with you, our main
21 concern is patient safety and patient transparency.
22 So if you were to take away that testing at the
23 Harvest Lot, as I was listening, so this is the first
24 time I've seen obviously this presentation. So as I
25 was thinking, if you are taking away that testing and

1 you would not know if it had been contaminated to the
2 (inaudible), as you had stated too numerous to count,
3 you wouldn't know that. So from a consumer and
4 patient transparency, in my opinion, is it important
5 that the consumer knows what the product was
6 throughout the whole process, would you want to know
7 that it was - I don't want to say remediated because
8 we're not saying that, the extraction process has
9 been used to produce a clean product.

10 So if you were not testing at the
11 harvest, you would not know that you would have to
12 label that for consumer transparency is one thought.

13 You did have a lot of questions. I'm sorry. So I
14 know that was one of them.

15 So we did the history and sort of what
16 about the harvest testing? What else?

17 MEMBER ROUSSEL: I'm sure the Board
18 has a certain level of responsibility, but for you,
19 as an employee of the program, how much time do you
20 guys dedicate time to evaluating the regs yourself
21 and looking at trends in testing microbial limits and
22 do you consider other regulations? I'm wondering as
23 we look at this it is a complicated process and I
24 think we'll talk about what motions we may want to
25 make.

1 But is the state already looking at
2 this and is this something that you keep apprised of?
3 Like if we come away from this saying I think it's
4 interesting, I think it needs more information, can
5 we ask the state to look further into it? Is this
6 something that you guys are already trending and
7 looking at on a frequent basis already?

8 DIRECTOR MENTCH: We're absolutely
9 involved in this, which is what - I will not miss the
10 CANNRA meeting because I feel like it's a huge
11 resource for us to learn what is -. So many states
12 are already ahead of Pennsylvania in this realm. So
13 there are committees in CANNRA that are working on
14 lab standardization and testing and so I am in
15 contact with directly more so with states really
16 close around us. So like Maryland is a huge resource
17 for me to see what they were going through because
18 they're ahead of us in that a lot of states are
19 looking for already state-run labs and standards that
20 were not quite there yet. So yes, we of course
21 looked at all of those things.

22 I was aware of where we landed as far
23 as those CFUs and where Pennsylvania standards fall
24 with other states. So it does give me some - you
25 know, it makes me feel good that we're in with the

1 majority of people with the 100,000 units and things
2 like that. So we do look at that.

3 When the temporary regulations became
4 final form that's really - and I was really just
5 starting as director, now it's making recommendations
6 on what we can do with lab oversight and some of
7 those things that we can make suggestions on. But
8 yeah, absolutely interested. Our department is
9 fully, you know, engaged in the lab space in all of
10 this. So this was particularly interesting because I
11 had not seen the original presentation from Organic
12 Remedies. I wasn't an employee at that point, so
13 trying to hear it in the old clips and readings and
14 notes just wasn't as good as, you know, I'm sure
15 being at the presentation. So this was very helpful.

16 CHAIR: I'm going to try to move along
17 and ask if anyone else has questions as well from the
18 Board. Thanks Laura.

19 DIRECTOR MENTCH: Thank you.

20 MEMBER ROUSSEL: Can I ask one
21 question before you go? You said that we're close to
22 having standards. Can you be specific about what
23 standards you're referring to?

24 DIRECTOR MENTCH: I don't mean
25 Pennsylvania, I mean nationwide with CANNRA is

1 working on. The committee is working on
2 recommendations for standardization in the lab space
3 as it pertains to all of this testing and whether
4 it's microbial or it's solvents or it's heavy metals
5 or the difference in the amount. And so it makes
6 sense to listen to those experts. As they said, U.S.
7 Pharmacopeia has come out with some things that
8 American Herbal Pharmacopeia as well, all really good
9 resources, but to get it together, CANNRA is were
10 really working on that. So I'm interested in seeing
11 when that white paper gets published.

12 MEMBER ROUSSEL: Thank you.

13 CHAIR: Thank you. Is there anyone
14 else from the committee or from the Board that has a
15 question before we move on?

16 MEMBER BRIGGS: Yes, I do. Diana
17 Briggs. I talked to David when I met with him last
18 week, I had read somewhere that other states are
19 allowing this extraction method. Do we know how many
20 other state programs - medical marijuana programs, of
21 course, allow this extraction method currently?

22 MR. VAILLENCOURT: Is that for me to
23 answer, Diana?

24 MEMBER BRIGGS: Do you have an answer
25 for that, David?

1 MR. VAILLENCOURT: Yeah. So the
2 answer that I know, I was able to look up Michigan,
3 Nevada's and Colorado's and know that those three do
4 state them. I can follow up with you guys to give
5 you the actual languages that would be helpful for
6 the record. And then I'm not aware of any states
7 that don't allow it, but I didn't have time or it
8 gets hard in the regulations to fill it in.

9 I don't know if Dr. Laura would have
10 the answers through CANNRA as well. But I think,
11 again, CANNRA really is the best use of resources to
12 filter any of these ultimate recommendations. They
13 get closer to recognizing the standards that are
14 being developed. So hopefully that first part at
15 least is helpful in the direct answer to your
16 question.

17 MEMBER BRIGGS: Thank you.

18 CHAIR: Thank you.

19 Are there any other questions?

20 Otherwise, I'll move on.

21 All right.

22 Again, thank you for raising this
23 issue to ensure that members of the public with
24 interest in this topic have sufficient notice of
25 this. We can include this as an agenda item on our

1 next meeting as well if we have more discussion.

2 So again, thanks the presenters next
3 steps are for the medical research subcommittee to
4 put forth a motion at the March 20th meeting and the
5 Board to vote.

6 So I want to thank the subcommittee
7 and the committee chairs for their work and the Board
8 as well.

9 Our next item under old business is
10 discussion of protections for healthcare provider
11 administration of state regulated medical marijuana
12 products brought forth by Dr. Roussel. I'm going to
13 turn it to Dr. Roussel.

14 MEMBER ROUSSEL: I spoke about it in
15 the subcommittee for providers for - I'm so sorry,
16 I'm just trying to get the notes for that. We had a
17 meeting where we had multiple people together to look
18 at providers of healthcare and their ability to
19 administer cannabis, and then, if needed, store it at
20 their facility for patients who have state cards and
21 state licensed product and we had some barriers, but
22 we are going to have another subcommittee meeting
23 before I actually do a report. So I have no
24 additional update other than what I did in my
25 subcommittee.

1 CHAIR: Perfect. Okay. Then we'll
2 move right on.

3 Next is new business. Sorry. We had
4 another serious medical condition for Chapter 20
5 research application we received earlier this month.

6
7 Dr. Shahoud, can you please provide us
8 an update on that application?

9 MEMBER SHAHOUD: Yes, sure.

10 Hello. The subcommittee has received
11 a serious medical condition for Chapter 20 research
12 application from Penn State College of Medicine for
13 type two diabetes on January 5th. The subcommittee
14 is in the process of reviewing the materials before
15 any recommendation is made to the full board. The
16 subcommittee will continue to meet to thoroughly
17 review the application and come to our recommendation
18 for the next board meeting.

19 Thank you.

20 CHAIR: Thank you so much. And thanks
21 for the subcommittee for reviewing that application.

22
23 Next item is the addition of advanced
24 practice nurses to the list of practitioners who can
25 certify medical marijuana patients in Pennsylvania,

1 brought forth by Dr. Christine Roussel.

2 MEMBER ROUSSEL: Thank you. The
3 regulatory review subcommittee met and we wanted to
4 make a motion for certified registered nurse
5 practitioners to be eligible to apply to be included
6 in the registry of practitioners who can certify
7 patients for medical marijuana for all serious
8 medical conditions allowed by the Commonwealth within
9 the scope of the Nursing Practice Act. That's the
10 formal motion.

11 And I just kind of would like to
12 discuss some considerations. You know, in our
13 document that was sent to everybody. It's definitely
14 within our CRNP scope of practice to order controlled
15 substances when it's clinically appropriate for
16 patients, whether it's in retail pharmacies receiving
17 a prescription for oxycodone or it's in a hospital.

18 A nurse practitioner can write for
19 their audit, and that would be filled based on their
20 relationship with their physician and what they can
21 prescribe for. Also worth mentioning, CRNPs can
22 treat all diseases per their practice act and as
23 such, should have unrestricted ability to certify
24 patients for all serious medical conditions approved
25 by the Commonwealth of PA.

1 Our big rationale for this is we want
2 to improve access to care for patients in our states.
3 You know, if you look at the U.S. in 2023, nurse
4 practitioners saw more than 1 billion patients across
5 the United States. That's a lot of patient care
6 business, a lot of care interactions, and they're
7 doing great care. We think that this should be an
8 ability for them to also be able to do this as well.

9

10 We met with the Board of Nursing, its
11 council and its Regulatory Review Committee were all
12 together in this motion. We have a letter of support
13 from the Board of Nursing. So we put forth this
14 petition.

15 So first we're making a motion. But I
16 will say the committee went ahead and made the motion
17 and then drafted the report just for - like get all
18 the work done at once. So I guess the first question
19 is, because - you know, I make the motion on behalf
20 of the Regulatory Review Committee. I don't know if
21 anybody would like to second the motion. And you
22 want just the words of the motion? I can say them
23 again.

24 CHAIR: Yes. Because one of the
25 concerns was you said certified, and I believe nurse

1 practitioners are actually licensed. I'm turning to
2 Matt for verification.

3 MEMBER EATON: Yes, certified
4 registered nurse practitioners are licensed.

5 CHAIR: Thank you.

6 MEMBER ROUSSEL: And the term CRNP was
7 actually recommended by the Board of Nursing, because
8 that was my question as well. So the motion is for
9 certified registered nurse practitioners to be
10 eligible to apply to be included in the registry of
11 practitioners who can certify patients for medical
12 marijuana for all serious medical conditions allowed
13 by the Commonwealth within the scope of the Nursing
14 Practice Act.

15 MEMBER EATON: Matthew Eaton. I'll
16 second the motion.

17 CHAIR: All right.

18 I will take a roll call. When I call
19 your name, please say aye or you're opposed or
20 abstain.

21 Colonel Paris.

22 MEMBER PARIS: Aye.

23 CHAIR: Christine Roussel?

24 MEMBER ROUSSEL: Aye.

25 CHAIR: Chief Engler?

1 MEMBER ENGLER: Aye

2 CHAIR: Matthew Eaton?

3 MEMBER EATON: Aye.

4 CHAIR: John Adams?

5 MEMBER ADAMS: Aye.

6 CHAIR: Dr. Shahoud?

7 MEMBER SHAHOUD: Aye.

8 CHAIR: Bhavini Patel?

9 MEMBER PATEL: Yes.

10 CHAIR: Dr. Kambic?

11 Dr. Lynch?

12 MEMBER LYNCH: Yes.

13 CHAIR: Diana Briggs?

14 MEMBER BRIGGS: Yes.

15 CHAIR: And I'm going to go back to
16 Dr. Kambic. Is he still on?

17 You can put a note into the chat if
18 you're not able to unmute, Dr. Kambic. He said yes.

19 Okay. Thank you.

20 In the chat. Motion has passed.

21 According to the report policy, the
22 subcommittee must submit a report by the next
23 meeting, but they've already done that, so thank you
24 for that expediency. The report will be distributed
25 to the governor, the Senate, the House of

1 Representatives, and Secretary of Health, and will be
2 public record under the Right to Know Act.

3 All right.

4 And then we have to set up the report
5 separately. I think we have to accept the report
6 separately; correct? Yes. All right.

7 So you all have received the report in
8 advance of this meeting, correct? So the motion we
9 have now to report policy. They must submit the
10 report and make it public. So we're all done with
11 that; right? Someone needs to make a motion to
12 submit the report.

13 MEMBER EATON: Matthew Eaton.

14 MEMBER ADAMS: I'll make a motion.

15 MEMMBER ROUSSEL: That was John Adams.

16 CHAIR: Thank you.

17 Second?

18 MEMBER EATON: Matthew Eaton, second.

19 CHAIR: Great. And I'll do the roll
20 call again.

21 Again, Colonel Paris, this is for
22 submission of the report, the final report.

23 MEMBER PARIS: Aye.

24 CHAIR: Christine Roussel?

25 MEMBER ROUSSEL: Yes.

1 CHAIR: Chief Engler?

2 MEMBER ENGLER: Yes.

3 CHAIR: Matthew Eaton?

4 MEMBER EATON: Yes.

5 CHAIR: John Adams?

6 MEMBER ADAMS: Yes.

7 CHAIR: Dr. Shahoud?

8 MEMBER SHAHOUD: Yes.

9 CHAIR: Bhavini Patel?

10 MEMBER PATEL: Yes.

11 CHAIR: Dr. Kambic?

12 MEMBER KAMBIC: Yes.

13 CHAIR: Dr. Lynch?

14 MEMBER LYNCH: Yes.

15 CHAIR: Diana Briggs?

16 MEMBER BRIGGS: Yes.

17 CHAIR: Thank you.

18 So the motion is passed, and this
19 report will be distributed as we've discussed
20 already, and it will be available under the Right to
21 Know law.

22 For clarification purposes, it does
23 not mean that the automatic changes are made to the
24 program by adopting this report. Section 1202 of the
25 Act governs the process for effectuating

1 recommendations of the Advisory Board. As noted,
2 specific reasons for the decision of the Secretary of
3 Health to effectuate or not, each recommendation will
4 be provided within 12 months of receiving the report
5 from the Advisory Board.

6 So thank you to the subcommittees and
7 chairs today for their work and updates. Next is
8 additional discussion, any questions or items to
9 discuss? All right. Hearing no discussions or any
10 more questions I want to thank everybody for your
11 participation, for joining the Board meeting today.

12 I look forward to seeing you at the
13 next meeting, March 20th. We again have the dates
14 listed up on the slide in front of you. If you have
15 problems, please let us know.

16 May I have a motion to adjourn the
17 meeting? Roussel.

18 MEMBER ROUSSEL: Roussel, motion to
19 adjourn the meeting.

20 CHAIR: Thank you so much.

21 Second?

22 MEMBER LYNCH: Lynch, second.

23 CHAIR: All in favor, say aye.

24 AYES RESPOND

25 CHAIR: Any opposed to ending this

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meeting? Thank you so much.

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MEETING CONCLUDED AT 11:43 A.M.

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CERTIFICATE

I hereby certify that the foregoing proceedings, hearing held before Chair Bogen, was reported by me on January 24, 2024 and that I, Erin Badstuebner, read this transcript and that I attest that this transcript is a true and accurate record of the proceeding.

Dated the 14 day of February, 2024.



Erin Badstuebner,
Court Reporter