

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF HEALTH

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IN RE: MEDICAL MARIJUANA ADVISORY BOARD

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BEFORE: DENISE JOHNSON, Chair
Robert Evanchick, Member
Christine Roussel, Member
Arion Claggett, Member
Carolyn Byrnes, Member
David Steffen, Member
John Adams, Member
Geith Shahoud, Member
Bhavini Patel, Member
Daniel Kambic, Member
William Goldfarb, Member
Shalawn James, Member
Diana Briggs, Member

HEARING: Thursday, July 28, 2022
10:01 a.m.

LOCATION: via Zoom

Reporter: Hannah Bartkowski

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KATELYN N. MALTAIS, ESQUIRE

Pennsylvania Department of Health

Room 825, H&W Building

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Counsel for Pennsylvania Department of Health

ALSO PRESENT:

PETE BLANK

ERIC HAUSER

MARK JUNE-WELLS

HOLLI SENIOR

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CHAIR: Well good morning everyone,
and welcome. Just as a reminder, these meetings are
broadcasted live, and thank you so much for joining us
for another virtual Board meeting. This is my first
meeting serving as Chair for this Board.

And before we get started and do our
roll call, I just want to take a moment to thank some
previous Board members for their service and also
introduce some new Board members, some new faces that
we have, changes have occurred since the last meeting.

So most of you are aware, I have been
the State's physician general since March of 2021.
And that's when I started serving as a member of this
Board. As of April 2022, I accepted the additional
role and responsibility of Acting Secretary of Health,
and that's impacted my role on the Board in a couple
of ways. First, I am honored to serve now as your
Chair. But that also means that I no longer serve on
the Medical Review Subcommittee, and I've designated
Carolyn Byrnes who is my Senior Advisor at the
Department of Health to serve in my physician general
seat on the Board and also to serve as Chair of the
Medical Review Subcommittee. And she's going to

1 continue to lead the work on that subcommittee has
2 already undertaken.

3 Right now, we'll take a moment after
4 we - after the roll call to have everyone introduce
5 themselves. But before I introduce another board
6 member, I want to take a minute to formally express my
7 sincere gratitude and thank you to a previous longtime
8 patient advocate, Luke Shultz, whose term expired in
9 April of this year. Many of you know Luke. He was a
10 passionate patient advocate and a key component of the
11 Board since its inception. He was a face and a voice
12 that helped law makers to understand the need to
13 ensure that when the Medical Marijuana Act was passed,
14 patients and caregivers had a seat at the table.

15 Luke's hard work and dedication was
16 simply unmatched, and he never stopped fighting for
17 the best interests of patients and caregivers since
18 the legislation was passed. His tireless efforts led
19 to several successful program enhancements and Board
20 achievements, including the addition of dry leaf.

21 I commend Luke for his time and
22 dedication and his commitment given to this Board, and
23 I personally and on the behalf of the Department of
24 Health want to thank him for his service. While Luke
25 will be truly missed, it's also a great pleasure that

1 I get to welcome Diana Briggs. She was appointed by
2 Governor Wolf in April.

3 Diana also is an avid patient advocate
4 who was instrumental in helping to get the Medical
5 Marijuana Act passed in Pennsylvania, and that made
6 her an obvious choice of the Governor. I'm grateful
7 to add her expertise and perspective to the Board. I
8 welcome you, Diana, as we continue to help guide the
9 State's successful Medical Marijuana Act.

10 MS. BRIGGS: Thank you. I'm very
11 excited to be here.

12 CHAIR: Great. At the beginning of
13 July, we were notified that we would be losing another
14 member of the Board, Janet Getzy Hart. Janet has also
15 been serving on the Board since its inception and was
16 instrumental in helping to develop the Board's bylaws
17 that are now used to govern the Board.

18 Her valuable expertise will be greatly
19 missed, but we're also extremely happy to welcome her
20 designee, Christine Roussel. She's a Pharm.D. and a
21 Board Certified oncology pharmacist, also Board
22 Certified sterile compounding pharmacist. Janet
23 serves as the Board of - serves as the Chair of the
24 Board of Pharmacy, which earned her a spot on the
25 Board, but she's designated Christine to serve on her

1 behalf. Christine is the Vice Chair of the State
2 Board of Pharmacy, and we look forward to having her
3 expertise available to us moving forward.

4 So one more person that I wanted to
5 make sure to mention this morning is Commissioner
6 Arion Claggett, who is in attendance today.
7 Commissioner Claggett was appointed to serve as he is
8 the Acting Commissioner for the Bureau of Professional
9 and Occupational Affairs at the Pennsylvania
10 Department of State. As of today, this is his first
11 official Board meeting where he has been able to
12 attend. So I wanted to make sure I welcomed him this
13 morning. Welcome, Commissioner.

14 MR. CLAGGETT: Thank you for having
15 me, Dr. Johnson. Good morning.

16 CHAIR: Our pleasure. So I think that
17 that concludes some of the major changes to the Board.
18 So at this time, I'd like to call the meeting to
19 order. This is the Medical Marijuana Advisory Board
20 meeting held at 10:00 a.m. on July 28th, 2022, and as
21 mentioned previously, is being broadcasted.

22 We will officially get started by
23 taking roll call. So first on my list, I have me, of
24 course. I'm here. Colonel Robert Evanchick?

25 MR. EVANCHICK: I am here, good

1 morning.

2 CHAIR: Thank you. Christine Roussel?

3 MS. ROUSSEL: Good morning, present.

4 CHAIR: Great. Commissioner Claggett?

5 MR. CLAGGETT: Good morning, present.

6 CHAIR: Great. Carolyn Byrnes?

7 Carolyn may be having some audio issues. I heard her
8 earlier, okay. And Chief Steffen?

9 MR. STEFFEN: Present.

10 CHAIR: Thank you. Attorney Adams?

11 ATTORNEY ADAMS: I'm present.

12 CHAIR: Great. Dr. Geith Shahoud?

13 MR. SHAHOUD: Present.

14 CHAIR: Thank you. Ms. Patel?

15 MS. PATEL: Present.

16 CHAIR: Thank you. Dr. Kambic?

17 MR. KAMBIC: Present.

18 CHAIR: Great. Dr. Goldfarb?

19 MR. GOLDFARB: Present.

20 CHAIR: Ms. James?

21 MS. JAMES: Present.

22 CHAIR: Great.

23 MS. BYRNES: Can you hear me now?

24 CHAIR: And - yes, we can hear you

25 Carolyn, great. And Dr. Briggs. It is Dr. Briggs,

1 doctor of pharmacy.

2 Correct? Diana?

3 MS. BRIGGS: I am not a doctor.

4 CHAIR: Okay, Ms. Briggs then.

5 MS. BRIGGS: I'm a patient advocate;
6 present.

7 CHAIR: Excellent. It sounds like we
8 have everyone here. I think we have someone that's
9 not on mute. Please mute your microphone if you're
10 not speaking. Great, okay. Good.

11 So I want to ensure that we have a
12 quorum. Legal counsel, Katelyn, do we have a quorum
13 today?

14 ATTORNEY MALTAIS: Good morning, Dr.
15 Johnson. We have a quorum this morning, we're good to
16 go.

17 CHAIR: Excellent. Okay, great. All
18 right.

19 So the next order of business is to
20 approve the minutes from the last meeting. So you all
21 would have gotten a copy of the minutes from the last
22 Board meeting that was held on March 22nd, 2022. I
23 hope you've had a chance to review. May I get a
24 motion to approve the minutes?

25 MR. GOLDFARB: So moved, Goldfarb.

1 CHAIR: Great, thank you, Dr.
2 Goldfarb. Do you I have a second?

3 MR. KAMBIC: Second, Kambic.

4 CHAIR: Thank you, Dr. Kambic. All in
5 favor, say aye.
6 (AYES RESPOND.)

7 CHAIR: Great. Is there anyone
8 opposed?
9 (NO RESPONSE.)

10 CHAIR: Any abstentions?

11 MR. CLAGGETT: Hello, I would like to
12 abstain because I wasn't at the meeting.

13 CHAIR: okay, was that Commissioner
14 Claggett?

15 MR. CLAGGETT: Yes, sorry.
16 Commissioner Claggett, yes.

17 CHAIR: Thank you. Okay.

18 The minutes from the March 22nd Board
19 meeting are approved. And now before we move on to
20 the agenda items today, since it's my first time
21 chairing the Board and we've not had the meeting since
22 March and we've had a lot of changes on the Board, I
23 was hoping we'd have a moment to just introduce
24 ourselves. And that being said, I'll go first.

25 So I'm Denise Johnson. As I said

1 before, serving as Acting Secretary of Health and
2 Physician General. I am an OBGYN physician by
3 training, spent many years in private practice, and I
4 received medical officer at a hospital in Western
5 Pennsylvania. So really glad to be a part of this
6 Board, have really been impressed by the formal
7 structure of our program here in Pennsylvania, and
8 really the detail and the patient-centric focus of it.

9 And so, I'm really glad to be a part of this Board
10 and to continue the great work that those before me
11 have started.

12 So next I will turn it over to Colonel
13 Evanchick.

14 MR. EVANCHICK: Good morning. I'm
15 Colonel Robert Evanchick, the Commissioner of the
16 Pennsylvania State Police. I've been a member of the
17 State Police for over 40 years. I also have previous
18 law enforcement experience as a local police officer
19 for almost three years.

20 I've been with the - the Commission
21 here for since its inception. I look forward to the
22 new members of the Board as well. Look forward to
23 continue working together and trying to find ways that
24 we can keep the program running in a successful, yet
25 appropriate format. Thank you.

1 CHAIR: Great. Thank you, Colonel
2 Evanchick. Next, Christine Roussel.

3 MS. ROUSSEL: Good morning. I am a
4 pharmacist that is, specializes in oncology. I am
5 currently Senior Executive Director of Pharmacy
6 Laboratory and Medical Research at Doylestown
7 Hospital. I am on the Pennsylvania Board of Pharmacy
8 representing institutional pharmacy. And then I also
9 serve for University of Sciences. I leave their
10 medical cannabis education program and helped form
11 that education program starting in 2016. So I'm
12 really excited to be here. I think the medical
13 marijuana program has brought so much to patient care,
14 and I look forward to serving and supporting.

15 CHAIR: Excellent, and we're glad to
16 have you. Welcome to the Board. Next, Commissioner
17 Claggett.

18 MR. CLAGGETT: Good morning, all. My
19 name is Arion Claggett. I am the Acting Commissioner
20 with the Bureau of Professional and Occupational
21 Affairs, which is professional licensing within the
22 Department of State. I've been here around three and
23 a half years, and I'm excited to be part of the Board.
24 Thank you.

25 CHAIR: Welcome, thank you so much.

1 Carolyn.

2 MS. BYRNES: Good morning, everyone.
3 I'm Carolyn Byrnes. I've been designated to fill the
4 position general seat on the Board. First, thank you
5 to Dr. Johnson for not only appointing me to the Board
6 but also providing me the opportunity to continue the
7 great work that the subcommittee was already
8 conducting under her leadership.

9 I've received my master's in public
10 health and epidemiology and a bachelor in science in
11 biology. I've served in the Secretary of Health
12 Office for the past seven plus years, and I'm
13 currently a Senior Advisor to the Secretary of Health
14 and Physician General.

15 I've served as a Senior Advisor since
16 2018, and previously as a special assistant to the
17 Secretary of Health. In the Secretary's Office, my
18 role has been focused on maternal health issues, the
19 opioid crisis, and for the past few years the COVID-19
20 pandemic. Since May 2021, I've assisted Dr. Johnson
21 with her Medical Marijuana Advisory Board duties,
22 including those of the Medical Review subcommittee.
23 And prior to my time at the Department, I worked as a
24 clinical research associate at Roswell Park Cancer
25 Institute managing the daily operations of

1 interventional study for three years.

2 Now I'll hand it back to you, Dr.
3 Johnson.

4 CHAIR: Excellent. Thank you so much,
5 Carolyn. Looking forward to you in this new role.
6 Chief Steffen.

7 MR. STEFFEN: Morning. My name's Dave
8 Steffen. I'm Chief of Police of the Northern
9 Lancaster County Regional Police Department. We are a
10 PLEAC accredited agency, and I've served on a Death
11 Review Board --- other Death Review Boards with the
12 Department of Health. Was instrumental in the
13 programing and rollout of the Narcan to law
14 enforcement through the Secretary of the PDAP
15 (phonetic) programming. I'm also just completing my
16 term as president of the Pennsylvania Chief of Police,
17 and will likely be replaced by the incoming president
18 or if I return as a designee. So thank you all.

19 CHAIR: Thank you, Chief Steffen.
20 Next I have Attorney Adams.

21 ATTORNEY ADAMS: Morning. I am the
22 District Attorney of Berks County. I have actually
23 other than one year, I have been on the Board since
24 its inception as I was the president of the District
25 Attorney's Association at the time that this Board

1 came into fruition. I've been the DA of Berks County
2 for 15 years, and have been practicing law for 32 plus
3 years. I've, you know, I have been and I think that
4 we're making a positive impact in Pennsylvania with
5 this program and I hope to see it continue and to
6 flourish. Thank you.

7 CHAIR: Great, thank you so much.
8 Next, Dr. Shahoud.

9 DR. SHAHOUD: Hi, good morning. Geith
10 Shahoud. I'm a child and adult psychiatrist. I am
11 the medical director of Southwood Psychiatric Hospital
12 in Pittsburgh, Pennsylvania. I mainly practice child
13 psychiatry. I have been practicing since 2004, and
14 thank you for being a member of the Board.

15 CHAIR: Thank you, Dr. Shahoud. Next,
16 Bhavini Patel.

17 MS. PATEL: Good morning, everyone.
18 My name is Bhavini Patel. I currently work in local
19 government in the Pittsburgh area, and I plan to
20 continue serving on the Board and also serving as the
21 Chair of Medical Research Subcommittee.

22 CHAIR: Thank you, Bhavini. Sorry
23 about the pronunciation.

24 MS. PATEL: That's okay.

25 CHAIR: I'll - I'll correct that.

1 Thank you so much.

2 MS. PATEL: Thank you.

3 CHAIR: Next I have Dr. Kambic.

4 MR. KAMBIC: Good day, Secretary. I'm
5 Dave Kambic. I've been on the Board a little over a
6 year now. I'm a lifelong Pennsylvanian. I just
7 started my 39th year in private practice as a family
8 doc in my home town of Steelton, Pennsylvania. I'm
9 also the program director for the family medicine
10 residency program at UPMC Harrisburg, which I've been
11 on that for 21 years. I've been in a program as a
12 certified physician since 11/1/17 when it actually
13 started, and tremendous advocate for the program and
14 I've seen the amount of good things that have come
15 about this with patient care. I wanted to continue to
16 support this program and continue to be a certified
17 physician for as long as I've been in my practice.

18 I think - we try to train our
19 residents into the virtues of - virtues of medical
20 marijuana because certainly there's not enough taught
21 in medical schools in our state about this. And that
22 way, we're having an impact on the next class of
23 physicians that go into practice to continue to use
24 this as a tool in a toolbox because it works very
25 well.

1 CHAIR: Great. Thank you so much, Dr.
2 Kambic. Next, Dr. Goldfarb.

3 MR. GOLDFARB: Good morning. I'm a
4 retired burn trauma surgeon in the Pittsburgh area who
5 also served in multiple administrative roles as the
6 Senior VP in Highmark Blue Cross Blue Shield and a
7 Chief Medical Officer at two of the facilities within
8 the Allegheny Health Network. I've been on this Board
9 since its inception, and I'm looking forward to
10 working with all of the new members.

11 CHAIR: Great. Thank you, Dr.
12 Goldfarb. And Shalawn James.

13 MS. JAMES: Good morning. My name is
14 Shalawn. I have been on the Board since its
15 inception. I am currently working as a consultant in
16 Maryland, Pennsylvania, and New Jersey around the
17 areas of diversity and inclusion and equity. And I've
18 been a lifelong advocate and a very strong advocate
19 for medical marijuana. I have a now 20-year-old son.
20 I think when I first started, he was about 15. So
21 with the Board, so he's now a 20-year-old son who does
22 have sickle cell disease and benefits from the medical
23 marijuana. And I look forward to working with all the
24 new members.

25 CHAIR: Great. Thank you so much.

1 And Diana Briggs.

2 MS. BRIGGS: Hi. My name is Diana,
3 and I was a founding member of Campaign for Compassion
4 which was the grassroots advocacy group that fought
5 for our medical marijuana program. As a caregiver
6 first for my son who is now 22, I started advocacy
7 when he was 14 for his epilepsy. Ryan is now a
8 shining example of the success of this program. He
9 has gone from 400 seizures a day to down to 25 with
10 just the help of medical cannabis.

11 After watching him and many others
12 find success with this program, I actually became a
13 patient and am also seeing great success. I honestly
14 do not know that I can fill the very large shoes left
15 by my fellow advocate and dear friend Luke Shultz, but
16 I can tell you there isn't a bigger cheerleader for
17 this program than myself and my family. So I'm very
18 excited to be here, and can't wait to see what we can
19 accomplish in the next year.

20 CHAIR: Wow. Thank you so much,
21 Diana. We are very glad to have you and looking
22 forward to your role here on the Board.

23 So thank you all for introducing
24 yourselves. I know that took some time, and it's
25 probably not the first time that you were asked to do

1 that and I'm sure that we'll have to do that again.
2 But it's really good for us to know who's on the Board
3 and hear a little bit about your background.

4 So the next item that we have on our
5 agenda is a program update. And I'm going to turn
6 things over to the program to update. As many of you
7 might recall, John Collins last week with the medical
8 marijuana program was at the time of the last Board
9 meeting in March. Right now, we are continuing to
10 search actively for a new director. And in the
11 meantime in the interim, the Department's Executive
12 Deputy Secretary, Pete Blank, has been leading our
13 office during this transition and is serving as the
14 interim active director of the program.

15 So Pete, if you would like to just
16 introduce yourself briefly and then share a program
17 update for us.

18 MR. BLANK: Absolutely. Thanks so
19 much, Dr. Johnson. I appreciate the introduction. So
20 for those that I haven't had a chance to meet yet, as
21 Dr. Johnson mentioned, my name is Pete Blank. I'm
22 currently the Executive Deputy Secretary here at the
23 Department of Health. Prior to this role, I've served
24 in the Policy Office most recently as Policy Director
25 and have had positions there 2018.

1 So I wanted to, you know, I know as
2 John and others have previously presented on some -
3 some program updates at these Board meetings. Wanted
4 to continue with that, and so we have a couple of
5 topics to discuss today. First one, I'll touch
6 briefly on some medical marijuana regulations then
7 move into some - some program data and some program
8 metrics for the Board's awareness.

9 And go to the next slide. So before I
10 jump into the program metrics, I do just want to make
11 sure that, you know, the entire Board is aware of the
12 process for the medical marijuana final form
13 regulations. So as many of you know, the Department
14 has been working on these final form regulations for
15 quite some time. And recently, earlier this month,
16 the Department of Health formally withdrew the medical
17 marijuana final form regulations from consideration by
18 IRRC, so the Independent Regulatory Review Commission.

19 And that was on July 13th, and really in order to
20 make technical edits to that final form packet.

21 The Department, you know, working
22 currently to make those edits and have a plan to
23 resubmit to IRRC as well as the stint, to the General
24 Assembly in the very near future. And just wanted to
25 make sure that the Board was aware of that - of that

1 progress. And also for - for awareness that temporary
2 regulations that have been in effect were for quite
3 some time will still be in effect until final approval
4 and promulgation of those - those final form
5 regulations. So again, I just wanted to make sure
6 that the Board had awareness of that progress to date.

7 So with that, I want to turn over to -
8 turn to some program metrics and - and share some data
9 since we last met in March of this year. So as you
10 see here again, some familiar numbers that the program
11 has reported out during the previous Board meetings.
12 And so we are seeing similar trends in program growth
13 since we last shared these numbers in March of this
14 year. I wanted to highlight a few things, most
15 notably over 413,000 active patient certifications and
16 over 1,800 approved practitioners are in the program
17 to date. So still seeing a robust participation in
18 growth amongst patients and practitioners.

19 Also since the March Board meeting,
20 wanted to call out here as well that the program has
21 surpassed over \$5 and a half billion in total sales.
22 And that was really what we've seen to date is close
23 to a \$1 billion dollar increase since this - this
24 information was presented at the March Board meeting.

25 So at that Board meeting, the most recent data we had

1 was the \$4.7 billion in total sales. So again, still
2 seeing those - those growth trends throughout the
3 program.

4 Next slide. So again, wanted to walk
5 through a couple more slides now on dispensary sales
6 and see how things are progressing. So you'll see
7 that we are, again, maintaining a growth trend here
8 and seeing these dispensary sales continue to
9 increase, but perhaps at a decreasing rate. So you
10 can see here this is, shows that - that increase and a
11 decrease in rate. Over the most recent 12-month
12 period so we can see that here on the slide. Next
13 page.

14 Again, another view looking at the
15 similar data. So dispensary sales by month since
16 January of 2020. Again, seeing those - those
17 increases across the months and starting to still see
18 that increase in trend but again at that decreasing
19 rate.

20 Next slide. Again, one more
21 presentation of - of the similar data. As we can see
22 in the most recent quarters over the last couple of
23 years, so for May and June, seeing those trends
24 continue upward. Next slide.

25 So now I'd like to take a few minutes

1 to discuss the permitting pricing trends. Again, I
2 know we do share some of these trends at previous
3 Board meetings. I wanted to make sure that we
4 provided an update since - since we last did that in
5 March. Next slide.

6 So you can see here on the slide that
7 this is kind of by product. And dry leaf continues to
8 be the most - the most common product, holding stable
9 at close to 45 percent of the market. And that's
10 followed closely by vaporization products, which are
11 again holding stable at around 35 percent. Next
12 slide.

13 So I know this is somewhat of a busy
14 slide, but I wanted to call a few things to your
15 attention. So first, you'll note that since we last
16 presented this information in March of this year at
17 the last Board meeting, several more dispensaries have
18 become operational. And so we are, you know, thankful
19 again for the permittees that we work with and our
20 field staff that have been able to, you know, work
21 together to make those - those dispensaries
22 operational. And secondly you can see here that the,
23 you know, the graph really indicates the continued
24 growth in the program, and this is again specific to
25 dry leaf sales over - over the time since January of

1 2020.

2 I wanted to call attention as well to
3 - to both the orange and the black line there. As you
4 can see, that downward trend for both retail and
5 wholesale dry leaf products. So we are continuing to
6 see that - that declining trend in price. And I know
7 we presented that information previously, but really
8 wanted to - to really show that overlay here as more
9 dispensaries become operational and as the program
10 grows, seeing that decrease in price.

11 Next slide. Again another look here
12 at the retail price per gram, that top line in orange,
13 and the wholesale price per gram below that in black.

14 And you'll note as well that continued decrease. And
15 I would just like to call that since the - the March
16 Board meeting, I know we had kind of called out
17 somewhat of a wider growth between retail and
18 wholesale price, we have seen that over the last
19 couple of months become a little more even in their
20 trends. So about a ten percent and seven percent
21 respectively between retail and wholesale price
22 decrease since about, you know, middle of the spring
23 this year. So I wanted to again call your attention
24 to those trends as previously presented at the Board
25 meeting. And please note that the program continues

1 to - to monitor these pricing trends as well as the
2 program metrics. And you know, keep - keep attuned to
3 what is happening across the industry and with the
4 program at a wider scale.

5 So with that, I'm happy to take any
6 questions or Dr. Johnson, turn it back to you for, to
7 continue with the agenda.

8 CHAIR: Great. Thank you so much for
9 that, Pete. Board members, do you have any questions
10 for Pete? Okay, great.

11 Well, hearing no questions, let's move
12 on to old business. I want to provide a brief update
13 on where we are with the chronic hepatitis report. As
14 many of you may recall, at the March - at the March
15 Board meeting, there was a report presented and
16 approved that recommended the addition of chronic
17 hepatitis as an approved serious medical condition.
18 Approved reports are then sent to the Secretary to
19 transmit notice to the Legislative Reference Bureau,
20 also known as the LRB, to set forth the rationale for
21 effectuating or declining that recommendation.

22 So while that report was initially
23 submitted to then-Acting Secretary Klinepeter, I'm
24 working with our legal counsel so that we can continue
25 to move the recommendation forward despite the changes

1 in the Board leadership.

2 The next item I want to talk about is
3 the health contact form feedback. And this is the
4 first time that you will have gotten feedback in your
5 packets, and that came in your electronic packet for
6 this Board meeting. Just to recap for those of you
7 who are not aware, at a previous Board meeting, Board
8 members wanted to find a way for the public to be able
9 to contact the Board or to send feedback.

10 We already had a way for the public to
11 provide feedback to the Department through the health
12 contact form. And so, we've made modifications to the
13 pre-existing form so that the process would be now to
14 allow individuals to submit information directly to
15 the Board.

16 So we committed to collecting and
17 sharing that information with Board members, and we
18 just wanted to acknowledge that we did fulfill that
19 commitment, and that information is provided in your
20 electronic Board packet.

21 As - I'll also note that we will
22 continue to monitor the process and make necessary
23 adjustments to improve our communication and ensure
24 that expectations are clear. But one example of that
25 is shortly after we implemented after this process,

1 based on the feedback we received we quickly learned
2 that people were selecting the wrong option. Since
3 the Board option is directly below the Office of
4 Medical Marijuana Option. So I think as you can
5 notice from some of the feedback in the forms, some of
6 those questions are really not directed towards the
7 Board. They really should be directed towards the
8 program, and so we need to clarify that.

9 So once we learned that, we put some
10 additional descriptive language in the options, and it
11 includes a step that requires the submitter to confirm
12 that their intent is, in fact, to provide their
13 feedback to the Board.

14 So that being said, we had a total of
15 11 submissions that we shared in your packet. And as
16 we go forward, we'll continue to share that feedback
17 with you.

18 Do I have any questions on that from
19 any Board members? All right.

20 So let's move on to the new business.

21 First we'll talk about the recent changes related to
22 the Board's subcommittees and expectations. So all of
23 you have been provided with an updated subcommittee
24 list in your electronic Board packet for your
25 reference. As I mentioned earlier prior to roll call,

1 we had a number of Board member changes since our last
2 meeting. So of course, that will affect the
3 subcommittees and their makeup.

4 While most of the changes have been
5 communicated to you previously, there are a couple
6 that you might - that you may be hearing about for the
7 first time because they were finalized more recently.

8 So before we move to the subcommittee updates, let me
9 highlight some of the changes first so that they're
10 captured on the record.

11 First I'll start with maybe the
12 biggest decision, which was the decision to dissolve
13 the Report Subcommittee. I think it's important to
14 note that the bylaws that govern the Board which also
15 establish and outline the Board's subcommittees was
16 proposed and adopted very early on in November 2018.
17 So after giving this a significant amount of thought
18 and taking into consideration the Board's
19 responsibilities and how they've changed over the
20 years, I think this change is both necessary and
21 timely.

22 So it will not only add value to the
23 other subcommittees, but it'll also ensure that the
24 work is distributed more evenly and responsibly. So
25 this means moving forward, the same subcommittee that

1 proposes a recommendation will be the subcommittee
2 responsible for seeing it through the appropriate
3 steps for advancements. There's not going to be a
4 separate subcommittee that just creates the report
5 based on that recommendation.

6 So the thought behind that's really
7 simple. Who better to effectively articulate, meaning
8 compiling the report for recommendation, than the
9 subcommittee that brought it forward in the first
10 place? So there won't be a duplication of that
11 effort.

12 I'm also aware that all of you are
13 extremely busy and you participate in various Boards,
14 have other responsibilities. So the last thing I want
15 to do is make anyone feel overwhelmed by this
16 responsibility or that it's too burdensome. So when
17 we decided to dissolve the reports committee, it was
18 important to make sure that all of you have the
19 adequate support and the necessary tools and resources
20 to help you fulfill that responsibility. So I have
21 asked Dylan Shaw, who many of you may be familiar with
22 at this point, to provide some additional
23 administrative support to Board members. So I would
24 encourage you to reach out to Dylan with any questions
25 that you have as we work through the changes that

1 we've outlined here today.

2 Also, it's a goal of mine to enhance
3 communication across the Board and encourage
4 participation and create awareness among Board
5 members. And one thing I've always heard each
6 secretary say which I will continue to say is,
7 regardless of what subcommittee that you're assigned
8 to, Board members have the ability to and they're
9 encouraged to participate in additional subcommittees
10 as well. But I realized that can be difficult for
11 Board members to participate or even know if they're
12 interested in participating without getting additional
13 details about when the subcommittees are meeting or
14 what they're discussing.

15 So I know that Dylan has already been
16 in contact with some of you, and I want to show you
17 that he'll be reaching out to the subcommittee chairs
18 on a more consistent basis. And he will also be
19 helping to collect meeting dates and times and
20 schedules and agenda items to be able to share them
21 with other Board members. Our goal is to make sure
22 that you're aware of what the other subcommittees are
23 working on with the hope that you can make an informed
24 decisions about your participation.

25 So I'll pause here for a moment to see

1 if anyone has any questions about that change. Okay.

2 All right.

3 So now that we talked about Dylan's
4 role and why we now have four subcommittees instead of
5 five, let's talk about some of the changes of the
6 subcommittees and acknowledge the members of each
7 subcommittee for the record.

8 So starting with the Regulatory
9 Subcommittee which is responsible for looking into
10 whether to change the types of medical professionals
11 who can issue certifications to patients, this
12 subcommittee will be chaired by one of our new Board
13 members, Christine Roussel, who is joining us for her
14 first meeting today. As mentioned earlier,
15 Christine's replacing Janet Getzy Hart on the Board.

16 So after shifting subcommittee members
17 around and making some changes at the beginning of
18 June, I felt it would be best to assign Christine to
19 simply replace Janet by participating on the same
20 subcommittees in the same capacity. And I was told
21 that Christine not only graciously accepted, but she
22 eagerly accepted so thank you so much, Christine.

23 So we're delighted to have you on the
24 Board taking on this new role, and other members who
25 are on the Regulatory Subcommittee are District

1 Attorney John Adams, Commissioner Arion Claggett, and
2 Dr. William Goldfarb. I think District Attorney
3 Adams, you're the only remaining member who was on the
4 Regulatory Subcommittee as all of the other members
5 are either new to the Board or new to the subcommittee
6 or both.

7 Any questions about that? All right.

8 So next we have the Patient and
9 Caregiver Subcommittee that is responsible for looking
10 at how to ensure affordable patient access to medical
11 marijuana. This committee is chaired by Shalawn
12 James. An additional Patient and Caregiver
13 Subcommittee members include Colonel Robert Evanchick,
14 Commissioner Arion Claggett, and Diana Briggs. Both
15 Arion and Diana are newer Board members to the - newer
16 Board members and new to the subcommittee.

17 Next is the Medical Review
18 Subcommittee that is responsible for whether it's a
19 change, add, or reduce the types of medical conditions
20 which qualify as serious medical conditions under this
21 act. And this is a subcommittee that I used to chair
22 when I served as physician general, and I've assigned
23 Carolyn Byrnes who I designated to serve on the Board
24 to also chair this subcommittee and continue to
25 advance the work that was already underway.

1 Additional Medical Review Subcommittee
2 members continue Dr. William Goldfarb, Dr. Daniel
3 Kambic, Dr. Geith Shahoud, and Shalawn James.

4 And lastly, we have the Medical
5 Research Subcommittee that is responsible for whether
6 to change the form of medical marijuana permitted
7 under this act. The Medical Research Subcommittee is
8 chaired by Bhavini Patel and additional Research
9 Subcommittee members include our two new members,
10 Christine Roussel and Diana Briggs, and then two
11 former members remain, District Attorney John Adams
12 and Chief David Steffen.

13 So I believe that should cover the
14 subcommittee changes. Again, you have been provided
15 in your packet an updated subcommittee list which
16 includes individual email addresses. If you're
17 serving as a subcommittee chair and have not yet made
18 contact with all of your subcommittee members, I would
19 encourage you to do so as soon as possible to
20 establish a working relationship and ensure an open
21 line of communication.

22 So moving right along, let's move on
23 to the subcommittee updates. I think before it was
24 determined that the best way to practice the progress
25 and chair information on an ongoing basis would be to

1 have each subcommittee provide an update at each Board
2 meeting about their activity since the previous
3 meeting. Board members were also queried ahead of
4 each Board meeting to determine if they had any
5 additional or specific agenda items that they would
6 like to include that would require deliberation.

7 At this time, I will ask each of the
8 subcommittee chairs or whoever they wish to designate
9 to provide us with an update. And first up, we'll
10 start with the regular - Regulatory Subcommittee chair
11 by Christine Roussel. Realizing Christine this is
12 your first meeting and you have a lot of information
13 to - to digest, and I don't really expect you to have
14 an update today, but I want to give you an opportunity
15 if there's anything that you want to share.

16 MS. ROUSSEL: Good morning. I'm
17 excited to be involved with this committee. And then
18 I think one of the things the committee does need to
19 do is we might need to look at the bylaws and update
20 them if needed to reflect the elimination of the
21 reporting committee. So I think that may be one of
22 the things on the near immediate to do list. But
23 otherwise, I look forward to providing you a more
24 robust update at the next meeting.

25 CHAIR: Great. Thank you so much,

1 Christine. Okay.

2 Moving on then, next we have the
3 Medical Review Subcommittee that's chaired by Carolyn
4 Byrnes. And Carolyn, do you want to provide an
5 update?

6 MS. BYRNES: Yes. Can you hear me?

7 CHAIR: Yes, we can. It's a little
8 low in your volume, but we can hear you.

9 MS. BYRNES: I'll get closer so you
10 can hear better. Good morning, everyone. While there
11 were no serious medical condition applications to
12 review for this meeting, I can assure that the Medical
13 Review Subcommittee has been busy over the past few
14 months.

15 As you may recall at a previous Board
16 meeting, the subcommittee was asked to research a
17 couple of times and report back to the Board with a
18 recommendation. First, I'd like to take a minute to
19 recognize the Medical Review Subcommittee members, Dr.
20 Kambic, Goldfarb, and Shahoud and Shalawn James.
21 Thank you for your time, effort, and continued
22 collaboration to help deliver what I believe to be an
23 effective policy and application.

24 Today, our subcommittee proposes a
25 process by which an ACRC interested in conducting

1 Chapter 20 research on a condition that is not already
2 qualified as a serious medical condition for medical
3 marijuana usage in Pennsylvania, may petition the
4 Medical Marijuana Advisory Board to have the condition
5 approved for medical marijuana usage for Chapter 20
6 research only.

7 It is important to note the following.
8 This application and policy are to approve conditions
9 for research and not individual research studies. And
10 once a condition is approved for research, any ACRC
11 may pursue research on that condition.

12 All Board members were provided both
13 the proposed policy and application in advance for
14 your review. And it has been provided in your
15 electronic Board packet sent for today's meeting.
16 First, let's discuss the proposed policy. The policy
17 outlines that an application must be submitted in
18 order to get a condition approved for research
19 purposes only. And that - and the specifics of
20 Chapter 20. Only a member of an ACRC can submit an
21 application. The process is similar to that of
22 serious medical - medical conditions for clinical use
23 where the application goes to the Medical Review
24 Subcommittee, then is presented to the Board for a
25 vote, and then goes to the secretary for

1 consideration.

2 If approved, any ACRC that wishes to
3 conduct a research study will need to comply with the
4 Office of Medical Marijuana's guidance documents for
5 Chapter 20 research studies on approved conditions.
6 Please note these guidance documents have not been
7 developed as this is a proposed policy that is not yet
8 approved. Once these guidance documents have been
9 published, the Board can begin accepting and reviewing
10 applications for conditions for research.

11 Now I'm going to move on to the
12 proposed application. The application includes
13 questions about the condition proposed for research
14 only, including the following. If this condition has
15 been approved in another state, rationale for choosing
16 this condition for research including any current
17 research evidence, the research question hypothesis
18 intended to be studied, and study designer methods,
19 the study population intended included rationale
20 whether the pediatric population is included,
21 documentation supporting efficacy of medical marijuana
22 as a treatment for the condition, and a description of
23 how medical marijuana is anticipated to improve the
24 condition for which the application is being
25 submitted.

1 The answers to these questions will
2 illustrate that research on the condition has been
3 thoroughly thought through the rationale for the
4 potential benefit and will help the medical marijuana
5 advisory Board assess the condition proposed for
6 research.

7 Before I turn things back over to Dr.
8 Johnson, I'd like to ask my subcommittee members if
9 they have anything they want to add to what I've said
10 or if there's anything that I may have missed or
11 perhaps wasn't clear.

12 MR. KAMBIC: Kambic, it's all clear.

13 MS. BYRNES: Okay, great.

14 MR. GOLDFARB: Agreed.

15 MS. BYRNES: Thank you Dr. Goldfarb
16 and Dr. Kambic. Since there are no more comments from
17 the subcommittee members, Dr. Johnson that concludes
18 my presentation on the proposed policy and
19 application.

20 CHAIR: Yeah, thank you very much
21 Carolyn. And thank you Medical Review Subcommittee
22 for really thoughtfully considering this. Since the
23 Board really has the authority to approve conditions
24 for research only, it was really important that we
25 came up with a clear process on how to do that, and it

1 really looks like you have really thought through the
2 options.

3 So for any Board members, are there
4 any questions that you have about this proposed
5 policy? Questions about it, any concerns, any
6 suggestions? So you all would have gotten a copy of
7 this policy - the application and the policy in your
8 packets. Do I have a motion to approve this policy?

9 MS. JAMES: Motion to approve.

10 CHAIR: I'm sorry, who was that?

11 MS. JAMES: Shalawn.

12 CHAIR: Shalawn, okay. Great.

13 Do I have a second?

14 MEMBER: I'll second.

15 CHAIR: Was that Dr. Goldfarb? I
16 couldn't hear.

17 MR. GOLDFARB: No, but I'll second.

18 CHAIR: Thank you, Dr. Goldfarb for
19 seconding. Do we have any other discussion? Okay.
20 All right.

21 We're going to ask for a vote, and I
22 think I need to go through the list. So you can tell
23 me yes or no when I call your name. So Colonel
24 Evanchick?

25 MR. EVANCHICK: Yes.

1 CHAIR: Okay, Christine Roussel?
2 MS. ROUSSEL: Yes.
3 CHAIR: Commissioner Claggett?
4 MR. CLAGGETT: Yes.
5 CHAIR: Carolyn Byrnes?
6 MS. BYRNES: Yes.
7 CHAIR: Chief Steffen?
8 MR. STEFFEN: Yes.
9 CHAIR: Attorney Adams?
10 ATTORNEY ADAMS: Yes.
11 CHAIR: Dr. Shahoud?
12 MR. SHAHOUD: Yes.
13 CHAIR: Bhavini Patel?
14 MS. PATEL: Yes.
15 CHAIR: And Dr. Kambic? Dr. Kambic?
16 We'll come back. Diana Briggs?
17 MS. BRIGGS: Yes.
18 CHAIR: Okay.
19 Is Dr. Kambic still with us? Okay.
20 Okay, so - okay.
21 So I have 11 yeses, no no's or no
22 abstentions.
23 MS. BYRNES: Doctor ---.
24 DR. GOLDFARB: You didn't finish the
25 roll call.

1 MS. BYRNES: Yeah, Dr. Johnson I think
2 you have Dr. Goldfarb and Shalawn, and then I know Dr.
3 Kambic, I'm not sure if he fell off the line. But you
4 have just -.

5 CHAIR: I see. I have, I think
6 Shalawn made the motion, Dr. Goldfarb seconded.

7 MS. BYRNES: Okay.

8 DR. GOLDFARB: Okay.

9 CHAIR: So do I have everyone? So I
10 have 11, and I don't have a vote from Dr. Kambic.

11 Is that correct? Okay.

12 So motion passes. Thank you, Medical
13 Review Subcommittee for your work on that. That's
14 excellent, great. Okay.

15 Next we have the Medical Research
16 Subcommittee chaired by Bhavini Patel. Bhavini, am I
17 pronouncing your name correctly? I - I need to get
18 this right.

19 MS. PATEL: It's Bhavini.

20 CHAIR: Bhavini, okay.

21 MS. PATEL: Yes.

22 CHAIR: All right.

23 Thank you so much. Would you like to
24 provide an update?

25 MS. PATEL: Yes. The Medical Research

1 Subcommittee did not meet, but we do look forward to
2 meeting between this meeting and the next meeting and
3 providing an update in between. We just had some
4 shifts in Board members that particularly impacted our
5 subcommittee, so we - we didn't have a meeting.

6 CHAIR: Great. Thank you so much,
7 Bhavini. I will - I will practice. I'll get this
8 right.

9 MS. PATEL: Thank you.

10 CHAIR: Okay.

11 So now we have the Patient and
12 Caregiver Subcommittee chaired by Shalawn James.
13 Shalawn.

14 MS. JAMES: Good morning. The Patient
15 and Caregiver Subcommittee also has not had an
16 opportunity to meet. We will be getting back together
17 and meeting in between our next meeting, but we are
18 excited to see that there is a downward trend for
19 patient costs and affordability for patients to access
20 the medical marijuana that they need. And we'll give
21 a more extensive report at the next meeting.

22 CHAIR: Great. Thank you so much for
23 that, Shalawn. Okay.

24 This should conclude the subcommittee
25 updates. The next item that I have on the agenda is a

1 new item that came out of Act 44 of 2021. And it will
2 be the Board's first time being presented with what is
3 referred to in the act as a research initiative.

4 So in summary, Act 44 allowed for
5 remediation on a very limited basis that grower
6 processors may apply a solvent based extraction method
7 to remediate a product that has mold or yeast product
8 on lab testing. That said product may only be
9 processed into a topical form and labelled as being a
10 remediated product.

11 Due to the strict limitations of this
12 provision, the authors of Act 44 also allowed for a
13 research initiative to be conducted to assist in
14 determining whether solvent based extraction methods
15 are safe for patients in other forms.

16 A research initiative is only for a
17 certified academic clinical research centers, or
18 ACRCs, and their clinical registrant, or CR, partners
19 to conduct a study on the safety and efficacy on a
20 solvent based extraction method of their choice.

21 Act 44 requires a specific process on
22 how this needed to occur, which includes several
23 steps. One of the steps include presenting the
24 research findings to the Medical Marijuana Advisory
25 Board and the Medical Research Subcommittee, hence

1 today's presentation. Then the Medical Research
2 Subcommittee can issue recommendations to the Board
3 based on the findings that are presented today at this
4 Board meeting.

5 The Board will vote on the
6 recommendations, and if approved, the Medical Research
7 Subcommittee will be responsible for compiling a
8 report that would then be sent to the Secretary
9 following the same process used when other
10 recommendations are brought forward and approved.

11 So at this time, I want to welcome
12 both Eric Hauser and Mark June-Wells who are joining
13 us today from Organic Remedies, and I'll turn things
14 over to Mark.

15 MR. JUNE-WELLS: Thank you for that,
16 Denise. And firstly, I'd like to start off by saying
17 thank you to this advisory Board for hearing us out
18 today and hearing about this research which we
19 understand can be somewhat boring. So I'm happy that
20 you guys allowed us to do that. We'd also like to
21 thank DOH for this opportunity to execute this
22 research and for our academic partner, Philadelphia
23 College of Osteopathic Medicine.

24 So this research was executed here at
25 Organic Remedies following Act 44, and this was an

1 initiative that was designed to determine whether the
2 extraction process could in fact sterilize plant
3 material, and thereby create clean extracts that fall
4 within the DOH compliance limits. Next slide, please.

5 So this talk will cover - well, I'll
6 just briefly go over the current state of regulations.

7 You guys know them very well, but we will just
8 briefly cover them. We'll also talk about the impact
9 on a medical marijuana business due to crop
10 destruction. We'll talk about the different types of
11 remediation techniques that exist out there and that
12 are approved by the FDA. We'll then go over the
13 purpose and goals of this study, and then we'll review
14 our manufacturing process, go over the study
15 methodology, our study findings, and then our
16 conclusions. Next slide, please.

17 So just briefly, these are the current
18 medical marijuana microbial limits for plant material
19 and extracts here in Pennsylvania. So for things like
20 E. coli and Salmonella. Obviously they cannot be
21 present, but you have limits on aerobic bacteria, less
22 than 10,000 colony forming units per gram, total yeast
23 and mold is the same limit. Total gram negative
24 bacteria less than 1,000 colony forming units per
25 gram. In the extracts, E. coli and Salmonella still

1 must be absent, total aerobic bacteria is 10,000
2 colony forming units, total yeast and mold is not
3 1,000 colony forming units, and total gram negative is
4 100 colony forming units.

5 It's - it's notable to say at this
6 point that if plant material does not pass these or
7 does not fall within the state limits that it cannot
8 be used in extraction. Next - next slide, please.

9 Okay.

10 So let's talk about what that means to
11 a company, just briefly. If in the best case
12 scenarios, the cost of flower production or terpene
13 product is about \$.75 per gram. That's in a very
14 refined greenhouse model. However if you're growing
15 in an indoor sort of environment, that can be as high
16 as \$2 per gram. So in a case like our product
17 facility where we're turning 100s of kilograms per -
18 per cycle, you can see that that would have a
19 significant impact on the revenue of the company if we
20 have to destroy it for not passing the - for not
21 falling within the microbial limits. So what does
22 this mean to the company? Obviously lost revenue is
23 number one, but then we are - we also have to, this
24 could limit employment opportunities or pay scales,
25 and most importantly it also has an impact on the cost

1 of the products to the patients. Next slide, please.

2 Okay.

3 So just briefly, the USP and the FDA
4 have a variety of different sterilizing techniques
5 that are used commonly in the food, pharmaceutical,
6 and nutraceutical industries as well as medical
7 devices. Those kind of - the types of sterilization
8 techniques that exist are things like steam
9 sterilization, dry heat sterilization, gas
10 sterilization such as ethylene oxide, ionizing
11 radiation, x-ray, gamma, et cetera, sterilizing
12 filtration which is basically characterized as a
13 filter sieve that is less than .2 micron which is
14 smaller than the size of a bacterial cell or a yeast
15 cell.

16 Furthermore, they also have a process
17 where multiple terminal, what we call terminal
18 sterilization techniques which are the ones I just
19 talked about are put into a manufacturing process,
20 most commonly things like sterilizing filtration at
21 multiple steps. That process is called unidirectional
22 aseptic processing, and our manufacturing facilities
23 here has followed the definition for FDA CFR 21 and
24 UST definitions for a unidirectional aseptic
25 processing to ensure that the product produced here

1 are indeed safe for patient consumption. Next slide,
2 please.

3 Okay.

4 So this is the purpose of our study.
5 The purpose was to evaluate the potential of a well-
6 designed solvent extraction process to deactivate and
7 remove microbial contaminants from compromised feed
8 material, thereby resulting in extracted products such
9 cannabinoids and terpenes that are free of that - of
10 those microbial contaminants and suitable for
11 consumption by the medical marijuana patients of
12 Pennsylvania.

13 So the goals were to evaluate the
14 efficacy of our system. We are a hybrid laboratory
15 that runs both hydrocarbons and supercritical carbon
16 dioxide, and to determine whether those manufacturing
17 lines could indeed take contaminated plant material
18 and produce sterile extracts that fall within PA -
19 Pennsylvania DOH limits. We also sought to determine
20 what the critical steps were that were important in
21 creating the sterilized extract, and to determine
22 whether our process could indeed provide - create
23 extracting material from contaminated feed material
24 that would confirm to the PA DOH regulations. Next
25 slide, please.

1 So before we got into the study, I
2 just wanted to take you through each of our
3 manufacturing lines. As I said, we're a hybrid
4 laboratory, so we run both carbon dioxide and
5 hydrocarbon extraction here. So we start off with
6 plant material. In the case of carbon dioxide plant
7 material, that plant material is ground and then it
8 goes through the extraction process. That creates a
9 crude full-spectrum extract. Following, we then
10 refine it using processes like winterization and
11 filtration. Winterization occurs in absolute ethanol
12 and at a temperature of negative 40 degrees C.
13 Filtration is a three step process that goes from 40
14 micron to 20 micron to .2 micron. And then we have a
15 clarification stage which uses activated carbon to
16 remove the chlorophyll from the extract. We then go
17 through sterilizing filtration once again, and then we
18 recover our refinement solvent which is absolute
19 ethanol.

20 Following, we then go through a
21 process called decarboxylation which converts the
22 cannabinoids from their acid form which are native to
23 the plants to their neutral form which are not native
24 to the plant, but desired by the consumer. And then
25 we can refine further through cannabinoid

1 distillation, which it essentially separates the
2 terpenes and the cannabinoids from each other which
3 there thereby allowing us to either further refine if
4 we wanted to separate those cannabinoids into
5 individual cannabinoids or utilize that product in an
6 engineered product such as a vaporizing oil, topical,
7 bar or otherwise as many products that we can make
8 from that.

9 And as you note, this little asterisks
10 that are near particular parts of this pipeline. And
11 that is where we tested the material for microbial
12 contamination, cannabinoids, terpenes, et cetera for
13 the study purpose. Next slide, please.

14 So this is our hydrocarbon
15 manufacturing pipeline. In this case, the plant
16 material is used in its native bud form so we do not
17 go through any grinding or anything like that. And we
18 execute the extraction process directly on that
19 material. We then winterize it, the temperature is a
20 bit different in this case. Maybe I should explain
21 winterization because I did forget to define that.

22 The purpose of winterization is to
23 remove fatty acids that were extracted during the
24 process to essentially make it more optically
25 appealing and functional as a raw material in

1 formulation. The difference in winterization in the
2 hydrocarbon pipeline compared to the carbon dioxide
3 pipeline is the temperature. It occurs at negative 80
4 C in the hydrocarbon pipeline.

5 We then go through the same filtration
6 process, we clarify in this particular case due to the
7 nature of the solvent in pharmaceutical grade
8 magnesium silicate. We then go through sterilizing
9 filtration once again, we recover the solvent, and
10 then just to ensure that we are within state and
11 federal limits for the solvent, we purge also the
12 remainder of the solvent. Again, there are asterisks
13 - the asterisks are to show where testing occurred
14 during this process. Next slide, please.

15 Okay.

16 Without boring you all to death by
17 going into our study design ad nauseam, we'll be happy
18 to provide you with a document that is complete write
19 up of this editor at your - at your desire. So as
20 I've already mentioned, we - the plant material is
21 treated slightly differently for carbon dioxide
22 extraction and hydrocarbon extraction so we have to
23 account for that. And as I've said, carbon dioxide
24 extraction requires that the plant material be ground
25 and hydrocarbon extraction can be done with the native

1 bud form.

2 What we did was we identified a couple
3 lots of plant material that did not conform to the
4 regulatory framework, and then combined them to create
5 a batch that was large enough to support two studies
6 with each having five replicates. I kind of already
7 talked about hydrocarbon processing, five replicates
8 again. We also talk about carbon dioxide processing.

9 We also had five replicates, so I'm not going to bore
10 you with any further details on that. As I said, if
11 you would like the document, we'd be happy to provide
12 it to you.

13 This process - this study was designed
14 around a statistical technique called repeated
15 measured analysis. Now I'm not going to bore you and
16 go too deep into that, but the - what that statistical
17 technique is capable of doing is determining the -
18 whether there are statistical differences in the
19 variables measured from one step in a process to the
20 next. So what this allowed us to do is essentially
21 determine where the major sterilization had occurred
22 in the process without have to run individual studies
23 on each process. So it allowed us to bring all of our
24 manufacturing together under one study and determine
25 what phase of that particular process had the biggest

1 impact on the sterilization of the contaminated
2 material.

3 And if you remember back to where all
4 those asterisks were, probably you don't remember, but
5 I'd be happy to again provide you the document. At
6 each sample point, five samples were collected and
7 each one was run in replicates of five to evaluate
8 what the microbial state of the phase was. Next
9 slide, please.

10 Okay.

11 So we're going to hop right into
12 results. First thing I'll tell you is that all of the
13 effort we put into designing a statistically ethical
14 study was all for naught. Done the reason for that is
15 is because at the first stage of extraction in both
16 paradigms, super critical food and hydrocarbon
17 extraction, the plant material was removed during the
18 first phase. I'm sorry, the contaminants were removed
19 during the first phase. So the whole repeated
20 measures analysis, we never had to run it nor could we
21 because if you do not have variation, you cannot run
22 statistics. So basic take-home message here is step
23 one is everything was removed from the contaminated
24 material or killed or wasn't extracted during that
25 process.

1 So if you look at the graphs there up
2 on your screen, there are three of them, total yeast
3 and mold top left, total aerobic bacteria top right,
4 and total anaerobic bacteria at the bottom. And you
5 can see that the parent material which is the plant
6 material was highly contaminated with all three of
7 those different microbial contaminants. Total yeast
8 and mold is so high that it could not be quantified,
9 and therefore I put in a value of one million colony
10 forming units per gram.

11 Now if you follow each graph from left
12 to right from parent material to the right, you'll see
13 that there are different stages in this process, okay?

14 So this is the hydrocarbon extraction here, and the
15 plant material was indeed highly contaminated with all
16 three of these microbial variables. And then
17 immediately following extraction, there is no more
18 microbial contaminants at all. I might also mention
19 that we were tracking the mycotoxins just in case they
20 were transferred from stage to stage. First of all,
21 they were not found in the parent material nor were
22 they found in any subsequent stage of extraction.
23 Next slide, please.

24 Okay.

25 So this is just in numerical format

1 for that same set of graphs. So at the top, top left
2 you'll see the stage. First stage is parent material,
3 second stage is raw extract, and the third stage is
4 the final raw material for hydrocarbon extraction. So
5 these numbers might be interesting for you guys to
6 read about, and I won't get into much about the
7 cannabinoids, terpenes, efficiencies, et cetera. But
8 if you first look at the parent material stage, you'll
9 see that you you'll have the raw numbers for the
10 contaminants that were present in the raw material.
11 And if you then go down to the next subsequent stages,
12 you'll see that in all replicates those microbial
13 contaminants were completely removed and there were no
14 mycotoxins present at all. Next slide, please.

15 So this is carbon dioxide extraction,
16 and you can see that there's more steps involved in
17 carbon dioxide extraction. However, the same patterns
18 still - still shows. The parent material was highly
19 contaminated with aerobic, anaerobic, and yeast and
20 molds. And following extraction, there's no more
21 microbial contaminants nor mycotoxins present. Next
22 slide, please.

23 This is again that numerical format,
24 and I'll just draw your attention to the parent
25 material on the right where we show the microbial

1 contaminants. And you can see that this having
2 contaminated in the plant material and then the four
3 subsequent stages are completely free of microbial
4 contaminants and the mycotoxins. Next slide, please.

5 So we went over that very quickly, but
6 what is - what are the ultimate findings of this?
7 Well we found through this research initiative that
8 the infrastructure that we have here, that we have
9 deployed here at Organic Remedies is capable of
10 producing extracts that comply with - that comply with
11 PA DOH standards. And that the extraction stage was
12 the most important stage of that. Furthermore, we -
13 we found that our, did this also from a manufacturing
14 standpoint showed us that our extraction and
15 refinement processes and the systems involved are well
16 designed and are highly efficacious for the removal of
17 biological contaminants and their metabolites.

18 Again, the critical phase was the
19 extraction step and all of the steps maintained or
20 enhance the capture of biological contaminants and the
21 metabolites.

22 So in - in conclusion, we would
23 suggest that the materials that were created from the
24 contaminated plant material are suitable for use in
25 the production of all of the different formats of

1 therapies that are available in the Pennsylvania
2 medical marijuana market. And next slide.

3 Thank you very much. My email address
4 is there should you have any additional questions, and
5 on top of that I'd like to just recognize Steve Hill
6 as our research partner, the Pennsylvania Candidates
7 Coalition who helped fund part of this project, and
8 Organic Remedies and their Board for participating in
9 funding this project. Thank you.

10 CHAIR: Great. Thank you so much for
11 that presentation. Before we move forward, does
12 anyone have any questions for Mark?

13 MS. ROUSSEL: Hi, this is Christine
14 Roussel. I do have a question. With your research, I
15 appreciate that your initial product was contaminated
16 with three of the categories of microorganisms, but
17 neither - none of your start material was ever
18 contaminated with E. coli or Salmonella. So are you
19 extrapolating your results to show that your
20 extraction process would also inactivate those
21 microorganisms and prevent them from being found in
22 the final product as well?

23 MR. JUNE-WELLS: Unfortunately, that
24 would be something I cannot do because they are indeed
25 different organisms. However, the literature does

1 suggest if you dive into the super critical carbon
2 dioxide sterilization literature, it does suggest that
3 it would work. But we do not have evidence of tha.t

4 MS. ROUSSEL: Thank you for the
5 clarification.

6 CHAIR: Great, thanks. So thanks for
7 that question, Christine. Any other questions from
8 Board members?

9 MS. BRIGGS: I do have a question.
10 This is Diana Briggs. Are other states allowing this
11 remediation? Do you know of any other states?

12 MR. JUNE-WELLS: In most states,
13 extraction is considered a pathway for utilization of
14 contaminated products because of the background
15 research that has been done in terms of these
16 extraction techniques, extraction solvents. I don't
17 want to say this has been done for cannabis. We may
18 be the first, I don't know that for sure. But I was
19 unable to find during my literature search many papers
20 associated with cannabis and sterilization at all.
21 And so, in other states I believe they're leaning on
22 the research out there in regards to hydrocarbon
23 sterilization and super critical carbon dioxide
24 sterilization paradigms and allowing for this type of
25 process to be used to capitalize on contaminated

1 material.

2 MS. BRIGGS: Thank you.

3 CHAIR: Great, thank you. Other Board
4 members, any other questions? Okay, great.

5 Well thank you so much for that
6 presentation. Really appreciate you coming to join us
7 today.

8 MR. JUNE-WELLS: Not a problem at all.
9 Thank you so much for having us.

10 CHAIR: Great. So I believe the
11 Medical Research Subcommittee then will consider the
12 presentation and we will get a report back from them
13 at our next Board meeting on their findings based on
14 this presentation. So thank you very much. And since
15 we have no more questions on this presentation, are
16 there any other topics that any Board members would
17 like to address at this time?

18 MS. BYRNES: This Carolyn. Can you
19 hear me?

20 CHAIR: We can hear you, Carolyn.

21 MS. BYRNES: Okay, great. I just
22 wanted to let everybody know that I'll be following up
23 with program staff regarding when the guidance
24 documents will be ready for the research, to approve
25 research conditions. Again once those are completed,

1 the Board will then be able to begin accepting and
2 reviewing applications for conditions for research.
3 So I'll have an update at the next meeting.

4 CHAIR: Great. Thank you for that,
5 Carolyn. Are there any other topics or any questions
6 from any Board members?

7 Well I do want to announce that the
8 next Board meeting is scheduled for September 22nd,
9 2022 from 10:00 to noon, and we are scheduled for some
10 virtual Board meeting as before. Anything else before
11 I ask for a motion for adjournment?

12 Well again, welcome to all our new
13 Board members, looking forward to working with all of
14 you. And at this time then since we have no other
15 comments or questions, may I have a motion for
16 adjournment?

17 ATTORNEY ADAMS: I'll make a motion.

18 CHAIR: Thank you, District Attorney
19 Adams.

20 MR. KAMBIC: Second, Kambic.

21 CHAIR: And Dr. Kambic, great. Good.
22 So all in favor of adjournment?

23 (AYES RESPOND.)

24 CHAIR: Any opposed?

25 (NO RESPONSE.)

1 CHAIR: All right.

2 Well thank you all. Again, always
3 appreciate your participation and attendance. I hope
4 you have a great rest of your week, thank you very
5 much.

6 * * * * *

7 MEETING CONCLUDED AT 11:20 A.M.

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I hereby certify, as the stenographic reporter, that the foregoing proceedings were taken stenographically by me, and thereafter reduced to typewriting by me or under my direction; and that this transcript is a true and accurate record to the best of my ability.

Dated the 1 day of September, 2022



Hannah Bartkowski,
Court Reporter