Mental Illness Psychotherapy Drug Task Force

October 18th, 2022
5:00 - 6:30 Pm
Multi-Agency State Office Building 1019 A/B

Zoom link:

https://utah-gov.zoom.us/j/88314834969?pwd=UTlKeDg4M1lUYmxvd24wb0svQlZZQT09

Co-chairs:

Mark Rapaport, MD

Chief Executive Officer, Huntsman Mental Health Institute

Michelle Hofmann, MD, MPH, MHCDS

Executive Medical Director, Utah Department of Health and Human Services

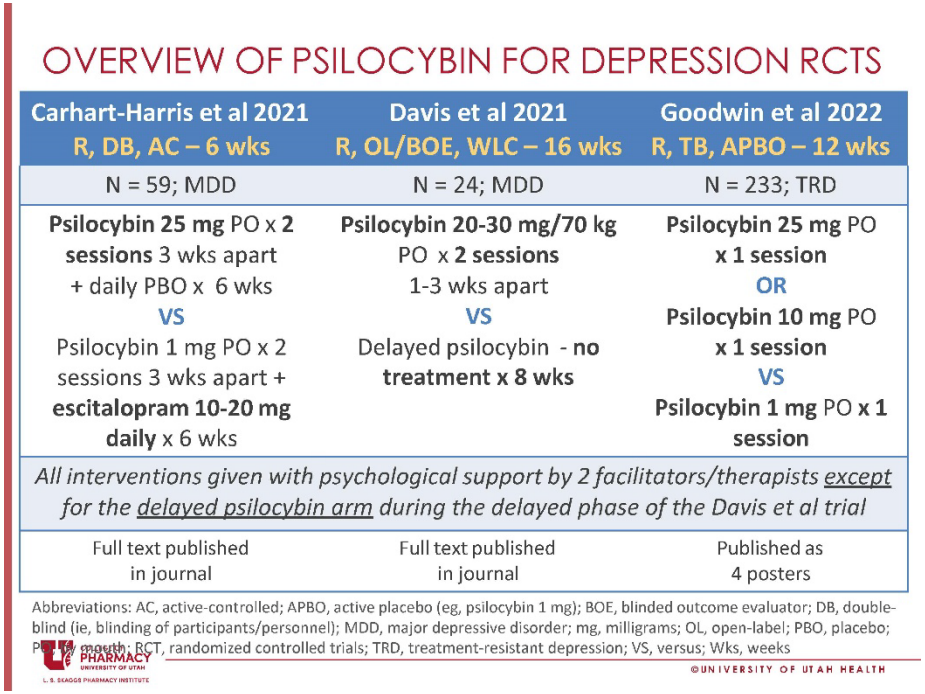
(Executive Director's Designee)

AGENDA ITEM	DISCUSSION	COMMENTS/ACTIONS / RECOMMENDATIONS
Welcome & Roll Call	Dr. Hofmann welcomed the group. Dr. Lewis motioned to approve the minutes and Dr. Rapaport seconded, the minutes were approved unanimously. No names and no extensions.	

Phase 2 Evidence Review and Updates **Presenter: Dr. Lauren Heath**	**Slide 1- Evidence Review: Psilocybin-Assisted Therapy for Depression Trials**  	**Dr. Mark Rapaport**: Lauren, if I remember right in your conclusions, you discussed the fact that the only data we have in terms of longer-term effects is sort of the small sample from the Davis trial which was, and was sort of done in Not quasi systematic way. So right now we don't have long term efficacy or safety data or information about sustained to fact. Is that correct? **Dr. Lauren Heath:** At the three trials the longest follow up with the good one, they measured a sustained effect through twelve weeks, but other than that the Davis date published a twelve month follow up on the entire cohort that received psilocybin. But it's very descriptive, and yes, other than that, we don't have additional information. **Dr. Michelle Hofmann:** I was struck by the more severe adverse events; it doesn't start out suicidal but becomes suicidal. **Dr. Benjamin Lewis:** I agree with you, Michelle. I think that's a really striking aspect of the compass phase to be results where the rates of serious adverse events predominantly suicidality and the non-responders. I would say among that population of people with treatment resistant depression, rates of suicide ideation and suicide attempts are unfortunately fairly high. But I do think that's a significant result from that study. **Dr. Mark Rapaport:**

Slide 2- Overview of Psilocybin for Depression RCTS

An overview of the three trials that were included in the evidence review, the Carhart-Harris et al and Davis et al, are in the first two columns were relatively small, enrolling twenty-four to fifty-nine participants, with major depressive disorder abbreviated MDD. The third trial and largest trial by Goodwin et al, enrolled two hundred and thirty-three participants with treatment, resistant major depression, or TRD and blinded participants, personnel, and outcome evaluators.



OVERVIEW OF PSILOCYBIN FOR DEPRESSION RCTS

Carhart-Harris et al 2021 R, DB, AC – 6 wks	Davis et al 2021 R, OL/BOE, WLC – 16 wks	Goodwin et al 2022 R, TB, APBO – 12 wks
N = 59; MDD	N = 24; MDD	N = 233; TRD
Psilocybin 25 mg PO x **2 sessions** 3 wks apart + daily PBO x 6 wks **VS** Psilocybin 1 mg PO x 2 sessions 3 wks apart + **escitalopram 10-20 mg daily** x 6 wks	**Psilocybin 20-30 mg/70 kg** PO x **2 sessions** 1-3 wks apart **VS** Delayed psilocybin - **no treatment x 8 wks**	**Psilocybin 25 mg** PO **x 1 session** **OR** **Psilocybin 10 mg** PO **x 1 session** **VS** **Psilocybin 1 mg** PO **x 1 session**
All interventions given with psychological support by 2 facilitators/therapists except for the delayed psilocybin arm during the delayed phase of the Davis et al trial		
Full text published in journal	Full text published in journal	Published as 4 posters

Abbreviations: AC, active-controlled; APBO, active placebo (eg, psilocybin 1 mg); BOE, blinded outcome evaluator; DB, double-blind (ie, blinding of participants/personnel); MDD, major depressive disorder; mg, milligrams; OL, open-label; PBO, placebo; PO, by mouth; RCT, randomized controlled trials; TRD, treatment-resistant depression; VS, versus; Wks, weeks

And actually that leads to a real question. So in those six cases you described, were those actually SAE's that were reported?

Dr. Lauren Heath:

Are you saying, the six participants?

Dr. Mark Rapaport:

Yeah, those six participants that hospitalization by definition, would be an SAE. So I'm just wondering whether those six instances were reported as SAE's?

Dr. Lauren Heath:

So I'm not certain of the sex events you're referring to.

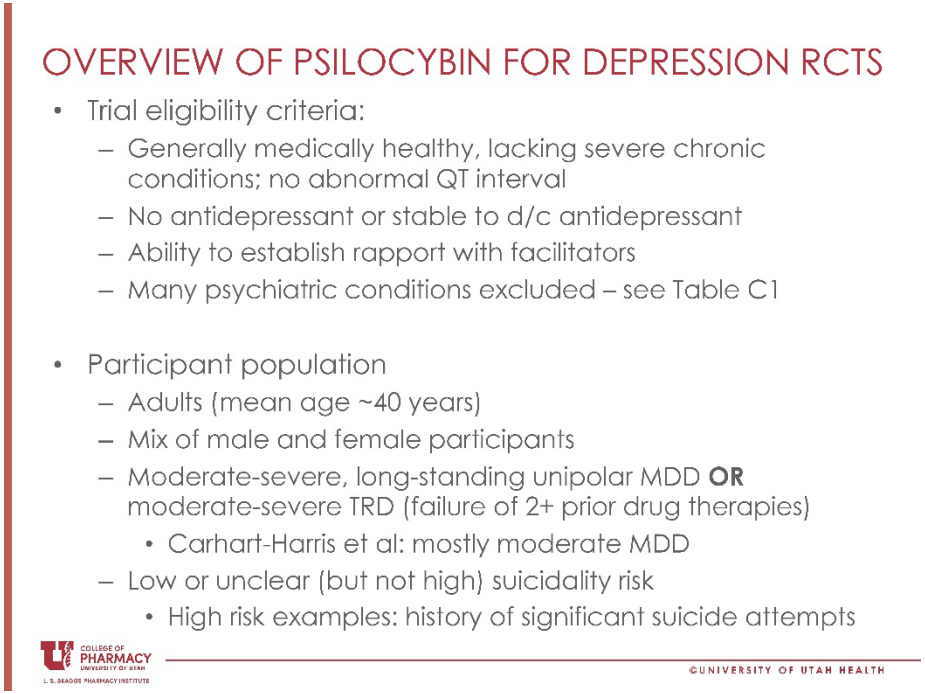
Dr. Mark Rapaport:

On one of your slides you had, I think 6 events, I think six events.

Dr. Lauren Heath:

The details we have about this trial are only in the poster format so we're somewhat inferring some information. This is the incidence in terms of just the overall incidence participants. There were five, and the twenty-five milligram are six, and the ten milligrams versus one in the one milligram arm. But if you look at the report their breakdown of the actual types of events in terms of two different follow up periods like through three weeks, and then from three weeks to twelve weeks. If you look in the appendix of the report, you'll see a table with the breakdown of that. But the majority of those events tended to be events of suicidal ideation, suicidal behavior, self injury. I don't know what combination of all of those events could have been the same person,

Slide 3- Trial Criteria



because there's more adverse events reported than the number of people that had events during the whole follow up, does that makes sense.

Dr. Mark Rapaport:

So we don't really know that there were five individuals in the twenty-five milligrams psilocybin group and we know that these specific events were recorded, but we don't know whether they were five individuals that we're talking about, that were suicidal or required hospitalization, or one individual with more than one of those correct?

Dr. Lauren Heath:

Those five individuals, all had some sort of serious events. If I look at the I'd have to look at the data to see which events were reported. I just they report the type of the event like not per participant through the whole follow up period. So those five individuals may have had more than one of those suicidal events. I guess I'm saying is that those by definition would be serious adverse events through the whole follow up.

Dr. Mark Rapaport:

I guess I'm saying is that those by definition would be serious adverse events ok that's what I was trying to get at. So we're not just looking at the presence of adverse events but were looking at SA's.

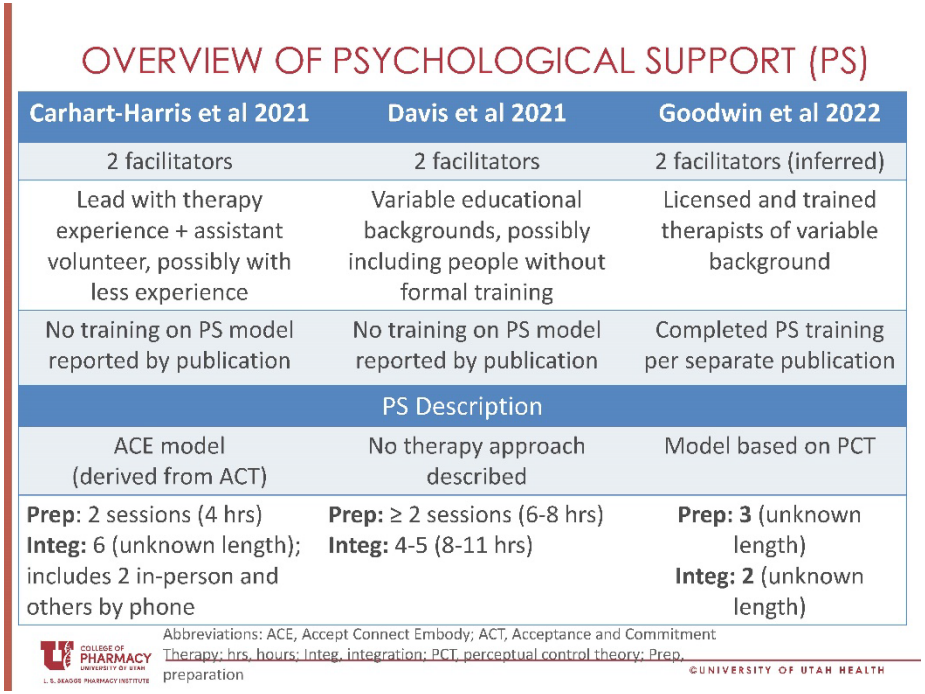
Dr. Lauren Heath:

Exactly, yes.

Dr. Mark Rapaport:

Slide 4- Training of facilitators

Generally, all three models describe the psychological support as being inner-directed and supportive in nature with incorporation of preparation and integration components both Carhart- Harris et al and Goodwin et al base their psychological support approach on a previously established therapy model that I note on the slide. Number of preparation and integration sessions variable across the trial, as shown in the bottom row of this table.



OVERVIEW OF PSYCHOLOGICAL SUPPORT (PS)

Carhart-Harris et al 2021	Davis et al 2021	Goodwin et al 2022
2 facilitators	2 facilitators	2 facilitators (inferred)
Lead with therapy experience + assistant volunteer, possibly with less experience	Variable educational backgrounds, possibly including people without formal training	Licensed and trained therapists of variable background
No training on PS model reported by publication	No training on PS model reported by publication	Completed PS training per separate publication
PS Description		
ACE model (derived from ACT)	No therapy approach described	Model based on PCT
Prep: 2 sessions (4 hrs) **Integ:** 6 (unknown length); includes 2 in-person and others by phone	**Prep:** ≥ 2 sessions (6-8 hrs) **Integ:** 4-5 (8-11 hrs)	**Prep: 3** (unknown length) **Integ: 2** (unknown length)

Abbreviations: ACE, Accept Connect Embody; ACT, Acceptance and Commitment Therapy; hrs, hours; Integ, integration; PCT, perceptual control theory; Prep, preparation

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And then there we're using an FDA or an EMA definition of what is considered a serious adverse event.

Dr. Lauren Heath:

They don't define how they to find it on the poster, I would guess that they probably use that definition.

Dr. Michelle Hofmann:

Other comments or questions related to the psilocybin review?

Bill Stilling:

So that was in the Goodwin study is that right? Cause I was just trying to look at the appendix, and it looks like there were two suicidal ideations in the control. Maybe I'm just reading the data wrong. I'm just trying to understand that myself, not being a clinician. But I mean that's an important thing and it needs to be teased out in terms of not jumping to some conclusion based on summary research but that I was just trying to figure it out in my own mind. Is that right that there were two patients with suicidal ideation three weeks afterwards in the control? It takes too much looking that's fine. I just wanted to raise my own confusion. I was looking on forty-eight of your report that came through today

Dr. Lauren Heath:

So were talking about the serious adverse events, so that in table D one it starts on page forty-four and that we are talking about the Goodwin et al trial. So if you scroll to kind of the bottom page forty four top of page forty-five, you'll see the description of the types of serious adverse events and they broke down the

	Slide 5- Efficacy Efficacy and the Carhart-Harris et al trial there was not a significant difference between two sessions of five and assisted therapy and daily escitalopram for change in depression symptoms six weeks from baseline. Secondary outcomes, including changes in depression symptoms using other depression scales tended to favor psilocybin assisted therapy but these comparisons were not adjusted for multiple comparisons providing formal statistical conclusions. In the Davis et al trial immediate psilocybin assisted therapy was significantly better than no treatment for reducing depression symptoms at one and four weeks after the 2nd psilocybin dose. At the Goodwin et al trial one session of high dose psilocybin 25 milligram but not the moderate 10 milligram dose was superior to low dose psilocybin 1 milligram three weeks after the last psilocybin dose. The bottom row shows the proportion of participants meeting criteria for remission of depression, symptoms or depression response defined as at least a fifty percent reduction in symptoms at the same time point as the primary outcome measure. For both the Carhart-Harris et al and Goodwin et al trials descriptively a greater proportion of participants that received high dose psilocybin achieved remission or a significant reduction in symptoms. However, for the Carhart-Harris et al trial that reported a statistical comparison only depression, remission significantly favored psilocybin over the comparator escitalopram.	nature of those serious adverse events to two reporting periods through three weeks, and then from three to twelve weeks, you'll have to look at both parts to see the nature of the study.

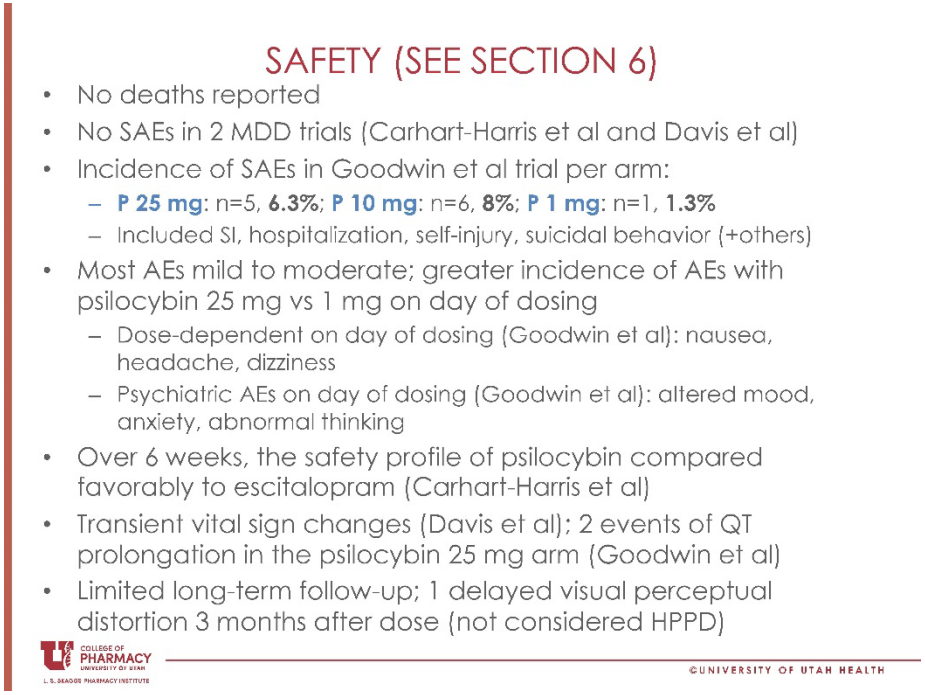
EFFICACY (SEE TABLE 2 OF REPORT)

Carhart-Harris et al 2021	Davis et al 2021	Goodwin et al 2022
Primary: Change in QIDS-SR-16 at week 6	*Primary:* Change in GRID-HAMD scores 1 & 4 weeks post 2nd psilocybin dose	*Primary:* Change in MADRS score 3 weeks post psilocybin dose
• No significant difference between psilocybin and escitalopram	• Immediate psilocybin significantly > no treatment at 1 & 4 wks with large effect size	• Psilocybin 25 mg significantly > 1 mg • No significant BGD (Psilo 10 mg vs 1 mg)
Depression Remission		
P: 57%; **E**: 28% (QIDS-SR-16) *Uncorrected* significant BGD	Between-group NR	**P 25:** 29.1%; **P1:** 7.6% (MADRS)
Depression Response (ie, ≥ 50% reduction in symptoms)		
P: 70%; **E**: 48% (QIDS-SR-16) No significant BGD, *uncorrected*	Between-group NR	**P 25:** 36.7%; **P1:** 17.7% (MADRS)

Abbreviations: BGD, between-group difference; E, escitalopram; GRID-HAMD, GRID Hamilton Depression Rating Scale; MADRS, Montgomery and Asberg Depression Rating Scale; NR, not reported; P, psilocybin; QIDS-SR, quick-inventory of depressive symptomatology-self-rated; wks, weeks

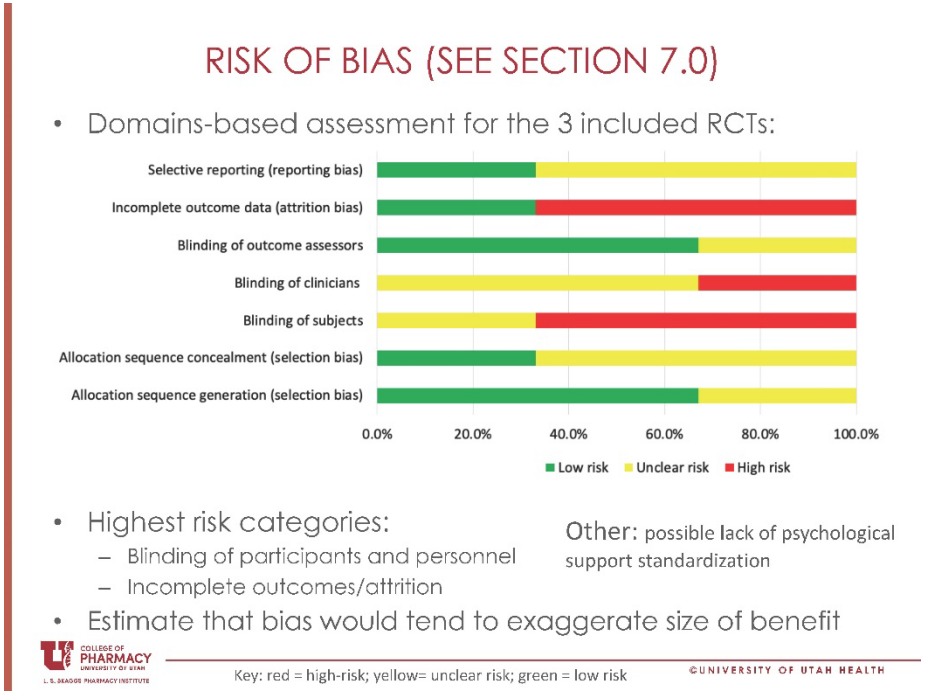
	Slide 6- Safety Briefly regarding safety no deaths were reported during the trial and no serious adverse events occurred during the Carhart-Harris et al trials. However, a numerically greater incidence of serious adverse events occurred in the moderate and high dose psilocybin versus low dose psilocybin arm and the Goodwin et al trial among people with treatment resistant depression. According to the limited reported information, it appears that these events primarily included instances of suicidal ideation, hospitalization, self-injury, and suicidal behavior. The investigators mentioned that three participants in the twenty-five-milligram arm with serious suicidal behavior, were considered non responders to the treatment. Goodwin et al describe that most events were mild to moderate and severity; and on the day of dosing a greater incidence of any adverse event occurred in the higher twenty-five milligram arm compared to the psilocybin one milligram arm in both the Carhart-Harris et al and Goodwin et al trials. Headache and nausea were the most frequent adverse events on the day of dosing after the day of dosing over six weeks the safety profile psilocybin been generally compared favorably to escitalopram. Davis et al described a few instances of transient increases in blood pressure and heart rate on the day of psilocybin dosing that did not require medical intervention and Goodwin et al reported two instances of Qt interval prolongation in the twenty-five milligrams psilocybin an arm detected on the day after dosing resolved within seven days after detection. Twelve months descriptive follow up was reported for the Davis et al trial only. They described that one participant experience a visual perceptual distortion event three months after the last psilocybin dose that they thought could have been psilocybin related. However, this event did not be criteria for hallucinogen persisting perception, disorder. We assess the risk of bias among the trials using a domains-based approach to assess major bias threats for randomized controlled trials. Refer to section seven as a report for details. This figure summarizes the proportion of the three trials with potential bias arising from each	

assessed factor. Red corresponds to high risk, yellow to unclear risk and green to low risk. Categories with the highest risk ratings with blinding of participants in personnel and nutrition bias from incomplete outcome data. An additional concern was a possibility of a lack of a psychological support standardization which introduces the possibility of variability in the delivery of the intervention. The lack of blinding or unblinding of participants. Nutrition bias tend to lead to exaggerated benefits that would favor psilocybin assisted therapy.



Slide 7- Risk of Bias

This figure summarizes the proportion of the three trials with potential bias arising from each assessed factor. Red corresponds to high risk, yellow to unclear risk and green to low risk. Categories with the highest risk ratings with blinding of participants in personnel and nutrition bias from incomplete outcome data. An additional concern was a possibility of a lack of a psychological support standardization which introduces the possibility of variability in the delivery of the intervention. The lack of blinding or unblinding of participants. Nutrition bias tend to lead to exaggerated benefits that would favor psilocybin assisted therapy.



End of presentation

Report Review / Discussion Of the Execute Summary **Dr. Mark Rapaport**	The first paragraph we talked about the fact that we were constituted because of legislation and then what our purpose was, which was to make recommendations on any psychotherapy drugs that the task force determined might enhance psychotherapy when treating a mental illness. We discussed who was involved. This describes the fact that because of the real interest in psychedelics we focused on that rather than on other compounds that have been used in terms of adjuvants for psychotherapy. We focused our work on MDMA and psilocybin, because that's on where the preponderance of literature was today. We talked a little bit about the results of the of the of the Literature Review and what we had determined about MDMA. It's used in PTSD and then psilocybin, its used in mood disorders in particular due to resistant depression, its also been used for symptoms of anxiety, depression and people towards end of life. We mentioned the fact that because of our initial review, we didn't believe there was enough literature, and enough data to really make any statements about LSD or Ayahuasca or ibogaine. We also made some recommendations based on what we had been asked to do in the task force and then we pointed out the differences between cannabis and what's going on with psilocybin and MDMA in the case of psilocybin and MDMA, they're both being fast tracked for new drug approval. There's FDA advisory committees available and will be evaluating the data from these trials. The FDA will be coming up with regulations regarding manufacturing standards, administration, storage, and safety standards for these compounds. And that we thought that the costs associated with them implementing psychedelic assisted psychotherapy ahead of the FDA approval might is going to be quite large and we needed to recognize and contract distinction to cannabis where there are no studies going on towards FDA approval there are in this case. Then the final paragraph describes the most rigorous and cost-effective approach to ensuring that the people of Utah have access to psychedelic assistance therapy, would be to wait for the fast track to FDA rulings on MDMA and Psilocybin and that FDA approval of the current NDA applications will introduce a needed financing mechanism through government and	

	commercial payers, which will again increase the access of care and equity associated with it. If the Legislature decides not to take this wait and pursues a course of action making these substances available to people of Utah more early than extensive manufacturing safety regulatory guidelines out line in this report below is going to be required, and there's going to need to be as a prerequisite. We think a fiscal analysis the one time and ongoing costs of such a program for the taxpayers of the people of Utah. So that's essentially what the summary says.	
Report Review / Discussion Introduction through Appendix A **Presenter:** **Dr. Michelle Hofmann**		**Dr. Michelle Hofmann:** I did dive into each of the specific things in statute, I thought this highlighted one could be addressed here. Whether they want to recommend any additional investigation to research needs is a part of the work, that we didn't cover. So I'm leaving this here as a placeholder so that we can. Any discussion, comments, thoughts or points of contention? With what Dr. Rapaport addressed in the executive summary? **Bill Stilling:** I had a few comments as I read through it. One is in the beginning when you talked about the fact that these certain other drugs weren't going to be considered. I thought it might be helpful and I actually sent Peter draft because I wasn't sure how to do this Google document thing. But the Legislature defines the psychedelic drugs, I'm sorry psychotherapy drugs to only include controlled substances and so I think, by

		legislative mandate we could only have considered controlled substances. So you know, I'm just stuck in a thing at the beginning, where it just says, that the purpose of it is to provide evidence-based recommendations on any, and then quoted the legislative language about controlled substances, which I think allows you to take out the information about cycloserine because those are not controlled substances. So I just thought it would shortcut that, and then create a definition upfront about what it is we're looking at. **Dr. Mark Rapaport:** I'm fine with that. This was a rough draft. I'm more than willing to accept comments. This is a rough draft. **Dr. Brent Kious:** I just wanted to ask a question about how we should understand the scope of potential recommendations regarding additional investigation and research. We could conjure up several billion dollar's worth of research and ask the Legislature to fund it. I'm guessing that's not what they have in mind. So how should we constrain those recommendations? **Dr. Michelle Hofmann:** I would say it's based on what we've done so far. If there's anything else like our recommendation is to delay until FDA authorization that's our first recommendation, and then everything else in this report quite different for implementation. If the Legislature decides to proceed in advance of an FDA authorization so I would say, you

		probably want to frame anything else we do on that if they choose that second option, what would we absolutely need to investigate. **Jeremy Christensen:** The thought that I had about making a strong recommendation just to delay until the FDA approves is that we just don't know if that's going to happen or not, I mean all the signs indicate that that's headed that way. But if it's not, should we be recommending to, you know, Just wait and see, or should we just put it more as a soft option both ways that if it were to get passed by the FDA then yeah, it would be a much more efficient cost, effective way. But there could be unforeseen delays in that. And do we want to give this strong recommendation as strong of a recommendation to set this aside. **Dr. Mark Rapaport:** Well, since we don't have the safety and efficacy and the long term safety data, I'd be reticent without long-term safety data without long-term efficacy data to feel comfortable. Both exposing citizens of Utah to things that we just aren't proven yet. I have real concerns about that as a physician. **Dr. Michelle Hofmann:** Lauren, can you? I know you couldn't find it in this really long document, you had a anticipated timeline on the MDMA at least a projected timeline. **Dr. Lauren Heath:** Yes, you know, from what I could read. This is from just kind of news sources,

		and maybe an announcement from the Biden administration that they project around May twenty, twenty-four, the MDMA could be approved. But that's just speculation based on where it is so far. **Dr. Michelle Hofmann:** To address your concern Jeremy, we should recommend a reevaluation time to see what the progress has been to reconsider whether enough has been learned to proceed outside of the FDA authorization. **Dr. Brent Kious:** I wonder how we should anticipate the way the FDA approval will affect the possibility of off label prescribing if, its like most FDA approvals. Then, once its FDA approved, we prescribe it off label however we'd like but it wouldn't surprise me if things didn't go exactly that way. Maybe they would use a different mechanism the FDA has been doing some rather innovative let's just say innovative things lately and so I wonder whether it would pay to include a suggestion that we would want to make space for off-label prescribing or compassionate use irrespective of what the FDA might recommend. In keeping with Dr. Rapaport's suggestion with which I agree that we really want a lot of safety data. I think, in palliative care indications, I'm not as concerned about safety. I just want to do what's beneficial to patients in terms of alleviating their suffering. **Bill Stilling:**

		One comment about that I don't disagree with the concept, but once we've got these controlled substances that are schedule one, which means by definition we have no medical use. Once they become approved for medical use it seems a little speculative to say, Well what would the FDA say? What would we do? It seems like it's going to be a couple of years out, and maybe a discussion for another day. I think it's an appropriate point, but it seems a little bit beyond what we're charged with because we're looking at these other kind of control substances just don't have any medical use, and therefore no indicated uses. **Dr. Brent Kious:** I agree it's very speculative, but I've come to not trust what the FDA does lately. **Dr. Michelle Hofmann:** We do have some pretty good recommendations around compassionate use that are well developed by you and others in our work group and so its not that we're being silent on the matter. **Dr. Benjamin Lewis:** I agree with what you've outlined Dr. Rapport and kind of resonate with some of these prior comments surrounding some uncertainties with FDA approval and the timeline, and how vulnerable that is to the political milieu that we live in, and also recognizing that not all indications, and I think in particular with MDMA awaiting FDA approval makes very clear sense here. Not all indications

		with psilocybin do I see as being equal in terms of long-term data on safety and efficacy. For instance, with existential distress associated with end of life we do have some data out to three years at this point, and that's a group for whom we otherwise have oftentimes little to offer and you so having avenues to re-evaluate that FDA timeline in particular related to palliative care and compassionate use does make good sense to me. **Dr. Mark Rapaport:** But also realize that the FDA also allows compassionate use. The one can do that with the FDA in fact, that's what that's actually the back door that allowed clozapine into the United States because enough psychiatrists we're using clozapine and demonstrating results based on compassionate. So there is a mechanism available through the FDA for compassionate use as well. **Dr. Michelle Hofmann:** I think that ones in the parking lot right now compassionate use we actually use after FSA authorization and the introduction. The executive director, who did have a comment related to the language that we're using, its sophisticated a lay audience wouldn't understand it. And that we might add a footnote perhaps to describe these substances and their recreational counter parts that might be more familiar in terms of things. Do others have thoughts on that?

		Dr. Benjamin Lewis: I think that can get a little complicated because the reference of those terms can be a little bit unclear. For instance, what ecstasy refers to can be somewhat variable, and you know, I think, including things like, magic mushrooms can invoke a lot of connotations that are unhelpful in general for folks. I don't see a solid rationale to include street names for the various drugs. **Dr. Elizabeth Howell:** I would say that street names change a lot. **Dr. Michelle Hoffman:** I feel like to anchor in the medical all as much as we can, think she was just proposing as a potential, but for people who might get overwhelmed by all the terminology. We added a kind of overarching, summary paragraph that I pull from the executive summary before we move into the different areas of the different steps that Dr. Heath did with the literature review. Starting with the clinical trials research moving into the annotated bibliography, also available in the appendix and then we took your highest level summaries Lauren and put them in here for each of the MDMA for PTSD and Psilocybin for depression. I just copied verbatim from the report the potential material for this report. Anything on the Evidence review and how its coming together in this document? **Dr. Mark Rapaport:**

		I think its good. **Dr. Michelle Hofmann:** Next we move into each of the work groups as I was taking the material that you populated, I had to make some decisions around trying not to be repetitive and having that each of the work groups activities be complementary. One of the other recommendations was that we anchor again to the things in intent language. And so we've added that at the beginning of each of these sections. **Dr. Brent Kious:** Oh, I guess my question was how we should evaluate things like stable and safe housing and stable and secure interpersonal relationships is eventually exclusionary factors. If one were to provide psychedelic, assisted therapy it seems to me that somebody who was lacking in secure interpersonal relationships might ultimately be because of severe existential distress and severe, depressive symptoms. Good candidate for psychedelic assisted therapy and so I would be loath to exclude them so I just wanted a bit of clarification about that. **Dr. Benjamin Lewis:** I can chime in there, Brent. And thanks for that that question. I added this just in the last couple of days, really getting at the idea that it's very easy to administer these drugs to people who would walk in the door per se, and I think potentially do a lot of harm. So if somebody takes MDMA and takes a highly an agent that

		induces significant neuroplasticity, and then returns to say, an abusive environment, a returns to an environment where they're homeless, living on the street, you could be amplifying and adding to trauma there in a way that would be, I think, frankly harmful. And so I think it probably makes sense to reword some of this, but I I think that that should be. I guess what I was trying to get at there is that that should be part of the evaluation in terms of administering a psychotherapy drug. Does somebody have a place? They're going to be returning to that safe right? And if not, they probably shouldn't be taking or shouldn't be administered. You know one of these agents? Are they living in an abusive household? I think that there are good theoretical reasons to think you could be compounding harm there by administering a substance like this? I think it there is a good question like, how are we to evaluate and quantify that. Maybe there could be more general language around just evaluating those contextual factors prior to administration. **Dr. Brent Kious:** But that seems reasonable to me, Ben especially articulating in the way you did, the ways that unstable environments could actually exacerbate symptoms. If someone were exposed to MDMA or Psilocybin. **Dr. Michelle Hofmann:** Unstable environments made treatment of individuals in unstable environment. **Dr. Mark Rapaport:**

		I changed the wording, I'm initially it's the wording included that indicated that the psychotherapy should be non-directive and supportive. And we do not know if that is the only form of psychotherapy that would be useful or not. I didn't want it codified that the psychotherapy associated with these treatments would have to be non-directive and supportive only as we're learning with what's being done with Ketamine and other substances. There may be times that other evidence-based psychotherapies are very useful and effective. So I just said psychotherapy processes should be conducted should be conducted in person and by train individuals. And didn't focus it only on it, being nondirective and supportive. That's why I took out that phrase. Another concern here is, although it is addressed later in the document when we talk about advanced preparation there we don't talk about any number of therapies. We're not saying you know somebody could say "Well, I'm sure I have a great rapport with this person". There's nothing saying that there are as in the case with MAPS program and other programs a number of sessions prior to somebody being administered the compound that was my concern and I'm not sure about the best way of handling that. But I would just want somebody to be seen at least once prior to being administrated the compound. **Dr. Benjamin Lewis:**

		I thought that was an important recommendation, and what I did, Dr. Rapaport was to change some of the language here, to say at least one preparation, and then some of the language a little bit above that emphasizes preparation. But I think that's important to specify explicitly like you suggested. **Dr. Michelle Hofmann:** This was a section; I'm wondering about using this model in some of the other areas where we become a little bit more clear. Execute director of were we added this proceeding in the absence of that day of FDA approval, I wonder if you just wanted to be a bit more systematic about saying something about doing this direction then these are the things we recommend and just calling it out more clearly. And we took a stab at doing it in this section, and we may want to be about that so the other sections as well. But for here this is very specific protocols that have been studied, and if you were to move ahead, we would want to align with what's been studied in terms of the protocol. **Dr. Mark Rapaport:** The thing I would remind folks is that the FDA will not be able to comment about the psychotherapy aspects of this. They will talk about the safety they will talk about the compounds itself, the manufacturing but it is not within their purview to discuss any sort of vetting or training or adherence to psychotherapy its not in their mandate.

		Dr. Michelle Hofmann: Is there a place you would want to reference that? **Dr. Mark Rapaport:** Well, it's just that we can't in the absence of authorization for specific drugs and psychotherapeutic modalities. They cannot, they will not do an authorization of any type around a psychotherapeutic modality. **Dr. Michelle Hofmann:** So we can just strike that for the use of specific drugs to enhance psychotherapy. Moving forward, for licenses and training needs I think there is this first question posed by Executive Director Gruber about our choice to have this board live within DHHS? I think it was a natural decision just based on our experience with cannabis if we don't proceed ahead of the FDA is that the right place for it or does it belong so where else in the state government, DOPL or somewhere else? **Bill Stilling:** You have the cannabis model. This is not just this is not simply a licensing matter that the statute, or, if it's passed, would address health in general, and so DOPL Enforcement will have to be part of it. But again, once you get into these schedule one controlled substances, it's best to leave DOPL out of it, unless the broader act is violent, and you can set up all the other stuff Department of Health and Human services and you need to address the licensing acts under title fifty-eight in terms of exceptions and things like that but DOPL would not be a good fit for this

		overall, so that this is one place where I think the cannabis act is a good model. **Dr. Michelle Hofmann:** Bill, would you mind adding a sentence or two in here that addresses that because I know the question is going to come. We've been dealing with it on the side and strenuously to retain the program in the health model. **Bill Stilling:** I can do that; I can submit a draft to Peter. I can just mend that, and I think he was going to add some of my edits but I'm not sure DOPL wants to have this. **Dr. Michelle Hofmann:** Next topic I think its from you Dr. Rapaport. **Dr. Mark Rapaport:** You know these are currently potentially complex compounds to use and I personally I'm not sure that I think I would be comfortable with this being prescribed and administered by non-physicians at this time and so I would be reticent to have physicians' assistance, and nurse practitioners have this within their school practice. I don't think you should have to be certified to recommend that a patient who would benefit from psychedelic assistance therapy. **Jeremy Christensen:** So just reflecting back on why we use those words in the first place it came up since these are not you know these are schedule one drugs that we couldn't say prescribe, and so I'm not attached to any of the words here whatever would make it clear that this would be provided by a

		doctor, whether we use recommended minister prescribed. **Dr. Michelle Hofmann:** I think that's another place where distinguishing whether we're proceeding with FDA authorization, where we can prescribe or our proceeding ahead of it where we can't and maybe just use some clarifying language that these are schedule one controlled substances which precludes us from prescribing in any model or we would move ahead. **Bill Stilling:** I could include a note somewhere in there, and it just something to the effect that uh, in terms of terminology, because I've done it in other places, I could just put terminology like that. Make it clear recommend means its kind of like because of the schedule one issue. So, people that are lay readers can understand that that's what we're talking about not just off the cuff you should do this is actually giving authority for someone. **Dr. Mark Rapaport:** Just as long as its also clear that you know a clinician who's treating a patient as treated to patient for a long time, and may not have gone through the certification process, could certainly discuss and recommend that patient be referred to somebody that could do it. That was where I was concerned about recommend. **Dr. Michelle Hofmann:** So we've got to word smith this area a little bit, that is the term adopted in the

		cannabis world. That the provider makes a recommendation, they don't prescribe, I can see why your concern is there. We'll think about that a little bit. Other discussion? Scroll down. **Dr. Brent Kious:** Michelle, I think this was a grammatical comment. Paraprofessionals should be considered by the PDB. But considered for what, presumably for being recipients of the authority to participate in psychedelic assistant psychotherapy. But it doesn't say. **Dr. Michelle Hofmann:** Then that's what you describe is there right, that potential support is should be considered as potential support personnel. **Dr. Brent Kious:** Yes **Bill Stilling:** One general comment: both this section and the regulation and ethics section is, there's often reference to the Utah code, annotated statutes, rules and such, I've cleaned some of that up but we have to very precise about that. And I'm not sure that the even if you have a PDB, whether it could promulgate regulations as opposed to the department. That's just something I just want to get that said that's something, I guess, like I've tried to fix it, it's not anybody's fault so much as it's just the way we talk about things until you get to talk to a lawyer, and they're very weird about rules and statutes. **Dr. Michelle Hofmann:**

		Any guidance you can add, we'll absorb all that and get an included bill. I appreciate that many of these are an advisory capacity to the department who gets the final say. So you're correct. Anything else in the last section of patient safety? Okay, we're some of the reframing to bring in the statutory language around the things that this work group addressed in an effort to not be implicative of what the subscribing section we left that material in that area, even though that would have ordinarily just limited this section to the other things on a package insert. **Dr. Brent Kious:** Michelle, I would still argue that the DEA's scheduling decisions may not bear any relationship to the potential for abuse of any substance. **Dr. Michelle Hofmann:** Should this say acetaldehyde dehydrogenase inhibitors? **Dr. Jennifer Strohecker:** Yes, I can verify this comment. Sorry I didn't clean that out. I'll let me verify that for the interaction. **Dr. Michelle Hofmann:** If the legislature decides to go ahead of the FDA authorization do we need to define a little bit more how that REMS program will be administered. Because part of the intent language asked us to provide recommendations on administration piece. Who would be administering that? If we went with a

		REMS like program ahead of the FDA authorization? **Bill Stilling:** Are you talking about manufacturing? For manufacturing that's a very difficult one for MDMA because precursor chemicals two list drugs creates a whole other level of complexity drugs. It certainly wouldn't be agricultural. **Dr. Jennifer Strohecker:** We talked about like a centralized database, too, as an option for this that I don't know who would control that without. Usually it is the manufacturer right? Or the wholesale distributor has a piece in that as well. **Dr. Michelle Hofmann:** We can also make a recommendation that's deserving of further study. **Dr. Michelle Hofmann:** Nothing else in the safety section, or even gone to ethical consideration and regulation. I did move a bunch of material into the appendix for your recommendation. Thank you for doing some work to bring in the intent language here and the background on the different associations, because that was one of the things, they asked us to do what organizations might reprise perspective. This is going to have to go through a plan language review in our department. I'm confident the people reading this will be able to understand it and maybe we can put some footnotes at the bottom. Add a

		list of abbreviations after the table of contents. **Dr. Brent Kious:** So the issue was the indications work group suggested video recording if there's a single therapist. That seems reasonable to me from one standpoint because with two therapists you have a second set of eyes to make sure there's no malfeasance. In some of the famous cases of things going sideways in psychedelic assisted therapy recently involved two therapists simultaneously engaged in impropriety and so I had aired on the side of a more conservative recommendation that all of these should be videotaped, and records kept. **Dr. Michelle Hoffmann:** Okay, so we will modify the section above that will recommend video recordings for all these treatments. **Dr. Benjamin Lewis:** I would add one comment to the below Section B where you your language here. Brent, might run a bit of foul of the MAPS training protocol. So you say here, therapists who provide psychotherapy drugs should not be required or permitted to participate in the use of psychotherapy drugs themselves. The MAPS training program has an avenue for therapist training to partake in sessions. I think it makes sense to not require this. But I think if you say something along the lines of not permitted that might end up conflicting with what ends up getting approved through established training. **Dr. Brent Kious:**

		What if we suggested permitted outside of established training programs? **Dr. Benjamin Lewis:** I think that's reasonable. **Dr. Brent Kious:** What I think I want to avoid is therapist using these things on a semi-regular basis as part of their own self therapy and in ways that could ultimately be deleterious. **Dr. Michelle Hoffmann:** So after themselves outside of established training programs. **Dr. Elizabeth Howell:** Its happening a lot already. **Dr. Benjamin Lewis:** I think you want to avoid any suggestion that would be relevant or required part of training. **Dr. Michelle Hoffmann:** Okay, I think we've pasted over Dr. Rapaport your other concern related to physicians versus other professionals, and we talked about through in terms of a group consensus. So what the general thought related to limiting this to positions versus including physicians assistance and nurse practitioners. **Dr. Brent Kious:** I guess my initial thought is that it's really important to be as conservative as possible if this is to be implemented, and it would be in keeping with the other ways we've tried to be cautious to limit this practice to the most extensively trained providers in the state

		that doesn't preclude it being changed over time to expand scope of practice for PA and APRN, who have been through appropriate training? But we could think of this as very tentative and experimental. We're trying something very new here, so let's be careful. **Bill Stilling:** The only thing I would suggest would be psychiatric nurse practitioners because they do specialize in it. I don't know enough about it but it's something to consider. **Dr. Mark Rapaport:** Well actually their training really isn't that extensive, and that's actually been an issue in this state. And so the Utah Psychiatric Association has been very concerned about that. **Dr. Michelle Hofmann:** Any objections to limiting this to physicians only and I think that language he commends like this is, if we decide to proceed ahead of the FDA in the earliest first phases of implementation. Anybody with reservations to that recommendation? Ok were on to the final section. I renamed it Conclusions and Next Steps at the recommendation of my boss. Because we did provide a summary of this basically rehash the recommendations summarized by Dr. Rapaport in the executive summary. I had a couple of comments stay around that projected the timeline of what we do know. Propose, close the reassessment

		at that time line but still stick with our stronger recommendations. A couple of other questions that it should include here, which is the status of the task force? Do we feel like we're done with the evidence review? Promising substance, mental health issues or do we want to ask for money to do more? Are we done. I think we need to state that pretty clearly. I am getting the funding estimates for what warrants work has done and we will include those in here in terms of the actual cost. **Dr. Mark Rapaport:** I actually think that people have worked very hard, and we've done as much as we can, knowing that sate of the field. So I was in favor of suggesting that the task force be ready to be sunset.
		END MEETING
Upcoming Meeting Date:		