Integrating Psychedelic Use: A Cautionary Note for Licensed Healthcare Providers

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Introduction

As popular media is regularly reporting, psychedelics are making their way "back" into mainstream culture. See, for example, *My adventures with the trip doctors; the researchers and renegades bringing psychedelic drugs into the mental health mainstream*, published by The New York Times Magazine in May of 2018 [1]. Licensed health care providers involve themselves professionally (taking classes, participating in FDA or DEA[2]-approved clinical research, investing in clinics and patents, offering "integration" services), and more personally (trying psychedelic substances themselves). In December of 2019, Psychology Today published *Ten Reasons Psychotherapists Should Learn About Psychedelics*[2]. Companies are publicizing plans for opening clinics or bringing the drugs to market. See, e.g., *Transforming psychedelics into mainstream medicines*, published online at www.statnews.com on January 7, 2020 [3].

This article hopes to prompt licensed clinicians to carefully examine some of the foreseeable consequences of offering psychedelic-assisted therapy (PAT), in particular, "integration" services, at this point and time. Often, most of the clinicians who are enthusiastic about providing PAT minimize the risks to their professional license. Also, many Masters-level therapists (the majority not being trained scientists) often have misunderstandings about the proven efficacy (to date) of PAT. Bringing PAT to market, mainly via unproven cost-saving changes in clinical research protocols, will pose additional ethical dilemmas and risks.

By "licensed," it means any provider who is licensed, regulated, or credentialed. By "PAT," it means activities -- marketed or understood as therapeutic (compared to recreational) -- surrounding the intentional dosing or ingestion of drugs defined as psychedelics (e.g., psilocybin, psilocin, LSD, ayahuasca, and other similar compounds). For this article, this category also includes non-hallucinogens, like MDMA and ketamine, which are currently associated with the resurgence in medicinal uses of psychedelics. The PAT-related activities discussed will include:

Health-care professionals who offer pre-dosing or post-dosing "integration services" to underground or aboveground psychedelic users.

Health-care professionals who offer, witness, and or supervise the actual aboveground dosing or ingestion of psychedelics or psychedelics-associated substance (e.g., ketamine) *outside of* a phase I, II or III FDA or DEA clinical trial (e.g., at an expanded access MDMA clinic, or one offering off-label use of ketamine).

Health-care professionals who encourage, offer, or participate in allegedly aboveground dosing and or "integration services" at a setting outside of the United States (for instance, Jamaica, Costa Rica, or Peru).

Underground situations, e.g., those in which health-care professionals engage in illegal possession or supervise the illegal dosing or ingestion, of psychedelic substances, will not be addressed.

This article is primarily for health care providers licensed in the United States. Importantly, this article is not offered or meant as legal advice – the reader should consult a licensed attorney in their state or district for any matters of concern. At times, to provide an example, the Oregon Revised Statute (ORS) or an Oregon Administrative Rule (OAR), which governs Regulated Social Workers in Oregon, will be cited. Because every career category of health care provider has its credentialing board, readers should review the laws pertaining to their specific practice(s).

Review

The circumstances in which psychedelics use occurs is typically divided into "aboveground" and "underground" settings. *Aboveground* use refers to the legal possession and use of psychedelics. *Underground* use refers to the illegal possession and use of psychedelics.

In the United States, generally speaking, the possession and use of psychedelics is highly illegal except for very limited and strictly controlled circumstances (e.g., FDA or DEA approved clinical trials, or an extremely narrow set of religious ceremonial uses acknowledged by the U.S. Supreme Court and thus tolerated by the US government [4]). Psychedelics (including MDMA) are Schedule I Substances under U.S. federal law (the most stringent prohibition, based on no recognized medicinal value [5]). Only ketamine, which is a uniquely distinct substance, is available by prescription (primarily used as an anesthetic [4]) but with other off label uses; it also has underground popularity [6]. Like MDMA, ketamine, along with some of its analogs are currently being researched and promoted as psychedelic-like substances with possible value for treating psychiatric conditions [5].

In addition to federal laws criminalizing the possession, selling, or use of these substances, states have prohibitions [7]. Furthermore, while there are efforts afoot to locally *de*criminalize these drugs in some U.S. cities or states (including Oregon), local rules do not, and will not, immunize the possessor or user from broader state or federal prosecution and constraints (something marijuana growers and retailers know only too well).

These prohibitions are important because most, if not all, licensed health care providers explicitly agree to comply with federal rules and regulations, and for a variety of reasons. These include requirements for eligibility and inclusion on insurance panels, use of electronic medical record portals, receipt of research or community health grants, or because their employment is contingent on federal tax dollars. Frankly, any local decriminalization is merely irrelevant if health-care providers want to maintain their credentials.

There are some countries outside of the United States, where the possession and use of psychedelic substances are purportedly legal or at least less criminalized. This means that it is (arguably) possible for a licensed health care provider (or anyone else) to have an "aboveground" experience with psychedelics outside the U.S.

FDA or DEA approved clinical trials involving psychedelics.

Researchers are working on PAT around the world. In the United States, permission to work with Schedule I drugs (or any others not yet approved and regulated by the FDA) comes from the FDA and DEA. The Multidisciplinary Association for Psychedelic Studies (MAPS) has been the leader in obtaining U.S. federal approval for research into the medicinal value of psychedelics, with a goal of getting psychedelics rescheduled (moved out of Schedule I).

To obtain FDA and DEA approval for a clinical trial involving psychedelics, a challenging set of applications must be completed and accepted, detailed protocols must be crafted and followed, and all the while the applicants face an ongoing endurance test of vetting and scrutiny by federal and state officials. It takes *years* to get the ball rolling, and it costs a great deal of money to 1) initiate the research and 2) to take it to completion. "Big Pharma" has little interest in funding this foundational line of research because there is little likelihood of profiting from the sale of these substances, let alone recouping any initial research investment, as any patents are expired, unavailable or deemed not lucrative.

While it *is* exciting that psychedelics such as psilocybin (psilocin) and MDMA have shown favorable results in their initial phase I and phase II FDA clinical trials, and have even been "fast-tracked" by the FDA, it is the phase III clinical trials that, arguably, will make or break the approval and entrance of a new therapeutic drug or drug application. Even Big Pharma has promising, fast-tracked drugs, aimed at alleviating symptoms of mental illnesses, that nevertheless encounter difficulties at phase III (e.g., Allergan's rapastinel [8][6]

and Johnson & Johnson's esketamine [7]). Each "phase" of FDA clinical trials typically has different goals, screening criteria, and protocols, and generates different types and volumes of data. For this article, the MAPS MDMA clinical trials will be the reference, although the points apply to any research into PAT.

The MAPS phase II MDMA trial data is from (only) 105 enrolled "participants" (volunteers who made it past an intense screening process), and 8 dropped out early[8]. In the current phase III MDMA trials, more robust data will be available about the effectiveness -- or the ineffectiveness – of the compound as *administered within the phase III therapy protocol*[8], as well as more information about side effects. It is crucial to remember that *we do not have phase III data yet, and the data collection process is occurring under a protocol distinct from phase II.* And while the FDA has approved expanded access for MDMA, initial enrollment is limited to 50 patients (to be spread across a maximum of 10 clinics) and the proposed protocol includes changes from the phase II and phase III protocols [9].

So, whether a health-care provider is contemplating trying out these drugs themselves or encouraging someone else to, thinking about offering psychedelic "integration" to clients, or possibly considering investing in a prospective commercial application or clinic, it is imperative to remember that we do not have a significant volume of robust clinical data yet.

There is, however, a lot of 1) media buzz about the phase I and phase II trials regarding "therapeutic" applications of psychedelics; 2) anecdotal knowledge from individuals who have taken, and continue to take, some form of these substances with the majority of these being "underground" and typically for recreational purposes; and 3) knowledge regarding the classification of these substances and that it is illegal to possess them in the United States.

The Intersection of Psychedelic-Assisted Therapy and a Professional License.

Predictably, in the face of so much kindling of the market for psychedelic-assisted therapy, an increasing number of licensed health care providers are offering, or seriously considering beginning to offer, "integration services" to psychedelic users. Indeed, the Psychology Today blog cited above offers clinicians a variety of rationales for signing up for an increasing variety of continuing education courses about psychedelics, marketing angles, and even practice tips regarding offering "integration."

While overtly pitched as a new and powerful way to help clients who are suffering from PTSD, depression, and other psychiatric conditions., the unspoken pitch is one of marketing: "here are ways to increase revenue in light of exciting clinical results."

Based on several face-to-face discussions with a wide variety of licensed professionals interested in psychedelic research and therapy, and on internet searches on the topic, a concerning view emerged. There is a prevalent assumption that as long as the health-care professional is not personally providing or ingesting the psychedelic substance, there is nothing wrong with offering "integration services" (however defined) to anyone who is interested and can afford the service.

Putting aside the "rightness" or "wrongness" of this assumption, the point of this article is to inform health-care professionals about the risks of engaging in PAT. The list of risks does not comprise an exhaustive list, but the objective is to give all health-care providers pause and to encourage discussion.

A professional license is a privilege, not a right (and why this distinction matters).

The basic health-care license is issued by a Board, typically comprised of licensed peers and usually a few members of the public. The Board operates by State law and an accompanying set of administrative rules.

Typically, the highest priority of a health profession board – the reason it exists – is to protect the public. Everything a Board does is (theoretically) related to this primary function. The Board requires

that a professional meet a specific educational standard before becoming licensed to practice, and the Board handles complaints about any licensee who behaves (on or off the clock) in a way that reportedly poses a hazard to the public, to clients, or to the profession itself.

Of relevance here, in order to get an initial license, and to continue to keep it, a health-care provider must have a reputation for knowing the rules, obeying the rules, obtaining satisfactory training, and acting with good judgment. In other words, a provider must be of good moral character and be fit to practice [10]. They must not pose a risk to the public or the profession (the exact language differs from state to state, board to board, but the bottom line is public safety).

It is essential to understand the following key points:

1.A license is a privilege, not a constitutional right.

2. A licensing Board has a statutory duty to receive and *investigate* concerns and complaints about health-care providers that (1) allege a violation of state law or rule, or (2) report an impairment. Peers may have a mandatory duty to report their concerns about a health-care provider to the Board [11]. There is no explicit limit on the range of circumstances that is reportable, or a limit on how long ago the worrisome event must have occurred [12]. A provider agrees to this oversight when they apply for and maintain their license. The Board does not have the luxury of ignoring valid concerns and complaints.

3. Licensing Boards had broad investigatory powers that operate before, and distinct from, evidentiary constraints in contested case (administrative) hearings. If a provider requests a formal hearing for a complaint filed against them, the Board typically proceeds and operates under administrative rules (a state's version of the federal Administrative Procedure Act (APA [13]). In many ways a provider is much more vulnerable in front of a licensing Board (pre-hearing), and under the APA protocol (during a contested case hearing), than they are as a litigant in a state or federal court (due to procedural and evidentiary rules).

4. If a licensing board contacts a provider about a concern or complaint (e.g., begins an investigation), they must file an answer or else they will likely end up losing their license [14]. Never ignore a Board.

5. Psychedelics are illegal to possess and ingest in the United States, outside of very narrow circumstances.

6. The off-label use of an FDA-approved drug (e.g., ketamine, or perhaps MDMA soon) may form the basis of a complaint to the board, particularly if the complaint raises issues of competency, client injury, or public safety.

7. If a provider is under investigation regarding an offer of "integration services" (or for any other conduct), it would be extremely foolish to provide *any* type of response without the assistance of an attorney experienced and specializing in defending identically licensed peers before the same Board. Most Boards have an attorney (often an Assistant Attorney General) assisting them in the investigation. Because a provider has so very much to lose, the provider will want an attorney who thoroughly understands the Board's legal process as well as the collateral consequences in state and federal court of any statements made by the provider to the Board. A simple "good faith" explanation about what a provider did, or is doing, can go sideways quickly. Note: these attorneys are very, very expensive (for obvious reasons). They will likely require a hefty

retainer fee upfront (before the attorney will begin work)

8. Under the rules of procedure which the Board operates under, a provider typically does not have the full set of rights given to a criminal defendant or a civil litigant appearing in a court of law. For instance, hearsay may be admissible in the investigatory stage, or during an administrative hearing, meaning the Board can consider the information and the provider may not have a right or opportunity to cross-examine the primary source[15]. Furthermore, while a provider presumably does have a constitutional right to remain silent (under the Fifth Amendment), "silence" can and probably will result in a license suspension or revocation. The Board is charged with protecting the public – not with protecting a provider's license or their livelihood. If there is a complaint relating to a client or public safety that the Board finds credible, and a provider stays silent, they may thereby avoid going to jail (for the moment) but they will likely lose their license.

9. Every time a provider files paperwork to become "credentialed" with a new insurance company or to be hired or given "privileges" by a hospital or other agency, these institutions typically ask whether the provider is currently, or has ever been, disciplined *or investigated* by the licensing board. Answering "yes" triggers more paperwork and more scrutiny and delay: it is a big red flag. If a provider must answer "yes," the asking party will typically want a full record of the matter (which is why an experienced attorney's assistance is so valuable). If the matter concerns illegal drugs, the applicant will likely not be a favored candidate for the job, credential, or insurance policy.

10. Many Boards have a legal responsibility to refer complaints involving criminal behavior to state and/or federal law enforcement [16].

11. Clinicians with the "deepest pockets" (the most robust professional liability coverage), and any type of state-issued credential, are vulnerable to complaints, charges, and civil tor lawsuits regarding actions and omissions committed by lower-level staff, including paid and unpaid interns, working at the clinical site.

Examples of Foreseeable Complaints.

The following scenarios will hopefully give the reader an idea of the kinds of complaints that a board might receive about "integration" services.

- A parent files a complaint against a provider, livid that the provider condones the illegal use of psychedelics by his 19-year old daughter, and that the provider bragged about their own "great" psychedelic experiences to his child. Note: technically, the adult client has not explicitly waived confidentiality.
- A client files a complaint asserting that a provider did not sufficiently warn him about the dangers of off-label use of ketamine, the provider exaggerated its efficacy, and the use has psychologically and physically harmed him, including so-called "integration services." He has incurred tens of thousands of dollars in bills from an in-patient hospital stay beginning one week after his last ketamine therapy.
- An estate of a client has filed a complaint. The client died in a single-car accident, which occurred 30 minutes after an "integration" session ended (after he left your office). The autopsy disclosed psychedelics found in his blood system, and a text on his phone indicates that his provider knew he planned on taking

psychedelics for the appointment. The client's estate has attached to their complaint a copy of their civil tort claims against the provider.

- A U.S. attendee from a group psychedelic dosing session held two years ago in Peru filed a complaint against a provider who provided clinical therapy services to the attendees in Peru. Last month, when both individuals were again in Peru (by coincidence), they engaged in sexual activity. The next day, the provider blocked the patient on the provider's phone. The patient requested (by mail) his Peru-era records from the provider, a request that was ignored. The patient provided the Board with a signed authorization for release of his confidential records, which the Board has attached to their letter to the provider, requesting a response [17]. The "clinic" has since closed, documentation in Peru was purposely minimized, and the provider has no client records from their work there. The provider does have a PayPal record reflecting that they were paid for services rendered in Peru, and phone and internet providers have plenty of email and text records supporting the patient's factual claims.
- The District Attorney has provided the Board with a certified copy of a grand jury indictment accusing a provider of manslaughter. A client died 75 minutes into a "magic mushroom session" at the provider's office. Although the provider did CPR and cooperated with law enforcement at the scene, the medical examiner has listed the psilocybin mushrooms as the cause of death. Unfortunately, the grand jury did not believe the provider's testimony that the provider did not provide the mushrooms. It is currently irrelevant that in two years, when the provider finally goes to trial, their defense attorney will successfully challenge the cause of death [18].
- The spouse of a U.S. attendee at a group psychedelic dosing session in Jamaica filed a complaint that a provider practiced unlicensed psychotherapy with his spouse in Jamaica, and with her later, via Skype (both live within the same state). Although the provider has a "bodywork" credential, they have never applied for credentialing from *this* Board. They do have sufficient education and training in "interpersonal therapy" such that the Board asserts jurisdiction over them (for the practice of counseling/therapy without a license). The provider was invited to "help" with the retreat in Jamaica (and expenses were covered) because of their training. The retreat website offers a full archive of events there. Skype (of course) has archives of the sessions with the spouse.
- Someone who shares a "turn-key" office writes the Board (and copies a provider's professional liability insurance carrier), wanting to know whether the Board approves of psychedelic "integration services" and if not, will they be at risk for discipline (or liability) for sharing an office space with the provider?
- The District Attorney informs the Board that a provider is under investigation for the distribution of psychedelics. The provider's "integration" client got busted and charged with possession of LSD and asserted (falsely) under oath that the provider was the source of the drugs. The fact that the client lied to protect his real source and assumed that the provider would not get in trouble if he named them because they are "credentialed" is currently beside the point.
- A peer files a formal complaint that a colleague is encouraging illegal drug use and going beyond the scope of their license by advertising "integration services" aimed at users of psychedelics. Four teens from the town (including siblings of two of the provider's adult clients) were hospitalized last week for ingesting the "wrong" kind of

little brown mushrooms, and a local radio station is publicizing the complaint.

- Law enforcement provides the Board with a copy of the report following the execution of a valid search warrant for a provider's office and or home, based on a judge finding "probable cause" existed that the provider possessed psychedelics. This followed upon a radio show in which the provider was interviewed about their training and enthusiasm for PAT. Everyone knows the provider just returned from Costa Rica where they were doing ayahuasca – they have been talking it up. The fact that the cops did not find anything is not particularly relevant.
- A client at an expanded access clinic is suing the physician for negligent supervision, emotional distress, and related medical bills suffered after the physician's "intern" broke off a sexual relationship that began the night of the client's first dosing session (1 year ago), after all staff (except the overnight CNA) had left the clinic. The intern had returned at the client's request via text that night, and they engaged in sexual activity and entered into a drama filled relationship. The relationship continued until two months ago, more than a year since the patient's treatment at the clinic had ended. The intern quit six months ago and has left the country. The physician had no direct personal knowledge of this affair but had heard rumors about it yet did not investigate.

The first question is: does a provider have $10,000 - $40,000 in cash, or other assets which they can easily liquidate, to hire an attorney to *begin* to help defend them in the matter before the Board? One should not assume that their agency, employer, or professional liability or malpractice insurance carrier is going to volunteer to assist and defend them. Defendants do not get a "court-appointed" attorney for Board matters (a civil, administrative proceeding), and providers likely are over-income for a court-appointed attorney in any related and pending criminal case. Collateral damage alert: a provider might abruptly receive notice that their professional malpractice insurance has been suspended or canceled (due to the ongoing Board investigation or criminal charges). This is another one of those credentialing questions that no one ever wants to have to answer "yes" to (Q: has your insurance ever been suspended or revoked?).

Next, let us look at files – one or more of which will likely be requested by the Board. This includes any and all informed consent paperwork, disclaimers, chart notes, time of sessions, if, how, and why a provider billed insurance for the session, and all related phone texts and email records. (If the complaint was not made by the client, and if there is no Release of Information signed by the client, a provider will need to carefully figure out what information they may lawfully turn over to the Board in your defense.) What did they charge? How long was the session? Who was billed, and under what diagnosis and which CPT code? How was it paid for? What *are* the overall billing practices? (Note: the argument that a provider did not charge for the session will not reduce the Board's jurisdiction or scrutiny.)

Next, the actual session. What happened? When? What was the length? What was the plan? Moreover, what -- exactly -- is "integration"?

The dictionary definition will be of little help [19]. The term is used, but not defined, in the most recent report on the MAPS MDMA clinical trials (Mithoefer et al. 2019 [8]). The MAPS Training Manual does not define it but does provide a dozen or so pages of suggestions and guidance for therapists who are providing post-dosing integration sessions [20]. (Concerning PAT, many readers would agree that "integration" generally refers to getting the most out of a psychedelic dosing session, in a positive way.)

Assuming that at some point, a provider and the Board can agree on what integration means (or at least the Board comes to an understanding about what the provider means), the next inquiry might be about training. What training does the provider have in providing "integration" for psychedelic dosing? How long have they been doing this? Ethically

(check current administrative rules), a provider is not supposed to offer services that they are not qualified to offer. What is the provider's experience and qualifications with psychedelics? (Bear in mind that for about fifty years, these substances have been highly illegal, and the Board is now asking pointed questions about the provider's private use and knowledge of illegal drugs, *and* the Board is documenting those answers – answers that are given under the penalty of perjury).

One point that is very important to make is that during the MDMA clinical trials, the post-dosing "integration" is not a stand-alone, post-dosing event. It occurs within an ongoing therapeutic relationship that begins with the first pre-dosing therapy session and is strengthened via the therapists' presence during the dosing session[21]. Therefore, arguably, successful "integration" as that term is used in the MDMA Training Manual and the clinical protocols to date is contingent upon the therapists' presence during the pre-dosing therapy *and* dosing sessions and continues until the participant is finished with the trial. One could even argue that "integration" includes the pre-dosing and dosing sessions. This may sound extreme, but it is plausible.

Importantly, neither the number of therapists present nor the continuity of their presence during each stage of the protocol (pre-dose, dosing, post-dosing) was a variable during the clinical trials. Therefore, there is no evidence, from these particular trials, as to how effective MDMA-assisted therapy *in toto* will be without the presence of two therapists throughout the entire protocol. Similarly, there is no evidence as to how effective "integration" (however defined) is, when applied to the experience of taking illegal drugs in an underground setting.

The point here is that when people read about these encouraging phase I and phase II clinical trial results and start asking around for "integration" services ("because I have already done the MDMA, I guess I just need to integrate it"), they are vulnerable to being exploited and hurt. Similarly, when a therapist gets excited about these clinical results and starts offering stand-alone post-dosing "integration," relying in good faith on the MAPS clinical data but not understanding how to read and interpret clinical results correctly, the therapist risks exploiting the client for financial gain, and possibly causing iatrogenic harm.

Going back to the Board's investigation, a provider might try explaining (rationalizing?) that their services are in the realm of "harm reduction" (as propounded by the authors of the Psychology Today blog). The Board will then proceed to look at their training in substance use and abuse in general, and in particular, their training in "harm reduction" concerning *psychedelics*. Are they a Certified Alcohol and Drug Counselor? If not, what classes, courses, and supervision have they had or taken, related to *harm reduction for psychedelic use*? Were the classes taught by credentialed educators? Did they obtain continuing education credits? What is the theory exactly? What do they assert are the *recognized harms* to the user of illegal psychedelics? What empirical evidence are they relying on? How did or would their *recommendations r*egarding "set and setting" reduce the risk of harm? And by how much? Furthermore, how do they know? Identify the *harm reduction* language in their advertising, and their client consent form and treatment plan. How much of each session was spent on *harm reduction* versus *integration*? Does their billing reflect the distinction, and if not, why not?

It looks and sounds like they think that the illegal possession and use of nonpharmaceutical grade psychedelics (whatever is offered for sale on the street as a psychedelic) can have a positive effect -- outweighing all harm -- if "integrated" properly. How do they even know what their client will ingest or has ingested? Did they or someone else test it? Did they offer to? Why not? Would this approach ("positive" pre- or post-dosing integration) work for other illegal drugs like heroin and methamphetamine, or troubling criminal behaviors like domestic violence? Is there an "upside" to such experiences? Why or why not?

A provider might offer the explanation that "published research has shown integration to be helpful." Providers should be prepared to answer questions about how closely their "integration services" follow the procedures in the published research they cite (FDA approved trials), how it

differed, and why those differences are unimportant. Explain their understanding of why the FDA requires three phases of clinical trials, pharmaceutical grade drugs, and the current clinical trial status of the drug(s) at issue. Explain how clinical trial outcomes are relevant to their assisting clients in "integrating" illegal acts with illegal drugs in non-clinical settings.

A provider might try offering an explanation involving their own or their client's "freedom of speech" or the right to encourage "cognitive liberty." The Board would likely promptly re-focus the provider on the fact that they are concerned about public safety, which includes first and foremost the provider's fitness to practice: the provider's moral character, and the illegal nature of psychedelics. The Board is not prohibiting or limiting the provider's constitutional rights to free speech or thought. They are free to take – or promote the taking of – illegal drugs. However, they are not free to keep their license while doing those things. The Board will remind the provider that their license is a privilege that can and will be suspended or revoked by them if they decide the provider is morally unfit to keep practicing.

For those readers who have never experienced a grilling by an administrative Board, or read a transcript of one, these questions may sound ridiculous or exaggerated, but they most assuredly are not. If a provider is in doubt, they should find an attorney who defends licensed health care professionals before their Board, and seek their counsel and, at the very least, inquire about the potential outcomes.

Other Ethical Quandaries.

As this goes to press, MAPS is finalizing the protocol to be used in expanded-access clinics for MDMA assisted psychotherapy. Negotiations are underway for how closely these clinics will have to follow the phase II and phase III FDA protocols (an issue that may constrain future off-label use of MDMA [22]). The phase II protocol was very labor-intensive. It was "based upon initial work with classic psychedelics and early reports of MDMA in a therapeutic setting [8]." For the initial round of MDMA-assisted therapy treatment, each of the two therapists were in direct face-to-face contact with the "volunteer" (and each other) for approximately 20 hours, for a minimum of 40 client-hours [23][8].Add to this the typical overhead expenses of clinic operation and a high cost per treatment is likely.

Importantly, the MAPS trials were and are primarily funded by MAPS -- a 501(c) non-profit (with taxpayers picking up the government agency tabs). The expanded access clinics will need to raise their *own* operating funds or pass those costs onto clients. Another challenging issue is staffing. To date, during the MDMA trials, both therapists must be attending to the client during the dosing sessions – therapists are not allowed to be doing other activities: they must be genuinely present and always attuned to the patient (no computer or phone use). As videotapes of these sessions show, this is not typical or comfortable work for the average health care professional (sitting bedside with a patient, with a 2nd therapist in the room, for 6-10 hours at a stretch, solely focused on the patient). Given the intensity of these sessions, it has been suggested that the therapist teams be limited to one dosing session per week. That is a significant constraint on resource scheduling and income generation.

The cost and staffing of PAT has been at the center of the discussion about 1) whether it is possible to provide effective PAT via a cheaper protocol, 2)if so, how to bring down the delivery cost of PAT (to a price that Medicaid and the Veterans Administration will tolerate) without losing efficacy, 3) how best to handle the recruitment, training, and retention of PAT therapists, and last but not least, 4) how to solve the dilemma of who does or does not get the treatment. Investors and clinicians are negotiating amongst themselves and with the government. See, e.g., *Expanded Access: Creating a Psychedelic Therapy Center in the Pacific Northwes t*[9], and the website at www.fieldtriphealth.com. For-profit clinics will be free to make as much profit as they can (and investors typically demand this). It is unclear how far these clinics will be allowed to stray from the phase II and phase III protocols, and what limits (if any) will be put on the prospective "off label" use of FDA-approved MDMA. It is unknown whether a

protocol with much-reduced staffing and or semi-private dosing environments will be affordable and effective.

So, when a client contacts a PAT provider, having relied on media reports generated by the two-therapist, private-room protocol, when and how will any change from this protocol be communicated to the client? What rationale or justification will be offered? What protections will be offered? Assuming there will be pressure to have non-credentialed sitters, replace one or both therapists, at least during the dosing sessions, will there be any meaningful oversight [24]? Given the milieu in which the encouraging data was generated, would a non-credentialed "sitter" working in an expanded access clinic nonetheless be practicing some form of psychotherapy (in the eyes of the patient), yet be doing so without a license? If so, is the credentialed therapist assisting in that unlicensed practice?

Similar ethical considerations confront clinicians who have been or are newly offering off-label ketamine-assisted therapy. It may be "legal," but given the lack of rigorous clinical trials demonstrating the safety and efficacy of these off-label uses, and the long-documented side effects, it is ethical? How are the risks, and the lack of robust evidence communicated to the patient? These clinics are planning to be in place and designed to quickly expand their offerings of PAT, if and when additional drugs become legally available. Assuming there will be a need for a credentialed psychotherapist on-site, what is an ethical caseload and FTE?

A primary goal of many researchers around the work has been to generate sufficient data to convince the U.S. government to move these drugs out of Schedule I (by generating evidence that the drugs *do* have medicinal value). Once that happens, the drugs may be legally manufactured or harvested and prescribed and possessed for medicinal purposes. Unless otherwise restricted, off-label use will likely explode, and manufacturers -- just like the clinicians -- will seek to maximize demand and profits. Specialty clinics will gain a competitive boost if regulators require that psychedelics only be provided at such locales, a requirement that may strike some as grounded more in capitalism than in safety and necessity (especially if credentialed "sitters" are not required for the dosing session, or that the existing protocol is further watered down). Oregon voters will be voting on this issue if enough signatures are gathered to put it on the ballot in 2020[25]. It seems evident that as with all retail level medicine, consumers with the most resources will continue to get the most helpful "set and settings," including as many credentialed therapists and as much privacy as they want. Those who can only afford the economy class protocol will get the "community" set and setting, with maybe one credentialed health care provider for the entire clinic population, popping his or her head in for a few minutes to see how it is going, with interns and minimum wage workers used for everything else.

Concerning traditional psychedelics, a version of this scenario is already playing out at a variety of out-of-country locations currently offering psychedelic-assisted "experiences" marketed as "aboveground." *MycoMeditations* (Jamaica) [10], *Soltara* (Costa Rica[11]), and the *McKenna Academy* (Peru) [12] are just a few examples [26].

Is it ethical for a health care provider to educate a client about these opportunities? Is it ethical to encourage a client to participate in them? Is it ethical to work for one?

It is a given that there are always risks involved in traveling to a foreign country, and one's vulnerability increases exponentially when one is in an altered state of consciousness in a foreign country. The topics of consumer and employee safety, and marketing-versus-the-reality, are hotly debated subjects, as reflected in online reviews and commentaries [27].Typically, the paying customer is required to waive any right to sue the operators for anything that occurs on foreign soil (whether related to the dosing session or not), or related to it upon the customer's return to the U.S [28]. If the customer chooses to indulge in the offered substance, there is no guarantee as to dosage, purity, or effects [29]. Typically, there are few or no credentialed health care providers on-site during the dosing, and no nearby hospital facilities or urgent care clinics [30]. Attendees may be pressured by hosts or other

participants to do additional dosing sessions, and or to increase their dosage during a session [31].

The legality and government oversight of the operation is typically very difficult to ascertain [32]. The screening and acceptance of potential customers (usually strangers to one another) is not transparent, and the group's final "mix" can turn out to be socially awkward or worse. (This could be overcome by organizing a group of sufficient size). Profits are needed and are maximized by having the largest number of customers assembled for each retreat. As in similar quasi-medical, retail operations, there is a weakened (if any) fiduciary duty owed by the retreat operators to the customers.

If the operators and their employees are not credentialed health care providers, there is no mechanism for oversight except for the foreign country's justice system (most of these host countries have much more pressing concerns, so governmental indifference is often at play). If there are credentialed clinicians associated with the retreat (website marketing), that does not mean they will be at *every* retreat and may no longer be associated (marketing is not always accurate [33]). If someone in a dosing group becomes obnoxious or violent, has a "bad trip," becomes ill, or dies, a patient likely will have to witness that (while tripping [34]). Unless the patient brings a friend, no one there will know them, or know how to help them if they feel agitated or scared. Some of the people attracted to and allowed to attend these psychedelic "tours" have serious psychological challenges (PTSD, addictions, personality disorders), and yet are encouraged by the tour companies to "come on down" and "get some help [35]." On the other hand, in a best-case-scenario, these destinations can and do provide an opportunity for someone to experience psychedelics in an ostensibly "aboveground" setting. A clinician making this decision for her or himself is one thing. A provider should avoid lending their credentials and reputation to these retreats, even in a good faith effort to facilitate or influence a client's decision.

Conclusion

Excitement is growing around the world about the potential decriminalization of psychedelics, and their potential to help people through PAT. It is not the intention of this article to diminish this excitement. Nevertheless, health care professionals need to minimize the risk of causing iatrogenic harm or endangering their ability to practice.

Providers, at the very least, should print out a copy of the current statutes and administrative rules governing their profession and *read them carefully*, including the definitions. A phrase such as "good moral character" sounds pretty fuzzy – but it will not necessarily work in their favor if their Board is under political, legal, or media pressure to "take action."

This article does not mean to imply that a licensed health care provider should decline to offer "integration services" or refuse to engage with clinics offering off-label uses of legal drugs. However, the provider needs to have their intention and their story straight. It helps if there is a single-story – the same story that gets told to everyone.

For those providers who have had pleasant or healing psychedelic experiences (whether aboveground or underground): there is no good reason to tell a client about that in detail. Any theoretical benefit of offering a more detailed description can't outweigh the very real risk that the client will minimize the risks they have taken, or are about to undertake, because a provider has "done it" and "it was worth it." As outlined in the thousands of published papers and books on psychedelic use, *there are real risks.* People do die during dosing sessions (as happened in California during an underground magic mushroom session in 2018). The ingestion of psychedelics per se does not immunize the user from cardiac arrest, stroke, seizures, just to name a few, and can, in fact, cause problems. This is the main reason why clinical trial volunteers are so thoroughly screened before being accepted as volunteers, and why participants are so closely monitored during dosing sessions[8].

If a provider is confident that offering integration services for the underground use of psychedelics is valid *and ethically defensible,* start a

workgroup and initiate a conversation with the licensing board and other practice partners. Assuming that clients do and will benefit from such services, what kind of training, precautions, protocols, and chart documentation would they want to see? It will be a friendlier conversation, and a more relaxed opportunity to spread the good news about the encouraging results coming out of psychedelic research.

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Jade, R. (2020, March). Integrating Psychedelic Use: A Cautionary Note for Licensed Health Care Providers. *The Journal of Psychedelic Psychiatry*, *2*(1).

REFERENCES:

1. Pollan, M. My adventures with the trip doctors; the researchers and renegades bringing psychedelic drugs into the mental health mainstream: The researchers and renegades bringing psychedelic drugs into the mental health mainstream. The New York Times Magazine [Internet] 2018 May 15 [cited 10 Jan 2020]. Available from: https://www.nytimes.com/interactive/2018/05/15/magazine/health-issue-my-adventures-with-hallucinogenic-drugs-medicine.html.
2. Bates, M., Neilson, E.M. Ten Reasons Why Psychotherapists Should Learn About Psychedelics: Here's how therapists can get involved in this groundbreaking field right now. Psychology Today [Internet] 2019 Dec 22 [Cited 10 Jan 2020]. Available from: https://www.psychologytoday.com/us/blog/psychedelics-now/201912/ten-reasons-psychotherapists-should-learn-about-psychedelics?eml
3. Raz, S. Transforming psychedelics into mainstream medicines. STAT [Internet] 7 Jan 2020 [cited 10 Jan 2020]. Boston Globe Media. Available at: https://www.statnews.com/2020/01/07/transforming-psychedelics-into-mainstream-medicines/.
4. Ketamine is a dissociative general anesthetic used in human and veterinary medical procedures: it produces effects very similar to PCP...[It was] first synthesized in 1962...[In 1992 it was] rated as a scheduled substance (depressant - Schedule III)." Inaba D.S., Cohen W.E. Uppers, Downers, All Arounders; Physical and Mental Effects of Psychoactive Drugs. 7th ed. Medford, OR: Paul J. Steinbroner; 2011. 6-19p.
5. Devlin, H. Ketamine-like drug for depression gets UK license; Psychiatrists divided on 'game-changing' esketamine due to potential for addiction. The Guardian [Internet] 2019 Dec 19 [cited 10 Jan 2020] Available at: https://www.theguardian.com/science/2019/dec/19/ketamine-like-drug-depression-uk-licence-esketamine.
6. Idrus, A.A. Allergan's NMDA drug rapastinel flops in phase 3 depression studies. Fierce Biotech (A division of Questex) [Internet] 2019 March 7 [cited 10 Jan 2020]. Available at: https://www.fiercebiotech.com/biotech/allergan-s-nmda-drug-rapastinel-flops-phase-3-depression-studies.
7. Pagliarulo, N. J&J's ketamine-based antidepressant sees mixed results in Phase 3. Big Pharma DIVE [Internet] 7 May 2018 [cited 10 Jan 2020]. Available at https://www.biopharmadive.com/news/johnson-esketamine-antidepressant-mixed-results-phase-3/522942/.
8. Mithoefer, M.C., Feducccia, A.A. et al. MDMA-assisted psychotherapy for treatment of PTSD: study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials. Psychopharmacology. 2019 May 7 [cited 10 Jan 2020] 236:2735-2745, at 2737, 2739. Available from: https://link.springer.com/content/pdf/10.1007%2Fs00213-019-05249-5.pdf https://doi.org/10/1007/s00213-019-05249-5. (hereafter cited as Mithoefer et al)
9. Crespi, T. Expanded Access: Creating a Psychedelic Therapy Center in the Pacific Northwest. MAPS Bulletin [Internet]. 2019 Winter [cited 10 Jan 2020]. 29:3:38-40p. Available at https://maps.org/news/bulletin/articles/438-maps-bulletin-winter-2019-vol-29,-no-3/7950.
10. Accessible at: https://www.mycomeditations.com/.
11. Accessible at: https://soltara.co/.
12. Contact information accessible at: https://mckenna.academy/

FOOTNOTES:

1. Rose Jade has a Certificate in Psychedelic-Assisted Therapies and Research from the California Institute of Integral Studies in San Francisco (2018 cohort). She has a BS in Biology from Massachusetts Institute of Technology, a JD from Northeastern University School of Law, and an MSW from Portland State University. She is a Licensed Clinical Social Worker and a Licensed Massage Therapist in Oregon. She has an inactive license with the Oregon State Bar. This article is not meant as legal advice. Rose Jade welcomes correspondence at rjalate@gmail.com. An earlier version of this article was published in 2018 by SSRN. Jade, R. Integrating Underground Psychedelic Use: A Cautionary Note for Licensed Health Care

Providers [Internet] 2018 Jul 3. Available from SSRN: https://ssrn.com/abstract=3181334

2. Referring to the federal United States government agencies: the Food & Drug Administration (FDA) and the Drug Enforcement Agency (DEA).

3. For a similarly themed article published in 2010, see Jade R. Current Research on the Human Experience of Spirituality Following the Ingestion of 'Magic' Psilocybin Mushrooms: An Annotated Bibliography for Social Workers and Other Health Care Professionals. 2010 Nov 26 (rev 2013 June 6). Available from: https://ssrn.com/abstract=1714051 or http://dx.doi.org/10.2139/ssrn.1714051.

4. See e.g, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006); Employment Division, Department of Human Resources of Oregon v. Smith, 494 U.S. 872 (1990), and the Religious Freedom Restoration Act (RFRA), 42 USC §2000bb, passed by the U.S. Congress in 1993.

5. For example, psilocybin and psilocin are controlled substances under Schedule I (c)(15) and (16), of the federal Controlled Substances Act, 21 U.S.C. 811 to 812.

6. "Ketamine...is known on the streets as "special K," "vitamin K," and "kit kat." *Ibid.*

7. Some 2017-era examples include: ORS 475.005 Definitions for ORS 475.005 to 475.285 and 475.752 to 475.980 *** (6) "Controlled substance": (a) Means a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS 475.035 (Authority to control schedule). ORS 475.752 (1) Except as authorized by [certain other sections]...it is unlawful for any person to manufacture or deliver a controlled substance. Any person who violates this subsection with respect to: (a) A controlled substance in Schedule I, is guilty of a Class A felony, except as otherwise provided in ORS 475.886***7) Notwithstanding subsection (3)(a) of this section, unlawful possession of a controlled substance in Schedule I is a Class B felony if: (a) The person possesses a usable quantity of the controlled substance and:(A) At the time of the possession, the person has a prior felony conviction; (B) At the time of the possession, the person has two or more prior convictions for unlawful possession of a usable quantity of a controlled substance; or (C) The possession is a commercial drug offense under ORS 475.900 (1)(b); or (b) The person possesses: (A) Forty or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide; or (B) Twelve grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin.

8. Allergan Plc. Allergan Announces Phase 3 Results for Rapastinel as an Adjunctive Treatment of Major Depressive Disorder (MDD) – Three acute pivotal studies did not meet their primary endpoint – – Interim analysis of relapse prevention study suggests the primary endpoint will not be met – ***We are deeply disappointed with these results, and they are a vivid reminder that drug development is extremely challenging, especially in mental health. We are grateful to the patients, their caregivers, and the investigators who supported these clinical studies. We remain committed to the development of new life changing medications to combat the rising global toll of mental illness," said David Nicholson, Chief Research & Development Officer at Allergan***In a previously conducted Phase 2 clinical study rapastinel demonstrated a rapid onset of antidepressant effect within one day, which continued for approximately seven days after a single injection." March 6, 2019. Press release available at: https://www.allergan.com/News/ http://www.prnewswire.com/news-releases/allergan-announces-phase-3-results-for-rapastinel-as-an-adjunctive-treatment-of-major-depressive-disorder-mdd-300808044.html.

9. The Expanded Access protocol differs from MAPS' ongoing Phase 3 clinical trials in that it is limited to treatment-resistant patients with moderate to severe treatment-resistant PTSD. Other differences are that the FDA is requiring at least one therapist of each therapy pair to have a medical or clinical doctorate degree (M.D., Ph.D., or equivalent), there is no control group, and patients are responsible for the costs of their own treatment...[This] protocol must still be approved by the U.S. Drug Enforcement Administration (DEA) and the Institutional Review Board (IRB)." FDA Agrees to Expanded Access Program for MDMA-Assisted Psychotherapy for PTSD, MAPS Press Release 17 Jan 2020 [cited 18 Jan 2020] Available from: https://maps.org/news/media/8008-press-release-fda-agrees-to-expanded-access-program-for-mdma-assisted-psychotherapy-for-ptsd.

10. OAR 877-015-0108 Eligibility Requirements. To be eligible for initial certificate of registration or license, a person must meet the requirements in sections (1) through (6) of this rule. *** (3): To be fit to practice social work in Oregon, the person must have demonstrated and must currently have: (2) (A) Good moral character. For purposes of this rule, lack of "good moral character" may be established by reference to acts or conduct which would cause a reasonable person to have substantial doubts about the individual's honesty, fairness, and respect for the rights of others and for the laws of the state and the nation. The conduct or acts in question should be rationally related to the applicant's fitness to practice social work; and (B) A personal history of conduct that is consistent with the standards contained in division 30 of this chapter of rules. *** (4) The person must be fit to practice social work in Oregon. In making this fitness determination, the board will consider whether the person is subject of an investigation or disciplinary action by a licensing board and the reasons for the action.

11. ORS 675.583 Duty to report evidence of impairment or unprofessional or prohibited conduct; confidentiality of information, limitation of liability. (1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a regulated social worker shall report to the State Board of Licensed Social Workers any information the regulated social worker has that appears to show that a regulated social worker is or may be an impaired professional...or may have engaged in unprofessional conduct according to the guidelines of the code of ethics*** Oregon Laws Chapter 676. Health Professions Generally. *** Reporting Obligations.

*** ORS 676.150 Duty to report prohibited or unprofessional conduct, arrests and convictions; investigation; confidentiality; immunity from liability. ***(2) Unless the state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a [health profession] licensee who has reasonable cause to believe that another [health profession] licensee has engaged in prohibited or unprofessional conduct shall report the conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting licensee shall report the conduct without undue delay, but in no event later than 10 working days after the reporting licensee learns of the conduct

12. OAR 877-040-0010 Form of Complaints. Any person may file a complaint alleging a violation of ORS 675.510 to 675.600 or of the rules of the board or an impairment. A complaint must identify the complainant and the respondent ORS 675.510 Definitions...(8) "Unprofessional conduct" includes, but is not limited to, any conduct or practice contrary to recognized standards of ethics of the social work profession or any conduct that constitutes or might constitute a danger to the health or safety of a client or the public or in any other manner fails or might fail to adhere to the recognized standards of practice."

13. ORS 675.540 Grounds for disciplinary action; authorized sanctions and penalties; investigations. (10 The State Board of Licensed Social Workers may impose any or all of the sanctions specified in subsection (2) of this section, upon proof, after a hearing pursuant to the provisions of ORS chapter 183 [Administrative Procedures Act] relating to a contested case***

14. OAR 877-030-0090 General Provisions Governing Conduct. (1) A regulated social worker must cooperate with the Board, its investigators, and its committees in investigations made under OAR Chapter 877. (2) A regulated social worker must fully comply with a final order issued to the regulated social worker by the Board.

15. OAR 183.450 Evidence in contested cases. In contested cases: (1) Irrelevant, immaterial or unduly repetitious evidence shall be excluded but erroneous rulings on evidence shall not preclude agency action on the record unless shown to have substantially prejudiced the rights of a party. All other evidence of a type commonly relied upon by reasonably prudent persons in conduct of their serious affairs shall be admissible. Agencies and hearing officers shall give effect to the rules of privilege recognized by law. Objections to evidentiary offers may be made and shall be noted in the record. Any part of the evidence may be received in written form. (2) All evidence shall be offered and made a part of the record in the case, and except for matters stipulated to and except as provided in subsection (4) of this section no other factual information or evidence shall be considered in the determination of the case. Documentary evidence may be received in the form of copies or excerpts, or by incorporation by reference. The burden of presenting evidence to support a fact or position in a contested case rests on the proponent of the fact or position. (3) Every party shall have the right of cross-examination *of witnesses who testify* and shall have the right to submit rebuttal evidence. Persons appearing in a limited party status shall participate in the manner and to the extent prescribed by rule of the agency***. [Emphasis added]

16. OAR 877-040-0016 Reporting Possible Prohibited Conduct to Law Enforcement Agency. (1) If, during the investigation of a complaint, a member of the Consumer Protection Committee or any board member believes a respondent has engaged in prohibited conduct, the committee or member must refer the case as soon as possible to the board for its review. The board will review the case not later than the next regularly scheduled board meeting and will determine whether it has reasonable cause to believe that the respondent has engaged in prohibited conduct. (2) If the board concludes there is reasonable cause to believe that the respondent has engaged in prohibited conduct, the board will present the facts to an appropriate law enforcement agency within 10 working days. (3) In this rule, the term "prohibited conduct" ...means conduct by a licensee that: (a) Constitutes a criminal act against a patient or client; or (b) Constitutes a criminal act that creates a risk of harm to a patient or client. The term "licensee"...includes all regulated social workers.

17. OAR 877-040-0015 Notification to Respondent. (1) The Consumer Protection Committee may send a letter to the respondent stating that nature of the investigation and, if appropriate, an authorization to release confidential records. The committee will ask the respondent to provide a written reply within 30 days together with documents the respondent considers relevant. (2) If the respondent replies to the request of the board, the reply is reviewed by the Consumer Protection Committee. The committee may ask for additional or more specific information.

18. Not every coroner or doctor is conversant with how psychedelics are metabolized, and easily debatable conclusions can be erroneously reached, some with serious legal and/or psychological consequences for third parties. Doctors, scientists or local District Attorneys who have specialized knowledge about the metabolism of psychedelics are obviously the best "messengers" for requesting reconsideration of a cause of death determination involving psychedelics. It saves enormous time and resources if this can happen *before* the Certificate is finalized, but that's not always how it goes. A helpful reference is Timmermans S. Postmortem: How Medical Examiners Explain Suspicious Deaths. Paperback ed. Chicago: The University of Chicago Press (2007).

19. According to the online Oxford Dictionary, to "integrate" means to "[c]ombine (one thing) with another so that they become a whole." With respect to psychology, "integration" is defined as "[t]he coordination of processes in the nervous system, including diverse sensory information and motor impulses." With regard to psychoanalysis, it is "[t]he process by which a well-balanced psyche becomes whole as the developing ego organizes the id, and the state that results or that treatment seeks to create or restore by countering the fragmenting effect of defense mechanisms."[Cited 10 Jan 2020] Available at: https://www.lexico.com/en/definition/integrate.

20. "Integration is viewed as an essential and ongoing process as the inner experiences catalyzed by MDMA-assisted sessions

continue to unfold. Follow-up contact with the therapists by phone and during scheduled integration visits is necessary to support successful integration. During these visits the therapists aim to address any difficulties that may have arisen following MDMA-assisted sessions and to anchor the lessons gained in a non-ordinary state of consciousness so they can be integrated into daily life." Mithoefer, M. A Manual for MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder. [Internet] 2017 May 22: Version 8.1 [Cited 10 Jan 2020]. MAPS, U.S. p8 (see also pp50-58). Available at: https://s3-us-west-1.amazonaws.com/mapscontent/research-archive/mdma/TreatmentManual_MDMAAssistedPsychotherapyVersion+8.1_22+Aug2017.pdf

21. "The successful use of MDMA in therapy depends on the sensitivity and talent of the therapist who employs it. The therapists work with the participant to establish a sense of safety, trust, and openness, as well as to emphasize the value of trusting the wisdom of the participant's innate capacity to heal the wounds of trauma. Greer and Tolbert suggest that 'the relationship should be oriented toward a general healing for the client, who should feel safe enough in the therapists' presence to open fully to new and challenging experiences.' Establishing these conditions requires that the therapists carefully set the parameters of treatment and prepare the participant before each MDMA-assisted session, and then provide appropriate support following the session so that the experience can be successfully integrated." - Mithoefer, MDMA Manual, pg 6 (citations omitted).

22. MDMA-assisted psychotherapy uses MDMA to improve the effectiveness of psychotherapy for PTSD. The treatment involves up to three administrations of MDMA, in conjunction with psychotherapy in a controlled clinical setting as part of a course of psychotherapy. Once approved, patients will not be able to take the MDMA home – patients won't be filling their prescriptions at their local pharmacy. Instead, MDMA-assisted psychotherapy treatment will only be available through a doctor and only in supervised therapeutic settings from certified clinicians." MAPS press release, 17 Jan 2020.

23. "Two to three non-drug 90-min therapy sessions prior to the first experimental session...[an] 8-h psychotherapy session...after [which] participants remained at the study site overnight with a supportive attendant. On the following day, they met with the therapists in a 90-min integration session ...[and] two to three more integration sessions occurred during the month after each experimental session. For 7 days following each experimental session, the therapy team checked in with the participants in brief telephone calls to assess wellbeing and safety....The same male/female therapy team was present for all therapy sessions for a given participant."Mithoefer et al, ibid., pgs 2737-2738.

24. For the expanded access MDMA clinics, the FDA agreed to one therapist being a not-yet-credentialed intern, but newly required at least one of the therapists be a doctorate-level clinician. MAPS press release, 17 Jan 2020. As stated in the MAPS Therapy Training Program Application Requirements: "If one of the practitioners on a therapy pair is not fully licensed, they may alternatively be enrolled in a mental health training program gaining supervised hours of experience (i.e. Marriage Family Therapist Practicum, Social Work Internship, and RN in supervised clinical practice to obtain Psychiatric/Mental Health certification, Psychiatry Residency), AND plan to pair only with a full licensed clinician to conduct psychotherapy who also meets the qualifications of the MDMA Therapy Training Program. *** MAPS Therapy Training Program Application Requirements [cited 22 Jan 2020]. Available from https://mapspublicbenefit.com/therapy-training/program-application-requirements/.

25. For more information, access https://psi-2020.org/the-measure/. This is distinct from a separate Oregon ballot measure effort that seeks to decriminalize drugs. For more information, access https://www.marijuanamoment.net/oregon-activists-begin-signature-gathering-for-2020-drug-decriminalization-initiative/.

26. I have attended one retreat put on by MycoMeditations in Jamaica, and one put on by the McKenna Academy in Peru.

27. Compare, for example reviews posted at https://www.tripadvisor.com/Attraction_Review-g635963-d15695234-Reviews-MycoMeditations_Psilocybin_Assisted_Retreats-Treasure_Beach_Saint_Elizabeth_Pari.html vs. comments posted on Psychedelics Today, explaining why they withdrew support for MycoMeditations as of October, 2018. [cited 22/Jan 2020] Available at https://psychedelicstoday.com/2018/10/24/statement-on-mycomeditations/. Katherine MacLean, PhD, formerly associated with psychedelic research at Johns Hopkins and MycoMeditations, posted on the Psychedelics Today website: *"...[I was] happy to endorse and help Mycomeds at different points, but we've all slowly come to similar conclusions. I have previously endorsed Mycomeds through video, podcasts, my newsletter/website/, social media etc. without any compensation beyond being paid at a reasonable rate for working directly with guests during and after retreats. If someone hears my endorsement, and then gets hurt or worse, I can't live with that pain and responsibility. I still worry about people's safety but I've done what I can. I love many of the people working with Mycomeds and I hope that this public discussion can encourage some very easy and needed adjustments so that they can continue helping people safely and effectively...I think that some of us who have been trained to respect confidentiality and clinical ethics are torn between reporting the safety concerns and protecting the retreat guests rights to privacy. I can say very generally that I witnessed 1-2 (potential) medical emergencies on each of two retreats I helped facilitate, and at least 1 person on each retreat who had multiple incidents of extreme physical reaction to the mushrooms (several hours of vomiting and diarrhea). The other guests who were trained medical professionals were the ones who attended these situations, as there are no medical professionals on Mycomeds staff (no one with clinical psych training either), and the closest health facility is 45 minutes away on bad roads. Mycomeds also accepts applicants who are at extreme risk of harm, including people with physical and psychological conditions that would almost always be excluded from other remote psychedelic or meditation retreats,*

and certainly screened out of clinical trials. I believe they are doing this to try to "save" people who are really suffering, but it endangers the guest and everyone else. I became uncomfortable offering prep and integration support for people with extreme depression, anxiety, suicidality, substance dependence ... and voiced my concerns about taking on such serious and vulnerable cases. But they continued to accept such folks and were not interested in incorporating my safety feedback...I believe there was (is?) so much potential for Mycomeds to be a truly great community resource. I recorded the [initial] interview [for Psychedelics Today] with [hosts] Kyle and Joe when I returned from the first retreat last December [?2017?]. A lot of amazing stuff happened that retreat and really, only that 1 person had a really tough time (medically). I learned a lot in preparing for and leading the women's retreat a few months later [?April 2018?], but it was definitely a more serious and vulnerable cohort. I hoped everything could change and improve after that, because those women were fierce and gave important feedback." This and additional comments are available at: https://www.facebook.com/Psychedelicstoday/posts/620955214967939?__tn__=-R.

28. This was my experience in Jamaica and Peru.
29. *Ibid.* To my knowledge, there was no external testing or measuring of the potency of any substance offered at Jamaica or Peru. Everyone in Peru became nauseous (as expected). Some people in Jamaica became nauseous. At least one person at each locale did not experience any significant "effects."
30. To my knowledge, there were no credentialed health care providers on site or nearby during the retreats I attended in Jamaica and Peru
31. This was my experience in Jamaica and Peru.
32. This was my experience in Jamaica and Peru.
33. This was my experience in Jamaica.
34. This was my experience in Jamaica and Peru.
35. This was my experience in Jamaica and Peru.