

# The Perilous Policy of Oregon's Psilocybin Services

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Psilocybin and other psychedelic compounds have the potential to treat psychiatric disorders in a radically different manner than traditional psychopharmaceuticals.<sup>1</sup> Their ability to alter neural connectivity in the cortex and to transform an individual's conscious experience suggests that they might be able to disrupt well-worn brain circuits that contribute to symptoms of depression, anxiety, and addiction.<sup>2</sup> Psychedelics remain classified on Schedule I of the Controlled Substances Act,<sup>3</sup> however, which renders their manufacture and administration illegal under federal law.<sup>4</sup> Despite a growing body of evidence indicating that psilocybin may be useful in the treatment of certain psychiatric conditions, the research regarding its safety and efficacy in clinical populations remains limited.

The federal legislation governing psilocybin has not prevented jurisdictions in the United States from legalizing their administration locally. In 2020, Oregon became the first state in the country to decriminalize the manufacture, delivery, and administration of psilocybin at supervised, licensed facilities.<sup>5</sup> The development of Oregon's psilocybin services offers a glimpse into one state's plan to legalize the administration of an insufficiently researched, unpredictable, and risky compound via a faux-therapeutic model with limited consideration of potential harms. The role of the forensic psychiatrist in future psilocybin-related litigation promises to be extensive, including assessment and

testimony related to negligence and fitness for duty, among others. Here I review the course by which Oregon decriminalized and developed services related to psilocybin administration, delineate various flaws of the process and outcome, and describe the potential for forensic psychiatrists to participate in evaluating the probable negative outcomes of the legislation.

## The Development of Psilocybin Services

In 2019, the therapist couple Thomas and Sheri Eckert sponsored the Psilocybin Service Initiative to obtain the necessary signatures required for the legalization of psilocybin services to appear as a ballot measure in the November 2020 election. In interviews around that time, Mr. Eckert expressed a goal of providing access to psilocybin to various populations, ranging from those with severe mood disorders to the public.<sup>6–8</sup> The Eckerts filed a ballot initiative on July 2, 2019 and submitted the required 112,020 sponsorship signatures on July 16, 2019. Following approval of the signatures one year later, the state approved Ballot Measure 109 for the November 2020 election.<sup>9</sup> The Oregon Psychiatric Physicians Association and American Psychiatric Association opposed the measure, highlighting the lack of Phase III clinical trials of psilocybin and the potential dangers of allowing nonphysician providers to administer an experimental drug to patients with medical and psychiatric disorders.<sup>10,11</sup>

Despite these legitimate and reasonable concerns, Oregon voters passed Ballot Measure 109 with 55.75 percent of the electorate in favor of the legalization of psilocybin administration at supervised, licensed facilities

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in the state.<sup>12</sup> Once codified as law, the ballot measure became Oregon Revised Statutes Chapter (ORS) 475A.<sup>13</sup> ORS 475A mandated the establishment of the Oregon Psilocybin Advisory Board (OPAB), a panel of 14 to 16 members appointed by the Governor, to provide advice to the Oregon Health Authority regarding the roll-out of psilocybin services following a two-year development period. OPAB activities during the development period included staffing the OPAB and its subcommittees, creating a rules framework for psilocybin services, developing a method by which to approve psilocybin facilitator training programs, fielding public listening sessions, and generating educational materials for regulatory agencies and the public.<sup>14</sup> The Oregon Health Authority adopted an initial subset of rules related to psilocybin product testing and training programs in May of 2022 and the remainder of rules, now published as Oregon Administrative Rules (OAR) 333-333, on December 27, 2022.<sup>15</sup> Anticipating the launch of psilocybin services in 2023, the Oregon Health Authority is now accepting license applications for psilocybin facilitators, manufacturers, service centers, and laboratories.

OAR 333-333 is extensive and delineates the types of psilocybin products that can be produced; standards for manufacturing and testing psilocybin products; licensing procedures for manufacturers, testing labs, service centers, and facilitators; a client bill of rights; and requirements for preparatory and treatment sessions.<sup>16</sup> Legal products include dry whole fungi, mycelium, and homogenized fungi; psilocybin extract; and edible psilocybin-containing products derived from the species *Psilocybe cubensis*. The rules outline the basic requirements of psilocybin facilitator training programs, including a total of 120 hours of instruction on history (12 hours), cultural equity (12 hours), safety and ethics (12 hours), science (four hours), facilitation skills (16 hours), preparation and orientation (16 hours), administration (20 hours), integration (12 hours), and group facilitation (16 hours), as well as 40 hours of practicum training at a psilocybin service center.<sup>17</sup> Psilocybin facilitator applicants must complete an approved training program and obtain a score of 75 percent on an examination to pass.<sup>18</sup> Though the rules do not list the minimum educational or training requirements to apply to be a facilitator, the Psilocybin Facilitator License Application Guide indicates that one must be 21 years old and have a high school diploma or its equivalent.<sup>19</sup> Despite these minimal requirements, facilitators are expected to

“utilize their training to distinguish between typical side effects of consuming psilocybin and medical emergencies.”<sup>20</sup> In addition, though facilitators are not allowed to “engage in any conduct that requires additional professional licensure while providing psilocybin services to clients, including but not limited to diagnosing and treating physical or mental health conditions,”<sup>21</sup> they are also expected to “determine whether they are able to provide psilocybin services to a client.”<sup>20</sup> Facilitators must also review an informed consent document with each client. The client must initial next to 30 statements, which include the following:

2. \_\_\_\_ *I understand that psilocybin services do not require medical diagnosis or referral and that psilocybin services are not a medical or clinical treatment.*
- ...
4. \_\_\_\_ *I understand that the risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary.*
5. \_\_\_\_ *I understand that some people have found psilocybin administration sessions to be challenging or uncomfortable. Common potential side effects include nausea, mild headache, fatigue, anxiety, confusion, increased blood pressure, elevated heart rate, paranoia, perceptual changes, altered thought patterns, reduced inhibitions, recovery of repressed memories and past traumas, and altered perception of time and one’s surroundings. If they occur, these side effects are usually mild and temporary. Because the potential risks and benefits of psilocybin administration are not fully understood, there may be unanticipated side effects* (Ref. 22, italics in original).

An individual in Oregon wishing to obtain psilocybin must go to a psilocybin service center and participate in a preparation session with a facilitator between one and 90 days prior to receiving psilocybin. Preparation sessions include a review of the informed consent document, the client Bill of Rights, and information regarding the product intended for administration.<sup>23</sup> The facilitator is also supposed to discuss the client’s willingness to receive “supportive touch” during the administration session, intention and expectations, and medical and psychiatric history. The only exclusionary criteria to receiving psilocybin are a positive response to whether or not the client has taken lithium in the last 30 days, if the client has thoughts or desire to self-harm, or if the client has a history of a diagnosis or treatment of “active psychosis.”<sup>24</sup> During the administration session, the client purchases the psilocybin product from a representative of the service center, consumes up to 50 milligrams of psilocybin by self-dosing, then sits with the facilitator for anywhere from one to six hours, depending on the dose of psilocybin consumed.<sup>25</sup> The facilitator

then offers the client the opportunity to participate in one or more integration sessions using a “nondirective facilitation approach.”<sup>26</sup>

### Perilous Policy

ORS 475A and OAR 333-333 are rife with flaws, starting with the alleged aim of the legislation. The statute opens with a set of legislative findings to justify psilocybin services, including the following:

The People of the State of Oregon find that:

- (1) Oregon has the one of the highest prevalence [sic] of mental illness among adults in the nation;
- (2) An estimated one in every five adults in Oregon is coping with a mental health condition;
- (3) The Governor has declared addiction as a public health crisis in this state;
- ...
- (5) Studies conducted by nationally and internationally recognized medical institutions indicate that psilocybin has shown efficacy, tolerability, and safety in the treatment of a variety of mental health conditions, including but not limited to addiction, depression, anxiety disorders, and end-of-life psychological distress;
- (6) The United States Food and Drug Administration has:
  - (a) Determined that preliminary clinical evidence indicates that psilocybin may demonstrate substantial improvement over available therapies for treatment-resistant depression; and
  - (b) Granted a Breakthrough Therapy designation for a treatment that uses psilocybin as a therapy for such depression . . .<sup>27</sup>

The legislative findings documented above suggest that the state's rationale for legalizing psilocybin administration was to combat its mental health and addiction crises. For many reasons, currently available research does not support such reasoning. First, data do not yet support the use of psilocybin for the treatment of psychiatric conditions. In 2020, a review of the research of psychedelics and psychedelic-assisted psychotherapy found insufficient evidence to warrant Food and Drug Administration approval of any psychedelic for the treatment of mental health conditions.<sup>28</sup> More recently, a meta-analysis of nine articles published within the last ten years assessing the effect of psilocybin on various psychiatric disorders found evidence of improvement in various self-report symptom measures, such as the GRID-Hamilton Depression Rating Scale (GRID-HAMD) and the 16-item Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR16).<sup>29</sup> Because of the studies' heterogeneity,

however, the authors noted that the insufficient body of research on psilocybin renders it “difficult to endorse the prescription of psilocybin in the treatment of psychiatric conditions” (Ref. 29, p 15) and emphasized the lack of research on the efficacy and safety of psilocybin in the treatment of mental disorders. ORS 475A's assessment of the state of the research on psilocybin is at the least a misleading overstatement, if not an outright fabrication.

Taking ORS 475A at its word, individuals with psychiatric disorders contributing to the mental health and addiction crises appear to be the targets of psilocybin services. The subjects of clinical trials assessing psilocybin in psychiatric disorders are not representative of clinical psychiatric populations, however, so there is no reason to believe that psilocybin services will help those with significant mental health needs in Oregon. Johns Hopkins University, a major contributor to the rebirth of psychedelic research, excludes from its studies individuals with a history of psychotic and bipolar disorders, as well as individuals with first- and second-degree relatives with such conditions.<sup>30</sup> Other researchers have used more extensive exclusionary criteria. A recent study that found that a two-dose course of psilocybin was as effective as escitalopram in moderate to severe depression excluded individuals with a history of psychosis, suicide attempts, and any suspected or diagnosed condition that “could jeopardize rapport between the patient and their two mental health caregivers within the trial” (Ref. 31, p 1403).

Research on psilocybin and addiction is similarly highly exclusionary. A recent trial that showed a decrease in the percentage of heavy drinking days in patients with alcohol dependence following two psilocybin sessions excluded subjects with any “major psychiatric and drug use disorders.”<sup>32</sup> The findings from these studies, though promising, are not generalizable to clinical psychiatric populations, so it is unreasonable to expect psilocybin to have an effect on Oregon's mental health and addiction crises. Furthermore, OAR 333-333 indicates that psilocybin facilitators are not allowed to diagnose individuals and do not require a psychiatric referral before administering psilocybin, so individuals who have never been represented in psilocybin research will likely begin to receive the drug in Oregon.

Not only has research failed to support the administration of psilocybin to clinical psychiatric populations for the treatment of psychiatric conditions, but

also OAR 333-333 will likely place vulnerable populations at risk of negative outcomes. The indications for psilocybin and psilocybin-assisted therapy have not been established, nor have the risks posed to various patient populations. In a recent podcast interview with Sam Harris, psychiatrist and leading psychedelic researcher Roland Griffiths described how patients in his clinical trials have developed mania following psilocybin-assisted psychotherapy sessions and expressed ongoing concern about the risk of *de novo* psychotic disorders resulting from treatment.<sup>33</sup> There is some research support for Dr. Griffiths' worries. A recent survey of more than 500 individuals self-reporting bipolar I and bipolar II diagnoses found that 32.2 percent ( $n = 174$ ) described unwanted outcomes during or within 14 days of a "full psychedelic trip" from psilocybin, including new or increasing manic symptoms (14.2%,  $n = 77$ ), sleep disruption (10.4%,  $n = 56$ ), anxiety symptoms (9.4%,  $n = 51$ ), and depressive symptoms (8.9%,  $n = 48$ ).<sup>34</sup> Eighteen or 3.3 percent of subjects had to use emergency services during or within 14 days of the psilocybin use. As noted above, because psilocybin facilitators in Oregon are not able to diagnose psychiatric disorders and do not require any mental health training, they will not be able to screen out patients with psychiatric disorders that pose a risk of negative outcomes and, in research contexts, would preclude participation.

ORS 475A's legislative findings provide a veneer of psychiatric justification for psilocybin services. As delineated above, this purported rationale does not hold up to scientific scrutiny. The allusion made by activists and policymakers to Oregon's mental health crisis in Ballot Measure 109 and ORS 475A was not just misguided, but dishonest and cynical. They suggested that psilocybin will alleviate Oregon's mental health and addiction crises without any supportive evidence. Despite allegedly operating under this intention, the OPAB (on which Eckert served as chair until his relationship with the CEO of a Dutch psychedelic company came to light)<sup>35</sup> mandated the use of a disclaimer-heavy informed consent document that requires facilitators to tell clients that psilocybin is "not a medical or clinical treatment."<sup>22</sup> If psilocybin is not a medical or clinical treatment, then it cannot reasonably be proposed that it will treat the patients with psychiatric and substance use disorders that constitute the state's mental health and addiction crises.

Perhaps the truth is that psilocybin services were never meant to address Oregon's mental health crisis.

The results of Ballot Measure 109, delineated thoroughly in OAR 333-333, represent legalization of recreational psilocybin administration under a contrived regulatory framework that lacks consideration of the potential harm to clients. At a minimum, OPAB should have established a process by which to provide medically monitored psilocybin-assisted psychotherapy. Instead, clients in Oregon can obtain a consciousness-altering drug from a high school graduate with no mental health training or experience and without psychiatric or general medical referral or prescription. The facilitator will inform the client that, even though psilocybin has more profound effects than any currently available psychotropic medication, it is not a medical treatment. Finally, the facilitator will describe a litany of potential medical and psychiatric side effects of psilocybin that one cannot reasonably expect somebody without medical training to identify or manage. After all, the 120-hour course required for licensure represents approximately 25 percent of the 625 hours of education and training that the state requires for someone applying for a massage therapist license.<sup>36</sup> If OPAB intended to establish a safe, rational process by which to offer psilocybin-assisted psychotherapy to clients in Oregon, then its members failed. Perhaps the real goal was to legalize recreational psilocybin administration under a faux-therapeutic guise.

### Forensic Forecast

For many reasons, it may have been better for Oregon to legalize recreational psilocybin outright, as the legal repercussions from its model will likely be extensive. Had the state legalized the recreational sale of psilocybin, sellers may have had limited liability for the outcomes of individuals consuming the product. Because the state has imposed the requirement of an administration session overseen by an inadequately trained facilitator with a pseudo-professional license at a designated service center, however, there will now be licensed individuals and facilities responsible for the negative outcomes that result.

Elsewhere I have described the various civil legal risks facing psychiatrists who incorporate psychedelics into their clinical practice, such as malpractice related to a lack of standards of care and the potential for inappropriate treatment with negative results.<sup>37</sup> In Oregon, however, there is no medical oversight to psilocybin services, which makes the potential for facilitators to be found negligent in their care more nebulous. OAR 333-333 indicates that facilitators "have a duty to put



clients' interest above their own and to use a standard of care that other reasonable facilitators would use under similar circumstances."<sup>20</sup> Nowhere does the state define the standards of care for psilocybin facilitation. This is not surprising. Had the state legalized psilocybin-assisted psychotherapy, then there would have been research and other publications from which to develop some standards of care for the "reasonable facilitator." Instead, the state created a new licensure pathway and explicitly barred facilitators with medical licenses or licenses in mental health fields like psychology or social work from "exercis[ing] the privileges of that license while providing services to clients."<sup>21</sup> In doing so, the state further obfuscated the ethical and practical obligations of psilocybin facilitators.

As there are no standards of care for Oregon's model of psilocybin administration, facilitators may reasonably face allegations of negligence if they fail to meet the expectations and requirements delineated in OAR 333-333. Clients face serious risk of medical and psychiatric harm if inadequately screened for psilocybin services. It is unclear how facilitators with no medical or mental health training or experience are supposed to assess clients' psychiatric history, including their history of psychiatric diagnosis and treatment. The list of yes-or-no screening questions described in OAR 333-333 is insufficient. A client with schizophrenia who has been stable on antipsychotic treatment for years could purposely or unintentionally obfuscate this history by responding "no" regarding a history of "active psychosis" and subsequently experience a relapse of psychotic symptoms during the psilocybin administration session. Should the patient require transfer to an emergency department or inpatient psychiatric hospitalization, the facilitator may have been negligent in failing to obtain the client's past psychiatric records. Perhaps a facilitator, lacking any understanding of psychotropic medications, accidentally allows a patient on various serotonergic agents for depression to receive psilocybin. If the client develops serotonin syndrome and dies, the facilitator may be negligent for failing to obtain the client's medication list and taking steps to mitigate the client's risk of interactions with psilocybin, not that anybody should reasonably expect a high school graduate to be able to perform such a task.

Even if a facilitator appropriately and adequately screens a client, situations may arise during a psilocybin session that require the facilitator to intervene in a

manner that conflicts with the expectations outlined in OAR 333-333. Clients may become agitated or aggressive while intoxicated with psilocybin,<sup>38</sup> a risk enhanced by their ability to administer the drug at self-determined, inappropriately high doses. OAR 333-333 only allows for "supportive touch," or touch "limited to hugs or placing hands on the client's hands, feet or shoulders" during the administration session.<sup>20</sup> I have recommended that all psychedelic treatment be medically monitored in case a patient requires a sedative or restraint beyond supportive touch.<sup>39</sup> In Oregon, however, facilitators will be unable to prevent clients from physical aggression directed toward the facilitator or anyone else, from entering other clients' treatment areas, or from leaving the service center. Because clients are only capable of consenting to supportive touch during administration sessions, any more forceful restraint or touch would violate OAR 333-333 and could potentially lead to a civil claim of battery.

One reason to restrict psilocybin facilitation to psychiatrists and other mental health professionals in the context of psilocybin-assisted psychotherapy is that such individuals hold licenses that require commitment to professional codes of ethics and conduct. Although OAR 333-333 prohibits facilitators from engaging in romantic relationships or sexual contact with clients and clients' relatives for one year following the provision of psilocybin services, facilitators will likely lack sufficient training and experience related to working with individuals in vulnerable, suggestible, and otherwise altered states of mind. They may fail to know how to manage powerful countertransference reactions toward clients and develop inappropriate relationships with them. Such cases could result in violations of OAR 333-333 and allegations of sexual battery. Even more concerning is the risk that the minimal requirements to become a psilocybin facilitator will attract grifters, wannabe gurus, narcissists, and psychopaths motivated to exercise control over clients in highly suggestible states. A recent podcast series described numerous instances of inappropriate sexual and physical contact between well-known psychedelic therapists and their clients, even in the context of clinical trials sponsored by the Multidisciplinary Association for Psychedelic Studies.<sup>40</sup> The risks posed by the inadequately trained and educated therapists in Oregon will be even greater. Fitness for duty evaluations of psilocybin facilitators who

engage in inappropriate relationships with clients may result.

Forensic psychiatrists interested in conducting evaluations related to the negative outcomes of Oregon’s psilocybin services will require extensive knowledge of psilocybin and Oregon’s legal and administrative framework. At a baseline, psychiatrists should understand psilocybin’s effects, risks, and the evolving research of its potential indications and psychiatric, medical, and pharmacologic contraindications. Assessing allegations of negligence in psilocybin administration requires a further understanding of the model of psilocybin services delineated in OAR 333-333 and the differences between Oregon’s psilocybin services and the model of psilocybin-assisted psychotherapy as described in research and other contexts, as aspects of OAR 333-333 fall below the expected clinical standards described elsewhere. Evaluating a psilocybin facilitator’s fitness for duty involves an awareness of the duties of psilocybin facilitators, as well as a recognition that Oregon’s model does not utilize trained psychotherapists or medical monitoring despite requiring facilitators to have specialized medical knowledge and skills. Cases stemming from Oregon’s psilocybin services promise to be complex, given the inadequacy of Oregon’s administrative rules and the evolving research into psilocybin as a psychopharmacologic treatment, and forensic psychiatrists may be best suited to identify the associated risks and pitfalls.

**Conclusion**

Though overhyped and insufficiently researched, psychedelics will likely play a role in psychiatric treatment in the future. By passing Ballot Measure 109, however, Oregon voters legalized the administration of a consciousness-altering agent to virtually all comers. OAR 333-333 allows facilitators and service center personnel to provide psilocybin to clients who lack any treatment indication, medical or psychiatric clearance, or even a prescription. OPAB has hamstrung psilocybin facilitators with unreasonable expectations of medical knowledge and skills despite minimal education and training requirements. It is highly probable that negative outcomes will result from Oregon’s misguided policy. Given the lack of research on the safety and efficacy of psilocybin in clinical populations, not to mention the general public, lawsuits will likely drive the establishment of standards of care for psilocybin facilitation, rather than science.

Forensic psychiatrists should play a role in assessing the results of psilocybin services gone wrong and help to redirect psilocybin services in a more rational, reasonable direction.

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