# **ESSAY**

# IN SEARCH OF: A FEDERAL SAFE HARBOR FOR STATE LEGALIZATION OF PSILOCYBIN

by

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In 2020, Oregon voters passed the Oregon Psilocybin Services Act (PSA). The PSA allows for the adult use of psilocybin at designated service centers and does not require a medicinal purpose for consumption. While the use of psilocybin

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becomes legal in Oregon in 2023 under the PSA, psilocybin remains a Schedule I substance under the federal Controlled Substances Act. This conflict between state legalization and federal prohibition creates significant challenges for individuals and businesses intending to abide by the requirements of the PSA—including the potential of jail time, fines, and forfeiture of property. This Essay explores three potential solutions the federal government might explore, akin to those utilized in the context of cannabis, that would create a safe harbor for state legalization of psilocybin in the midst of conflicting federal law.

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#### INTRODUCTION

Recent medical research is establishing the powerful therapeutic uses of psilocybin in the treatment of a variety of mental health conditions. Studies show that patients with advanced cancer suffering from treatment-resistant anxiety and/or depression experience significant reductions in both anxiety and depression following a single, guided treatment with psilocybin, with no safety concerns or clinically significant adverse events.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Charles S. Grob, Alicia L. Danforth, Gurpreet S. Chopra, Marycie Hagerty, Charles R. McKay, Adam L. Halberstadt & George R. Greer, Pilot Study of Psilocybin Treatment for Anxiety in Patients with Advanced-Stage Cancer, 68 ARCHIVES GEN. PSYCHIATRY 71, 76 (2011); Roland R. Griffiths, Matthew W. Johnson, Michael A. Carducci, Annie Umbricht, William A. Richards, Brian D. Richards, Mary P. Cosimano & Margaret A. Klinedinst, Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial, 30 J. PSYCHOPHARMACOLOGY 1181, 1195 (2016); Matthew W. Johnson & Roland R. Griffiths, Potential Therapeutic Effects of Psilocybin, 14 NEUROTHERAPEUTICS 734, 735, 738 (2017); Stephen Ross, Therapeutic Use of Classic Psychedelics to Treat Cancer-Related Psychiatric Distress, 30 INT'L REV. PSYCHIATRY 317, 327 (2018); see also Tara C. Malone, Sarah E. Mennenga, Jeffrey Guss, Samantha K. Podrebarac, Lindsey T. Owens, Anthony P. Bossis, Alexander B. Belser, Gabrielle Agin-Liebes, Michael P. Bogenschutz & Stephen Ross, Individual Experiences in Four Cancer Patients Following Psilocybin-Assisted Psychotherapy, 9 FRONTIERS PHARMACOLOGY, Apr. 3, 2018, at 5, doi:10.3389/fphar.2018.00256. See generally Lauren Slater, How Psychedelic Drugs Can Help Patients Face Death, N.Y. TIMES MAG. (Apr. 20, 2012), https://www.nytimes.com/2012/04/22/magazine/how-psychedelic-drugs-canhelp-patients-face-death.html.

The therapeutic use of psilocybin may be an effective treatment for cluster headaches; alcohol, drug, and nicotine addiction and withdrawal; obsessive-compulsive disorder; inflammatory disease; dementia; and certain eating disorders.<sup>2</sup>

Despite the clear promise of psilocybin to relieve a variety of health conditions, it is not available outside the research setting. Psilocybin is classified as a Schedule I drug regulated by the federal Controlled Substances Act (CSA) and is considered to have no legitimate medical use.<sup>3</sup> Accordingly, it cannot be prescribed by a physician

<sup>&</sup>lt;sup>2</sup> See Katherine Ellison, A New Treatment May Halt Cluster Headaches. But Some Say Psychedelic Drugs Are the Real Answer, WASH. POST (Apr. 3, 2021, 10:00 AM), https://www.washingtonpost.com/health/cluster-headaches/2021/04/02/66ac73f0-8cdc-11eb-9423-04079921c915\_story.html; Martin Andersson, Mari Persson & Anette Kjellgren, Psychoactive Substances as a Last Resort—A Qualitative Study of Self-Treatment of Migraine and Cluster Headaches, HARM REDUCTION J. 14:60, 64–65 (Sept. 5, 2017), https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0186-6; Gigen Mammoser, Mushrooms as Medicine? Psychedelics May Be Next Breakthrough Treatment, HEALTHLINE (Feb. 12, 2019), https://www.healthline.com/health-news/benefits-of-medical-mushrooms; Emily Jarvie, This New Company Believes Psychedelics Can Treat Dementia, PSYCHEDELIC SPOTLIGHT (Oct. 15, 2021), https://psychedelicspotlight.com/return-health-launches-to-treat-dementia-with-psychedelics/; Sarah-Catherine Rodan, Phillip Aouad, Iain S. McGregor & Sarah Maguire, Psilocybin as a Novel Pharmacotherapy for Treatment-Refractory Anorexia Nervosa, 5 OBM NEUROBIOLOGY (SPECIAL ISSUE), June 24, 2021, at 7–8, 15–16, doi:10.21926/obm.neurobiol. 2102102.

<sup>&</sup>lt;sup>3</sup> Controlled Substances Act, 21 U.S.C. § 812(c); Drug Enf't Admin., Drug Fact Sheet: PSILOCYBIN 2 (2020), https://www.dea.gov/sites/default/files/2020-06/Psilocybin-2020\_0.pdf. A petition to reschedule psilocybin from Schedule I to Schedule II was filed with the Drug Enforcement Agency (DEA) on February 2, 2022, by Petitioners Dr. Sunil Aggarwal and the Advanced Integrative Medical Science (AIMS) Institute based in Seattle WA. The DEA denied said petition on September 23, 2022, stating that the Food and Drug Administration had not articulated any acceptable medical use for psilocybin. The denial is being appealed in the Ninth Circuit. Authors Kathryn L. Tucker and Holly Martinez are two of the attorneys representing Petitioners in that appeal. See Sam Reisman, Physician Renews Bid to Reschedule Psilocybin in 9th Circ., LAW360 (Oct. 20, 2022), https://www.law360.com/articles/1541981. Rescheduling is a goal of the ongoing research efforts, and the main avenue to legalization. However, rescheduling is often a long, difficult process. See, e.g., Joseph Hartunian, Getting Back on Schedule: Fixing the Controlled Substances Act, 12 ALBANY GOV'T L. REV. 199, 200, 207, 211-12 (2019) ("[D]etermining the schedule of a substance has become a bureaucratic mess that leads to federal agency slow walking and delayed scheduling and rescheduling. . . . Since the CSA was enacted into law in 1970, just thirteen substances have been removed from Schedule I into a less regulated classification, and only two since 1990."). See also Mason Marks, Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 69, 116 (2018) (noting that the DEA changes its categorization of Schedule I substances relatively infrequently, moving a substance from Schedule I to Schedule II only five times in over 40 years).

and is not legally accessible to those who might benefit from it as a therapeutic treatment.<sup>4</sup>

Psilocybin is listed in a group of 17 hallucinogenic substances on Schedule I—the most strictly regulated category reserved for drugs deemed to have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety." The CSA provides that "[i]t shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly... from a practitioner...." Simple possession of a controlled substance under the CSA carries a maximum prison sentence of one year. Harsher penalties attach to manufacturing or distributing a Schedule I drug without authorization, including a possible 20-year prison sentence. In addition to incarceration, violations of the CSA can result in hefty fines and property forfeiture.

The ongoing conflict embroiling safe injection sites exemplifies the risk of various penalties that can arise with violations of the CSA.<sup>10</sup> The federal "Crack House" statute makes it a crime punishable by up to 20 years in prison to "make property available to others 'for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance." "Because safe injection site clients would be at the property for the purpose of using illegal drugs, facility operators—including employees—would almost certainly be susceptible to charges for maintaining

<sup>&</sup>lt;sup>4</sup> For an overview of the history of psilocybin research and regulation, see Kathryn L. Tucker, *Oregon's Pioneering State Law to Allow Access to Psilocybin, a New Palliative Care Tool for Patients Suffering Anxiety and Depression*, 57 Willamette L. Rev. 13, 16–22 (2020). *See generally* Michael Pollan, How to Change Your Mind: What the New Science of Psychedelics Teaches Us About Consciousness, Dying, Addiction, Depression, and Transcendence (2018).

<sup>&</sup>lt;sup>5</sup> OFF. OF DIVERSION CONTROL, U.S. DRUG ENF'T ADMIN., PRACTITIONER'S MANUAL 5 (2006); *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/drug-scheduling (last visited Dec. 30, 2022).

<sup>6 21</sup> U.S.C. § 844(a).

<sup>&</sup>lt;sup>7</sup> *Id*.

<sup>&</sup>lt;sup>8</sup> See Brian T. Yeh, Cong. Rsch. Serv., RL30722, Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws 1–3 (2015).

<sup>&</sup>lt;sup>9</sup> See, e.g., 21 U.S.C. § 853(a); 21 U.S.C. § 848(a).

<sup>&</sup>lt;sup>10</sup> Safe injection sites offer a venue for individuals to safely use illegal drugs under the supervision of trained professionals. They are a harm reduction measure, aimed at allowing people to use drugs safely, which is especially pertinent when considering the recent uptick in overdose deaths across the United States due to fentanyl. *See* Alex Kreit, *Safe Injection Sites and the Federal "Crack House" Statute*, 60 B.C. L. REV. 413, 416 (2019).

<sup>11</sup> Id. at 417 (quoting 21 U.S.C. § 856(a)(1) (2012)).

drug-involved premises." This is relevant when considering a federal safe harbor measure adequate to protect the implementation of the Oregon Psilocybin Services Act (PSA),13 discussed further infra, because the PSA requires psilocybin-assisted therapy to be administrated in a designated and approved "psilocybin service center."14 Guidelines for the operation of a psilocybin service center under the PSA specifically distinguish medicinal administration in a number of ways—no diagnoses are allowed, no therapizing is allowed, and there are to be no follow-up plans made in conjunction with treatment. 15 While this seeks to address a much more liberal take on psilocybin usage, it is captured in the broad prohibition language that the federal crack house statute seeks to address with no meaningful recourse. Therefore, since consumers would be at a psilocybin service center for the purpose of using psilocybin—currently a Schedule I drug—in a manner that has no medicinal nexus in its authorization for use, facilitators, operators, and employees of such service centers would also all be at risk of being charged for maintaining drug-involved premises under the federal "Crack House" statute and could face harsh penalties under federal law.

In addition to possible federal criminal exposure, another source of risk is the possible restriction or revocation of medical practitioners' Drug Enforcement Agency (DEA) registrations, should they choose to offer treatment using psilocybin, in violation of the CSA. The DEA's registration process for practitioners allows them to utilize controlled substances subject to regulation; however, there is no registration for the therapeutic use of a Schedule I substance. <sup>16</sup> Registration does not consider the nuance of state permissibility.

Given the barriers to federal reform, advocates have turned to state and local governments to expand access to psilocybin and other psychedelic treatments. Oregon is among the states leading the charge. In the fall of 2020, voters in Oregon passed the first state measure to legalize psilocybin therapy, beginning in 2023.<sup>17</sup>

<sup>12</sup> *Id.* at 417–18; *see* United States v. Safehouse, 985 F.3d. 225, 232 (3rd Cir.) (finding operation of a safe site in violation of the CSA), *reh'g en banc denied*, 991 F.3d 503 (2021), *cert denied*, 142 S.Ct. 345 (2021). "To break the law, Safehouse need only 'knowingly and intentionally' open its site to visitors who come 'for the purpose of . . . using' drugs. The text of the statute focuses on the third party's purpose, not the defendant's. Even if we read paragraph (a)(2) as Safehouse does, its purpose is that the visitors use drugs. That is enough to violate paragraph (a)(2). . . . Under \$856(a)(2), the defendant must knowingly and deliberately let another person use his property for drug activity." *Id.* at 232.

<sup>&</sup>lt;sup>13</sup> Oregon Psilocybin Services Act, 2021 Or. Laws ch. 1, §§ 3–129 (Ballot Measure 109) (codified at Or. Rev. Stat. §§ 475A.210–722 (2022)).

<sup>&</sup>quot;Psilocybin service center' means an establishment: (a) At which administration sessions are held; and (b) At which other psilocybin services may be provided." *Id.*  $\S$  5(13).

<sup>&</sup>lt;sup>15</sup> *Id.* §§ 5(16), 26(1)(b) ("A psilocybin service center is not a health care facility.").

<sup>&</sup>lt;sup>16</sup> OFF. OF DIVERSION CONTROL, *supra* note 5.

Oregon Psilocybin Services Act § 13.

The tension between state and federal law poses some obvious challenges for reformers, even if they comply strictly with the state's regulations.

Springboarding off a seminal article by Chemerinsky et al., <sup>18</sup> this Essay discusses three possible options to provide those acting in compliance with Oregon's law with some form of safe harbor under federal law if psilocybin remains on Schedule I, <sup>19</sup> including:

- adoption of policy by the U.S. Department of Justice (DOJ) to refrain from enforcing federal law in light of Oregon's law to permit and regulate the manufacture, distribution, and therapeutic use of psilocybin;
- a revocable waiver issued by the DEA from the CSA's psilocybin provisions; and,
- a congressional amendment of the CSA to allow states to opt out of the CSA's psilocybin provisions.<sup>20</sup>

## I. OREGON'S PIONEERING LAW

The majority of criminal law in the United States is established by the states, which hold police powers to regulate for the general welfare of their citizens. Accordingly, state governments are the entities that decide what substances are considered illegal for the purposes of the most common drug enforcement actions. <sup>21</sup> Every state has its own version of the federal CSA; however, states differ in the specifics of scheduling and criminal penalties. For instance, some states use categorical descriptors (e.g., Hawaii uses the terms "dangerous," "harmful," and "detrimental" drugs<sup>22</sup>), while others separate cannabis from other Schedule I drugs to accommodate less severe penalties.<sup>23</sup> Additionally, some states deviate from federal law by

<sup>&</sup>lt;sup>18</sup> Erwin Chemerinsky, Jolene Forman, Allen Hopper & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74 (2015).

<sup>&</sup>lt;sup>19</sup> Rescheduling of psilocybin off Schedule I would be the most effective way to enable access to the drug. There is ample reason to view psilocybin as improperly included on Schedule I, as detailed in the rescheduling petition. *See* Ben Adlin, *Seattle Doctor Files DEA Petition to Reschedule Pscilocybin for Medical Use*, Marijuana Moment (Feb. 4, 2022), https://www.marijuanamoment.net/seattle-doctor-files-dea-petition-to-reschedule-psilocybin-for-medical-use/. Recent petitions to reschedule psilocybin from Schedule I to Schedule II would have major implications for the PSA if successful. *See* Reisman, *supra* note 3.

<sup>&</sup>lt;sup>20</sup> These options are discussed in Chemerinsky et al., *supra* note 18, in the context of cannabis.

<sup>&</sup>lt;sup>21</sup> For a thorough analysis of the differences in state and federal laws and law enforcement for drugs, see generally *id*.

<sup>&</sup>lt;sup>22</sup> HAW. REV. STAT. § 712-1240.

<sup>&</sup>lt;sup>23</sup> Oregon reclassified marijuana from Schedule I to Schedule II. *See* S.B. 728, 75th Leg. Assemb., Reg. Sess. (Or. 2009), 2009 Or. Laws ch. 898, § 2 (codified as Or. Rev. Stat. § 475.059), *repealed by* Amendments to the Control and Regulation of Marijuana Act, 2017 Or. Laws ch. 21, §§ 1–129; Or. Admin. R. 855-080-022 (2017). Michigan classifies "marihuana" as

adding a crime separate from possession known as a "use provision," which criminalizes using or "be[ing] under the influence of controlled substance[s]."<sup>24</sup>

With respect to psilocybin, most states' categorization mirrors that of the federal government—production and distribution of psilocybin can carry heavy fines and significant jail time. In 2017, Oregon dramatically reduced penalties for the possession of psychedelics, including psilocybin. First-time possession of small amounts was downgraded from a Class B felony, which carried a maximum potential penalty of ten years in prison, to a Class A misdemeanor with a maximum penalty of one year in prison. Later, in 2020, Oregon became the first state in the country to decriminalize the personal possession of all illegal drugs, including psilocybin. Cooking the prison of the prison of the prison of the personal possession of all illegal drugs, including psilocybin.

Most notably, also in 2020, Oregon adopted, via citizen initiative, Measure 109, the Oregon Psilocybin Services Act (PSA). This law makes use of psilocybin in a supervised setting legal under Oregon state law.<sup>27</sup> The PSA is heavily regulated and

- a Schedule I drug though it is deemed "a schedule 2 controlled substance if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with this act and as authorized by federal authority." MICH. COMP. LAWS § 333.7212(1)–(2) (2022). Michigan legalized medical marijuana in 2008. See generally MICH. COMP. LAWS §§ 333.26423, .26424(4)(j), .26426(6) (2022) (effective Dec. 4, 2008). Furthermore, many states have successfully carved out protections for medical marijuana without addressing or changing the schedule of marijuana under state law. These include Montana, Nevada, New Mexico, and Washington. See H.B. 701, 67th Leg. Assemb., Reg. Sess. § 3 (MONT. 2021); NEV. REV. STAT. § 453.096 (2022); H.B. 356, 54th Leg. Assemb., First Sess. § 2 (N.M. 2019); WA. INITIATIVE MEASURE 502 § 1 (2012).
- <sup>24</sup> See Nat'l Crim. Just. Ass'n with U.S. Dep't of Just. Bureau of Just. Assistance, A Guide to State Controlled Substances Acts 8 (rev. ed. Jan. 1999).
- <sup>25</sup> H.B. 2355, 79th Legis. Assemb., Reg. Sess. § 9(3)(a) (Or. 2017). California's Proposition 47, passed in 2014, had a similar impact on drug possession law. *See Proposition 47: The Safe Neighborhoods and Schools Act*, CAL. CTS., https://www.courts.ca.gov/prop47.htm (last visited Jan. 9, 2022).
- Measure 110 was passed in November 2020. *See* Drug Addiction Treatment and Recovery Act, 2021 Or. Laws ch. 2, §§ 1–26 (Ballot Measure 110) (codified at Or. Rev. STAT. § 430.383 (2022)).
- Oregon Psilocybin Services Act, 2021 Or. Laws ch. 1, § 33 (Ballot Measure 109) (codified at Or. Rev. STAT. §§ 475A.210–722 (2022)). The Measure makes explicit that it does not "exempt a person from a federal law or obstruct the enforcement of a federal law." *Id.* § 4(7). This recognition is implicit in § 63. *See id.* § 63 ("this 2020 Act serves the purpose of exempting the person that holds the license from the criminal laws *of this state* for possession, delivery or manufacture of psilocybin products, provided that the person complies with all state laws . . . .") (emphasis added). Since the passage of Oregon's PSA, other states have proposed similar measures. *See, e.g.*, Eric Wilkinson, *Bill to Legalize Psilocybin for Therapeutic Use Introduced in Washington*, KING 5 NEWS (Jan. 24, 2022, 5:39 PM), https://www.king5.com/article/news/politics/state-politics/psilocybin-magic-mushrooms-legalization-bill-introduced/281-3849f67f-0695-483b-8353-6b2d09afce2d.

establishes a two-year "program development period" for the Oregon Health Authority (OHA), advised by a Psilocybin Advisory Board established within the OHA, to develop and adopt regulations governing the manufacture, transportation, delivery, sale, and purchase of "psilocybin products" and the provision of "psilocybin services." Administration of psilocybin must take place with a trained and licensed psilocybin "facilitator" at a licensed "psilocybin service center" and must consist of a preparation session and an administration session. An "integration session" must also be offered but is not mandatory. Assuming all requirements are met, licensees "are exempt from the criminal laws of [Oregon] for possession, delivery or manufacture of psilocybin, aiding and abetting another in the possession, delivery or manufacture of psilocybin, or any other criminal offense," which involves the possession, delivery, or manufacture of psilocybin.

Despite Oregon's enactment of the PSA, psilocybin remains illegal under federal law unless rescheduled.<sup>32</sup> The core of the friction between the federal government and states in this battle is the ever-looming shadow of Congress's powers under the commerce clause. Coupled with federal regulation of a significant portion of the mechanisms needed to legitimize a business today, the only feasible guarantee is a federal legislative amendment, safe harbor, or jurisprudence. Given the lack of bipartisanship in Washington, D.C., and the politicization of the Supreme Court of the United States, it would be more feasible to advocate for some safe harbor to

<sup>&</sup>lt;sup>28</sup> Oregon Psilocybin Services Act § 5(12)(a)–(b), (17).

<sup>&</sup>lt;sup>29</sup> *Id.* § 36. The restriction of delivery of psilocybin services to a service center may present a disability rights issue for those who have physical disability and/or are disabled due to advanced illness, making visiting a service center impossible under federal disability law. 42 U.S.C. § 12132. Delivery of psilocybin services may require reasonable modification of the law to allow services at a location other than a service center, for example, in the patient's home.

Oregon Psilocybin Services Act § 37(1). Interestingly, the psilocybin service facilitator need not hold a degree from a university, college, post-secondary institution, or other institution of higher education. See id. § 30(3). Also interesting is the fact that the PSA does not restrict psilocybin therapy to those with a medical diagnosis. It is to be available for "all persons 21 years of age and older . . . for whom psilocybin may be appropriate." See id. § 2(1)(c). No medical condition or diagnosis can be required to be eligible for psilocybin services. Id. § 8(4).

<sup>31</sup> Id. § 104.

<sup>&</sup>lt;sup>32</sup> 21 U.S.C. § 812(c). There may be exceptions to this general rule, for example, state and federal Right to Try laws are intended to allow therapeutic use of certain investigational drugs by patients with life-threatening illnesses. Psilocybin meets the requirements to be deemed an eligible investigational drug under the terms of these statutes. DEA rejected a request to allow access under these laws, leading to litigation challenging the agency's position. Advanced Integrative Med. Sci. Inst. v. Garland, 24 F.4th 1249, 1252 (9th Cir. 2022). A cohort of eight states joined an amicus in support of petitioners, alarmed at the DEA overreach into a traditional state domain: the regulation of the practice of medicine. *Id.* at 1251. The court dismissed the case, having determined that it did not have jurisdiction to consider the issue, without reaching the merits. *Id.* at 1252. Petitioners then filed a Request for Waiver and a Petition to Reschedule, leaving the issue in play and outcome yet to be determined. *See* Adlin, *supra* note 19.

be provided by the federal government with regard to psilocybin use in Oregon, as well as in any other states adopting laws permitting and regulating access to this substance.<sup>33</sup>

Three options are worthy of consideration and were discussed at length in the context of cannabis by Chemerinsky et al. First, the DOJ could adopt a policy to refrain from taking prosecutorial action related to the manufacture, distribution, or possession of psilocybin where state law permits and regulates its use.

An example of such policy emerging and evolving over time occurred in the case of cannabis. The Clinton administration engaged in enforcement activities, followed by similar conduct in the early years of the Obama administration.<sup>34</sup> Policy eventually evolved to refrain from federal enforcement through the issuance of various memoranda by the DOJ, including several by Deputy Attorney General James Cole.<sup>35</sup> It should be noted that the heavily regulatory structure of the PSA appears to address each of the elements identified in the first Cole memorandum as necessary to support adoption of federal nonenforcement policy:<sup>36</sup>

- (1) preventing the distribution of controlled substances to minors;<sup>37</sup>
- (2) preventing revenue from the sale of controlled substances from going to criminal enterprises;<sup>38</sup>
- (3) preventing the diversion of controlled substances from states where it is legal under state law in some form to other states;<sup>39</sup>

<sup>&</sup>lt;sup>33</sup> See, e.g., Chemerinsky et al., supra note 18.

<sup>&</sup>lt;sup>34</sup> Robert A. Mikos, A Critical Appraisal of the Department of Justice's New Approach to Medical Marijuana, 22 STAN. L. & POL'Y REV. 633, 633, 637–38 (2011).

<sup>&</sup>lt;sup>35</sup> See Dep't of Just., Off. of the Deputy Att'y Gen., Memorandum on Guidance Regarding Marijuana Enforcement (Aug. 29, 2013), https://www.justice.gov/iso/opa/resources/305201 3829132756857467.pdf; see also Mikos, supra note 34, at 638–39 (analyzing DOJ enforcement guidance).

<sup>&</sup>lt;sup>36</sup> Mikos, *supra* note 34, at 638–39.

<sup>&</sup>lt;sup>37</sup> Oregon Psilocybin Services Act § 2(1)(e)(A) (psilocybin services can only be provided to persons 21 years of age and older); *id.* § 29 (psilocybin service center operator must verify person's age); *see id.* § 54 (prohibition against selling or delivering psilocybin products to persons under 21 years of age).

The PSA addresses this concern by requiring particularized licensing measures for those producing, distributing, and selling psilocybin in accordance with the Act and by requiring that psilocybin be consumed on site. *See generally id* § 91(2), (5) (preventing even licensed manufactures from operating psilocybin farms with on-site commercial sale of psilocybin products).

<sup>&</sup>lt;sup>39</sup> See Oregon Psilocybin Services Act § 46 (preventing diversion of psilocybin products).

- (4) preventing state-authorized controlled substances activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;<sup>40</sup>
- (5) preventing violence and the use of firearms in the cultivation and distribution of controlled substances;<sup>41</sup>
- (6) preventing drugged driving and the exacerbation of other adverse public health consequences associated with the use of controlled substances;<sup>42</sup>
- (7) preventing the growth of controlled substances on public lands and the attendant public safety and environmental dangers posed by production on public lands;<sup>43</sup> and
- (8) preventing possession or use of controlled substances on federal property. 44

However, the second Cole memorandum was rescinded by the next administration in 2018, reflecting the reality that DOJ policy can, and typically does, shift with the political winds. <sup>45</sup> The commitment to federal nonenforcement by the DOJ in guidance memoranda, hence, appears to offer only a tenuous and temporary safe harbor.

Thus, calls for the Biden administration to "decline to prosecute anyone that participates in Oregon's . . . psilocybin program, as long as Oregon keeps the program under tight control," while reasonable, likely do not go far enough. Experts on U.S. drug policy have noted that "experience demonstrates that attempting to quash state drug reforms is unlikely to succeed and might even prove counterproductive and that tolerating such reforms better serves the interests of the federal government." It is correct that, as a practical matter, the DOJ does not have enough resources to make much of a dent in the market for a federally prohibited drug on its own. Because states handle the vast majority of all criminal drug cases,

<sup>&</sup>lt;sup>40</sup> See id. § 132.

<sup>&</sup>lt;sup>41</sup> See id. § 64(1)(f) (giving discretion to the Oregon Health Authority to revoke licenses to manufacturers of psilocybin if the licensee is convicted of a felony, or misdemeanor committed on the manufacturing premises); see id §§ 42, 97(4), 110 (authorizing agency inspection of business documentation and premises from licensure application through testing and distribution).

<sup>&</sup>lt;sup>42</sup> See id. § 8(2)(c).

<sup>43</sup> See id. §§ 91(2), 91(5), 97.

<sup>&</sup>lt;sup>44</sup> See id. § 4(6).

<sup>&</sup>lt;sup>45</sup> See Dep't of Just., Off. of the Att'y Gen., Memorandum on Marijuana Enforcement (Jan. 4, 2018), https://www.justice.gov/opa/press-release/file/1022196/download.

<sup>&</sup>lt;sup>46</sup> Robert A. Mikos, *We Need a Cole Memorandum for Magic Mushrooms*, U. ILL. L. REV. Online (Biden 100 Days: A Symposium), Apr. 30, 2021, at 87, 91, https://illinoislawrev.web. illinois.edu/wp-content/uploads/2021/04/Mikos.pdf.

<sup>&</sup>lt;sup>47</sup> *Id.* at 88.

when states stop arresting and prosecuting people for using or growing a banned substance, there is very little the DOJ can do to restore the deterrent effect. And, under the anti-commandeering federalism doctrine, the federal government cannot compel states to carry out federal regulatory programs. States do not have to ban federally banned substances under state law and can refuse to prosecute crimes related to such substances.

A second option, and a better solution than a possibly temporary DOJ memorandum articulating a policy to refrain from prosecuting in a state that has acted to legalize and regulate a substance, would be for the DEA to grant a revocable waiver of the CSA's psilocybin provisions, allowing Oregon to experiment with its PSA with clear permission from the federal government barring federal law enforcement. This approach of "permissive federalism" offers advantages over a DOJ guidance memo.

Federal prosecutorial abstinence still leaves concerns other than those about law enforcement extant, including banking, tax, and other matters. Federal prohibition makes banks, attorneys, insurance companies, health care providers, potential investors, and others unwilling to participate; these actors cannot function in an environment where state law permits something that federal law forbids. For example, in the case of banks being unable to engage with cannabis businesses for fear of federal prosecution and loss of license, "businesses that legally grow, market, or sell cannabis in [legalized states] are generally locked out of the banking system, making it difficult for them to maintain a checking account; access credit; accept credit and debit cards; meet payroll; or pay tax revenue." The exclusion from traditional banking systems has created an enormous safety issue that flies in the face of the foundational pillars of the Cole memorandum: the goal of reducing violence and firearm use in relation to growing and cultivating cannabis is frustrated when thefts, robberies, burglaries, and murders are linked to these "high-volume cash businesses." The

<sup>&</sup>lt;sup>48</sup> Chemerinsky et al., *supra* note 18, at 103.

<sup>19</sup> Id.

<sup>&</sup>lt;sup>50</sup> See id. at 115. Interestingly, the DEA's ability to grant such a waiver could also offer a path for the DEA to accommodate access to psilocybin under Right to Try laws. See Advanced Integrative Med. Sci. Inst. v. Garland, 24 F.4th 1249, 1261–62 (9th Cir. 2022). A Request for Waiver was submitted after the Ninth Circuit found insufficient finality in prior agency action. See Adlin, supra note 19.

<sup>&</sup>lt;sup>51</sup> For example, a physician who might want to include psilocybin therapy in his or her palliative care practice cannot risk losing their DEA registration by acting in violation of federal law, even if state law permits the conduct. *See generally Advanced Integrative Med. Sci. Inst.*, 24 F 4th at 1254

<sup>&</sup>lt;sup>52</sup> Safe Banking Act, CONGRESSMAN ED PERLMUTTER, https://perlmutter.house.gov/safe-banking-act/ (last visited Dec. 30, 2022).

<sup>&</sup>lt;sup>53</sup> Id.

continued use of cash in the industry makes it increasingly difficult to ensure revenue doesn't fall into the hands of criminal enterprises, gangs, and cartels—another matter the Cole memorandum seeks to address.

On the matter of community injustice, segments of intergovernmental agencies such as the Bureau of Indian Affairs are not governed by the DOJ, leaving a large loophole in federal enforcement. For example, The Bureau of Indian Affairs continuously prosecutes individuals living within Native American territories pursuant to federal law even when state law is permissive, <sup>54</sup> perpetuating a gross legal divide in the enforcement of laws in Native American communities. Most importantly, consumers of these products, who may be fully in compliance with state law, still risk losing their jobs, parental rights, and various government benefits if their use comes to light. <sup>55</sup> The lack of legislative coverage has a chilling effect on businesses subject to federal regulations that would otherwise be open to integrating the cannabis and psilocybin markets into their model. These businesses will be unable and/or unwilling to provide investment capital, legal advice, health care services, or other basic professional services necessary for psilocybin therapy to function in any sort of optimum fashion for fear of revocation of their licenses. This brings us back to the federal "Crack House" statute issue discussed *supra*.

There have been numerous congressional proposals in recent years for passage of stand-alone safe harbor laws surrounding Schedule I substances. The Secure and Fair Enforcement Banking Act of 2021 (the "SAFE Banking Act"), which seeks to "harmonize federal and state law by prohibiting federal regulators from taking punitive measures" against banks that provide services to cannabis-related businesses and ancillary businesses that serve them,<sup>56</sup> made it through the U.S. House of Representative *five times*, only to repeatedly fail in the U.S. Senate.<sup>57</sup> Provisions of the SAFE Banking Act were added to the National Defense Authorization Act for Fiscal Year 2021; however, the provisions were later stripped from the Act in September,

Morgan Lee, Cannabis Bust on Native American Land Highlights Legal Divide, PORTLAND PRESS HERALD (Nov. 22, 2021), https://www.pressherald.com/2021/11/22/cannabis-bust-on-native-american-land-highlights-legal-divide/.

<sup>55</sup> See Chemerinsky et al., supra note 18, at 97–100.

<sup>&</sup>lt;sup>56</sup> Safe Banking Act, supra note 52; SAFE Banking Act of 2021, H.R. 1996, 117th Cong. § 2 (as passed by H.R., Apr. 19, 2021).

<sup>57</sup> H.R. 1996; Safe Banking Act, supra note 52. The Drug Policy Alliance (DPA), backs the Marijuana Opportunity Reinvestment & Expungement (MORE) Act and believes it should be passed first to address injustices and move the focus away from industry support—which is a widely used criticism by members of Congress that is a thinly veiled attempt to pass their namesake. See Press Release, Drug Pol'y All., Marijuana Opportunity Reinvestment & Expungement (MORE) Act Reintroduced in the House (May 28, 2021), https://drugpolicy.org/press-release/2021/05/marijuana-opportunity-reinvestment-expungement-more-act-reintroduced-house.

despite the SAFE Banking Act's rare bipartisan support.<sup>58</sup> The latest push for passage of the SAFE Banking Act now comes from the bankers themselves to add its provisions as an amendment to the National Defense Authorization Act.<sup>59</sup> In addition, NY-14 Representative Alexandria Ocasio-Cortez and TX-2 Representative Dan Crenshaw worked to pass an amendment to the National Defense Authorization Act in the House that would require the Department of Defense to study the therapeutic benefits of psilocybin and MDMA, in addition to medicinal cannabis, for qualifying service members.<sup>60</sup> There is an expectation that it may fail in the Senate, which highlights a distinct lack of any decisive national legislation.<sup>61</sup>

There have been two notable moves from the executive branch related to its ongoing endeavor to change the landscape of Schedule I substances. In September 2021, the Biden administration issued a recommendation to Congress on reducing barriers to scientific research for all Schedule I substances. This proposal was developed by the Office of National Drug Control Policy (ONDCP), the Department of Health and Human Services (HHS), and the DOJ. While this guidance was primarily a part of a larger effort on the part of the administration to address addiction and the overdose epidemic, there is a strong suggestion that this administration understands just how powerful the use of psilocybin in the medical setting can be—one of the key reasons for this recommendation is to "expand[] the research of Schedule I substances to help advance evidence-based public policy." The Assistant Secretary for Health at HHS stated, "[e]xpanding the nation's public health approach to substance use disorders is essential to our strategy to bringing down the rates of overdose death." To that point, in December 2021, the DEA and National Institute on Drug Abuse testified at a House Energy and Commerce subcommittee

<sup>&</sup>lt;sup>58</sup> As of November 2021, 180 bipartisan members of Congress and 39 bipartisan senators are cosponsors of the SAFE Banking Act. The bill is also supported by governors from 21 states and territories. *Safe Banking Act, supra* note 52.

<sup>&</sup>lt;sup>59</sup> Pete Danko, *Who's Urging Cannabis Banking Reform Now? Bankers*, PORTLAND BUS. J. (July 13, 2022), https://bizjournals.com/portland/news/2022/07/13/safe-banking-ndaa.html/.

<sup>&</sup>lt;sup>60</sup> Austin Ahlman, *House Moves to Expand Psychedelic Therapy Research*, INTERCEPT (July 14, 2022, 12:25 PM), https://theintercept.com/2022/07/14/ptsd-psychedelic-therapy-research-congress/.

<sup>&</sup>lt;sup>61</sup> Mia McCarthy, *AOC Finds Unlikely Ally to Back Pentagon Psychedelic Studies*, BLOOMBERG LAW (Jul. 28, 2022, 2:45 AM), https://news.bloomberglaw.com/health-law-and-business/aoc-finds-unlikely-ally-to-back-pentagon-psychedelic-studies.

White House, Press Release, Biden-Harris Administration Provides Recommendations to Congress on Reducing Illicit Fentanyl-Related Substances (Sept. 2, 2021), https://www.whitehouse.gov/ondcp/briefing-room/2021/09/02/biden-harris-administration-provides-recommendations-to-congress-on-reducing-illicit-fentanyl-related-substances/.

<sup>&</sup>lt;sup>63</sup> *Id*.

<sup>&</sup>lt;sup>64</sup> *Id*.

<sup>65</sup> Id.

hearing, expressing support for the ONDCP research plan. <sup>66</sup> Additionally, the most recent call to action was a demand from the House Committee on Appropriations for the Government Accountability Office to review state, local, and tribal psilocybin programs for the purposes of improving access to federally authorized use, determining barriers to access under the Religious Freedom Restoration Act, and assessing the general impact of states' legally sanctioning use of psilocybin. <sup>67</sup> However, while these policies in the legislature and executive branch have the potential to shift the national landscape regarding the enforcement and research of Schedule I drugs, they do little to offer a safe harbor to those interested in interacting with the Oregon PSA.

A third and perhaps the best solution, based on the cannabis experience, is a proposal that could also work in the psilocybin context: adoption of an amendment to the CSA by Congress to allow states to opt out of the CSA provisions governing psilocybin, "making conduct allowed by state law actually legal under federal law in that state." A measure to accomplish this has been introduced in the cannabis context: the "Strengthening the Tenth Amendment Through Entrusting States" (STATES) Act. This Act would eliminate regulatory controls and administrative, civil, and criminal penalties under the Controlled Substances Act for cannabis-related activities that comply with state law, which could serve as a model for respecting state laws authorizing and regulating the use of psilocybin.

## **CONCLUSION**

Psilocybin, currently a Schedule I controlled substance, appears to have a clear benefit in alleviating a wide variety of health conditions. Oregon adopted its Psilocybin Services Act in 2020, making regulated therapeutic use of psilocybin legal under state law beginning in 2023. The federal government should respect Oregon's

<sup>&</sup>lt;sup>66</sup> The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances: Hearing Before the Subcomm. on Health (Comm. on Energy & Com.), 117th Cong. (2021) (statement of Louis J. Milione, Principal Deputy Adm'r, U.S. Drug Enf't Agency); id. (statement of Nora D. Volkow, Dir., Nat'l Inst. on Drug Abuse, Nat'l Insts. of Health).

<sup>&</sup>lt;sup>67</sup> Lara Goldstein, Federal Update: Psychedelic Policy Review Demanded by Congressional Principals, Here's What's Happening, BENZINGA (June 27, 2022, 4:26 PM), https://www.benzinga.com/markets/cannabis/22/06/27869750/federal-update-psychedelic-policy-review-demanded-by-congressional-principals-heres-whats-happen.

<sup>&</sup>lt;sup>68</sup> See Chemerinsky et al., supra note 18, at 116.

<sup>&</sup>lt;sup>69</sup> S. 1028, 116 Cong. § 1 (2019) (as introduced Apr. 4, 2019).

<sup>&</sup>lt;sup>70</sup> *Id.* § 2. Additionally, the latest in amendment proposals is the STATES Act championed by Representative Nancy Mace (R-SC), the language of which leaves open the potential to write in psilocybin alongside cannabis with little fanfare. *See* Daniel S. Nuñez Cohen, Barry M. Hartman, Brenden R. Chainey & Scott J. Gelbman, *In the Weeds: The States Reform Act of 2021, the Latest Comprehensive Cannabis Reform Bill*, NAT'L L. REV. (Nov. 15, 2021), https://www.natlawreview.com/article/weeds-states-reform-act-2021-latest-comprehensive-cannabis-reform-bill.

law, and, at a minimum, the DOJ should issue guidance stating that no federal law enforcement action will be taken for conduct compliant with the PSA. A precedent for such policy was set with the second Cole memorandum issued by the DOJ during the Obama administration. Better still would be the grant of a revocable waiver of the CSA's psilocybin provisions by the DEA, allowing Oregon to experiment with its PSA with clear permission from the federal government barring federal law enforcement. Most effective of all would be the amendment of the CSA by Congress to allow states to opt out of the CSA provisions governing psilocybin, making conduct allowed by state law fully legal under federal law in that state.