Research Report

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Considering Alternatives to Psychedelic Drug Prohibition

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Published by the RAND Corporation, Santa Monica, Calif.

About This Report

Psychedelic substances, such as LSD and psilocybin mushrooms, have long been touted as holding promise for treating various mental health conditions, and the past decade has seen another round of enthusiasm for this hope. Although the clinical research (and associated media reports) on these substances continues to grow, what receives less attention is the changing policy landscape for some psychedelics in the United States. Despite the federal prohibition on supply and possession—outside approved clinical research, the Food and Drug Administration's Expanded Access program, and some religious exemptions—some state and local governments are loosening their approaches to some psychedelics. Some states are implementing or considering approaches that legalize some forms of supply for any reason. It seems likely that more jurisdictions will consider and implement alternatives to prohibiting the nonclinical supply of some psychedelics, possibly including retail sales. The primary goal of this mixed-methods report is to present new data and analysis to help inform policymakers participating in these discussions in the United States, but much of this report should also be useful to decisionmakers in other countries. These insights should also be useful to anyone who is interested in learning more about these substances and the public policy issues surrounding them.

This report builds on RAND's foundational research on the policy issues surrounding cannabis legalization and our 2022 report on *Psychedelics and Veterans' Mental Health* (Pardo et al., 2022). Given this report's focus on equity considerations for changing psychedelics policy (especially for Indigenous Peoples), it benefited greatly from a collaboration with the RAND Center to Advance Racial Equity Policy.

RAND Drug Policy Research Center

This research was conducted in the Drug Policy Research Center. For 35 years, the center has conducted research to help decisionmakers in the United States and abroad address issues involving alcohol and other drugs. In doing so, the Center brings an objective and data-driven perspective to this often emotional and fractious policy arena. For more information, visit www.rand.org/well-being/justice-policy/centers/dprc.html.

Funding

This research was supported by RAND Epstein Family Veterans Policy Research Institute, the RAND Drug Policy Research Center, and a gift to RAND from the Sergey Brin Family Foundation.

Acknowledgments

We have many people to thank for supporting this research and teaching us about the complexities of psychedelics and spiritual medicines. We are indebted to the key informants who agreed to speak with us in formal and informal settings, ranging from leaders in Indigenous communities to policy experts to those with deep knowledge of the clinical research on psychedelics. We also thank the more than 3,700 people who completed our nationally representative survey on psychedelics. And we could not have conducted the survey without the support of the amazing folks at NORC at the University of Chicago. Thank you!

We are indebted to those who reviewed this manuscript as part of RAND's quality assurance process: Wayne Hall (emeritus professor at the National Centre for Youth Substance Use Research at the University of Queensland), Nicole Redvers (an Indigenous Global Health researcher and associate professor at the Schulich School of Medicine & Dentistry at the University of Western Ontario), Susan Sohler Everingham (senior operations researcher at RAND), and Brett Waters (co-founder and executive director, Reason for Hope; co-founder, Veteran Mental Health Leadership Coalition). Their questions and suggestions significantly improved the quality of the report.

We are also grateful for the feedback we received from Jon Caulkins, Cailtin Dorsch, Keith Humphreys, Bob Jesse, Rob MacCoun, Danye Medhin, Roland Neil, Bryce Pardo, Peter Reuter, and Constanza Sánchez-Avilés. We also want to acknowledge the insights we received from Malcolm Garland and Stacey Wallin of the Psychedelic Safety Institute and thank them for letting us include some of their frameworks in Chapter 3. This project also benefited from the early contributions of Justin Hummer and research support from Samantha Pérez Dávila. Maria Vega and Babitha Balan provided amazing editorial assistance, and we appreciate everything they did to improve this manuscript. The views presented in this report do not necessarily reflect the views of these individuals.

During the time this research was undertaken, coauthor Rhianna Rogers was director of the RAND Center to Advance Racial Equity Policy. She has since assumed the position of chief diversity, equity, inclusion, and accessibility officer at the U.S. Department of the Treasury. The views expressed in this report are the authors' and do not necessarily reflect the views of the U.S. Department of the Treasury, the U.S. government, research sponsors or clients, peer reviewers, or others involved in this publication.

Summary

Psychedelic substances have long been touted as holding promise for treating severe and chronic forms of depression, anxiety, and posttraumatic stress disorder (PTSD). The past decade has seen another round of enthusiasm for this hope that has broadened to some other mental health conditions. Some individuals are also turning to psychedelics in the hopes of finding meaning in life, spiritual guidance, better connections with others, and for other reasons. Although there was a similar interest in the clinical research on some of these substances in the 1950s and 1960s, it was largely halted because of a growing backlash against the nonclinical use of these substances.

Psychedelics are also receiving more attention from decisionmakers, the media, and other members of the public because there is an emerging industry and a changing policy landscape in the United States.[1] Despite the federal prohibition on supply and possession—outside approved clinical research, the Food and Drug Administration (FDA)'s Expanded Access program,[2] and some religious exemptions—a few states are implementing or considering approaches that legalize some forms of supply for some of these substances *for any reason* under state law. So far, the federal government has not indicated that it will block or challenge the ongoing legalization efforts in Oregon and Colorado. It is unclear whether it will continue with this nonenforcement approach or try something different.

But this is a very short time frame and narrow perspective through which to think about psychedelics. Some Indigenous groups have used some of these substances as spiritual medicines in traditional healing and ceremonies for millennia (Schultes, Hofmann, and Rätsch, 2001). These experiences are sometimes ignored because they do not fall nicely into clinical trial or cost-benefit frameworks. Furthermore, some of these Indigenous groups and their resources are being exploited because of the renewed interest in these substances (Celidwen et al., 2023).

It seems likely that more states and localities will consider and implement alternatives to prohibiting the supply of some psychedelics, possibly including retail sales. The primary goal of this report is to help inform those discussions in the United States, but much of the text should also be of interest to those participating in these debates in other countries.

[1] There are online markets for psychedelics with social media influencers playing a growing role in marketing efforts (see, e.g., Ricciardi, 2024).

[2] As noted in FDA (2024):

> Sometimes called "compassionate use," expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Nomenclature

There is considerable discussion about what constitutes a psychedelic drug (see, e.g., Calvey and Howells, 2018; Nichols, Nichols, and Hendricks, 2023). This report largely focuses on the classic psychedelics (i.e., N,N-Dimethyltryptamine [DMT]; lysergic acid diethylamide, commonly known as LSD; mescaline/peyote; psilocybin/psilocin) as well as ibogaine and 3,4-Methylenedioxy-methamphetamine (MDMA, commonly known as ecstasy or Molly). This report does not focus on ketamine or phencyclidine (commonly known as PCP or angel dust). This does not mean that we should ignore synthetically produced dissociative anesthetics; for readers seeking additional information on ketamine, see Sinner and Graf (2008); Morgan and Curran (2012), Domino (1980), Lodge and Mercier (2015), and Humphreys et al. (forthcoming). It is also important to note that in some settings, such as in the National Survey on Drug Use and Health (NSDUH),[3] some of these drugs are referred to as *hallucinogens*. Because these substances produce a range of effects, which may or may not include hallucinations, we avoid this term except when referring to data from surveys that use the term.

As noted, many nonsynthetic substances have histories of use in Indigenous communities that sometimes still use them in spiritual ceremonies, as a means of healing, and in other traditional rites. In these communities, these substances are generally referred to as *sacred relatives*, *spiritual medicines*, or *sacraments*. Importantly, Indigenous groups do not refer to these substances as *psychedelics* or *psychedelic medicines* (Celidwen et al., 2023). When discussing use by Indigenous Peoples in traditional religious practices, we will generally refer to these substances as *Indigenous traditional medicines* or *spiritual medicines*.[4]

Although this report does discuss some of the published and ongoing clinical research conducted on psychedelics, it is largely focused on policies related to supply and use outside the FDA drug evaluation and approval process. Although some may refer to FDA-approved use as *medical* or *therapeutic*, we prefer to refer to it as *clinical* use that is prescribed or administered by licensed clinical providers (who are often physicians but can also be other medical providers, such as nurse practitioners).

Structure and Methodology

As noted, much of the attention being given to psychedelics in recent years has been about the findings from small clinical trials that suggest these drugs could eventually be prescribed or administered by clinicians to treat various mental and physical health disorders—that is not the main focus of this report. Although this report is primarily concerned with nonclinical uses and supply, we

[3] NSDUH is an annual survey that covers substance use, mental health, and many other topics. It typically surveys about 70,000 people ages 12 and older. There is additional information about it in Chapter 2.

[4] We should also be clear about what we mean by *Indigenous*. This report generally follows the direction of the United Nations Declaration on the Rights of Indigenous Peoples that considers collective self-identification as Indigenous to be a fundamental criterion (United Nations, Office of the High Commissioner for Human Rights, 2008). We further acknowledge that Indigenous groups vary considerably, and that laws and policies can affect Indigenous groups in different ways based on government recognition, location, wealth, and a variety of other factors.

do not ignore the emerging clinical research and the role it has played in influencing policy change at the nonclinical level.

The report includes five chapters. Chapter 1 provides an overview of psychedelics policy in the United States, highlighting the current federal approach and recent changes that have occurred at the state and local levels. Chapter 2 presents insights on psychedelics use in the United States, including data from a new nationally representative survey we fielded for this report. It also discusses the economics of these markets, including new information on how psilocybin is obtained and expenditures. Chapter 3 focuses on the consequences—both positive and negative—of using psychedelics, largely drawing on insights from the peer-reviewed literature and our key informant interviews. Chapter 4 builds on Chapter 1 and presents a taxonomy of alternatives to prohibiting the supply of psychedelics and discusses some of the other design considerations. Chapter 5 presents a logic model for thinking about how a change in a supply policy could influence key outcomes. It also walks through some of the possible consequences for making changes to psilocybin policy at the state and/or federal level that could be adapted to other psychedelics. We also include four case studies (mostly outside the United States) focused on psychedelics policy and practice in Appendix A.[5]

The analysis uses a mixed-methods approach, including primary data collection (quantitative and qualitative), secondary data analysis, and collecting insights from peer-reviewed and gray literatures. The quantitative primary data are from a survey (the 2023 RAND Psychedelics Survey [RPS]) we created that was administered to AmeriSpeak panelists. AmeriSpeak is a probability-based panel funded and operated by NORC at the University of Chicago, designed to be representative of the U.S. adult household population (further discussed in Chapter 2). The qualitative primary data are based on 18 structured interviews with individuals from the United States and abroad, including legal experts, policy advocates, regulators, clinical researchers, mental health care providers, and representatives from organizations working in the emerging psychedelics industry (further discussed in Chapter 3). We also had several discussions about spiritual medicines with members of Indigenous communities who chose to not go on the record. Secondary data analyses primarily focus on data from national sources, such as the NSDUH and the National Incident-Based Reporting System (discussed in Chapter 2 and Appendix D, respectively).

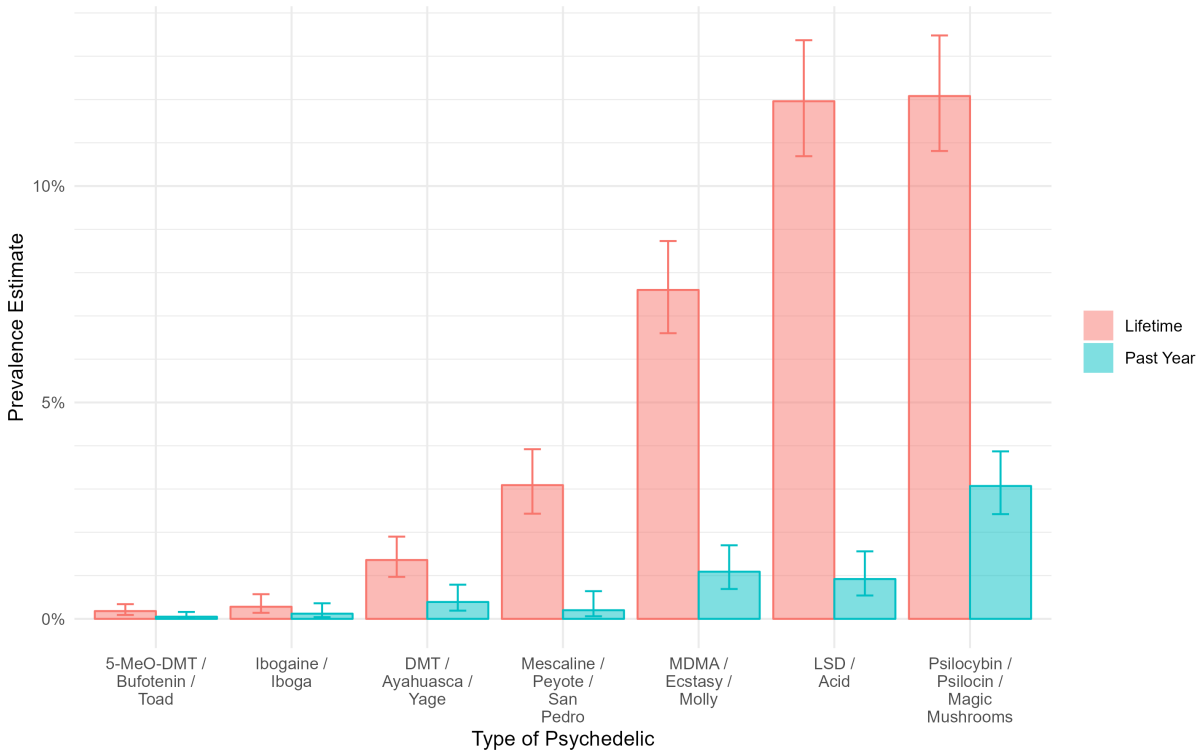
Nothing in this report should be interpreted as a rejection or endorsement of traditional supply prohibition or its alternatives. The goal is simply to provide information to ground policy debates and to highlight multiple policy options that could be considered. Comparing these alternatives with prohibition and with one another is a challenging task. Perspectives on psychedelics policy will be shaped by such factors as an individual's values, their preferences for risk, basic facts about these markets, and the consequences of using these substances.

[5] This report covers many the issues relevant to current policy discussions about psychedelics, but it is not exhaustive. For example, it does not cover issues related to patents for psychedelic substances (for more on that, see Gerber et al., 2021; Marks and Cohen, 2022; and Press, 2022) or what legal changes in the United States could mean for international treaties on drug control. While the report does address religious exemptions for some psychedelics (see Appendix A and the section titled "Federal Laws and Policies on Psychedelics" in Chapter 1), it does not get into much detail about U.S. Tribal law and sovereignty (for insights about federal policy on Tribal cannabis, see Stoa 2023). This is very much an area ripe for future research.

Key Insights

- **Unlike people who use cannabis and many other drugs, infrequent users of psychedelics account for most of the total days of use.** Chapter 2 estimates the total number of days of use in the past month in 2022 for the drugs that the NSDUH classifies as hallucinogens and cannabis by frequency of use. A major takeaway from our analyses is the extent to which infrequent users drive the market for psychedelics. For cannabis, it is negligible: Those who reported using five or fewer days in the past month account for about 5 percent of the total use days in the past month. For psychedelics, that figure is closer to 60 percent.
- **To provide some perspective on the size of the market, we used 2022 NSDUH data to estimate that the total number of use days for psychedelics—a proxy for the size of the market—is two orders of magnitude smaller than it is for cannabis.** There are multiple ways to estimate the size of drug markets, including total amount of substance consumed or the amount of money spent. Because these outcomes are not readily available for the various psychedelics, we focus on another measure: the total number of use days. The total number of use days in the past month for cannabis was on the order of 650 million whereas the comparable figure for hallucinogens was closer to 7 million. It is no surprise that the figure for cannabis is much higher than it is for hallucinogens, but thinking about this in terms of use days provides more insight about the relative size of these markets.
- **Among drugs generally classified as psychedelics, psilocybin has the highest past-year and past-month prevalence rates for U.S. adults.** Information about the past-year and past-month prevalence of many psychedelics, including psilocybin, is not available in the NSDUH. Figure S.1 displays the lifetime and past-year prevalence rates for psychedelics asked about in the 2023 RPS. Lifetime use of psilocybin and LSD/acid are the highest and comparable (approximately 12 percent; or approximately 31.5 million people), but past-year prevalence rates for psilocybin (3.1 percent; approximately 8.1 million people) surpasses that of all other substances (all of which are under 1 percent except MDMA, which is 1.1 percent). Past-month use of psilocybin (not shown in this figure) also exceeds that of the other psychedelic drugs (0.9 percent vs. 0.2 percent or lower). For comparison purposes, the RPS estimates past-year and past-month prevalence of cannabis to be about 30 percent and 20 percent, respectively.

Figure S.1. Lifetime and Past-Year Prevalence Rates for Various Psychedelic Substances Among U.S. Adults in 2023



SOURCE: Features information from the 2023 RPS.

- **Among those reporting the use of psilocybin in the past year, nearly half reported microdosing the last time they used it.** Those who microdose psychedelics use small amounts (often 1/10th to 1/20th of a typical dose commonly used for a nonclinical or clinical effect; however, there is no agreed standard), often a few times a week for multiple weeks, maybe longer. These subthreshold doses do not produce the effects typically associated with full doses. The 2023 RPS asked whether respondents microdosed psilocybin the last time they used it, and 47 percent of those who used in the past year reported this was the case. This percentage may be an underestimate of the overall prevalence of microdosing because this figure does not include those who microdose but did not do so the last time they used psilocybin.
- **The scientific literature is limited in its understanding of the consequences of using psychedelics and preventing and mitigating adverse events.** Although some Indigenous Peoples have used some of these substances for centuries or millennia, many questions remain in the scientific literature about which substances, doses, and settings work best for treating various health conditions and minimizing adverse reactions. Much of the attention on psychedelics in recent years has been about clinical trials that could eventually lead to some of these substances being prescribed or administered by licensed clinicians to treat various mental

health disorders; however, important issues have been raised about some of these studies. Guidelines for preventing and mitigating adverse events related to use in non-Indigenous settings are beginning to take shape. These include public education about the effects and potential risks, standards for informed consent, and expanded training for first responders and health care professionals. We have much to learn about these guidelines and hope they will be subject to rigorous evaluation.

- **Meaningful policy discussions should include Indigenous Peoples who are community authorized to speak on these matters.** Some members of Indigenous communities have tremendous experience with supervised use of some spiritual medicines and addressing adverse reactions. Insights from these individuals are also important for thinking about how policy changes could affect the availability of these substances for religious and spiritual uses. Those facilitating these discussions should follow Free, Prior, and Informed Consent (FPIC) and offer reciprocity when appropriate; for more on this, see the box entitled "Including and Listening to Indigenous Peoples in Policy Discussions" in Chapter 1.[6]
- **Those participating in psychedelics policy debates and analysis should be specific about the changes being considered, implemented, or evaluated**. A lesson from other areas of drug policy analysis is the importance of being clear about the policy regime under consideration. *Decriminalization* typically refers to classifying possession of small amounts for personal consumption as a noncriminal offense but still illegal (often subject to punishment with a fine or other civil sanction, sometimes similar to a traffic ticket).[7] Decriminalization differs from deprioritization in that (1) there is an explicit change in the criminal law, and (2) there can be a different risk of arrest or citation for possession. Decriminalization also differs from legalization approaches that explicitly allow some form of production and supply. There are also different forms of legalization that are expected to have different effects on availability, prices, consumption, and development of product variations.
- **Most of the policy changes happening at the state and local levels focus on supporting research and deprioritizing the enforcement of certain laws about psychedelics, respectively, but some states have legalized some forms of supply and others are considering it**. Since 2019, more than two dozen localities have deprioritized the enforcement of some state laws regarding psychedelics, generally making it a low or the lowest priority for local law enforcement officials. Also, a series of state laws have been passed to support clinical research on psychedelics or create task forces to explore policy changes. Despite the federal prohibition, a few states have also legalized some forms of supply under state law. Voters in Oregon and Colorado passed ballot initiatives to legalize the administration of psilocybin in

[6] As noted by the Food and Agriculture Organization of the United Nations (2016, p. 5):

> In an FPIC process, the "how," "when," and "with and by whom" are as important as "what" is being proposed. For an FPIC process to be effective and result in consent or lack of it, the way in which the process is conducted is paramount. The time allocated for the discussions among the indigenous peoples, the cultural appropriateness of the way the information is conveyed, and the involvement of the whole community, including key groups like women, the elderly and the youth in the process, are all essential. A thorough and well carried FPIC process helps guarantee everyone's right to self-determination, allowing them to participate in decisions that affect their lives.

[7] This change was implemented in Oregon with Measure 110, although legislation was recently signed into law making possession a misdemeanor offense beginning in September 2024.

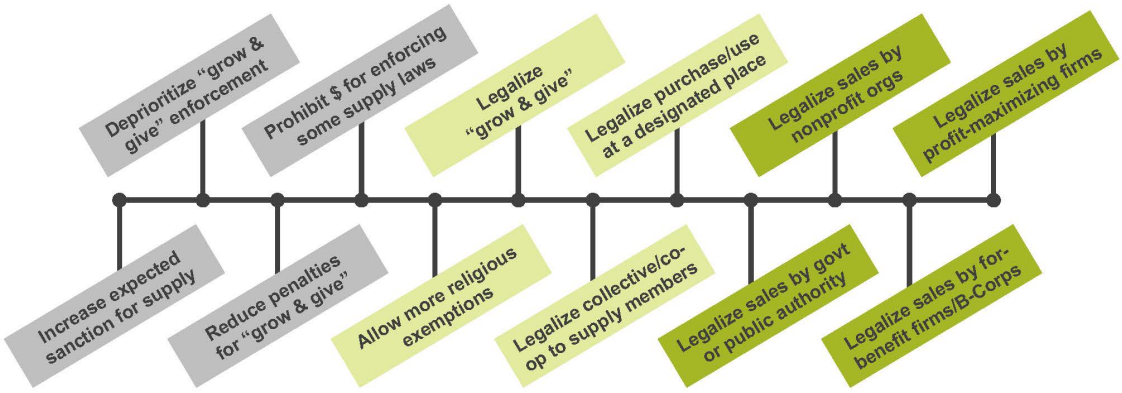
state-licensed supervision facilities (not for retail sales as is the case in states that have legalized cannabis). The Colorado initiative also legalized possessing, growing, and sharing of psilocybin, psilocin, DMT, ibogaine, and mescaline (excluding peyote) under state law—this is sometimes referred to as the grow-and-give model. Discussions about changing laws about psychedelics are happening in other states. For example, an initiative similar to Colorado's initiative may be on the ballot in Massachusetts in November 2024, and there is a new bill in New York that would allow retail psilocybin sales and require individuals to obtain a user permit to possess or purchase psilocybin. To obtain a permit, people ages 18 and older would have to undergo a health screening, participate in an in-person or online educational course, and successfully complete a test.

- **There are many supply policy options between prohibition and legalizing production and sales by for-profit companies.** Whereas alternatives to cannabis supply prohibition in the United States has largely focused on the for-profit commercial approach (often with an allowance for home production), there are many options. Figure S.2 displays 12 options that can be placed into three general categories (denoted by shading):
  - policy and legal changes while supply remains prohibited (gray shading)
  - some supply is legal but traditional retail sales remain prohibited (lighter green)[8]
  - some supply is legal and traditional retail sales are authorized by various sellers (darker green).

  Although some of these approaches are similar to what has been discussed for cannabis (Caulkins et al., 2015), there can be some important differences for psychedelics (e.g., requiring use in a designated facility or allowing religious exemptions). Furthermore, the decision about how these substances are supplied is only one of the many choices confronting those who seek to regulate them in connection with nonclinical purposes.

[8] We refer to the term *traditional retail sales* as meaning that any adult can walk in and purchase the product from a retail outlet or have it delivered.

Figure S.2. Alternatives to Traditional Supply Prohibition of Psychedelics (Outside Being Administered or Prescribed by a Licensed Clinical Provider)



Notes: These options are not mutually exclusive and could vary by substance. "Grow and give" also includes foraging for small amounts.
Inspired by Caulkins et al. (2015).

- **Policymakers need to consider the role of supervision and facilitators.** In Figure S.2, the "Legalize purchase/use at a designated place" tab would include the supervision models passed in Oregon and Colorado. The screening, supervision, and/or integration provisions in those models could play an important role in many of these supply options. Although almost all of those who currently use psilocybin do so without supervision from a formal facilitator or shaman (see Chapter 2), there is demand for facilitation, trip-sitters, and retreats, and it could increase after a policy change. Policymakers need to decide whether they want to promote or create incentives for people to use facilitators, and, if so, whether any type of regulation will be imposed (e.g., licensing requirements; liability insurance). Either way, there will be some facilitators willing to provide these services outside what is legally allowed (this has long been happening and may now be on the rise) and policymakers—and possibly voters—will need to decide whether it will be a low or high priority to spend enforcement resources on suppressing this group.

- **The role of price as a regulatory tool may matter less for psychedelics compared with many other drugs.** The report presents a model for thinking about how different supply models and regulatory design considerations will influence key outcomes. Price changes play a role in that model, and it is expected that reducing legal risk and increasing legal production will drive down wholesale prices of these substances. Whether this translates into reductions in *retail* prices would depend on regulatory design considerations. The extent to which retail price drops would influence overall consumption of psychedelics is also unclear. Aside from those who microdose, most people who use psychedelics do so infrequently. Thus, given the infrequent purchases, price changes *might* not matter as much as they do for other substances

that are consumed frequently, even daily, such as alcohol and cannabis. This, of course, is an empirical question that should be examined in future research, and the answer could differ by product and the role of supervision in the regulatory model.

- **It is critical to improve the data infrastructure on psychedelics to better support policy analyses.** When developing this report, it became clear how little has been published about the markets and patterns of use for many psychedelics—especially psilocybin. This gap creates challenges for projecting the consequences of a possible policy change. We tried to fill in a small part of this large gap with the RPS, but much more could be done. For example, the Substance Abuse and Mental Health Services Administration could consider updating its annual NSDUH questionnaire about prevalence and frequency of use about psychedelics (e.g., including past-year and past-month psilocybin prevalence, subset by microdosing status) and possibly add a rotating module about quantities consumed, expenditures, intentions for using specific psychedelics, details of the experience, the role of supervision, and the long-term effects both positive and negative. Another example: There is a need to conduct qualitative research (ideally longitudinally) with those who use psychedelics and those who produce and distribute these substances in legal or illegal settings.

- **Now is the time for U.S. federal policymakers to decide whether they want psilocybin and other psychedelic substances to follow in the footsteps of the for-profit cannabis model.** The federal government has multiple options when it comes to the supply of psychedelics outside the traditional FDA process, but it does not have unlimited time. Federal decisionmakers are in a somewhat similar position to where they were in 2012 after voters in Colorado and Washington passed cannabis legalization but with an important difference: The cannabis initiatives allowed for commercialized retail sales, while the initiatives for state-legal access to supervised psilocybin services passed in Colorado and Oregon are much more restrictive. Now is the time for federal policymakers to decide what they want these supply models to look like and to start taking action. Or, if they prefer a patchwork of state policies—possibly including those that allow for commercial supply and promotion—they can do nothing and just watch the industry grow. If that happens, it can be difficult to make major changes to supply or regulations, but that will depend on the size and political power of the industry that has taken root.

Although this report is largely focused on nonclinical supply and use, this should not be interpreted as indifference or a dismissal of the clinical research and its applications. To the contrary, we are thrilled that more-randomized clinical trials are being conducted with the ultimate aim of reducing the burdens on those with mental health conditions and their loved ones. There is concern, however, that if moves to expand nonclinical supply do not go well (e.g., they are poorly regulated and/or there are a series of high-profile negative events related to the use of psychedelics), they could create a backlash that may have a chilling effect on the research. Looking at what happened with clinical research on psychedelics after the 1960s, this is not an idle concern.

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Chapter 1

The Policy Landscape for Psychedelics in the United States

Introduction

Psychedelic drugs have long been touted as holding promise for treating severe and chronic forms of depression, anxiety, and posttraumatic stress disorder (PTSD). The past decade has seen another round of enthusiasm for this hope that has broadened to some other mental health conditions. Some individuals are also turning to them in the hopes of finding meaning in life, spiritual guidance, and better connections with others (see Chapter 2). Although there was a similar interest in the clinical research on these substances in the middle of the 20th century, it was largely halted because of a growing backlash against the nonclinical use of these substances (see, e.g., Pollan, 2019).

But this is a very short time frame in which to think about psychedelics. Some Indigenous groups have used some of these spiritual medicines in traditional healing and ceremonies for millennia (Schultes, Hofmann, and Rätsch, 2001). These experiences are sometimes discounted or ignored because they do not fall neatly into clinical trial or cost-benefit frameworks. Furthermore, some of these Indigenous groups and their lands are being exploited because of the renewed interest in these substances (Celidwen et al., 2023).

In the United States, the federal government's Controlled Substances Act (CSA) prohibits the production, supply, and possession of most psychedelics outside some clinical and research settings and a few religious exemptions (Public Law 91-513, 1971). For most well-known drugs, states have parallel laws prohibiting production, supply, and possession; however, this is not the case for cannabis in many states. This inconsistency creates myriad challenges from a regulatory perspective (e.g., reduced access to banking, lack of consistency for testing protocols) and has created a fragmented industry that prevents very large corporations from getting involved in the market. Some see this as a problem, others are pleased.

States have laws prohibiting the production, supply, and possession of psychedelics, but this is starting to change in a few places. Some local governments are also changing their approach to how they enforce state laws on psychedelics. These changes are motivated in part by the new wave of clinical research and the positive media attention it has generated.[9]

This chapter provides an overview of the current policy landscape concerning psychedelics in the United States. Because there are different views on what constitutes a psychedelic drug, we begin by describing the interpretation we will use in this report. Next, we discuss federal policy and the

[9] For a historical take on overly positive media coverage of psychedelics, see Siff (2015). There was eventually a lot of negative coverage about psychedelics, some of which exaggerated the harms (see, e.g., Schlag et al., 2022).

exemptions to these laws, which largely focus on traditional uses by Indigenous communities. Later, we describe how an increasing number of state and local governments are changing their approaches to psychedelics and then offer concluding thoughts.

Key Insights from Chapter 1

- Debate persists about which substances fall into the class of psychedelics. When this report discusses psychedelics (or spiritual medicines or sacraments when discussing use by Indigenous Peoples), we are generally talking about the classic psychedelics (N,N-Dimethyltryptamine [DMT], lysergic acid diethylamide (commonly known as LSD), mescaline, and psilocybin), ibogaine, and 3,4-Methylenedioxy-methamphetamine (MDMA, commonly known as ecstasy or Molly).
- The supply and possession of classic psychedelics, ibogaine, and MDMA are prohibited by the U.S. federal government except for approved clinical research, the Food and Drug Administration (FDA)'s Expanded Access program (so far only for MDMA), and some religious exemptions.
- Most of the policy changes happening at the state and local levels focus on supporting research and deprioritizing the enforcement of certain psychedelics laws, respectively, but some states have legalized some forms of supply and others are considering it.
- The term *decriminalization* is often used to describe the policy changes regarding psychedelics that are happening at the state and local levels, but this usage creates confusion. In empirical drug policy analysis, *decriminalization* typically refers to making possession of small amounts of drugs for personal use a noncriminal offense; it usually has nothing to do with supply. The only place that did pass a law to decriminalize the possession of psychedelics (and other controlled substances) was Oregon, but that law was recently changed.

What Are Psychedelics?

There is considerable discussion about what constitutes a psychedelic drug (see, e.g., Calvey and Howells, 2018), and the definitions have become more scientific over time. Some of these substances have also been referred to as *psychotomimetics*, *hallucinogens*, or *entheogens*; however, the first name is no longer used, and researchers have called the second option into question.[10] *Entheogen*, which translates to "manifesting the god within," is sometimes used to highlight the spiritual aspects of these substances. It is also sometimes used by those who want to remove the association of these substances with negative views that some people have of the use of psychedelics in the 1960s and 1970s (Steinhardt, 2020).

[10] As noted in Nichols (2020):

> When I began my graduate studies in 1969, it was politically correct in scientific circles to refer to these substances only as psychotomimetics, a negative term suggesting that they fostered a mental state resembling psychosis. . . . Later, as it was realized that these compounds did not provide very realistic models of psychosis or mental illness, it became more correct to refer to them as hallucinogens, again a pejorative term suggesting that they principally produce hallucinations. Yet that is not what they do in most users at ordinary doses, so this term likewise is not particularly descriptive or useful, although it is still widely used and seems to remain the preferred name for these substances in most scientific writing.

As understanding about how these substances work on the brain has improved, researchers have offered more-scientific definitions. For example, Johnson et al. (2019, p. 84) note that the "classic psychedelics," such as LSD, mescaline, DMT, and psilocybin, "are psychoactive compounds that exert effects through agonist (including partial agonist) activity at the serotonin 2A receptor (5-HT_{2A}R)." Although Johnson and colleagues note the critical role of 5-HT_{2A}R agonism, they also argue that "other receptor-level mechanisms also contribute to classic psychedelic effects."

There are substances besides the "classics" that are sometimes referred to as psychedelics. In an FDA guidance document about clinical investigations of psychedelic drugs, the agency uses the term *psychedelic* as shorthand for the classics and "entactogens or empathogens such as methylenedioxymethamphetamine (MDMA)" (FDA, 2023a). Ibogaine is often considered a psychedelic for its ability to produce hallucinations and other effects at certain doses (see, e.g., Heink, Katsikas, and Lange-Altman, 2017), and it is one of the five substances covered by Colorado's new approach to nonsynthetic psychedelics (further discussed below).[11]

A relatively new scientific journal in this space, *Psychedelic Medicine*, also had to wrestle with the issues about what types of research to publish and what substances would be considered. In a proposed consensus statement, the editorial board concluded:

> Thus, although ketamine and MDMA may not be considered serotonergic psychedelics, they do inform on the potential role of glutamate as well as 5-HT_{2A} receptor function in their action. Hence, the journal may include research studies of compounds that affect consciousness, although not necessarily by direct stimulation of 5-HT2A receptors. The journal will not be generally interested in studies of anticholinergics or cannabinoids, which in some cases might be considered to be hallucinogens. (Nichols, Nichols, and Hendricks, 2023)

Some Indigenous groups have used some of these substances for spiritual ceremonies (as a means of healing) and in other traditional rites for millennia (Schultes, Hofmann, and Rätsch, 2001). In these communities, these substances are generally referred to as *sacred relatives*, *spiritual medicines*, or *sacraments*. Indigenous groups do not refer to these substances as "psychedelics" or "psychedelic medicines," and consumption that is not guided or sanctioned is usually discouraged (Celidwen et al., 2023). For those who generally use the term *psychedelics*—as we do in this report—it is important to recognize that this is a construct and, therefore, may not be acknowledged in some contexts. When discussing use by Indigenous Peoples in traditional ceremonial practices, we will generally refer to these substances as *Indigenous traditional medicines* or *spiritual medicines*.

Table 1.1 lists the substances we refer to when using the term *psychedelics* throughout this report; it is not intended to be a universal list of all substances sometimes referred to as psychedelics. When addressing specific substances, this report will largely focus on the classics as well as ibogaine and MDMA but not ketamine or phencyclidine (PCP/angel dust). This does not mean we should ignore the potential benefits of synthetically produced dissociative anesthetics—especially ketamine—and for readers seeking additional information on these substances, see Sinner and Graf (2008); Morgan and Curran (2012), Domino (1980), Lodge and Mercier (2015), and Humphreys et al. (forthcoming).

[11] There is also some discussion about whether cannabis should be considered a psychedelic (Richard, 2018).

Table 1.1. Major Substances Considered in This Report

Substance	Is It Naturally Occurring?[a]	Typical Duration for a Typical Dose[b]	Typical Modes of Consumption in the Unites States at Present
N,N-Dimethyltryptamine (DMT, a key component of ayahuasca)	Yes; various plants	Ayahuasca tea, up to 5 hours, multiple doses often given in traditional settings over the course of days; synthetic DMT, about 15 minutes when smoked	Orally or smoked/vaped. Ayahuasca is a tea usually made from the *Psychotria viridis* shrub and *Banisteriopis caapi* vine native to the Amazon. Synthetic DMT is a powder that is commonly smoked or vaped.
5-methoxy-N,N-Dimethyltryptamine (5-MeO-DMT)	Yes; various plants and some toads	About 20 minutes when smoked and slightly longer when snorted	Smoked or snorted. Toxins secreted by Sonoran toads of the southwestern United States and northern Mexico that dry as crystals are collected. Synthetic 5-MeO-DMT is a powder.
12-Methoxyibogamine (Ibogaine)	Yes; primarily the iboga plant	Usually 24 hours, can be as long as 72 hours	Orally. Root bark shavings of *Tabernanthe iboga* shrub native to West Africa are chewed or ground and eaten as a powder.
Lysergic acid diethylamide (LSD; also known as acid)	No	About 12 hours	Orally. This is taken as a solution soaked into blotter paper or as a pill.
3,4,5-Trimethoxyphenethylamine (mescaline)	Yes; various cacti, including peyote	Up to 12 hours	Orally. Peyote cactus (*Lophophora williamsii)* of Mexico and North America is dried and ground to be mixed into a liquid or taken as a capsule. It can also be eaten fresh. Also found in wachuma or San Pedro cactus from South America.
3,4-Methylenedioxy-methamphetamine (MDMA; also known as ecstasy or Molly)	No[c]	6 to 8 hours	Orally. Taken as a pill, capsule, or powder.
O-phosphoryl-4-hydroxy-N,N-dimethyltryptamine (Psilocybin) and its active metabolite 4-hydroxy-N, N-dimethyltryptamine (Psilocin)	Yes; various mushrooms and truffles	5 to 6 hours	Orally. Eaten fresh or dried. It can also be ground into a powder and incorporated into a tea or taken in a capsule.

[a] Some naturally occurring substances are also synthetically produced.

[b] Not a microdose, durations are based on Nutt, 2023.

[c] Although MDMA is synthetically produced, safrole (a liquid that can obtained from the oil of sassafras and other plants and trees; see National Center for Biotechnology Information, undated) and essential oils rich in safrole are sometimes used in the MDMA production process (U.S. Drug Enforcement Administration [DEA], undated-b). There have been reports of environmental damage attributed to the illegal production of these precursor chemicals (see, e.g., MacKinnon, 2009).

As discussed, the substances we are including as psychedelics in this report operate in various parts of the brain. However, there are some common effects of experiencing a typical full dose of these substances. Nutt (2023) describes these common effects as changes to sensory perceptions; cognition; emotions; and sense of time, place, and self. Nutt also describes common physical effects during a psychedelic experience, such as nausea, vomiting, muscle spasms, temperature fluctuations, seizures, and dizziness. Although most psychedelic experiences are described as intense—as with most drugs—effects can vary among experiences and individuals. Variation in experience is affected by dose but can also be influenced by how the substance is taken, a person's genetics, a person's mindset going into the experience (i.e., the set), and the physical and social environment of the experience (i.e., the setting) (see, e.g., Zinberg, 1984; Hartogsohn; 2017; Nutt, 2023).

Federal Laws and Policies on Psychedelics

Although some of the substances listed in Table 1.1 have been used for millennia, others were not discovered until the 20th century. Many of these drugs were not prohibited in the United States until the mid-to-late 1960s ("2 States in West Ban Sale of LSD," 1966; Oram, 2016), but some were prohibited before,[12] some after.[13] With the passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513, 1971), the federal government consolidated several federal drug laws and created a revised system for categorizing controlled substances.

Title II of that Act, also referred to as the CSA, classifies controlled substances into five schedules based on the "drug's acceptable medical use and the drug's abuse or dependency potential" (Public Law 91-513, 1971; DEA, undated-a). In general, the lower the schedule, the more restrictions are imposed on that substance. All the psychedelic substances listed in Table 1.1 are classified as Schedule I.

When thinking about the CSA and scheduling, it can be useful to think about two buckets: those without a federally recognized medical value (Schedule I) and everything else (Schedules II–V) (Caulkins et al., 2016). New substances can be added to these schedules, and it is also possible for drugs to be moved into different schedules through legislative or administrative actions. Substances can also be removed from the CSA (i.e., descheduled; see Lampe, 2023) and some people have offered ideas and legislation about creating new schedules (e.g., see Nelson, 2015; Humphreys, 2016).

The illegal possession and trafficking of controlled substances are associated with different levels of criminal penalties, the severity of which are, in general, inversely related the schedule number (DEA, undated-a; DEA, 2020). Although federal agencies do make some arrests for possession, they are mostly concerned with large-scale production and trafficking. The vast majority of arrests happen at the state and local level (for more on this, see Appendix D).[14]

Federal law does provide some avenues for legally accessing and using some of these substances: clinical trials, compassionate use outside clinical trials, and religious exemptions (all discussed in the next section).

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[12] For example, peyote possession was banned in more than a dozen states by 1930 (Stork and Schreffler, 2014).

[13] The DEA added MDMA as a Schedule I drug in 1985 (Corwin, 1985).

[14] Our rough estimate is that the total number of federal, state, and local arrests for psychedelics in 2023 was likely in the low double-digit thousands for 2022; probably accounting for no more than 2 percent of drug arrests made that year (see Appendix D).

A few bills related to psychedelics were introduced to the U.S. Congress in the 2023 legislative cycle, but none focused on legalizing supply for nonmedical purposes. The most notable congressional legislation was an amendment that passed as part of the National Defense Authorization Act for fiscal year 2024 to fund clinical research potentially involving active-duty military service members with PTSD or traumatic brain injury (Jaeger, 2023). Additional congressional bills that were introduced include the VISIONS Act, which would prohibit federal funds from being used to enforce drug laws against state-regulated psilocybin programs, and other bills intended to clarify the federal Right to Try law or reschedule substances approved as breakthrough therapies (both described below) (Office of Congressman Robert Garcia, 2023; U.S. House of Representatives, 2023b; U.S. Senate, 2023).

Clinical Trials

Schedule I drugs can be used in human research, albeit with some additional controls not applicable to some other controlled substances. There is an increasing number of clinical trials with some of these substances (further discussed in Chapter 3).

Formulations of LSD, MDMA, and psilocybin have been given the "Breakthrough Therapy" designation by the FDA for specific mental health conditions (Heal et al., 2023; Hippensteele, 2024). This designation means that these investigative drug products are eligible for the following from the FDA: "All Fast Track designation features; Intensive guidance on an efficient drug development program, beginning as early as Phase 1; Organizational commitment involving senior managers" (FDA, 2018). This designation, however, does not guarantee that these substances will be rescheduled and allowed for clinical use. Furthermore, if this change does happen, it is the specific formulations that will likely be rescheduled, not the active ingredients (see discussion in Marks and Shachar, 2023).

In January 2024, the U.S. Department of Veterans Affairs (VA) announced a request for applications for VA investigators to conduct research using MDMA and psilocybin assisted therapy for PTSD and depression (VA, 2024). And in March 2024, the National Institute on Drug Abuse awarded a pharmaceutical company with a multi-year grant to develop an ibogaine analog—with a supposedly safer cardiac profile (see Chapter 3)—to treat opioid use disorder (Health Management, 2024).

Compassionate Use Access Outside Clinical Trials

It is also possible for some individuals to obtain drugs for clinical purposes outside clinical trials under U.S. federal law. One way is through the FDA's Expanded Access program:

> Sometimes called "compassionate use," expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.
>
> Expanded access may be appropriate when all the following apply: Patient has a serious or immediately life-threatening disease or condition; There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or

> condition; Patient enrollment in a clinical trial is not possible;[15] Potential patient benefit justifies the potential risks of treatment; Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication. (FDA, 2022b)

Those seeking expanded access must have a licensed physician who also believes this is an appropriate course of action and the manufacturer must agree. As the FDA tells potential applicants:

> It is important to note that, even if you meet the criteria under the law and FDA regulations, the licensed physician, the Institutional Review Board (IRB), and the company all need to agree that expanded access is appropriate for you in order for you to receive the investigational medical product. In addition, there may be costs not covered by third-party payers such as private insurance or Medicare. (FDA, 2022b)

With respect to psychedelics, the Multidisciplinary Association for Psychedelic Studies (MAPS) received authorization to provide expanded access to MDMA-assisted therapy to 50 patients at up to ten sites in the United States (MAPS, 2020). (See the box entitled "FDA Submission on MDMA-Assisted Therapy for PTSD" in Chapter 3 for more information.) As of May 2024, we are not aware of patients receiving expanded access to the other Schedule I psychedelics. Compass Pathways, a company that produces synthetic psilocybin for clinical trials, noted: "We are actively assessing which patient populations could be eligible for a compassionate use/expanded access programme, and we are working with regulatory authorities to determine the appropriate timing and conditions to offer pre-approval access to COMP360 psilocybin therapy" (Compass Pathways, undated).

There is also another theoretically possible compassionate use mechanism allowed under federal law: Right to Try. In 2018, Congress passed a law that in some ways is very similar to the FDA's Expanded Access program (Public Law 115-176, 2018). The goal of the Right to Try law is to make investigational drugs available to patients with life-threatening conditions who have exhausted approved treatment options and are unable to participate in a clinical trial.[16] An important difference between the Right to Try and Expanded Access program is the role of the FDA. For the former, the FDA plays a largely administrative role in "receiving and posting certain information submitted to the agency"; it does not review or approve requests for this program. For the latter, the FDA determines whether Expanded Access program requests can proceed and is "committed to enhancing access to promising investigational medicines" (FDA, 2022b). The FDA also maintains a website with all the Expanded Access forms that need to be completed by licensed physicians and manufacturers (FDA, 2024).

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[15] FDA (2022b) lists these examples: "[T]here are no ongoing trials, a patient may not have access to a clinical trial or may not be eligible for the clinical trials, distance to get to a trial prevents access."

[16] The law states (Public Law 115-176, 2018):

> (A) who has been diagnosed with a life-threatening disease or condition (as defined in Section 312.81 of Title 21, Code of Federal Regulations (or any successor regulations)); (B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—(i) is in good standing with the physician's licensing organization or board; and (ii) will not be compensated directly by the manufacturer for so certifying; and (C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent.

We are unaware of anyone who has been given access to psychedelics under the federal Right to Try law or under similar laws that have been passed in most states. The DEA notes that substances included in Schedule I are illegal under federal law even under Right to Try laws (Law, 2022). This would mean that doctors and producers providing these substances would be in violation of the CSA and subject to penalties. Legislation was introduced in the U.S. House of Representatives and U.S. Senate in 2022 to help remove this barrier by explicitly allowing Right to Try access to Schedule I drugs that have undergone a Phase 1 trial, but these bills did not advance (U.S. House of Representatives, 2023b; Booker, 2022). As noted earlier, the bill was reintroduced in the House of Representatives in March 2023. The Breakthrough Therapies Act (U.S. Senate, 2023; U.S. House of Representatives, 2023a) similarly seeks to resolve the Right to Try problem by enabling the DEA to expedite moving a drug with Schedule I active ingredients to Schedule II if it receives a "Breakthrough Therapy" designation or "Expanded Access" approval.

Religious Exemptions

There are also exemptions to the federal prohibition for the supply and possession of *some* psychedelics as part of *some* religious practices. In this space, some have challenged laws that are believed to substantially burden religious exercise allowed under the First Amendment.

After the passage of the CSA, the DEA interpreted it to "exempt peyote use in the religious ceremonies of the Native American Church (NAC)" (Olson, 1981). The DEA then requested that the U.S. Department of Justice (DOJ)'s Office of Legal Counsel weigh in on some legal questions related to this exemption. In a 1981 memorandum opinion for the chief counsel of the DEA, the Office of Legal Counsel noted that this exemption "accurately reflects Congress' intent to exempt the religious use of peyote by the NAC and other bona fide religions in which the use of peyote is central to established religious beliefs, practices, dogmas, or rituals" (Olson, 1981).

In 1990, the U.S. Supreme Court ruled that denial of state unemployment benefits because of the plaintiffs' peyote use as part of the NAC (which violated state law) was not a violation of the First Amendment's free exercise clause (Employment Division, Department of Human Resources of Oregon v. Smith, 1990).[17] In response to this and another case related to Indigenous groups but not substance use, Congress in 1993 passed the Religious Freedom Restoration Act (RFRA), which

> [p]rohibits any agency, department, or official of the United States or any State (the government) from substantially burdening a person's exercise of religion even if the burden results from a rule of general applicability, except that the government may burden a person's exercise of religion only if it demonstrates that application of the burden to the person: (1) furthers a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.[18]

[17] For more on NAC, see Appendix A.

[18] The Supreme Court eventually ruled this only applied to the federal government. As noted by Litman (2023):

> In 1997, the Supreme Court held that Congress did not have the power to pass the RFRA as applied to state officials. In response, many—but not all—states passed their own state-level RFRAs. Most of the drug law enforcement happens at the state level, leaving communities in states without their own RFRA without a solid defense.

In 1994, Congress went a step further and passed an amendment to the American Indian Religious Freedom Act of 1978 specifying that "the use, possession, or transportation of peyote by an Indian for bona fide traditional ceremonial purposes in connection with the practice of a traditional Indian religion is lawful, and shall not be prohibited by the United States or any State" (Public Law 103-344, 1994). Even the U.S. military, which has very strict rules about substance use, allows peyote to be used by members of the military under the auspices of this amendment and offers guidelines for such use (e.g., no use on duty or 24 hours before active duty; see Department of Defense Instruction 1300.17, 2020).

The DEA has created a process for religious groups to seek exemptions to the CSA for other substances. Federal court challenges have led to a few decisions that now allow preparations of DMT-containing products in religious ceremonies (e.g., Gonzales v. O Centro Espirita Beneficente União do Vegetal, 2006, and Church of the Holy Light of the Queen v. Mukasey in Oregon, 2009). [19]

There are also a growing number of entities that refer to themselves as "psychedelic churches" (e.g., see Zide Door in Oakland, California).[20] These organizations operate throughout the country and provide psychedelics (often ayahuasca, sometimes psilocybin) to members, but they have not been legally exempted from the CSA and are subject to arrest, prosecution, and possibly sanctions.

Local and State Policy Changes on Psychedelics

In 2019, voters in the city of Denver, Colorado, passed a local initiative to deprioritize the enforcement of laws prohibiting the use and possession of psilocybin mushrooms (Denver Colorado Initiated Ordinance 301, 2019).[21] This local action kicked off a wave of state and local changes to psychedelics policy (Siegel et al., 2022). These state and local policy changes are sometimes broadly referred to as *decriminalization*; however, a more nuanced categorization can better describe the range of psychedelics policy changes underway in the United States. This report builds on the categories described by Pardo et al. (2022). It focuses on what has been implemented to date, not all possible options (additional models for supply are discussed in Chapter 4):

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[19] As of the publishing of this report, we learned of another church (Church of the Eagle and the Condor [CEC]) that settled out of court with the DOJ and the U.S. Department of Homeland Security to allow CEC to import, manufacture, distribute, and possess ayahuasca for religious ceremonies (Church of the Eagle and the Condor v. Garland et al., 2024). A new U.S. Government Accountability Office (GAO) report argues that the DEA should improve its religious exemptions petition process for psilocybin (mushrooms) and other controlled substances (McNeil, 2024). The author notes that "GAO is making four recommendations to DEA, including that DEA should establish timeframes to make determinations on completed religious exemption petitions under the Religious Freedom Restoration Act. DEA concurred with each of the recommendations" (McNeil, 2024, p. i).

[20] For a journalistic account of the psychedelic churches emerging throughout the United States, see Dilworth (2024).

[21] In the United States, the federal government and states prohibit the *possession* of controlled substances. Use itself typically is not prohibited, but there are exceptions. For example, when President Joseph R. Biden announced his second proclamation about issuing pardons for certain cannabis offenses in December 2023, the proclamation specified that it expands the relief to cover certain "provisions of the Code of Federal Regulations, including as enforced under the U.S. Code, that prohibit only the simple possession or use of marijuana on federal properties and locales" (White House, 2023; DOJ, Office of the Pardon Attorney, 2024). Furthermore, use of these substances can sometimes trigger criminal penalties for some groups (e.g., those under community supervision who test positive for drug use). Some of the psychedelics policy changes in this chapter refer to both possession and use; in those cases, we keep both words. That said, there is much to be learned about how probation and parole agencies are (or are not) changing their approaches to psychedelics in jurisdictions that have changed their policies.

1. **research**—forms stakeholder groups and/or allocates funding to study the safety, efficacy, and policy reform options for psychedelic substances
2. **deprioritization**—does not change the penalties for certain offenses, but makes their enforcement a low priority for law enforcement officials
3. **limits on use of enforcement funding**—forbids law enforcement officials from using government funds to enforce certain laws
4. **defelonization**—reduces the penalties for certain offenses from felonies to less serious criminal offenses, such as misdemeanors
5. **decriminalization**—reduces the penalties for certain offenses (typically possession for personal use) so they are no longer criminal offenses, but they are still illegal (e.g., violators receive a civil fine)[22]
6. **legalization of cultivation and sharing**—allows adults to use, possess, cultivate, and share nonsynthetic psychedelics without involving payments; typically applies to small amounts and sometimes referred to as the *grow-and-give model*.
7. **legalization of supervised consumption**—establishes a regulated market for the supervised administration of psychedelic substances, usually involving licensing for cultivation, manufacture, testing, and facilitators who can administer the substances.

In facilitating precise and productive terminology around psychedelics policy developments in the United States, the categorizations of policies presented above somewhat differ from psychedelics policy taxonomies previously proposed by Marks (2023b) and Siegel et al. (2022). The primary distinction between the above categorizations and the psychedelics policy taxonomy presented by Marks (2023b) concerns the category of decriminalization. Whereas Marks discusses decriminalization of psychedelics in a manner that encompasses the above categories of deprioritization, defelonization, and decriminalization, this report splits these into separate categories. In their analysis of state-level psychedelics policy developments in the United States, Siegel and colleagues similarly identified decriminalization as one category of psychedelics policy (Siegel et al., 2022). As the authors did not analyze local policies under the scope of their study, such policies as deprioritization were not included in their taxonomy.

The policy categorizations used in this chapter are not an exhaustive list of all the policies that could be implemented as an alternative to psychedelics prohibition in the United States; rather, we list only the policies that have been implemented (we discuss a full range of supply options in Chapter 4; also see Transform Drug Policy Foundation, 2023). There are no entries for the for-profit commercial model because that has not been adopted in any state for psychedelics. That said, there was an effort in California to put an initiative on the 2024 ballot to legalize the production and sale of psilocybin to adults for any reason; however, initiative organizers did not submit the required signatures to be included on the 2024 ballot before the January deadline (Ballotpedia, undated-b).

[22] For example, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) refers to *decriminalization* as

> the removal of criminal status from a certain behaviour or action. This does not mean that the behaviour is legal, as noncriminal penalties may still be applied. With respect to the drug debate, this concept is usually used to describe laws addressing personal possession or use rather than drug supply (EMCDDA, 2016).

Local Policy Changes

Local changes to psychedelics policy (Table 1.2; see Appendix B for complete list) have generally been enacted through city council ordinances, ballot initiatives, or by executive order of the mayor. All 26 of the identified current local policy changes fall into the deprioritization category, as defined above, and some of them also go a step further and prohibit government funds from being used to enforce certain psychedelics laws. Although some are narrowly focused on possession and use laws (12 percent), most are not. For example, Oakland's measure that was passed in 2019 deprioritizes enforcement of laws on planting, cultivation, purchasing, transporting, distributing, engaging in practices, and possession by adults for entheogenic plants or plant compounds classified as Schedule I in the CSA. Twenty-three of the 26 local policy changes deprioritized cultivation; 20 deprioritized the sharing, transfer, distribution, or sale of some psychedelics; and nine prohibit local law enforcement officials from using government funds to enforce some psychedelics laws.

A few of these ordinances deprioritize enforcement of offenses relating to psilocybin specifically, but the majority of actions apply to a general set of "entheogenic plants and fungi." Many local deprioritization policies do not extend to the peyote cactus or mescaline derived from it in an effort to support ecological conservation and Indigenous access.[23]

Table 1.2. Summary of 26 Local Policy Changes

Characteristic	Number (%)
Deprioritizes some offenses regarding psychedelics	26 (100%)
Prohibits funds from being used to enforce some laws regarding psychedelics	9 (35%)
Only covers possession and/or use	3 (12%)
Only covers psilocybin	2 (8%)
Deprioritizes cultivation	23 (88%)
Deprioritizes sharing/transfer/distribution/sale of some psychedelics	20 (77%)

NOTE: See Appendix B for full list of local policy changes.

Commonalities between local policy changes often result from the adoption of similar policies between geographically (and demographically) similar localities. For example, six local jurisdictions in Northern California, seven in Massachusetts, and six in Michigan have enacted similar deprioritization policies. Similarities in the text of these policy changes often result from the work of nationwide advocacy groups that provide draft ordinances and guidance to local organizers (Decriminalize Nature, 2020). Additional details written into some local policy changes beyond broad deprioritization include

[23] The ceremonial ingestion of peyote as a sacred medicine is a central practice of the NAC and other Indigenous groups in the United States (Muneta, 2020). See Appendix A for a discussion of ecological conservation issues related to peyote cacti.

- statements of support for changes to policy at the state or national level
- data collection efforts and/or panels to review the impact of policy changes
- community and youth education initiatives
- safe storage practices and lock box programs.

State Policies

State-level changes with respect to psychedelics, of which there have been more than a dozen since 2019 (see Appendix B), have happened by popular vote through ballot initiatives and, more commonly, through legislation.[24] Legislative changes have happened through specific bills related to psychedelics or as part of larger funding bills, as noted in the "Legal Mechanism" column of the table in Appendix B. Broader changes to drug policy, like the decriminalization of possession of controlled substances in Oregon's Measure 110, can also affect the state-level legal status of some activities related to psychedelics and are therefore included in Appendix B. A few state supreme court rulings, such as The State of New Hampshire v. Mack and State of New Mexico v. Pratt, have clarified when and how policies related to psychedelics should or not be enforced, but these are not included Appendix B (New Hampshire House of Representatives, 2023; State of New Mexico v. Pratt, 2005). State governors could also potentially issue executive actions that affect psychedelics policy, but we are not aware of any that have been issued.

The changes in state-level psychedelics policies differ from local changes in the specificity of substances included. State-level policies almost always list psychedelic substances individually, and state policies that apply specifically to psilocybin are most common. MDMA is the second most commonly mentioned substance in recent state policies related to psychedelics.

Almost all the policy changes happening through the traditional legislative process fall into the research category. These policy changes set up stakeholder groups to generate reports on potential future changes to legislation, establish pilot programs that provide access to psychedelics and report results, or provide funding for clinical trials. Notable exceptions to this trend are a defelonization policy in New Jersey[25] that applies to possession of psilocybin and efforts in Oregon and Colorado that legalize some forms of supply for some psychedelics. Both legalization policies were passed by popular vote through ballot initiatives (in 2020 and 2022, respectively), and some clarifying legislation has followed. Below, we discuss the Oregon and Colorado cases in more detail.

Oregon. Enacted in January 2021, Oregon's Measure 109 (the Oregon Psilocybin Services Act, OPSA) legalized supervised consumption of psilocybin under state law for adults ages 21 and older under a licensing and regulatory program developed by the Oregon Health Authority (OHA) and

[24] Although Appendix B focuses on legislation or ballot initiatives that passed, there were multiple bills to legalize some forms of supply that were introduced or under consideration in 2023. A few examples include California (Senate Bill 58), Connecticut (House Bill 5102), Illinois (House Bill 0001), Massachusetts (House No. 1754/Senate No. 1009), Missouri (House Bill 1154), New Jersey (Senate No. 2934/Assembly No. 4911), New York (Assembly Bill 00114), and Rhode Island (House Bill 5923). This list is not exhaustive.

[25] We include New Jersey's defelonization bill specific to psilocybin in our table, but we note that multiple states (e.g., California) have defelonized the possession of all or most controlled substances.

implemented by the Oregon Psilocybin Services (OPS) section, a division of the OHA.[26] The OHA's regulations concern the manufacturing, transportation, delivery, sale, and purchase of psilocybin products and the provision of *psilocybin services*, a term defined as "the preparation, administration, and integration sessions provided by a licensed facilitator" (OHA, 2024, p. 1). To regulate these psilocybin services, the OHA has established four types of licenses that can be applied for: facilitator licenses, service center licenses, manufacturer licenses, and laboratory licenses.

Licensed facilitators are required to be present with individuals receiving psilocybin services at licensed service centers, with the aim of the facilitator being to support the psilocybin-assisted therapy session without directing the experience of the individual (OHA, undated-a). The facilitators *cannot* diagnose or treat physical or mental health conditions while providing psilocybin services to clients (OHA, undated-b; OHA, undated-c).[27] Facilitators must be Oregon residents ages 21 and older with at minimum a high school diploma or equivalent, and the licensing of a facilitator is subject to the passing of a criminal background check, the completion of an OPS-approved psilocybin facilitator training program involving a total of 120 hours of instruction and 40 hours of practicum training at a psilocybin service center, and a minimum score of 75 percent on an OPS-administered exam (Holoyda, 2023).

The training programs themselves are not licensed by the OPS—rather, the OPS approves the curriculum proposed, and the Oregon Higher Education Coordinating Commission (HECC), independently licenses the training program as a valid educational program (OHA, 2024). Both the curriculum approval and the HECC licensure must be maintained to remain as an eligible education program for psilocybin services training.

Licensed manufacturers are permitted to cultivate and process psilocybin products, and licensed laboratories that have been accredited by the Oregon Environmental Laboratory Accreditation Program test the psilocybin products produced by manufacturers.

The OPS began accepting license applications on January 2, 2023. The first state-licensed psilocybin service centers opened to the public in spring 2023 (Lekhtman, 2023). The OPS records the total number of licenses, training program applications, and worker permit applications submitted and approved; as of March 2024, the OPS has received and issued the following (OHA, 2024):

- 341 facilitator license applications, with 276 issued
- 746 worker permit applications, with 523 issued
- 29 manufacturer license applications, with nine issued
- 41 service center license applications, with 23 issued
- two testing lab license applications, both issued

[26] Although frequently referred to as Measure 109, the OPSA was codified as Oregon Revised Statutes Chapter (ORS) 475A after being passed.

[27] The facilitator scope of practice specifies:

> (1) A facilitator shall not 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. (2) A facilitator is prohibited from transferring, selling or otherwise handling any psilocybin product while they are facilitating a preparation, administration or integration session, regardless of whether the facilitator is also a licensee representative of a service center. (3) If a facilitator holds a professional license in another field, the facilitator shall not exercise the privileges of that license while providing psilocybin services to clients (Office of the Oregon Secretary of State, 2022).

- 27 training program curriculum applications, with 23 issued.

To access psilocybin services, individuals must be age 21 or older and have no history of psychosis, no desire to self-harm, and no prior consumption of lithium in the past 30 days (Holoyda, 2023). Unlike facilitators, people seeking access do not need to be Oregon residents. After applying to a service center for access to psilocybin services, individuals first engage in an in-person preparation session with a licensed facilitator in which the individual and facilitator discuss information regarding the psilocybin product and experience, including inter alia informed consent for facilitator-client touch, follow-up dosing, data protection, and medical history. At this stage, both the facilitator and the individual can decide whether to proceed with the psilocybin administration session. If both do, the administration session is then organized at a service center. This administration session involves the purchasing of psilocybin and consumption at the service center, under supervision of the facilitator. A final, optional session under Oregon's psilocybin service program is an integration session in which individuals can request referral to health, safety, and support resources.

The program has faced criticism for inaccessibly high cost of services and a taxation structure that has been unable to cover the cost of program administration (Sadiq, 2023; Effinger, 2023). Of the 23 service centers that have received a license since the beginning of the program, one Portland-based center has since shut down, quoting an insufficient number of clients to remain in operation prior to closing in March 2024 (Olson, 2024; Stringer, 2024). One psilocybin wholesale company announced in March 2024 that it will lower its wholesale price of psilocybin from $1.50 per milligram (mg) to $1/mg, with the company suggesting that this adjustment may benefit service centers by allowing them to lower their client-facing service prices or increase profits ("Satya Therapeutics Announces Reduced Wholesale Psilocybin Prices in Oregon," 2024). However, the program is still very much in its infancy, and the longer-term trends in client-facing prices, demand, and overall sustainability remain to be seen.

Colorado. Colorado passed Proposition 122, the Natural Medicine Health Act, in November 2022. This initiated state statute mandates the state government to establish a regulated Natural Medicine Access program, which will permit supervised consumption of psilocybin and psilocin (Colorado Proposition 122, 2022).

As of May 2024, the state government of Colorado is establishing the regulatory framework to implement the Natural Medicine Access program. The Colorado Department of Regulatory Agencies (DORA) is tasked with regulating the new profession of psychedelics facilitators, while the Colorado Department of Revenue is tasked with regulating the manufacturing, cultivation, and distribution of psilocybin and psilocin for healing centers. Both state departments are given regulatory recommendations by the newly established Natural Medicines Advisory Board, which was created as a division of DORA under Colorado Senate Bill 23-290 (2023). The bill additionally created an American Tribes and Indigenous community working group to make regulatory recommendations based on the likely effects of Proposition 122 on Indigenous Peoples.

The Natural Medicines Advisory Board has proposed two license types for psychedelics facilitators in Colorado: one for individuals who do not have a behavioral, mental health, or medical license in Colorado; and a clinical facilitator license for those who do (for more details, see Vicente LLP Team, 2024). Although residents and nonresidents of Colorado can apply to be a facilitator under the current proposed regulations, residents of the state will be prioritized. The current

proposals to implement the Natural Medicine Access program additionally include the licensing of healing centers akin to Oregon's service centers, cultivation facilities, product manufacturers, and testing facilities. Further regulatory nuances, such as psilocybin and psilocin dosage caps and telehealth allowances, have yet to be drafted as of April 2024.

The first healing centers that will administer psilocybin or psilocin under supervision are set to open in 2025 (Psychedelic Alpha, undated-a). After the launch of the program and no earlier than 2026, regulators will have the option to allow additional psychedelic substances at healing centers, including ibogaine, DMT, or mescaline (Ballotpedia, undated-a).

Alongside the mandate to establish a Natural Medicine Access program, the Natural Medicine Health Act legalized the consumption, possession, growth, and nontransactional sharing (the grow-and-give model) of five psychedelic substances for adults 21 and older: psilocybin; psilocin; DMT from ayahuasca; ibogaine; and mescaline, excluding mescaline from the peyote cactus (Colorado Proposition 122, 2022).

Including and Listening to Indigenous Peoples in Policy Discussions

In the "Local and State Policy Changes on Psychedelics " section of this chapter, we highlight how an increasing number of states are setting up task forces or other commissions related to changing psychedelics laws. According to the experiences of one of the authors of this report (Rogers) and some of the interviews conducted for this project, there is concern that the views and preferences of Indigenous groups will be considered in these policy conversations only marginally, if at all. This can happen because of intentional decisions by those facilitating these groups (e.g., those simply trying to check a diversity box, not really interested in dialogue; for more on tokenization in this space, see George et al. [2020]) or by those who genuinely want to hear and learn from Indigenous Peoples but are not sure about the appropriate person or group to contact. There can be traditions or hierarchies in Tribes with respect to spiritual medicines and who may be able to talk about them.

The traditions and practices of Indigenous Peoples can be eminently helpful in designing new guided protocols that are needed. But it is not just about learning from these groups (and making sure there is reciprocity for their time and effort); it is also about making sure any policy changes respect the traditions of Indigenous Peoples and do not create situations that can harm these groups or deny them opportunities. Those facilitating these discussions should recognize Free, Prior, and Informed Consent (FPIC) and be careful not to be extractive.[a] Those creating or participating in these policy working groups or commissions could also reach out to organizations, such as the National Congress of American Indians, International Indian Treaty Council, and NAC (especially with respect to peyote), if they do not have the appropriate local contacts.

[a] For more on FPIC, see Food and Agriculture Organization of the United Nations (2016).

Concluding Thoughts

The policy landscape regarding psychedelics is starting to change in the United States. Despite the federal prohibition of supply and possession, some states are implementing or considering approaches that legalize some forms of supply for some of these substances outside approved medical research, the FDA's Expanded Access program, and some religious exemptions. So far, the Biden administration

has not indicated that it will block or challenge the ongoing efforts in Oregon and Colorado. It remains to be seen whether this continues, and there is also a possibility that the federal approach could change with a new administration (Kilmer and Ramchand, 2023). Moreover, it seems likely that more states and localities will consider and possibly implement alternatives to prohibiting the supply of some psychedelics.

As the policy landscape about psychedelics changes, future policy research will undoubtedly be undertaken on the likely effects of these developments. The National Institute on Drug Abuse recently issued a notice of special interest, calling for "grant applications that examine the impact of changing state and local psychedelic and dissociative drug policies" (U.S. Department of Health and Human Services [HHS], 2023). In answering such calls, researchers could learn from two decades of cannabis policy research by giving express consideration to the details of the policies that they aim to evaluate (additional items to consider are discussed in the section titled "Improving Policy Research on Psychedelics" in Chapter 5).

Chapter 2

Psychedelics Use and Markets in the United States

Introduction

This chapter focuses on the use of psychedelics in the United States and offers some market insights. The data available for such an exercise are limited, so we fielded our own nationally representative survey (the 2023 RAND Psychedelics Survey, or RPS) to help fill some of these gaps. Our goal is to present some baseline information to help ground policy discussions and inform analyses about alternatives to prohibiting the supply of psychedelic substances.

We begin by describing the primary data sources used for these analyses, and why fielding the 2023 RPS was necessary. Next, we present information about the prevalence, frequency, and quantity consumed of various psychedelics, respectively. We then describe characteristics of individuals' last use of psilocybin, including the form they consumed and who was with them when they used. The final sections focus more on the markets for psychedelics, with new data on how psilocybin is obtained, including information about the amount of money people spend on psilocybin. Lastly, we offer insights about prices and production costs.

Data

The three data sources discussed in this section are the National Survey on Drug Use and Health (NSDUH), Monitoring the Future study, and the RPS.

National Survey on Drug Use and Health

The NSDUH is an annual survey sponsored by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) that provides estimates of substance use behaviors and mental health symptoms, and associated constructs, among the U.S. civilian, noninstitutionalized population. In 2022, the survey was administered both in person and via the web. In 2022, the NSDUH sample size included 71,369 completed interviews, representing a 12.1 percent response rate. Just under half (42.4 percent) of surveys were completed via the web; the remainder were completed in person (SAMHSA, 2023).

Key Insights from Chapter 2

- Unlike people who use cannabis and many other drugs, infrequent users of psychedelics account for most of the use days.
- To provide some perspective on the size of the market, we used NSDUH data to estimate that the total number of use days for psychedelics—a proxy for the size of the market—is two orders of magnitude smaller than it is for cannabis.
- Within the class of drugs generally classified as psychedelics, psilocybin has the highest past-year and past-month prevalence rates among U.S. adults ages 18 and older.
- Among those reporting past-year use of psilocybin, nearly half reported microdosing the last time they used.

The NSDUH currently asks respondents about their lifetime use of the following:

- LSD, also called acid
- PCP, also called angel dust or phencyclidine
- peyote
- mescaline
- psilocybin
- ecstasy or Molly, also called MDMA
- ketamine, also called Special K or Super K
- DMT, also called dimethyltryptamine
- AMT, also called alpha-methyltryptamine
- Foxy, also called 5-MeO-DIPT
- *salvia divinorum*.

Since 2002, the survey has also asked about past-year and past-month use of LSD and MDMA. Since 2006, it has asked about past-year and past-month use of ketamine, DMT/AMT/Foxy (all three substances are included in one question), and *salvia divinorum*. Thus, the NSDUH lacks detailed information on psilocybin, ibogaine, and mescaline—all for which, as described in Chapter 1, the policy landscape is changing.

NSDUH also includes a few questions about frequency of use. It asks about the total number of days used for any of these hallucinogens in the past 12 months and in the past 30 days.

Although the NSDUH lacks specificity on past-year and past-month use for certain types of psychedelics, as a repeated, cross-sectional data source, it provides information about trends in substance use behaviors over time. Later in this chapter, we present data on trends over time from 2002 to 2022. We present these data, however, with important caveats:

- In 2015, the term "Molly" was added to the questions about use of ecstasy/MDMA.

- In 2015, "any hallucinogen use" was expanded to include ketamine, DMT, and *salvia divinorum*, which were not included under "any hallucinogen use" from 2006 to 2014.
- Data from 2020 should not be compared with years prior or later because of a suppressed data collection time frame as a result of the coronavirus disease 2019 (COVID-19) pandemic and the introduction of web-enabled data collection.
- Data from 2021 should not be compared with 2019 or earlier years because of web-enabled data collection (SAMHSA, 2023).

Monitoring the Future

The Monitoring the Future survey, sometimes referred to as the National High School Senior survey, is an annual survey conducted by the University of Michigan. The main cross-sectional survey aims to capture the beliefs, attitudes, and behaviors of a nationally representative sample of students in grades 8, 10, and 12 in the United States regarding substance use (Miech et al., 2024),[28] and it has surveyed 12th grade students since 1975. Since 2019, students have completed the survey using electronic devices.

With respect to psychedelics, Monitoring the Future asks all respondents about lifetime, past-year, and past-month use of the following:[29]

- hallucinogens
- LSD
- hallucinogens other than LSD, including psilocybin (or "shrooms")
- MDMA (or ecstasy or Molly)
- PCP
- salvia

[28] Monitoring the Future conducts additional surveys that target specific subpopulations of interest, including college students and high school graduates, in both cross-sectional and longitudinal (panel) forms. However, the most-detailed analyses of substance use behaviors concerns the cross-sectional primary survey conducted with students in grades 8, 10 and 12.

[29] In 2022, Monitoring the Future noted:

> Versions of this monograph before 2022 included an appendix that reported trends in specific drugs that fall under the omnibus categories of amphetamines, hallucinogens other than LSD, tranquilizers, narcotics other than heroin, and sedatives (barbiturates). For example, among 12th grade students who reported use of a hallucinogen other than LSD the survey asked a randomly-selected group to mark which specific drugs they had used, such as psilocybin ("shrooms") and/or peyote. This appendix was discontinued because the 12-month prevalence of each of the omnibus categories fell below 3% in 2022, resulting in even smaller numbers of users of the constituent drugs and, consequently, unstable estimates. The questions remain on the survey, and this appendix will be reinstated if prevalence increases in the coming years. (Miech et al., 2023, p. 25)

Later in this chapter, we present data on past-year prevalence trends for some of these categories from 1975 to 2023. We present these data, however, with important caveats. As noted by Miech et al. (2024, p. 170),

> In 2001, a revised set of questions on other hallucinogen use [besides LSD] was introduced. Other psychedelics was changed to other hallucinogens and shrooms was added to the list of examples. From 2001 on data points are based on the revised question.

Miech et al. (2024, p. 89) also notes,

> In 2014 some questionnaire forms in the survey included "Molly" as an example of MDMA, along with ecstasy, and the inclusion of this example appeared to make relatively little difference in the overall prevalence of MDMA. In 2015 the remaining forms were changed to also include "Molly" as an example in the questions about MDMA.

2023 RPS

We fielded the 2023 RPS because the two primary datasets used to estimate national patterns of drug use in the United States have limited information about psychedelics. The 2023 RPS was administered to AmeriSpeak panelists. AmeriSpeak is a probability-based panel funded and operated by NORC[30] at the University of Chicago. The survey is designed to be representative of the U.S. household population. Randomly selected U.S. households are sampled using area probability and address-based sampling, with a known, nonzero probability of selection from the NORC National Sample Frame. The sampling frame excludes individuals who live in group quarters, which include such living situations as nursing homes and prisons. These sampled households are then contacted by U.S. mail, telephone, and field interviewers (face to face). The panel provides sample coverage of approximately 97 percent of the U.S. household population. Most AmeriSpeak households participate in surveys by web, non-internet households can participate in AmeriSpeak surveys by telephone. The weighted recruitment rate into the AmeriSpeak panel is 22.1 percent and the weighted panel retention rate is 78.8 percent.[31]

The RPS was fielded in December 2023 to 16,466 AmeriSpeak panelists, and 4,263 (25.9 percent) completed the screener questions.[32] Of these, 3,801 were deemed eligible and 3,791 completed the survey with validated responses (99.7 percent interview completion rate; 97.5 percent via web, 2.5 percent via telephone, 2.9 percent in Spanish). Weights are created to adjust for nonresponse to benchmarks of household-dwelling adults ages 18 and older using benchmarks derived from the American Community Survey 2021 Public Use Microdata Sample.

[30] Formerly known as the National Opinion Research Center.

[31] AmeriSpeak has also provided data on the prevalence of food allergies in the United States (Gupta et al., 2019), experiences of discrimination in the U.S. health care system (Nong et al., 2020), attitudes about vaccine uptake (Fisher et al., 2020), depression during COVID-19 (Abdalla et al., 2021), firearm purchasing (Crifasi et al., 2021), and uptake of telemedicine (Ray et al., 2023).

[32] The survey was fielded from December 14, 2023, to January 2, 2024, although we term it the *2023 Rand Psychedelics Survey* (*2023 RPS*) for simplicity.

Respondents were initially asked, "Have you ever used any of the following substances?" The options were as follows:

- alcohol
- marijuana/cannabis/Delta-9 THC (please do not include CBD-only products or hemp derived products, like Delta-8)
- MDMA/ecstasy/Molly
- psilocybin/psilocin/magic mushrooms (please do not include Amanita muscaria/Fly Agaric mushrooms)
- LSD/acid
- DMT/ayahuasca/yagé
- 5-MeO-DMT/bufotenin/toad
- mescaline/peyote/San Pedro
- ibogaine/iboga
- none of these.

Those who responded yes to using of any of these substances were then asked the last time they used it (past 30 days; past year but not in the past 30 days; and more than one year ago). We included several additional questions for those reporting psilocybin use; the question wording and response options are presented in the relevant sections of this chapter.

Prevalence of Use

Data from the 2023 RPS show that in 2023, 12.1 percent of adults ages 18 and older had used psilocybin in their lifetime (approximately 31.7 million people) and 12.0 percent had used LSD/acid (approximately 31.5 million people).[33] Although comparable proportions had used these substances in their lifetimes, a greater proportion used psilocybin in the past year (3.1 percent; approximately 8.1 million people) than LSD/acid (0.9 percent; approximately 2.4 million people). Fewer than 1 percent of adults had used any psychedelic in the past month, but psilocybin was the most commonly used (0.9 percent; Table 2.1).[34]

[33] Population figures based on a U.S. Census Bureau estimate of total U.S. population (334,914,895), with 78.3 percent being 18 or older (262,238,363) (U.S. Census Bureau, undated-b).

[34] Data from the 2023 RPS were also used to examine the last time individuals used psilocybin among those who had used but not in the past year. We examined this information by age strata, and younger respondents have a higher share of more-recent use: 43.2 percent of 18- to 25-year-olds who ever used psilocybin (but not in the past year) used it as recently as one to two years ago. Among lifetime users older than 60, most (66.3 percent) used psilocybin ten or more years ago; however, 20.4 percent used one to two years ago. A somewhat similar pattern is seen among 45- to 59-year-olds.

Table 2.1. Lifetime, Past-Year, and Past-Month Prevalence of Various Psychedelics from the 2023 RPS

	Lifetime		Past Year		Past Month	
Substance	**%**	**95% CI**	**%**	**95% CI**	**%**	**95% CI**
Alcohol	85.9%	(84.1, 87.5)	68.3%	(66.2, 70.3)	55.2%	(53.0, 57.3)
Cannabis	56.0%	(53.8, 58.1)	29.8%	(27.9, 31.8)	20.2%	(18.5, 22.0)
Psychedelics						
Psilocybin/psilocin/magic mushrooms	12.1%	(10.8, 13.5)	3.1%	(2.4, 3.9)	0.9%	(0.5, 1.4)
LSD/acid	12.0%	(10.7, 13.4)	0.9%	(0.5, 1.6)	0.2%	(0.1, 0.4)
MDMA/ecstasy/Molly	7.6%	(6.6, 8.7)	1.1%	(0.7, 1.7)	0.2%	(0.1, 0.4)
Mescaline/peyote/San Pedro	3.1%	(2.4, 3.9)	0.2%	(0.1, 0.6)	0.2%	(0.1, 0.6)
DMT/ayahuasca/yagé	1.4%	(1.0, 1.9)	0.4%	(0.2, 0.8)	0.1%	(0.0, 0.4)
Ibogaine/iboga	0.3%	(0.1, 0.6)	0.1%	(0.0, 0.4)	0.0%	(0.0, 0.2)
5-MeO-DMT/bufotenin/toad	0.2%	(0.1, 0.3)	0.0%	(0.0, 0.2)	0.0%	(0.0, 0.1)

NOTE: CI = confidence interval.

We sought to compare the response to the 2023 RDS with NSDUH. To do so, we compared prevalence data from the 2023 RPS with NSDUH 2022 prevalence data for comparable items (as of March 2024, the most recent year available for NSDUH microdata is 2022). The comparable items we selected were lifetime and past-year use of alcohol, cannabis, LSD/acid, MDMA; and lifetime use of psilocybin. These estimates are presented in Table 2.2. As seen in Table 2.2, the estimates from both data sources are of comparable magnitude, with the exception of lifetime, past-year, and past-month cannabis use; the RPS figures are slightly higher.[35] The comparability of these estimates for other substances from the RPS lends credibility to the validity of our estimates for substance use behavior *not* asked on the NSDUH, particularly past-year use of psilocybin.

Data from NSDUH can be used to understand changes in past-year use of all hallucinogens, DMT, LSD, and MDMA among the U.S. population ages 12 and older from 2002 to 2022. These data are presented in Figure 2.1; however, readers should be very careful about making comparisons over time because of changes in the survey methodology and questions (see notes of Figure 2.1). The figure highlights that the prevalence of past-year use of all hallucinogenic substances remained broadly stable over the period from 2006 to 2015, with prevalence of past-year use remaining between 1.36 percent (95 percent CI: 1.24, 1.49) and 1.77 percent (95 percent CI: 1.62, 1.94) without consistent upward or downward trends. Noting that ketamine, DMT, and *salvia divinorum* were added to the "all hallucinogens" category in 2015, the years between 2015 and 2020 saw an increase in

[35] It is unclear why there appears to be a difference for cannabis but not the other substances, but cannabis measures are becoming increasingly unreliable with the proliferation of CBD and hemp-derived products.

past-year prevalence, rising from 1.77 percent (95 percent CI: 1.62, 1.94) to 2.58 percent (95 percent CI: 2.31, 2.88) over the five-year period. Significant changes to the survey methodology in 2020 and 2021 means trends over this period cannot be analyzed; however, in 2022, NSDUH estimates that 3.2 percent (95 percent CI: 2.95, 3.48) of the U.S. population ages 12 and older used a hallucinogen in the past year.

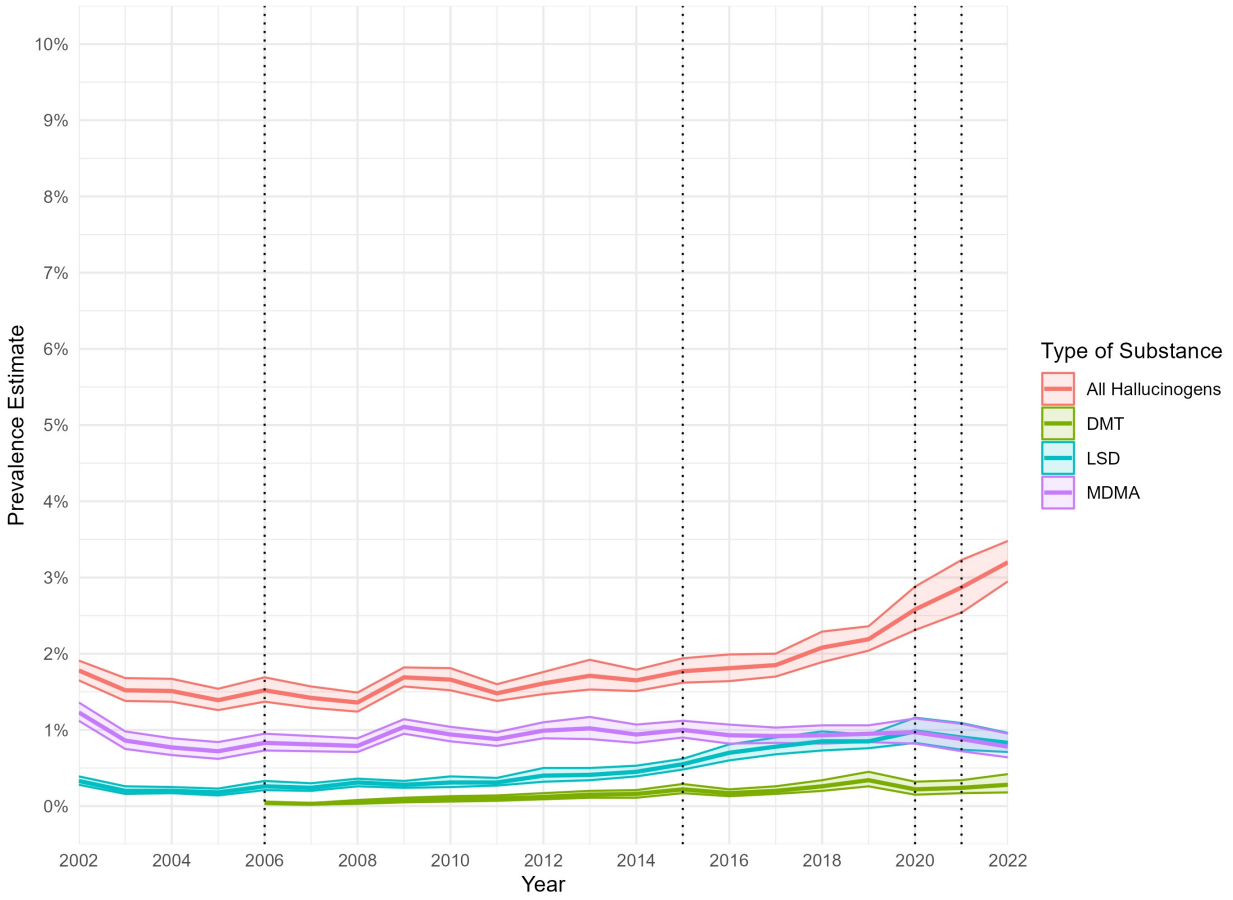
The NSDUH past-year prevalence estimates additionally highlight that past-year use of DMT has remained consistently lower than LSD and MDMA past-year use, but gradually increased from 0.04 percent (95 percent CI: 0.03, 0.06) in 2006 to its peak at 0.34 percent (95 percent CI: 0.26, 0.45) in 2019. Past-year use of MDMA has remained relatively stable in prevalence from 2003 to 2020 with fluctuations from 0.72 percent (95 percent CI: 0.62, 0.84) to 1.04 percent (95 percent CI: 0.95, 1.14), while LSD has seen a gradual increase from its lowest estimated prevalence of 0.18 percent (95 percent CI: 0.14, 0.23) in 2005 to 0.98 percent (95 percent CI: 0.83, 1.16) in 2020. The 2022 estimates suggest that LSD and MDMA have similar past-year prevalences of 0.83 percent (95 percent CI: 0.81, 0.96) and 0.78 percent (95 percent CI: 0.64, 0.95), respectively.

Table 2.2. Prevalence of Alcohol, Cannabis, and Psychedelics Among Adults 18 and Older: Estimates from 2023 RPS and 2022 NSDUH

	Lifetime		Past Year		Past Month	
Substance	**RPS**	**NSDUH**	**RPS**	**NSDUH**	**RPS**	**NSDUH**
Alcohol	85.9% (84.1, 87.5)	84.0% (83.3, 84.6)	68.3% (66.2, 70.3)	67.3% (66.4, 68.1)	55.2% (53.0, 57.3)	53.0% (52.1, 53.8)
Cannabis	56.0% (53.8, 58.1)	50.3% (49.2, 51.4)	29.8% (27.9, 31.8)	23.0% (22.2, 23.7)	20.2% (18.5, 22.0)	16.0% (15.4, 16.6)
Psilocybin/psilocyn/ magic mushrooms	12.1% (10.8, 13.5)	12.4% (11.9, 13.0)	3.1% (2.4, 3.9)		0.9% (0.5, 1.4)	
LSD/acid	12.0% (10.7, 13.4)	12.1% (11.5, 12.8)	0.9% (0.5, 1.6)	0.8% (0.7, 1.0)	0.2% (0.1, 0.4)	0.2% (0.1, 0.2)
MDMA/ecstasy/ Molly	7.6% (6.6, 8.7)	8.5% (8.0, 9.1)	1.1% (0.7, 1.7)	0.8% (0.6, 1.0)	0.2% (0.1, 0.4)	0.1% (0.1, 0.2)
Mescaline/peyote/San Pedro[a]	3.1% (2.4, 3.9)		0.2% (0.1, 0.6)		0.2% (0.1, 0.6)	
Mescaline[a]		3.1% (2.7, 3.5)				
Peyote[a]		2.2% (1.9, 2.5)				
DMT/ayahuasca/yagé[a]	1.4% (1.0, 1.9)		0.4% (0.2, 0.8)		0.1% (0.0, 0.4)	
DMT[a]		1.6% (1.4, 1.8)		0.3% (0.2, 0.4)		0.1% (0.0, 0.1)
Ibogaine/iboga	0.3% (0.1, 0.6)		0.1% (0.0, 0.4)		0.0% (0.0, 0.2)	
5-MeO-DMT/bufotenin/ toad[a]	0.2% (0.1, 0.3)		0.0% (0.0, 0.2)		0.0% (0.0, 0.1)	

[a] The NSDUH asks about mescaline and peyote separately; the RPS asks about them in a single question. For DMT, the NSDUH asks a single question, “DMT, also called dimethyltryptamine, AMT also called alpha-methyltryptamine, or Foxy, also called 5-MeO-DIPT”; in the RPS, DMT was combined in a single item with ayahuasca and yagé, and 5-MeO-DMT was combined with bufotenin and toad. Empty cells denote information that is not directly comparable across surveys.

Figure 2.1. Trends in Past-Year Use of Any Hallucinogen, DMT, LSD, and MDMA for Those 12 and Older, NSDUH, 2002–2022



NOTE: Dotted vertical lines refer to changes in survey methodology and/or questions related to psychedelics. See the data descriptions earlier in this chapter (SAMHSA, 2023).

Given the recency of the policy changes highlighted in Chapter 1, there has not been much policy analysis or evaluation. A new descriptive paper (Monte et al., 2024) uses data from multiple cross-sections of the Survey of Nonmedical Use of Prescription Drugs to compare the prevalence of psychedelic drug use in Oregon and Colorado with the rest of the country over two periods (pre-period: 2019–2020; post-period, 2021 to the first quarter of 2023; n=267,268). Given the differences in policy changes in Oregon and Colorado, the timing of these changes, the complicating role of COVID-19, and the fact the authors did not include control variables in the analyses, one should not interpret these findings as causal (i.e., changes in patterns of use are attributable to the policy changes). Monte and colleagues found that the prevalence of past-year psychedelic drug use (i.e., MDMA, LSD, psilocybin, and ketamine) in Oregon and Colorado increased from 3.28 percent (95 percent CI: 2.66, 3.89) in the 2019–2020 period to 5.44 percent (95 percent CI: 4.63, 6.24) in the 2021–2023 period—an increase of 65.9 percent. This change was greater than the U.S. national average increase (excluding Colorado and Oregon) in past-year psychedelic drug use of 18.3 percent (based on the Survey of Nonmedical Use of Prescription Drugs, not NSDUH). With respect to past-year initiation of use, they report that the rates in "Oregon and Colorado rose from 1.5% (95% CI 1.07% to 1.93%)

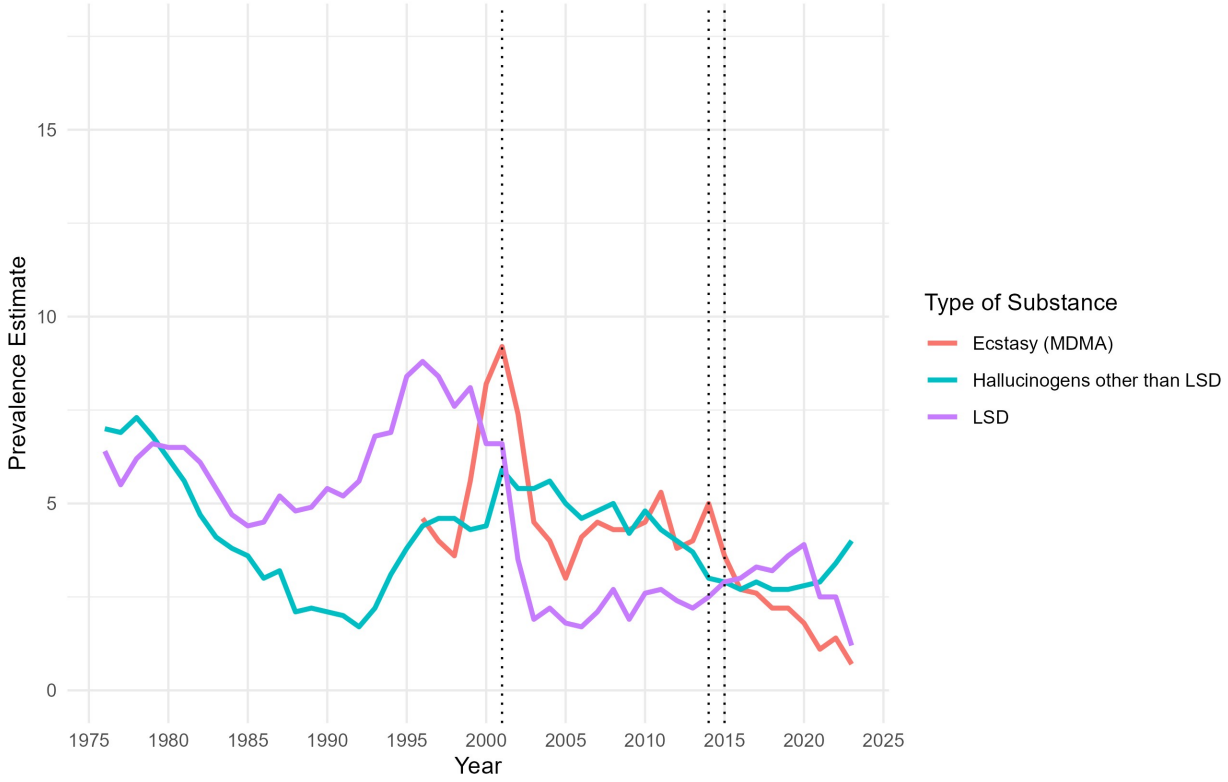
to 2.14% (1.62% to 2.66%), a 43% increase, compared to other U.S. states where values have only risen from 1.44% (1.37% to 1.52%) to 1.65% (1.57% to 1.73%), representing a 15% increase" (Monte et al., 2024, p. 284). We suspect researchers will publish more-rigorous comparisons with these and other data soon.

Data from the Monitoring the Future survey can be used to show long-term changes in past-year use of psychedelics among 12th graders; these trends are presented in Figure 2.3.[36] Both LSD and hallucinogens other than LSD (primarily psilocybin) saw a gradual decline in the 1980s and sharp increases in past-year prevalence among 12th graders in the early 1990s (parallel to what is seen with cannabis; not displayed). Past-year LSD use appeared to have peaked among 12th graders in 1996, with hallucinogens other than LSD appearing to have peaked five years later in 2001; however, as noted earlier in this chapter, there were changes in 2001 in the questions about hallucinogens other than LSD. LSD saw a sharp decline in past-year prevalence in 2001 and the following few years, possibly associated with rapid reductions in its availability in the United States at the turn of the millennium because of law enforcement action (Grim, 2009; Miech et al., 2024). Past-year MDMA use also appeared to have peaked among 12th graders in 2001, followed by a general but inconsistent decline for the next two decades.

For 2023, the past-year prevalence rates for LSD, MDMA, and hallucinogens other than LSD were 1.2 percent, 0.7 percent, and 4.0 percent, respectively. Although the prevalence rates for LSD and MDMA declined after 2020, the rates increased for hallucinogens other than LSD—the category that includes psilocybin—over this period.

[36] We focus on the samples from grade 12 because they provide the longest time series—going back to 1975. This section is based on the online analysis tool that reports the point estimates but not the CIs.

Figure 2.2. Trends in Past-Year Use of Psychedelics for High School Seniors, Based on 1975–2023 Monitoring the Future Survey



SOURCE: Adapted from Miech et al., 2024.
NOTE: 95% CIs were not reported for these estimates. Meich et al. (2023) note that "[i]n 2001, a revised set of questions on other hallucinogen use was introduced. Other psychedelics was changed to other hallucinogens and shrooms was added to the list of examples. From 2001 on data points are based on the revised question."
With respect to MDMA, Meich et al. (2023) note: "In 2014 some questionnaire forms in the survey included 'Molly' as an example of MDMA, along with ecstasy, and the inclusion of this example appeared to make relatively little difference in the overall prevalence of MDMA. In 2015 the remaining forms were changed to also include 'Molly' as an example in the questions about MDMA."

Frequency of Use

Prevalence provides an important measure of substance use, but frequency of use is necessary (though not sufficient) to assess the likely effects on health and market outcomes. NSDUH data can be used to provide estimates of reported *total use days*, which is an estimate of the total number of days hallucinogens were used across all those who used (Midgette et al. 2019). The 2023 RPS asked specifically about the frequency of use of psilocybin among past-year and past-month users as well as recency of use among lifetime users who did not use in the past year.

Insights for all Hallucinogens from NSDUH

Table 2.3 presents estimates of the total number of days of use in the past month for the drugs NSDUH classifies as hallucinogens and for cannabis, by frequency of use. These figures can provide useful insights about the size of the markets, although it would be more informative if we had data about the total quantities consumed or expenditures (further discussed later in this chapter in the "Characteristics of Individuals' Last Use of Psilocybin" and "How Is Psilocybin Obtained and How Much Do Consumers Spend?" sections.). But information on amounts consumed and expenditures is not readily available, so we proceed with this exercise to help get a sense of the order of magnitude of market size.

Table 2.3. Total Past-Month Use Days by Frequency of Past-Month Use, 2022 NSDUH

Past-Month Use Days Categories	Category Midpoints	Hallucinogens		Cannabis	
		Number of People	Total Use Days	Number of People	Total Use Days
1–2 days	1.5	1,644,385	2,466,578	8,060,760	12,091,140
3–5 days	4	457,275	1,829,100	5,801,175	23,204,700
6–19 days	12.5	126,227	1,577,832	8,260,421	103,255,263
20–30 days	25	43,824	1,095,599	20,492,494	512,312,346
	Total	2,271,711	6,969,109	42,614,850	650,863,449

NOTE: Based on weighted analysis of the hallndaypm and mrjmdays variables in the 2022 NSDUH microdata. These figures are based on participants ages 12 and older. The NSDUH hallucinogens category includes LSD (or acid); PCP (or angel dust or phencyclidine); peyote; mescaline; psilocybin; ecstasy or Molly/MDMA; ketamine/Special K/Super K; DMT; AMT; and Foxy; and *salvia divinorum*. hallndaypm = number of days used hallucinogens in past month; mrjmdays = number of days used marijuana in past year.

The 2022 NSDUH microdata include variables recoded by SAMHSA for days used in the past month, focusing on four categories: one to two days in the past month, three to five days, six to 19 days, and 20 to 30 days. For these estimates, we focus on the midpoints (1.5, 4, 12.5, and 25, respectively). We focus on past-month instead of past-year use days for two reasons. First, the past-year categories are too broad (e.g., the lowest category is one to 11 days, and taking the midpoint would lead to a major overestimate for substances that are infrequently used, such as psychedelics). Second, people are more likely to accurately remember how frequently they used in the past month versus the past year.

There are two major takeaways from Table 2.3. The first is the extent to which infrequent users drive the market. For cannabis, it is negligible: Those reporting using five or fewer days in the past month account for about 5 percent of the total past-month use days. But for hallucinogens, that figure is closer to 60 percent. Another way to think about this: Almost 50 percent of past-month cannabis users consumed on a daily or near-daily basis; for psychedelics, it was about 2 percent.

The second major takeaway is that, in terms of the national total for the number of days used, the figure for cannabis is about two orders of magnitude larger than it is for all the substances lumped into NSDUH's hallucinogen category. For 2022, the estimated total of past-month use days for cannabis was about 650 million, whereas the comparable figure for hallucinogens was closer to 7 million. Of course, it is no surprise that the figure for cannabis is much larger than it is for hallucinogens just based on the prevalence figures presented in the previous section.

Insights for Psilocybin from RPS

For those who used psilocybin in the past year but not the past month, frequency of use was assessed by asking: "In the past year, on how many days did you use psilocybin mushrooms or products containing psilocybin or psilocin?" with the following response options: "1 or 2 days," "3 to 5 days," "6 to 10 days," and "11 days or more." Similar phrasing was used for past-month users, except the question referred to the past 30 days and respondents could select a number of days between 1 and 30. Those who used in the past 30 days were not asked about frequency of use in the past year.

Table 2.4 presents these results, and the main takeaway is that the majority of people who used psilocybin in the past year used it infrequently. Among past-year but not past-month users, more than half (57.8 percent) used psilocybin on one or two days in the past year, almost one-third (29.8 percent) used three to five days, and 11.5 percent used six or more days. Those who used in the past month were more-frequent users: Just under one-third used one or two days, another one-third used three to five days, and the remaining one-third used six or more days (only 4 percent used more than ten days in the past month; Table 2.4). Among past-month users, the mean number of days used was 4.6 (95 percent CI: 3.2, 6.0).

Table 2.4. Frequency of Psilocybin Use by Recency of Use Among Those Who Used in the Past Year

	Percentage of Users	95% CI	Weighted Number of Adults Ages 18 and Older
Past-year use but no use in past month			
1–2 days in past year	57.8%	(44.3, 70.2)	3,258,832
3–5 days in past year	29.8%	(18.7, 44.0)	1,680,159
6–10 days in past year	7.4%	(3.3, 15.8)	417,221
11 days or more in past year	4.1%	(1.5, 11.0)	231,163
Past-month use			
One or two days in past month	32.2%	(15.7, 54.6)	709,525
3–5 days in past month	31.0%	(13.7, 56.0)	683,083
6–10 days in past month	29.2%	(7.8, 66.8)	643,420
11–20 days in past month	2.9%	(0.3, 19.8)	63,901
21–30 days in past month	1.1%	(0.1, 8.4)	24,238

NOTE: Weighted number assumes 252,955,199 people 18 or older in the adult population (U.S. Census Bureau, undated-a). Of these, 3.1 percent, or an estimated 7,841,611 adults, used psilocybin in the past year, of whom 28.1 percent (*N* = 2,203,492) used in the past month.

We also asked all those who used psilocybin in the past year whether they microdosed the *last time* they used it. Respondents who microdosed psychedelics used small amounts (typically 1/10th to 1/20th of a dose, but there is no standard definition of microdosing), often a few times a week for multiple weeks, maybe longer. These sub-threshold doses do not produce the effects typically associated with full doses.

Specifically, the survey asked: "Did you microdose the last time you used psilocybin mushrooms or products containing psilocybin or psilocin?"[37] Forty-seven percent (46.9 percent, 95 percent CI: 35.3 percent, 58.8 percent) of those who used psilocybin in the past year reported microdosing the last time they used the substance; among past-month users, 65.6 percent (95 percent CI: 42.7 percent, 83.0 percent) reported microdosing the last time they used. Not surprisingly, those who microdosed used psilocybin more frequently than those who did not report microdosing the last time they used. For instance, 10 percent of those who microdosed the last time they used psilocybin used it 11 days or more in the past year, compared with 4.1 percent of all past-year users (no past-year non-microdosers reported using 11 days or more in the past year; see Table 2.5).[38] The main takeaway is that those who use psilocybin frequently were much more likely to report microdosing the last time they used. This point is made even clearer by the data presented in Table 2.6: Among those who used in the past year,

[37] Respondents were provided with the following definition: "Microdosing is taking a fraction of a regular dose (a subperceptual dose) that is much lower than you would take to 'trip' or hallucinate on these substances." We should note that there is no agreed-upon standard about what constitutes a microdose for the various psychedelics.

[38] These estimates exclude individuals who used in the past month, because they were not asked about past-year frequency of use, only past-month frequency of use. Small cell counts prohibited us from examining past-month frequency of use among those who used in the past month by microdose status.

approximately one-third of those who used on five or fewer days microdosed the last time they used, versus two-thirds of those who used six to ten days in the past year and all of those who used 11 or more days.

Table 2.5. Frequency of Past-Year Psilocybin Use Among Those Who Did Not Use in the Past Month, by Whether Their Most Recent Use Was by Microdosing

	PY, but not PM use: All		PY, but not PM use: Microdose at last use		PY, but not PM use: Non-microdose at last use	
	%	95% CI	%	95% CI	%	95% CI
1–2 days	57.8%	(44.3, 70.2)	49.7%	(31.4, 68.1)	63.0%	(43.8, 78.8)
3–5 days	29.8%	(18.7, 44.0)	25.0%	(12.7, 43.4)	33.0%	(17.7, 53.0)
6–10 days	7.4%	(3.3, 15.8)	12.6%	(4.3, 31.5)	4.0%	(1.3, 11.4)
11 days or more	4.1%	(1.5, 11.0)	10.4%	(3.7, 25.9)	0	N/A

NOTE: PM = past month; PY = past year.

Table 2.6. Frequency of Microdosing at Most-Frequent Use Among Those Who Did Not Use in the Past Month, by Frequency of Past-Year Psilocybin Use

	PY but not PM Use: All		PY but not PM Use: Microdose at Last Use		PY, but not PM Use, Non-Microdose at Last Use	
	%	95% CI	Row %	95% CI	Row %	95% CI
1–2 days	57.8%	(44.3, 70.2)	34.1%	(19.9, 51.8)	66.0%	(48.2, 80.1)
3–5 days	29.8%	(18.7, 44.0)	33.1%	(15.4, 57.4)	66.9%	(42.6, 84.6)
6–10 days	7.4%	(3.3, 15.8)	67.1%	(30.9, 90.3)	32.9%	(9.7, 69.1)
11 days or more	4.1%	(1.5, 11.0)	100%	N/A	0%	N/A

NOTE; PM = past month; PY = past year.

Characteristics of Individuals' Last Use of Psilocybin

In addition to whether they microdosed, we also asked individuals who used psilocybin in the past year the form they consumed, their reasons for using, and whether they were supervised (and by whom) and who they were with *the last time they used psilocybin*. Estimates are provided in Tables 2.7 through 2.10.

The most common way psilocybin was used was as whole, fresh, or dried mushrooms (56.2 percent), followed by in processed or edible form (22.4 percent) and then in a tea or drink (14.3 percent). However, use of whole, fresh or dried mushrooms was more common among those who did not microdose the last time they used (70.7 percent) compared with those who did (39.7 percent). For

those who microdosed, a greater proportion than those who did not use psilocybin in a tea or drink (24.0 percent vs. 5.8 percent), in an edible form (26.6 percent vs. 18.7 percent), or in a capsule or tablet (7.9 percent vs. 3.3 percent), although we note that the small sample sizes yield large CIs around these estimates.

Table 2.7. Form of Psilocybin Used at Last Use Among Individuals Who Used in the Past Year

	Past-Year Use: All		Past-Year Use: Microdose at Last Use		Past-Year Use: Non-Microdose at Last Use	
	%	95% CI	%	95% CI	%	95% CI
Whole, fresh, or dried mushrooms	56.2%	(43.9, 67.7)	39.7%	(24.6, 57.1)	70.7%	(53.9, 83.2)
Truffles	0.8%	(0.1, 5.5)	1.7%	(0.2, 11.6)	0.0%	(0.0, 0.0)
In a tea or drink	14.3%	(6.3, 29.5)	24.0%	(9.0, 50.2)	5.8%	(2.3, 13.8)
In a processed edible form (e.g., a chocolate bar)	22.4%	(13.9, 34.1)	26.6%	(14.5, 43.6)	18.7%	(8.1, 37.5)
In a capsule or tablet	5.5%	(2.7, 10.6)	7.9%	(3.6, 16.8)	3.3%	(0.8, 12.6)
Other	0.6%	(0.1, 2.4)	0.0%	(0.0, 0.0)	1.1%	(0.3, 4.6)

Respondents in the 2023 RPS who used psilocybin in the past year were asked, "What were your intentions for the experience the last time you used psilocybin mushrooms or products containing psilocybin or psilocin?" Response options are provided in Table 2.8. The most commonly endorsed option among all those who used was "Fun (e.g., for a sense of joy, pleasure, or play, including at a party or other social gathering)," reported by 59.1 percent of those who used in the past year. However, between 40 percent and 50 percent also reported improved mental health (48.8 percent), personal development (45.2 percent), curiosity (42.9 percent), spiritual growth (41.3 percent), and cognitive enhancement (41.2 percent).[39]

[39] We examined differences by those who reported microdosing the last time they used versus those who did not (not shown), and though some were qualitatively different, only one difference that was statistically (and substantively) significant: Fewer of those who microdosed the last time they used reported taking psilocybin for interpersonal bonding relative to those who did not microdose (13.5 vs. 33.3 percent).

Table 2.8. Intentions for Using Psilocybin at Last Use Among Individuals Who Used in the Past Year

Intention	%	95% CI
Fun (e.g., for a sense of joy, pleasure, or play, including at a party or other social gathering)	59.1%	(47.0, 70.3)
Improved mental health (e.g., to decrease symptoms of a mental health condition, such as depression or PTSD, or a substance use problem	48.8%	(37.1, 60.7)
Personal development (e.g., existential exploration, personal growth, self-awareness)	45.2%	(33.6, 57.4)
Curiosity (e.g., to witness whatever unfolds with no particular goal or aim	42.9%	(32.0, 54.6)
Spiritual growth (e.g., greater connection with nature or the sacred)	41.3%	(30.0, 53.7)
Cognitive enhancement (e.g., heightened creativity, performance, or problem solving)	41.2%	(29.7, 53.7)
Interpersonal bonding (e.g., to connect with a friend, family member, or romantic partner)[a]	24.0%	(15.8, 34.8)
Community bonding (e.g., to connect with your family, community, or social group)	15.0%	(8.8, 24.4)
Improved physical health (e.g., to decrease symptoms of a physical ailment or enhance physical performance)	14.9%	(8.9, 23.9)
Escapism (e.g., to avoid feelings of pain or discomfort)	10.4%	(5.7, 18.4)
Other	0.7%	(0.1, 5.0)

[a] Denotes $p < 0.05$ in weighted logistic regression models between those who microdosed the last time they used and those who did not. Respondents were asked to check all that apply.

As will be made clear throughout this report, supervision of psychedelics use sessions is an important consideration for those attempting to minimize harms related to use and possibly maximize the benefits. Although 40.4 percent of individuals who used psilocybin in the past year reported being supervised during their past-use session, most were supervised by someone they knew (37.8 percent). Around 1 percent (95 percent CI: 0.2, 6.4) of respondents were supervised by a shaman or spiritual religious leader, while none reported being supervised by a licensed clinical provider (Table 2.9).

Table 2.9. Supervised When Using Psilocybin at Last Use Among Individuals Who Used in the Past Year

	%	95% CI
No, I was not supervised	59.6%	(47.6, 70.7)
Yes, I was supervised by a certified or licensed medical professional	0.0%	(0.0, 0.2)
Yes, I was supervised by a shaman or spiritual/religious leader	1.2%	(0.2, 6.4)
Yes, I was supervised by someone I know (e.g., a friend or acquaintance)	37.8%	(27.0, 50.0)
Yes, I was supervised by someone else (e.g., a stranger or unlicensed therapist)	0.0%	(0.0, 0.0)
Other	1.1%	(0.2, 4.6)

Few individuals who used psilocybin were in a group but were the only person using (10.4 percent). The other groups were evenly distributed at roughly 30 percent each: Those using alone, with a group in which some were also using psilocybin, or with a group in which everyone was using psilocybin.

Table 2.10. Accompaniment When Using Psilocybin at Last Use Among Individuals Who Used in the Past Year

	Past-Year Use: All	
	%	95% CI
I was alone	28.4%	(18.2, 41.5)
I was with one or more people, some of whom also were using them	32.1%	(22.6, 43.3)
I was with one or more people, all of whom also were using them	29.1%	(19.4, 41.2)
I was with one or more people but I was the only person using them	10.4%	(5.7, 18.1)
Other, please specify	0	

Quantity Consumed (Dose)

It is critical to have a sense of the amounts people are using—not just the prevalence and frequency—when thinking about the consequences of using drugs and making projections about policy changes. But estimating quantities consumed can be especially challenging because many, if not most, people consuming psychedelics do not know how much of the active ingredient is in the material they are using (e.g., amount of psilocybin or psilocin in a mushroom). This is also important information when thinking about those who microdose versus those who typically use larger doses of psychedelics.

Neither NSDUH nor RPS ask about quantity consumed during a day of use; however, two recent peer-reviewed articles provide some insights based on clinical studies and other sources. Thomas et al. (2023) present estimates for "typical medium-high doses" and Polito and Liknaitzky (2022) offer ranges for "typical recreational or therapeutic dose range" and "plausible microdose dose range" (Table 2.11). Of course, the amounts consumed by those using in clinical versus more-natural settings can differ, sometimes dramatically, and even within clinical settings doses may differ.

Table 2.11. Dose Estimates for Various Psychedelics

	Thomas et al., 2023	Polito and Liknaitzky, 2022	
Substance	**"Typical medium-high dose"**	**"Typical recreational or therapeutic dose range"**	**"Plausible microdose dose range"**
O-phosphoryl-4-hydroxy-N,N-dimethyltryptamine (*Psilocybe cubensis* dried mushroom)	Dried mushrooms containing both psilocybin and psilocin: 3.5 g[a] (oral)	3–5 g	0.1–0.5 g
O-phosphoryl-4-hydroxy-N,N-dimethyltryptamine (Synthetic psilocybin)	30 mg (oral)	17–30 mg	0.8–5 mg
4-hydroxy-N, N-dimethyltryptamine (Psilocin, the active metabolite in psilocybin)[b]	20 mg (oral)		
Lysergic acid diethylamide (LSD; also referred to as acid)	150 mcg (base)	100–200 mcg	0.7–3.5 mg/70 kg
N,N-Dimethyltryptamine (DMT)	30 mg (fumarate)	25 mg	8–9 mg
5-methoxy-N,N-Dimethyltryptamine (5-MeO-DMT)	10 mg via vaporization or intramuscular injection (base)		
12-Methoxyibogamine (ibogaine)	1,250 mg (hydrochloride)	1,000–2,000 mg/70 kg (possibly starting at 200 mg/70 kg)	20 mg/70 kg
3,4,5-Trimethoxyphenethylamine (mescaline)	750 mg (hydrochloride)		
3,4-Methylenedioxymethamphetamine (MDMA; also referred to as ecstasy or Molly)	150 mg (hydrochloride)		

NOTE: kg = kilogram; mcg = microgram.

[a] As noted in Thomas et al. (2023), "[P]silocybin and psilocin content of mushroom material carrier weight varies widely among species and even from specimen to specimen, so any weight limit for psychoactive mushroom material or other carrier weights must be understood as imprecise."

[b] Psilocybin metabolizes into psilocin, which acts on the serotonin receptors. Psilocyn is also present in some mushrooms.

How Is Psilocybin Obtained and How Much Do Consumers Spend?

Understanding how individuals obtain psilocybin and, for those who purchase it, how much they spend provides insights into the current market. This information can also be critical for trying to project the consequences of different approaches to legalizing supply. When we asked those using in the past year how they last obtained the psilocybin they used, close to half (49.3 percent) bought psilocybin from another individual and an additional 30 percent got it from someone for free (Table 2.12). Others (10.3 percent) bought the drug either from a retail outlet or online (both illegal), and 3.8 percent of those surveyed grew, cultivated, or foraged mushrooms.

Table 2.12. How Did You Obtain Psilocybin Mushrooms or Products Containing Psilocybin or Psilocin the Last Time You Used Them?

	%	95% CI
Bought them from someone in person	49.3%	(37.6, 61.1)
Bought them online	4.3%	(1.8, 10.1)
Bought them from a store in person	6.0%	(2.8, 12.7)
Paid a facilitator or guide to provide them along with other services	0.2%	(0.0, 1.1)
Traded them for something	3.2%	(1.1, 9.1)
Grew, cultivated, or foraged them myself	3.8%	(1.7, 8.1)
Got them from someone for free	30.0%	(20.9, 41.1)
Other	1.0%	(0.1, 6.1)

NOTE: 2.1 percent of the sample skipped this question.

Tables 2.13 and 2.14 focus on how much people spent on products containing psilocybin.[40] Among those who used psilocybin in the past month, 46.6 percent did not pay for it, while 42.1 percent of those who used in the past year (but not the past month) did not pay for it. Among those who used in the past month, almost half (46.4 percent) spent between $10 and $100 for psilocybin in the past month (Table 2.13). Among those who used in the past year, but not in the past month, 43 percent spent between $20 and $100 in the past year (Table 2.14). However, we must note the especially wide CIs around these figures.

[40] Those who used psilocybin in the past month/past year were asked, "In the past 30 days/past year, how much money did you spend on psilocybin mushrooms or products containing psilocybin or psilocin? Please answer in U.S. dollars."

Table 2.13. Past-Month Expenditures on Psilocybin for Those Reporting Past-Month Use

	%	95% CI
I did not pay for them	46.6%	(22.2, 72.8)
$10 or less	2.7%	(0.5, 13.8)
$10.01 to $20	18.7%	(6.6, 42.9)
$20.01 to $50	16.0%	(5.9, 36.7)
$50.01 to $100	11.7%	(3.3, 33.7)
$100.01 to $200	4.3%	(0.5, 27.6)
More than $200	N/A	N/A
I paid for services that included them	N/A	N/A
I don't know	N/A	N/A

Table 2.14. Past-Year Expenditures on Psilocybin for Those Reporting Past-Year Use, but Not in the Past Month

	%	95% CI
I did not pay for them	42.1%	(30.0, 55.3)
$10 or less	3.6%	(1.1, 11.1)
$10.01 to $20	0.9%	(0.2, 3.5)
$20.01 to $50	19.3%	(10.6, 32.6)
$50.01 to $100	23.7%	(13.3, 38.7)
$100.01 to $200	6.5%	(2.9, 13.9)
$200.01 to $500	0.0%	(0.0, 0.3)
$500.01 to $1000	N/A	N/A
More than $1000	N/A	N/A
I paid for services that included them	0.6%	(0.1, 4.4)
I don't know	3.2%	(0.7, 13.7)

If we take the midpoints of these ranges and top code the largest category at $250 for past-month expenditures, the mean past-month spending on psilocybin among those who reported using in the past month is $23.77 (95 percent CI: $6.42, $41.12). For those using in the past year but not the past month, the mean expenditure in the past year is $36.13 (95 percent CI: $25.43, $46.83). Excluding those who received the drug for free (and for whom the amount they spent on psilocybin was set at $0), the mean past-month spending on psilocybin is $44.56 (95 percent CI: $21.24, $67.88). For those using in the past year but not the past month, the mean expenditure in the past year is $64.30 (95 percent CI: $52.13, $76.47).

We can also use these figures to get a sense of the total amount of money spent on mushrooms and other products containing psilocybin in the past year. For simplicity, we will focus on round

numbers. The U.S. population in 2023 who was 18 or older was about 260 million (U.S. Census Bureau, undated-a), and our past-month prevalence rate of 1 percent puts the number of people who used psilocybin in the past month at 2.6 million. If we multiply this figure by the average monthly spending ($24) and then by 12 to generate an annual figure, we estimate that adults spent $750 million on psilocybin products in 2023. There will be spending by those younger than 18, our survey may have missed some people who did not want to report their drug use, and some people will spend resources producing their own psilocybin mushrooms, so it does not seem unreasonable to suggest that U.S. residents spent on the order of $1 billion on psilocybin in 2023. Just to put this in perspective, the last year for which we have total spending on cannabis, cocaine, heroin, and methamphetamine is 2016, and it was estimated that Americans spent about $150 billion on these substances that year (Midgette et al., 2019).

Insights About Retail Prices and Production Costs

As will become clear in Chapters 4 and 5, knowing the prices that people pay for any drug is a critical element for projecting the effects of various policy changes; however, systematic price data on psychedelics are hard to come by. First, price questions are not included in nationally or state-representative surveys, such as NSDUH, RPS, or California Health Interview Survey (one of the biggest state-run health surveys in the country). Second, to make sure we are comparing apples to apples across time and locations, it is more helpful to not just know the raw price but the potency- or purity-adjusted price (e.g., price per 10 mg of psilocybin). Third, there can be quantity discounts that also have to be considered when thinking about prices (Caulkins and Padman, 1993; Smart et al., 2017).

Although it is not uncommon to read media reports for the prices of common doses of one-eighth of an ounce of psilocybin mushrooms being in the ballpark of $35 or a dose of LSD (100–150 mcg) for $10 or less (Ray, 2023; Williams, 2023), there can be major variation in these prices. Prices can depend on several factors, such as the amount purchased, location of purchase, level of enforcement, type of mushroom, time of year, and type of product (dried mushroom vs. chocolate bar). The EMCDDA attempts to collect price and purity information annually for LSD, MDMA, and other substances at the retail and wholesale level, but not all countries consistently report this information (EMCDDA, undated). Still, this could be a useful model for U.S. federal and state agencies while more rigorous price and purity systems are established for psychedelics.

The cost to produce various psychedelics also differ, especially when thinking about those that are nonsynthetic versus those that are produced in a lab. There can be massive variation even if we just consider psilocybin. Some people will forage for *Psilocybe cubensis* or other members of the *Psilocybe* genus, so the only cost of production is the time they spend collecting and possibly the cost of a food hydrator, desiccants, and airtight containers (but some people will just air dry or not dry them at all; see, e.g., SeattleMet, 2023). Some may also purchase spore kits or spore syringes to grow psilocybin mushrooms at home. These items can vary in price depending on the type of mushroom and amounts purchased, but it is not uncommon for psilocybin spore syringes to be sold online for around $20.

It is unclear the extent to which there is a large wholesale market for psilocybin involving entities that grow large amounts or purchase from multiple producers and then distribute them to those who

sell at the retail level (versus those who self-produce smaller amounts or get them from those who forage or self-produce). There have been reports of arrests involving very large quantities of psilocybin mushrooms (e.g., DEA, 2016; Collins, 2023), but little is known about whether these are outliers. But with large grows, one would expect there to be economies of scale that lead to lower production costs.

We conclude with some insights about the production of legal mushrooms in the United States that you would buy at a grocery store or eat at a restaurant. The U.S. Department of Agriculture (2022) reports that at the farmgate, mushroom producers earned about $1 billion in 2022. The department also reports the farmgate price per pound of mushrooms, ranging from about $0.70 for agaricus (the most commonly consumed mushrooms in the United States; see Du et al., 2021) to such specialty mushrooms as Shiitake that are closer to $4 per pound. At $4 a pound, that works out to less than a penny per gram (453.6 grams in a pound). When thinking about producing psilocybin mushrooms at a mass scale, one must also incorporate the cost of drying and possibly other costs that differ from other mushrooms.[41] But this example suggests that if psilocybin mushrooms were legalized and commercial production was allowed, the production costs could be extremely low.

[41] Mushrooms can lose more than 90 percent of their weight when dried. Here is a thought experiment using round numbers and a host of assumptions: If it costs $4 to produce a pound of wet psilocybin mushrooms, another $1 to dry that pound (this is just a guess), and the dried weight is 10 percent of the wet weight, that would put a pound of dried mushrooms at the farmgate at $50 ($4/10% + $10), or about $0.11 per gram. That would put the farmgate cost for one-eighth of an ounce of legal mushrooms at about 40 cents. There are no systematic data on retail psilocybin mushroom prices—but, as noted, $35 for one-eighth of an ounce is not an unreasonable price in many parts of the country. This suggests there could be a large retail price drop if commercial production and retail sales were allowed (and there was neither a minimum unit price nor a large tax). We hope to see more-rigorous analyses of the economics of psilocybin production in future research.

Chapter 3

Consequences of Using Psychedelic Substances

Introduction

In this chapter, we discuss some of the positive and negative consequences of psychedelics use. The goal of this chapter is not to render judgment on whether it is a good idea for an individual to use psychedelics. Furthermore, this chapter is not a systematic review of all potential consequences of using psychedelics—we leave the assessment of the safety and efficacy of these substances for treating specific conditions to the FDA and similar agencies outside the United States. Although this chapter does provide a general assessment of psychedelics as a group, these substances can vary dramatically in potential risks and benefits. Additionally, effects are dependent on the dose, setting of the experience, and other such factors as the mental and physical state of an individual and their vulnerability to develop serious mental health conditions (Zinberg, 1984).

In this chapter, we begin by describing the types of research used to assess the consequences of psychedelics, ranging from clinical trials to surveys to qualitative research. We then summarize the potential benefits and risks of using psychedelics to individuals respectively. Lastly, we discuss strategies that may prevent or mitigate adverse events for some individuals.

What Types of Evidence Exist About the Potential Consequences of Using Psychedelics?

Research into the potential consequences of using psychedelics is developing rapidly. Before addressing the findings from this emerging literature, we describe the types of evidence currently available and some of their strengths and weaknesses. This chapter primarily focuses on peer-reviewed studies from four types of research: clinical research, surveys, qualitative studies, and observational studies. We also discuss information from a few non-peer-reviewed sources and interviews conducted for this report by our own team.

Note that most of these sources do not incorporate insights from thousands of years of Indigenous spiritual medicines that contain substances we have classified as psychedelics for the purposes of this report. There is some limited evidence from sociological or anthropological studies reporting on Indigenous traditions, which are discussed below and in some of the case studies in Appendix A.

Key Insights from Chapter 3

- The scientific literature is limited in its understanding of the consequences of using psychedelics and mitigating adverse events. Although some Indigenous Peoples have used some of these substances for centuries or millennia, many questions remain in the scientific literature about which substances, doses, and settings work best for treating various health conditions and minimizing adverse reactions.
- There is an increasing number of clinical trials demonstrating that some of these psychedelic substances may be useful treating some mental health conditions. Some of the clinical trials have faced criticisms, mostly related to poor blinding, associated expectancy effects, and small samples.
- With respect to risk of addiction, Humphreys et al. (forthcoming) note, "Other than ketamine and perhaps MDMA, psychedelic drugs do not seem to have significant addictive liability." The fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-V) includes a diagnosis of *hallucinogen use disorder*, which is characterized by problematic use that can lead to "significant impairment or distress" (American Psychiatric Association, 2013). In 2022, 0.2 percent of adults met criteria for hallucinogen use disorder (Center for Behavioral Health Statistics and Quality, 2023), and an estimated 2 percent of individuals who initiate use exhibit symptoms within two years of use (Stone, Storr, and Anthony, 2006). Those experiencing hallucinogen use disorder (or its equivalent in the DSM) were more likely to be using MDMA (Wu et al., 2009).
- There are other risks associated with these substances—e.g., the cardiovascular risks associated with ibogaine—and the risks can vary by substance, dose, set, and setting. There are concerns that use of psychedelics could worsen health outcomes for some individuals, especially if the use is not supervised or if individuals are not properly screened.
- Adverse events can sometimes last well beyond the psychedelic experience. That said, just because someone has an adverse event or challenging experience does not mean that it was not also beneficial in some respects.
- Best practices for mitigating adverse events for use outside Indigenous settings are still in development. Different substances can require different mitigation strategies and there is a need to conduct rigorous research on these approaches.

Clinical Research

Clinical trials are highly controlled studies that assess the safety and efficacy of a treatment on human subjects for health-related or behavioral outcomes (National Institutes of Health, 2017). Recently, multiple concerns have been raised within the scientific community about some of the clinical trials that study psychedelics (see, e.g., van Elk and Fried, 2023; Humphreys et al., forthcoming). These concerns do not mean that the results of these clinical trials should be disregarded but rather that some additional knowledge is required to adequately assess the insights from these studies. To that end, this section introduces some basic aspects of clinical trial design, how they relate to the clinical study of psychedelics, and what concerns have been raised.

In recent studies of the clinical effects of psychedelics, the treatment under assessment usually involves a combination of one or more doses of a psychedelic substance along with some supportive

clinical supervision, often referred to as psychedelic-assisted psychotherapy or therapy (Penn et al., 2021).[42] Supervision in clinical trials is commonly provided by multiple medical or mental health clinicians over a series of sessions before and after psychedelics are administered (Reiff et al., 2020). The clinical setting and formal supervision are quite different from nonclinical use of psychedelics, which implies that outcomes in a clinical setting may not be generalizable to nonclinical uses (Glynos et al., 2023). Additionally, to standardize doses and adhere to FDA guidelines, the psychedelics used in clinical trials are often synthesized or highly refined formulations that may have different effects from psychedelics commonly used in a nonclinical setting, especially those that are naturally occurring (Siegel et al., 2021).

Key differences in the design of clinical trials define which participants are given the treatment and whether the participants or the investigators know who has been given a treatment. These aspects of a study design are critical for assessing how likely it is that the outcome of a study was really the effect of the treatment rather than some other confounding factor. In a randomized controlled trial (RCT), participants are randomly assigned to the treatment or the control condition.[43] *Blinding* refers to the knowledge, by the participant or by investigators, of whether a participant has received the treatment or not. Blinding is especially difficult in clinical trials of psychedelics because of the well-known, generally strong effects of psychedelics, which can complicate the clear interpretation of study results (Muthukumaraswamy, Forsyth, and Lumley, 2021). A recent review shows that, in many studies of psychedelic substances, providers and participants often properly guess the group to which they were assigned, meaning that blinding is unsuccessful and the observed improvement may result from "expectancy effects" (Humphreys et al., forthcoming). Some clinical trials of psychedelics can also be described as "open-label," where the participants and the researchers are not blinded to whether the participant was assigned to the treatment or control condition.

In addition to these considerations, a 2023 systematic review of randomized clinical trials on psychedelic medicine identified several additional concerns, including small sample sizes and sampling bias (Hovmand et al., 2023). *Small sample size* means the number of participants in the study was relatively low, which reduces the certainty of the study results. All the studies included in this 2023 systematic review except one enrolled fewer than 100 participants, with more than half enrolling fewer than 50 participants. *Sampling bias*, also sometimes referred to as *selection bias*, refers to the characteristics of the study participants and how representative they are of the population on which the study is focused. This review found study participants were primarily White with a high level of educational attainment.[44] Of ten studies included in the review, only one study was rated low risk for bias overall. Notably, this study rated as low risk of bias was also industry-sponsored, which opened

[42] The definition and use of the term *psychotherapy* in psychedelic treatment has recently been debated, with some arguing that therapy accompanying the administration of psychedelics is necessary for safety and others arguing that the effects of psychedelics in a clinical setting are largely physiological and should be separated by design from the potential confounding effects of psychotherapy (Goodwin et al., 2023; Decekel, Lepow, and Guss, 2024; Alpert et al., 2024).

[43] A placebo is usually a substance that is known to have no effect. However, because of the noticeable effects of psychedelics, *active placebos* are sometimes employed in clinical trials studying psychedelics. Active placebos that have been used include a lower dose of the psychedelic substance in the treatment or another substance that produces some noticeable effects on the senses (Luoma et al., 2020).

[44] In some studies, a substantial proportion of participants also had prior experience with psychedelic drugs (Humphreys et al., forthcoming).

the results up to a risk of industry sponsorship bias,[45] another common concern in clinical research (Holman and Elliott, 2018).

A summary of concerns with clinical research on psychedelics and suggested solutions was recently published by van Elk and Fried (2023).[46] Additional concerns raised in their article include invalid statistical inferences, short study durations, and a lack of reporting on adverse events. The authors provide multiple examples to illustrate the issue of invalid statistical inferences in studies on psychedelics, where the conclusions stated in a particular study do not follow logically from the data.[47] They also echo the concern that more long-term follow-ups on studies about psychedelics are needed.

An *adverse event* is defined by the FDA as "any undesirable experience associated with the use of a medical product in a patient," which may include hospitalization, disability, or other important medical events (FDA, 2023b). As we will discuss later in this chapter, adverse events resulting from the use of psychedelics inside or outside the clinical setting are often poorly defined, not systematically assessed, and likely underreported (Breeksema et al., 2023).

Surveys

Analyses of data from anonymous surveys published in the academic literature are a common tool for understanding behaviors related to controlled substances like psychedelics in both clinical and non-clinical settings. Nationally representative surveys, such as the NSDUH and RPS discussed in Chapter 2, aim to recruit survey participants that accurately reflect the characteristics of those living in the United States. Some other surveys investigating the use of psychedelics employ a convenience sampling method where respondents are recruited from a target population of those who have used these substances. Those participating in convenience surveys often do not represent all individuals who use these substances, but that does not mean they cannot provide useful information (e.g., see Kilmer et al., 2013).[48]

General population surveys like NSDUH generally do not collect more-specific information about intentions for use, where and how individuals are using, adverse events, or other information that would be useful to inform decisionmaking. As noted in Chapter 2, that is why we fielded the RPS. There have been some less representative surveys that include detailed question on these topics. Some examples include the following:

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[45] Industry sponsorship bias is described by Hovmand et al. (2023) in this way:

> This tendency is supported by a 2017 Cochrane meta-analysis which compared industry-sponsored research with otherwise funded research, and found that industry-sponsored research were more likely to favor the sponsor's products (relative risk=1.27; 95% CI 1.17–1.37) and that authors' conclusions were more favorable (relative risk=1.34; 95% CI 1.19–1.51) (Lundh et al., 2017).

[46] van Elk and Fried also raise issues about blinding that received additional attention in a subsequent letter to the editor by Schenberg (2024). For those interested in this topic, we encourage you to read these pieces and the civil social media exchange between the authors (see Fried, 2024).

[47] Humphreys et al. (forthcoming) highlight similar concerns.

[48] This can also be an issue for well-funded nationally representative surveys, especially those focused on more-stigmatized drugs (e.g., see Reuter, Caulkins, and Midgette, 2021).

- In 2021, survey respondents were recruited at a psychedelics advocacy event in Michigan as well as via online interest groups to answer questions about their use of a variety of psychedelics, including information on doses, motivations for use, setting, supervision, product testing, and communications with health care providers about their use (Glynos et al., 2023).
- A survey was fielded in 2022 to Canadian psychedelics users that covered a broad range of substances and asked about a variety of detailed topics, including motivations for use; co-use of other substances; sources; intense positive and challenging experiences; setting; and supervision (Lake and Lucas, 2023).
- A global survey was recently fielded investigating extended difficulties following the use of psychedelics, which will be discussed in more detail later in this chapter (Jules Evans et al., 2023).
- Other recent surveys have focused on the use of particular psychedelic substances, including an investigation into psilocybin mushroom use in the United States and the Global Ayahuasca Survey (Matzopoulos et al., 2022; Bouso et al., 2022).

Qualitative Studies

Qualitative studies often come from such fields as sociology or anthropology and commonly focus on use of specific substances in specific regions or by distinct cultural groups. For example, the use of iboga in the West African Bwiti culture is described in detail by Bekale and Alagidede (2021). The ceremonial use of ayahuasca in the Shipibo culture of Peru and its crossover into other areas and practices is described in Gonzalez et al. (2021). A detailed annotated bibliography of Indigenous uses of psilocybin mushrooms was recently published that identifies 49 texts (Spiers et al., 2024). These types of sources can provide useful additional context and best practices in the use of psychedelics that are not well-known and/or less studied outside Indigenous populations.

Observational Studies

Other types of observational analyses can uncover useful information about the potential benefits and risks of psychedelics. Trends in hospitalizations or other types of health care utilization related to psychedelics can be useful indicators, but to assess whether policy changes cause these outcomes, rigorous quasi-experimental analyses must be conducted. There are also case reports that can provide insights to motivate additional monitoring and analysis of the benefits and risks of psychedelics.

Other Sources

In this category are publications outside the traditional academic journal model, which these days are usually available online. Commonly, these are reports created by nonprofits and other groups that intend to inform the emerging psychedelics industry. The following are some examples of sources and descriptions of the organizations that created them and informed some of our thinking on these issues. Each of these sources provides information that is presented from the perspective of the sponsoring organization. In 2021, a technical report on ayahuasca summarizing the effects, potential uses, and

safety of the substance was released by the International Center for Ethnobotanical Education, Research, and Service (ICEERS), a nonprofit organization dedicated to transforming society's relationship with traditional Indigenous medicines (Bouso et al, 2021). In the same year, a report was released by the Psychedelic Science Funders Collaborative (PSFC), a nonprofit collaborative of philanthropists dedicated to supporting psychedelic medicine and science (PSFC, 2021). Professional practice guidelines for psychedelic-assisted therapy were recently released by the American Psychedelic Practitioners Association (APPA), a newly established professional group looking to set standards for psychedelic practitioners, in partnership with BrainFutures, a national nonprofit that works in on mental health issues (APPA and BrainFutures, 2023). Finally, the United Nations Office on Drugs and Crime's most-recent *World Drug Report* includes a chapter on recent developments involving psychedelics (United Nations, Office on Drugs and Crime, 2023).

RAND Interviews for This Study

This section—and Appendix A—relies on insights generated from a series of expert interviews conducted by our research team that were approved by RAND's Internal Review Board. Our team conducted interviews with key informants in a variety of roles related to psychedelics and spiritual medicines. We conducted semistructured interviews on the record with 18 individuals from the United States and abroad, including legal experts, policy advocates, regulators, clinical researchers, mental health care providers, and representatives from organizations working in the emerging psychedelics industry. We recruited interviewees with a range of perspectives on psychedelics policy, from those who support changes to psychedelics policy to those who are more hesitant about moving away from prohibition. To broadly classify, eight were in the policy/legal space, six were associated with the psychedelics industry, and four were clinical.[49]

We also conducted a series of nearly two dozen informal conversations with Indigenous community members. There has been a lack of trustworthiness in the environment perpetrated on Indigenous groups with valid reasons to be cautious, including in research partnerships (Burnette et al., 2014). Our team learned from decolonizing methodologies[50] to inform a respectful dialogue with Indigenous community members (Smith, 2022). General insights from these conversations have been integrated throughout this report, but no direct quotations are included.

What Does the Evidence Indicate About Potential Benefits?

Although there is a growing literature investigating the potential clinical benefits of some psychedelics, as of May 2024, there is not any FDA-approved use of the classic psychedelics, ibogaine,

[49] Two of the experts we spoke to in a formal interview setting self-identified as Indigenous.

[50] A *decolonial methodological approach* is one rooted in the understanding that colonization has marginalized Indigenous perspectives in research and, therefore, works to place Indigenous perspectives and knowledge at the center of a study. To this end, Smith (2022) encourages researchers to question their own biases throughout the research process and to maintain a collaborative, reflective, and respectful research approach with Indigenous Peoples.

or MDMA to treat any medical conditions in the United States.[51] The previous section of this chapter discusses concerns that have been raised about clinical trials in this field in detail. We must also reiterate that use in a controlled setting with a regulated product, clinical supervision (sometimes by multiple medical officials), and counseling sessions before and after the experience may not produce the same consequences as persons using unregulated psychedelics on their own.

Clinical. There has been an explosion of review articles largely focused on clinical trials for psychedelics; at least 50 published since 2022 alone (see Appendix C). These reviews of clinical studies focused on psychedelics reveal a list of commonly researched conditions: depression (including treatment-resistant depression), anxiety, PTSD, substance use disorders (alcohol and drug use disorders), and palliative or end-of-life care. General effects on cognition, such as memory and attention, are also commonly researched (Cardoso and de Barros Viana, 2023). Other conditions mentioned, but studied less frequently, include sexual function, obsessive compulsive disorder, migraines, and anorexia. Psilocybin was the most often reviewed psychedelic substance in these studies, followed by LSD and DMT.[52] Evidence for the efficacy of MDMA or mescaline was assessed in these reviews less frequently. There was very little research on the efficacy of 5-MeO-DMT or ibogaine in these recent reviews of clinical trials.

Do psychedelics help improve these clinical conditions? Some of the studies included in these reviews show promising results, depending on the substance(s) and condition(s) examined. As highlighted by Humphreys et al. (forthcoming), the strongest quality evidence indicates that MDMA with psychotherapy may yield reductions in PTSD symptoms; psilocybin with psychotherapy may yield reductions in depressive symptoms, symptoms associated with alcohol use disorder, and end-of-life dysphoria. Clinical trials with larger, more representative groups of participants with longer follow-ups can tell us more about which substances and approaches are most effective at treating various health conditions.[53]

It is important to remember that there are different types of clinical trials (MD Anderson Cancer Center, 2024). Phase I trials tend to be small and focus on the dose and safety of the patient. Phase II trials tend to be larger and focus on effectiveness of the substance on a particular disease or condition. Phase III trials are often conducted at multiple sites and usually have larger samples than the Phase II trials. Phase III trials are typically the final step before an application is made to the FDA for clinical use. Most of the research on psychedelics has not been in Phase III trials, and it should be noted that even making it to Phase II is not a great predictor of a drug making it through the process. Van Norman (2019) noted: "Phase II clinical studies represent a critical point in determining drug costs,

[51] We use the term *clinical* here broadly to mean outcomes related to mental health, physical health, or behavior that might typically be treated by a licensed medical professional or mental health care provider. In 2023, Australia approved the prescription of MDMA and psilocybin for PTSD and treatment-resistant depression, respectively (Haridy, 2023; Humphreys et al., forthcoming).

[52] As this report was near completion, a new review page on the effects of psilocybin and mental health was published by the National Center for Complementary and Integrative Health (undated), which is part of the National Institutes of Health. Readers may also be interested in the recent review by Nayak and Johnson (2023), which covers the classic psychedelics and MDMA.

[53] After reviewing the evidence on psychedelics and other treatments for depression, Meling et al. (2024) concluded: "It is likely that larger and better-controlled psychedelic trials will demonstrate smaller effect sizes that are more comparable to other conventional and emerging treatments for mood disorders."

and Phase II is a poor predictor of drug success: >30% of drugs entering phase II studies fail to progress, and >58% of drugs go on to fail in Phase III."

There have been completed Phase III trials of MDMA-assisted therapy and two with psilocybin-assisted therapy that are ongoing. The two Phase III trials of MDMA-assisted therapy focused on PTSD, one involving 90 participants and another with 104 participants (Mitchell et al., 2021). The results were both positive and an application was made to the FDA in December 2023 (see the box entitled "FDA Submission on MDMA-Assisted Therapy for PTSD" on the next page). However, on June 4, 2024, an FDA Advisory Committee reviewed the evidence from these trials, listened to public comment, and voted on the question, "Do the available data show that the drug is effective in patients with posttraumatic stress disorder?" Of the 11 individuals voting, nine voted "No" and two voted "Yes" (Tin, 2024). The FDA is not required to follow the vote of the Advisory Committee but is expected to make its decision on the application by August 11, 2024.[54]

There are also two ongoing Phase III trials to study the administration of psilocybin under supportive conditions in participants with treatment-resistant depression. One focuses on a single dose with an anticipated sample size of 255 participants, the other includes repeated doses and is expected to have a sample size of 568 participants (Compass Pathways, 2024a; Compass Pathways, 2024b).

[54] For critical assessments of these trials, see FDA (2024) and the draft report from the Institute for Clinical and Economic Review (ICER; Mustafa et al., 2024). The final ICER report is expected to be released around June 27, 2024. For a response to the draft ICER report by those who worked on these trials, see Beachy et al. (2024).

FDA Submission on MDMA-Assisted Therapy for PTSD

On December 11, 2023, a new drug application for MDMA-assisted therapy for PTSD was submitted to the FDA. The agency approved "Priority Review" status for the submission on February 13, 2024, with a target date of August 11, 2024, for a decision on approval (Beachy et al., 2024). As stated by the FDA, the designation of "Priority Review" of a submission indicates that the substance in question, if approved, would "significantly improve the treatment, diagnosis, or prevention of serious conditions" (FDA, 2022a). Although MDMA-assisted therapy was granted a "Breakthrough Therapy" designation in August 2017, the application marks the first new drug application submission to the FDA that concerns the use of a psychedelic substance in assisting therapeutic treatment (Hippensteele, 2024).[a]

The new drug application was submitted by Lykos Therapeutics, formerly the Multidisciplinary Association for Psychedelic Studies Public Benefit Corporation (MAPS PBC), with the application including two Phase III RCTs that demonstrated statistically significant decreases in both clinician-administered tests for PTSD severity and PTSD-associated functional impairment compared with placebo with therapy (Mitchell et al., 2021). The most recent of these Phase III trials on MDMA-assisted therapy for PTSD included 15 sessions (three of which involve taking MDMA) over three to four months (Mitchell et al., 2021). The eight-hour administration sessions involve multiple clinical professionals, including an individual licensed to administer the substance and two psychotherapists per session.[b]

If MDMA-assisted therapy gets approved by the FDA to treat PTSD, there will be a host of administrative and logistical issues that will need to be addressed—especially for those who receive health care through the U.S. Department of Veterans Affairs. In the context of veterans, Ramchand (2023) argues we should be considering: "(1) how the cost of psychedelic treatment will affect access, (2) whether the U.S. Department of Veterans Affairs (VA) should provide psychedelic treatment directly or outsource such care, and (3) what kinds of safety rails are needed to ensure that veterans receive the highest-quality care." There are related issues surrounding the creation of a workforce that can provide these treatments (to veterans and nonveterans alike) that need to be factored into these discussions. In an April 2024 letter to the Under Secretary of Veterans Affairs for Health, nine members of Congress wrote:

> We're concerned that if VA is not prepared to implement emerging psychedelic-assisted therapies when they become available, veterans will be left to navigate providers outside VA who may not have the specialized expertise in addressing their unique needs and the relevant military context of their trauma. The potential lack of in-house capacity at the VA could threaten the mental health of our nations' veterans and carries significant cost implications for VA (McGarvey et al., 2024).

On June 4, 2024, an FDA Advisory Committee reviewed the evidence from these trials, listened to public comment, and voted on the question, "Do the available data show that the drug is effective in patients with posttraumatic stress disorder?" Of the 11 individuals voting, nine voted "No" and two voted "Yes" (Tin, 2024). The FDA is not required to follow the vote of the Advisory Committee and is expected to make its decision on the application by August 11, 2024.

[a] If the FDA does approve the application, it is likely that the Lykos drug product will be set at Schedule II-V but the active ingredient (MDMA) will remain Schedule I (see discussion in Marks and Shachar, 2023).
[b] As noted earlier in this chapter, there is a lot of ongoing discussion about how much we can learn from these trials.

Spiritual. Other potential types of benefits from using psychedelics are related to spirituality. Although Indigenous cultures and traditions vary widely, some common Indigenous uses of spiritual medicines are presented in the box entitled "Common Purposes for Spiritual Medicines Among Indigenous Groups" on the next page; we also provide additional examples in Appendix A. We also

want to make it clear that some non-Indigenous Peoples also use these substances for spiritual purposes (See Table 2.8).

Common Purposes for Spiritual Medicines Among Indigenous Groups

Spiritual and religious ceremonies: Many Indigenous cultures view psychedelics as sacred medicines that can help people connect with the spirit world and gain insights into their own lives. Ceremonial uses often take place in a communal setting. For example, the Huichol people of Mexico use peyote in their annual pilgrimage to Wirikuta, a sacred site in the Chihuahuan Desert.

Healing and medicine: Some Indigenous Peoples have also used spiritual medicines to treat a variety of physical and mental health conditions, including depression, anxiety, addiction, and PTSD. For example, the Mazatec people of Mexico use psilocybin mushrooms to address what is commonly thought of as depression and anxiety.

Initiation and coming-of-age rituals: In some Indigenous cultures, spiritual medicines are used as part of initiation or coming-of-age rituals. This is often seen as a way to help young people transition into adulthood and gain new insights into their lives. For example, the Yanomami people of Venezuela use ayahuasca in their *yanomami shabonos*, or communal houses, as part of a young person's coming-of-age ceremony.

Personal growth and development: Some Indigenous People use spiritual medicines for personal growth and development. This can involve using psychedelics to explore their own consciousness, appreciate the natural world, or connect with their spirituality. Personal growth uses may take place in private spaces in smaller groups.

A 2019 survey comparing naturally occurring (nondrug) and psychedelic-occasioned God encounter experiences[55] found several similarities in the spiritual experiences of both groups[56] (Griffiths et al., 2019). Notably, in their survey, a larger percentage of the respondents whose experience was occasioned by psychedelics reported a decreased fear of death after the experience (Griffiths et al., 2019). A systematic review of psychedelics and mystical experiences found some evidence that mystical experiences may also support positive outcomes of clinical treatments using psychedelics (Ko et al., 2022). Another recent survey recruited respondents who had experienced a belief-changing psychedelic experience (Nayak et al., 2023). Although the respondents in Nayak et al. (2023) may not be representative of all psychedelics users and experiences, the authors did note some interesting findings among this group of people who use psychedelics, including an increase in those who reported they changed from nonbeliever to believer in an ultimate reality or higher power after the experience.

Other reported benefits. In addition to clinical conditions and spirituality, improvements in well-being and quality of life have also been reported after using psychedelics. Jules Evans et al. (2023) conducted a systematic review of studies that assessed the effects of psychedelics on psychological

[55] The authors of the survey define a *God encounter experience* as a religious experience that is interpreted by the individual as an encounter with the God of their understanding, a higher power, ultimate reality, or an aspect or emissary of God, such as an angel.

[56] About 75 percent of individuals in both the nondrug and psychedelics groups also rated the God encounter experiences they described as one of the top five most meaningful experiences of their lifetime.

outcomes, including both observational and laboratory-based studies that used a baseline (pre-) and follow-up (post-) method for analyzing the effects of psychedelics consumption. The authors identified a range of positive effects, such as improvements in mood, mindfulness, social measures like empathy or compassion, and positive behavior changes, across a range of clinical and nonclinical studies. However, Ricarda Evans et al. (2023) noted that only 14 of their 48 included studies used a placebo-based control group with double-blind allocation and a standardized treatment, while all others did not adhere to such standards of experimental control, limiting the quantity of methodologically rigorous evidence. (For more on limited evidence, see the box entitled "Limited Evidence on Microdosing " on the next page.)

Similarly, a report analyzing self-report data from the Global Ayahuasca Survey summarized a set of commonly reported personal insights from ayahuasca drinkers, such as new understanding of childhood events, better awareness of how to care for their bodies, and purpose or direction in their lives (Perkins et al., 2021).[57] However, caution must be used when interpreting the results from a convenience survey that may have been more attractive to those who had a positive experience. There are also potential issues with the aforementioned expectancy effects that should be considered.

[57] In our interviews, interviewees mentioned such benefits as getting unstuck from entrenched thought patterns and creating resiliency from difficult situations: "Using psychedelics is preventative care for when someone loses a loved one or have an accident. They can handle that and know what to do for themselves by knowing the wisdom of their body" (Interviewee 05); "A benefit of experiencing psychedelics is that they allow someone to get past [a] stuck point. Instead of dealing with rock, you're dealing with cloud. You can't see through either, but a cloud is easier to move through. Psychedelics provide that cloud to move through in [a] safer and more consistent way so they can experience [the] world in [a] way that's healthier and more calm" (Interviewee 07).

Limited Evidence on Microdosing

The use of psychedelic substances in low, often sub-threshold doses—colloquially known as *microdosing* and often (but not always) reported for LSD and psilocybin consumption—is a long-standing but under-researched substance use pattern (Petranker et al., 2024). In a recent systematic review of microdosing research, Polito and Liknaitzky (2022) identified 44 studies published from 1955 to 2021, including retrospective survey studies using self-reported measures of microdosing, prospective observational studies, and laboratory (clinical) studies. The authors' review of this evidence base found commonly reported effects of microdosing to include altered time perception, improved pain tolerance, positive shifts in cognitive processing, and positive shifts in mental health indicators. After reviewing several modern, placebo-controlled laboratory-based studies on the effects of microdosing, they concluded that well-controlled, low risk-of-bias confirmatory clinical trials are still scarce. Multiple studies were found to have high risk of bias, and questions remained concerning the extent to which reported effects were driven by participants' expectation of strong responses to microdosing.

These concerns around scarce high-quality confirmatory clinical trials are similarly echoed in a systematic review of psychedelic research on mental health (Lo et al., 2024). The authors' review of 19 studies published between 2012 and 2022 found positive effects of microdosing on various mental health outcomes, including daily function and cognitive processing. However, as with the review by Polito and Liknaitzky (2022), concerns around the expectancy effect driving some positive outcomes undermined confidence in the effects of microdosing on mental health, as well as reliance on self-reported data. There is also a recent review by Rouaud, Calder, and Hasler (2024) suggesting that future research on microdosing psychedelics should focus on risk of cardiac fibrosis and valvulopathy.

What Does the Evidence Indicate About Potential Risks?

Although the safety profile of psychedelics may be better than many other controlled substances, it is still important for policymakers to understand the nonzero potential risks of psychedelics.[58] There is some tension among researchers assessing adverse events in clinical research on psychedelics. Two reviews of adverse events in clinical research published in the same 2022 volume of the *Journal of Psychopharmacology* illustrate this factor (Schlag et al., 2022; Breeksema et al., 2022). The overall takeaway of Schlag and colleagues' review is that many negative perceptions of psychedelics are not supported in the academic literature, and it is imperative to ensure balanced media reporting to allow research into psychedelics to continue. Meanwhile, Breeksema and colleagues concluded that adverse events are poorly defined and likely underreported in the context of clinical research because of the lack of systematic assessments and sample selection that often favors study participants who have experienced psychedelics previously.

What is more certain is that many of the risks associated with psychedelic substances are unique to the substances themselves. There appear to be cardiotoxicity risks associated with ibogaine. Between 1990 and 2008, there were 19 fatalities related to the use of ibogaine outside West Central Africa. In six of these, cardiac disease was a contributing condition (Alper, Stajić, and Gill, 2012). A

[58] There are also risks that are specific to individual psychedelic substances, such as cardiac events related to the use of ibogaine (Rocha et al., 2023) or the potential for a substance use disorder involving MDMA (Uosukainen et al., 2015), that should be investigated and considered when specific substances are included in policy changes.

review by Rocha et al. (2023) presents a series of case reports of serious cardiotoxicity among individuals without evidence of previous histories, leading the authors to conclude "that screening is an important risk prevention factor but does not totally exclude the cardiovascular risk related to the use of ibogaine."[59]

With respect to risk of addiction, Humphreys et al. (forthcoming) note that "Other than ketamine and perhaps MDMA, psychedelic drugs do not seem to have significant addictive liability." The *DSM-V* includes a diagnosis of "hallucinogen use disorder," which is characterized by problematic use that can lead to "significant impairment or distress" (American Psychiatric Association, 2013). In 2022, 0.2 percent of adults met criteria for hallucinogen use disorder (Center for Behavioral Health Statistics and Quality, 2023) and an estimated 2 percent of individuals who initiate use exhibit symptoms within two years of use (Stone et al., 2006). Those experiencing hallucinogen use disorder (or its equivalent in the DSM) were more likely to be using MDMA (Wu et al., 2009). Although case reports of withdrawal symptoms following continued use are rare, there is evidence of tolerance to the substance and, perhaps more importantly, some people who use MDMA become concerned about their use (Degenhardt, Bruno, and Topp, 2010).

Breeksema and colleagues' (2022) review identifies several categories of adverse events resulting from clinical research into psychedelics. The limitations associated with clinical trials of psychedelics and their beneficial effects carry over to our understanding of adverse events: Sometimes, such events are not reported and details of these events (e.g., severity, duration, resolution) may also not be available. Nonetheless, adverse events during a psychedelic experience ranged from physical effects like headache and nausea to psychological effects like paranoid thoughts and dissociation, which were sometimes severe and reported to persist for up to two months after administration. Difficulties in the days and weeks following a psychedelic experience were also summarized by Breeksema and colleagues, including anxiety, panic, and suicidal ideation with a few instances of adverse events requiring hospitalization.

Looking outside clinical evidence can reveal additional insights about the potential risks of using psychedelics in a variety of settings. This could happen as a result of intentional use or someone who inadvertently used (e.g., did not realize a chocolate bar contained psilocybin). An analysis of hospital data from the state of California found that emergency room visits and hospitalizations related to hallucinogens increased between 2016 and 2022 with a peak in 2021 (Garel et al., 2024).[60] The increase in visits was 54 percent (from 2,260 to 3,476), and it would be ideal to compare that figure with the change in total number of psychedelics use days in California, preferably by age group; unfortunately, those data are not readily available. National data from NSDUH suggest that total use days in the past month increased from 3,729,000 in 2015 to 6,969,109 in 2022—an increase of 87 percent; however, care must be used when making NSDUH comparisons before and after 2021 (see Chapter 2).

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[59] There is increasing interest in research focused on synthetic forms of ibogaine that are nontoxic and nonhallucinogenic (see e.g. Cameron et al., 2021).

[60] *Hallucinogens* were defined for this analysis from the California hospital reporting codes "including serotonergic psychedelics [e.g. psilocybin, lysergic acid diethylamide (LSD), mescaline, N,N-D-methyltryptamine (DMT)], psychostimulants [e.g. 3,4-methylenedioxymethamphetamine (MDMA) or ecstasy] and dissociative anesthetics [e.g. phencyclidine (PCP), ketamine]" (Garel et al., 2024, p. 961).

Another analysis by Farah et al. (2024) used the National Poison Data System to analyze reported psilocybin-related cases among individuals ages 13 to 25 across the United States. Over the decade-long period of 2013 to 2022, the analysis found just more than 4,000 psilocybin-related exposures—a call from an individual to a poison center where there is actual or suspected contact between that individual and the substance in question—of which 65.8 percent were single-substance exposures. From 2013 to 2018, rates of exposure did not have statistically significant variation over time. Psilocybin-related cases saw a statistically significant increase among adolescents in 2019, followed by young adults in 2020.

To investigate the prevalence of adverse events following psychedelic experiences among the U.S. population, Simonsson et al. (2023) collected nationally representative survey data from Americans who had ever used psychedelics in their lifetime. They found that 8.9 percent of these respondents reported functional impairment[61] that lasted longer than one day after a psychedelic experience, and 2.6 percent of respondents reported seeking medical, psychiatric, or psychological assistance following their most challenging psychedelic experience. A survey of Norwegian students who reported having a memorable experience with psychedelics found that 23.1 percent of respondents experienced adverse reactions that lasted more than one day after taking a psychedelic (Kvam et al., 2023). Although nearly half (10.6 percent of the total sample) of these adverse reactions resolved in a few days, 4.5 percent of respondents experienced adverse reactions lasting a few weeks, 3.8 percent lasted a few months, and 4.2 percent of respondents experienced adverse reactions for more than a year. The most commonly reported adverse reactions among Norwegian students were sadness, anxiety, and headache.

Another recent study recruited survey respondents who have experienced extended difficulties in the weeks, months, and years following psychedelic experiences (Jules Evans et al., 2023). The most commonly reported extended difficulties noted in this survey were feelings of anxiety and fear, existential struggle, social disconnection, depersonalization,[62] and derealization.[63] The most commonly reported durations of the extended difficulties in the survey were one to three years and more than three years, suggesting that these difficulties can persist for long periods.

However, even if there is an adverse consequence associated with using a substance, it still could have provided some benefit. Psychedelic experiences can be powerful and bring up emotions or feelings that are disturbing. But so too can many trauma-focused psychotherapies, including such evidence-based therapies as prolonged exposure or cognitive processing therapy, used to treat PTSD. For example, trauma survivors may experience high levels of distress when reliving their trauma as part of these treatments, but those who eventually habituate to such retellings of the incident(s) generally experience the greatest improvements (Jaycox, Foa, and Morral, 1998).

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[61] Functional impairments included feeling anxious, difficulty sleeping, difficulty making decisions, feeling disconnected, feeling distant from others, being bothered by little things, headaches or body pains, re-experience of past stressful events, trouble enjoying things, and sensitive hearing.

[62] The study authors described *depersonalization* as a respondent feeling loss of self (in a way that felt unpleasant and difficult to manage), fragmented, dissociated, or disconnected or untethered from their former self or from their body.

[63] *Derealization* is described by the study authors as the experience of confusion or uncertainty over what is real. Respondents described feeling like they were in a dream, afterlife, purgatory, a movie, a computer game, or fake reality.

There is also a risk of harm related to misconduct by someone who is with the person having a psychedelic experience. Some participants in clinical trials have called for more attention to be given to the potential for inappropriate interactions between therapists and patients during these trials (McNamee et al., 2023). As described in McNamee et al. (2023), individuals under the influence of medium to high doses of psychedelics are vulnerable in a variety of ways, including physical vulnerability to sexual assault and psychological vulnerability to overdependency on their therapists. These concerns extend beyond clinical trials to other settings where guides, spiritual leaders, or other facilitators accompany individuals during psychedelic experiences.[64]

Some of our interviewees emphasized the need for standards of informed consent as the use of psychedelics in religious or wellness settings grows in popularity and as legal statuses shift. Informed consent in the context of psychedelics means a clear explanation of what will happen (including supportive touch from facilitators, doses, and religious or other views that may be shared during the experience) is given to all participants and explicitly agreed to before the experience takes place.

It is clear that adverse events do occur, even in clinical settings. However, the prevalence, frequency, and risk factors for these adverse events requires more study. To help summarize the types of harms and misconduct commonly reported in association with psychedelic experiences, we highlight two typologies developed by the Psychedelic Safety Institute,[65] shown in the box entitled "Psychedelic Harm and Misconduct Typologies" on the next page.

[64] There are also examples in the popular literature of the misuse of psychedelics of cults to recruit, exploit and abuse followers (see Hall, 2022).

[65] The Psychedelic Safety Institute is a think tank dedicated to promoting harm reduction information in the psychedelic ecosystem, including policymaking, clinical research, and consumer safety.

Psychedelic Harm and Misconduct Typologies

Harm Typology. "Psychedelic difficulties" are negative outcomes that leave individuals worse off following psychedelic use. "Adverse Effects" (or Events) describe undesirable effects during or after psychedelic use, which may occur even within an overall positive experience. "Extended Difficulties" are prolonged experiences, lasting days to years, that can impair daily functioning

Physiological Harms: This includes physical disease and injury.
Psychological Harms: This includes negative impacts on perception, emotional experience, mood, or cognition.
Behavioral Harms: This includes impaired executive function and social functioning, lifestyle deterioration, or increased aggressive or antisocial behavior.
Existential and Spiritual Harms: This includes ontological harms (derealization, demoralization, nihilism, existential struggles), escapism (overfixation on altered states), and epistemic harms (reduction in capacity for meaning-making, critical decision-making).

Misconduct Typology. This typology details the types of misconduct psychedelic practitioners may engage in. A "psychedelic practitioner" guides individuals through psychedelic experiences, serving various therapeutic, spiritual, or personal growth purposes, and may include ceremonial or spiritual leaders, regardless of formal training or compensation, with a primary responsibility for participant well-being during these experiences. This typology is organized into two categories of misconduct.

Category 1 Misconducts include behaviors that are inappropriate in an absolute sense. These behaviors tend to be explicit and easy to identify. Many of these behaviors are explicitly illegal or against practitioner regulations.

Sexual Misconduct: Sexual relationships between psychedelic practitioners and participants are universally inappropriate due to the power dynamics and vulnerability of participants. This encompasses a range of behaviors such as harassment, inappropriate comments and touch, and exploitation.
Financial Exploitation: Financial exploitation occurs when practitioners misuse their position to gain financial advantages from participants, including asking for money during the psychedelic experience, making guarantees based on financial contributions, or using manipulative tactics to extract additional funds.
Fraud: Fraud involves practitioners intentionally deceiving, including misrepresenting substances, qualifications, or benefits.
Physical Abuse: Intentional physical harm or trauma to a participant through bodily contact is inappropriate during a psychedelic experience, and informed consent must be obtained beforehand if the experience may involve physical touch, discomfort, or pain.
Violation of Consent and Coercion: A violation of consent occurs when a practitioner engages in any activity without obtaining clear, voluntary, and informed agreement. Coercion includes pressuring participation, dosage, or continued use.

Category 2 Misconducts include inappropriate behaviors that may be more challenging to identify objectively, particularly in the context of a psychedelic experience. These include, but are not limited to:
Discrimination: Occurs when a practitioner provides differential treatment based on personal characteristics.
Abandonment: Abandonment in the context of psychedelic experiences occurs when a practitioner leaves a participant unsupervised, either temporarily or for an extended period during the experience.
Appropriation: Occurs when a practitioner inappropriately and without consent adopts cultural practices for personal gain during psychedelic practices.
Verbal Abuse: Occurs when practitioners' use of fear, intimidation, belittlement, derogatory language, or slurs, is inappropriate in psychedelic experiences.
Breach of Confidentiality: Occurs when practitioners disclose a participant's confidential information without consent.
Negligence: Occurs when practitioner fails to screen for contraindications, communicate risk, provide a safe environment, or appropriately respond to an emergency.

SOURCE: Information provided by the Psychedelic Safety Institute to the authors.

When thinking about changes to supply policy—especially if it involves for-profit companies with incentives to innovate and promote—it should be acknowledged that the products available after legalization—and their consequences—could be very different from what is currently consumed (see, e.g., the various cannabis and hemp-derived products proliferating throughout the United States).

What Strategies May Mitigate Harms and Adverse Events?

Best practices for mitigating adverse events are still in development outside Indigenous settings; however, insights can be drawn from documentation of traditional and Indigenous practices. We have mostly relied on suggestions from our expert interviewees for the considerations included in this section.[66] Different substances can require different mitigation strategies, and there is a need to conduct rigorous research on these strategies.

The considerations below are organized into three sections: strategies that can be employed to potentially mitigate adverse events before a psychedelic experience, during the experience, and after the experience.[67]

Before

Preparation before a psychedelic experience is common in Indigenous practices as well as clinical, religious, and retreat settings. For example, the Bwiti practices for iboga ceremonies include a long period of preparation that may take months to years, and those with underlying physical or mental conditions are generally not allowed to consume iboga in the traditional practices (Bekale and Alagidede, 2021). Retreat centers in the Netherlands offering legal experiences with psilocybin truffles also offer a variety of types of preparation, including detailed information about what to expect during the experience and training in breathing and meditation practices. Our interviewees also emphasized that ensuring access to safe substances is critical to reducing potential adverse events, including the following:

- *Public education*. Educating the public, especially vulnerable populations, about the effects and potential risks of psychedelics in a nonstigmatizing way can help individuals make informed decisions as psychedelics become more widely available. Public education can also assist community members in supporting individuals who may have an adverse experience with psychedelics.
- *Screening*. Screening consumers in a retail setting or participants in a guided setting for risk factors or other safety considerations, even for simple standards such as a minimum age of consumption, can help mitigate adverse events. This is especially true for contraindications.

[66] As this report was being finalized, a consensus statement from "27 individuals representing the perspectives of clinicians, researchers, Indigenous groups, industry, philanthropy, veterans, retreat facilitators, training programs, and bioethicists" was published about how to handle five ethical issues related to psychedelic clinical care: reparations and reciprocity, equity, and respect; informed consent; professional boundaries and physical touch; personal experience; and gatekeeping (McGuire et al., 2024).

[67] This before, during, and after organizing principle is used here with the acknowledgement that some of these topics may cross over in a nonlinear way, especially as they are practiced in Indigenous cultures.

Risk factors may vary by substance (e.g., people with cardiovascular conditions may not be appropriate for ibogaine).

- *Mental and physical preparation.* Guidelines and standards for mental and physical preparation could be developed as part of public education campaigns and/or as community standards for guided experiences.
- *Informed consent.* In any setting where psychedelics are provided, participants should be made fully aware of likely effects, procedures, and potential risks in advance. Participants should grant explicit consent to the circumstances of a guided psychedelic experience.
- *Safety of substances.* Manufacturing standards, clear labeling, and available resources for drug checking can increase the safety of psychedelic substances.

During

Supervision or guidance from experienced practitioners, especially for individuals experiencing psychedelics for the first time, is common in some settings. Ideas about best practices for dosing and the physical setting of psychedelic experiences were also often discussed in expert interviews, including the following:

- *Responsible supervision.* To serve individuals who seek support during a psychedelic experience from trained professionals, there is a need for training and standards as well as accountability for misconduct. Support for communities of practice that can promote and enforce best practices among practitioners may reduce adverse events, as can legal enforcement for misconduct. Individuals must also feel protected to come forward, and there must be mechanisms in place to come forward to report misconduct by practitioners.
- *Dosing.* Starting with a low or trial dose to see how an individual reacts to a particular substance is often recommended. Factors beyond body weight or concentration of a substance that may contribute to the effects of psychedelics, such as mental state or interactions with other substances, are areas that could use more study.
- *Supportive setting.* Being in nature or a sacred space as well as the experience of music and other sounds can help create a supportive setting for psychedelic experiences.
- *Safe setting.* Experiencing psychedelics in settings that do not include potential hazards (e.g., bodies of water or heights, such as tall buildings or rooftops) may reduce the potential for physical injuries.

After

Following a psychedelic experience, individuals sometimes seek to integrate their experience, either individually or with guidance. The term *integration* in the context of psychedelic experiences has been defined as a process of "making sense of, working through, translating, and processing the content of their psychedelic experience" to incorporate the experience into their life in a healthy way (Bathje, Majeski, and Kudowor, 2022). Integration sessions guided by clinicians are often built into the design of clinical research involving psychedelics (Brennan, Kelman, and Belser, 2023). Individuals who

experience adverse events or extended difficulties after a psychedelic experience may seek support from first responders, health care professionals, or their personal networks. A recent study elicited written data on coping experiences from individuals who have had extended difficulties after a psychedelic experience (Robinson et al., 2024). Individual strategies reported in the study included meditation, prayer, and such self-education activities as reading and journaling. Those who reached out to others for help from friends, family, therapists, or other professionals reported that feeling heard, feeling accepted, and hearing about similar experiences were the most supportive to their coping. Some other options include the following:

- *First-responder training.* Training in the basics of how to respond to difficult psychedelic experiences for emergency medical services professionals, emergency room and other hospital staff, police, 911 and 988 dispatchers, and college campus security can potentially improve the outcomes for those who experience adverse events and interface with first responders.
- *Health care professionals training.* Widely distributed resources and basic training for mental health care professionals, primary care doctors, and others to whom patients might go for support may promote integration and coping.
- *Self-reflection and self-care.* Individuals can benefit from resources that assist in self-reflection activities, such as educational resources about coping with adverse events.
- *Community support.* Availability and awareness of support services, such as support groups or specially trained care providers whom friends and family of individuals seeking assistance can recommend, may promote coping. General awareness in the public of the risks of psychedelics and possible best practices for safer use can also be beneficial.

Chapter 4

Supply Architectures and Regulatory Design Considerations for Psychedelics

Introduction

People choose to use psychedelics for many reasons. Some use them for pleasure and enjoyment, some for spiritual or personal enlightenment or as part of a religious practice, and others to treat a mental health condition. Much of the attention being given to psychedelics in recent years has been about clinical trials that could eventually lead to these substances being prescribed or administered by clinicians to treat various mental health disorders. That is not the focus of this chapter. The focus here is on the various ways psychedelics could be supplied to people *outside* a licensed clinical provider prescribing or administering a controlled substance.

When considering alternatives to prohibiting the supply of psychedelics, decisionmakers confront several options, each with its own benefits, costs, and likely unintended consequences. The types of outcomes considered, and the weights given to them, will depend on values and preferences of the decisionmakers, something we further discuss in Chapter 5. All these factors will, in turn, shape the policy levers considered, discussed, and possibly implemented.

Chapter 1 highlighted some alternatives to prohibiting the supply of some psychedelics in the United States; however, these are not the only possible options. When assessing supply policy alternatives, it is useful to distinguish between *supply architectures* and *design considerations* (Caulkins et al., 2015). The former addresses issues about how drugs are produced and distributed to consumers, and which entities get to participate in these activities. The latter addresses regulatory and administrative decisions that can affect these regimes, such as which products will be allowed and whether there will be product testing (and if so, for what), restrictions on advertising, taxes on the products, quantity limits, and user licenses. Decisionmakers will confront many choices about both categories that will ultimately influence how policy change affects public health, public safety, social equity, and other outcomes.

Although some of these choices could be like those considering regulations for cannabis and alcohol, there are some that could be very different for psychedelics given the effects of these substances. For example, a major decision could be about the role of screening, supervision, and integration. Another emerging issue is whether adults should be required to get a user permit that could require undergoing a health screening and taking a course before they are able to legally possess (or potentially purchase) these substances.

The goals of this chapter are to (1) present a taxonomy of supply architectures and (2) highlight some of the major policy design considerations. One should not confuse our omission of federally approved medical options for disdain or ignorance of that approach. Although there is tremendous activity happening in the clinical trial space (and to a much, much lesser extent, the FDA's Expanded Access program; see Chapter 1), there is also a growing debate about making some psychedelics more available to all adults and not necessarily for treating a specific medical condition by a licensed clinician. Our goal is to help inform these discussions about nonclinical supply options.

Key Insights from Chapter 4

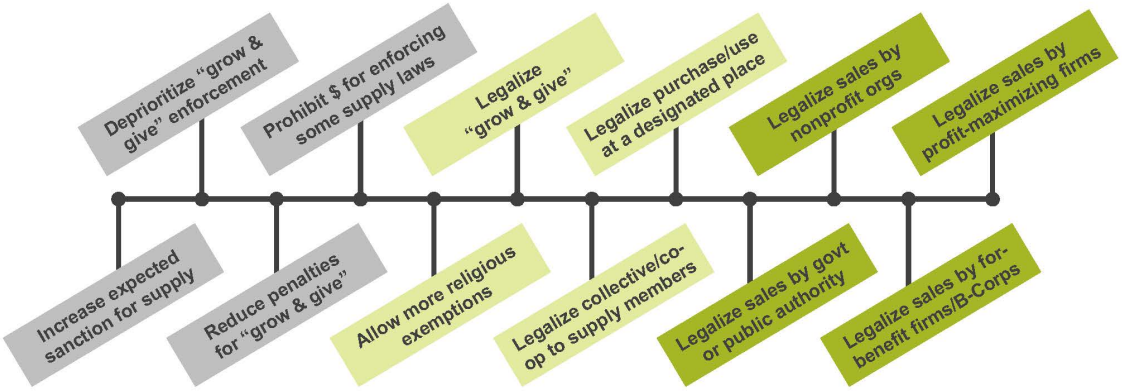
- Those participating in psychedelics policy debates and analysis should be specific about the changes being considered, implemented, or evaluated.
- For those considering alternatives to prohibiting the supply of some psychedelics, there are many choices they will confront that will likely shape what these policy changes mean for public health, public safety, social equity, and other outcomes.
- There are many supply policy options between prohibition and legalizing production and sales by for-profit companies.
- When thinking about regulations for psychedelics for nonclinical purposes, policymakers need to consider the role of facilitators or guides and whether supervision will be required, regulated, or incentivized.

Supply Architectures

Overview of the Taxonomy

Figure 4.1 displays the taxonomy that will be discussed in this chapter. It is rooted in a framework created for cannabis by Caulkins et al. (2015), but they are not identical. The goal is to highlight some of the major alternatives to what we think of as status quo or traditional supply prohibition and how it is enforced (i.e., in most states and localities not highlighted in Chapter 1 and Appendix B); this taxonomy does not focus on policies exclusively focused on possession. Although most of the boxes represent a liberalization or relaxation of current laws or efforts when it comes to the provision of psychedelics, change does not have to be unidirectional. It is theoretically possible that some jurisdictions could move toward increasing penalties and/or enforcement against those supplying psychedelics.

Figure 4.1. Alternatives to Traditional Supply Prohibition of Psychedelics (Outside Being Administered or Prescribed by a Licensed Clinical Provider)



Notes: These options are not mutually exclusive and could vary by substance. "Grow and give" also includes foraging for small amounts.
Inspired by Caulkins et al. (2015).

The options presented in Figure 4.1 are not mutually exclusive. For example, as we have seen with cannabis legalization in many parts of the United States and most of Canada, most jurisdictions that allow retail sales also allow for home production. It is also possible that different supply models could be applied to different types of psychedelic substances.

These 12 options can be placed into three general categories (denoted by shading):

1. policy and legal changes while supply remains prohibited (gray shading)
2. some supply is legal but traditional retail sales are not authorized (lighter green)
3. some supply is legal and traditional retail sales are authorized (darker green).

By "traditional retail sales," we mean that any adults can walk in and purchase the product from a retail outlet or have it delivered.

Before walking through these approaches, the box entitled "Primer on Drug Prohibition, Supply, and Prices" on the next page offers some background information about drug prohibition, supply, and prices.

Primer on Drug Prohibition, Supply, and Prices

To generalize, the expected sanction for committing a crime is a function of the probability of detection, the probability of conviction, and the sanction given conviction. Economic theory suggests that that if the expected sanction is high enough, rational actors will be deterred from breaking the law because the expected benefit of committing the crime will not be as great as the expected sanction. In practice, there is evidence suggesting that people often do not act rationally, especially with respect to how they discount future events (e.g., hyperbolic discounting; Ainslie and Haslam, 1992). That said, there is also evidence suggesting that criminal deterrence is possible with the bulk of the evidence suggesting that celerity and certainty of being sanctioned for a violation are much more important than the severity of the sanction (Travis, Western, and Redburn, 2014; Chalfin and McCrary, 2017).

In the context of drug supply, prohibition inflates the retail price for two main reasons: (1) Suppliers charge a premium for their risk of arrest, incarceration, and violence (Reuter and Kleiman, 1986; Caulkins and Reuter, 2010), and (2) the "structural consequences of illegality" make it much harder to produce, package, and sell prohibited drugs (Reuter, 1983). With respect to the extent prohibition can raise prices, Pardo, Kilmer, and Taylor (2023) noted:

> Prohibition and a base level of enforcement surely increases retail prices. For example, by the time a kilo of fentanyl leaves Mexico and ends up in New York City, the price jumps from roughly $20,000 to $50,000. If you were to ship that same kilo via FedEx, it would cost less than $100 to transport. But once a retail market is established, increasing enforcement (in terms of arrests or prison sentences) yields diminishing returns and isn't expected to make much of a difference in the price. At best there may be temporary disruption, but it usually doesn't take long for established markets to adapt.

The main goal of increasing drug prices is to reduce consumption. There is a lot of evidence suggesting that people who use drugs respond to price increases by reducing consumption, even those who use frequently and may have a substance use disorder (Gallet, 2014); however, we are not aware of price elasticity estimates for psychedelics. Although some people think that those suffering from addiction do not care about price, many frequent users will spend a significant part of their income on these substances. Thus, price matters a lot to them.

Although price may be an important component when thinking about public policy on most intoxicating substances, one could argue it is much less relevant for the classic psychedelics, ibogaine, and MDMA. These substances are not typically compulsively used in large amounts, and even heavy users do not spend much on these substances over the course of a year. Insights into the economics of these markets are further addressed in Chapter 2.

Policy and Legal Changes While Supply Remains Prohibited

This section highlights options for changing public policy on psychedelics supply while supply and possession remain illegal.

Increase the Expected Sanction for Illegal Supply

Although most of the current policy discussion about changing policy on psychedelics for nonclinical supply has been on reducing or eliminating the expected sanction, it is possible that some may push for *increasing* the expected sanction for those supplying psychedelics. One could imagine multiple scenarios where this might happen. For example, as psychedelics become more popular, we

could see more adverse effects, or at least more publicized negative stories. This could galvanize political support for increasing enforcement and/or penalties against those supplying psychedelics.

Another example is that there could be a push by some members of the growing psychedelics industry to make it harder for those to obtain psychedelics in the unregulated market; one approach for doing so could be to crack down on illegal suppliers in terms of increased arrests and/or penalties. An increasing number of companies are investing serious resources in producing psychedelics for the clinical market, but it would be naïve to think some are not also eyeing a potential adult use market in which use does not require approval from a licensed clinical provider. But whether it is for the clinical or nonclinical market, these companies could face competition from those supplying similar substances in the unregulated market. This effort could take the form of opposing ballot initiatives that allow the grow-and-give model or actively supporting campaigns of politicians who push for stepping up enforcement and/or penalties on illegal market actors.

Deprioritize Grow-and-Give Enforcement

As described in Chapter 1, this approach does not change the penalties related to a law; it reduces the expected sanction by reducing enforcement risk. More than two dozen local governments throughout the United States have deprioritized the enforcement of certain offenses related to certain psychedelics through ballot initiatives, local legislation, or mayoral executive order. In many cases, deprioritization makes this enforcement a low or one of the lowest priorities for police officers. In some places, deprioritization pertains only to possession offenses; in other places, it also covers some form of supply (e.g., sharing small amounts for personal use). In still other places, it is ambiguous (See Chapter 1).

When referring to the term *grow and give*, we are discussing the phenomenon of cultivating or foraging for personal use and sharing small amounts with other adults; remuneration for the product is not allowed. (So far, there had not been much discussion about allowing people to produce small batches of LSD or MDMA). Depending on the text of the law, there can be a gray area in the grow-and-give model—someone could trade goods for drugs or sell a token (e.g., a piece of digital art for $50) and then give people the drugs for free. This is a common tactic for selling cannabis in Washington, D.C., which technically allows only the grow-and-give model (Solano, 2023); there are also reports of shops and delivery services in the District of Columbia doing something similar with psilocybin mushrooms (Lizza, 2022). In Colorado, there are already examples of people selling educational classes or psychedelic guiding services and providing the psilocybin for free (Kenney, 2023).

The overall effect of deprioritizing the enforcement of the grow-and-give model will depend on existing penalties and the probability of arrest and conviction for psychedelics offenses. In theory, deprioritizing could increase consumption if it sends a signal that these substances are safe to use; however, we are not aware of any empirical assessments of this. We are also unaware of any official national figures for the number of arrests involving psychedelics, which is important for thinking about the effects of these changes; however, our rough estimate is that it was likely in the low double-digit thousands for 2022; probably accounting for no more than 2 percent of drug arrests made that year (see Appendix D).

Reduce Penalties for the Grow-and-Give Model

A state or the federal government could also reduce the penalties for the grow-and-give model. The new penalty may be a fine or some other civil sanction. As noted in Chapter 1, Oregon decriminalized the possession of all controlled substances and those caught by police with small amounts have to either pay a fine of up to $100 or undergo a short needs assessment; they may be referred to services but are not required to receive them (note this was significantly amended in April 2024; beginning in September 2024, possession will be a misdemeanor offense).

Another example would be defelonization, which would move a criminal offense to a misdemeanor, meaning that lower penalties would apply if convicted. New Jersey recently implemented a version of this approach for those caught possessing small amounts of psilocybin; however, supplying this substance remains a more serious offense.[68]

Prohibit Funds from Being Used to Enforce Certain Supply Laws

Another option under a prohibition regime is to prohibit funds from being used to enforce certain laws pertaining to psychedelics supply. This approach could be used for prohibiting law enforcement agencies from enforcing laws against the grow-and-give model or other forms of supply, such as state-legal supervision models. As noted in Appendix B, this type of approach has been implemented in some of the local jurisdictions that deprioritized the enforcement of some laws regarding psychedelics. This approach has also been used at the federal level to prevent federal funds from being used to crack down on those participating in state-legal medical cannabis markets (further discussed in Chapter 5).

Some Supply Is Legal but Traditional Retail Sales Are Not Authorized

The options in this category make some type of supply legal for adults outside nonclinical purposes, but consumers cannot simply walk into a store and purchase the substance for off-premises use or have it delivered like one would do for pizza.[69]

Expand Religious Exemptions

Chapter 1 highlights how the U.S. federal government allows some psychedelics to be used for some religious and spiritual purposes. The DEA can still play a role with respect to monitoring and regulating supply in these instances—especially for ayahuasca, which is imported from other countries. As noted in the "Peyote and the NAC" case study in Appendix A, the American Indian Religious Freedom Act Amendments (AIRFAA) of 1994 makes it clear that the law "does not prohibit such reasonable regulation and registration by the DEA of those persons who cultivate, harvest, or distribute peyote as may be consistent with the purposes of this section and section 1996 of this title" (Public Law 103-344, 1994).

[68] Although most states use the felony/misdemeanor distinction to describe the severity of the offense, in New Jersey, the terms "indictable offense" and "disorderly person crime" are used instead.

[69] For useful insights about noncommercial alternatives to drug prohibition, see MacCoun (2013).

If the goal is to increase access to these substances, one approach would be to give additional groups exemptions for religious use. This would put additional pressure on the DEA to decide what constitutes a genuine religion. Litman (2023) argues that the DEA should not be put in that position and that there is a federal agency that is well suited to make this distinction—the Internal Revenue Service (IRS).[70]

Legalize the Grow-and-Give Model

Most states that have legalized cannabis allow this option, and Colorado recently implemented this option for psilocybin, psilocin, ibogaine, mescaline, and DMT. California's Senate Bill 58—which was vetoed by the governor in October 2023 (Newsom, 2023)—would have also legalized the grow-and-give model for these substances; however, that bill specified quantity limits.

Legalize Nonprofit Collectives/Cooperatives/Social Clubs That Only Supply to Members

Another option is to allow individuals to join collectives or cooperatives (sometimes referred to as social clubs) that produce psychedelics only for its members. Members could donate time helping to cultivate, package, or distribute products and/or pay a membership fee for a certain amount of product (e.g., a certain number of grams of dried psilocybin mushrooms per year).

As seen with cannabis in the United States and abroad, there are a lot of different approaches to implementing and operating collectives/cooperatives/social clubs (Pardal, 2022). For example, in Uruguay, cannabis collective operators and members must register with the government, and the number of members and amounts produced are capped. And in some places in the United States, the collective model for medical cannabis essentially turned into retail outlets where membership and donations were very transactional.

One design consideration for this approach is who is allowed to become a member: Any adult? Those with a medical recommendation? Those who have undergone a set of trainings? Another

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[70] Litman (2023) also argues:

> As it currently stands, the Internal Revenue Service is the federal agency evaluating religious sincerity in the eyes of the law. Churches are not required to file to be recognized as 501(c)(3) tax exempt organizations, but many do because a determination letter may be required to open a bank account, rent property, or induce significant donations. One possible short-term solution to streamlining the DEA exemption process would be to create an automatic DEA exemption once communities have been granted tax exempt status. This would require a shift in IRS policy to allow for charitable organizations conducting illegal activities, something addressed in a pending U.S. District Court case, Iowaska Church of Healing v. Rettig. This streamlining process would still result in religious communities being forced to comply with the same tracking and storage requirements as other DEA- licensed medical researchers and professionals, arguably substantially burdening their religious practice.

Relatedly, another approach could be to largely ignore organizations claiming to be a religion that want to use psychedelics. The Church of Ambrosia, which includes more than 80,000 members, has a few outlets in the California Bay Area where members can pay a small amount and then pick up psilocybin mushrooms for take-home use (Kane, 2023). Although this church does not have an exemption from the DEA and could be raided at any point, shutting it down does not appear to be a major federal or state priority.

important consideration is the extent to which on-site consumption would be allowed—or perhaps even required—at the collective.[71]

Legalize Purchasing and Using at a Designated Place, Likely with Some Form of Supervision

In this model, the state licenses those who produce the product and the place where consumption occurs. Take-home doses are not allowed. Some of the design considerations associated with this model are whether a use session must be supervised and, if so, by whom and to what extent (e.g., whether a post-use integration session is required).

A version of this model is operating in the United States. The licenses are now being distributed in parts of Oregon (see Chapter 1), and individuals can now receive these services; they are expected to go into effect in Colorado in 2025. Both states will initially allow psilocybin, and the Colorado law allows for the possibility of adding other nonsynthetic psychedelics circa 2026 (Oregon could also expand beyond psilocybin, but this would require another initiative or new legislation). An initiative very similar to Colorado's initiative may be on the ballot in Massachusetts in November 2024.

Some Supply Is Legal and Traditional Retail Sales Are Authorized

The supply options listed in this section allow for some form of traditional retail sales where anyone (over a certain age threshold) can walk into an authorized retailer and make a purchase or place an order for delivery. The main distinction between these options is *who* is authorized to sell these substances.

Legalize Sales by Government or Public Authority

This approach was implemented in various states after the repeal of alcohol prohibition and about a dozen states still limit liquor sales to state-run stores or designated agents (National Alcohol and Beverage Control Association, undated). The justification for this approach is that it makes it easier for the government to (1) control which products are sold and the prices and (2) collect government revenues. The lack of retail competition limits a race to the bottom with respect to prices and the need for promotion, but it does not necessarily eliminate it. Unless the state serves as the producer (which is possible but seems unlikely in the United States), there will likely be some advertising by suppliers to create brand loyalty. And if the government becomes dependent on revenues from selling psychedelics (which does not seem very likely; see Chapter 2), it could move to promote sales like it does with the lottery.

The state store approach has not gained much traction in U.S. cannabis legalization discussions, but it has been adopted in some parts of Canada for cannabis (Canadian Centre on Substance Abuse and Addiction, undated). For cautious jurisdictions, this is an example of a middle ground alternative to supply prohibition that could be tried for a few years before deciding whether to allow profit-maximizing firms to enter the retail markets (Caulkins et al., 2015).

[71] For some additional thoughts on this approach, see Harder, Steinmetz, and Kohek (2023).

Legalize Sales by Nonprofit Organizations

To avoid creating a for-profit model while not limiting sales to state stores, another option would be to limit sales to nonprofit organizations—perhaps those with a focus on health outcomes. However, nonprofit does not mean nonrevenue. There are some nonprofit organizations that tend to act like profit-maximizing entities (e.g., some hospitals in the United States; see Christensen, 2023), but this is usually not the case.

There is some precedent for this in the United States. When New York distributed its first wave of retail licenses for adult-use cannabis, it limited them to equity applicants and nonprofit organizations (Steinhardt, 2022).

Legalize Sales by For-Benefit Companies or B Corps

If a jurisdiction is going to allow for-profit companies to sell psychedelics at the retail level or offer them as part of a retreat, it could require that companies focus on the triple-bottom line of people, planet, and profits. This can be done by limiting licenses to companies that register as for-benefit corporations or those receiving B Corps certification from the B Lab (B Lab Global, undated). These are choices that are much easier to make when creating a new industry than when trying to change after the industry has already developed.

Legalize Sales by Conventional For-Profit Companies

A final alternative to prohibiting the supply of psychedelics outside the clinical model is to allow these substances to be sold like most other retail products: by profit-maximizing businesses. This approach dominates discussions of cannabis legalization in the United States, but there is much more interest in some of the less commercial options outside the United States (Kilmer and Pérez-Dávila, 2023; Pardal et al., 2023).

The overall consequences of the profit maximization approach (and others) will be shaped by several design considerations, discussed in the next section. In general, this for-profit approach tends to benefit consumers by maximizing competition to push retail prices down and reduce search costs, but much will depend on retail outlet density and access to delivery. Those who prioritize public health sometimes oppose this approach because it incentivizes some members of the industry to push against regulations and taxation, which can hurt their bottom line (see discussion in Pacula et al., 2014). As entities amass more profits, they have more resources to lobby politicians and regulators to fight against policies that are not in their financial interest.

Regulatory Design Considerations

For states considering whether to legalize some forms of psychedelics supply, deciding who gets to supply the product is only one of the choices they must make—especially if retail sales are allowed. There are many additional choices that need to be made about regulation and enforcement that can affect who is allowed to consume, what they consume, how much they consume, where they consume, and with whom. Table 4.1 provides a nonexhaustive list of some of the regulations that may be applied to legal psychedelics. The examples listed in the third column are not necessarily endorsements.

Although many of the regulations listed in the table can be applied to many drugs (e.g., alcohol, cannabis), we also include a section about facilitation and supervision that is specific to psychedelics. Chapter 1 and Figure 4.1 highlight the supervision models passed in Oregon and Colorado. The screening, supervision, and/or integration provisions in those models could play an important role in many of these supply options. Although almost all of those who currently use psilocybin do so without supervision from a formal facilitator or shaman (see Chapter 2), there is demand for facilitation, "trip-sitters," and retreats, and it could increase after a policy change. Policymakers need to decide whether they want to promote or create incentives for people to use facilitators, and, if so, whether any type of regulation will be imposed (e.g., licensing requirements, liability insurance). Either way, there will be some facilitators willing to provide these services outside what is legally allowed (indeed, this has long been happening and may now be on the rise) and policymakers—and possibly voters—will need to decide whether it will be a low or high priority to spend enforcement resources on suppressing this group.

Table 4.1. Examples of Regulations that Could Be Applied to Legal Psychedelics

Area of Regulation	Precedent Pertaining to Currently Legal Products or Activities	Examples of Application to Psychedelics
Product regulations		
Rules on types of products that are permitted	Jurisdictions at various times have banned absinthe and Everclear even when allowing most types of alcohol	Do not allow synthetic formulations
Restrictions on additives/ products attractive to children	Flavorings (except menthol) are banned from cigarettes.	Ban fruit flavors and psychedelic-infused candies or chocolates
Testing	Most states that have legalized cannabis require the product to be tested for molds, pesticides, and potency. Oregon also requires psilocybin be tested for its supervised model.	Require mushrooms to be tested for impurities and psilocybin/psilocin levels
Potency/strength regulation	Quebec limits cannabis products.	Create a cap on the psilocybin/psilocin content of mushrooms or truffles sold
Product labeling	Australia adopted plain packaging for all tobacco products in 2012; similar efforts are being pursued in other countries.	Require unbranded packaging devoid of logos or any form of commercial design
Packaging requirements	Child-resistant packaging is standard on a number of household items, including prescription and over-the-counter medications, vitamins, pesticides, and household chemicals.	Require psychedelics to be sold in resealable opaque child-resistant containers

Area of Regulation	Precedent Pertaining to Currently Legal Products or Activities	Examples of Application to Psychedelics
Supervision/facilitation		
Licensing for facilitators	Oregon requires facilitators to have a high school degree, complete a psilocybin training program, and pass an exam administered by OPS.	Could adopt Oregon approach or require more education and/or training
Licensing/inspections for supervision facilities, including retreat centers	It is common for government regulators to conduct compliance checks of government-licensed facilities, from bars to mental health facilities.	Random compliance checks to make sure licensed facilities are distributing licensed products, but will need to be mindful not to interrupt or create a hostile environment for those being supervised
Providing resources to protect people who use psychedelics under supervision	Medical boards have hotlines and online portals for making complaints against licensed clinical providers.	Create a hotline staffed by counselors to field calls/texts about a problem during supervision or adverse events
Seller and sales regulations		
Sold in certain types of outlets only	States that have legalized cannabis only allow it to be sold in stores that sell cannabis.	Require that psychedelics be sold only in psychedelics-only stores or only through online vendors
Limit or prioritize licenses for certain groups	Some states give licensing preferences to certain groups for cannabis businesses to promote social equity.	Give licensing preferences to those living on Tribal lands
Outlet density and location restrictions	Washington state restricts the total number of legal cannabis outlets.	Limit outlet density to ensure there is no overavailability in any area
Regulations on days of sale and hours of operation	Most states limit the times when alcohol and cannabis can be sold. Several states ban the sale of alcohol for off-premise consumption on Sundays.	Restrict sales of psychedelics to same outlet hours as cannabis sales
Quantities and promotional discounting, free samples	In response to grocery stores using alcohol as a loss leader to get people into the stores, the United Kingdom banned promotions that sold alcohol below cost.	Prohibit coupons, discounts, and giveaways (e.g., free psychedelics with purchases of other goods)
Minimum pricing	Many states have minimum pricing laws for cigarettes.	Require that a milligram of psilocybin be sold for no less than $X/mg

Area of Regulation	Precedent Pertaining to Currently Legal Products or Activities	Examples of Application to Psychedelics
Marketing regulations[a]		
Restrictions on advertising, physical location and size of ads	Washington state bans advertising within 1,000 feet of schools and playgrounds; in the Netherlands, only establishments that refrain from advertising are exempted from cannabis law enforcement.	Prohibit off-premises advertising
Restrict electronic advertising	Finland bans alcohol-branded social media communication.	Make refraining from sponsoring games and other online contests a condition for licensure
Restrictions on product placement and sponsorship	The FDA bans the tobacco industry from sponsoring sporting and entertainment events.	Prohibit psychedelics firms from sponsoring sporting and entertainment events, or any event at post-secondary educational institutions
Restrictions on ads targeting youth	Both the tobacco companies and the beer industry have been challenged for the use of youth-oriented marketing materials. The character Joe Camel was effectively removed due to court challenges.	Prohibit use of cartoon figures, animals, and other marketing images geared toward youth
Possession/use regulation		
Age restrictions on possession, use, and purchase[b]	Most states allow civil and sometimes criminal penalties for minors caught possessing, using, or purchasing (PUP) cigarettes or alcohol, although tobacco PUP laws are weakly enforced.	Restrict possession, use, and purchasing by individuals younger than 21 years of age
Quantity limits	States limit the amount of various cannabis products that can be purchased at one time.	Could impose limits on the weight/amount of various psychedelics that could be obtained in one transaction
User licenses or permits	States could think of this option as somewhat similar to a driver's license.	Require adults to undergo a health assessment and take a short course before getting a license to legally possess (and, if applicable, purchase) psilocybin
Restrictions on reasons for use	Most U.S. states have medical cannabis programs that allow access for those who receive a recommendation from a licensed physician to treat certain health conditions.	Only allow psychedelic sales to those with a recommendation from a licensed physician[c]

Area of Regulation	Precedent Pertaining to Currently Legal Products or Activities	Examples of Application to Psychedelics
Penalties for providing access to minors	Many states have social host policies that hold property owners responsible for underage drinking held on their properties. Both state-imposed liability and private party civil liability apply.	Impose civil penalties on those who provide access to psychedelics to minors

NOTE: Parts of this table are reproduced from Pacula et al. (2014). Listed examples are not necessarily endorsements.

[a] This section largely pertains to marketing restrictions when a state legalized supply and possession but they are still illegal under federal law.

[b] Similar to many other drugs, clinical research into psychedelics is limited to adult participants, so there is little RCT evidence on the consequences of psychedelics use by children and young adults; however, some traditional/spiritual groups allow underage participants but sometimes limit the dose or save them for a rite of passage. As noted in a recent report on psilocybin exposures reported to U.S. Poison Control centers, there does seem to be an increase in youth exposure to psychedelics as these substances become more widely available (Farah et al., 2024). Public education around safe storage guidelines and public programs that promote safe storage, such as the distribution of free lock boxes, may help prevent unintended youth exposures to psychedelics.

[c] For more information on this idea, see Ferenstein, 2024.

Another idea in Table 4.1 deserving of additional analysis and discussion in debates about regulating psychedelics is licensing people to use these substances (Kleiman, 1992; MacCoun, Reuter, and Schelling, 1996). Although one version of this idea would include the medical recommendation approach implemented in many states for cannabis (a separate entry in the table; for more information, see Ferenstein, 2024), licensing could be more broadly applied as a process akin to obtaining a driver's license: People would have to pass a test and/or take a course before getting a license to possess or purchase psychedelics.[72] A bill was proposed in New York that would require those ages 18 and older to undergo a health screening, take a course, and successfully complete a test to receive a permit to legally use psilocybin under state law (New York Assembly Bill A10375, 2024). Adults with a permit would be authorized to (1) purchase psilocybin from a licensed business, (2) personally cultivate psilocybin mushrooms, and (3) provide them to other permit holders as long as there is no remuneration. This user license approach raises a number of implementation questions (e.g., if health screening is required, what will it entail? Who develops the course? Who administers and grades the test? How long will the license last?) and would likely impose costs for government agencies and people who want to legally use these substances under state law. All the regulations discussed in Table 4.1 come with costs (and hopefully benefits), and decisionmakers will need to be thoughtful about these costs and benefits—and how they are distributed—when considering whether and how to regulate psychedelics.

[72] Kleiman (1992) refers to this option as a *positive license*, and he also discusses *negative licenses* in which the default is that all adults get a license but it could be revoked if certain eligibility conditions are violated (e.g., driving while under the influence of a drug). This negative license approach has been taken seriously for alcohol in some jurisdictions in the United States and United Kingdom (Kilmer, Midgette, and Nicosia, 2024).

The effectiveness of these regulations will depend, in part, on the level of monitoring and enforcement. If there is little to no enforcement (e.g., testing the testers, secret shopper tests, compliance checks), there will be little incentive for suppliers to comply.

When considering the consequences of various combinations of regulations, analyses should also consider what they mean for the use of illegally produced products. Those whose primary goal is to get rid of the illegal market will likely want fewer regulations and lower prices. Those more concerned with public health may tolerate a longer time horizon to significantly reduce the size of the illegal market if it means that there will be less promotion, higher prices, and product restrictions.

Finally, it is common to hear claims that if novel products are too expensive or hard to access in a legal market, consumers will obtain them the illegal market. That argument may have made sense with cannabis in areas where loose medical cannabis markets and minimal enforcement meant that there was already product innovation and sales of potent nonflower products before nonmedical legalization. But this argument against regulating newly legal substances may make less sense if the products that are not permitted to be produced (or heavily restricted) are not easy to access in the illegal market.

Concluding Thoughts

Nothing in this chapter should be interpreted as an endorsement or rejection of traditional supply prohibition or its alternatives. The goal is simply to highlight multiple policy options that could be considered. Comparing these alternatives with traditional supply prohibition and to one another is a challenging task, and it will be shaped by such factors as values, risk preferences, and some basic facts about these markets and the consequences of using these substances. The next chapter offers a logic model for thinking about how supply and regulatory decisions may affect key outcomes and provides some additional insights about state and federal policy options.

Chapter 5

Assessing the Implications of Changing Psychedelics Supply Policy

Introduction

Chapter 4 highlighted many of the choices confronting jurisdictions that are considering alternatives to prohibiting the supply of psychedelics and various approaches to regulating these substances. This chapter goes further and offers frameworks for thinking about some of the benefits and harms associated with these options. The focus of this chapter is primarily on U.S. state-level changes, but many of these options also apply to those considering changes at the federal level. In addition, we offer some insights about federal options ranging from legalizing commercial sales to stepping up the enforcement of laws prohibiting psychedelics.

This chapter is structured as follows. We begin with a brief discussion about perspectives and values, which shape how individuals may weigh the consequences of various outcomes of policy change. Next, we highlight the key categories of outcomes that could be considered by policymakers and then offer a logic model for thinking about the mechanisms by which various policy changes could affect these outcomes. Next, we present an approach for making comparisons across different policy designs and offer some possible insights about the effects, with a special focus on psilocybin because that is the subject of many policy proposals and changes. Later, we focus specifically on some of the federal policy options, with a focus on efforts that could be considered if psychedelics outside clinical use settings remain prohibited at the federal level. Lastly, we conclude with some ideas for improving data collection that can help facilitate analyses of psychedelics policies.

Key Insights from Chapter 5

- Now is the time for U.S. federal policymakers to decide whether they want psilocybin and possibly other psychedelics to follow in the footsteps of the for-profit cannabis model.
- People can disagree on the preferred course of action on psychedelics depending on their perspectives, values, and preferences for risk. Understanding this context up front may lead to more-productive policy conversations.
- Policy discussions should include Indigenous Peoples who are community authorized to speak on these matters.
- Data do not yet exist for rigorously comparing different approaches for legalizing certain psychedelics, but experiences with cannabis and alcohol indicate that it is possible have useful conversations about how some of these changes could play out in the United States.
- The data infrastructure needs to be improved to better support policy analyses. This involves not only expanding questions asked in general population and convenience surveys, but also conducting qualitative research with people who use psychedelics (ideally longitudinally) and those who produce and distribute these substances.

Role of Perspective and Values

Is further liberalization of laws on psychedelics a good thing? Answers will likely depend on many factors, such as the specific legal and enforcement regime (see Figure 4.1), which substances are being considered, whether sales and promotion are allowed, strength of regulation and enforcement, and projections about what future products containing psychedelics will look like. It will also depend on an individual's values, aversion to risk, and perspective. For example, those who are morally opposed to intoxication will likely oppose changes; those who are morally opposed to the government telling them what they can consume will likely feel the opposite. There are also some individuals—especially Indigenous Peoples—who believe some of these substances are living beings that are integral to their traditional and spiritual practices (see discussion in Fotiou, 2020, and Appendix A of this report).

Others may be more interested in taking a cost-benefit approach when deciding about policy change. There can be multiple perspectives on this topic, too. Some people may want to focus on costs and benefits to taxpayers or government agencies, others may want to take a societal perspective that considers additional outcomes. For example, the benefits associated with using psychedelics for spiritual or religious purposes or for pleasure are real, but estimating these values can be challenging. The public health perspective generally focuses on minimizing health risks and does not put much value—if any—on experiences intended for spiritual growth or enjoyment.

Some may also want to consider how the costs and benefits are distributed across different groups. For example, should priority be given to the outcomes for vulnerable populations (e.g., those suffering from treatment-resistant mental health conditions) or on those who have been subject to hundreds of years of discrimination and violence (e.g., Indigenous populations)?

This chapter largely leans more toward a cost-and-benefits perspective because that is common in policy discourse and this is a policy report. We conclude by noting that whatever perspective one takes, it can be very useful to make this perspective clear when engaging in debates about psychedelics. People can disagree on the preferred course of action depending on their perspectives, values, and preferences for risk. Understanding this context up front may lead to more-productive policy conversations.

Outcomes to Be Considered in Psychedelics Policy Analyses

There are several outcomes that could be considered when exploring alternatives to prohibiting the supply of psychedelics. Here, we focus on four categories: health, criminal legal consequences, public budgets, and spiritual and other perceived benefits of use.

Health

The mental health consequences of using psychedelics can range from potentially improving various disorders like PTSD or substance use disorders to generating adverse reactions and worsening some mental health conditions. Chapter 3 discusses what is known about some of these effects. There may also be effects on physical health, including an increased risk of accidents when people are under the influence, and, in the case of ibogaine, increased risk of cardiac problems. The psychedelics currently available in illegal markets may sometimes be contaminated (e.g., MDMA mixed with adulterants like methamphetamine), leading to other health risks. It is important to acknowledge, as discussed in Chapter 3, that many questions remain about the potential health risks and benefits of using psychedelics.

Criminal Legal Consequences

Although Appendix D makes it clear that the number of arrests involving psychedelics is currently very low, it is not a given that arrests related to psychedelics will remain low after a policy change. Given what we have seen following the liberalization of cannabis policies, we would expect arrests for possessing psychedelics to go down; however, it may not be the same for those under the legal age of consumption. A summary of the research on cannabis legalization in the United States finds that, in general, cannabis arrests among youth did not decrease and may have increased in some places (Wadsworth et al., forthcoming).

When thinking about the criminal legal consequences related to this topic, one must also consider the possible downstream effects of an arrest, such as convictions, sanctions, collateral consequences associated with a drug arrest or conviction, and referrals to treatment or other services. There can also be criminal legal contacts related to use, such as public intoxication or impaired driving. Although this factor does not seem to be much of an issue right now with respect to psychedelics, this may not always be the case.

Aside from the interactions related to drug laws, there may also be issues related to facilitators or guides who act in bad faith or victimize those they are guiding (as discussed in Chapter 3). Psychedelic

experiences can leave some individuals especially vulnerable, so supervision plays a larger role with psychedelics compared with most other substances. This accordingly deserves special attention in policy analyses, education efforts, and possible regulations.

Finally, there may be additional fines or sanctions associated with those who sell psychedelics in legal markets, but there are restrictions on who can purchase them (e.g., fines associated with underage sales in areas where sales are legal only to those over a certain age).

Public Budgets

For some policymakers, how a policy change affects state and local budgets is a factor that can influence their decisions. This will be shaped by the tax base/rate and licensing fees as well as other regulatory decisions, such as the level of government regulation and the enforcement of these regulations. As noted, this will also be affected by changes in health care utilization and criminal legal interactions.

Spiritual and Other Perceived Benefits of Use

This category captures perceived benefits of use that can be hard to describe and even harder to measure, let alone monetize for a cost-benefit calculus. As made clear in Appendix A and elsewhere throughout this report, some Indigenous communities and/or religions treat these substances as an integral part of their traditions and spiritual beliefs. Many in the 2023 RPS describe using psychedelics for pleasure, connecting with nature, changing their perspective, and reducing stress (see Chapter 2).

Equity Considerations

The issue of equity is also important when thinking about these outcomes. In the United States, there is ample evidence that access to health care, arrests and criminal sanctions, and resource availability are unequally distributed across the population. Certain populations, including Indigenous communities, racial/ethnic minority groups, and rural communities may suffer disproportionately across these domains. When considering alternatives to prohibiting the supply of psychedelics, one should consider whether the alternative will reinforce existing inequities or be developed proactively to minimize them. This is especially true for supervision models that may be too expensive for many potential consumers.

Indigenous groups with traditional practices that involve spiritual medicines we have categorized as "psychedelics" in this report may also be vulnerable to access issues as policies change. Some Indigenous groups may lose protections for traditional use that once existed or miss out on protections that are based on government recognition or specific exemptions from previous prohibition policies. The vulnerability of Indigenous groups' ability to access these substances as policies change is not limited to those groups that are geographically located in or near the United States. Growing demand for psychedelics can disrupt natural sources of spiritual medicines that Indigenous groups rely on, as is the case for peyote (Muneta, 2020). As is discussed in the case studies in Appendix A, increasing global demand for psychedelics and related services can also put economic

pressures on vulnerable groups and lead to harmful cultural appropriation that strips Indigenous groups of their ability to maintain their traditional practices.

But how can policy reforms influence the outcomes in all four categories? The next section offers a logic model intended to show the various mechanisms.

A Logic Model for Thinking About Changes to Psychedelic Supply Policy

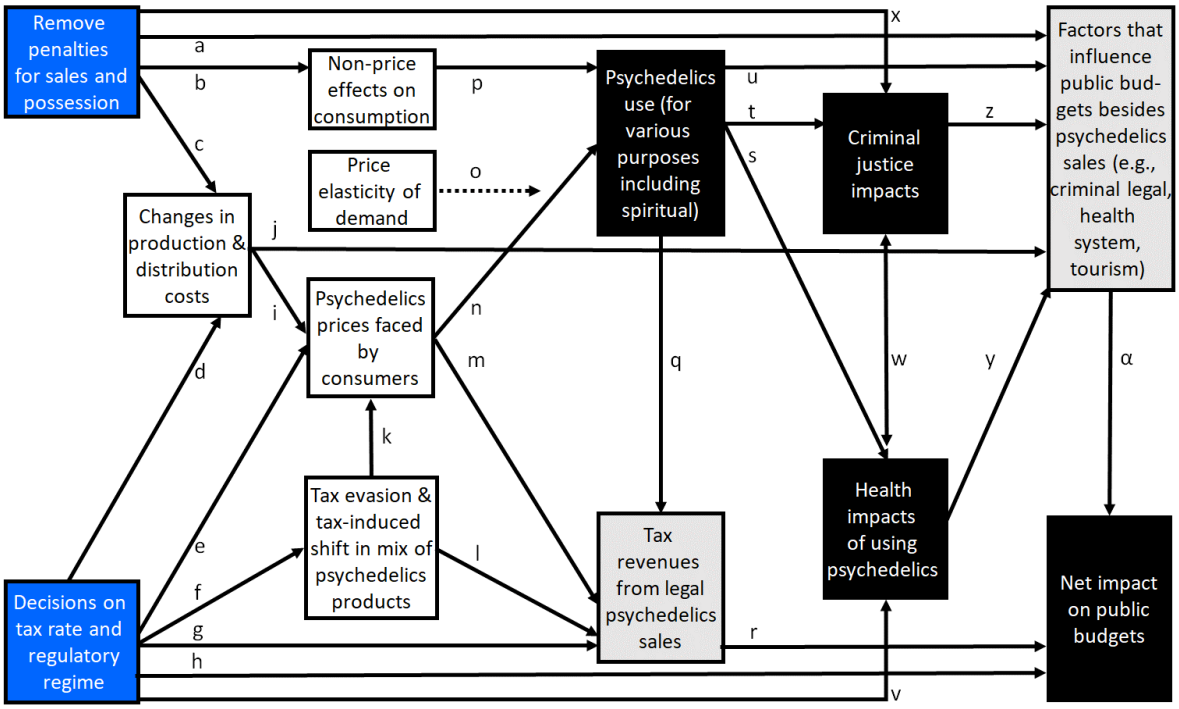
Projecting the effects of changing psychedelics supply policy on health, criminal legal, public budget, and spiritual and other intangible outcomes hinges on estimates of current consumption, current and future prices, how responsive use is to price changes (i.e., elasticity), taxes levied and possibly evaded, and the aggregation of many nonprice effects (e.g., changes in perceived risk that may influence consumption).[73]

The data do not yet exist to conduct a cost-benefit analyses of the various supply options. Presenting a framework that walks through the various mechanisms by which psychedelics policy change might influence outcomes can shape future data collection and analysis; it can also help in identifying connections that are not intuitively obvious but turn out to be very important.

Figure 5.1 presents a diagram showing how changes in psychedelics supply policy could influence health, criminal legal consequences, public budget, and spiritual and other perceived benefits. The boxes in blue in the far-left corners represent the government's decision to legalize some form of supply and possibly taxes and regulation, and the black boxes capture the main outcomes of interest. The other boxes and arrows (labeled with letters) demonstrate the various ways that legalization can influence these outcomes. Boxes for tax revenues from legal sales and other factors that influence the budgets (besides legal psychedelics sales, if allowed) are gray to highlight that they are important intermediate outcomes to the final budget figures.

[73] This section relies heavily on Kilmer et al. (2010). Although much of the text is similar, it has been augmented.

Figure 5.1. Logic Model of How Changing Psychedelics Supply Policy Affects Key Outcomes



NOTE: Adapted from Kilmer et al., 2010, p. 16.

Starting at the top left of Figure 5.1, legalization would remove the penalties for selling and possessing psychedelics. Doing so would immediately lower production and distribution costs (indicated by arrow c); an important share of the price currently paid for illegal drugs comes from having to compensate suppliers for participating in a black market and for the inefficiencies created by having to operate covertly (Reuter and Kleiman, 1986; Caulkins and Reuter, 1998, 2010). Post-legalization, users would no longer face this enforcement "tax." However, as noted in Chapter 4, governments can keep prices inflated if they choose to do so. Additionally, prices might fall because of shifts in production techniques (e.g., larger and more-efficient growing techniques for psilocybin mushrooms) and advances in production and processing technologies (Caulkins and Reuter, 2010). Prices might also be affected by regulatory decisions about supervision (e.g., bundling the product with supervisions services).

There are many ways that legalization could influence consumption besides through its effect on price, and, as we have noted, price changes may matter less for psychedelics compared with other drugs, such as alcohol or cannabis. The reductions in legal penalties are obvious, but there are other mechanisms, including advertising (if allowed), a change in social norms, availability, and perceived harmfulness (MacCoun, 1993, 2010; Pacula, 2010); these are represented by arrow b to the "Non-price effects on consumption" box in the figure. At the bottom left of the figure, we show that legalizing psychedelics would require decisions about the regulatory regime and the tax rate, if any, and these decisions may vary considerably by jurisdiction.

There are six arrows coming from the box in the bottom left, and we discuss them in a counterclockwise manner. The regulations imposed (e.g., type of products allowed, role of supervision) are expected to influence health outcomes (v), both in positive and potentially adverse ways (see Chapter 3). Because it costs money to regulate and collect taxes, there is a direct link between the blue box and black budget box (h). Setting the tax rate also obviously influences tax revenues directly (g), but taxes can also elicit a behavioral response (f), including both tax evasion (purchasing untaxed psychedelics from the unregulated market) and a shift in the mix of types of psychedelic products consumed; a fixed excise tax per gram may give users an incentive to shift to smaller quantities of higher-potency forms. For psychedelics purchased in the legal market, tax rates also directly influence the prices faced by consumers (e). The regulation of the industry will also influence the production and distribution costs (d). The arrows pointing to the psychedelics-consumption box come from these nonprice effects (p) and from price (n).

The impact of price on consumption (n) will depend not only on how much legalization influences price (e, i, and k) but also on the sensitivity of users and potential users to price (o; represented by the arrow coming from the "Price Elasticity of Demand" box). But as demonstrated in Chapter 2—and unlike what we see for cannabis and alcohol—frequent users do *not* dominate the markets for psychedelics; it is the infrequent users who do not spend much on these substances on an annual basis. Thus, price might not matter as much as it does for other substances; however, we are not aware of any estimates of the price elasticity of demand for psychedelics and whether it differs for those who primarily microdose. Even if price plays a minor role in consumption decisions in the current market, that does not mean it will remain the case, especially if legal changes lead to product innovation and an increase in marketing.

The effect on criminal legal outcomes will be shaped by not only changes in criminal penalties (*x*) but also what happens to consumption (*t*). As noted in the previous section, some jurisdictions observed an increase in youth cannabis arrests after cannabis legalization. To the extent that psychedelics policy influences mental health outcomes, it could also influence the criminal justice impacts (w). For example, there is literature linking mental health treatment with reduced criminal activity (e.g., see Deza, Maclean, and Solomon, 2022).

We also know that criminal justice involvement can influence health outcomes (see, e.g., Wang, Macmadu, and Rich, 2019); thus (w) is a double-pointed arrow. The effects on health outcomes will be influenced by this relationship and changes in consumption patterns (s), and they may also be influenced by the regulations imposed by the government (v). As noted, these regulations could influence what types of products get sold, the quantities sold, and requirements about the role of supervision.

The story gets even more complex when thinking about the effect of changes in psychedelics policy on public budgets. Revenues will obviously be influenced by the tax rate (g), consumption (q), and price (through the sales tax) (m), but we must also consider the role of tax evasion (l). Tax evasion influences both tax revenues and the average price paid by consumers (k). If the price for untaxed, unregulated psychedelics is substantially different from the prices charged in the legal market, this evasion-induced price decrease could lead to a further increase in consumption. The gray box at the top-right corner represents the factors that could influence state and local budgets besides tax revenue from legal sales. These would include changes in government expenditures on law enforcement (a),

changes in government expenditures on drug treatment, or tax revenues from other goods that are purchased (or not purchased) because of a change in psychedelics consumption and production (j, s; e.g., supervision services, alcohol), and the criminal legal and health effects (y, z). This box would include the impacts of tourism if psychedelics are legally available in some places but not others. It is this box (α) in combination with tax revenues (r) and the regulation costs (h) that generate the net impact on state and local budgets.

Although this logic model is complex, it is not exhaustive. One could include other outcomes and possibly add additional arrows between some of the boxes. The goal of this exercise is to better understand the main mechanisms by which policy change could influence key outcomes. Price plays an important role in this model, but it is unclear the extent to which price drops will influence overall consumption of psychedelics (arrow o). As noted in Chapter 2, outside those who microdose, most people who use psychedelics use them infrequently. Whereas roughly 70 percent of past-year cannabis users consumed in the past month, it is the inverse for psilocybin: Roughly 30 percent of past-year psilocybin users used in the past month—and that includes those who were microdosing. Thus, given the infrequent purchases, price changes might not matter as much as they do for other substances, such as alcohol and cannabis. This, of course, is an empirical question that should be examined in future research.

There are also obvious tensions within this model. For example, with arrow (s), would an increase in consumption outside clinical settings be a net positive or negative for health? As noted multiple times in this report, much will depend on who is using (e.g., youth, experienced users, those with mental health conditions) as well as the substance, dose, and setting where consumption takes place. When thinking about changes to supply policy—especially if it involves for-profit companies—it should be acknowledged that the products available after legalization could be very different and have different consequences from what substances are currently consumed.

We did not insert a box for equity-related issues into the figure, but not because it is not important. To the contrary, for those interested in how legalization affects certain groups, it may be possible in the future to use this logic model and obtain group-specific parameters to make projections. But it is not just about the outcome boxes. The decisions about who gets to supply, how potential tax revenues will be allocated, and whether previous psychedelics offenses will be sealed or expunged likely have equity implications (Kilmer et al., 2021). But these might not be the main equity drivers when thinking about changing policies for some psychedelics. As noted elsewhere in this report, considering how these changes could affect Indigenous Peoples—especially if patents are involved (e.g., see Marks and Cohen, 2022)—must be part of the discussion. There are also issues around safeguarding that are especially important when thinking about the use of these substances by vulnerable populations (Table 4.1).

Comparing Different Alternatives for State-Level Legalization of Psilocybin

We do not have solid estimates of most of the parameters highlighted in the logic model, but we can still make general comparisons for some of the supply models highlighted in Chapter 4. For example, Caulkins et al.'s (2015) analysis of cannabis policy options was conducted when very little

information was available about the causal effects of nonmedical cannabis legalization, similar to where we are now with psychedelics policy. In that spirit, we offer some thoughts about relative comparisons instead of offering quantitative assessments.

This section largely focuses on psilocybin given that its prevalence is the highest among psychedelics and its inclusion in many of the psychedelics policy changes that have been implemented or considered to date. This focus should not be interpreted as a judgment on the possibility of changing policies on other substances; the framework presented could easily be applied and adapted to other psychedelic substances. Given the evidence about the different consequences and experiences associated with these psychedelic substances (Chapter 3), it likely makes more sense to consider each substance individually when conducting policy analyses.

Table 5.1 offers insights about alternatives to the status quo prohibition of psilocybin for use outside FDA-approved purposes—this includes those using for nonclinical purposes as well as those using for medical purposes but not as prescribed and administered by a licensed clinical provider. The rows focus on five alternatives to prohibition highlighted in Figure 4.1: the grow-and-give model, nonprofit collectives, the supervision model, government sales, and for-profit sales. Column 2 offers examples of jurisdictions that have implemented this approach for some psychedelics or cannabis.

The other columns in Table 5.1 include policy considerations raised earlier in this volume. To compare the models for each of these considerations, we typically use a low/medium/high ranking but sometimes note when models are believed to be lowest or highest for a particular topic or offer a hybrid when there is more uncertainty (e.g., low/medium). This is an admittedly crude approach, but we generally do not have enough data to make more-precise comparisons. Furthermore, there are a host of regulatory choices within a legalization model that can shape outcomes of interest. Still, we think this approach is helpful for beginning to make comparisons and informing conversations about these different approaches. Each of the following paragraphs focuses on a specific column of Table 5.1, explaining how they were rated.

Table 5.1. Key Insights About Some State-Level Legalization Models for Psilocybin

(1) Policy Option	(2) Examples	(3) Possibility for a Reduction in Retail Price	(4) Incentive for Legal Suppliers to Promote Use	(5) Potential for Product Innovation	(6) Product Quality Assurance and Labeling	(7) Cost or Effort of Government Control and Regulations	(8) Ability to Generate State Revenue
Grow-and-give model	Colorado for five nonsynthetic psychedelics	Low	Lowest	Low	Low	Lowest	Lowest
Nonprofit collective	Cannabis in Uruguay	Low	Low	Low	Low/Medium	Low/Medium	Low
Supervision model	Psilocybin in Oregon (and eventually Colorado)	Lowest	Medium/High	Low	High	Medium/High	Medium
Government sales	Cannabis in Quebec	Medium/High	Low/Medium	Medium/High	High	Highest	Highest
For-profit sales	Cannabis in many U.S. states	Highest	Highest	Highest	High	High	Medium/High

Column 3 of Table 5.1 considers the possibility of these models reducing the retail price faced by consumers. The supervision model implemented in Oregon has the lowest probability of lowering prices because it may lead to higher prices given it is likely to be heavily regulated with a relatively small amount of production. The costs for the substance are often bundled with supervision services, so this complicates the price estimates. The grow-and-give model is rated low as are nonprofit collectives, assuming there are restrictions on the number of members (e.g., in Uruguay, the cannabis social clubs have between 50 and 99 members [Pardal et al., 2023]). Government sales is rated medium/high because the government could set a price just below the illegal market, but it may also decide to keep prices low to accelerate the decline of the illegal market and/or make tested and regulated psilocybin more affordable. The for-profit sales model has the highest probability of pushing down retail costs assuming taxes and fees are not exorbitant, and the number of production licenses are not significantly restricted.

Column 4 of Table 5.1 focuses on incentives for legal suppliers to promote use. The grow-and-give model is rated the lowest for legal suppliers to promote use, and nonprofit collectives are also considered low because they do not have a profit motive. Government sales is considered low/medium because one of the reasons to adopt this approach is to control marketing; however, as we have seen with state lotteries, once state governments become dependent on these revenues, they will often start promoting.[74] The supervision model with for-profit businesses is medium/high, and we would expect the for-profit model without restrictions on supervision to have the highest incentives for promotion.

Column 5 of Table 5.1 focuses on the potential for these models to produce product innovation, meaning that new types of products are developed and marketed to consumers. This is happening at a large scale in the cannabis space, especially with edible products and drinks. The grow-and-give model, nonprofit collectives, and the supervision models are expected to have low innovation potential given the lack of profit motive for the first two and the likely restrictions on the products that can be used in the supervision model. This potential to produce product innovation is ranked medium/high for the government sales model because it has the most control over what products gets sold and highest for the for-profit model given the need for product innovation in a competitive industry. Although one can think of product innovation with respect to new candies, soft drinks, vape pens, or higher-potency products, it is also an issue when thinking about patents for psychedelic substances—and the potential implications of these patents for Indigenous communities (see, e.g., Gerber et al., 2021; Marks and Cohen, 2022; Press, 2022).

Column 6 of Table 5.1 focuses on product quality assurance and labeling. The grow-and-give model is low because neither would be required. A nonprofit collective is classified as low/medium because testing may not be required, but presumably the collectives would impose some type of quality control (e.g., verifying the types of mushrooms). The other models will likely require testing, packaging, and labeling and are all classified as high.[75] However, the integrity of the testing will be a function of enforcement and monitoring by the regulatory agencies involved. As we have seen with

[74] Revenues from state lotteries are much higher than any realistic projection for taxes on psilocybin, so this is probably a minor possibility.

[75] There is also the issue of what is required to be on the label. For example, Oregon requires labs to test for psilocin content, but it does not have to be listed on the product label (OHA, 2024).

cannabis, there is good reason to be skeptical of the THC levels reported on packages sold by state-licensed retailers (see e.g., Schwabe et al., 2023; Geweda et al., 2024).

Column 7 of Table 5.1 is similar to Column 6 but focuses on the cost or effort of government control and regulations, not just quality assurance and labeling. The cost or effort of government control and regulations will depend on choices made about items listed in Table 5.1 (see below), such as enforcement checks, coordinating a "test the tester" system, possibly creating and staffing a new regulatory agency. The cost or effort of government control and regulations will be the lowest for the grow-and-give model, although, in theory, there could still be arrests for those exchanging products for some form of remuneration (which is typically prohibited in the grow-and-give model). Nonprofit collectives are classified low/medium because there will need to be some government oversight and possibly some compliance checks. Government sales will be the highest because this will likely require the creation of brick-and-mortar state stores, although an online-only option could reduce costs. In this model, government agencies will also be doing a lot of staffing and management. For-profit sales will be high because there can be important costs associated with implementing a licensing system as well as with monitoring and enforcement. The supervision model is listed as medium/high because it will likely generate many of the same costs as the for-profit model but presumably for fewer outlets and thus smaller.

Column 8 of Table 5.1 focuses on the ability of the model to generate state revenue. The grow-and-give model will clearly be the lowest because the government will not collect any revenues except for taxes collected by those purchasing materials to produce mushrooms at home (e.g., food dehydrator, jars). Nonprofit collectives will also be low, but there could be income taxes paid by those working there, although some collectives involve people donating their time in return for product. Compared with the other models, the supervision model would likely be medium depending on the number of licensed businesses, the number of people they hire, and how the state taxes the supervision services. Government sales would be the highest because it keeps all the "profits" that would typically go to licensees in the for-profit model. The for-profit model is listed as medium/high, but this will be shaped by the factors influencing the supervision model and decision about tax bases and tax rates (for more on this, see Caulkins et al., 2015). Note that how these models ultimately influence health care utilization and costs will also have implications for public budgets.

Table 5.1 does not include a column about impeding access for Indigenous use. We don't see this as a major issue for psilocybin in the United States given the ease of production or foraging, but this is an important consideration that should be part of policy analyses for other naturally occurring substances, such as mescaline and ayahuasca. Indeed, some deprioritization measures related to mescaline and the grow-and-give model in Colorado explicitly state that the mescaline cannot come from the peyote cactus. There are concerns that this could reduce the supply of peyote available to Indigenous communities using this spiritual medicine for ceremonies and traditional rites. And this is not just about Indigenous communities in the United States. As discussed in Appendix A, there is already an issue about access to iboga in Gabon because of exports to other countries. If jurisdictions in the United States (including the federal government) were to eventually legalize certain naturally occurring psychedelics without increasing sustainable access, those who truly care about equity and Indigenous communities will need to make sure concerns about access for Indigenous Peoples are

addressed and that members of these communities are included in these conversations (see the box entitled "Including and Listening to Indigenous Peoples in Policy Discussions" in Chapter 1).

A Final Note on Permanency

A change in psychedelics policy need not be permanent. Policymakers and those writing ballot initiatives could build in some sort of sunset clause. There is also the possibility of the legislature repealing or amending a law, as is now happening with decriminalization of the possession of controlled substances in Oregon. However, the ability of the legislature to change a passed ballot initiative differs by state. It could also become harder if the policy has been in effect for multiple years and/or some actors may lose profits if there is a major policy change.

Possible Federal Actions on Psychedelics Outside FDA-Approved Purposes

The federal government currently has multiple options when it comes to the supply of psychedelics, but it does not have unlimited time. Federal decisionmakers are in a somewhat similar position to where they were in 2012 after voters in Colorado and Washington passed cannabis legalization but with an important difference: The cannabis initiatives allowed for commercialized retail sales, while the initiatives for state-legal access to supervised psilocybin services passed in Colorado and Oregon are much more restrictive. Now is the time for federal policymakers to decide what they want these markets to look like—or not look like—and to start taking action. If they prefer a patchwork of state models—possibly including those that allow for commercial supply and sales—they can do nothing and just watch an industry develop.

This section discusses some of these federal policy options, building on ideas previously published by the authors (Kilmer and Ramchand, 2023; Kilmer and Priest, 2023) while offering some additional policy levers. These options fall into two general categories: Those that involve congressional action and those that do not. We should note that these actions are not necessarily mutually exclusive, and different approaches could be taken for different substances. This is also not an exhaustive list of potential options.[76]

Policy Changes Involving Congressional Action

Policy changes may need to be implemented by federal agencies and departments and may conflict with and/or have implications for international treaty obligations.[77]

[76] For those interested in the conflicts between FDA-regulated products and state-regulated psychedelics, see Marks (2023a).

[77] For additional thoughts on psychedelics and the United Nations drug treaties, see Transform Drug Policy Foundation (2023).

Legalize Supply and Possession and Create a Regulatory Framework

Congress could pass a law that removes psychedelics from the CSA (i.e., deschedule), eliminates criminal and civil penalties related to specific psychedelic compounds, and creates a federal regulatory framework for the substance(s). This effort could look like the regulatory models for alcohol or tobacco, something more like a dietary supplement, or something very different.

Deschedule and Leave It to the States

A related option is for Congress to deschedule psychedelics from the CSA, eliminate criminal and civil penalties related to psychedelics, and not create a federal framework. This would leave the policy and regulatory decisions up to the states, which may continue to prohibit supply and possession. (Note: This option and rescheduling also appear in the section about options not involving congressional action).

Reschedule

Congress could also reschedule psychedelics within the CSA, but this would still keep them prohibited for nonclinical purposes.[78] Depending on what level these substances are rescheduled to, this change could have multiple implications ranging from changing federal criminal penalties to reducing the federal tax burden for psychedelics businesses.[79] For more on this, see Ball (2021) and Lampe (2024).

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[78] On April 30, 2024, it was reported that the DEA agreed with the HHS recommendation to reclassify cannabis from Schedule I to Schedule III; there are some additional steps that need to happen before it is official (see Miller et al., 2024). HHS produced a 250-page report to justify the reclassification and one noteworthy component is how it determined whether marijuana had a "currently accepted medical use," or CAMU (HHS, 2023). As noted by HHS (2023, p. 73),

> After the Presidential request in October 2022, HHS (through FDA and NIDA [National Institute on Drug Abuse]) applied a two-part test to evaluate CAMU (hereinafter, "CAMU test"); this test takes into account the current widespread medical use of marijuana under the supervision of licensed health care practitioners (HCPs) under state-authorized programs. Under Part 1 of the CAMU test, the Office of the Assistant Secretary for Health (OASH) considered whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions. Part 2 of the CAMU test, performed by the FDA, evaluated whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied.

HHS concluded that marijuana did have a CAMU, but the issue remains whether this two-part test will be used to consider the reclassification of some psychedelic substances in the future.

[79] As noted in Lampe (2024),

> The prohibition on business deductions in Section 280E of the Internal Revenue Code applies to any trade or business that "consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted."

Make Federal Funding to States Contingent on Adopting a Certain Supply Model or Regulation

Regardless of whether CSA is changed, the federal government could shape what state markets/regulations look like by making certain federal funds dependent on a choice (e.g., not creating a commercial market). This is what the federal government did when it wanted all states to pass laws raising the age to purchase alcohol to 21 years old; it made access to the full amount of federal highway funds allocated to each state contingent on raising the age threshold. Eventually, all states complied.

Pass a Budget Rider or Bill Preventing Federal Enforcement of Certain State Legalization Models

In each federal budget cycle since fiscal year 2014, Congress has "passed an appropriations rider barring the DOJ from using taxpayer funds to prevent states from 'implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana'" (Lampe, 2024).[80] This has allowed medical cannabis businesses and patients to ignore the possibility of federal intervention. Something similar could be passed for psychedelics, but it could also be used for shaping what these markets could look like. For example, the amendment could prohibit federal funds from being used to enforce federal drug laws about psilocybin in states that allow supervision models or home grow; however, this "permission" would not apply to other models. A stand-alone bill could also be passed preventing federal funds from being used for enforcement against state-regulated psychedelics programs, such as the VISIONS Act introduced in 2023 (Office of Congressman Robert Garcia, 2023).

Change Federal Penalties for Possessing, Producing, and Selling Psychedelics

This option would keep psychedelics federally prohibited but change penalties associated with producing and selling. Although this would likely be in the direction of reducing sentences, Chapter 4 does highlight a potential scenario when Congress could be pressured to raise penalties for certain offenses.

Policy Changes Not Involving Congressional Action

These primarily involve the DOJ, which oversees the DEA, but not exclusively.

Deschedule or Reschedule

Neither descheduling nor rescheduling requires congressional action. The President can ask the HHS Secretary and the Attorney General to initiate the administrative process to review how

[80] Lampe (2024) also notes:

> Courts have interpreted the appropriations rider to prohibit federal prosecution of state-legal activities involving medical marijuana. However, it poses no bar to federal prosecution of activities involving recreational marijuana. Moreover, the rider does not remove criminal liability; it merely limits enforcement of the CSA in certain circumstances while the rider remains in effect.

substances are scheduled in the CSA. After receiving a recommendation from HHS, the DEA ultimately decides whether the substance should be rescheduled or descheduled. Because the HHS and DEA recently recommended rescheduling cannabis from Schedule 1 to Schedule III (see footnote 78 earlier in this chapter), it seems unlikely HHS or DEA would recommend psychedelics be descheduled from the CSA anytime soon.

Expand Religious Exemptions

As noted in Chapter 1, the DEA has allowed a handful of exemptions to bona fide religious organizations that use certain psychedelics for spiritual purposes and traditional practices, but it has been resistant to doing so. One option to increase access would be to increase the number of exemptions granted by the DEA.

In May 2024, the author of a GAO report argued that the DEA should improve its religious exemptions petition process for psilocybin (mushrooms) and other controlled substances (McNeil, 2024). The author offered these four recommendations and stated that the DEA concurred with each of them (McNeil, 2024, p. 45):

- The DEA administrator should more clearly communicate the types of information that Religious Freedom Restoration Act petitioners should provide to allow DEA to evaluate petitions for religious sincerity. (Recommendation 1)
- The DEA administrator should more clearly communicate the standards and relevant factors to Religious Freedom Restoration Act petitioners in making a determination related to religious sincerity. (Recommendation 2)
- The DEA administrator should establish timeframes for DEA to make determinations on completed religious exemption petitions to provide Religious Freedom Restoration Act petitioners with DEA's final determinations. (Recommendation 3)
- The DEA administrator should provide Religious Freedom Restoration Act petitioners with information for petitioners to be able to receive updates on the agency's progress related to exemption reviews. (Recommendation 4)

DOJ Could Publish a Guidance Memo to Shape the Market

Another option would be for DOJ to produce a guidance memo letting states know that supply and possession of most psychedelics is illegal under federal law and that DOJ will use its discretion to determine which products or actions it will tolerate.[81] For example, DOJ could make it clear that state-licensed supervision or home grow models would not be a high priority for federal law enforcement but that companies selling or promoting these products without FDA approval would be.

This approach is not unheard of, especially because federal prosecutors have limited resources and need to decide which cases to prioritize. We saw something similar for cannabis after Colorado and Washington state passed legalization in 2012. In 2013, DOJ published a memo essentially indicating

[81] This subsection is largely reproduced from Kilmer and Priest (2023) and Kilmer and Ramchand (2023).

that while cannabis sales and possession were illegal under federal law, it would not be a federal enforcement priority to block state legalization efforts as long as certain guidelines were followed. Something similar could be created for those participating in state-legal psychedelics markets.[82]

Support Research, Prevention, and Efforts to Reduce Risky Use

Regardless of the legal status, federal agencies could support research and efforts to prevent and mitigate risks. Beyond the current and past federal support for clinical trials, the National Institute on Drug Abuse also has a call out for proposals focused on psychedelics policy research (HHS, 2023). And with the Office of National Drug Control Policy (ONDCP)'s new focus on harm reduction, it could also consider supporting drug checking programs that include psychedelics (especially for MDMA, which is sometimes mixed with methamphetamine and other substances). There could also be federally funded prevention messaging supported by ONDCP or the Centers for Disease Control and Prevention (CDC).

Intensify Enforcement and Prosecution

There is also nothing preventing federal law enforcement agents from cracking down on those currently licensed to produce and distribute psilocybin in Oregon and other states in the future. Although "cracking down" could involve arrests and criminal penalties, there are other options (e.g., using the CSA's "crack house statute" to threaten those who own buildings where psychedelics are produced or administered).[83]

Table 5.2 provides some summary information on these options and our assessment about what they mean for the ability for federal government to shape how psychedelics are supplied and regulated outside FDA-approved purposes. Once again, we reiterate that these options may not necessarily be mutually exclusive and could differ by psychedelic substance.

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[82] As this report was nearing completion, another approach for DOJ and the states implementing medical programs for psilocybin was proposed: creation of a research program under Section 872 of the CSA (Pennington, Stark, and Esselman, 2024, pp. 11–12). The authors argue,

> Section 872 [of the CSA] authorizes the [Attorney General] AG to carry out research projects related to controlled substances for a number of purposes—including to "develop information necessary to carry out [scheduling duties under the CSA]." To facilitate these research programs, Section 872 empowers the AG to both protect the confidentiality of all involved and exempt them from state or federal prosecution for otherwise-illegal possession, distribution, dispensing, and use of controlled substances in the research program. In 1972, the AG invoked Section 872 to permit methadone treatment to proceed as a research project and granted absolute confidentiality to the patient records of those involved. . . . The state and federal governments should follow a similar approach to psilocybin legalization. By treating state medical psilocybin treatment as research programs of the AG under Section 872 of the CSA, the federal government could learn from state-level experience in administering and regulating psilocybin; gather the data necessary to support HHS's Part 1 and Part 2 analyses for potential rescheduling of naturally occurring psilocybin and other important policy reforms; and, at the same time, protect patient confidentiality and ensure those involved are immune from liability under state and federal law. States seeking to promote safe and equitable access to psilocybin should develop and propose a Section 872 program to the AG.

This idea is deserving of additional analysis.

[83] For more on the section of the CSA that is referred to as the "crack house statute," see Lampe (2019).

Table 5.2. U.S. Federal Options on Psychedelics Supply for Non-FDA Approved Purposes

Federal Option	Requires Congressional Action	Federal Agencies Possibly Involved[a]	Ability for Federal Government to Shape How Psychedelics Are Supplied/Regulated at the State Level
Legalize and create a regulatory framework	Yes	FDA, ATF, perhaps a new agency	High
Deschedule and leave it to the states	Not necessarily	Possibly none	Low
Reschedule	Not necessarily	HHS, DOJ, FDA	Low
Make federal funding to states contingent on (not) adopting a certain supply model or regulation	Yes	DOJ, perhaps others	Medium
Pass a budget rider or bill preventing federal enforcement of certain state legalization models	Yes	DOJ	High
Change federal penalties for possessing, producing, and selling psychedelics	Yes	DOJ	Low
Expand religious exemptions	No	DOJ (DEA), possibly IRS	Low
DOJ could publish guidance memo shaping the market	No	DOJ	High
Support research, education, and efforts to reduce risky use	Maybe, if extra funding is needed	NIH, CDC, ONDCP	Low
Intensify enforcement and prosecution	Not necessarily	DOJ	Medium

[a] These are just possibilities, and it is entirely possible other federal agencies/department could be involved. These lists should not be considered exhaustive.
NOTE: ATF = Bureau of Alcohol, Tobacco, and Firearms and Explosives; NIH = National Institutes of Health.

Improving Policy Research on Psychedelics

Chapter 3 highlighted some of the questions that still need to be addressed about the clinical uses of various psychedelics, ranging from measuring the longer-term outcomes of these experiences to understanding the impacts of altering different components of the setting (e.g., number of facilitators, role of music). This section largely focuses on areas where additional research and funding could improve knowledge on psychedelics *outside clinical settings* and policy analyses of alternatives to prohibiting the supply of psychedelics outside FDA regulation.

Survey Research

In this section, we include some ideas for adding questions to general population surveys or web-based convenience samples. Most of these correspond to the tables presented in Chapter 2. For decisionmakers and others seriously considering these additions, we hope they will conduct the appropriate psychometric testing and focus groups to make sure the added questions are accurately capturing the constructs that the surveys are trying to measure. Some are fairly straightforward (e.g., prevalence and frequency) while others are more complex (e.g., quantity consumed, intentions for use, and consequences of use).

Prevalence and frequency (Tables 2.1–2.4). Given the increasing prevalence of psilocybin use, it would make sense to start including detailed questions about past-year and past-month psilocybin prevalence as well as frequency in the NSDUH and other general population surveys. As noted in Chapter 2, asking about the number of use days in the past year and past month would also be useful for assessing the consequences of use and measuring the size of the market.

Form of use (Table 2.7). As noted in Chapter 2, those using psilocybin in the past year most commonly used it in whole mushroom form (56 percent), but 22 percent reported consuming it as a processed edible, like a chocolate bar. Because we still have much to learn about how the form of use affects the user experience and specific consequences, collecting this information is critical.

Microdosing (Tables 2.4, 2.5, and 2.11). To better understand frequency and consequences of use, surveys should also include more questions about microdosing (there's also need to come up with a standard definition). Among those who reported microdosing in the past year or month, it will be informative to ask about the number of times they also used that substance for a "full" experience.

Quantity consumed (Table 2.11). As noted, many people consuming psychedelics do not know how much of the active ingredient is in the material (e.g., amount of psilocybin or psilocin in a mushroom). But at least knowing the number of grams or pills consumed during a typical use day can be informative. Surveys could also add pictures with the substances next to other items (e.g., a coin or credit card) to help get a sense of the raw quantities. One could also ask questions about the duration of the experience. For those who are microdosing, knowing the weight of how much they purchased during their last purchase and how long it lasted (e.g., did it last for X number of use days?) could help provide general information about quantity consumed.

Expenditures (Tables 2.13 and 2.14). Because many people may not know how much they consumed, collecting expenditure information (amount spent and frequency of purchases) may provide additional insights about the intensity of consumption; it is also critical for estimating total spending on psychedelics. Information will also have to be collected on sharing and possible reselling (e.g., what share of your last purchase did you consume vs. give away or sell to others?). Because some people produce or forage their own psychedelics, questions will also need to be included about this aspect. It will also be useful to include questions about expenditures on supervision services, which could be bundled with the product being purchased.

Source of psychedelics (Table 2.12)**.** Knowing where people obtained these substances not only provides useful insights about the market (e.g., from a state-licensed provider, from a friend, grew/foraged themselves), but it can also provide some information about whether the individual was using a regulated and tested product.

Prices. As noted in Chapter 2, there is not much systematic data on the retail prices for various psychedelics, especially when it comes to quantity discounts. Getting a sense of the regional (or state) differences and whether these prices change after a policy reform will be important for assessing the consequences of the change (See discussion around Figure 5.1).

Intentions for use (Table 2.8). Understanding all the reasons people use these substances is especially helpful for assessing the extent to which consumers are attempting to treat mental health conditions, seeking a spiritual experience, or largely using for fun or pleasure. We offer several possibilities for intentions to use in Table 2.8, but this should not be considered definitive or exhaustive. Asking about the use of these substances for specific mental health conditions (which we did not do) should be incorporated into these surveys if there is space available.

Consequences of use. Depending on the recency and frequency of use, these questions could provide insights about long- and short-term consequences, both good and bad. As noted in Chapter 3, there is much to learn about adverse consequences and whether those who had a challenging experience in the short run still found the experience beneficial. This is an area where focus groups and proper psychometric testing of questions will be critical, and hopefully there will eventually be some type of standardization across various surveys asking about these consequences.

Setting and supervision (Tables 2.9 and 2.10). As made clear in many parts of this report, the setting of the experience and the role of supervision are believed to help reduce the risk of harm and improve the chance that users achieve their goals for the session(s). However, this is very much an empirical question as researchers have not been able to compare the rigorous experiences in clinical settings with those who use these substances, perhaps by themselves or without a formal guide, in other settings. Furthermore, little is known about which components of the setting and supervision make the most difference (e.g., whether two facilitators are needed or would one be sufficient, whether group therapies produce the same effects as those that are individualized).[84] Admittedly, it will be difficult to answer these questions using survey data alone (especially if the data are only cross-sectional) but collecting details about the setting and role of supervision could provide useful insights for those who are designing research experiments on these topics.

Ethnographic and Qualitative Research

Although these surveys could provide useful information, they will likely be limited by the number of questions they can ask. There is also a need for rigorous ethnographic and qualitative research with people who use psychedelics, ideally following these individuals over time. But it is not just those who use psychedelics who should be the focus of these studies. There is much to learn from interviewing and observing those who produce and distribute these substances. Little is known about the illegal markets for these substances, and generating this baseline information is critical for projecting the consequences of various policy changes.

There is also much to learn about how Indigenous Peoples are being affected by these policy changes inside and outside U.S. settings. Within the United States, understanding the similarities and differences that these policies may be having compared with changes with cannabis policies would be

[84] There are also questions about the role of music in these sessions. For more on this, see O'Callaghan et al. (2020).

very insightful, especially in terms of potential conflicts with Tribal law and sovereignty. We suspect much of this could be learned through interviews and review of legal documents.

Analysis of Those Participating in State-Legal Supervision Programs

There is also information to learn from those who are paying for state-licensed psilocybin services. A bill passed in Oregon (Senate Bill 303) requires service centers to collect and report certain client and service center data to OPS beginning in 2025 (OHA, undated-c). However, the OHA also notes that "[as] a reminder, separate from SB 303 data collection, if a licensed service center chooses to voluntarily report data to a third party, they must first receive client consent prior or during a preparation session using the Notice and Opt-Out of Disclosure of De-identified Data and Authorization to Disclose Personal Identifiable Information forms in accordance with current administrative rules on client confidentiality" (OHA, undated-c). One wonders about the possibility of making the de-identified individual level data available to researchers (e.g., reason(s) for use, type of dose, amount paid). And what about the possibility of following up with these individuals? These concerns raise a host of ethical and legal questions (e.g., to what extent the Health Insurance Portability and Accountability Act could play a role in these state-licensed but federally prohibited systems[85]), but, given minimal data available outside federally approved clinical research settings, it seems worth it to have these conversations and consider the pros and cons of the various options for data collection and analysis.[86]

[85] Marks (2023a) argues,

> Because supported adult use programs likely lie outside the health care system, potentially skirting federal drug regulations and research standards, clients may lack protections of the federal Common Rule, which defines basic requirements for obtaining informed consent and ensuring research protocols comply with ethical standards. Moreover, psychedelic client data [are] unlikely to be covered by the Health Insurance Portability and Accountability Act (HIPAA).

[86] For additional ideas on possible surveillance systems, see Black et al. (2024).

Chapter 6

Concluding Thoughts

As more jurisdictions consider alternatives to prohibiting the supply of various psychedelics to be used for any reason, there will be a demand for policy analyses to guide these discussions and decisions. This report is intended to serve as a baseline for those analyses—offering new data, frameworks, and insights about the various policy options. This report is certainly not the final word on this topic, but it should advance thinking on these issues and hopefully make policy debates on this topic more productive.

Chapter 1 is intended to provide an overview of the psychedelics policy landscape in the United States, and how it has started to change in some places. Chapter 2 provides baseline information about the prevalence and frequency of psychedelics use, with a special focus and additional questions about psilocybin because it has the highest past-year and past-month prevalence rates in the United States among the classic psychedelics, ibogaine, and MDMA. Having this information is critical for projecting the effects of various policy changes. We hope future surveys include more-detailed questions about psychedelics and that researchers conduct the appropriate psychometric testing of surveys beforehand to confirm respondents are accurately responding to these questions. Chapter 3 provides an overview of the consequences of using psychedelics, both positive and negative. This is a rapidly advancing area of research, and much more will be learned from studies with a longer follow-up. We also make it clear that just because a psychedelic experience has some negative or challenging consequences does not necessarily mean that it does not also produce some positive effects as well. These are complex substances, and the consequences will be shaped by the amount of the specific substance consumed, the experience and mindset of the person consuming, and the setting.

Chapters 4 and 5 focus on the variety of policy changes that could be adopted, with a special focus on the United States. Chapter 4 presents a taxonomy of policy changes for the nonclinical supply of psychedelics and lists several policy design issues that can shape how a policy change affects health, safety, social equity, and other outcomes. For jurisdictions considering alternatives to prohibiting the supply of some psychedelics, one could think of this as a comprehensive but nonexhaustive checklist of issues to consider. Chapter 5 provides a framework for beginning to compare different U.S. state policy options for psilocybin and explores the U.S. federal options for nonclinical supply of psychedelic substances. With respect to the former, we expect there will be more empirical research available to inform some of these comparisons in the future.

This report highlights multiple ways that discussions about the legalization of various psychedelics could differ from what we saw and see happening with cannabis policy debates in the United States. Some examples include the following:

- Reducing arrests will likely be less of a justification for policy reform. Whereas there were more than 650,000 arrests for cannabis in 2018 in the United States (Gramlich, 2020), the

total number of arrests for psychedelics in 2022 was likely in the low double-digit thousands (Appendix D).

- Potential tax revenues will likely not be a major factor given how small these markets are relative to other illegal drugs. Our rough calculation suggests that on the order of $1 billion may have been spent on purchasing psilocybin throughout the country in 2023 (Chapter 2).
- Although price is a major policy lever when we think about regulating cannabis, alcohol, and many other drugs that are often used frequently, it will likely play much less of a role for psychedelics because infrequent users drive currently drive the market and they tend to spend relatively little on these substances (Tables 2.3, 2.4, 2.13, and 2.14).
- The role of supervision will likely play a much larger role in policy discussions surrounding the legalization of psychedelics for nonclinical purposes. Even in places that do not adopt the supervision model being implemented in Oregon and Colorado, policymakers will likely confront many decisions surrounding the regulation of facilitators and supervision settings (Chapters 3 and 4).

But there are also some likely similarities, especially if some states eventually allow commercial production and retail sales of some psychedelics. The product proliferation in the cannabis market over the past few decades has been tremendous, and it would be naïve to think this will not occur once the industry has the freedom to innovate in the psychedelics space. Relatedly, it is not hard to imagine a move to synthetic or possibly semisynthetic products (such as the Delta-8-THC sold in many parts of the country that is synthesized from CBD[87]) in nonclinical markets.

We cannot reiterate enough the importance of being specific about the policy changes being considered or analyzed. As noted in Chapter 1, the term *decriminalization* often gets used as a generic term to describe many of the recent changes to psychedelics policies, but this is a very specific term that typically describes only one type of intervention: keeping possession of small amounts for personal use illegal but no longer making it a criminal offense. What is happening in localities with the deprioritization of the enforcement of certain psychedelics laws is not decriminalization. Similarly, Chapters 4 and 5 make it clear that there are many types of legalization, ranging from allowing only the grow-and-give model to the profit-maximizing commercial model, with various options in between. Greater specificity about which of these changes is proposed (and implemented) should lead to richer and more-detailed policy discussions.

Those participating in these debates should also acknowledge that people are coming to these discussions with different experiences, perspectives, and values. Thus, it should not be surprising when people disagree about the proper course of action on psychedelics. This does not mean there is not a role for rigorous empirical analysis, but the insights from data and reports such as this one may be only one factor influencing someone's policy preferences.

A consistent theme throughout this report has been the need to acknowledge and respect the insights from Indigenous communities and make sure that issues surrounding equity are incorporated into analyses and policy discussions. Although equity is a major factor in today's discussions about cannabis policy—as it should be—that was not always the case (Kilmer and Kilmer Neel, 2020).

[87] Although Delta-8-THC occurs naturally in trace amounts of cannabis, the products that are commercially available are synthesized from CBD (see e.g., Michigan Cannabis Regulatory Agency, undated).

However, many jurisdictions have implemented cannabis equity programs without conducting analyses about whether these state and local efforts will achieve the expected outcomes, especially if there is a change in federal policy (Kilmer et al., 2021). We hope those participating in psychedelics policy discussions will be analytical, forward-thinking, and inclusive when it comes to efforts intended to address equity issues.

Finally, although this report is largely focused on nonclinical supply and use, this should not be interpreted as indifference or a dismissal of clinical research and its applications. To the contrary, we are thrilled that more randomized clinical trials are being conducted to help reduce the burdens on those with mental health conditions and their loved ones. There is concern, however, that if moves to expand nonclinical supply do not go well (e.g., it is poorly regulated and/or there are a series of high-profile negative events related to psychedelics use), it could create a backlash that may have a chilling effect on the research. Based on what happened with clinical research on psychedelics after the 1960s, this is not an idle concern.

Appendix A

Case Studies of Supply Models for Psychedelic Substances

Introduction

This appendix presents four examples of how specific psychedelic substances are supplied in various parts of the world: psilocybin mushrooms in Jamaica, peyote (and the NAC) in the United States and Canada, iboga in Gabon, and ayahuasca in Peru. These case studies are intended to be illustrative of various approaches to supply, but these examples are not an exhaustive assessment of the variation across substances, locations, and cultures.

Our discussion of these examples provides context and analysis of *supply models*, meaning how a particular psychedelic substance is produced and accessed by those who use it. For example, a psychedelic substance could be administered by a religious or spiritual leader in a ceremonial context, administered under supervision by a medical professional, or purchased in a retail setting and self-administered.

Discussions in this appendix include an overview of the legal status of the substance and related activities in a particular jurisdiction as well as ethical and equity issues arising from the way the substance is supplied. We examine details of both the overall supply architecture (e.g., does the government license suppliers?) and policy design considerations (e.g., what are the requirements to receive a license?) for each case study.

Psilocybin Mushrooms in Jamaica

Background

Psilocybin mushrooms are gaining popularity in Jamaica as interest in psychedelics from foreigners increases, although traditional, plant-based remedies in general are viewed favorably in the island nation (De La Haye et al., 2022). There is also some evidence for the historical use of psilocybin mushrooms by the Indigenous Taíno Peoples in the Caribbean, including Jamaica (Nieves-Rivera, Muñoz-Vázquez, and Betancourt-López, 1995). Despite some domestic interest, international tourism makes up a large share of the unregulated market for psilocybin mushrooms in Jamaica, as suggested by Jamaican Senator Dr. Saphire Longmore (Smith, 2022). Jamaica's history as a British colony with extensive sugar plantations built on the labor of African slaves informs the power dynamics of any facet of the Jamaican tourism industry (Aarons, 2020). Many of the new businesses in Jamaica's burgeoning psilocybin mushroom industry are owned by, invested in, and/or staffed by

foreigners, commonly from the United States and Canada (Chappell and Ellsworth, 2022; Busby, 2023).

Legal Status

According to Jamaican Senator and attorney Sherene Golding Campbell, psilocybin mushrooms are legal to grow in natural habitats, but preparing mushrooms for human consumption (e.g., by drying or combining into capsules, foods, or drinks) is currently prohibited (Campbell, 2023). Despite the law, Senator Campbell stated there is no active enforcement against possessing, manufacturing, or distributing psilocybin mushrooms. In 2021, the Jamaican Minister of Agriculture and Fisheries released a statement regarding interim protocols for the cultivation and processing of psilocybin mushrooms expressing the government's interest in working with the industry (Ministry of Agriculture, Fisheries and Mining, 2021).

Supply Model

The supply of psilocybin mushrooms is unregulated in Jamaica, meaning there is no specific licensing or regulations for the cultivation, manufacturing, distribution, or retail sales of these substances. A 2023 industry report on psychedelics lists Jamaica as one of the top international destinations for multiday retreats where psilocybin mushrooms are provided by retreat facilitators alongside such wellness-oriented activities as meditation and yoga (Hardman, 2023). Companies with industrial-scale cultivation capacity operate openly (Havn Life, 2021). Given the lack of enforcement and the scale of cultivation, it is likely that most of the mushrooms sold or distributed in Jamaica are grown domestically rather than imported. Mushroom products, such as capsules containing psilocybin, are also available to the public in retail locations (Busby, 2023). Additionally, clinical research into the use of psilocybin mushrooms for psychedelic-assisted psychotherapy treatments is taking place in Jamaica (De La Haye et al., 2023).

Additional Considerations

Policies related to psychedelics in such places as the United States and Canada could affect the market for psilocybin mushrooms in Jamaica, but this remains to be seen. Similarly, foreign investments in companies that operate in Jamaica could change as policies change in other jurisdictions.

Peyote and the NAC

Background

Peyote (*Lophophora williamsii*) is a cactus native to southern Texas and parts of northern and central Mexico (Dinis-Oliveira, Pereira, and Dias da Silva, 2019). When consumed, peyote has

psychedelic effects that are primarily attributed to mescaline, although the cactus contains a variety of compounds that may act together to enhance the effects of mescaline (Dinis-Oliveira, Pereira, and Dias da Silva, 2019). The top of the peyote cactus contains the highest concentration of mescaline and grows above the ground in a disc-shape, commonly referred to as a *button*, which can be harvested from the root allowing the cactus to regrow (Dinis-Oliveira, Pereira, and Dias da Silva, 2019). However, peyote cacti are very slow growing, sustainable harvesting techniques can be challenging to implement, and the concentration of mescaline as well as the size of the button are affected by harvesting (Kalam et al., 2013). In the United States, peyote has become scarce in its natural habitat as a result of a combination of land development, a lack of interest in peyote conservation from local landowners, overharvesting by licensed harvesters, and destructive harvesting by illegal market harvesters (Terry and Trout, 2017; Muneta, 2020).[88] Peyote faces similar, but unique, obstacles where it grows in the wild in Mexico (Muneta, 2020).

Strong archeological evidence supports the Indigenous use of peyote in North America for thousands of years (El-Seedi et al., 2005; Terry et al., 2006). Today, peyote is consumed ceremonially as a sacrament by members of the syncretic NAC (Halpern et al., 2005; Lawlor, 2021). The NAC was founded in Oklahoma in 1918 following a long period of displacement and loss of traditional ways among Indigenous groups who had been forcibly moved onto reservations (Jones, 2007). The modern NAC has been described as a confederation of churches with more than 180 chapters[89] across the United States and Canada (Feeney, 2016). Although there is variation among chapters of the NAC, these organizations consistently combine traditional Indigenous symbols and rituals with Christian ethics and beliefs (Jones, 2007). The ceremonial ingestion of peyote as a sacred medicine is a central practice of the NAC and has been compared with the Christian use of bread and wine in the sacrament of Communion (Jones, 2007). The importance of peyote as an integral part of the NAC religion and the importance of the NAC to the Indigenous community has also been formally supported by the National Congress of American Indians, the largest and most representative organization of Indigenous groups in the United States (National Congress of American Indians, 2009).

Peyote ceremonies in the NAC are all-night communal rituals with prayer, drumming, singing, and religious communion followed by a community meal in the morning (Jones, 2007; Lawlor, 2021). There is a common general structure to peyote ceremonies in the NAC with consistent leadership roles among the participants (Jones, 2007; Lawlor, 2021). Ceremonies may be attended as frequently as once a week or as infrequently as once a year (Prue, 2014). A 2005 study found no evidence of psychological or cognitive deficits among NAC members who regularly ingested peyote in a religious setting (Halpern et al., 2005). NAC peyote ceremonies are often called for a purpose, such as curing an illness, praying for someone serving in the armed forces, blessing someone with a particular problem, or to celebrate and give thanks (Jones, 2007; Golden, 2022).

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[88] Peyote primarily grows on private lands in South Texas, which have been encroached on by urban sprawl. The remaining natural habitats of peyote are commonly owned by ranchers who seek to maximize the value of their land by creating game hunting reserves or leasing their land for oil drilling (Muneta, 2020).

[89] NAC chapters are often organized under a larger central church. The four largest and most-influential central churches are the NAC of North America (NACNA), NAC of Oklahoma, Azee' Bee Nahaghá of Diné Nation (ABNDN), and the NAC of South Dakota (Feeney, 2016).

Legal Status

Although peyote is a Schedule I substance under the CSA, NAC members currently have a legal exemption to use peyote in "bona fide religious ceremonies" under the 1994 AIRFAA (Terry and Trout, 2017; also see Chapter 1). As a result of the decentralized organization of the NAC, the legal definition of a member of the church has been difficult to define. With a few exceptions among individual court cases, the peyote exemption has generally been interpreted as applying to members of federally recognized Indigenous Tribes with at least 25 percent Indigenous blood (Feeney, 2016; Muneta, 2020). This definition excludes Indigenous members of the church who belong to Tribes that are not federally recognized and non-native members of the NAC, such as spouses, who may practice the religion earnestly (Muneta, 2020).

Supply Model

The legal supply of peyote to members of the NAC has primarily been provided by a small number of non-Indigenous distributors in southern Texas who register annually with the DEA and the Texas Department of Public Safety, pay licensing fees, and report on peyote harvests (Feeney, 2016; Céspedes, 2018). Licensed distributors organize peyote pickers, usually family and members of their local community, to harvest peyote under agreement with private landowners where the cactus grows in the wild (Muneta, 2020). This supply model has been declining in relevance as the economic situation shifts in South Texas and the wild peyote gardens become increasingly overharvested. As few as four licensed peyote distributors were licensed in Texas in 2018 (Céspedes, 2018).

Some members of the NAC are reluctant to cultivate peyote in greenhouses due to their religious beliefs about the nature of peyote and how it grows (Muneta, 2020). Additionally, many Tribal groups lack the resources to invest in the complex agricultural infrastructure required to grow peyote in greenhouses (Muneta, 2020). However, some cultivation efforts led by Indigenous groups in cooperation with the DEA are beginning to make progress in South Texas. A cultivation facility recently constructed by the Indigenous Peyote Conservation Initiative (IPCI) aims to preserve the traditional ways of harvesting peyote in its natural habitat while supporting the growth of young plants. The IPCI facility operates as a nursery for the first three to four years of the peyote cactus life cycle, then the plants are transplanted into the wild, rather than grown for the full life cycle in a greenhouse (IPCI, undated). The facility also operates as a gathering space for prayer and other Indigenous traditions related to the harvest of peyote (IPCI, undated). Facilities like the one run by IPCI, whose leadership is primarily made up of members of the NAC, are still required to register annually with the DEA and follow local regulations under the AIRFAA peyote exemption (Muneta, 2020).

Additional Considerations

NAC leaders have been pushing the U.S. federal government to take a more active role in the conservation of peyote habitats and access by NAC members (Golden, 2022; Thompson, 2023). A key proposal is a request for federal funding to compensate landowners in South Texas for land that

could be converted into protected peyote habitat and used for other Indigenous-led conservation activities (Thompson, 2023).

Beginning in 2019, several local governments in the United States have deprioritized the enforcement of state laws that prohibit the cultivation, distribution, and possession of some psychedelic substances, including peyote and/or mescaline.[90] Increasing mainstream interest in peyote will likely put even more strain on the already dwindling native population of the cactus (Terry and Trout, 2017; Golden, 2022). Indigenous groups have called on local governments to exclude peyote and mescaline from these policy changes and allow Indigenous groups to take the lead on any policy changes related to peyote (National Council on Native American Churches and IPCI, 2020; National Congress of American Indians, 2021; IPCI, 2023). Some local governments have followed these requests, excluding peyote from their policy changes, while others have not. Indigenous groups have clashed with activist groups, particularly Decriminalize Nature, over this topic (National Council on Native American Churches and IPCI, 2020; Labate and Feeney, 2022; IPCI, 2023). Furthermore, it has been reported that the leaders of the NAC want "the U.S. government to enforce laws that prohibit non-Natives from using the drug" (Thompson, 2023).

Iboga in Gabon

Background

Iboga (*Tabernanthe iboga*) is a fruiting tree that is native to the tropical forests of Central and West Africa (Bading-Taika et al., 2018). Parts of the tree, particularly the root bark, contain iboga alkaloids that have been used by the Indigenous Peoples of the region for medicinal and spiritual uses for thousands of years (Eastman and Barsuglia, 2023; Faura and Langlois, 2020). Iboga plants take a minimum of five to seven years to mature before they are ready for harvesting, and older plants yield more-potent harvests (Eastman and Barsuglia, 2023). Iboga thrives in a tropical forest environment and can be challenging to cultivate outside its native habitat (Faura and Langlois, 2019). However, cultivation efforts have increased in recent years in response to the growing demand and rapid loss of the native supply (Nuwer, 2023).

The alkaloid ibogaine is the primary psychedelic compound in the iboga plant, although, like some other naturally occurring psychedelic substances, some claim the full effects of the plant may result from the interactions of a variety of plant components (Bading-Taika et al., 2018). Ibogaine is also found in other plants that are easier to cultivate, such as *Voacanga africana*. Synthesis of ibogaine is also possible in a laboratory setting (Faura and Langlois, 2019), and there is increasing interest in synthetic forms that are nonhallucinogenic and nontoxic (Cameron et al., 2021)

Although native iboga trees can be found in other parts of Central and West Africa, the plants are mostly concentrated within the country of Gabon (Faura and Langlois, 2019). Gabon's small land area of around 267,000 square kilometers is nearly 90 percent covered in tropical forests and situated on the west coast of Africa (Gardinier, van Hoogstraten, and Weinstein, undated). The majority of

[90] These local policy changes are described in detail in Chapter 1.

Gabon's population is urban with only about 10 percent of the population inhabiting the rural forests of the region where iboga grows in the wild (Gardinier, van Hoogstraten, and Weinstein, undated). The sparse population in Gabon's rural forests makes it easy for illegal logging to threaten iboga's natural habitat and for poachers to harvest iboga unsustainably for resale in the illegal market (Faura and Langlois, 2020).

Bwiti is an ancestral spiritual tradition practiced in Gabon and neighboring countries that uses the iboga plant as a link to the spirit world (Faura and Langlois, 2020). An estimated 5 percent of Gabon's 2.3 million people practice Bwiti and the use of iboga is considered a traditional medicine, which is often combined with Western medicine in Gabon to heal nonphysical ailments, such as mental health issues or substance use issues (Nuwer, 2023; Faura and Langlois, 2020). Within the Bwiti practice, iboga is used for spiritual growth in addition to healing and provides an opportunity for practitioners to become "better than well" (Faura and Langlois, 2020). Within Bwiti, iboga is primarily consumed in a communal, ceremonial setting (Bekale and Alagidede, 2021). Initiation is an important aspect of Bwiti ceremonies; however, ceremonies may also be held for other purposes, such as the commemoration of life events or to pray for blessings (Bekale and Alagidede, 2021). Bwiti ceremonies use the consumption of iboga as just one key to accessing spiritual insight; sacred music, dance, chanting, ritual garments, and the location of the ceremony all play a role (Bekale and Alagidede, 2021).

Iboga has a powerful effect when consumed in large doses, and ceremonial consumption often consists of a large dose taken by a small number of participants while the rest of the initiated community consumes small doses to stay awake and present (Nyongo-Ndoua, Didier, and Vaghar, 2018). Initiation ceremonies commonly last three days and can extend up to five days with new initiates under the influence of iboga for most of the ceremony (Nyongo-Ndoua, Didier, and Vaghar, 2018; Bekale and Alagidede, 2021). New initiates to Bwiti undergo a long period of preparation that includes refraining from ingesting other substances that may interact negatively with iboga, such as alcohol and certain nuts, and those with underlying physical or mental conditions are generally not allowed to consume iboga (Bekale and Alagidede, 2021). The administration of iboga for new initiates is a gradual process that is closely monitored by Bwiti leaders and members of the community throughout the ceremony (Bekale and Alagidede, 2021). Bwiti initiates may also occasionally self-administer small doses of iboga outside ceremonial contexts, which is said to reduce tiredness and hunger, increase attention spans, and increase virility in men (Faura and Langlois, 2020).

Legal Status

Iboga is protected under Gabonese law and the government has been working in recent years to take the lead on creating a regulated international market for the plant (Eastman and Barsuglia, 2023). The Gabonese government declared iboga a national treasure in 2000 and ratified the Nagoya Protocol in 2011, an international agreement that details a framework for FPIC as well as access and benefit-sharing for biocultural resources, such as iboga and the traditional stewards of those resources

(Faura and Langlois, 2020).[91] In 2019, the Gabonese government took initial steps toward implementing the Nagoya Protocol by suspending the exportation of wild-harvested iboga (Faura and Langlois, 2019). Under the 2019 policy, the Ministry of Waters and Forests was granted the authority to allow cultivators to export iboga (Faura and Langlois, 2020). Blessings of the Forest, a local environmental group, has been collaborating with the Gabonese government to ensure that export permits are granted to iboga plantations that follow the requirements of the Nagoya Protocol. In 2023, the first legal exports of iboga were shipped out of the country in small quantities, setting the foundation for a regulated international market (Nuwer, 2023; "Filament Health Announces . . .," 2023). The requirements of the Nagoya Protocol as implemented for iboga in Gabon include traceability of where iboga plants were cultivated, sales to customers operating legally in their own country, and reciprocity to local communities (Faura and Langlois, 2020).

Traditional medicine, including Bwiti spiritual practices involving iboga, is not actively repressed or prohibited in Gabon (Faura and Langlois, 2019). An individual must be registered with the government as a traditional healer to harvest iboga in the wild and transport it across the country legally; however, there is no formal legislation or regulatory framework for the practice of traditional medicine (Faura and Langlois, 2020). Bwiti practitioners report that government officers often misinterpret the 2019 policy and confiscate any iboga found within the country, even if there is no suspicion of intent to export illegally (Faura and Langlois, 2020).

Supply Model

The majority of iboga consumed both inside and outside Gabon comes from wild-harvested sources in Gabonese forests, although interest in cultivation is growing as international interest in ibogaine increases (Faura and Langlois, 2019; Nuwer, 2023). Cultivation of iboga is in early stages in Gabon and has two primary pathways: community plantations and large private plantations (Faura and Langlois, 2020). The initial regulated exports of iboga in 2023 came from private plantations (Nuwer, 2023). Most rural Gabonese still harvest wild iboga for their own ceremonial use, and urban Gabonese can purchase iboga at large markets in cities (Faura and Langlois, 2020). However, the quality and availability of iboga to urban Gabonese people has been declining in recent years and prices have grown exponentially as international demand puts pressure on wild iboga sources (Faura and Langlois, 2020). Bwiti practitioners have also seen an increase in tourists seeking initiation into Bwiti, which has been welcomed by some Bwiti communities as a potential avenue for support and resources (Bekale and Alagidede, 2021).

In 2019, Faura and Langlois estimated that there were 80 to 90 international treatment centers outside Gabon offering the administration of iboga or ibogaine for substance use or mental health disorders. In a survey of these treatment centers, the majority reported *Tabernanthe iboga* as their source of ibogaine, which, at the time, could be accessed only through the unregulated market, likely from Gabonese sources (Faura and Langlois, 2019).

[91] The Nagoya Protocol has been ratified by many countries; however, the United States, Canada, and Russia are notable exceptions. The Nagoya Protocol is part of a larger legal instrument called the Convention on Biological Diversity, which the United States signed but did not ratify because of concerns over intellectual property rights of U.S. corporations, potential implementation costs, and autonomy over natural resource management (Wahal, 2022).

Additional Considerations

The consumption of iboga is considerably riskier than many other psychedelic substances, especially outside the context of traditional use (Litjens and Brunt, 2016). As described previously, the Bwiti tradition has a series of safeguards in place to screen and prepare participants before they ingest iboga (Bekale and Alagidede, 2021). As interest in iboga and ibogaine grows outside the Bwiti context in Gabon, safety issues should be considered (Rocha et al., 2023). Some safety issues may be less obvious than others. For example, iboga's natural habitat lies at sea level and the medical risks of ingesting iboga are increased at high altitudes because of the impacts of the plant on the human cardiovascular system (Eastman and Barsuglia, 2023).

Although the Gabonese government has taken initial steps to implement the Nagoya Protocol, growing international interest in iboga and ibogaine does not guarantee the traditional Bwiti stewards of the plant will benefit from commercialization (Faura and Langlois, 2020). Companies that seek patents on ibogaine do not acknowledge or compensate Bwiti communities (Nuwer, 2023). The Bwiti traditions make up an Indigenous culture that has survived colonial occupation and continues to face domestic opposition from dominant Abrahamic religions brought to Gabon by Western missionaries, especially Evangelical Christians (Bekale and Alagidade, 2021; Faura and Langlois, 2020). Although Bwiti is a recognized traditional religion in Gabon, there is a lack of institutional support and Bwiti practices are often viewed by the Gabonese government as an obstacle to the spread of Western medicine in rural areas (Faura and Langlois, 2019; Bouso and Sánchez-Avilés, 2020). In this context, and considering Gabon's history in the transatlantic slave trade, a lack of reciprocity from the Western commercialization of ibogaine for medical use is seen by those in the Gabonese iboga advocacy community as especially exploitative (Nuwer, 2023).

Ayahuasca in Peru

Background

Ayahuasca is a "decoction," or boiled herbal drink, and usually includes two primary ingredients: *Banisteriopsis caapi*, a vine growing in the Amazon jungle; and *Psychotria viridis*, a flowering shrub in the coffee family that contains DMT, the substance responsible for ayahuasca's psychedelic effects (Bouso et al., 2021). DMT can also be smoked or injected—however, when ingested, it must be combined with an monoamine oxidase inhibitor (MAOI), such as *Banisteriopsis caapi*, to prevent it from being metabolized during digestion in a way that inactivates its psychedelic effects (Bouso et al., 2021).

When smoked or injected, DMT has very fast-acting, intense, and short-lived effects lasting up to 30 minutes (Strassman and Qualls, 1994). However, when ayahuasca is ingested, the psychedelic effects begin 30 minutes to 60 minutes after consumption and can last up to six hours (Riba et al., 2001). Although DMT is similar in structure to psilocybin and psilocin, unlike other psychedelics, it is endogenously produced in many animals, including humans, with increased production observed following cardiac arrest (Dean et al., 2019). The word *ayahuasca* is a compilation of two Quechua words: *aya*, meaning "dead body," and *waskha* meaning "braided or twisted cord or wire" (ICEERS,

undated). Other names for ayahuasca include Caapi, Dápa, Mihi, Kahí, Natem, Pindé, Yajé, Daime, and Vegetal (ICEERS, undated).

In the Amazon rainforest regions of Peru, mestizo[92] and Indigenous shamans adhere to *vegetalismo*, a religious practice whereby shamans gain healing power and knowledge from plants in the region, including those used to make ayahuasca (Labate and Cavnar, 2014). Shaman-led ayahuasca ceremonies have created an increasingly popular ayahuasca tourism industry, including companies and nonprofits that advertise their services internationally and locally in Peru (Fu, Morales, and Cabada, 2021). An analysis of websites offering ayahuasca experiences to travelers showed that the large majority (77.3 percent) are offered in Peru, with most being offered by Indigenous Peoples (50.7 percent) or locals (17.3 percent) and some offered by foreigners (28 percent) (Fu, Morales, and Cabada, 2021).

Ayahuasca retreats are typically offered as a package, including food and accommodations, for an average of nine days at a cost of $163 per day (Fu, Morales, and Cabada, 2021). Most ceremonies are held in rural areas (81 percent), but some are held in urban areas (11 percent) and usually take place in a lodge or recreation center (Fu, Morales, and Cabada, 2021). Ceremony practices vary widely and are highly dependent on the shaman leading them.

Religious groups, such as Unaio do Vegetal and Santo Daime, and other individuals have also adopted ayahuasca ceremonial practices and preparations and spread them all over the world, including the United States (ICEERS, undated). Additionally, ayahuasca can also be purchased in powdered form or as a resin for independent consumption both within Peru and online for shipping to another country (Hartman, 2021).

Legal Status

The psychoactive alkaloid DMT is classified as a Schedule I controlled substance under the 1971 United Nations Convention on Psychotropic Substances (United Nations, 1971).[93] However, when Peru signed this treaty, the country specifically included a reservation for traditional use of ayahuasca by Indigenous groups (United Nations, 1971). Additionally, in 2008, the Peruvian government formally recognized ayahuasca as part of its national cultural heritage (ICEERS, undated; Peru National Institute of Culture, 2008). In this declaration, the director of the Peruvian National Institute of Culture distinguished Indigenous use from commercial or consumer use outside the context of Indigenous practices, signaling that the government primarily intends to protect traditional use.

Although the Peruvian government does not currently regulate any activities related to ayahuasca, it is unclear whether nontraditional use of ayahuasca will be regulated in the future, especially as ayahuasca tourism increases (ICEERS, undated). However, ICEERS[94] Ayahuasca Defense Fund has received reports that ayahuasca lodges in Iquitos are in the process of creating standards and best practices to ensure safety and quality of ayahuasca (ICEERS, undated). ICEERS also reports that

[92] A person of mixed race in Latin America, with a combination of European and Indigenous ancestry.

[93] It is the psychoactive compound—not the plant—that is included in Schedule I. For more, see International Narcotics Control Board (2013), United Nations, Office on Drugs and Crime (2019), and Transform Drug Policy Foundation (2023).

[94] The ICEERS is a nonprofit focused on issues related to the globalization of ayahuasca and other ethnobotanicals.

many institutions of shamans and other purveyors of ayahuasca have formed with the goal of establishing similar widespread standards, but thus far have been unsuccessful (ICEERS, undated).

Supply Model

Although *Psychotria viridis* grows natively in many areas of the Amazon rainforest, consumption of ayahuasca is most common in Peru due to ayahuasca tourism (Fu, Morales, and Cabada, 2021). It has been reported that Peru is also the largest source of ayahuasca sent to other countries in various forms, including plants, resins, and powders, which facilitate easier preparation (Fu, Morales, and Cabada, 2021); however, we are unaware of official statistics on this. As a result, various groups have expressed concerns about conserving Peru's limited supply of ayahuasca plants. For instance, groups like the Rainforest Healing Center have emerged that offer ayahuasca retreats while also focusing on preserving *Banisteriopsis caapi*, which takes three years to fully mature before harvesting (Rainforest Healing Center, undated).

Peru is not only exporting ayahuasca, but also knowledge of Indigenous rituals and processes associated with preparation and consumption (Gearin, 2022). In some cases, non-Peruvians have come to Peru to train with a local shaman to administer ayahuasca within Peru or in other countries (Gearin, 2022). This sometimes leads to new rituals or variations on traditional practices forming, including new religions focused on ayahuasca consumption outside Peru (Gearin, 2022).[95]

Additional Considerations

Despite the potential positive impact of increased tourism on Peru's economy, local attitudes toward ayahuasca use vary. Some locals value the perceived healing aspect of ayahuasca for humanity as a whole, including tourists, while some are concerned about harms from misuse or appropriation of Indigenous traditions (Fraser, 2017). Some Indigenous Peoples think shamans offering ayahuasca ceremonies to tourists and mentoring foreigners in its practices for monetary gain are acting unethically (Fraser, 2017). Additionally, both locals and non-Peruvians have expressed concerns about "pseudo shamans" who are not just capitalizing on the commercialization of ayahuasca but may harm tourists through unsafe practices, economic exploitation, or sexual assault (Fraser, 2017).

There are also concerns that mentoring non-Indigenous Peoples in ayahuasca practices minimizes the ability of shamans to train their own community members in these practices (Gearin, 2022). However, there is also recognition of the primary importance of survival of these Indigenous communities overall, which is advanced by monetizing ayahuasca ceremonies and creating jobs in rural areas high in unemployment (Gearin, 2022).

[95] A search of ayahuasca webpages offering retreats and other services showed that, as of 2020, only 1.5 percent of ayahuasca ceremonies are offered in the United States (Fu, Morales, and Cabada, 2021). The number may have changed over the past four years.

Appendix B

State and Local Policy Reforms Related to Psychedelics in the United States

Table B.1. displays state and local policy changes that have been enacted in the United States since 2019.

Table B.1. State and Local Policy Reforms Related to Psychedelics in the United States

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Cities and counties					
Denver, Colo.	May 2019	Deprioritization; prohibits funds from being used for some law enforcement actions	Passed by popular vote	Deprioritizes enforcement of laws on personal use and possession by adults (21 and older); prohibits the city from spending resources to impose criminal penalties for the personal use and possession of psilocybin mushrooms by adults (21 and older)	Psilocybin mushrooms
Oakland, Calif.	June 2019	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on planting, cultivation, purchasing, transporting, distributing, engaging in practices, and possession by adults; prohibits the use of city funds or resources to assist in the enforcement of laws imposing criminal penalties for the use and possession of entheogenic plants by adults	Entheogenic plants or plant compounds on the Federal Controlled Substances Schedule I list
Ann Arbor, Mich.	September 2020	Deprioritization; prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, or possessing; prohibits commercial sales or manufacturing; prohibits the use of city funds and resources in any investigation, detention, arrest, or prosecution arising out of alleged violations of state and federal law	Entheogenic plants or plant compounds on the federal Schedule I list
District of Columbia	November 2020	Deprioritization	Passed by popular vote	Deprioritizes enforcement of laws on noncommercial planting, cultivating, purchasing, transporting, distributing,	Entheogenic plants and fungi with naturally occurring psychedelic substances,

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
				possessing or engaging in practices by adults (18 and older)	including ibogaine, DMT, mescaline, psilocybin or psilocyn
Somerville, Mass.	January 2021	Deprioritization; prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing; prohibits commercial sales; prohibits the use of city funds and resources to assist the enforcement of laws imposing criminalities for use and possession	Entheogenic plants; defined as the full spectrum of psychedelic plants, fungi, and natural materials containing indole amines, tryptamines, phenethylamines, including psilocybin mushrooms, ayahuasca, cacti, and iboga
Washtenaw County, Mich.	January 2021	Deprioritization	Prosecutor's office policy (following Ann Arbor's policy)	Deprioritizes enforcement of laws on use, possession, cultivation, purchasing, transporting, and small-scale distributing by adults; applications for expungement; prohibits large-scale, for-profit distribution, sales to children, operating vehicles under the influence	Entheogenic plants or plant compounds on the federal Schedule I list; defined as the full spectrum of plants, fungi, and natural materials and/or their extracted compounds, limited to those containing the following types of compounds: indole amines, tryptamines, and phenethylamines
Cambridge, Mass.	February 2021	Deprioritization; Prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing; prohibits commercial sales or manufacturing, possessing, or distributing on school grounds, driving under the influence, or public disturbance; prohibits the use of city funds and resources to assist in the enforcement of laws imposing criminal penalties for use and possession	Entheogenic plants and plant-based compounds on the federal Schedule I list and under state law

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Northampton, Mass.	March 2021	Deprioritization; prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing; prohibits commercial sales or manufacturing, possessing or distributing on school grounds, driving under the influence, or public disturbance; prohibits the use of city funds and resources to assist in the enforcement of laws imposing criminal penalties for use and possession	Entheogenic plants; defined as the full spectrum of psychedelic plants, fungi, and natural materials containing indole amines, tryptamines, phenethylamines, including psilocybin mushrooms, ayahuasca, cacti, and iboga
Santa Cruz, Calif.	September 2021	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on cultivation, use, or possession by adults (21 and older) for personal use	Entheogenic plants and fungi on the federal Schedule I list, except peyote and entheogenic cacti that contain phenethylamine compounds such as mescaline
Grand Rapids, Mich.	September 2021	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on possession and use; prohibits any criminal activity, including commercial sales or manufacturing, possessing or distributing in schools, driving under the influence, or public disturbance	Entheogenic plants and fungi; defined as the full spectrum of plants, fungi, and natural materials that can benefit psychological and physical wellness, can inspire personal and spiritual well-being, and can reestablish humans' unalienable and direct relationship to nature
Easthampton, Mass.	October 2021	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distribution by caregivers, engaging in practices with, and/or possessing; prohibits commercial sale, cultivation for large-scale distribution, possessing or distributing on school grounds, use or distribution to	Entheogenic plants and fungi, except Lophophora (peyote cactus) and animal-derived controlled substances

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
				individuals younger than 21, driving under the influence, or public disturbance	
Detroit, Mich.	October 2021	Deprioritization	Passed by popular vote	Deprioritizes enforcement of laws on personal possession and therapeutic use by adults	Entheogenic plants; defined as the full spectrum of psychedelic plants, fungi, and natural materials containing indole amines, tryptamines, phenethylamines
Seattle, Wash.	October 2021	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on entheogen-related activities, including possession, cultivation for use in religious, spiritual, healing, or personal growth practices and sharing with co-practitioners without financial or other consideration	Entheogens; encompasses any living, fresh, dried, or processed plant or fungal material, including teas or powders, that may contain currently scheduled or analog psychoactive indolamines, tryptamines, or phenethylamines, including psilocybin mushrooms, ayahuasca tea, mescaline, and iboga, except peyote cactus and iboga must be sustainably produced
Arcata, Calif.	October 2021	Deprioritization	City council ordinance	Deprioritizes enforcement of laws concerning personal use, cultivation, possession, purchasing, transporting, and engaging in practices with entheogens for adults (21 or older); prohibits commercial sales and manufacturing, possessing or distributing near schools, driving under the influence, or causing a public disturbance or jeopardizing public	Entheogenic plants and fungi on the federal Schedule I list

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
				safety resulting from influence of consumption	
Port Townsend, Wash.	December 2021	Deprioritization; prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on adults (18 or older) engaging in entheogen-related activities, including the cultivation for use in religious, spiritual, healing, or personal growth when done in a nonpublic place; prohibits the city and all city departments from expending city funds or resources to directly assist in the enforcement of laws imposing criminal penalties, including investigation, detection, arrest, and prosecution, for the planting, cultivation, gathering, transportation, distribution, possession, or usage	Entheogens; encompasses any living, fresh, dried, or processed plant or fungal material, including teas or powders, that may contain currently scheduled or analog psychoactive indolamines, tryptamines, or phenethylamines, including psilocybin mushrooms, ayahuasca tea, mescaline, and iboga
Hazel Park, Mich.	March 2022	Deprioritization; prohibits funds from being used for some law enforcement actions	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, or possessing; prohibits possessing or distributing in schools, consumption or usage by minors, driving under the influence of these materials, public disturbance, or commercial sales or manufacturing; prohibits the use of city funds or resources to investigate, detain, arrest, or prosecute individuals found planting, cultivating, purchasing, transporting, distributing, and possessing	Entheogenic plants; defined as the full spectrum of plants, fungi, and natural materials and/or their extracted compounds, limited to those containing the following types of compounds: indole amines, tryptamines, and phenethylamines

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Amherst, Mass.	July 2022	Deprioritization	Town council resolution	Deprioritizes enforcement of laws on possession and use; prohibits commercial sale, distribution (especially on school grounds), driving under the influence, and public disturbance	Entheogenic plants, including psilocybin mushrooms, ayahuasca, cacti, and iboga
San Francisco, Calif.	September 2022	Deprioritization	Board of Supervisors' measure	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing	Entheogenic plants and plant-based compounds on the federal Schedule I list
Ferndale, Mich.	February 2023	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, or possessing; prohibits possessing or distributing these materials in schools, consumption or usage by minors, driving under the influence of these materials, public disturbance, or commercial sales or manufacturing	Entheogenic plants
Jefferson County, Wash.	May 2023	Deprioritization	County commissioners' resolution (following Port Townsend policy)	Deprioritizes enforcement of laws on activities by adults (including planting, cultivation, gathering, or sharing of entheogens for use in religious, spiritual, healing, or personal growth practices when ingested out of view of the public, transporting, distributing, or possessing when no dangerous activity is present); prohibits commercial sales, possessing or distributing in schools, driving under the influence, or public disturbance	Entheogens; defined as the full spectrum of psychedelic plants, fungi, and natural materials (including living, fresh, dried, or processed plant or fungal material, including teas or powders) containing indole amines, tryptamines, or phenethylamines, including psilocybin mushrooms, ayahuasca, cacti containing mescaline, and iboga
Salem, Mass.	June 2023	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on psychedelic-assisted therapeutic	Psilocybin-containing fungi

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
				services, possession, sharing or cultivation, purchasing, transporting, and the use or possession without the intent to distribute; prohibits commercial sales or manufacturing, possessing or distributing on school grounds, driving under the influence, or public disturbance	
Berkeley, Calif.	July 2023	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on possession, cultivation, processing, and preparation for personal use; prohibits giving away, sharing, distributing, transferring, dispensing, or administering to another individual, organization, or group	Psychedelic-drug-containing plants and fungi, except mescaline (biosynthesized or in peyote cactus)
Minneapolis, Minn.	July 2023	Deprioritization; prohibits funds from being used for some law enforcement actions	Mayor's executive order	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, or possessing; prohibits commercial sales or manufacturing, possessing or distributing in schools, driving, operating, or being in physical control of a motor vehicle; or possessing a weapon while under the influence, or the commission of any public disturbance; prohibits city resources from knowingly being used in any investigation, detention, or arrest arising out of alleged violations of state or federal law for engaging in planting, cultivating, purchasing, transporting, distributing, and possessing	Entheogenic plants; defined as the full spectrum of plants, fungi, and natural materials and/or their extracted compounds, limited to those containing the following types of compounds: indole amines, tryptamines, and phenethylamines, including psilocybin mushrooms, ayahuasca tea, mescaline, and iboga (with the exception of peyote)

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Portland, Maine	October 2023	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on adults (21 and older) personal use, sharing without compensation, possession and cultivation for personal use; prohibits selling, distributing, administering to another individual, distributing on school grounds, operating under the influence	Psychedelic plants and fungi, especially those containing psilocybin, psilocyn, ibogaine, mescaline (with the exception of peyote) and DMT
Eureka, Calif.	October 2023	Deprioritization	City council ordinance	Deprioritizes enforcement of laws on planting, cultivating, purchasing, transporting, distributing, engaging in practices with, or possessing; prohibits activities by minors, commercial sales, distribution in schools, driving under the influence, public disturbance, jeopardizing public safety	Entheogenic plants and fungi
Provincetown, Mass.	December 2023	Deprioritization	Select Board resolution	Deprioritizes enforcement of laws on adults planting, cultivating, transporting, distributing, engaging in practices with, and/or possessing; prohibits commercial sale, distribution near schools, driving under the influence, public disturbance	Psychedelic plants and fungi, such as psilocybin mushrooms, ayahuasca, ibogaine, and mescaline-containing cacti
States					
Oregon	January 2021	Legalization of supervised consumption	Ballot initiative	Created a license and regulatory framework for production, transportation, delivery, sale, and purchase of psilocybin, and facilitation of psilocybin services, for adults (21 and older); created a Psilocybin Advisory Board	Psilocybin

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Oregon	February 2021 (significantly amended in April 2024)	Decriminalization	Ballot initiative	Reclassified personal possession of controlled substances as a civil offense or misdemeanor, based on the quantity; incentivized and funded treatment services; criminal drug activities and possession of larger amounts are still criminal offenses	Most controlled substances, including psychedelics
New Jersey	February 2021	Defelonization	State legislation	Changed possession of 1 ounce or less of psilocybin to a disorderly offense from a third-degree indictable offense (i.e., felony)	Psilocybin
Connecticut	June 2021	Research	Included in a bill revising public health statutes	Assembled a working group to study the health benefits of psilocybin	Psilocybin
Texas	June 2021	Research	State legislation	Initiated a study of alternative therapies to treat PTSD in veterans	MDMA, psilocybin, and ketamine
Utah	March 2022	Research	State legislation	Established a Mental Illness Psychotherapy Drug Task Force to study psychotherapy drugs not currently legal	Controlled substances not currently available for legal use that may be used to treat mental illness
Washington	March 2022	Research	Included in state budget bill	Allocated funds to establish a stakeholder group to generate a report on psilocybin services and opportunities	Psilocybin
Connecticut	May 2022	Research	Included in state budget bill	Allocated $1 million in funding over two years and set guidelines for a psychedelic assisted therapy pilot program for veterans, first responders, and direct health care workers to be administered by an in-state medical school; established a Psychedelic Treatment Advisory Board	Psilocybin, MDMA

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
Maryland	May 2022	Research	State legislation	Established a fund to study alternative therapies to treat PTSD and traumatic brain injuries in veterans	Psychedelics including MDMA, psilocybin, ketamine
Colorado	June 2022	Legalization of supervised consumption (trigger law dependent on federal re-scheduling)	State legislation	If MDMA as part of a prescription drug is moved from the federal Schedule I list, then prescribing, dispensing, transporting, possessing, and using that prescription drug would be legal in Colorado	MDMA
Colorado	November 2022	Legalization of cultivation and sharing Legalization of supervised consumption	Ballot initiative	Legalized all five substances for possession, growing, sharing, and use but not retail sale for adults ages 21 or older (the grow-and-give model); established supervised use of psilocybin mushrooms at licensed facilities by adults (21 or older) with the possibility of adding other substances in the future	Psilocybin, psilocin, DMT, ibogaine, and mescaline (excluding peyote)
Arizona	January 2023	Research	Included in state budget bill	Established an advisory council and allocated funds for competitive research grants for clinical trials using psilocybin mushrooms with veterans, first responders, frontline health care workers, and people from underserved communities as research subjects to treat a wide variety of physical and mental health conditions	Whole mushroom psilocybin
Washington	January 2023	Research	State legislation	Established a psilocybin treatment pilot program with populations including first responders and veterans; established a psilocybin advisory board and task force to develop guidance for a	Psilocybin

Jurisdiction	Date Enacted	Policy Change	Legal Mechanism	Activity	Substances
				regulatory framework for therapeutic use	
Minnesota	February 2023	Research	Included in state health budget bill	Established a Psychedelic Medicine Task Force to report on the use of psychedelic medicines to treat mental health conditions	MDMA, psilocybin, and LSD
Nevada	June 2023	Research	State legislation	Established a Psychedelic Medicines Working Group to develop a plan for therapeutic use	Entheogens, including psilocybin and psilocin

SOURCE: The authors compiled a database of policy changes from publicly available information on state and local government websites. Most policy changes were initially identified from legalization and decriminalization trackers (Psychedelic Alpha, undated-a; Psychedelic Alpha, undated-b) and ongoing reporting by Marijuana Moment (undated).

[a] The ballot initiative reads (City of Detroit, 2021) : “Shall the voters of the City of Detroit adopt an ordinance to the 2019 Detroit City Code that would decriminalize to the fullest extent permitted under Michigan law the personal possession and therapeutic use of Entheogenic Plants by adults and make the personal possession and therapeutic use of Entheogenic Plants by adults the city's lowest law-enforcement priority?" But in its endorsement of the initiative, the *Detroit Free Press* noted: “Approval of Prop E would not legalize use of such plants, but simply direct the Detroit Police Department to cease directing resources to investigating and prosecuting Detroiters for the use of such substances” ("Endorsement: Vote Yes on Props R and E . . .", 2021). Because the initiative does not specifically prohibit funds from being used to investigate and prosecute these cases, we do not classify this as a change that "[p]rohibits funds from being used to enforce some psychedelic laws" (as seen in Table 1.2).

Appendix C

Summary of Recent Reviews of Clinical Trials on Psychedelics

To identify the recent systematic and meta-reviews of clinical trials for psychedelics discussed in this appendix, we conducted a search using RAND's custom Primo search tool for reviews published since 2022. This effort involved inputting relevant keywords to identify such reviews into the Primo, which provides a streamlined service to search and access online scholarly materials, including a significant number of journals and knowledge databases, such as PubMed and EBSCO. Our Primo search identified 116 records; 54 of these reviews were selected for inclusion based on relevance to the safety and efficacy of psychedelics. These 54 records were then categorized by members of our team by the psychedelic substances and the conditions they reviewed; a tally of the categorizations is available in Table C.1. Note that the categories are not mutually exclusive, so totals are not sums for each row or column.

Table C.1. Categorizations of Reviews of Clinical Trials on Psychedelics

	Depression	Anxiety/PTSD	SUD	Palliative[a]	Cognition	Spiritual	Sex	Totals
Psilocybin	33	25	18	16	7	4	0	46 of 54
LSD	15	15	12	10	8	3	0	25 of 54
DMT[b]	16	13	12	8	6	4	0	23 of 54
MDMA	8	9	6	6	3	1	2	15 of 54
Mescaline	3	3	4	3	3	2	0	8 of 54
5-MeO-DMT	0	0	0	0	1	2	0	2 of 54
Ibogaine	1	0	0	0	1	0	0	2 of 54
Totals	35 of 54	28 of 54	21 of 54	16 of 54	9 of 54	5 of 54	2 of 54	

NOTE: SUD = substance use disorder.
[a] The "Palliative" category also includes the use of psychedelics in general end-of-life care. Some reviews assessing end-of-life care also combined studies that looked at anxiety or depression related to end-of-life care with other studies of more-generalized depression and anxiety. For these cases, all the relevant condition columns are counted.
[b] DMT in these reviews applies most commonly to ayahuasca, but in some cases may also refer to smoked synthetic DMT.

Appendix D

How Many Arrests Are Made for Psychedelics in the United States?

Official national figures for the number of arrests involving psychedelics do not exist. Our rough estimate is that it was likely in the low double-digit thousands for 2022; probably accounting for no more than 2 percent of drug arrests made that year.

Since 2021, the Federal Bureau of Investigation (FBI) has transitioned to a new approach for estimating national crime and arrest data that does not include specific arrests for psychedelics on its "Crime Data Explorer" webpage. But even before the change, the previous version of the national arrest statistics (the annual *Crime in the U.S.* report) did not list arrests for specific psychedelics (which likely fall in the FBI's "Other narcotics" or "Dangerous drugs" categories) (FBI, undated). Another limitation of the "old approach" (i.e., the Summary Reporting System) was that the arrest data followed the "hierarchy rule" where only the most serious charge gets reported. Thus, if someone was arrested for robbery and possessing a drug, only the robbery charge would get reported in the national statistics.

The FBI's new approach relies on data from the National Incident-Based Reporting System (NIBRS), which includes detailed information on crime incidents recorded by state, local, and some federal law enforcement departments. A major advantage of this new system is that it records multiple arrest offenses per incident (in the above example, the robbery and drug possession offenses would be recorded). At the end of 2022, NIBRS covered "13,293 law enforcement agencies whose jurisdictions covered more than 256 million United States inhabitants" (FBI, 2023); or about 77 percent of the U.S. population.

Although the summary data provided by the FBI do not include information about arrests for psychedelics, analysis of the NIBRS microdata provides more insights (openICPSR, 2024).[96] For each incident, law enforcement officials can report up to three specific drugs believed to be involved in the incident (alcohol is a separate category). There are 16 suspected drug types, with separate "LSD" and "Other Hallucinogens" categories, that include "BMDA or White Acid; DMT; MDA; MDMA; Mescaline or Peyote; Psilocybin; STP; Spice; Dronabinol or Marinol; etc.," (FBI, 2021). Therefore, the "Other" category is going to overestimate for psychedelics because we do not consider synthetic cannabis to be a psychedelic (e.g., Spice, a synthetic cannabinoid). There is a separate category for PCP that we also do not consider a psychedelic for this analysis.

[96] The NIBRS data made publicly available by ICPSR are extracts of what gets reported to the FBI. Although an extract includes up to three offenses per incident, the full file provided by law enforcement agencies report up to ten offenses; however, this does not appear to be a noteworthy concern for drug arrests (Lantz and Wenger, 2019).

Of the 11,207,634 observations included in 2022 incident-level file, 1,149,684 (10.3 percent) were classified as involving a drug offense ("Drug/Narcotic Violations" or "Drug Equipment Violations" categories).[97] Offenses in the "Drug/Narcotic Violations" category include information about the specific drug(s) involved, but offenses in the "Drug Equipment Violations" category do not. We have 990,803 incidents involving the "Drug/Narcotic Violations" category, of which 10 percent were missing data about the specific drug(s) seized (leaving a total of 891,483).[98] Of these 891,483 incidents involving a drug offense in which a specific drug was identified, 1.6 percent (14,202) listed either "LSD" or "Other Hallucinogens" as one of the substances involved.[99] Remember, the "Other Hallucinogens" category includes some substances we do not consider psychedelics.

Not all incidents in NIBRS lead to an arrest. In the case of incidents involving drugs seized, it could be the case that police found drugs but no one was around. Or maybe for intelligence reasons the police seized drugs but chose to not make an arrest. Our calculations suggest that, for these incidents where LSD and/or other hallucinogens were seized, 76.5 percent were linked to an arrest, which could include being taken into custody or being given a citation.[100]

NIBRS does not include most arrests made by federal agencies; however, it is well known that federal arrests account for a very small share of total drug arrests in the United States. This is because federal officials tend to focus on traffickers further up the supply chain. The DEA is the lead federal body addressing crime related to illegal drugs. In fiscal year 2021, the DEA made 28,224 arrests, of which 13 percent (3,625) were in the "Other" category that includes several substances including "non-opioid pharmaceutical controlled substances, other depressants, sedatives, ephedrine, pseudoephedrine, hallucinogens, synthetic cannabinoids, other steroids, equipment to manufacture controlled substances, and drug-use paraphernalia" (Motivans, 2024). For fiscal year 2022, U.S. Customs and Border Protection reported that, of its 62,645 seizure events, 2 percent (1,223) involved LSD (U.S. Customs and Border Protection, 2024); the "Other" category that could contain other psychedelics is extremely broad.[101]

Thus, it is virtually impossible to estimate the precise number of arrests involving psychedelics, but one can get a sense of the order of magnitude with simple back of the envelop calculation. If we take that 14,202 from the 2022 NIBRS and assume those drug offenses that do not specify a substance follow a similar distribution to those that do, this would increase the total to 18,333

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[97] That is, V20061, V20062, or V20063 = (351 or 352). These variables refer to the three most serious offense codes associated with an incident. Note that the "Drug Equipment Violations" category do include information on drug type.

[98] There are nine separate variables per incident for suspected drug type (V30121, V30122, V30123, V30161, V30162, V30163, V30201, V30202, V30203). For some of these variables, the drug type is unknown or missing. Of the 1,149,684 drug offenses, we looped through these nine variables and found that 78 percent (891,483) had at least one specific drug noted.

[99] There are two main sources for downloading NIBRS data: those cleaned and processed by the National Archive of Criminal Justice Data (NACJD) and those cleaned and processed by Jacob Kaplan (openICPSR, 2024). Their approaches are not identical, and there could be differences depending on when the data were cleaned (the raw data are updated over time). We report data from NACJD in this appendix but also conducted similar runs with the data cleaned by Kaplan; the final numbers were very similar (14,202 vs. 14,254).

[100] According to calculations using the data processed by Kaplan, we found that of the 14,254 incidents, 76.5 percent of them had a matching incident identification in the arrest segment.

[101] According to data from psilocybin mushroom seizures reported to High-Intensity Drug Trafficking Areas in the United States between 2017 and 2022, Palamar et al. (2024) notes, "There were 402 seizures in 2017 compared to 1396 in 2022. . . . [and] In terms of weight, 226.0 kg was seized in 2017 vs. 844.0 kg in 2022."

incidents (*14,202 + (1,149,684 – 891,483)*1.6%*). If we then assume for the moment that the drug incidents covered by the NIBRS agencies covering 77 percent of the population are representative of the other 23 percent of the U.S. population, the total number of incidents for psychedelics would increase to 23,809 (18,333/77 percent). To convert this to arrests, we would want to multiply by the aforementioned 76.5 percent, which puts the figure at 18,214 arrests. Add in a few thousand federal arrests, this would put the total still below 30,000. These are big assumptions, and they may be incorrect, but it seems reasonable to assert that the total number of arrests for psychedelics in 2022 was likely in the low double-digit thousands.

Abbreviations

AIRFAA	American Indian Religious Freedom Act Amendments
APPA	American Psychedelic Practitioners Association
CSA	Controlled Substances Act
DEA	U.S. Drug Enforcement Administration
DMT	N,N-Dimethyltryptamine
DOJ	U.S. Department of Justice
DSM-V	*Diagnostic and Statistical Manual of Mental Disorders*, 5th edition
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FBI	Federal Bureau of Investigation
FDA	U.S. Food and Drug Administration
FPIC	Free, Prior and Informed Consent
GAO	U.S. Government Accountability Office
HHS	U.S. Department of Health and Human Services
ICEERS	International Center for Ethnobotanical Education, Research, and Service
IPCI	Indigenous Peyote Conservation Initiative
IRS	Internal Revenue Service
LSD	lysergic acid diethylamide
MAPS	Multidisciplinary Association for Psychedelic Studies
MDMA	3,4-Methylenedioxymethamphetamine
NAC	Native American Church
NIBRS	National Incident-Based Reporting System
NSDUH	National Survey on Drug Use and Health
OHA	Oregon Health Authority
ONDCP	Office of National Drug Control Policy
OPS	Oregon Psilocybin Services
OPSA	Oregon Psilocybin Services Act
PCP	phencyclidine
PSFC	Psychedelic Science Funders Collaborative
PTSD	posttraumatic stress disorder
RCT	randomized controlled trial
RFRA	Religious Freedom Restoration Act
RPS	RAND Psychedelics Survey
SAMHSA	U.S. Substance Abuse and Mental Health Services Administration
VA	U.S. Department of Veterans Affairs

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