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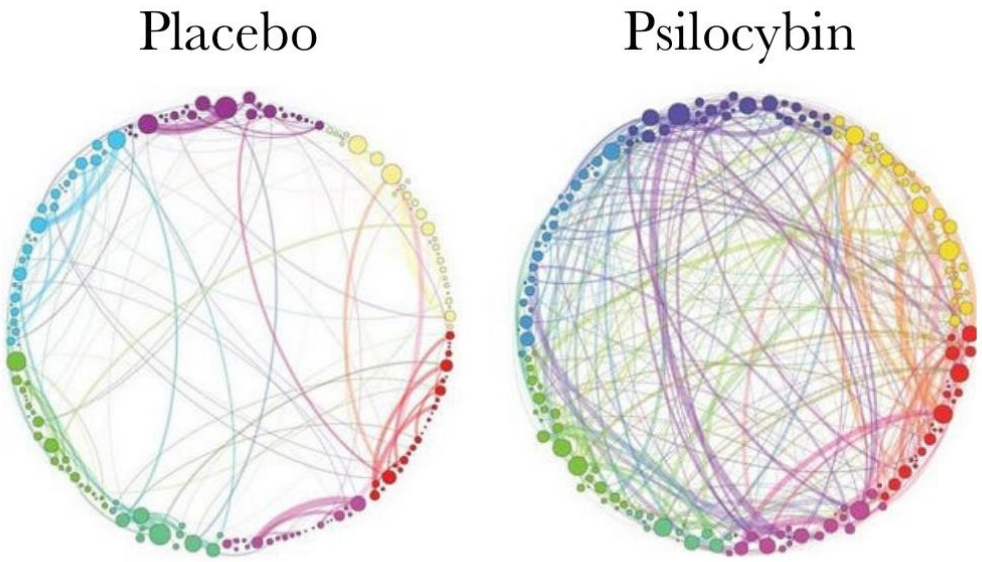
NOT GROOVY MAN: PSILOCYBIN'S LONG AND COMPLICATED HISTORY WITH THE LAW, AND ITS POTENTIAL TO TREAT THE GROWING MENTAL HEALTH CRISIS IN AMERICA

Zachary LeCompte[*]



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I. INTRODUCTION

Today, the United States ("U.S.") faces a growing mental health crisis, reaching all demographics and causing widescale consequences. Every year, 1-in-5 Americans suffer from some form of mental illness.[1] Suicide rates have increased 35% over the past two decades,[2] and serious mental illness[3] is estimated to cause $193.2 billion in lost earnings[4] across the U.S. economy each year. Current treatment options are moderately effective but fall short of addressing the growing prevalence of mental illness in the U.S. However, a potential treatment option shows promise where traditional methods fail. The psychedelic compound, psilocybin, has been found to provide immediate and long-lasting benefits as a treatment for depression—with minimal side effects and low potential for dependence or abuse.[5]

Unfortunately, psilocybin—and psychedelics in general—have a long and complicated history with the law. In the U.S., psychedelics once showed great potential as a treatment for mental illness, producing a plethora of research in the 1960s[6] but soon found themselves in the government's crosshairs because of their growing role in the counterculture movement. Ultimately, psychedelics produced moral panic because of their close association with the counterculture movement and Vietnam War opposition, resulting in several legislative Acts and the creation of new government agencies to regulate psychedelics.[7] Ultimately, psychedelics found themselves banned from all corners of society, including medical research.

Several decades later, psilocybin managed to work its way back into the field of medicine, once again showing great potential in medical research. Today, both the public at large and governmental agencies tasked with regulating psilocybin support exploring the use of psilocybin to treat some forms of mental illness and thereby address the U.S.'s growing mental health crisis.[8] This Article will examine psilocybin's potential use in treating mental illness and the

1. *See* DHHS, KEY SUBSTANCE USE, *infra* note 9.

2. *See* NIMH, *Suicide*, *infra* note 35.

3. *See infra* Part II-A(ii) for the definition of "serious mental illness."

4. *See* Ronald C. Kessler et al., *infra* note 51.

5. *See* Hartej Gill et al., *infra* note 63.

6. Thousands of studies were performed on over 40,000 patients. *See* David E. Nichols, *infra* note 113.

7. *See infra*, Part III-A(ii)-(iv) for discussion of psychedelics association with the counterculture movement and the resulting regulations and restrictions placed on the substances.

8. *See infra*, Part III-A(v)-(vii) for discussion of the growing support for psychedelics and the associated legal and governmental developments.

government's potential role in regulating psilocybin and/or other psychedelics once they are ready for clinical implementation.

II. FACTUAL BACKGROUND

A. Mental Illness In The U.S.

Mental Illness is a common and pervasive issue in the U.S.[9] Data from a 2020 survey compiled by the National Institute of Mental Health ("NIMH") provided estimates regarding the prevalence of mental illnesses that are currently diagnosable or diagnosable within the past year.[10] Developmental and substance abuse disorders were excluded, and the results were sorted into two broad categories: Any Mental Illness ("AMI") and Serious Mental Illness ("SMI"). AMI refers to all recognized mental, behavioral, or emotional disorders and can vary in impact ranging from zero to mild to severe impairment.[11] SMI is more narrowly defined as mental, behavioral, or emotional disorders resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.[12] Examples of SMI include Major Depressive Disorder, Bi-Polar Disorder, and Schizophrenia.

1. Any Mental Illness

According to the NIMH study, around 52.9 million adults in the U.S. were living with some form of mental illness in 2020.[13] That equates to 21.0% of the adult population, or approximately 1-in-5 U.S. adults.[14] As Figure 1 shows, approximately 1-in-4 women and 1-in-6 men reported living with AMIs in 2020.[15] Additionally, AMIs impacted various racial groups, spanning from 13.9% of Asians to 22.6% of Whites—all the way to an astonishing 35.8% of respondents who reported two or more races. Lastly, while the reported prevalence of

9. *See* U.S. DEP'T OF HEALTH AND HUMAN SERV., SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2020 NATIONAL SURVEY ON DRUG USE AND HEALTH (2021) (providing statistics for adults over 18 with any or serious mental illness) [hereinafter DHHS, KEY SUBSTANCE USE].

10. *Id.* at 1-5.

11. Nat'l Inst. of Mental Health, *Mental Health Information—Statistics: Mental Illness*, https://www.nimh.nih.gov/health/statistics/mental-illness.shtml [https://perma.cc/6RUS-UZ7Q] [hereinafter NIMH, *Mental Illness*].

12. *Id.*

13. DHHS, KEY SUBSTANCE USE, *supra* note 9, at 32.

14. *Id.*

15. NIMH, *Mental Illness*, *supra* note 11.

AMIs decreased by age group, respondents who reported living with AMIs still ranged between 30.6% and 14.5% depending on the age bracket.[16]

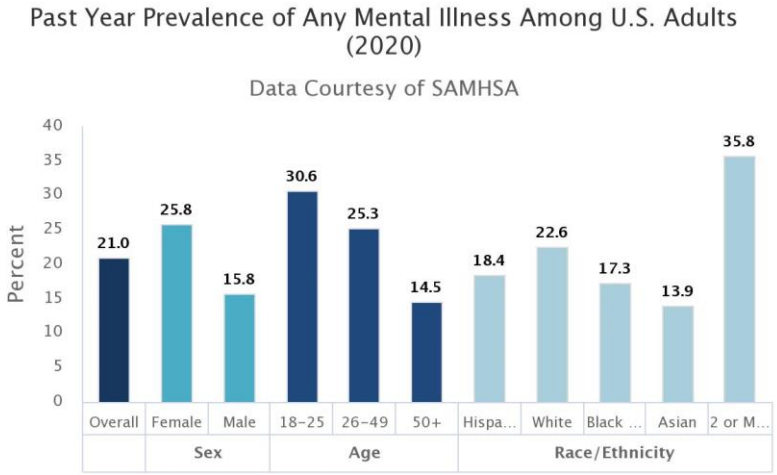

Figure 1

2. Serious Mental Illness

According to the NIMH's 2020 data, approximately 14.2 million people aged 18 or older were dealing with SMIs, representing 5.6% of all U.S. adults.[17] Similar to reported AMIs, SMIs appeared widely across different ages, sexes, and races. Figure 2 shows that as among cohorts, SMIs were more likely in females (7.0%), those between ages 18-25 (9.7%), and those reporting two or more races (9.9%).[18]

16. DHHS, KEY SUBSTANCE USE, *supra* note 9, at 32.
17. *Id.*
18. NIMH, *Mental Illness*, *supra* note 11.

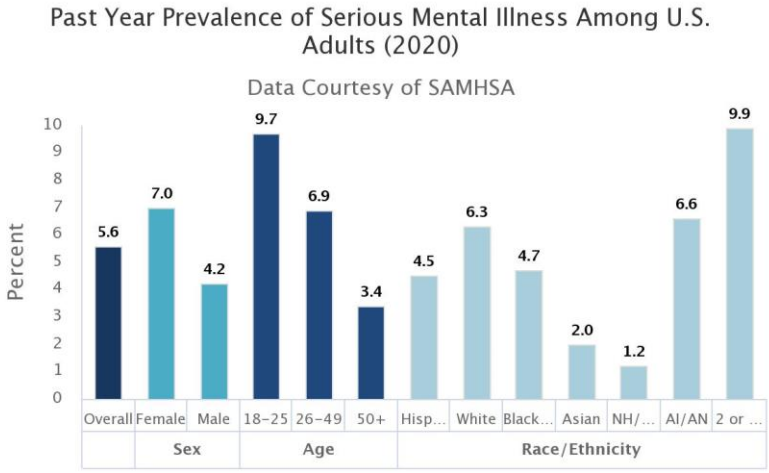

Figure 2

3. Depression and Anxiety

Two of the most common mental illnesses that impact Americans are Depression and Anxiety. Depression comes in various forms, varying slightly and ranging from mild to severe symptoms.[19] Depression causes symptoms that affect how you feel, think, and handle daily activities, such as sleeping, eating, or working.[20] While the root cause of Depression is unknown, research suggests that a combination of genetic, biological, environmental, and psychological factors play a role.[21]

According to the 2020 NIMH data, an estimated 21.0 million U.S. adults had at least one major depressive episode.[22] That represented 8.4% of all U.S. adults.[23] Much like the trends for AMI and SMI, major depression was more prevalent in women than men (10.5% compared to 6.2%) and individuals between the ages of 18-25 (17.0%).[24] Figure

19. Nat'l Inst. of Mental Health, *Mental Health Information—Health Topics: Depression*, https://www.nimh.nih.gov/health/topics/depression/index.shtml (last updated February 2018).

20. *Id*.

21. *Id.*

22. DHHS, KEY SUBSTANCE USE, *supra* note 9, at 31.

23. *Id*.

24. Nat'l Inst. of Mental Health, *Mental Health Information—Statistics: Major Depression*, https://www.nimh.nih.gov/health/statistics/major-depression.shtml [https://perma.cc/8MJV-A6FD] [hereinafter NIMH, *Major Depression*].

3 shows the findings across all groups surveyed.[25] Further, of the 21 million adults who had at least one major depressive episode, over two thirds (14.8 million adults) reported that the episode caused severe impairment of their daily activities.[26] That number represents 6.0% of all U.S. adults.[27]

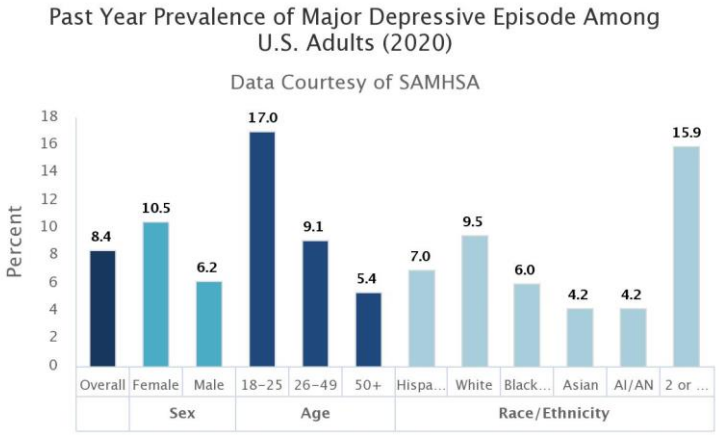

Figure 3

However, anxiety disorders—which include a range of similar yet distinct diagnoses—are the most common mental illnesses in the U.S.[28] According to the Anxiety & Depression Association of America ("ADAA"), an estimated 40 million adults deal with anxiety disorders each year.[29] Like depression, research suggests that anxiety is caused by a variety of factors, including genetics, brain chemistry, personality, and life events.[30] Comorbidity of anxiety and depression are very common, as nearly half of those diagnosed with depression are also diagnosed with an anxiety disorder.[31] The most common anxiety disorder diagnosed alongside depression is Generalized Anxiety Disorder, affecting 6.8 million adults each year.[32] Additionally, each year Social Anxiety Disorder affects 15 million adults, and Specific

25. *Id*.

26. DHHS, KEY SUBSTANCE USE, *supra* note 9, at 31.

27. *Id*.

28. Anxiety & Depression Ass'n of Am., *Understand Anxiety & Depression*, https://adaa.org/understanding-anxiety/facts-statistics [https://perma.cc/ZUH5-X4PA] [hereinafter ADAA, *Understand Anxiety*].

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

Phobias affect 19 million.[33] Despite anxiety disorders being highly treatable, the ADAA found that only 36.9% of those suffering from depression or anxiety received treatment.[34]

B. Impacts of Mental Illness on the Individual and Society

1. Suicide and Other Health Concerns

The most frequently discussed public health concern surrounding mental illness is the risk of suicide. In 2019, according to the Center for Disease Control ("CDC"), suicide was the tenth leading cause of death overall in the U.S.[35] Additionally, suicide was the second leading cause of death of individuals aged 10-34 and the fourth leading cause of those aged 35-54.[36] Further, Figure 4 reveals a troubling trend[37]: the suicide rate in the U.S. increased 35.2% from 1999 to 2018—jumping from 10.5 per 100,000 people to 14.2 per 100,000.[38] Figure 4 also shows that males are significantly more likely than females to commit suicide.

However, the 2020 NIMH data revealed that adult females in the U.S. reported a higher prevalence of suicidal thoughts than men, at 5.2% compared to 4.5%.[39] Figure 5 ultimately shows that 12.2 million adults reported having serious thoughts of suicide in 2020.[40]

33. *Id.*

34. *Id.*

35. Nat'l Inst. Of Mental Health, *Mental Health Information—Statistics: Suicide*, https://www.nimh.nih.gov/health/statistics/suicide.shtml [https://perma.cc/CG9A-YJ6V] [hereinafter NIMH, *Suicide*].

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id*.

40. *Id*.

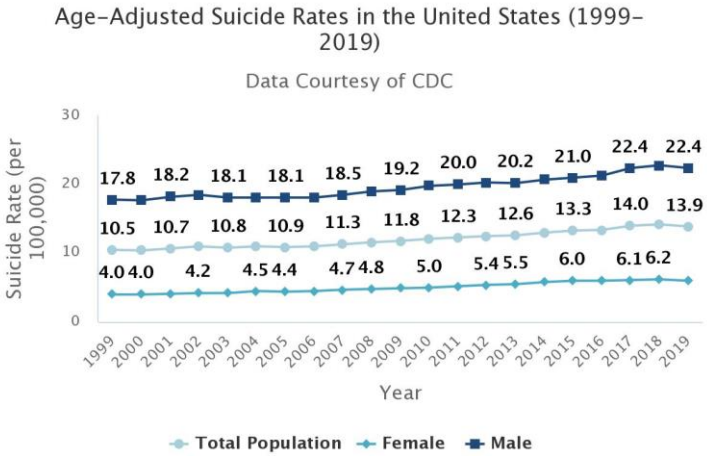

Figure 4

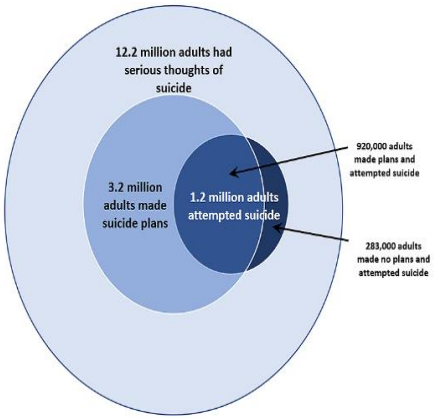

Figure 5

Additionally, there are other—less discussed—health concerns that are correlated with the presence of a mental illness. People with depression have a 40% higher risk of developing cardiovascular and metabolic diseases than the general population, and people with SMIs are nearly twice as likely to develop these conditions.[41] Further, 32.1% of adults in the U.S. who were suffering from a mental illness in 2020 also developed a substance abuse disorder.[42] Unhealthy coping methods and/or an inability to maintain a healthy diet and exercise often contribute to the development of such issues.

2. Family and Community Concerns

Untreated or undertreated mental illness can take a toll on families and communities who are left to care for those afflicted. In 2016, it was estimated that at least 8.4 million people in the U.S. provided care to an adult with mental and/or emotional health issues.[43] Further, it was estimated that such caregivers spent up to 32 hours per week providing unpaid care.[44] In addition to the time and effort involved, caring for those with mental illnesses can lead to financial burdens on families,

41. Nat'l All. on Mental Illness, *Mental Health By the Numbers*, https://nami.org/mhstats [https://perma.cc/WW4P-JUVG] [hereinafter Nat'l All. on Mental Illness, *Mental Health*].

42. *Id*.

43. Nat'l All. for Caregiving, *On Pins & Needles: Caregivers of Adults with Mental Illness* 15 (2016). https://www.caregiving.org/wp-content/uploads/2020/05/NAC_Mental_Illness_Study_2016_FINAL_WEB.pdf.

44. *Id*. at 17.

such as time off work and hospital bills. Mood disorders are also the most common cause of hospitalization in the U.S. for all people under the age of 45 (excluding pregnancy and birth related visits), and an estimated 1-in-8 emergency room visits (12 million in total) involved mental illness or substance abuse disorders.[45]

Moreover, mental illness has become intertwined with all facets of community life, ranging from education to housing to the criminal justice system. Regarding education, high school students displaying signs of depression are twice as likely to drop out of school compared to other students.[46] Regarding housing, 20.8% of the homeless population in the U.S. suffer from mental illness.[47] However, the mental health crisis is most visible in the criminal justice system. A 2017 special report by the Department of Justice found that 37% of all adults incarcerated in the state and federal prison systems and 44% of jail inmates had been diagnosed with a mental illness during their lifetime.[48] When looking at youths incarcerated in the juvenile justice system, 70% have a diagnosed mental illness.[49]

3. Economic Concerns

Mental illness also impacts the U.S. economy. Untreated or undertreated individuals are not always able to perform optimally at work. The rate of unemployment among U.S. adults with a diagnosed mental illness is over a full percent higher than those without a mental illness, 6.4% compared to 5.1%, respectively.[50] Between higher levels of unemployment and lower levels of productivity, serious mental illness is estimated to cause $193.2 billion in lost earnings across the U.S. economy each year.[51] Additionally, depression is a leading cause of disability worldwide and the leading cause of disability in the U.S. for ages 15-44.[52] In total, mental illness—especially depression and anxiety disorders—are estimated to cost the global economy $1 trillion in lost productivity each year.[53]

45. Nat'l All. on Mental Illness, *Mental Health*, *supra* note 41.

46. *Id*.

47. *Id*.

48. JENNIFER BRONSON & MARCUS BERZOFSKY, INDICATORS OF MENTAL HEALTH PROBLEMS REPORTED BY PRISONERS AND JAIL INMATES, 2011-2012, 1 (2017).

49. Nat'l All. on Mental Illness, *Mental Health*, *supra* note 41.

50. *Id*.

51. Ronald C. Kessler et al., *Individual and Societal Effects of Mental Disorders on Earnings in the United States: Results from the National Comorbitiy Survey Replication*, 165(6) AM. J. PSYCH. 703, 703 (2008).

52. Nat'l All. on Mental Illness, *Mental Health*, supra note 41.

53. *Id*.

C. Current Treatment Options for Mental Illness

Despite available treatment options, sizeable numbers of Americans suffering from mental illness do not receive treatment, including 34% of those suffering from major depression[54] and 63% of those suffering from anxiety.[55] For those who do seek treatment, the most common forms are medication and psychotherapy or a combination of the two.[56] If those treatment options fail, further measures such as Transcranial Magnetic Stimulation or Electroconvulsive Therapy may be employed.[57]

1. Medication

Antidepressants are one of the most common drugs prescribed to treat depression and anxiety disorders and can also be used to treat other mental illnesses and physical conditions. Antidepressants work by interacting with neurotransmitters in the brain, such as serotonin, norepinephrine, and dopamine.[58] There are many different classes of antidepressants, each working in slightly different ways.[59] Overall, antidepressants are a moderately effective form of treatment and most commonly paired with some sort of therapy to maximum their effectiveness.[60]

54. *See* NIMH, *Major Depression*, *supra* note 24 (providing that only 66% of adults 18 years and older received treatment for symptoms associated with their major depression).

55. *See* ADAA, *Understand Anxiety*, *supra* note 28.

56. *See* Nat'l Inst. of Mental Health, *Mental Health Information—Health Topics: Depression*, https://www.nimh.nih.gov/health/topics/depression/index.shtml (last updated February 2018) (providing that medication and psychotherapy are useful treatments for depression).

57. *Id.*

58. Mayo Clinic Staff, *Antidepressants: Selecting One That's Right for You*, MAYOCLINIC.ORG, https://www.mayoclinic.org/diseases-conditions/depression/in-depth/antidepressants/art-20046273 (last updated December 31, 2019) [hereinafter Mayo Clinic Staff, *Antidepressants*].

59. *Id*. (For instance, while SSRIs block the reabsorption of serotonin into neurons, SNRIs block the reabsorption of both serotonin and norepinephrine into neurons).

60. *See* NIMH, *Major Depression*, *supra* note 24, at Figure 7. This source has since been updated and now only possesses 2 figures, but when this Article was written, Figure 7 (as reproduced below as Figure 6) existed.

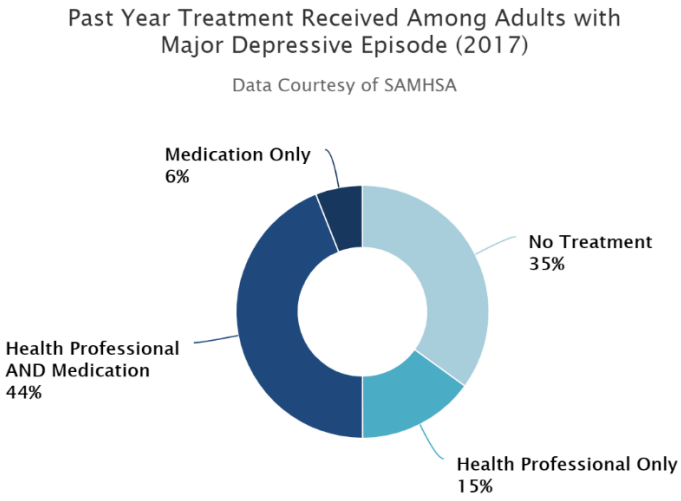

Figure 6

However, antidepressants have their limitations—they often take too long to show benefits. Additionally, finding the correct medication for a patient can be difficult. In some cases, improvements on antidepressants are made in a few weeks, but other times it may take 6 weeks or more.[61] These longer periods may occur because patients need to try several medications before they find the most effective one.[62] In fact, approximately 50% of patients do not respond to the first-line medications prescribed.[63] Once the correct medication is found, and the dosage reaches a therapeutic level, patients are often instructed to take antidepressants daily for extended periods of time to prevent relapses. According to the National Center for Biotechnology Information ("NCBI"), treatment with antidepressants typically continues for 4 to 9 months after the cessation of depressive signs and symptoms, but some patients remain on the medication for years to prevent the return of symptoms.[64]

Additionally, the NCBI reported that the effectiveness of antidepressant medications also depends on the severity of the depression being treated. According to the NCBI, antidepressants are

61. Mayo Clinic Staff, *Antidepressants*, *supra* note 58.

62. *Id*.

63. Hartej Gill et al., *The Emerging Role of Psilocybin and MDMA in the Treatment of Mental Illness*, 20 EXPERT REV. OF NEUROTHERAPEUTICS 1263, 1265 (2020).

64. Nat'l Ctr. for Biotechnology Info., *Depression: How Effective Are Antidepressants?*, available at https://www.ncbi.nlm.nih.gov/books/NBK361016/ [https://perma.cc/JTZ9-NTEH].

effective in treating moderate to severe, but not mild, cases of depression.[65] Antidepressants' effectiveness vary for each patient, which is why certain antidepressants may work for some patients but not others.

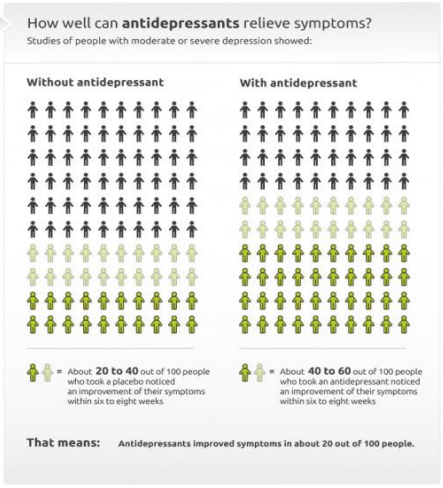

Figure 7

After examining the results of many studies, the NCBI found that the most prescribed medications[66] improved patients' symptoms, within 6 to 8 weeks, only marginally better than the placebo, as seen in Figure 7.[67] Thus, while antidepressants' benefits usually outweigh the costs, they are not effective for everyone. According to the NCBI, nearly half of patients on antidepressants may not experience improvements after 6 to 8 weeks and must continue trying different medications.[68]

Because antidepressants may produce negative side effects and lack efficacy in treatment, people may give up on treatment altogether. In fact, 42% of patients discontinue using antidepressants after the first 30 days, and 72% discontinue within the first 3 months.[69]

2. Common Classes and Side Effects of Medicine

The most common class of antidepressant is the Selective Serotonin

65. *Id*.

66. The two medications being (i) selective serotonin reuptake inhibitors and (ii) serotonin and norepinephrine reuptake inhibitors.

67. Nat'l Ctr. for Biotechnology Info., *supra* note 64.

68. *Id.*

69. Gill, *supra* note 63, at 1270-71.

Reuptake Inhibitor ("SSRI"), which blocks neurons from reabsorbing serotonin, making serotonin more available in the brain.[70] SSRIs tend to cause fewer side effects than other classes of antidepressants, which is one main reason why they tend to be the first choice of doctors. Unfortunately, as mentioned, approximately 50% of patients fail to respond to SSRIs as a first line treatment option.[71] Poor responses to and potential side effects of SSRIs often lead to patients becoming frustrated, bearing poor outcomes.[72]

Common side effects of SSRIs range from mild to severe. Mild side effects include nausea, headache, and drowsiness.[73] Severe side effects include agitation and restlessness, erectile disfunction and other sexual problems, weight gain or loss, and the possibility of increased thoughts of suicide or suicidal behavior—especially within the first few weeks of starting the medication.[74] Another rare side effect is Serotonin Syndrome ("SS"), caused by high levels of accumulated serotonin in the body, which can lead to high fevers, confusion, tremors, lack of coordination, major changes in blood pressure, and rapid heart rates.[75] SS normally only occurs when multiple medications or supplements are used in conjunction with one another. Lastly, patients forgoing treatment with SSRIs need to wean off their medications, because abrupt stoppages (or missing several doses) can cause withdraw-like symptoms.[76]

The second most common class of antidepressant is the Serotonin and Norepinephrine Reuptake Inhibitors ("SNRI"), which helps block both the serotonin and norepinephrine neurotransmitters in the brain.[77] SNRIs work similar to SSRIs, but they are more effective in regulating the brain nerve cell circuitry responsible for regulating mood, which also makes it an effective medication for certain types of chronic pain that may accompany depression.[78] Like SSRIs, approximately 50% of

70. Mayo Clinic Staff, *Selective Serotonin Reuptake Inhibitors (SSRIs)*, MAYOCLINIC.ORG, https://www.mayoclinic.org/diseases-conditions/depression/in-depth/ssris/art-20044825 (last updated September 17, 2019) [hereinafter Mayo Clinic Staff, *SSRIs*].

71. Gill, *supra* note 63, at 1265.

72. *Id*.

73. Mayo Clinic Staff, *SSRIs*, supra note 70.

74. *Id*.

75. *Id*.

76. *Id*.

77. Mayo Clinic Staff, *Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)*, MAYOCLINIC.ORG, https://www.mayoclinic.org/diseases-conditions/depression/in-depth/antidepressants/art-20044970 (last updated October 5, 2019).

78. *Id*. Also note that the common potential side effects of SNRIs are also similar to SSRIs, including nausea, headache, drowsiness, erectile disfunction and other sexual problems, possibility of increased thoughts of suicide or suicidal behavior, and serotonin syndrome. Certain SNRIs have also been found to raise blood pressure or worsen liver problems. Lastly, like SSRIs, stopping the medication should

patients fail to respond to SNRIs when used as a first-line treatment method.[79]

The final two most common classes of antidepressants are Tricyclic and Tetracyclic Antidepressants ("Cyclics") and Monoamine Oxidase Inhibitors ("MAOIs").[80] Cyclics were some of the earliest antidepressants developed and work similar to SNRIs by blocking the reuptake of serotonin and norepinephrine, increasing the level of neurotransmitters in the brain.[81] However, Cyclics also affect other chemical messengers in the brain and can therefore produce a greater number of side effects.[82] MAOIs were the first antidepressants developed and work by blocking an enzyme called monoamine oxidase, which is responsible for the removal of norepinephrine, serotonin, and dopamine from the brain.[83] However, MAOIs also affect other neurotransmitters in the brain and digestive tract, which leads to unpleasant side effects.[84]

3. Psychotherapy

Psychotherapy is a general term for treating mental illness by talking with a trained psychiatrist, psychologist, or other mental health provider.[85] The main goals of psychotherapy are to help patients learn

be done under doctor supervision because abrupt stoppage or several missed doses can lead to withdraw-like symptoms. *Id.*

79. Gill, *supra* note 63, at 1265.

80. Mayo Clinic Staff, *Antidepressants*, *supra* note 58.

81. Mayo Clinic Staff, Tricyclic Antidepressants and Tetracyclic Antidepressants, MAYOCLINIC.ORG, https://www.mayoclinic.org/diseases-conditions/depression/in-depth/antidepressants/art-20046983 (last updated October 8, 2019).

82. *Id*. Common side effects include drowsiness, constipation, blurred vision, urine retention, drops in blood pressure when standing, weight loss or gain, tremors, and erectile dysfunction and other sexual problems. More severe potential side effects include disorientation, an increased or irregular heartbeat, more frequent seizures in people with a history of seizures, serotonin syndrome, and a possibility of increased thoughts of suicide or suicidal behavior. Additionally, like stopping SSRIs and SNRIs, stopping Cyclics should be conducted under doctor supervision because abrupt stoppage or several missed doses can lead to withdraw-like symptoms. Because of the higher occurrence of side effects, Cyclics have generally been replaced by SSRIs and SNRIs. However, Cyclics remain a viable and common choice for patients who have not responded to SSRIs and SNRIs or other forms of treatment. *Id*.

83. Mayo Clinic Staff, *Monoamine Oxidase Inihibitors (MAOIs)*, MAYOCLINIC.ORG, https://www.mayoclinic.org/diseases-conditions/depression/in-depth/maois/art-20043992 (last updated September 12, 2019).

84. *Id*. Common side effects include nausea, constipation, diarrhea, insomnia, dizziness, and weight gain. Less common potential side effects include increased thoughts of suicide, involuntary muscle jerks, low blood pressure, muscle cramps, tingling sensations in the skin, and reduced sexual desire and erectile dysfunction. Like other medications, serotonin syndrome is a possible but rare side effect. The most unique downside to MAOIs is that patients need to limit their diets because MAOIs can cause dangerous interactions with certain foods, such as aged cheeses, beer, cured meats, and fermented soy products. *Id*.

85. Mayo Clinic Staff, *Psychotherapy*, MAYOCLINIC.ORG, https://www.mayoclinic.org/tests-

about their condition, moods, feelings, thoughts and behaviors, as well as how to respond to challenging situations with healthy coping skills.[86] As reported in Figure 6 in Part II-C(1), psychotherapy is the other most common form of treatment for mental illness and frequently used in conjunction with medication. In some cases, psychotherapy can be just as effective without medication, but for most moderate to severe cases of mental illness, psychotherapy is most effective when they are paired.[87]

There are many different forms of psychotherapy.[88] Some work better for treating certain mental illnesses, and sometimes therapists will use a combination of techniques during treatment.[89] Therapists consider patients' unique circumstances and preferences when determining the technique or combination of techniques that will be most effective for them.[90]

Unlike medications, psychotherapy has little to no risks or side effects.[91] However, there are practical limitations to psychotherapy that hinder its effectiveness in treatment. One drawback is that it can be difficult to find a therapist accepting new patients, which can force patients to wait extended periods of time before beginning treatment. Additionally, given the sensitive and emotional nature of therapy, a patient may need to visit several different therapists before they find one with whom they feel comfortable.[92] This means that patients may go several weeks before receiving meaningful treatment.

Individual therapy sessions may also be lengthy and time-consuming. Psychotherapy first sessions are typically structured more

procedures/psychotherapy/about/pac-20384616 (last updated March 17, 2016).

86. *Id*.

87. *Id*.

88. Some of the most common techniques used, which have proven to be effective, are: Cognitive behavioral therapy (CBT) helps to identify unhealthy, negative beliefs and behaviors and replace them with healthy, positive ones. Dialectical behavior therapy is a type of CBT that teaches behavioral skills to help to handle stress, manage your emotions and improve your relationships with others. Acceptance and commitment therapy (ACT) helps to become aware of and accept your thoughts and feelings and commit to making changes, increasing one's ability to cope with and adjust to situations. Psychodynamic and psychoanalysis therapies focus on increasing one's awareness of unconscious thoughts and behaviors, developing new insights into one's motivations, and resolving conflicts. Interpersonal psychotherapy focuses on addressing problems with one's current relationships with other people to improve one's interpersonal skills — how to relate to others, such as family, friends and colleagues. Supportive psychotherapy reinforces one's ability to cope with stress and difficult situations. *Id.*

89. *Id*.

90. *Id*. In addition to different techniques, psychotherapy is also offered in different formats, including individual, couple, family or group therapy sessions.

91. *Id*. (Generally the only risks posed by psychotherapy result from exploring painful feelings and traumatic experiences, but the risks are minimized by working with a trained professional.)

92. *Id*.

like a mutual interview than a treatment session[93]—an opportunity for therapists to learn about the patient's health history and current situation. This allows the therapist to determine the technique(s) most likely to benefit the patient.[94] First sessions are also an opportunity for patients to learn about the therapist's credentials and personality, goals and plans for treatment, and whether they feel comfortable enough with the therapist to continue treatment.[95] Once a treatment plan is established, patients will usually meet regularly with their therapists weekly or bi-weekly for about 45 minutes to an hour per session. The length of sessions depends on the patient's specific mental illness, severity of symptoms, how quickly the patient is making progress, and how much support they receive at home. Ultimately, it could take months or even years for the patient to reach the point where they no longer feel the need to continue treatment.[96]

The need to continue therapy for years raises a third practical limitation of psychotherapy: cost. First, patients normally must find a therapist covered by their insurance plan, which can be difficult. Second, even if a therapist is covered under a patient's plan, it may only cover a limited number of psychotherapy sessions per year, meaning patients may either be forced to attend fewer sessions than they need or cover the cost out-of-pocket for more sessions.[97] Third, even if an insurer does not limit the number of sessions, some may require a co-pay from the patient.[98] Finally, to be successful in treatment, patients may need to travel to and participate in therapy sessions weekly, forcing them to miss work or use sick and/or vacation time to cover their absences. While the benefits of psychotherapy for some patients may outweigh the costs, the costs for others may force them to attend less sessions than they need or forgo therapy altogether.

4. Treatment-Resistant Options

Sometimes, traditional treatment methods like medication and psychotherapy are ineffective or are unable to alleviate symptoms quickly enough to treat severe emergency cases. In these instances, there are alternative methods doctors can employ, such as electroconvulsive therapy and transcranial magnetic stimulation.

93. *Id*.
94. *Id.*
95. *Id*.
96. *Id*.
97. *Id*.
98. *Id*.

i. Electroconvulsive Therapy

Electroconvulsive therapy ("ECT") carries an uneasy stigma in popular culture because of its early iterations, before the use of anesthetics, but is now considered a safe and effective procedure for treating severe, treatment-resistant cases of depression and other severe mental illnesses.[99] ECT is undergone with general anesthesia and works by passing small electric currents through the brain, intentionally triggering a brief seizure—usually lasting less than 60 seconds.[100] ECT is thought to cause changes in brain chemistry that can quickly reverse symptoms of certain mental illnesses.[101] It is undetermined exactly how ECT works in treating severe depression and other mental illnesses.[102]

ECT is an important and effective treatment for those who have not responded to other methods or for those who cannot take medications, such as pregnant women who cannot tolerate the side effects. However, there are several practical limitations to ECT. First, ECT may come with moderate to severe side effects.[103] Second, ECT is time-consuming for the patient. Normally, patients are unable to work on their treatment days because they undergo anesthesia, and recovery time is necessary to regain functioning.[104] Lastly, ECT can be expensive, even when covered by insurance, because it requires more elaborate hospital procedures involving anesthetics and other

99. Mayo Clinic Staff, *Electroconvulsive Therapy (ECT)*, MAYOCLINIC.ORG, https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894 (last updated October 12, 2018).

100. Before the procedure doctors will complete a full medical evaluation (e.g., physical examination, blood tests, electrocardiogram, psychiatric assessment) to ensure the patient is healthy enough to receive the procedure. During the procedure itself, the patient is given a general anesthetic and muscle relaxant to ensure that the patient is unconscious and to prevent any associated injuries. The patient's brain activity, blood pressure, heart rate, and oxygen use are all continually monitored to ensure safety. ECT treatments are typically given two to three times a week, for three to four weeks, or a total of six to twelve treatments. The number of treatments needed will depend on the severity of symptoms that the patient is experiencing and how quickly one responds. Many patients begin to notice improvements after approximately six treatments, but full improvement for patients typically takes longer. *Id.*

101. *Id.*

102. *Id*.

103. Most common are physical side effects such as nausea, headache, jaw pain, and muscle aches—likely stemming from both the anesthetics and medically-induced seizure used to perform ECT. ECT may also cause confusion post-treatment, including not knowing where one is or what they are doing for minutes to hours at a time. These symptoms may persist beyond that time span, but rarely last several days or longer. Similarly, some people have lost memories of events occurring right before treatment. Sometimes patients experience more serious memory loss, spanning weeks or months prior to treatment (and rarely, even years). Such memory loss associated with ECT is known as *retrograde amnesia.* Memory problems tend to improve within a few months after treatment has ended.

104. As a result, patients must miss work and recruit people to drive them to and from their appointments. Because ECT treatments span multiple days to multiple weeks, and its side effects can persist for months after treatment, patients' daily lives may be substantially disrupted by it.

technology that traditional methods do not. Because of ECT's serious potential for side effects as well as the practical burdens associated with receiving it, it is typically only used when other treatments have failed and a psychiatrist deems it necessary.

ii. Transcranial Magnetic Stimulation

A newer development in psychiatric treatment of severe and treatment-resistant depression is repetitive transcranial magnetic stimulation ("rTMS"), a non-invasive procedure using magnetic fields to stimulate nerve cells in the brain to improve symptoms of depression.[105] Similar to ECT, rTMS is not completely understood, although it is thought to help treat depression by activating brain regions with decreased activity.[106] Unlike ECT, however, rTMS does not require anesthesia, can be performed in an outpatient facility, is non-invasive, and is not seizure-inducing.[107] As a result, side effects of rTMS are usually mild, and patients can drive themselves to and from treatment.[108]

Most of the downsides to rTMS are practical. The treatment is more limited in those it can be used on,[109] and the treatment involves daily sessions of approximately 1 hour, 5 days a week, for 4 to 6 weeks.[110] Further, several weeks of treatment may be required before the patient experiences any relief, which can be discouraging. Lastly, cost considerations are important. Many major health insurers will cover rTMS, but they typically require that other options have been explored first (typically 2-4 different kinds of antidepressant medications, at

105. Mayo Clinic Staff, *Transcranial Magnetic Stimulation*, MAYOCLINIC.ORG, https://www.mayoclinic.org/tests-procedures/transcranial-magnetic-stimulation/about/pac-20384625 (last updated November 27, 2018) [hereinafter Mayo Clinic Staff, *TMS*]. The treatment delivers repetitive magnetic pulses, so it is commonly called repetitive TMS ("rTMS"). During the treatment, an electromagnetic coil is placed against the patient's scalp near their forehead, and an electromagnet painlessly delivers a magnetic pulse that stimulates nerve cells in the regions of the brain responsible for mood control.

106. *Id*.

107. *Id*.

108. *Id*. Common side effects of rTMS include mild to moderate headaches, lightheadedness, tingling and/or twitching of facial muscles, and scalp discomfort at the sight of the stimulation. Most side effects improve shortly after the session concludes and tend to decrease over time with additional treatment sessions. Uncommon but serious side effects can include seizures, mania in those with bi-polar depression, and hearing loss if inadequate ear protection is provided during the treatment. Because rTMS is a newer treatment, more research is necessary to determine whether there are any long-term side effects of the treatment. *Id*.

109. People with any medical implants or devices, familial histories of seizures or epilepsy, or other mental disorders such as substance abuse and bi-polar may be disqualified from treatment.

110. Mayo Clinic Staff, *TMS*, *supra* note 105. That means that patients may need to be away from work for one to two hours every day for four to six weeks to complete treatment.

minimum).[111] Further, even if the patient's insurer covers rTMS it can be difficult to find a provider covered under their insurance plan, and co-pays and out of pocket costs can be sizeable given that 20-30 sessions are typically required.[112]

D. Psychedelics as an Emerging Breakthrough Treatment Option

Today, researchers are once again experimenting with psilocybin in the treatment of mental illnesses such as depression, anxiety, and addiction. Psilocybin and other psychedelics were major topics of research in the 1950s and 1960s. In fact, between 1950 and the mid-1960s there were more than 1000 clinical papers discussing 40,000 patients, several dozen books, and 6 international conferences on psychedelic drug therapy.[113] As discussed in the next Section, however, several political and legal developments in the 1960s and 1970s halted the research. Nonetheless, beginning in the 1990s and early 2000s, interest in psilocybin began to resurface when its potential as a treatment for mental illnesses was slowly reexamined. So far, the results have been positive and produced optimism that psilocybin may be an effective treatment to help address the growing mental health crisis in the U.S.

1. How Psychedelics Work

Like antidepressant medications, ECT, and rTMS, there is no definitive answer as to how exactly psilocybin works in treating symptoms of depression and anxiety. One possible explanation is that psilocybin's structure closely resembles serotonin's structure.[114] Once psilocybin is ingested, it quickly dephosphorylates[115] to form the active compound psilocin, whose structure is nearly identical to serotonin.[116] This similarity allows the compound to attach to

111. Ben Spielberg, *How Much Does TMS Therapy Cost?*, TMSBRAINHEALTH.COM, https://www.tmsbrainhealth.com/tms-therapy/how-much-does-tms-therapy-cost/ (August 18, 2020).

112. Mayo Clinic Staff, *TMS*, *supra* note 105. Additionally, some insurers will not cover maintenance or continual treatments, so after reaching a certain number of sessions insurers may refuse to cover any more treatments.

113. David E. Nichols, *Psychedelics*, 68(2) PHARMACOLOGICAL REV. 264, 267 (2016) (quoting JAMES B. BAKALAR & LESTER GRINSPOON, PSYCHEDELIC DRUGS RECONSIDERED, 192 (1979)).

114. Nat'l Ctr. for Biotechnology Info., *PubChem Compound Summary, Serotonin* (2021) *available at* https://pubchem.ncbi.nlm.nih.gov/compound/Serotonin. Serotonin has the chemical name 5-hydroxytryptamine (last visited Apr. 12, 2021). Both compounds are a type of tryptamine.

115. Dephosphorylation is the process of removing a phosphate group by hydrolysis.

116. Nat'l Ctr. for Biotechnology Info., *PubChem Compound Summary: Psilocybine* (2021) *available at* https://pubchem.ncbi.nlm.nih.gov/compound/Psilocybine (last visited Apr. 12, 2021).

serotonin receptors in the brain and mimic the effects of serotonin.[117] In particular, psilocybin/psilocin interact with one serotonin receptor especially well—$5HT_{2A}$—which is found predominantly in the central nervous system and cerebral cortex of the brain.[118] Because serotonin is an important neurotransmitter for the regulation of mood, the interactions between psilocybin/psilocin and the $5HT_{2A}$ serotonin receptors may explain why the compound seems to help alleviate symptoms of depression and anxiety.

Dr. Robin Carhart-Harris, a researcher from Imperial College London, offers another possible explanation for psilocybin's effectiveness in treating depression and anxiety. One of Dr. Carhart-Harris's 2014 studies demonstrated that psilocybin reduces blood flow and activity within the default-mode network of the brain ("DMN").[119] The DMN regions serve as important connector hubs for the routing and integration of information through various parts of the brain, acting as a central orchestrator of global brain function.[120]

Additionally, the DMN engages in high-level operations such as self-reflection, theory of mind, and mental time travel.[121] The DMN is typically found to be over engaged in those with depression and anxiety, leading to excessive self-reflection, worry, and rumination on past events.[122] Thus, it is possible that reduced activity in the DMN network caused by psilocybin helps alleviate symptoms. Psilocybin may therefore prove effective for treating depression and anxiety by "dismantling reinforced patterns of negative thought and behavior by breaking down the stable spatiotemporal patterns of brain activity upon which they rest."[123]

The last explanation, which is less scientific, is that treatment with psilocybin can induce a mystical experience that allows the patient to gain a greater perspective on life.[124] The mystic experience can help the patient confront negative emotions and past traumas and work through these tribulations with a therapist's or "guide's" counsel.[125]

117. *Id*.

118. *Id*.

119. Robin L. Carhart-Harris, et al., *The Entropic Brain: A Theory of Conscious States Informed by Neuroimaging Research with Psychedelic Drugs*, 8 FRONTIERS IN HUM. NEUROSCIENCE, 1, 10, Figure 5 (2014).

120. *Id*. at 6.

121. *Id*.

122. *Id.* at 9-10.

123. *Id*. at 14.

124. MICHAEL POLLAN, HOW TO CHANGE YOUR MIND: WHAT THE NEW SCIENCE OF PSYCHEDELICS TEACHES US ABOUT CONSCIOUSNESS, DYING, ADDICTION, DEPRESSION, AND TRANSCENDENCE (2018) (exploring new life perspective gained after introduction of psilocybin).

125. *Id*.

This approach stems from the work of older psychiatrists such as Sigmund Freud and Carl Jung and has difficulty gaining approval among members of the scientific community.[126]

2. Studies and Results

Despite being classified as a Schedule I drug under the Controlled Substances Act,[127] numerous studies from the past decade cite psilocybin as a potential treatment for depression, anxiety, and other mental illnesses. ClinicalTrials.gov currently lists 91 different studies—ranging from Early Phase 1 to Phase 2—exploring psilocybin's potential to treat mental illnesses such as Major Depressive Disorder, Treatment Resistant Depression, Type 2 Bi-Polar Depression, Anorexia Nervosa, Alcohol Dependence, and Obsessive-Compulsive Disorder.[128] More importantly, completed studies already suggest that psilocybin is efficacious and safe.

3. Efficacy

Dr. Carhart-Harris performed a pilot study in 2016, which found that two sessions of psilocybin-assisted therapy, spaced seven days apart, resulted in significantly reduced depressive symptoms one week after the treatment and similar improvements in anxiety.[129] These reductions in symptoms remained at a three-month follow up appointment, showing that just one or two treatments can provide long-lasting relief of symptoms.[130]

Another 2011 study involved psilocybin-assisted psychotherapy for cancer patients suffering from depression and anxiety.[131] In this study, patients reported continued improvements in anxiety 3 months following treatment and significant improvements in depressive symptoms 6 months following treatment.[132] Similarly, patients in a separate 2016 study reported continued and significant antidepressant and anxiolytic effects at a 6 and a half month follow up.[133]

Hundreds of studies involving psilocybin have either been

126. Carhart-Harris et al., *supra* note 119, at 14-15.

127. 21 U.S.C. §812(c), Schedule I(c)(15).

128. *See* Nat'l Ctr. Biotechnology Info., *Psilocybin,* https://pubchem.ncbi.nlm.nih.gov/compound/Psilocybine#section=ClinicalTrials-gov&fullscreen=true (2021) (reporting current clinical trial).

129. Gill, *supra* note 63, at 1266.

130. *Id*.

131. *Id.*

132. *Id*.

133. *Id*.

completed or are underway, and the growing body of results shows psilocybin's strong potential to treat certain mental illnesses. Following a 2020 Johns Hopkins University study, Dr. Alan Davis, an adjunct professor of psychiatry and behavioral sciences at Johns Hopkins, commented: "[t]he magnitude of the effect we saw was about four times larger than what clinical trials have shown for traditional antidepressants on the market."[134] Because of its demonstrated efficacy, psilocybin is gaining momentum as a potential treatment for various mental illnesses.

4. Safety and Side Effects

To gain FDA approval, as well as acceptance in the medical community more generally, psilocybin would need to show that, in addition to being efficacious, it does not cause major side effects or threaten patients' health and wellbeing. So far, studies reveal that psilocybin does not produce major side effects. The participants in Dr. Carhart-Harris's study experienced no serious adverse physical or psychological side effects from ingesting psilocybin.[135] However, shortly after ingesting psilocybin, mild temporary physical side effects included mild nausea, confusion, tiredness, minor increases in blood pressure and heart rate (not clinically severe), and anxiety.[136]

Regarding other side effects, data compiled from several different studies showed that, following psilocybin-assisted therapy, there was no indication of increased drug abuse, persisting perception disorders, prolonged psychosis, or other long-term deficits in participants.[137] While some concerns existed as to whether psychedelics could exacerbate underlying mental health disorders or increase suicidality, the data showed that "no significant association was found between lifetime use of psychedelics and increased mental health treatment or suicidal thoughts, plans, or attempts."[138]

In total, adverse reactions from psilocybin were few in number, resolved quickly, and were mostly associated with the highest doses of psilocybin—and the patients experiencing them showed no long-term

134. Johns Hopkins Medicine Newsroom, *Psychedelic Treatment with Psilocybin Relieves Major Depression, Study Shows*, HOPKINSMEDICINE.ORG (November 4, 2020), https://www.hopkinsmedicine.org/news/newsroom/news-releases/psychedelic-treatment-with-psilocybin-relieves-major-depression-study-shows.

135. Gill, *supra* note 63, at 1265.

136. *Id*.

137. Jeremy Daniel & Margaret Haberman, *Clinical Potential of Psilocybin as a Treatment for Mental Health Conditions*, 7 THE MENTAL HEALTH CLINICIAN 24, 25 (2017).

138. *Id*.

negative side effects after follow-ups 8 to 16 months later.[139] Such promising results, however, may be attributable to the extensive screening that ensures that participants are physically and mentally fit for the study. Treatment is also provided under controlled conditions with controlled doses to minimize the possibility of patients having "bad trips" and putting themselves in dangerous situations, which was a major factor in psychedelics garnering a bad reputation in the 1960s.[140]

Lastly, concerns as to toxicity or potential for drug abuse seem to be unsubstantiated. Studies of psilocybin show that the compound is low in chronic toxicity and moderate in acute toxicity, which means that it carries little risk of overdose.[141] The Netherlands conducted a review of psilocybin use and came to similar conclusions, stating that "public health risks were negligible" and the average lethal dose in rat studies was 17 kg of mushrooms.[142] Further, studies investigating psilocybin's abuse potential show no cases of physical dependence or withdrawal symptoms following discontinuation of the drug.[143]

Of course, the psilocybin experience (or "trip") by nature includes psychological effects such as perceptual changes, visual distortions, intensified emotions, an altered perception of time and self, and an increased introspective focus.[144] These effects are one of the main purposes of psilocybin-assisted therapy—to "harness the psychospiritual experiences that may be induced … and direct them into therapeutic experiences."[145] The psychological effects tend to last several hours, depending on dosage, during which time the psilocybin assisted therapy is conducted.[146] Such an experience may create risks for the patient if the dosage is not properly determined or there is inadequate supervision over the session, which is why doses and distribution are carefully monitored.[147]

5. The Hope

Psilocybin's potential use as a treatment for depression is spurring hope for many reasons. As discussed above, current treatment options

139. *Id*.

140. *Id*. at 26-27.

141. *See* Gill, *supra* note 63, at 1265 (noting the low risk of overdose toxicity because of cardiovascular events or respiratory depression.)

142. Daniel & Haberman, *supra* note 137, at 25.

143. Gill, *supra* note 63, at 1265.

144. *Id*.

145. *Id*. at 1266.

146. *Id*.

147. *Id*. at 1265.

for mental illnesses are not always effective or efficient, and the nation is facing a severe and increasing mental health crisis. Medications, psychotherapy, and more intensive methods can be used to treat the more prevalent mental illnesses such as depression and anxiety, but they come with a litany of flaws as well. The cost of refilling a medication monthly, seeing a therapist weekly, having to receive treatment in inpatient or outpatient facilities, and finding providers who are covered under health insurance can produce further difficulties for patients already struggling with their mental health. Further, ineffective first line treatments, adverse side effects, and prolonged waits (weeks or even months) before a medication begins to work can push patients away from treatment altogether.[148]

Early studies show that psilocybin-assisted therapy can be effective with only 1 or 2 sessions per year, providing quick and long-lasting relief of symptoms of depression and anxiety. Some have even compared the results to ECT (providing a "reboot" of the mind) but without the associated costs, side effects, and 2-3 week waiting period to see results.[149] If patients are able to get long-lasting relief quickly, it would save them costs on prescriptions, co-pays, hospital bills, time off work, transportation costs, and lost productivity. Additionally, psilocybin-assisted therapy could serve as an alternative for patients seeking to avoid the chronic side effects of medications or other treatment-resistant options, such as ECT.

While psilocybin would not be a panacea, and optimism should be tempered until a deeper and stronger body of research has developed around the safety and effectiveness of psilocybin on a large scale, it is easy to see why many are so excited by their prospect. Rosalin Watts, a clinical psychologist who worked alongside Dr. Carhart-Harris on his psilocybin and depression studies, stated "I believe [psilocybin] could revolutionize mental health care."[150] However, that revolution has been deterred for many years, and may still be slowed, by the complicated legal relationship between psychedelics and the law.

148. *Id*. at 1263, 1265.

149. POLLAN, *supra* note 124, at 381.

150. *Id*.

III. LEGAL BACKGROUND

A. History of Psychedelics and the Law

1. The Early Days

Psychedelic mushrooms were first introduced to mainstream U.S. culture on May 13, 1957, when *Life* magazine published a lengthy article written by R. Gordon Wasson, a Vice President of J.P. Morgan Chase.[151] In 1955, Wasson traveled to a remote mountain village in Oaxaca, Mexico and became the first westerner to participate in the sacred *velada*, referring to a spiritual journey using psilocybin mushrooms.[152] In his article, Wasson recounted his journey and experience with the psychedelic compound. The article was read by millions, and Wasson re-told his story on the CBS show *Person to Person*.[153] Little did the public know that research had already begun on the potential medical uses of psychedelics.

In 1938, Swiss chemist Albert Hoffman was developing pharmaceutical drugs for his employer, Sandoz, when he inadvertently developed the drug lysergic acid diethylamide (LSD-25).[154] After preliminary testing showed little promise for the substance as a useful drug to treat any of the time's pressing ailments, he shelved the product. However, he revisited the compound in April 1943 and accidentally absorbed some it, discovering its psychedelic effects.[155] By 1950, Sandoz had made the compound available to researchers, who began experimenting with it, hoping to discover potential therapeutic applications. A process called psycholytic LSD therapy was used for treating mental disorders such as depression, anxiety, addiction, and more—and a 1967 metanalysis of studies conducted between 1953 and 1965 estimated the therapy was successful in up to 70% of anxiety cases and 62% of depression cases.[156] Further, following his return from Mexico, Wasson sent Hoffman some of the mushrooms he brought home from his trip, and in 1958, Hoffman was able to isolate and create synthetic versions of psilocybin and psilocin.[157] This allowed psilocybin to be distributed and used in studies as well.

151. *Id*. at 104.
152. *Id*. at 110.
153. *Id*. at 113.
154. *Id*. at 23.
155. *Id*.
156. *Id*. at 15.
157. *Id*. at 113.

The promise these compounds showed led to studies and trials, quickly spreading to elite institutions such as Spring Grove State Hospital in Maryland ("Spring Grove") and Harvard University.[158] The studies also produced quality results. At Spring Grove, the experiments were considered well-designed, and the results were regularly published in respected peer-reviewed journals such as *JAMA* and *Archives of General Psychology*.[159] In fact, support for the work was so strong that, following an hour-long CBS "special report" on the hospital's work with alcoholics, the Maryland state legislature established a multi-million-dollar research facility on the Spring Grove campus.[160]

However, most other contributors to psychedelic research had a reputation for loose procedures, and it was common practice for them to use the drugs they were studying themselves as a way to "better understand" the experience.[161] Some considered self-experimentation the ethical thing to do—otherwise researchers would be treating the patients as "guinea pigs."[162]

2. Expansion of the Food and Drug Administration and Research Halt

In 1962, the looser procedures that had become customary in the psychedelic research community were curtailed following the "thalidomide disaster,"[163] which prompted amendments to the Federal Food, Drug and Cosmetic Act.[164] The amendments, commonly referred to as the Kefauver-Harris Amendments, established a new framework requiring drug manufacturers to prove with scientific data that a medication was not only safe but also effective.[165] The amendments expanded the Food and Drug Administration's ("FDA") power over the application, approval, and regulation of new "investigational" drugs.

Major changes caused by the amendments included: (1) requiring

158. *Id*. at 55.

159. *Id*. at 56.

160. *Id*. at 57.

161. *Id*. at 146.

162. *Id*.

163. James H. Kim & Anthony R Scialli, *Thalidomide: the tragedy of birth defects and the effective treatment of disease*, 12 Toxicological Sciences 1 (2011) (discussing thalidomide and its impact on embryonic development). Thalidomide was a widely used drug in the 1950s and early 1960s for the treatment of nausea in pregnant women. It became apparent in the 1960s that thalidomide treatment resulted in severe birth defects in thousands of children. The public controversy led to many countries drastically increasing regulations and oversight of drug research and development. *Id.* at 1-2.

164. Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040, codified at 21 U.S.C. §301 *et seq.*

165. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

that manufacturers prove the effectiveness of drug products before they go on the market and report any serious side effects afterward; (2) requiring that evidence of effectiveness be based on adequate and well-controlled clinical studies conducted by qualified experts and study subjects give their informed consent; (3) providing the FDA with 180 days to approve a new drug application, which would be required before the drug could be marketed in the U.S.; (4) mandating that the FDA conduct a retrospective evaluation of the effectiveness of drugs approved for safety between 1938 and 1962; (5) allowing the FDA to set good manufacturing practices for industry and mandated regular inspections of production facilities; (6) transferring to the FDA control of prescription drug advertising, which would have to include accurate information about side effects; and (7) controlling the marketing of generic drugs to keep them from being sold as expensive medications under new trade names.[166]

3. Public Enemies

Increased FDA oversight probably should have tightened procedures across the psychedelic research community, but by the time the Kefauver-Harris Amendments were passed, researchers had already begun down a precipitous path that would ultimately cost the entire community. One of the main culprits was Timothy Leary, a professor of psychology at Harvard University. After receiving his Ph.D. from Berkeley University, Leary started at Harvard in 1959,[167] where he and fellow psychologist Richard Alpert started the Harvard Psilocybin Project, which aimed to document psilocybin's effects on human consciousness.[168]

By 1962, various faculty members and administrators at Harvard had started complaining about the project, criticizing the scientific merit and professional standards of the program.[169] Among the chief complaints were that Leary and Alpert were using psilocybin along with their subjects and not following accepted scientific methods of experimentation (i.e., poorly controlled conditions and non-random selection of subjects).[170] Additionally, the school newspaper, the Harvard Crimson, printed editorial columns accusing Leary and Alpert

166. *Id*.

167. Harvard University, *Timothy Leary*, *People*, HARVARD.EDU, https://psychology.fas.harvard.edu/people/timothy-leary (last accessed March 27, 2022) [https://perma.cc/PJT8-C4HH] [hereinafter Harvard University, *Timothy Leary*].

168. *Id*.

169. *Id*.

170. *Id*.

of not merely researching the scientific potential of the drugs but also actively promoting their recreational use.[171] Ultimately, in 1963, Alpert was fired for administering psilocybin to an undergraduate student off-campus—in violation of an agreement that they would only accept graduate students as test subjects. Leary was fired as well, and the Harvard Psilocybin Project was thereby abruptly ended.[172]

However, being fired from their respective university positions did not stop Leary and Alpert from becoming icons of the counterculture.[173] The story of their downfall at Harvard became national news, *Look* magazine wrote a feature article about the incident, and soon millions of people heard about the controversy at Harvard surrounding the exotic new drugs.[174] Shortly after, Alpert embarked on a spiritual journey to the East and adopted the name Baba Ram Dass before writing a book titled *Be Here Now*, which became a countercultural success and was described as a "modern spiritual classic."[175]

Leary also embraced his role as a countercultural icon and spent the following years on the government's radar for his cultural influence.[176] He became famous for speaking at the first Human Be-In in January 1967 at Golden Gate Park in San Francisco. The event drew 25,000 young people, and Leary freely distributed LSD to attendees, before making headlines by telling the "hippies" in attendance to "turn on, tune in, and drop out."[177] While that quote became his defining line, he also made controversial statements such as "LSD is more frightening than the bomb" and "the kids who are taking LSD aren't going to fight your wars…They're not going to join your corporations."[178] He became so controversial that, by 1971, President Richard Nixon declared Timothy Leary "the most dangerous man in America."[179]

All this controversy came at a time when psychedelic use was not only rising among young people but also celebrities and the wealthy. By the 1960s, psycholytic LSD therapy was "routine practice" in wealthy areas of Los Angeles, such as Beverly Hills.[180] Celebrities such as Jack Nicholson, James Coburn, Lord Buckley, and Cary Grant

171. *Id*.
172. *Id*.
173. *Id*.
174. POLLAN, *supra* note 124, at 202.
175. Harvard University, *Timothy Leary*, *supra* note 167.
176. POLLAN, supra note 124, at 204.
177. *Id*.
178. *Id*. at 205.
179. *Id*. at 58.
180. *Id*. at 156.

had not only participated in, but gave interviews and/or wrote articles about, their experiences with psychedelics.[181] Additionally, artists such as Bob Dylan, Mick Jagger, John Lennon and the Beatles, and The Grateful Dead embraced psychedelics—and the band's experiences with the drugs influenced their works.[182]

Ultimately, the growing mainstream popularity of the drugs, in conjunction with the rising counterculture and opposition to the Vietnam War, overwhelmed the research community's fruitful and legitimate results. By the end of 1966, the FDA, pursuant to the Kefauver-Harris Amendments, had begun sending letters to psychedelic researchers across the U.S., ordering them to stop their work.[183] By 1970, psychedelics had become a "scientific embarrassment"—but not because of their scientific failure—because of their close association with the counterculture and disgraced scientists, like Timothy Leary.[184] The larger moral and cultural views of the country also turned on psychedelics, treating them as a pariah.

4. The Controlled Substances Act of 1970

The moral panic over the widespread use of psychedelics in the U.S. prompted President Nixon to launch the War on Drugs. In 1968, Congress passed the Staggers-Dodd Bill—an amendment to the Food, Drug and Cosmetic Act, which "increas[ed] the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs."[185] The Bill made possession of psychedelics like LSD, psilocybin, and psilocin illegal at the federal level.[186] Shortly after, the Controlled Substances Act of 1970 ("CSA")[187] was passed, which effectively terminated psychedelic research.

The CSA became effective on October 27, 1970 and was enacted to revamp drug laws in the U.S., providing that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people."[188] In doing so, the CSA acknowledged that "[m]any of the drugs included within this title

181. *Id*. at 156-57.

182. *Id*. at 114.

183. *Id*. at 217.

184. *Id*. at 58.

185. Pub. L. No. 90-639, 82 Stat. 1361 (1968).

186. *See id.* at "penalties 52 Stat 1040" (explaining that such drugs were illegal under the Federal Food, Drug and Cosmetic Act).

187. Comprehensive Drug Abuse Prevention and Control Act, Pub. L. No. 117-80, 84 Stat. 1236, codified at 21 U.S.C. §801 *et seq*.

188. §801(2).

have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."[189] To accommodate for medical use, the CSA defined and differentiated the substances it covered.

The CSA defined a controlled substance as "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title."[190] The aforementioned definition established the "scheduling system."[191] The CSA then establishes what drugs or compounds fall under each category.[192] The CSA made the possession, use, and sale of psilocybin, along with other psychedelics like LSD and peyote, illegal and placed them under Schedule I,

189. §801(1).

190. §802(6).

191. See § 812(b) reproduced below:

(1) SCHEDULE I.

(A) The drug or other substance has a *high potential for abuse*.

(B) The drug or other substance has *no currently accepted medical use* in treatment in the United States.

(C) There is a *lack of accepted safety* for use of the drug or other substance *under medical supervision*.

(2) SCHEDULE II.

(A) The drug or other substance has a *high potential for abuse*.

(B) The drug or other substance *has a currently accepted medical use* in treatment in the United States or a *currently accepted medical use with severe restrictions*.

(C) Abuse of the drug or other substances *may lead to severe psychological or physical dependence*.

(3) SCHEDULE III.

(A) The drug or other substance has *a potential for abuse less than the drugs or other substances in schedules I and II*.

(B) The drug or other substance *has a currently accepted medical use* in treatment in the United States.

(C) Abuse of the drug or other substance *may lead to moderate or low physical dependence or high psychological dependence*.

(4) SCHEDULE IV.

(A) The drug or other substance has a *low potential for abuse relative to the drugs or other substances in schedule III*.

(B) The drug or other substance *has a currently accepted medical use* in treatment in the United States.

(C) Abuse of the drug or other substance may lead to *limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III*.

(5) SCHEDULE V.

(A) The drug or other substance has a *low potential for abuse relative to the drugs or other substances in schedule IV*.

(B) The drug or other substance *has a currently accepted medical use* in treatment in the United States.

(C) Abuse of the drug or other substance *may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV*. (emphasis added).

192. *See* §812(c) (categorizing illicit compounds into Schedules I -V. Note, this provision is subject to a later amendment. *See also* §811.

meaning that they were deemed to present "*high potential for abuse*," have "*no currently accepted medical use*," and have a "*lack of accepted safety … under medical supervision.*"[193] Because of these determinations, the FDA halted research on psychedelics and clinical trials across the country, including studies which may have advanced psychedelics in the medical field, squashing the hope that psilocybin would become a useful treatment for various mental illnesses. In 1976, the last remaining psychedelic research program from the first wave officially closed.[194]

In 1973, shortly after Nixon officially declared the "War on Drugs," he used the CSA to create the Drug Enforcement Administration ("DEA"), which would serve as a special police force to enforce the enacted drug laws.[195] In doing so, the Attorney General was authorized to "coordinate all activities of executive branch departments and agencies which are directly related to the enforcement of laws respecting narcotics and dangerous drugs."[196] The CSA also granted the Attorney General the authority to "add to such a schedule or transfer between such schedules any drug or other substance."[197] The responsibility of investigating the scheduling and re-scheduling of substances was subsequently delegated to the DEA's Administrator.[198] Proceedings to have a drug added to, removed from, or transferred between schedules can be initiated by the DEA, the Department of

193. *See* §812(b)(1)(A)-(C) (explaining what constitutes a Schedule I drug).

194. POLLAN, *supra* note 124, at 218.

195. This was done by way of Reorganization Plan No. 2 of 1973, which merged the Office for Drug Abuse Law Enforcement and the Office of National Narcotics Intelligence together to form the DEA. *See e.g.*, EXECUTIVE ORDER NUMBER 11727 of July 6, 1973, 38 Fed. Reg. 18357 (Jul. 10, 1973); History.com Editors, *War on Drugs*, HISTORY.COM, (May 31, 2017) https://www.history.com/topics/crime/the-war-on-drugs.

196. EXECUTIVE ORDER NUMBER 11727 of July 6, 1973, 38 Fed. Reg. 18357 (Jul. 10, 1973). Within this scope of authority is the ability to regulate and handle applications from those who hope to conduct business with a scheduled substance—including manufacturing, researching, importing, exporting, and distributing. To apply, a DEA Form 225 needs to be completed and submitted, along with an application fee ranging from several hundred to several thousand dollars, pursuant to 21 CFR Ch. II, Pt. 1313. Information needed in the application includes the researchers' qualifications, research protocol, and institution where the research will take place, among other things. *See* DEP'T OF JUSTICE, DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., *DEA Form 225 - New Application for Registration* https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm (last accessed Apr. 6, 2022) (explaining the process).

197. 21 U.S.C. §811(a)(1).

198. *See e.g.*, 28 C.F.R. § 0.100 (1987); Ams. for Safe Access v. DEA, 706 F.3d 438, 439 (D.C. Cir. 2013) (stating the CSA allows the Attorney General to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. Pursuant to 21 U.S.C. § 811(a), the Attorney General has delegated this authority to the Drug Enforcement Administration Administrator); United States v. Gordon, 580 F.2d 827, 831 (5th Cir. 1978) *cert. denied*, 439 U.S. 1051 (1978) (affirming the district court's opinion that 21 U.S.C. § 801 et seq. does not unconstitutionally delegate power to define otherwise legal activity to the Attorney General, nor does it unconstitutionally sub-delegate such power to the DEA); 21 U.S.C. § 871(a).

Health and Human Services ("HHS"), or by petition from any interested party.[199]

In determining whether to schedule, re-schedule, or de-schedule a substance, the DEA is required to consult with the Secretary of the HHS, and the Secretary's recommendations as to "scientific and medical matters," including whether a drug or other substance should be controlled, are binding on the DEA.[200] However, if the Secretary does recommend that the drug be controlled, the Attorney General has the authority to initiate proceedings based on a determination of whether "the facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules."[201]

5. Renewed Interest in Psychedelic Research

Although the "War on Drugs" slowed in the mid-to-late 1970s, particularly during the four-year term of President Jimmy Carter, the "War" was reignited and expanded in the 1980s under President Ronald Regan.[202] In 1986, with the passage of the Anti-Drug Abuse Act,[203] drug enforcement laws were further strengthened through the introduction of mandatory minimum sentences for drug offenses.[204] This kept public interest in psychedelic research muted throughout the period, and funding for research projects was scarce due to the federal

199. *See* U.S. DRUG ENF'T ADMIN., *The Controlled Substances Act,* https://admin.dea.gov/drug-information/csa (last accessed March 31, 2022) (providing interested parties include the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen).

200. Pursuant to 21 U.S.C. §811(b), the DEA is required to "request from the Secretary (of HHS) a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance." The Secretary is then required to submit to the Attorney General their written recommendations, within a reasonable time, "with respect to the appropriate schedule, if any, under which such drug or other substance should be listed." The Secretary's recommendations are binding on the Attorney General as to "scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." *Id.*

201. *See* §811(b) and *See* §811(c) (listing the following important factors to be considered by the Secretary and the DEA when determining appropriate scheduling: (1) Its actual or relative potential for abuse; (2) Scientific evidence of its pharmacological effect, if known; (3) The state of current scientific knowledge regarding the drug or other substance; (4) Its history and current pattern of abuse; (5) The scope, duration, and significance of abuse; (6) What, if any, risk there is to the public health; (7) Its psychic or physiological dependence liability; (8) Whether the substance is an immediate precursor of a substance already controlled under this title).

202. History.com Editors, *supra* note 195.

203. Pub. L. No. 99-570, 100 Stat. 3207 (1986).

204. History.com Editors, *supra* note 195.

status of the substances.[205]

However, interest in psychedelics remained strong in some underground circles. In 1992, the National Institute on Drug Abuse worked with an FDA advisory committee and convinced officials to allow continued research into psychedelics.[206] Shortly after, in 1993, the Heffter Research Institute opened as a "scientific research organization dedicated to scientific research into the medical value of psychedelics, which particularly focused on the use of psilocybin."[207] Studies were then relaunched across the country at high-profile schools like the University of California Los Angeles, University of New Mexico, Johns Hopkins University, and New York University to study the use of psilocybin as a potential treatment for disorders such as OCD, substance abuse, depression, and anxiety.[208]

Additionally, in the early 1990s, the Multidisciplinary Association for Psychedelic Studies (MAPS)[209] gained FDA approval to begin testing another psychedelic, Methylenedioxymethamphetamine ("MDMA"), to treat mental illness.[210] Private funding from donors, as well as sources like the Heffter Research Institute and MAPS, is mainly responsible for funding studies involving psychedelics, as public funding is unlikely due to psychedelics' Schedule I status.[211] Regardless, the difficulties in designing, funding, and conducting clinical trials to study psychedelics in medical treatment have not tempered interest. As mentioned in Part III-A(3), there are now hundreds of completed and active clinical trials involving psilocybin and other psychedelic compounds.

6. Legal and Governmental Developments

Following the revival of psychedelic research, support from the legal community and the public began to mount for limiting or removing restrictions on drugs that had been banned under the CSA.

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205. Daniel & Haberman, *supra* note 137, at 25.

206. *Id*.

207. David E. Nichols, *The Heffter Research Institute: Past and Hopeful Future*, *46*(1) *Journal of Psychoactive Drugs* 20, 20 (2014).

208. *Id*.

209. MAPS was founded in 1986, and it is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts so as to benefit people from the careful uses of psychedelics and marijuana. For more information on MAPS see https://maps.org/about.

210. Greg Ferenstein, *Psychedelics and Mental Health Care – What Policymakers Need to Know*, NISKANEN CTR. (May 22, 2020), https://www.niskanencenter.org/psychedelics-and-mental-health-care-what-policymakers-need-to-know/.

211. *History of Psychedelic Law*, MR. PSYCHEDELIC LAW, https://www.mrpsychedeliclaw.com/history/ (last visited March 31, 2022).

i. Legal Developments

One of the first developments in the legal community aimed at loosening restrictions on scheduled drugs stemmed from the 1990 U.S. Supreme Court decision *Employment Div., Dep't of Human Res. v. Smith*.[212] In *Smith*, the Court answered whether the Free Exercise Clause of the First Amendment is violated when a state withholds unemployment benefits from persons who had been fired from their jobs for using controlled substances in religious ceremonies.[213] In the case, respondents were members of the Native American Church and ingested peyote, a Schedule I psychedelic substance, as part of a religious ceremony, and they were fired from their jobs at a private drug rehabilitation center as a result.[214] Upon their firing, respondents applied for unemployment benefits and were denied because being discharged for prohibited drug use constituted "work connected misconduct."[215]

While the Supreme Court of Oregon ruled in favor of the respondents, finding that state prohibitions on the religious use of peyote was a violation of the Free Exercise Clause of the U.S. Constitution, the petitioners successfully appealed to the Supreme Court of the United States. There, the Court held that a state could withhold unemployment benefits from an employee who had been fired for testing positive for a controlled substance, if such conduct was a violation of a constitutional state law.[216] The Court emphasized that "[they] have never held that an individual's religious beliefs can excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate."[217]

Subsequently, in response to the holding in *Smith*, Congress passed legislation[218] which extended a regulatory exemption for peyote use—which had previously been in place for the Native American Church–to all members of every recognized Indian Tribe.[219] This legislation established that "the use, possession, or transportation of peyote by an Indian for bona fide traditional ceremonial purposes" was lawful and not to be prohibited so long as it was "in connection with the practice of a traditional Indian religion."[220]

212. Emp't Div., Dep't of Human Res. v. Smith, 494 U.S. 872 (1990).
213. *Id*. at 874.
214. *Id*.
215. *Id*.
216. *Id*. at 890.
217. *Id*. at 878-79.
218. 21 C.F.R. §1307.31 (1973).
219. 42 U.S.C. §1996a.
220. §1996a(b)(1). Congress felt the need to enact such a law because lawmakers were concerned

Also following the holding in *Smith*, Congress passed the Religious Freedom Restoration Act of 1993 ("RFRA"), which extended stronger federal free exercise protections.[221] A decade following enactment of the RFRA, another case involving the religious use of a Schedule I psychedelic substance came to the Supreme Court—*Gonzales v. O Centro Espirita Beneficente Unaio do Vegetal*, which involved the UDV Church, a Christian sect who used the sacramental tea *hoasca*, containing the Schedule I substance DMT, for communion.[222]

In 1999, U.S. Customs intercepted a shipment to UDV that contained three drums of *hoasca*,[223] seized the shipment, and then threatened UDV with prosecution.[224] UDV filed suit against the U.S. Attorney General and other federal agencies, alleging that applying the CSA against them violated the RFRA.[225] The Government argued that, despite substantially burdening a sincere religious exercise, enforcing the CSA was the least restrictive means of achieving the compelling governmental interests of protecting the health and safety of UDV members and preventing the diversion of *hoasca* for recreational use.[226] In fact, the Government argued that the CSA on its own "serves a compelling purpose and simply admits of no exceptions," so there was no need to assess the particulars of UDV's usage or weigh the impact of an exception.[227]

The Court ultimately ruled in favor of UDV, holding that the Government failed to demonstrate a compelling interest in barring the UDV's sacramental use of *hoasca*.[228] To support the view that exceptions were permissible, the Court analyzed the CSA itself, which "contains a provision authorizing the Attorney General to 'waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and

that only 28 states had enacted their own laws similar to the existing federal protections of peyote use, and that the ruling in *Employment Division v. Smith* held that the First Amendment didn't protect Native American practitioners who use peyote in religious ceremonies in those states. *See* §1996a(a) (providing Congressional findings and declarations for legalizing peyote use among those engaging in ceremonial purposes connected to a traditional Indian religion).

221. Pub. L. No. 103-141, § 2, 107 Stat. 1488 (1993) (codified as 42 U.S.C. §§ 2000bb *et seq*.).

222. 546 U.S. 418, 425 (2006).

223. Hoasca is a tea brewed from two plants that grow in the Amazon River Basin, which contains DMT and is used for its hallucinogenic effects during religious ceremonies. *Id.* at 418.

224. *Id*.

225. *Id.* at 425-26.

226. *Id*. at 426. Note: the government also argued it was necessary to comply with the 1971 United Nations Convention on Psychotropic Substances, a treaty signed by the U.S. in 1971, but the Court stated that the treaty did not apply to *hoasca.*

227. *Id*. at 430.

228. *Id*. at 439.

safety.'"[229] The Court also cited other exceptions already made for Schedule I bans for religious use, such as the exceptions for peyote discussed above, which "fatally undermine[d]" the Government's broader arguments.[230] These decisions, and the legislative measures that stemmed from them, slowly began to open the door for expanded uses of Schedule I substances for legitimate purposes—and coincided with the renewal of psychedelic research in the 1990s and 2000s.

ii. Governmental Developments

Recently, U.S. government agencies have indicated that they would be willing to loosen restrictions on psilocybin and other psychedelics to allow continued research into their potential role in treating mental illness. In 2017, researchers Roland Griffiths and Stephen Ross showed the FDA results from their clinical trial using psilocybin for end-of-life anxiety in cancer patients. The FDA was impressed enough to request that Griffiths and Ross expand their focus to include the study of psilocybin to treat depression.[231] Regulators felt that the data contained a strong enough "signal" that psilocybin could treat depression, concluding it would be a shame to ignore its potential given the current need for treatment and limitations associated with current treatment options.[232]

In January 2018, the DEA decided to streamline the application process for researchers hoping to study Schedule I substances that were not currently approved for medical use.[233] Then-acting DEA Administrator Robert W. Patterson stated in a press release, "[the DEA is] committed to finding new and innovative ways to meet the needs of the research community," and that "[r]esearch is the bedrock of science, and we will—as we have for many years—continue to support and promote legitimate research with Schedule I controlled substances."[234] The DEA also noted that, as of December 2017, more than 590 researchers had registered with the DEA to study Schedule I substances, and "every researcher who has submitted a valid research proposal has been approved."[235] Further, they acknowledged that researchers often conduct multiple studies, so the number of approved

229. *Id*. at 432.

230. *Id*. at 433-34.

231. POLLAN, *supra* note 124, at 375.

232. *Id*.

233. U.S. DRUG ENF'T ADMIN., *DEA Speeds Up Application Process For Research On Schedule I Drugs* (January 18, 2018), https://www.dea.gov/press-releases/2018/01/18/dea-speeds-application-process-research-schedule-i-drugs.

234. *Id*.

235. *Id*.

studies was larger than the 590 approved researchers.[236]

Finally, in 2018,[237] and then again in 2019,[238] the FDA extended a "Breakthrough Therapy" designation to several clinical trials of psilocybin. The FDA defines the Breakthrough Therapy designation as:

> a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).[239]

Granting several psilocybin trials this designation suggests that the government is becoming more amendable to the idea of using psilocybin to treat mental illness.

7. Localized Support and Initiatives

In addition to developments in the law and government, data suggests the greater public has also grown to accept psychedelic substances as a potential treatment for mental illness and would like to see the "War on Drugs" come to an end. The 2019 Welfare, Work, and Wealth National Survey, conducted by the Cato Institute, found that 55% of Americans favored decriminalizing drugs, defined as "recategorizing drug offenses from felonies to civil offenses," which means drug offenses would be addressed through tickets and fines rather than arrests and incarceration.[240] A breakdown of the polling across political lines shows strong bipartisan support for decriminalizing drug offenses, as seen in Figure 8 below.[241]

236. *Id*.

237. Rich Haridy, *Psychedelic psilocybin therapy for depression granted Breakthrough Therapy status by FDA*, NEW ATLAS (October 24, 2018), https://perma.cc/F63T-YNER.

238. Yasemin Saplakoglu, *FDA Calls Psychedelic Psilocybin a 'Breakthrough Therapy' for Severe Depression*, LIVESCIENCE (November 25, 2019), https://perma.cc/UVG2-DHDD.

239. U.S. FOOD & DRUG ADMIN., *Breakthrough Therapy*, (January 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy.

240. Emily Ekins, *Poll: 55% of Americans Favor Decriminalizing Drugs*, CATO INSTITUTE (October 2, 2019, 9:15 AM), https://perma.cc/S4E9-MLQA.

241. *Id*.

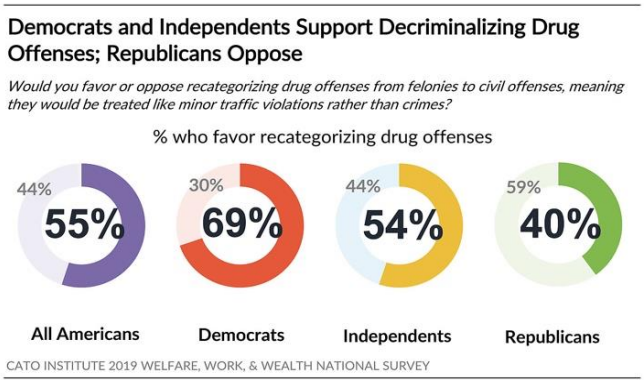

Figure 8

In addition, members of the public have proposed ballot initiatives at the state and local levels to either decriminalize the possession of controlled substances such as psilocybin or decriminalize the supervised use of psilocybin with a licensed professional in a therapeutic setting.[242]

i. State Ballot Initiatives

On November 3, 2020, voters in Oregon approved Oregon Measure 109, Psilocybin Mushroom Services Program Initiative, which authorizes the Oregon Health Authority to create a program to permit licensed service providers to utilize psilocybin and other fungi products to treat individuals aged 21 or older for a variety of mental illnesses.[243] Over 2 million voters participated in the election, and the measure passed with 55.75% in favor and 44.25% opposed.[244] Also on November 3, 2020, voters in Washington, D.C. approved Initiative 81, the Entheogenic Plants and Fungus Measure, which required police to treat the non-commercial cultivation, distribution, possession, and use of entheogenic plants[245] and fungi as falling within the lowest level of law enforcement priorities.[246] Nearly 220,000 residents voted on the

242. Jessica Callahan & Michelle Kirby, *Legal Status of Psychedelic Drugs and Research Involving Possible Medical Uses* at 1, CONN. OFF. OF LEG. RSCH. (Dec. 15, 2020).

243. *Id.*

244. *Oregon Measure 109, Psilocybin Mushroom Services Program Initiative (2020)*, BALLOTPEDIA, https://perma.cc/CQ86-E8CZ (last visited Apr. 6, 2022).

245. Entheogenic plants and fungi are defined in the initiative as "species of plants and fungi that contain ibogaine, dimethyltryptamine, mescaline, psilocybin, or psilocyn." *See* Callahan & Kirby, *supra* note 242, at 3; *Washington, D.C., Initiative 81*, *infra* note 247.

246. Callahan & Kirby, *supra* note 242, at 3.

initiative, which passed with 76.18% in favor and 23.82% opposed.[247]

In addition to the ballot measures which have passed in Oregon and Washington D.C., bills have also been introduced in New York and Iowa to remove psilocybin from Schedule I status under those respective states' laws.[248] Additionally, a legislator in Iowa introduced HF 249, which would allow the use of psilocybin, MDMA, and other psychedelics for medical treatment when used under rules approved by the state pharmacy board.[249] Several other state legislatures, such as New Jersey, Vermont, and California, have seen similar bills introduced aimed at decriminalizing psilocybin and other psychedelics.

ii. Municipality Ordinances

Denver was the first city to pass a local ordinance decriminalizing the possession and use of psilocybin mushrooms when voters approved Initiated Ordinance 301: Denver Psilocybin Mushroom Initiative ("I-301") on May 7, 2019 by a narrow margin of 50.64% in favor and 49.36% opposed.[250] The stated purpose of the initiative was to deprioritize the imposition of criminal penalties for the possession of psilocybin and prohibit the city and county from expending resources on the imposition of criminal penalties.[251]

The ballot initiative also provided for the creation of an 11-member Psilocybin Mushroom Policy Review Panel to assess effectiveness of the ordinance in its ability to reduce arrests and prosecutions while maintaining the safety of local residents, which included representation from organizations such as the Denver City Counsel, local law enforcement agencies, the District Attorney's office, and others.[252]

In 2019, shortly after Denver voters passed I-301, the Oakland City Council voted unanimously to decriminalize psilocybin mushrooms, ayahuasca, iboga, and psychoactive cacti through Resolution 87731.[253]

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247. *Washington, D.C., Initiative 81, Entheogenic Plants and Fungus Measure (2020)*, BALLOTPEDIA, https://perma.cc/7FLA-CR3W (last visited Apr. 6, 2022).

248. Callahan & Kirby, *supra* note 242, at 1.

249. *Id*.

250. *Denver, Colorado, Initiated Ordinance 301, Psilocybin Mushroom Initiative (May 2019)*, BALLOTPEDIA, https://perma.cc/C6W2-CYJZ (last visited Apr. 6, 2022).

251. *Id*. Specifically, "(1) deprioritize, to the greatest extent possible, imposition of criminal penalties on persons twenty-one (21) years of age and older for the personal use and personal possession of psilocybin mushrooms; and (2) prohibit the City and County of Denver from spending resources on imposing criminal penalties on persons twenty-one (21) years of age and older for the personal use and personal possession of psilocybin mushrooms. *Id.*

252. *Id*.

253. Leah Asmelash & Saeed Ahmed, *Oakland Residents Won't be Busted for Using 'Magic*

In January, 2020, the Santa Cruz City Council voted unanimously to decriminalize the possession and use of psychoactive plants and fungi by adults over the age of 21—provided the use was personal and not commercial.[254] In September 2020, the Ann Arbor City Council voted unanimously to decriminalize psilocybin and other psychedelics by making the "planting, cultivating, buying, transporting, distributing, engaging in practices with or possessing 'entheogenic plants' or plant compounds" the lowest priority for law enforcement.[255] In 2021, several more localities passed decriminalization initiatives, including Washtenaw County, Michigan[256] and Cambridge, Massachusetts.[257]

B. Future Obstacles For Psychedelics

As discussed above, there is growing support in the U.S. for using psilocybin and other psychedelics to treat mental illness. However, because of the current legal obstacles in their path—the FDA, the DEA, the United Nations Convention on Psychotropic Substances, and the threat of public backlash—it is unclear when psychedelics may be ready for clinical implementation.

1. The FDA Process

First, it takes a long time for treatments to gain FDA approval. The approval process includes four main phases. The first three phases occur before a drug or treatment gains approval. Phase 1 focuses on establishing a drug's safety profile, Phase 2 assesses the drug's effectiveness and side effects compared to a placebo with a small set of volunteers, and Phase 3 examines effectiveness and side effects on a large scale while examining different dosages of the drug rather than as against a placebo.[258] It typically takes around six years on average

Mushrooms' and Other Psychedelic Drugs, CNN (June 5, 2019, 5:51 PM), https://www.cnn.com /2019/06/05/health/oakland-decriminalizes-magic-mushrooms-trnd/index.html.

254. Harmeet Kaur, *Santa Cruz Decriminalizes Magic Mushrooms and Other Natural Psychedelics, Making it the Third US City to Take Such a Step*, CNN (February 3, 2020, 7:50 PM), https://www.cnn.com/2020/01/30/us/santa-cruz-mushrooms-psychedelics-trnd/index.html.

255. Associated Press, *Ann Arbor Decriminalizes Magic Mushrooms, Psychedelic Plants*. U.S. NEWS & WORLD REPORT, (2020, September 26, 2020 10:57 AM) https://www.usnews.com/news/best-states/michigan/articles/2020-09-26/ann-arbor-decriminalizes-magic-mushrooms-psychedelic-plants.

256. Jerilyn Jordan, *Washtenaw County Says Cases Involving Natural Psychedelics Will No Longer Be Charged*, DETROIT METRO TIMES (Jan. 12, 2021, 12:39pm), https://perma.cc/JU4V-KBPM.

257. Marc Levy, *War on Use of Mushrooms, Cacti, Ayahuasca Has Been Called Off in Cambridge by Council Order*, CAMBRIDGE DAY (Feb. 4, 2021), https://perma.cc/S365-Y3GE.

258. Leigh Ann Anderson, *FDA Drug Approval Process*, DRUGS.COM (April 13, 2020), https://perma.cc/V9C2-HED6.

Phase 1: About 20 to 80 healthy volunteers to establish a drug's safety and profile, and takes about

for a treatment to pass the first three stages of testing. Once these phases are complete, and the data shows the treatment has enough potential, then the FDA Advisory Board may grant the treatment final approval.[259]

Once a treatment is approved by the FDA Advisory Board, it becomes available for physicians and patients. In Phase 4, post-marketing studies are then conducted in the real-world setting to monitor for previously undetected side-effects as well as the treatment's effectiveness.[260] Because many psilocybin and psychedelic trials are currently in Phase 1 or 2, it could likely be another 4-6 years before the treatments are ready for FDA approval—even those that have been granted a "Breakthrough Therapy" designation and are eligible for accelerated approval.

Additionally, even if a treatment gains FDA approval, that does not mean it can quickly and easily be introduced to the marketplace. Obstacles such as patent disputes, manufacturing or sourcing issues, and controlled substance scheduling can nevertheless stand in the way of a treatment achieving widespread use.[261]

2. The DEA

Second, psilocybin's and other psychedelics' Schedule I status means they are still illegal under federal law—no matter how many states decriminalize or legalize their use. The DEA could therefore raid a facility performing a treatment with psychedelics and seize all the substances in its possession, regardless of whether it is legal in the state in which the facility was located. In fact, during the wave of states legalizing medical marijuana, the DEA received significant criticism for taking a particularly strong stance on enforcing the CSA. The DEA raided dispensaries in California, most notably in Santa Cruz[262] and

1 year. Safety, metabolism and excretion of the drug are also emphasized.

Phase 2: Roughly 100 to 300 patient volunteers to assess the drug's effectiveness in those with a specific condition or disease. This phase runs about 2 years. Groups of similar patients may receive the actual drug compared to a placebo (inactive pill) or other active drug to determine if the drug has an effect. Safety and side effects are reviewed.

Phase 3: Typically, several thousand patients are monitored in clinics and hospitals to carefully determine effectiveness and identify further side effects. Different types and age ranges of patients are evaluated. The manufacturer may look at different doses as well as the experimental drug in combination with other treatments. This phase runs about 3 years on average.

259. *Id*.

260. *Id*.

261. *Id*.

262. Maria Alicia Gaura, *Santa Cruz Officials Fume Over Medical Pot Club Bust / DEA Arrests Founders, Confiscates Plants*, SFGATE.COM (Sept. 6, 2002), https://perma.cc/3A59-RYB5.

Los Angeles.[263] Then-acting Administrator for the DEA, Chuck Rosenberg, called medical marijuana a "joke" and stated that the DEA would not consider rescheduling marijuana to allow for more comprehensive research.[264]

In response to the DEA's hostility toward medical marijuana, the ACLU sued the DEA over the raid of the Santa Cruz dispensary. In *County of Santa Cruz v. Gonzalez*, the United States District Court for the Northern District of California denied the DEA's motion to dismiss the case.[265] The Court cited *Conant v. Walters*, a case from the United States Court of Appeals for the Ninth Circuit, where Chief Judge Alex Kozinski stated in a concurring opinion that "applied to our situation…much as the federal government may prefer that California keep medical marijuana illegal, it cannot force the state to do so."[266]

The DEA has also faced criticism over its persistent refusal to reschedule marijuana. In 2014, MAPS and the Drug Policy Alliance ("DPA") co-published a report, which criticized the DEA's refusal to reschedule marijuana and claimed they were actively subverting the rescheduling process.[267] MAPS and DPA claimed that the report "reveal[ed] a number of DEA practices that maintain the existing, scientifically unsupported drug scheduling system and obstruct research that might alter current drug schedules" while "fail[ing] to act in a timely fashion when confronted with evidence for scheduling certain drugs less severely."[268] Despite the negative attention from organizations such as MAPS and DPA, as well as proposed legislation from prominent politicians such as Senators Elizabeth Warren (D), Cory Gardner (R), and Chuck Schumer (D), which aimed to protect residents in legalized marijuana states from federal seizures, as of 2021, the DEA has maintained its refusal to re-schedule marijuana.[269]

263. Tami Abdollah, *DEA Raids Marijuana Outlets*, L.A. TIMES (Jan. 18, 2007, 12 AM), https://perma.cc/64XB-YSSF.

264. Tim Devaney, *Marijuana Supporters Petition White House to Fire DEA Chief*, THE HILL (Nov. 10, 2015, 3:17 PM), https://perma.cc/HTP9-KCAP.

265. AM. CIV. LIBERTIES UNION, PRESS RELEASE, *Federal Court Rules U.S. Government May Not Deliberately Subvert California's Medical Marijuana Laws* (Aug. 20, 2008), https://perma.cc/63EN-QWUG. *See also* County of Santa Cruz, et al. v. Alberto Gonzalez, et al., Case 5:03-cv-01802-JF, Doc. No. 186, Unpublished Order (N.D. Cal. San Jose Division 2008) *available at*: https://www.aclu.org/legal-document/santa-cruz-v-mukasey-order-denying-government-motion-dismiss?redirect=cpredirect/36494.

266. *Id*. *See also* Conant v. Walters, 309 F.3d 629, 645 (9th Cir. 2002).

267. *The DEA: Four Decades of Impeding and Rejecting Science*, DRUG POL. ALL. 1 (June 8, 2014).

268. *Id*. at 2. Full report can be found at: https://drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf.

269. Tony Newman & Jolene Forman, *U.S. Senators Elizabeth Warren and Cory Gardner Announce Landmark Bipartisan Bill to Protect States' Rights to Legalize Marijuana*, DRUG POL. ALL. (June 7, 2018), https://perma.cc/YW5Y-YM7N .

Thus, even if psilocybin were to receive FDA approval for treating mental illnesses, such as depression and anxiety, it could be met with DEA resistance. DEA resistance could make it difficult for physicians across the country to use psilocybin for treatment on a larger scale.

3. The Convention on Psychotropic Substances

Third, another potential obstacle to rescheduling psilocybin is that the U.S. was a signatory to the United Nations treaty at the Convention on Psychotropic Substances ("Convention") in Vienna, Austria on February 21, 1971.[270] According to the CSA:

> If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) [21 USCS § 812(b)] and without regard to the procedures prescribed by subsections (a) and (b) of this section.[271]

To date, psilocybin is still listed as a Schedule I drug under the Convention, although there is slightly more flexibility allowed under the Convention than the CSA.

For instance, Article 7 of the Convention states that Schedule I substances should be prohibited for all uses "except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them."[272] This provides greater flexibility than the CSA, which prohibits any use of Schedule I substances because they are deemed to have "no accepted medical use" by definition.

Additionally, the official *Commentary on the Convention on the Psychotropic Substances* highlights that while psychedelic compounds are classified as Schedule I, the natural material (plant, fungi, etc.) is not meant to be included in the scheduling. Commentary 32-12 states:

> Schedule I does not list any of the *natural hallucinogenic materials* in question, but only chemical substances which constitute the active principles contained in them. The inclusion in Schedule I of the active principle of a substance does not mean that the substance itself is also included therein if it is a substance clearly distinct from the substance constituting its active principle. This view is in accordance with the

270. Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 [hereinafter Convention].

271. 21 U.S.C. §811(d)(1).

272. Convention, *supra* note 270, at art. 7(a).

> traditional understanding of that question in the field of international drug control.[273]

In other words, the actual mushrooms, which contain psilocybin, as well as "preparations" of those mushrooms, such as tea, are not covered under the scheduling—only the chemical compound psilocybin is covered. This position was reiterated in a 2001 letter from Herbert Schaepe, Secretary of the United Nations International Narcotics Control Board, which stated "[a]s a matter of international law, no plants (natural material) containing psilocin and psilocybin are at present controlled under the Convention on Psychotropic Substances of 1971. Consequently, preparations made of these plants[274] are not under international control and, therefore, not subject of the articles of the 1971 Convention."[275]

As made evident by Mr. Schaepe's statements, the compound psilocybin, and any synthesized versions of the compound, would be covered under the Convention's Schedule I designation—but not psilocybin mushrooms. Therefore, pursuant to the Convention, the U.S. has no obligations to designate plants or fungi containing psychedelic compounds as Schedule I substances. Unfortunately, most studies and trials use a synthetic version of the compound, which means that the government is likely to err on the side of caution when handling the scheduling of psilocybin under the auspices of its Convention obligations. In fact, the government relied on the Convention obligations under the CSA when arguing their case in *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, even though the substance at issue in that case was tea made from a natural plant—and thus clearly fell under the exception.[276]

4. A Second Moral Panic

Finally, a potential obstacle to the widespread acceptance of psilocybin and other psychedelics as treatment options for mental illness stems from the growing number of state and municipality measures passed in the absence of meaningful federal action. Local ordinances, such as those in Washington D.C., Denver, Oakland, and

273. Commentary on the Convention on Psychotropic Substances, U.N. Doc. E/CN.7/589, at 387 (1976).

274. Preparations refers to by-products of the natural plants, such as teas.

275. U.N. Int'l Narcotics Control Bd., Letter dated Sept. 13, 2001 *from* the Secretary of the Board *to* the Netherlands Chief Inspectorate for Health Care, *available at* https://www.erowid.org/plants/mushrooms/mushrooms_law12.pdf.

276. Defendant's Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction at 16, O Centro Espirita Beneficiente Uniao do Vegetal v. Ashcroft, 389 F.3d 973 (10th Cir. 2004) (No. 04-1084). (Citing Convention obligations under 21 USCS §811(d)(1)).

Santa Cruz, all allow for the decriminalization of psilocybin regardless of how it is used. By states and municipalities moving too quickly to decriminalize or legalize the compounds before proper research and regulatory guidelines can be completed, they run the risk of igniting a second moral panic that could once again place psychedelic compounds in the government's crosshairs.

Any adverse reactions or fatalities stemming from improper or unsupervised use of psychedelics could paint the substances in a negative light and lead to an overstating of their dangerousness, similar to what occurred in the 1960s and 1970s. Psychedelics have numerous areas in which they could be useful, even outside the medical realm, such as for religious, spiritual, and creative purposes. However, if widespread psychedelic use grows outside the medical community, more people may associate it with these nonmedical uses. Thus, if non-medical uses of psilocybin become embroiled in a scandal or controversy, all other potential areas of application could suffer the consequences.

IV. DISCUSSION

As discussed above, psilocybin and other psychedelics have garnered a negative reputation in the U.S. over the past four to five decades. However, this reputation has been largely unjustified, and the acrimony towards these substances is misplaced. Psilocybin and other psychedelics have the potential to provide people immense value, so long as the federal government can ease restrictions on the substances without violating its international obligations.

Two specific areas where psilocybin could provide benefits to Americans, which have a close connection to the mental health crisis plaguing the nation, are the use of psilocybin as a medical treatment and as a tool for religion and spirituality.

A. Psilocybin as a Medical Treatment

As discussed at length in this Article, citizens in the U.S. are suffering in mass from mental illness. Recall from Part II-A(1), 1-in-5 Americans suffer from a mental illness every year, suicide rates have increased 35% over the past two decades—with new figures expected to worsen following the prolonged COVID-19 pandemic—and mental illness is estimated to cause $193.2 billion in lost earnings across the U.S. economy each year. Making matters worse, many of the current treatment options available to those suffering are, unfortunately, insufficient to properly address the crisis.

However, a growing body of research has shown psilocybin's potential efficacy in treating many of the most common mental illnesses Americans suffer from today, such as depression and anxiety. Over the past decade, hundreds of clinical trials have explored whether psilocybin-assisted therapy could effectively treat various mental illnesses, and the results have been promising. Recall the pilot study from Part II-D(3), published in 2016, which found two sessions of psilocybin-assisted therapy, spaced seven days apart, resulted in significantly reduced depressive symptoms lasting at least three months after the treatment as well as similar improvements in anxiety.[277] Further, a follow-up study at Johns Hopkins University found similar results, with anti-depressive effects remaining with many participants for at least a full-year.[278] At a time when many Americans are struggling with mental illness and frustrated with ineffective treatments, psilocybin could show promise as a new treatment option to help address the mental health crisis in the U.S.

Unfortunately, current Schedule I regulations of psilocybin, such as restrictions on manufacturing as well as possession and use of the substance, make it difficult to study.[279] Not only is the supply of psilocybin for research purposes limited, but under this regulatory framework, it is difficult for universities to obtain federal grants to fund the projects, forcing researchers to rely on private sources of funding to conduct the studies. In fact, in October 2021, Johns Hopkins University was awarded a federal research grant to study psilocybin's potential as a smoking cessation treatment, which marked the first federal grant for psychedelic medical research in 50 years.[280]

If the federal government were to ultimately re-schedule psilocybin, removing it from Schedule I status, then these obstacles would be substantially lessened and research could begin in earnest, potentially

277. Gill, *supra* note 63, at 1266.

278. *See* Natalie Gukasyan et al., *Efficacy and Safety of Psilocybin-Assisted Treatment for Major Depressive Disorder: Prospective 12-month Follow-Up*, 36(2) J. OF PSYCHOPHARMACOLOGY 151, 157 (2022) (concluding "[t]he results of this long-term follow-up of participants who were not blinded to the drug condition suggest that psilocybin-assisted treatment for MDD produces large and stable antidepressant effects throughout at least 12 months after treatment." No participants experienced serious adverse effects or exacerbation of depressive symptoms).

279. *See* 21 U.S.C. § 826(1) (requiring the Attorney General to "establish production quotas for each basic class of controlled substance in Schedules I and II … to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks"); *See also* Advanced Integrative Med. Sci. Inst., PLLC v. Garland, No. 21-70544, 2022 U.S. App. LEXIS 2718, at *10 (9th Cir. Jan. 31, 2022) (reasoning "[b]ecause substances in Schedule I are deemed to have no accepted medical use under the CSA, they can be produced, dispensed or possessed only in the context of research, and this research requires a special registration"); U.S.C. 21 C.F.R. §§ 1301.18, 1301.32.

280. *Johns Hopkins Medicine Receives First Federal Grant for Psychedelic Treatment Research in 50 years*, JOHNS HOPKINS MED. (Oct. 18, 2021), https://perma.cc/RMZ7-E6FX.

leading to widescale implementation of psilocybin-assisted treatment.

B. Psilocybin as a Tool for Religion and Spirituality

Clinical treatment for mental illness is not the only method in which psilocybin could help alleviate the mental health crisis in the U.S. Religion and spirituality have been shown to have a positive impact on mental health.[281] Religion can have a positive impact on mental health by providing people with a feeling of purpose in life, a sense of structure, and oftentimes, a group of people to connect with over similar beliefs.[282] Similarly, spirituality can have a positive impact on mental health by providing people with a sense of connection to something bigger than oneself.[283] In support of these findings, research has suggested that religious beliefs and spirituality practices can be beneficial for coping with stress and one's mental health generally.[284]

Psilocybin and other psychedelics have long been associated with spirituality and religion. Many notable advocates of psilocybin, both historical and modern, acknowledge the spiritual benefits they derive from its usage. Recall from Part III-A(3) that the first experiment conducted by Timothy Leary and Richard Alpert at the Harvard Psilocybin Project was aimed at documenting psilocybin's effects on human consciousness.[285] And following his termination from Harvard, Mr. Alpert changed his name to Ram Dass and embarked on a spiritual journey to the East—ultimately writing a book titled *Be Here Now*, which was described as a "modern spiritual classic."[286]

Even the modern renaissance of psilocybin research has included religion and spirituality as a potential application. The landmark 2006 study that sparked the widespread renewal of interest in psychedelic research, conducted by Dr. Griffiths at Johns Hopkins, was intended to explore whether psilocybin-induced mystical-type experiences could provide substantial and sustained personal meaning and spiritual significance.[287] The study's abstract stated that while psilocybin had been used for centuries for religious purposes, little was known about

281. Luna Greenstein, *The Mental Health Benefits of Religion & Spirituality*, NAMI.ORG: BLOG (Dec. 21, 2016), https://perma.cc/M2VQ-FKC8.

282. *Id*.

283. *Id*.

284. Abraham Vergehese, *Spirituality and Mental Health*, 50(4) INDIAN J. OF PSYCHIATRY 233 (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2755140/.

285. Harvard University, *Timothy Leary*, *supra* note 167.

286. *Id.*

287. R. R. Griffiths et al., *Psilocybin Can Occasion Mystical-Type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance,* 187 PSYCHOPHARMACOLOGY 268 (2006).

the acute and persisting effects from a scientific standpoint.[288] The study recruited adult volunteers who considered themselves to be spiritually or religiously active, and the results were illuminating—volunteers "rated the psilocybin experience as having substantial personal meaning and spiritual significance and attributed to the experience sustained positive changes in attitudes and behavior consistent with changes rated by community observers."[289]

The idea of psilocybin or other psychedelics as a tool for religious or spiritual practices would not be novel to the legal world, either. As discussed in Part III-A(7), the Supreme Court granted an exemption to the CSA in *Gonzales v. O Centro Espirita Beneficente Unaio do Vegetal*, holding that the state could not show a compelling interest sufficient to prevent the UDV church from using *hoasca* (a tea which contains the Schedule I substance DMT) as part of their religious exercise under the RFRA. The United States District Court for the District of Oregon later cited to this case in its decision to allow members of the Brazilian Santo Daime religion to import and consume ayahuasca as part of their religious ceremonies, subject to certain reasonable restrictions.[290]

If the federal government were to reschedule psilocybin to a lower level, such as Schedule III, IV or V, it could be used more freely for religious and spiritual purposes, which could also help alleviate the mental health crisis in the U.S.

V. RECOMMENDATION

Federal action is key to expanding access to psilocybin because any conflicting state law, enacted to reschedule psilocybin under the state's own regulatory legal framework, would be in direct conflict with the CSA and run afoul of the Supremacy Clause.[291] Further, as discussed in Part III-B(2) regarding marijuana, while the federal government has allowed states the leeway to craft their own laws regarding marijuana legalization, this does not mean it will abstain from enforcing federal law within those states.

288. *Id*. at 268.

289. *Id*.

290. Church of the Holy Light of the Queen v. Mukasey, 615 F. Supp. 2d 1210, 1214, 1220-1221 (D. Or. 2009) (The court's original injunction was *vacated* in Church of the Holy Light of the Queen v. Holder, 443 Fed. App'x. 302, 303 (9th Cir. 2011) and remanded with instructions to "fashion an injunction limited in scope to its conclusion that the government failed to show that its interests justify prohibiting outright the Church's importation of Daime tea solely for use at Church ceremonies." On remand, the District Court issued a one-sentence injunction, stating "Defendants are enjoined from prohibiting plaintiffs' importation, storage, distribution, and use of Daime tea for plaintiffs' religious ceremonies.").

291. U.S. Const. art. VI, cl. 2.

Additionally, local and statewide initiatives to decriminalize the possession and use of psilocybin are not a permanent fix to the conflict of law issue. Decriminalization initiatives do not run afoul of the Supremacy Clause because they do not alter the regulation of psilocybin but rather leave enforcement of drug laws mainly in the federal government's hands. However, because enforcement is left to federal authorities, those who use or possess psilocybin within these jurisdictions still face the threat of arrest and prosecution. Further, decriminalization does not address the main crux of the issue—federal regulation and enforcement severely limits the production and distribution of psilocybin and makes widespread research and implementation of psychedelic treatments for mental illnesses extremely difficult.

Rescheduling psilocybin would be complicated at the federal level due to the U.S.'s status as a signatory to the Convention on Psychotropic Substances ("Convention"), as discussed in Part III-A(3). According to the CSA:

> *If control is required by United States obligations under international treaties, conventions*, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems *most appropriate to carry out such obligations*, without regard to the findings required by subsection (a) of this section or [21 USCS § 812(b)] and without regard to the procedures prescribed by subsections (a) and (b) of this section.[292]

Due to the U.S.'s obligations under the Convention, psilocybin must be scheduled in a manner consistent with the Convention's definition—even if the standard process of determining the appropriate scheduling would point to a lesser schedule.

Thus, the U.S. should take two steps to make psilocybin more accessible for research and treatment of mental illnesses: (1) reduce or remove restrictions under the Convention; and (2) reschedule psilocybin under the CSA.

A. Reduce or Remove Restrictions Under the Convention

First, to make psilocybin more accessible for research and treatment of mental illnesses, the federal government could formally request that the compound be rescheduled under the Convention. If the rescheduling is unsuccessful, the U.S. could then opt for a more drastic measure—denouncing the Convention and removing their obligations altogether.

292. 21 U.S.C. §811(d)(1) (emphasis added).

1. Rescheduling Psilocybin Under the Convention

Article 2 of the Convention outlines the process for a Party to request to transfer a currently controlled substance from one schedule to another as well as the removal of a substance from the schedules permanently.[293] Under Article 2, the Party must notify the Secretary-General of the United Nations of its request and provide supporting information to justify rescheduling the substance. The Secretary-General is then responsible for transmitting the notification and relevant supporting information to the other Parties, the Commission on Narcotic Drugs of the Council (the "Commission"), and to the World Health Organization ("WHO").[294] The WHO's Expert Committee on Drug Dependance ("ECDD")[295] is then responsible for investigating the substance, including factors such as the likelihood of abuse, the degree of danger the substance poses the public health, and the usefulness of the substance in medical therapy.[296]

After completing its new assessment, the ECDD communicates any new findings regarding an updated assessment of the substance to the Commission as well as any new recommendations for scheduling the substance.[297] The Commission is then responsible for deciding whether to reschedule the substance, considering the WHO's assessment and recommendation[298] along with any relevant economic, social, legal, and administrative factors.[299] If the Commission determines that rescheduling the substance is appropriate, the Secretary-General is to communicate the decision to all Parties to the Convention, the WHO, and the International Narcotics Control Board. The decision to reschedule would become effective 180 days following the date of such communication.

2. Why It Could Work

Requesting a transfer between schedules is a viable path to rescheduling psilocybin for several reasons. First, the WHO

293. Convention, *supra* note 270, at art. 2, ¶ 1 The WHO can also independently initiate the review process.

294. *Id.* at art. 2, ¶ 2.

295. The WHO Expert Committee on Drug Dependence (ECDD) consists of an independent group of experts in the field of drugs and medicines. The Committee is convened by WHO about once a year to review the public health impact of psychoactive substances and make recommendations to the international community.

296. Convention, *supra* note 270, at art. 2, ¶ 4.

297. *Id*. at ¶ 6.

298. The WHO's assessment is determinative as to medical and scientific matters. *Id.* at ¶ 5.

299. *Id.* at ¶¶ 5,6.

acknowledges that mental health is an "integral and essential component of health," and the "promotion, protection and restoration of mental health can be regarded as a vital concern of individuals, communities and societies throughout the world."[300] Further, the WHO estimates that approximately 280 million people worldwide, or 5.0% of the adult population, suffer from depression, making it a leading cause of disability worldwide and a major contributor to the overall global burden of disease.[301] They also estimate that another 60-70 million people suffer from bi-polar disorder, schizophrenia, and other psychoses.[302]

The WHO thereby acknowledges that depression and other mental illnesses negatively impact people across the globe. Further, the WHO has already expressed a commitment to improve mental health treatment under their Mental Health Action Plan 2013-2030. With the growing body of scientific literature supporting psilocybin as an effective and safe method of treating depression and other mental illnesses, the WHO should look favorably upon expanding its use to help treat some mental illnesses.

Second, the WHO's ECDD has already shown a willingness to evaluate new scientific research and recommend rescheduling substances currently regulated under international treaties such as the Convention. On January 24, 2019, the ECDD formally recommended rescheduling several cannabis and cannabis-related substances under the Convention and the Single Convention on Narcotic Drugs ("Convention on Narcotics").[303] Their recommendations included removing cannabis from Schedule IV of the Convention on Narcotics[304] and removing tetrahydrocannabinol from Schedule I status under the Convention and adding it to the much less restrictive Convention on Narcotics Schedule I.[305]

Third, the Commission has also expressed willingness to consider the ECDD's relevant new findings and recommendations and formally reschedule substances under the Convention and Convention on Narcotics. On December 2, 2020, the Commission voted to adopt the

300. *Mental Health*, WORLD HEALTH ORG., https://www.who.int/data/gho/data/themes/mental-health (last visited March 31, 2022).

301. *Depression*, WORLD HEALTH ORG. (Sept. 13, 2021), https://www.who.int/news-room/fact-sheets/detail/depression.

302. *Mental Disorders*, WORLD HEALTH ORG. (November 28, 2019), https://www.who.int/news-room/fact-sheets/detail/mental-disorders.

303. Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151.

304. The Schedule system under the Convention on Narcotics is opposite that of the Convention and CSA, with Schedule IV being the most restrictive and Schedule I being the least.

305. World Health Org., *Recommendation Letter Regarding Pre-Review of Cannabis and Cannabis Related Substances*, (January 24, 2019).

ECDD's recommendation to remove cannabis and cannabis resin from the highly restrictive Schedule IV.[306] Further, while they did not adopt the other recommendations, several of the votes were decided by narrow margins.[307] This suggests that a recommendation to reclassify psilocybin to a lower schedule to allow for more extensive research and medical use would be considered seriously by the Commission. Further, several of the States represented on the Commission are currently home to ongoing clinic trials for psilocybin as a treatment for mental illness, including the U.S., the United Kingdom, the Netherlands, Spain, Canada, and Germany.[308]

3. Benefits

Rescheduling psilocybin under the Convention would not force States to adopt lesser restrictions on the compound. However, it would allow the U.S. (and other States) to reschedule psilocybin under the CSA to a less restrictive schedule while maintaining its obligations under the Convention. Further, it would allow the U.S. to work cooperatively with its international allies to ease restrictions rather than doing so unilaterally.

4. Denounce the Convention

If the Commission does not accept a recommendation from the ECDD to reschedule psilocybin, the U.S. could opt to denounce the Convention and remove themselves from the treaty. This would remove its international obligations and allow the U.S. to unilaterally reschedule psilocybin under the CSA. Article 29 of the Convention allows for any Party to denounce the Convention by an instrument in writing submitted to the Secretary-General.[309]

While a denunciation of the Convention would allow the U.S. to freely craft their drug laws how it pleases, it is not the best possible

306. *UN Commission on Narcotic Drugs Reclassifies Cannabis to Recognize Its Therapeutic Uses*, WORLD HEALTH ORG. (Dec. 4, 2020), https://www.who.int/news/item/04-12-2020-un-commission-on-narcotic-drugs-reclassifies-cannabis-to-recognize-its-therapeutic-uses.

307. U.N. Commission on Narcotic Drugs, *Press Statement Regarding Vote on Cannabis and Cannabis-Related Substances Recommendations*, (December 2, 2020).

308. For a list of Members of the Commission on Narcotic Drugs during U.N. the Jan. 1, 2022 session see https://perma.cc/2DUB-PALE . For a list of countries with clinical trials see *Treatment-Resistant Depression (TRD)*, COMPASS PATHWAYS, https://compasspathways.com/our-research/psilocybin-therapy/clinical-trials/treatment-resistant-depression//#from-subnav (last accessed April 2, 2022).

309. If the denunciation were received by the Secretary-General on or before July 1 of the year, it would become effective on January 1 of the following year. If it were received after July 1, it would become effective on July 1 of the following calendar year. Convention, *supra* note 264, at art. 29.

solution. 184 nations are parties to the Convention, including all of the U.S.'s major allies. Thus, withdrawing from the Convention could cause tension for the U.S. on the global stage. Further, the Convention does serve a useful purpose for the U.S., as it helps regulate many harmful substances on a global scale—such as heroin—and places meaningful restrictions on the production and transportation of those substances. Therefore, the best option would be to propose a rescheduling of psilocybin under the Convention.

B. Reschedule Psilocybin under the CSA

As discussed in Part III-A(4), the Administrator of the DEA has authority under the CSA to reschedule a substance or remove a substance from the schedules completely.[310] Upon petition, the Administrator would refer the case to the HHS for an investigation into the scientific merits of the petition[311] while the DEA conducts their own parallel investigation on behalf of the Attorney General.[312] The findings and recommendations from these investigations would then be presented to the Attorney General to make the final decision.

As mentioned previously, the HHS evaluations and recommendations are binding on the Administrator as to scientific and medical matters as well as whether the substance should be scheduled at all. However, if HHS does recommend a certain level of scheduling, the Attorney General holds broad discretion to determine the appropriate schedule.[313] When considering the appropriate schedule, the Attorney General must take into account the eight factors determinative of control outlined in the CSA.[314] However, Schedule I substances present an additional wrinkle to the analysis, as they, by definition, have "no currently accepted medical use in treatment in the United States" whereas every other schedule is defined as having a "currently accepted medical use."[315] This distinction has served as the basis for many challenges to Schedule I designations, and in response,

310. 21 U.S.C. §811(a)(1) and (2).

311. Grace Wallack & John Hudak, *Marijuana Rescheduling: A Partial Prescription for Policy Change*, 14 OHIO ST. J. CRIM. L. 207, 209 (2016)

312. *Id*.

313. 21 U.S.C. §811(b).

314. §811(c). The factors include: (1) Its actual or relative potential for abuse; (2) Scientific evidence of its pharmacological effect, if known; (3) The state of current scientific knowledge regarding the drug or other substance; (4) Its history and current pattern of abuse; (5) The scope, duration, and significance of abuse; (6) What, if any, risk there is to the public health; (7) Its psychic or physiological dependence liability; (8) Whether the substance is an immediate precursor of a substance already controlled under this title. *Id.*

315. §812(b).

the DEA created an additional test to determine what qualifies as a "currently accepted medical use," which has been subsequently refined by the courts.

In 1994, the United States Court of Appeals for the D.C. Circuit outlined a five-part test in *Alliance for Cannabis Therapeutics v. DEA* to determine whether a substance had a currently accepted medical use. The factors stated that: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.[316] Ultimately, in that case, the DEA reasoned that cannabis did not have a currently accepted medical use because numerous experts testified that the medicinal value of marijuana had never been proven in sound scientific studies, which outweighed any anecdotal evidence in support.

Later, in *Americans for Safe Access v. DEA*, the D.C. Circuit again heard arguments arising from a denied petition to reschedule marijuana from Schedule I to Schedule II, IV, or IV.[317] In that case, the court elaborated further on the third prong, explaining what an "adequate and well-controlled study" was. The court upheld the DEA's interpretation, meaning that studies of efficacy must be "similar to what the FDA requires for a New Drug Application."[318] Under this definition, the DEA reasoned that the presence of over 200 peer-reviewed articles and limited number of Phase 1 trials were insufficient to rise to the level of an accepted medical use. Rather, the DEA emphasized that Phase 2 and 3 clinical trials were necessary to show adequate and well-controlled studies because it was at that stage of the FDA process where researchers began to explore and demonstrate (Phase 2) or confirm (Phase 3) therapeutic efficacy and benefit in large numbers of patients.[319]

Accordingly, the first obstacle that psilocybin would have to clear for the Attorney General to initiate proceedings to reschedule it would be to show it has an accepted medical use. However, clearing this obstacle should not be an issue under the five-prong test outlined by *Alliance* and *Americans*. Regarding the first prong, psilocybin's chemistry is known and reproducible. Psilocybin was first isolated by Albert Hoffman in 1957, and the first reproduced synthetic psilocybin product shortly

316. 15 F.3d 1131, 1135 (D.C. Cir. 1994). This test was to be applied in addition to the eight-factor test of the CSA, in effect creating a two-step approach. The five-factor approach to determine whether a substance was eligible for Schedule I due to no accepted medical use, and if it did have an accepted medical use then the eight-factor examination to determine the appropriate schedule in II-V.

317. 706 F.3d 438, 439 (D.C. Cir. 2013).

318. *Id*. at 451.

319. *Id*.

followed in 1958.[320]

Turning to the second and third prongs, regarding safety and efficacy studies, there have been dozens of peer-reviewed studies published over the past decade highlighting the safety and efficacy of psilocybin as a potential treatment for various mental illnesses. Further, even the heightened requirement in *Americans* can likely be satisfied, as a cursory glance at ClinicalTrials.gov reveals over 40 current or completed Phase 2 studies regarding the safety and efficacy of psilocybin.[321] This is bolstered by the fact that, as highlighted in Part III-A(6), the FDA was so impressed with the results of two Phase 2 studies of psilocybin that they granted the treatments a "breakthrough therapy" designation, which is reserved for especially promising treatments and expedites the treatment's progression through the clinical trial phases.

The fourth and fifth factors, acceptance by qualified experts and widely available scientific evidence, should also not pose major hurdles. Aside from the early supporters of psilocybin research, there continues to be a growing number of scientists across the country—and across the globe—who report positive findings regarding psilocybin's potential to treat mental illness. And the growing body of scientific research into the safety and efficacy of psilocybin is readily available to the scientific community through various journals and professional publications.

Once an "accepted medical use" is sufficiently established and accepted by the Attorney General, the focus would turn to the appropriate new Schedule for psilocybin.[322] At this point, the determination would turn on the Attorney General's perception of psilocybin's threat to public health and how readily accessible it should be. Studies of psilocybin show low levels of physical dependance, low levels of toxicity, and limited potential for abuse, all of which would suggest that a lower schedule would be appropriate under the eight CSA factors.[323] However, psilocybin's and other psychedelics' long-standing reputation, paired with the federal government's long-standing reluctance to move substances down the scheduling system due to potential political ramifications, suggest that the Attorney General would be very conservative with the rescheduling of psilocybin. Thus, the three most likely schedules for psilocybin would be Schedule II, III, or IV. Each schedule, and psilocybin's relative fit within each, is assessed in turn.

320. Daniel & Haberman, *supra* note 137, at 24.

321. Search Results for "Psilocybin", CLINICALTRIALS.GOV, https://perma.cc/5J2K-BSFS (last accessed April 2, 2022).

322. According to the CSA, Schedule I substances have no currently accepted medical use. §812(b)(1).

323. Matthew W. Johnson, et al., *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143 (2018).

1. Schedule II

Schedule II would represent the most conservative level for psilocybin but would not be the right fit. Schedule II is defined as appropriate for substances with a high potential for abuse and severe psychological and physical dependence.[324] As previously discussed in this Article, studies report that psilocybin has a low potential for abuse and shows little to no likelihood of physical dependence.[325] If the HHS's scientific findings supported this position, its findings would be binding on the Attorney General, and she would need to proceed accordingly—likely precluding psilocybin's rescheduling to Schedule II. However, if HHS felt that more research was needed to confidently determine abuse and dependence potential and found the research inconclusive, the Attorney General would still hold wide discretion over the decision.

In the case of inconclusive findings regarding potential for abuse and dependence, Schedule II would be the most likely location for psilocybin as it represents the "safest" political move for the federal government while still increasing access to researchers and patients.[326] While Schedule II would still require federal quotas on production,[327] it would make it easier for researchers to acquire funding for studies, and upon FDA approval, would allow doctors to begin treating patients with psilocybin under stringent conditions.[328]

2. Schedule III

Schedule III would represent the best balance between a conservative and liberal approach to rescheduling psilocybin and would be a good fit for the substance. Schedule III is for substances with a potential for abuse less than the substances found in Schedules I and II and which may lead to moderate or low levels of physical dependence.[329] This fits psilocybin well because, as discussed, studies show low levels of physical dependence and potential for abuse lower than what is found with Schedule I and II substances like heroin, fentanyl, and amphetamine.[330]

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324. 21 U.S.C. §812(b)(2).

325. Johnson et al., *supra* note 323, at 150.

326. Federal law permits individuals to obtain Schedule II, III, IV, or V drugs for personal medical use with a valid prescription. Ams. For Safe Access v. DEA, 706 F.3d 438, 442 (D.C. Cir. 2013). (*citing* 21 U.S.C. § 829(a)-(c)).

327. §826(1).

328. Other Schedule II substances include Oxycodone, Fentanyl, and Amphetamine (Adderall), whose restrictions regarding usage and prescription should color the idea of how accessible psilocybin may be as a Schedule II substance.

329. §812(b)(3).

330. *See generally* Johnson et al., *supra* note 323.

Further, the most comparable treatment to psilocybin assisted therapy currently used is administering ketamine, and its derivative esketamine, to treat treatment-resistant depression.[331] Ketamine is a Schedule III substance, which has been a workable designation to balance the interests of expanding access to the drug while ensuring patients receive safe substances under doctor supervision in controlled settings. There are important differences, however. Most notably, ketamine has substantial reinforcing and toxic effects and has been a growing substance of abuse among younger populations.[332]

Schedule III would be appropriate for psilocybin because it would keep psilocybin tightly regulated, thus avoiding a second "moral panic," while also greatly increasing access to the substance for research and treatment purposes. This scheduling would also comport with the preferences stated by Johns Hopkins researchers, who advocate for rescheduling psilocybin but believe that "conditions should be tightly controlled and that when taken for a clinical reason, it should be administered in a health care setting monitored by a person trained for that situation."[333] Additionally, being removed from Attorney General production quotas means that the production quantity could increase, which would make it more available for potential supervised use as a religious or spiritual tool.

3. Schedule IV

Schedule IV would be the most liberal rescheduling of psilocybin and expand access to it the most. Psilocybin would fit the definition of Schedule IV, which includes substances with lower potential for abuse and physical or psychological dependance than Schedule III substances.[334] Additionally, the Johns Hopkins researchers mentioned above have also advocated for rescheduling psilocybin to Schedule IV.[335] A Schedule IV designation would place psilocybin in the same class as Xanax and Valium, which can be acquired through a pharmacy with a prescription from a doctor. Thus, a Schedule IV designation would greatly increase potential access to the greater population.

However, rescheduling psilocybin to Schedule IV may not be wise at

331. Jennifer Chen, *How Ketamine Drug Helps With Depression*, YALE MEDICINE (March 9, 2022), https://www.yalemedicine.org/news/ketamine-depression.

332. Yu Liu, et al., *Ketamine Abuse Potential and Use Disorder*, 126(1) Brain Research Bulletin 68 (2016).

333. *Reclassification Recommendations for Drug in 'Magic Mushrooms'*, JOHNS HOPKINS MEDICINE (Sept. 26, 2018), https://perma.cc/P6YC-5YK9.

334. One prominent example would be the comparison of psilocybin to ketamine, as psilocybin has lower levels of toxicity and potential for physical dependence than ketamine—which is currently in Schedule III. *See* Matthew W. Johnson, et al., *supra* note 323, and Yu Liu, et al., *supra* note 332.

335. *Id*.

present. Even the Johns Hopkins researchers mentioned above expressed reservations about releasing psilocybin directly to patients through prescriptions. The fear is that increasing access too drastically and quickly could increase the chances of the substance being misused before research is complete. If any high-profile cases of misuse went public, then there could be a second "moral panic." Such a setback could lead the government to clamp down on psilocybin again and cause further delays in research and implementation of psilocybin-assisted therapy.

VI. CONCLUSION

Psilocybin and other psychedelics hold great promise and potential to alleviate the ongoing mental health crisis in the U.S. by filling a gap where current treatment options fail. For decades, the government and the law stood in the way of meaningful progress in the study of psychedelics, but the tides seem to be turning. The government could aid in the progress by rescheduling psilocybin under the CSA to Schedule III, or alternatively Schedule II or IV, and proposing to reschedule psilocybin under the Convention on Psychotropic Substances. Now the questions that seem to remain are: how quickly will the government move out of the way? And will they stay out of the way?