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Controlled Substance Regulation for the COVID-19 Mental Health Crisis

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RECENT DEVELOPMENTS

CONTROLLED SUBSTANCE REGULATION FOR THE COVID-19 MENTAL HEALTH CRISIS

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The COVID-19 pandemic is producing widespread loss of life, unemployment, and social isolation that is triggering a mental health crisis. Experts warn there could be record levels of depression, suicide, and substance use disorders. The U.S. healthcare system is not prepared. It lacks the resources to provide prolonged psychotherapy at scale, and existing drug treatments are ineffective in about half the people who try them. Amid worsening mental health-related morbidity and mortality, the experimental drugs psilocybin and 3,4-Methylenedioxymethamphetamine (MDMA) are an untapped resource. These drugs belong to a class of compounds called the psychedelics, which has been criminalized and stigmatized by the U.S. war on drugs for over fifty years. The U.S. Drug Enforcement Administration (DEA) classifies them as Schedule I controlled substances with a high potential for abuse and no currently accepted medical uses. However, recent clinical trials conducted in the United States and abroad undermine the DEA's position and suggest that psilocybin and MDMA can safely treat a variety of mental health conditions. Moreover, unlike existing therapies, they act quickly, and their benefits are often sustained.

This Article explores the legal obstacles to administering psilocybin and MDMA to mitigate the COVID-19 mental health crisis. It surveys the scientific evidence for their use and outlines a path toward rapid deployment. Due to the urgent need for effective mental health treatments, the DEA should deschedule psilocybin, reschedule MDMA, and lift annual aggregate production quotas on these drugs. The Food and Drug Administration (FDA) should issue emergency use authorizations (EUAs) for their therapeutic use. To

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enhance safety, the FDA Commissioner can attach conditions of use to the EUAs, comparable to Risk Evaluation and Mitigation Strategies (REMS), such as requiring psilocybin and MDMA to be administered in controlled settings under professional supervision.

Prior to the onset of COVID-19, several cities decriminalized psychedelics while acknowledging their therapeutic benefits. The U.S. Department of Justice (DOJ), which enforces violations of the federal Controlled Substances Act (CSA), should pledge not to prosecute individuals who use psychedelics in accordance with state and local laws. Meanwhile, amid growing national scrutiny of law enforcement policies and procedures following high-profile police killings, Congress should reevaluate the DOJ's prominent role in U.S. drug policy. It has come to light that the war on drugs rests on a foundation of misinformation and racial animus, which has devasted communities of color. Moreover, due to restrictions on research and development, the drug war adversely impacts people with mental health conditions by depriving them of effective drug therapies. Accordingly, Congress should amend the CSA to shift drug control from law enforcement agencies to science and public-health oriented agencies, such as the FDA and the National Institutes of Health. This restructuring of responsibilities would align federal controlled substance regulation with state drug control, which is overseen by public health agencies instead of law enforcement.

INTRODUCTION

Long before the COVID-19 pandemic, the United States faced rising rates of depression, suicide, and drug overdose deaths.[1] Since 1999, the national suicide rate has increased steadily, rising by over 25% to reach 48,344 deaths in 2018.[2] Annual drug overdose deaths have also increased in the past two decades, reaching 71,327 in 2019.[3] The pandemic is exacerbating these problems, and experts warn it is triggering a national mental health crisis.[4]

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1. Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 69, 71 (2018).

2. *Fatal Injury and Violence Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/injury/wisqars/fatal.html (last visited Nov. 21, 2020).

3. *Provisional Drug Overdose Death Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (Nov. 12, 2020) (data table for figure 1a) (showing there were 71,327 reported deaths in the United States from drug overdose in the 12-month period ending December 2019). This number underrepresents the total overdose deaths that year, which the CDC predicts will reach 71,975 when all data has been processed. *Id.*

4. William Wan & Heather Long, *'Cries for Help': Drug Overdoses Are Soaring During the Coronavirus Pandemic*, WASH. POST (July 1, 2020, 9:00 AM), https://www.washingtonpost.com/health/2020/07/01/coronavirus-drug-overdose/ (reporting that in 2020, suspected overdoses increased nationwide by 18% in March and 42% in May). It is believed that social isolation has contributed to the increased overdose rate and made it less likely that friends and family members will discover people who overdose and call 911. *Id.* According to a spokeswoman for the Cook County, Illinois, Medical Examiner, "[i]f it weren't for [COVID-19], these opioid deaths are all we'd be talking about now." *Id.*; *see also Issue Brief: Reports of Increases in Opioid- and Other Drug-Related Overdose and Other Concerns During COVID Pandemic*, AM.

Some analysts estimate the pandemic will kill up to 75,000 Americans by suicide and drug overdose due to "coronavirus despair."[5] Millions more will experience complicated grief due to the loss of family members, depression stemming from unemployment and social isolation, and post-traumatic stress disorder (PTSD) from working on the frontlines as healthcare providers or receiving treatment as patients in intensive care units.[6]

The U.S. healthcare system is unprepared. It lacks the resources to offer prolonged psychotherapy to those affected, and existing psychiatric drugs such as selective serotonin re-uptake inhibitors (SSRIs) are ineffective in 30–

MED. ASS'N., https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf (Oct. 31, 2020) (providing that more than forty states saw "increases in opioid-related mortality as well as ongoing concerns for those with a mental illness"); Jason Oliveira, *Fresno County Sees Spike in Suicides During COVID-19 Pandemic*, ABC30.COM (July 13, 2020), https://abc30.com/coronavirus-suicide-covid-pandemic-fresno-county/6315879/ (noting the suicide rate in Fresno County, California, in June 2020 was the highest rate in past three years); *Suicide Rates Spike Through COVID-19 Pandemic*, KGUN9.COM, https://www.kgun9.com/news/coronavirus/suicide-rates-spike-through-covid-19-pandemic (May 19, 2020, 10:52 AM) (confirming a sharp rise in suicides in Tucson, Arizona, in March 2020, including fifteen suicides in a two-week period); Brooke Griffin, *Suicide Rates in Oklahoma Spike Due to COVID-19*, NEWSON6.COM (July 26, 2020, 4:28 PM), https://www.news9.com/story/5f1df58ea717d00d80c4a709/suicide-rates-in-oklahoma-spike-due-to-covid19 [https://web.archive.org/web/20200727120553/https://www.newson6.com/story/5f1df58ea717d00d80c4a709/suicide-rates-in-oklahoma-spike-due-to-covid19] (mental health experts reporting "a sharp increase in suicide" in Oklahoma since the start of the pandemic).

5. Mallory Simon, *75,000 Americans at Risk of Dying from Overdose or Suicide Due to Coronavirus Despair, Group Warns*, CNN, https://www.cnn.com/2020/05/08/health/coronavirus-deaths-of-despair/index.html (May 8, 2020, 12:23 PM).

6. *See* Pål Kristensen et al., *Predictors of Complicated Grief After a Natural Disaster: A Population Study Two Years After the 2004 South-East Asian Tsunami*, 34 DEATH STUD. 137, 143 (2010) (finding that nearly 50% of people who lose loved ones in natural disasters displayed symptoms of complicated grief two years after the disaster); Barbara J. Jefferis et al., *Associations Between Unemployment and Major Depressive Disorder: Evidence from an International, Prospective Study (the Predict Cohort)*, 73 SOC. SCI. & MED. 1627, 1631 (2011) (noting that becoming unemployed is "associated with moderately raised risks of reporting depressive symptoms and major depression [six] months later"); Kee-Lee Chou et al., *The Association Between Social Isolation and DSM-IV Mood, Anxiety, and Substance Use Disorders: Wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions*, 72 J. CLINICAL PSYCHIATRY 1468, 1468 (2011) (reporting that social isolation is associated with a higher risk of mental health problems); Tara Law, *'We Carry that Burden.' Medical Workers Fighting COVID-19 Are Facing a Mental Health Crisis*, TIME (Apr. 10, 2020, 2:03 PM), https://time.com/5817435/covid-19-mental-health-coronavirus/; Talha Khan Burki, *Post-Traumatic Stress in the Intensive Care Unit*, 7 LANCET RESPIRATORY MED. 843, 843 (2019) (concluding that people who survive treatment in an intensive care unit are at heightened risk for developing post-traumatic stress disorder (PTSD)).

50% of people who use them to alleviate depression.[7] Similarly, 50% of people treated for PTSD do not respond to existing drug therapies.[8] Moreover, drug treatments for anxiety disorders leave up to 30% of people with little or no improvement in their conditions.[9] Second-line treatments for mental health conditions such as electroconvulsive shock treatment (ECT), deep brain stimulation, and psychosurgery are invasive, carry significant risks, and yield inconsistent results.[10] To grasp the current state of mental healthcare and how unprepared society is for the COVID-19 mental health crisis, consider that ECT—a technology invented in the 1930s—remains one of the safest and most effective therapies for treatment-resistant depression.[11]

Because society lacks safe, affordable, reliable, and fast-acting mental health treatments, millions will be left without symptomatic relief. The resulting widespread psychological and physical impairment will further damage the economy and strain our healthcare system.[12] Despite the lack of effective therapies, research and development on psychiatric drugs is

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7. Maurizio Fava, *Diagnosis and Definition of Treatment-Resistant Depression*, 53 BIOLOGICAL PSYCHIATRY 649, 655 (2003) (finding that 50% to 60% of patients do not achieve an adequate response following antidepressant treatment); Natalia Olchanski et al., *The Economic Burden of Treatment-Resistant Depression*, 35 CLINICAL THERAPEUTICS 512, 513 (2013) (concluding that approximately 30% of patients treated for depression do not achieve remission after trying four different antidepressants); Alison Little, *Treatment-Resistant Depression*, 80 AM. FAM. PHYSICIANS 167, 167 (2009) (finding that "between one and two-thirds of patients will not respond to the first antidepressant prescribed, and 15 to 33 percent will not respond to multiple interventions").

8. Stephen N. Xenakis, *Posttraumatic Stress Disorder: Beyond Best Practices*, 31 PSYCHOANALYTIC PSYCH. 236, 237 (2014).

9. Alexander Bystritsky, *Treatment-Resistant Anxiety Disorders*, 11 MOLECULAR PSYCHIATRY 805, 807 (2006).

10. *E.g.*, Khalid Saad Al-Harbi, *Treatment-Resistant Depression: Therapeutic Trends, Challenges, and Future Directions*, 6 PATIENT PREFERENCE ADHERENCE 369 (2012); Aazaz U. Haq et al., *Response of Depression to Electroconvulsive Therapy: A Meta-Analysis of Clinical Predictors*, 76 J. CLINICAL PSYCHIATRY 1374 (2015) (reporting that "[r]oughly one-third of individuals with depression do not respond to electroconvulsive therapy."); Alik S. Widge et al., *Closing the Loop on Deep Brain Stimulation for Treatment-Resistant Depression*, 12 FRONTIERS NEUROSCIENCE 1, 8 (2018).

11. *See* Edward Shorter, *History of Psychiatry*, 21 CURRENT OP. PSYCHIATRY 593, 597 (2008); Owais Tirmizi et al., *Electroconvulsive Therapy: How Modern Techniques Improve Patient Outcomes*, 11 CURRENT OP. PSYCHIATRY 24, 25–26 (2012) (discussing how modern methods of administering electroconvulsive shock treatment (ECT) have improved efficacy and safety).

12. *See* Martin Knapp & Gloria Wong, *Economics and Mental Health: The Current Scenario*, 19 WORLD PSYCHIATRY 3, 5 (2020) (reporting that the estimated global cost of impact of mental, neurological, and substance use disorders was $2.5 trillion in 2010).

stagnating as drug makers reduce their investment in the field.[13] Nevertheless, there is an untapped resource that could meet the urgent need for innovative treatments.

The experimental drugs psilocybin and 3,4-Methylenedioxymethampheta mine (MDMA) offer hope supported by Food and Drug Administration (FDA)-sanctioned clinical trials.[14] They are members of a class of compounds called the psychedelics, a heterogeneous group of natural and synthetic compounds known to alter mood, perception, and cognition.[15] Other examples include lysergic acid diethylamide (LSD), ketamine, and N,N-Dimethyltryptamine (DMT).[16]

Psilocybin is produced by over 150 mushroom species of the genus *Psilocybe* that grow in abundance worldwide.[17] It shows potential for treating depression, anxiety disorders, and substance use disorders.[18] MDMA is a synthetic compound and the active ingredient in the street drug "ecstasy."[19] It shows great promise as a treatment for PTSD.[20] However, to make psilocybin and MDMA accessible to mitigate the COVID-19 mental health crisis, the FDA and the DEA must update antiquated policies and regulations that are remnants of the failed U.S. war on drugs.

Alternatively, cities and states can decriminalize or legalize psychedelics, a trend started in 2019 by voters in Denver, Colorado, which has spread to other cities and states.[21] Oakland and Santa Cruz, California have implemented their own psychedelic decriminalization measures, and Washington, D.C. and

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13. Richard A. Friedman, *A Dry Pipeline for Psychiatric Drugs*, N.Y. TIMES (Aug. 19, 2013), https://nyti.ms/1alq5AD.

14. *See generally* Marks, *supra* note 1 (discussing approaches to research and development on psychedelic medicines).

15. *See id.* at 80–87 (reviewing the history, safety, and use of natural and synthetic psychedelics).

16. *Cf.* David E. Nichols, *Psychedelics*, 68 PHARMACOLOGICAL REVS. 264, 266, 268 (2016) (discussing "classic serotonergic hallucinogens (psychedelics)" and noting that ketamine "ha[s] a different mechanism of action" than these classic psychedelics).

17. Gastón Guzmán, *The Hallucinogenic Mushrooms: Diversity, Traditions, Use and Abuse with Special Reference to the Genus Psilocybe*, *in* FUNGI FROM DIFFERENT ENVIRONMENTS 256, 261 (J.K. Misra & S.K. Deshmukh eds., 2009).

18. *See* Marks, *supra* note 1, at 81.

19. *Id.* at 85.

20. *Id.* at 85–86.

21. *See* Dustin Marlan, *Beyond Cannabis: Psychedelic Decriminalization and Social Justice*, 23 LEWIS & CLARK L. REV. 851, 854 (2019) (describing legislative actions across the country to decriminalize psilocybin and other naturally occurring psychedelics).

Oregon followed suit in November 2020.[22] However, unless federal drug regulation is updated, individuals who act in accordance with state and local psychedelics laws may be prosecuted and incarcerated, frustrating efforts to mitigate the COVID-19 mental health crisis.

This Article makes novel contributions to a small but growing body of psychedelics jurisprudence.[23] It surveys the evidence supporting the therapeutic administration of psilocybin and MDMA and addresses leading arguments against their decriminalization. This Article describes the laws preventing their widespread medical use and recommends regulation that will push psychiatric drug research into the future while making MDMA and psilocybin available quickly to address the emerging mental health crisis.

Because there is a dearth of psychedelics jurisprudence, this Article relies heavily on a large body of marijuana jurisprudence, which is far richer and broader in scope. State and federal marijuana case law, regulation, and proposed legislation are relevant to psychedelics because they provide a roadmap and identify potential pitfalls for developing future psychedelics laws.

This Article contains four parts. Part I analyzes the science behind the therapeutic use of psilocybin and MDMA and explains why they represent a promising new frontier for psychopharmacology. Though the U.S. war on drugs has demonized them and categorized them as heavily restricted Schedule I controlled substances, clinical trials conducted in the past twenty years suggest that they are safe and effective for treating a variety of conditions. Part II analyzes current FDA and DEA policies regarding

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22. Mason Marks, *As Cities Decriminalize Psychedelics, Law Enforcement Should Step Back*, HARV. L.: BILL OF HEALTH (Aug. 5, 2020), https://blog.petrieflom.law.harvard.edu/2020/08/05/psychedelics-psilocybin-war-on-drugs-decriminalization/; Justin Wm. Moyer, *D.C. Voters Approve Ballot Question to Decriminalize Psychedelic Mushrooms*, WASH. POST (Nov. 3, 2020, 8:24 PM), https://www.washingtonpost.com/local/dc-politics/dc-magic-mushrooms-result/2020/11/03/bb929e86-1abc-11eb-bb35-2dcfdab0a345_story.html; *Oregon Measure 109 Election Results: Legalize Psilocybin*, N.Y. TIMES [hereinafter *Oregon Measure 109 Results*], https://www.nytimes.com/interactive/2020/11/03/us/elections/results-oregon-measure-109-legalize-psilocybin.html (Nov. 20, 2020, 3:10 PM); *Oregon Measure 110 Election Results: Decriminalize Some Drugs and Provide Treatment*, N.Y. TIMES [hereinafter *Oregon Measure 110 Results*], https://www.nytimes.com/interactive/2020/11/03/us/elections/results-oregon-measure-110-decriminalize-some-drugs-and-provide-treatment.html (Nov. 20, 2020, 3:10 PM).

23. *See* Matt Lamkin, *Legitimate Medicine in the Age of Consumerism*, 53 U.C. DAVIS L. REV. 385, 387–88, 390–92 (2019) (arguing that federal controlled substance regulation should make room for drugs with benefits that do not fit neatly into the government's current dichotomy between medical use and illicit use, which is often incoherent); Marks, *supra* note 1, at 74–75 (analyzing social and legal obstacles to the adoption of psychedelic medicines and recommending paths to overcome them); Marlan, *supra* note 21 (justifying the decriminalization of psychedelics using principles of social justice while advocating for neurodiversity).

Schedule I controlled substances and explains how these agencies could expedite the availability of psilocybin and MDMA. Part III analyzes state and local movements to decriminalize and legalize psychedelics and explains how these efforts might address the emerging mental health crisis. Part IV offers recommendations for state and federal regulation. It distinguishes between short-term recommendations that should be implemented immediately to address mental health conditions associated with COVID-19, and long-term recommendations, which require more careful planning to make controlled substance regulation more equitable and adaptable in the future.

In the short-term, the DEA should deschedule psilocybin, removing it from federal control, and reschedule MDMA by moving it from Schedule I to Schedule IV. Meanwhile, the DEA should lift annual aggregate production quotas on psilocybin and MDMA, and the FDA should issue EUAs for the therapeutic use of psilocybin and MDMA-assisted psychotherapy. Concurrently, Congress and the DOJ should ensure that people acting in accordance with state and local psychedelics laws are not prosecuted for violations of the CSA.

In the long-term, legislators at all levels of government should implement social equity programs in conjunction with psychedelic decriminalization and legalization measures to compensate for the war on drugs. The DEA and FDA should expand the range of evidence they consider when contemplating whether to schedule or reschedule controlled substances. To that end, Congress should amend the eight scheduling factors elaborated by the CSA, and the five factors used by courts and the DEA to evaluate "currently accepted medical use," to ensure that they are more balanced and less negatively biased and inclined towards restrictive scheduling. Specifically, Congress should include factors that acknowledge and analyze the benefits to individuals and society of the controlled substances being considered for scheduling or rescheduling. Finally, Congress should amend the CSA to put public health officials, rather than law enforcement, in control of U.S. drug scheduling.

I. THE NEXT GENERATION OF PSYCHOPHARMACOLOGY

Indigenous cultures have used naturally occurring psychedelics in spiritual and therapeutic contexts for centuries.[24] Examples include peyote and ayahuasca, which are derived from plants; psilocybin, which is produced by certain species of fungi; and DMT, which is extracted from the toad species

24. Jamilah R. George et al., *The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion*, 4 J. PSYCHEDELIC STUD. 4, 4–6 (2020) (describing the ceremonial and therapeutic use of psychedelics by indigenous peoples of Africa, North America, Central America, and South America).

Bufo alvarius.[25] Unlike naturally occurring psychedelics, synthetic varieties were discovered in the twentieth century. The German pharmaceutical company Merck first produced MDMA in 1912, Swiss chemist Albert Hoffman first synthesized LSD in 1938, and U.S. drug maker Parke-Davis first created ketamine in 1962.[26] As young chemicals in the global pharmacopoeia, synthetic psychedelics lack the long history of medical and spiritual use by indigenous cultures.

Though many psychedelics substances have therapeutic properties, this Article focuses on psilocybin and MDMA for two reasons: First, due to their current positions in the U.S. drug development pipeline, clinical testing has progressed far enough to produce significant evidence regarding safety and efficacy, which makes them good candidates for addressing the COVID-19 mental health crisis. Second, they are usually associated with fewer and less-severe adverse effects than other psychedelics.[27]

The DEA categorizes psilocybin and MDMA as Schedule I controlled substances, which the CSA defines as drugs having "a high potential for abuse" and "no currently accepted medical use in treatment in the United States."[28] The CSA governs all aspects of controlled substances handling, including manufacturing, distribution, import and export, dispensing, possession, and

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25. *See* Peter N. Jones, *The Native American Church, Peyote, and Health: Expanding Consciousness for Healing Purposes*, 10 CONTEMP. JUST. REV. 411, 411–14 (2007) (discussing the use of peyote cactus in the religious ceremonies of Native Americans); Luis Eduardo Luna, *Indigenous and Mestizo Use of Ayahuasca: An Overview*, ETHNOPHARMACOLOGY AYAHUASCA 1, 2–4 (2011) (describing the use of ayahuasca by indigenous and mestizo populations); George et al., *supra* note 24, at 5; Filip Tyls et al., *Psilocybin – Summary of Knowledge and New Perspectives*, 24 EUR. NEUROPSYCHOPHARMACOLOGY 342, 343 (2014) (discussing the ceremonial and scientific use of mushrooms containing psilocybin); Andrew T. Weil & Wade Davis, *Bufo Alvarius: A Potent Hallucinogen of Animal Origin*, 41 J. ETHNOPHARMACOLOGY 1, 4–5 (1994) (describing the activity of 5-methoxy-*N,N*-dimethyltryptamine, a psychedelic derived from the venom of the toad species *Bufo alvarius*).

26. Roland W. Freudenmann et al., *The Origin of MDMA (Ecstasy) Revisited: The True Story Reconstructed from Original Documents*, 101 ADDICTION 1241, 1242 (2006); Albert Hofman, *The Discovery of LSD and Subsequent Investigations on Naturally Occurring Hallucinogens*, *in* DISCOVERIES IN BIOLOGICAL PSYCHIATRY 91, 91 (Frank J. Ayd, Jr. & Barry Blackwell eds., 1970); Georges Mion, *History of Anesthesia: The Ketamine Story – Past, Present and Future*, 34 EUR. J. ANESTHESIOLOGY 571, 572 (2017).

27. *See, e.g.*, Giovanni Martinotti et al., *Hallucinogen Persisting Perception Disorder: Etiology, Clinical Features, and Therapeutic Perspectives*, 8 BRAIN SCIS. 1, 13 (2018) (concluding that Hallucinogen Persisting Perception Disorder, a rare but serious side effect of psychedelics, is more often associated with consumption of illicit lysergic acid diethylamide (LSD) than with other psychedelics such as psilocybin and 3,4-Methylenedioxymethamphetamine (MDMA)).

28. 21 U.S.C. § 812(b)(1)(A)–(B).

research.[29] Congress passed the CSA in 1970 to replace an existing patchwork of federal drug legislation and to bring the United States into compliance with the 1961 U.N. Single Convention on Narcotic Drugs (the Single Convention).[30] However, psychedelics were excluded from the scope of the Single Convention.[31] Many psychedelics were brought under international control by the U.N. Convention on Psychotropic Substances of 1971 and under federal control with the Psychotropic Substances Act of 1978.[32] When passed, the CSA placed dozens of synthetic and naturally occurring substances into five schedules.[33] It also gave the U.S. Attorney General the power to classify and reclassify drugs into those schedules.[34] These five schedules can be arranged along a continuum where Schedule I compounds are said to have the highest potential for dependence and abuse, and Schedule V compounds are said to have the lowest potential for dependence and abuse.[35]

According to the U.S. Court of Appeals for the District of Columbia: "Schedule I drugs are subject to the most severe controls and give rise to the harshest penalties for violations of these controls; they are deemed to be the most dangerous substances, possessing no redeeming value as medicines."[36] This categorization makes them illegal to manufacture, possess, or use outside of limited medical research, which is heavily restricted and stigmatized.[37] In contrast, the substances in Schedules II through V have currently accepted medical applications.[38] Moreover, if they become FDA-approved, a process that is separate from scheduling, then they can be marketed and prescribed by licensed healthcare providers. In contrast, Schedule I drugs cannot be administered outside of the research context, and it is challenging to research their mechanisms of

29. *Id.* § 812(b); *see also* Marlan, *supra* note 21, at 870.

30. *See* Kevin A. Sabet, *Much Ado About Nothing: Why Rescheduling Won't Solve Advocates' Medical Marijuana Problem*, 58 WAYNE L. REV. 81, 83 (2012).

31. United Nations Single Convention on Narcotic Drugs, art. 2, Mar. 20, 1961, 18 U.S.T. 1411, 520 U.N.T.S. 210.

32. The International Drug Control Conventions, *Schedules of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol*, U.N. Doc. ST/CND/1/Add.1/Rev.6 (May 7, 2020), http://undocs.org/ST/CND/1/Add.1/Rev.6.

33. *See* Michael Gabay, *The Federal Controlled Substances Act: Schedules and Pharmacy Registration*, 48 HOSP. PHARMACY 473, 473 (2013).

34. *Id.*

35. John A. Gilbert, Jr., *DEA Regulation of Controlled Substances and Listed Chemicals*, 65 FOOD & DRUG L.J. 623, 624 (2010).

36. All. for Cannabis Therapeutics v. Drug Enf't Admin., 930 F.2d 936, 937 (D.C. Cir. 1991).

37. *See* Marks, *supra* note 1, at 79 (explaining the Drug Enforcement Administration's (DEA's) regulation of psychedelics).

38. Gilbert, *supra* note 35, at 624.

action and therapeutic benefits.[39] Experts say this research is "difficult and in many cases almost impossible."[40]

Despite large obstacles, in recent years some researchers have gained permission to administer Schedule I drugs to small groups of patients. Their growing body of research undermines the DEA's classification of MDMA and psilocybin.[41] When administered in controlled settings, these drugs appear to have fewer and less-severe side effects than many FDA-approved medicines, including widely prescribed psychiatric drugs.

In 2016, a team at Johns Hopkins University demonstrated that a single dose of psilocybin significantly reduced depression and anxiety in people with life-threatening cancer diagnoses.[42] There were no serious adverse events, and the benefits persisted for up to six months.[43] Interestingly, over two-thirds of participants ranked the study among the top five most meaningful experiences of their lives.[44] In 2017, researchers at Imperial College London demonstrated that two doses of psilocybin decreased symptoms of treatment-resistant depression. In this study too, there were no serious adverse events, and the benefits lasted for six months.[45] In 2018, a study published in *The Lancet Psychiatry* showed that MDMA-assisted psychotherapy significantly reduced symptoms of PTSD in veterans and first responders.[46] These and many other clinical trials suggest that psilocybin and MDMA are safe when administered under professional supervision, and their utility as medical therapies is too great to ignore.[47]

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39. David J. Nutt et al., *Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation*, 14 NATURE REVS. NEUROSCIENCE 577, 577 (2013).

40. *Id.*

41. *Id.*

42. Roland R. Griffiths et al., *Psilocybin Produced Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial*, 30 J. PSYCHOPHARMACOLOGY 1181, 1195 (2016).

43. *Id.*

44. *Id.* at 1186, 1190, 1193.

45. Robin L. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: Six-Month Follow-Up*, 235 PSYCHOPHARMACOLOGY 399, 400, 403–05 (2018).

46. Michael C. Mithoefer et al., *3,4-Methylenedioxymethamphetamine (MDMA)-Assisted Psychotherapy for Post-Traumatic Stress Disorder in Military Veterans, Firefighters, and Police Officers: A Randomized, Double-Blind, Dose-Response, Phase 2 Clinical Trial*, 5 LANCET PSYCHIATRY 453, 493 (2018).

47. *See* Marks, *supra* note 1, at 85–86; *see also* Michael C. Mithoefer et al., *MDMA-Assisted Psychotherapy for Treatment of PTSD: Study Design and Rational for Phase 3 Trials Based on Pooled Analysis of Six Phase 2 Randomized Controlled Trials*, 236 PHARMACOLOGY 2735, 2739–41 (2019) (finding that most adverse effects were rated mild or moderate and that report frequency

The physiologic mechanisms of psilocybin and MDMA are not well understood, which may seem controversial. However, the effects of most psychiatric drugs, including common antidepressants such as SSRIs, are equally mysterious. SSRIs increase communication between neurons that use serotonin as a means of information processing by inhibiting its removal from the synaptic cleft, the space between adjacent neurons.[48] As a result, serotonin remains in the cleft longer to stimulate adjacent neurons. However, beyond that, nobody understands how SSRIs reduce the symptoms of depression or why they are effective in some people and ineffective in many others. Part of the reason is that psychiatry lacks a biological understanding of mental illness. Scientists know that depression is associated with lower levels of serotonin; however, they do not understand why or what the implications of this observation might be.

A leading theory on the mechanism of action of psychedelics holds that they affect a brain system called the default mode network (DMN).[49] The DMN comprises regions of the brain that facilitate self-reflection.[50] When people think about themselves, their past, or their future, the DMN becomes active.[51] However, when people focus on cognitively intensive tasks that distract them from self-reflection, such as playing musical instruments or completing math problems, the DMN deactivates.[52]

Functional neuroimaging studies, which display visual representations reflecting the activity of brain regions in real time, suggest that psychedelics inhibit DMN activation. When this disruption occurs, research subjects may temporarily experience what is called "ego disintegration," where they feel as though they no longer exist or have become one with the universe, other people, and other living things.[53] It is unclear whether these subjective

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decreased within seven days of each treatment session); *see also,* Robin L. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: An Open-Label Feasibility Study*, 3 LANCET PSYCHIATRY 619, 623–26 (2016); Charles S. Grob et al., *Pilot Study of Psilocybin Treatment for Anxiety in Patients with Advanced-Stage Cancer*, 68 ARCHIVES GEN. PSYCHIATRY 71, 78 (2011) (explaining that results from psilocybin trial support continued investigations of medical uses of hallucinogenic compounds).

48. Pau Celada et al., *The Therapeutic Role of 5-HT1A and 5-HT2A Receptors in Depression*, 29 J. PSYCHIATRY NEUROSCIENCE 252, 254 (2004).

49. Robin Carhart-Harris et al., *How Do Hallucinogens Work on the Brain?*, 27 PSYCH. 662, 665 (2014).

50. Yvette I. Sheline et al., *The Default Mode Network and Self-Referential Processes in Depression*, 106 PROC. NAT'L ACAD. SCIS. U.S. Am. 1942, 1946 (2009) (describing the role of the default mode network in self-reflection).

51. *Id.*

52. *Id.*

53. Carhart-Harris, *supra* note 49, at 665.

experiences are necessary for psychedelics to exert therapeutic effects. However, researchers suspect that disrupting the DMN promotes flexible, less constrained thought patterns that are clinically useful.[54] In other words, by temporarily inhibiting DMN activity, psychedelics may allow people to shift perspectives and overcome maladaptive thought patterns associated with mental illness.[55]

Research also suggests that psilocybin may decrease activation of brain circuits associated with fears that are implicated in PTSD and other anxiety disorders.[56] One might assume that suppressing fear and suppressing maladaptive thought patterns could be habit-forming. It is well established that people with mental health conditions often use drugs to reduce emotional distress.[57] However, evidence suggests that most psychedelics are not addictive.[58] One literature review ranked psilocybin the least addictive and lethal drug of twenty substances studied.[59] According to pharmacology expert David Nichols: "Although there is a general public perception that psychedelic drugs are dangerous, from a physiologic standpoint they are in fact one of the safest known classes of [Central Nervous System] drugs."[60] Nevertheless, they are not entirely without side effects.

Psychedelics can cause perceptual and emotional disturbances that produce transient anxiety and paranoia, which some people find distressing. These

54. *See* Taylor Lyons & Robin Lester Carhart-Harris, *More Realistic Forecasting of Future Life Events After Psilocybin for Treatment-Resistant Depression*, FRONTIERS PSYCH., Oct. 12, 2018, at 1, 5–7 (concluding that disruption of the inflexibly negative thought patterns of treatment-resistant depression after the administration of psilocybin may be due to inhibition of the default mode network).

55. *See* Robin L. Carhart-Harris et al., *The Entropic Brain: A Theory of Conscious States Informed by Neuroimaging Research with Psychedelic Drugs*, FRONTIERS HUMAN NEUROSCIENCE, Feb. 3, 2014, at 1, 12.

56. *See* Peter Oehen et al., *A Randomized, Controlled Pilot Study of MDMA (3,4-Methylenedioxymethamphetamine)-Assisted Psychotherapy for Treatment of Resistant, Chronic Post-Traumatic Stress Disorder (PTSD)*, 27 J. PSYCHOPHARMACOLOGY 40, 41 (2013) (noting that MDMA may also facilitate "processing of traumatic material and better encod[e] positive emotional experiences").

57. James M. Bolton et al., *Self-Medication of Mood Disorders with Alcohol and Drugs in the National Epidemiologic Survey on Alcohol and Related Conditions*, 115 J. AFFECTIVE DISORDERS 367, 370 (2009).

58. Nichols, *supra* note 16, at 275.

59. Robert S. Gable, *Toward a Comprehensive Overview of Dependence Potential and Acute Toxicity of Psychoactive Substances Used Nonmedically*, 19 AM. J. DRUG & ALCOHOL ABUSE 263 (1993).

60. Nichols, *supra* note 16, at 275.

effects are usually temporary and resolve within hours.[61] Therapists reduce the risk of adverse reactions by administering psychedelics in supportive environments, carefully controlling the dose, and screening patients for preexisting conditions that could be exacerbated by the treatment.[62] In exceptionally rare cases, individuals have reported consuming psychedelics and experiencing perceptual disturbances that continued for months or years.[63] This phenomenon is referred to as Hallucinogen Persisting Perception Disorder (HPPD).[64] Though concerning, HPPD is more often associated with consumption of illicit LSD than with the use of psilocybin and other psychedelics.[65]

MDMA has been observed to cause some neurotoxicity in laboratory animals when administered chronically and in high doses.[66] However, researchers believe it is safe at therapeutic, and relatively low, doses in humans.[67] FDA-sanctioned Phase 1 and Phase 2 clinical trials completed by the Multidisciplinary Association for Psychedelic Studies (MAPS) support this conclusion, and ongoing Phase 3 trials are producing additional data.[68] However, adverse events, including hyperthermia, renal failure, and

61. Jeffrey A. Lieberman & Daniel Shalev, *Back to the Future: Research Renewed on the Clinical Utility of Psychedelic Drugs*, 1 J. PSYCHOPHARMACOLOGY 1198, 1199 (2016).

62. *Id.* at 1198.

63. Fabida Noushad et al., *25 Years of Hallucinogen Persisting Perception Disorder—A Diagnostic Challenge*, 8 BRIT. J. MED. PRACS. 805, 805 (2015) (noting a case where a middle-aged man experienced "unusual and distressing visual experiences" for more than two decades after using LSD in his early twenties).

64. Marie-Laure Espiard, *Hallucinogen Persisting Perception Disorder After Psilocybin Consumption: A Case Study*, 20 EUR. PSYCHIATRY 458 (2005) (describing one case in which an eighteen-year-old man reported experiencing perceptual disturbances for eight months following the consumption of psilocybin and marijuana); *see also* John H. Halpern & Harrison G. Pope Jr., *Hallucinogen Persisting Perception Disorder: What Do We Know After 50 Years?*, 69 DRUG & ALCOHOL DEPENDENCE 109 (2003); Noushad et al., *supra* note 63, at 805.

65. Martinotti et al., *supra* note 27, at 5.

66. Giula Costa et al., *Progression and Persistence of Neurotoxicity Induced by MDMA in Dopaminergic Regions of the Mouse Brain and Association with Noradrenergic, GABAergic, and Serotonergic Damage*, 32 NEUROTOXICITY RSCH. 563, 563, 569, 573 (2017).

67. Lisa Jerome et al., *Long-Term Follow-Up Outcomes of MDMA-Assisted Psychotherapy for Treatment of PTSD: A Longitudinal Pooled Analysis of Six Phase 2 Trials*, 237 PSYCHOPHARMACOLOGY 2485, 2486 (2020).

68. David E. Carpenter, *Psychedelic Pioneer Rick Doblin on FDA Trials of MDMA: Most Important Reality Check of MAPS' 34-Year History*, FORBES (May 12, 2020, 11:42 AM), https://www.forbes.com/sites/davidcarpenter/2020/05/12/psychedelic-pioneer-rick-doblin-on-fda-trials-of-mdma-most-important-reality-check-of-maps-34-year-history/#612f34d5230a.

pulmonary edema, have been reported in the medical literature.[69] The MDMA consumed in these case reports was manufactured illegally under unknown conditions, and contamination cannot be ruled out as the cause.[70] Administering MDMA in controlled settings reduces the risk of adverse reactions. The safety of MDMA-assisted psychotherapy is further enhanced by the fact that under these conditions, people need only receive it a few times to benefit. This is unlike traditional therapies, which often require ongoing administration for years or even for the life of the individual.

Though psychedelics are associated with some adverse events, they should not be judged against the impossible standard of a hypothetical drug with no side effects. Instead, their safety records must be compared to those of existing medicines, including those that are FDA-approved and those that are sold over the counter without a prescription. A logical point of comparison is SSRIs, which are associated with numerous risks such as gastrointestinal and intracranial bleeding, electrical disturbances of the heart, metabolic disturbances, and seizures.[71] Some SSRIs have been linked to an increased risk of suicide.[72] Lithium, a drug commonly prescribed to treat bipolar disorder, is considered highly toxic outside of its narrowly recommended dosage range, and it is linked to increased risk of kidney

69. *See* Astrid Haaland et al., *Isolated Non-Cardiogenic Pulmonary Edema—A Rare Complication of MDMA Toxicity*, 35 AM. J. EMERGENCY MED. 1385.e3, 1385.e5 (2017); K.J. Dar & M.E. McBrien, *MDMA Induced Hyperthermia: Report of a Fatality and Review of Current Therapy*, 22 INTENSIVE CARE MED. 995, 995 (1996).

70. *See* sources cited *supra* note 69.

71. Rebecca Anglin et al., *Risk of Upper Gastrointestinal Bleeding with Selective Serotonin Reuptake Inhibitors with or Without Concurrent Nonsteroidal Anti-Inflammatory Use: A Systemic Review and Meta-Analysis*, 109 AM. J. GASTROENTEROLOGY 811, 811 (2014) (finding that selective serotonin re-uptake inhibitor (SSRI) consumption is "associated with a modest increase in risk of upper gastrointestinal tract bleeding," which is elevated when SSRIs are administered alongside non-steroidal anti-inflammatory drugs such as ibuprofen); Wei Cheng Yuet et al., *Selective Serotonin Reuptake Inhibitor Use and Risk of Gastrointestinal and Intracranial Bleeding*, 119 J. AM. OSTEOPATHIC ASS'N 102, 103 (2019); Geoffrey K. Isbister et al., *Relative Toxicity of Selective Serotonin Reuptake Inhibitors (SSRIs) in Overdose*, 42 J. TOXICOLOGY: CLINICAL TOXICOLOGY 277, 278 (2004) (finding a significant association between the SSRI citalopram and QTc prolongation, an electrical abnormality of the heart that can lead to serious cardiac arrhythmias); Terry S. Viramontes, *Antidepressant-Induced Hyponatremia in Older Adults*, 31 CONSULTANT PHARMACIST 139 (2016) (finding that anti-depressant induced hyponatremia is fairly common in older adults); Trevor Hill et al., *Antidepressant Use and Risk of Epilepsy and Seizures in People Aged 20 to 64 Years: Cohort Study Using a Primary Care Database*, 15 BMC PSYCHIATRY 315 (2015) (finding that all classes of antidepressants are associated with a significant increase in seizures).

72. Ed Silverman, *Suicide Should Prompt SSRI Review*, BMJ, Apr. 29, 2019, at 161.

disease and failure.[73] Antipsychotics, which are commonly prescribed to treat schizophrenia, bipolar disorder, and treatment-resistant depression, are associated with increased risk of osteoporosis, type II diabetes, glaucoma, and permanent neurologic damage.[74]

Even commonly used over-the-counter medications, such as ibuprofen and acetaminophen, are associated with serious and life-threatening adverse events. Ibuprofen is associated with gastrointestinal ulcers, bleeding, and kidney abnormalities.[75] Acetaminophen is linked to increased risk of liver damage and failure.[76] Acetaminophen overdose is the leading cause of calls to U.S. poison control centers, prompting over 100,000 calls per year.[77] However, despite these nontrivial risks, ibuprofen and acetaminophen are widely available without prescriptions.

Alcohol and tobacco may be the most harmful substances of all, yet they are available without a prescription at pharmacies, grocery stores, and gas stations in every city. Alcohol is responsible for an estimated 88,000 annual U.S. deaths due to cirrhosis of the liver and cancer of the mouth, throat, liver, and breast.[78] Tobacco is responsible for a staggering 480,000 U.S. deaths from smoking and more than 41,000 deaths due to secondhand smoke inhalation. Smoking increases the risk of death due to cancers, diabetes, heart disease, lung disease, and stroke.[79] Despite their well-established risks for causing life-threatening disease, and physical and psychological dependence, alcohol and tobacco may be purchased and consumed by anyone of legal age. Though these drugs are highly regulated, they do not

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73. Ursula Werneke et al., *A Decision Analysis of Long-Term Lithium Treatment and the Risk of Renal Failure*, 126 ACTA PSYCHIATRICA SCANDINAVICA 186, 186–87 (2012).

74. *See* Simon Matthew Graham et al., *Risk of Osteoporosis and Fracture Incidence in Patients on Antipsychotic Medication*, 10 EXPERT OP. DRUG SAFETY 575, 575–76, 586–87 (2011); Michael E.J. Lean & Frank-Gerald Pajonk, *Patients on Atypical Antipsychotic Drugs Another High-Risk Group for Type 2 Diabetes*, 26 DIABETES CARE 1597, 1597–98 (2003); Rajiv Tandon & Michael D. Jibson, *Extrapyramidal Side Effects of Antipsychotic Treatment: Scope of Problem and Impact of Outcome*, 14 ANNALS CLINICAL PSYCHIATRY 123, 123–24 (2002).

75. K.D. Rainsford, *Ibuprofen: Pharmacology, Efficacy and Safety*, 17 INFLAMMOPHARMACOLOGY 275, 292 (2009).

76. William M. Lee, *Acetaminophen and the U.S. Acute Liver Failure Study Group: Lowering the Risks of Hepatic Failure*, 40 HEPATOLOGY 6, 6 (2004).

77. *Id.*

78. *Alcohol Facts and Statistics*, NAT'L INST. ALCOHOL ABUSE & ALCOHOLISM, https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/alcohol-facts-and-statistics (last visited Nov. 21, 2020).

79. *Smoking and Tobacco Use Fast Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (May 21, 2020).

appear in the schedule of controlled substances. If they were scheduled, they would have to be categorized in Schedule I.

When the risks of psilocybin and MDMA are compared against the risks of common prescription and over-the-counter medications, and recreational drugs such as alcohol and tobacco, their impressive safety profile comes into focus. The scheduling of one class of drugs further illustrates glaring inconsistencies in U.S. drug scheduling. During the COVID-19 pandemic, psychiatrists have reported an increase in requests for benzodiazepine prescriptions.[80] People are using them to treat COVID-19-related anxiety. However, they often produce unpleasant and dangerous side effects, including cognitive impairment, memory loss, aggression, increased fall risk in the elderly, and paradoxically, increased anxiety.[81] Benzodiazepines can produce strong physical and psychological dependence, and drug experts report that many deaths attributed to the opioid crisis are actually caused by benzodiazepines.[82] However, despite their many significant risks, the DEA classifies benzodiazepines as Schedule IV controlled substances. Another Schedule IV substance is the hypnotic drug Zolpidem, which causes hallucinations, sleepwalking, amnesia, and suicidality.[83] The categorization of benzodiazepines and hypnotics in Schedule IV—while psilocybin and MDMA are categorized in Schedule I—highlights inconsistencies in the DEA's management of controlled substances that must be addressed.

Psilocybin and MDMA may be safe and effective alternatives to benzodiazepines and other drugs that are commonly used in psychiatry. They are generally considered safe, and the margin of safety is increased by administering them under professional supervision.[84] Unlike traditional therapies for mental illness, such as the SSRIs—which can take weeks or months to produce benefits—and benzodiazepines—which produce dangerous side effects, including agonizing physiological withdrawal—

80. Jack Turban & Jessica Gold, *The Pandemic Is Spiking Anxiety. Before You Take Anti-Anxiety Medication, Understand the Risks*, WBUR (May 18, 2020), https://www.wbur.org/cognoscenti/2020/05/18/coronavirus-anxiety-benzos-jack-turban-jessica-gold.

81. Malcolm Lader, *Benzodiazepine Harm: How Can It Be Reduced?*, 77 BRIT. J. CLINICAL PHARMACOLOGY 295, 295–96 (2012).

82. Christopher Lane, *The Disturbing Rise in Benzodiazepine Prescriptions*, PSYCH. TODAY (Jan. 23, 2020), https://www.psychologytoday.com/us/blog/side-effects/202001/the-disturbing-rise-in-benzodiazepine-prescriptions (reporting that up to 30% of deaths attributed to opioid overdose are actually due to benzodiazepine misuse).

83. Carmen K. Wong, et al., *Spontaneous Adverse Event Reports Associated with Zolpidem in the United States 2003–2012*, 13 J. CLINICAL SLEEP MED. 223, 223 (2017).

84. Marks, *supra* note 1, at 99.

psychedelics act quickly and their effects are often long lasting.[85] Moreover, they are often effective in the 40%–50% of people who do not respond to SSRIs and other traditional therapies.

The effectiveness of MDMA-assisted psychotherapy at treating PTSD in veterans and first responders suggests it could be effective at treating PTSD in healthcare workers caring for patients with COVID-19. Working in emergency rooms and intensive care units without adequate personal protective gear has been described by healthcare providers as working under battlefield conditions.[86] They act as intermediaries between people treated in isolation and their families, and when patients die, they convey the news to next of kin.[87] These responsibilities put healthcare workers under considerable stress, and there is growing concern that many will experience severe mental illness and attempt suicide.

MDMA-assisted psychotherapy may be equally effective for patients who are quarantined and treated in intensive care units, which is associated with increased risk for developing PTSD.[88] In the coming months and years, these individuals must cope with complicated emotions, including grief, anxiety, and depression. A lack of effective therapies may cause them to resort to problematic substance use and other maladaptive behaviors, including self-harm and suicide. Psilocybin and MDMA could help turn the tide. However, their stigmatization and categorization as Schedule I substances will delay Psilocybin's and MDMA's availability for years.

If psilocybin and MDMA are considered safe by many experts, how did they come to be misunderstood and miscategorized? The psychedelics are casualties of the U.S. war on drugs. In the 1950s and 1960s, Western scientists began publishing their investigations into the therapeutic effects of psilocybin, MDMA, and other psychedelics such as LSD.[89] In 1968, a group

85. *See* Stephen Ross et al., *Rapid and Sustained Symptom Reduction Following Psilocybin Treatment for Anxiety and Depression in Patients with Life-Threatening Cancer: A Randomized Controlled Trial*, 30 J. PSYCHOPHARMACOLOGY 1165, 1175 (2016).

86. *See* Caroline Orr, *'COVID-19 Kills in Many Ways': The Suicide Crisis Facing Health-Care Workers*, NAT'L OBSERVER (Apr. 29, 2020), https://www.nationalobserver.com/2020/04/29/analysis/covid-19-kills-many-ways-suicide-crisis-facing-health-care-workers (discussing how healthcare providers are "forced to work exhausting hours, often in overcrowded and under-resourced settings . . . while dealing with the fear" of contracting the virus).

87. *Id.*

88. John Griffiths et al., *The Prevalence of Post-Traumatic Stress Disorder in Survivors of ICU Treatment: A Systemic Review*, 33 INTENSIVE CARE MED. 1506, 1516 (2007).

89. *See, e.g.*, Betty Grover Eisner & Sidney Cohen, *Psychotherapy with Lysergic Acid Diethylamide*, 127 J. NERVOUS & MENTAL DISEASE 528, 529–30 (1958); Jonathan O. Cole & Martin M. Katz, *The Psychomimetic Drugs: An Overview*, 187 JAMA 758, 758–60 (1964); J. Carranza-Acevedo, *Hallucinogens vs. Psychotherapy*, 113 BRIT. J. PSYCHIATRY 1156, 1156 (1967).

of psychotherapists concluded "that trained personnel can implement the psychedelic procedure with relatively high safety; and . . . [LSD's] judicious use can . . . facilitate the achievement of a variety of psychotherapeutic objectives."[90] They were not alone. However, any progress was short-lived. In the 1960s, the use of psychedelics became stigmatized due to its association with countercultural movements, such as opposition to the Vietnam War.

More recently, it has become apparent that the U.S. war on drugs, of which the CSA is a cornerstone, is based on false information.[91] In 2016, Harper's Magazine published a 1994 interview with John Ehrlichman, a former aide to President Nixon.[92] Ehrlichman revealed that the war on drugs was manufactured as a political tool to oppress Black Americans and liberals who opposed the war.[93]

President Nixon's plan worked. For decades, the war on drugs has devastated communities of color by incarcerating millions, disrupting families, and reinforcing social inequality.[94] But racial minorities are not the only vulnerable groups impacted. The war on drugs has had other, less obvious casualties. Whereas people of color are disproportionately impacted by racial profiling and overly aggressive policing, people with disabilities, such as depression and anxiety disorders, have been denied access to potentially life-saving medications due to a longstanding prohibition on psychedelics research.[95]

While other drug classes, such as gene therapies and biologics, have improved significantly in the past decade, psychiatric drug development is stagnating.[96] Antidepressants have changed little since the first SSRI,

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90. Sanford Unger et al., *LSD-Type Drugs and Psychedelic Therapy*, *in* RESEARCH IN PSYCHOTHERAPY 521, 521 (John M. Shlien ed., 1968).

91. Marlan, *supra* note 21, at 870.

92. Tom LoBianco, *Report: Aide Says Nixon's War on Drugs Targeted Blacks, Hippies*, CNN, https://www.cnn.com/2016/03/23/politics/john-ehrlichman-richard-nixon-drug-war-blacks-hippie/index.html (Mar. 23, 2016, 3:14 PM); Dan Baum, *Legalize It All*, HARPER'S MAG., https://harpers.org/archive/2016/04/legalize-it-all/ (last visited Nov. 21, 2020) ("We knew [that] . . . by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities.").

93. *Id.*

94. *See* Doris Marie Provine, *Race and Inequality in the War on Drugs*, 7 ANN. REV. L. SOC. SCI. 41, 48–49 (2011); Max Daly, *How the War on Drugs Enables Police Brutality Against Black People*, VICE (June 8, 2020, 8:41 AM), https://www.vice.com/en_in/article/3azbek/how-war-on-drugs-enables-police-brutality.

95. Jeff Grabmeier, *Racial Profiling Shows Unequal Justice for Blacks, Book Says*, OHIO STATE NEWS (Aug. 8, 2000), https://news.osu.edu/racial-profiling-shows-unequal-justice-for-blacks-book-says/.

96. *See* Friedman, *supra* note 13.

fluoxetine, was introduced in 1986.[97] Meanwhile, as U.S. rates of depression and suicide are rising, exacerbated by the COVID-19 pandemic, pharmaceutical companies are shutting down psychiatric research programs and investing in other areas of drug development that promise a greater return on their investment.[98] Had the war on drugs, the CSA, and the Psychotropics Act of 1978 not removed psychedelics from clinical research, psychiatric drug development could have taken a different path that would have incorporated psychedelics as medicines. Psychedelic medicines might be far more advanced than they are today, incalculable suffering could have been prevented, and millions of lives potentially saved.

Decades later, after widespread acknowledgement that the U.S. war on drugs was ineffective at reducing crime and drug use, there has been a resurgence of scientific interest in psychedelics. Though still difficult, some scientists have gained the DEA's permission to conduct limited clinical research, and trials of psilocybin and MDMA-assisted psychotherapy have been completed or are underway at respected universities around the world.[99] However, despite rapid scientific progress in the past two decades, antiquated federal drug policies--now fifty years old—severely limit scientific progress and prevent advancements from reaching those who may need them the most. The following section describes how Congress and federal agencies can compensate for past harms and usher in a new era of mental health by reducing limitations on the next frontier of psychiatric drugs.

II. HASTENING THE AVAILABILITY OF PSYCHEDELIC THERAPIES

This section analyzes different paths to making psilocybin and MDMA available to mitigate the COVID-19 mental health crisis. It argues the DEA should reschedule psilocybin and MDM given the weight of available evidence for their safety and efficacy, revelations that their placement in Schedule I was

97. Marks, *supra* note 1, at 75.

98. *See* Leo Sher, *The Impact of the COVID-19 Pandemic on Suicide Rates*, 113 QJM: INT'L J. MED. 707, 707 (2020).

99. Peter Gasser et al., *Safety and Efficacy of Lysergic Acid Diethylamide-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Diseases*, 202 J. NERVOUS MENTAL DISEASE 513, 519 (2014) (describing LSD-assisted psychotherapy research completed in Switzerland); *MDMA-Assisted Psychotherapy for PTSD: Israel*, MULTIDISCIPLINARY ASS'N PSYCHEDELIC STUD. [hereinafter *MDMA-Assisted Psychotherapy*], https://maps.org/research/mdma/ptsd/israel (last visited Nov. 21, 2020) (describing MDMA-assisted psychotherapy research conducted in Israel); *Phase 2 Study: Treating PTSD with MDMA-Assisted Psychotherapy*, MULTIDISCIPLINARY ASS'N PSYCHEDELIC STUD. CAN., https://mapscanada.org/phase2/ (last visited Nov. 21, 2020) (describing a MDMA-assisted psychotherapy research conducted in Canada); Carhart-Harris et al., *supra* note 45, at 399 (describing psilocybin-assisted psychotherapy conducted in England).

based on misinformation and political propaganda, and the urgent need for innovative mental health treatments. Rescheduling would increase access to these drugs for research scientists and people who might benefit from their therapeutic effects. Meanwhile, the FDA should make psilocybin and MDMA-assisted psychotherapy available through EUAs for the treatment of mental health conditions caused or exacerbated by COVID-19 and its social effects.

Before discussing the procedures for drug rescheduling and EUAs, it is helpful to define several sets of terms that may cause confusion. The first set is controlled substance "decriminalization" versus "legalization." Decriminalization involves abolishing or reducing criminal penalties imposed for drug manufacturing, distribution, possession, sale, and consumption. This Article will refer to reductions of criminal penalties as partial decriminalization and abolition of criminal penalties as full decriminalization. Jurisdictions may choose to decriminalize only some drug related activities, such as possession, while leaving others subject to criminal prosecution, such as distribution. Alternatively, partial decriminalization may entail leaving criminal penalties in place while resolving not to enforce them.

Portugal famously decriminalized illicit drug use in 2001 by making it an administrative offense rather than a criminal offense.[100] Instead of imprisoning people whose drug use becomes problematic, police refer them to specialized Commissions for the Dissuasion of Drug Addiction, comprised of attorneys, social workers, and healthcare professionals.[101] However, the Portuguese model remains somewhat paternalistic and punitive. Offenders may be forced to complete community service and pay fines.[102] They may be banned from entering public places, and if the offender possesses a professional license, it may be suspended.[103]

In 2017, Oregon partially decriminalized many illicit drugs, including psychedelics, by reducing penalties for their possession from felonies to misdemeanors.[104] In 2019, Denver, Colorado became the first U.S. city to partially decriminalize mushrooms containing psilocybin by making enforcement of related criminal statutes the city's lowest law enforcement

100. Jordan Blair Woods, *A Decade After Drug Decriminalization: What Can the United States Learn from the Portuguese Model*, 15 UDC/DCSL L. REV. 1, 5 (2011).

101. Caitlin Elizabeth Hughes & Alex Stevens, *What Can We Learn from the Portuguese Decriminalization of Illicit Drugs*, 50 BRIT. J. CRIMINOLOGY 999, 1002 (2010).

102. *Id.*

103. *Id.*

104. Nicole Lewis, *Oregon Bill Decriminalizes Possession of Heroin, Cocaine and Other Drugs*, WASH. POST (July 11, 2017, 5:36 PM), https://www.washingtonpost.com/news/post-nation/wp/2017/07/11/oregon-legislature-passes-bill-decriminalizing-heroin-cocaine-meth-possession-hoping-to-curb-mass-incarceration/.

priority.[105] However, in U.S. cities where psychedelics have been partially decriminalized, their cultivation, possession, distribution, and consumption remain illegal at state and federal levels, and prosecutors sometimes seek harsh penalties, including incarceration.[106]

Unlike decriminalization, legalization entails complete removal of criminal and administrative sanctions.[107] It often involves creation of regulatory systems that allow for legal manufacturing, distribution, administration, and consumption of a drug. Legalization is more active than decriminalization. Decriminalization is a relatively hands-off approach to drug control in which government reduces or declines to enforce criminal penalties. Alternatively, legalization often involves a government's active participation in a drug market. Currently, over half the states in the U.S. have implemented some form of marijuana legalization that involves active regulation by state government.[108]

The second set of terms is "medical use" versus "recreational use" of controlled substances. Medical use typically requires a prescription or recommendation by a health care provider. In contrast, recreational use involves consumption of drugs by individuals of legal age without a health care provider's prescription or recommendation. Some advocates prefer the term "adult use," instead of recreational use, because they believe it is less stigmatizing; the remainder of this Article will use that term. In some states, systems for medical and adult use coexist and have different, sometimes overlapping, sets of regulations.

The third set of terms is "rescheduling" versus "descheduling" of controlled substances. Rescheduling a substance involves moving it from one tier of the controlled substances schedule to another. In contrast, descheduling entails removing a drug from the controlled substances schedule entirely so that it is no longer under federal control.

The fourth distinction involves the regulation of a controlled substance versus the regulation of psychotherapy that is assisted by the administration of that controlled substance. Psilocybin and MDMA are currently undergoing FDA-sanctioned clinical trials as part of psychedelic-assisted

105. Nicole Chavez & Ryan Prior, *Denver Becomes First City to Decriminalize Hallucinogenic Mushrooms*, CNN, https://www.cnn.com/2019/05/08/us/denver-magic-mushrooms-approved-trnd/index.html (May 9, 2019, 4:25 PM).

106. Conor McCormick-Cavanagh, *Man Accused of Selling Mushrooms Faces Up to Twenty Years*, WESTWORD (July 25, 2020, 7:23 AM), https://www.westword.com/news/denver-man-charged-dealing-mushrooms-psilocibin-twenty-years-11756016.

107. Hughes & Stevens, *supra* note 101, at 999.

108. Jeremy Berke & Shayanne Gal, *All the States where Marijuana is Legal—and 5 More that Just Voted to Legalize it*, BUS. INSIDER, https://www.businessinsider.com/legal-marijuana-states-2018-1 (Nov. 4, 2020).

psychotherapy. Once those trials are completed, psilocybin and MDMA-assisted psychotherapy could potentially become FDA-approved. However, the substances themselves would not become FDA-approved unless each compound underwent a full series of clinical trials where they are administered without an accompanying psychotherapy.

The final distinction involves state versus federal controlled substance scheduling. In addition to the DEA's schedule of controlled substances, states have their own controlled substance schedules, and a compound could be rescheduled at the state level while remaining a Schedule I compound at the federal level. Notably, state-level controlled substance schedules are typically maintained by state medical or public health agencies. For example, in Alabama, the controlled substances list is overseen by Alabama Public Health, whereas in Texas, the list is administered by the Department of State Health Services.[109] In contrast, the federal controlled substance schedule is administered by the DEA, a law enforcement agency within the DOJ. These distinctions will be revisited in Part IV of this Article, which argues that Congress should amend the CSA to shift federal drug control from the DOJ and DEA to scientific and public health-oriented agencies, such as the National Institutes of Health (NIH) or FDA. Such a shift would help address historical injustices perpetrated by the war on drugs. It could also help insulate U.S. drug policy from political influence and enable federal drug regulation to adjust to changing conditions including national emergencies, such as the COVID-19 pandemic.

The following sections describe the process for rescheduling psilocybin and MDMA under U.S. law. Rescheduling can occur through legislative, administrative, or judicial action. On the administrative side, "any interested party" can petition the DEA to reschedule drugs.[110] On the legislative side, Congress can amend the CSA to reclassify controlled substances.[111] Finally, on the judicial side, individuals or organizations can file claims against the DEA in federal court and attempt to compel the agency to reschedule controlled substances.[112]

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109. *See Controlled Substances*, ALA. DEP'T PUB. HEALTH, https://www.alabamapublichealth.gov/pharmacy/controlled-substances.html (Oct. 21, 2019); Schedules of Controlled Substances – Drug Manufacturers and Distributors, TEX. DEP'T HEALTH SERVS., https://dshs.texas.gov/drugs/controlled-substances.aspx (Oct. 27, 2020).

110. 21 U.S.C. § 811(a).

111. Grace Wallack & John Hudak, *Marijuana Rescheduling: A Partial Prescription for Policy Change*, 14 OHIO ST. J. CRIM. L. 207, 208 (2016).

112. *See, e.g.*, Ams. for Safe Access v. Drug Enf't Admin., 706 F.3d 438, 439–40, 442 (D.C. Cir. 2013) ("The CSA permits the DEA to reclassify drugs to less restrictive schedules according to various statutory criteria, and interested parties can petition the DEA for such action.").

A. Administrative Rescheduling

Administrative rescheduling is a complex process involving collaboration between multiple federal agencies, including the FDA, DOJ, and the U.S. Department of Health and Human Services (HHS).[113] The U.S. Attorney General, who derives the power to reschedule drugs from the CSA, can initiate rescheduling.[114] The DEA Administrator typically acts on behalf of the Attorney General in drug scheduling matters.[115] Alternatively, the Secretary of HHS, or any other interested party from within or outside the government, can petition the DEA for rescheduling.[116] The process starts when a party files a petition with the agency.[117] Upon receipt, the DEA Administrator performs an initial review and refers the case to HHS for a scientific evaluation of its merits.[118]

Responsibility for the HHS evaluation is delegated to the FDA due to its scientific expertise.[119] After completion, the FDA forwards the results to the DEA.[120] Meanwhile, the DEA conducts its own evaluation of the petition and combines its findings with those of the FDA.[121] Finally, the DEA publishes its decision on the petition in the Federal Register.[122] Notably, the CSA specifies that the HHS evaluation binds the Attorney General, and if the decision is that a drug not be scheduled, then the Attorney General cannot schedule it.[123] However, if HHS recommends that a drug be scheduled, the Attorney General has broad discretion to decide which schedule it falls into.[124]

When considering a substance for initial scheduling or evaluating the merits of a rescheduling petition, the Attorney General considers eight factors under the CSA.[125] Most of the eight factors are evaluated under a presupposition

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113. *See* 21 U.S.C. § 811.

114. *Id.*

115. *See* 28 C.F.R. § 0.100(b) (2019).

116. 21 U.S.C. § 811(a).

117. *Id.*

118. *Id.* § 811(b).

119. *See* Wallack & Hudak, *supra* note 111, at 209.

120. 21 U.S.C. § 811(b).

121. John Hudak & Grace Wallack, *How to Reschedule Marijuana, and Why It's Unlikely Anytime Soon*, BROOKINGS: FIXGOV (Feb. 13, 2015), https://www.brookings.edu/blog/fixgov/2015/02/13/how-to-reschedule-marijuana-and-why-its-unlikely-anytime-soon/.

122. *Id.*

123. 21 U.S.C. § 811(b).

124. *Id.* § 811(a)(1)(B).

125. *Id.* § 811(c) (delineating the factors, including the substance's actual or relative potential for abuse; the scientific evidence regarding the substance's pharmacologic effects, if they are known; the state of current scientific knowledge regarding the substance; the history and

that the substance is addictive and will be abused.[126] For instance, evaluating its "potential risk to public health" nudges one to assume that the drug harms the public.[127] This negative bias is problematic because many substances are considered for scheduling based on little evidence or on evidence of relatively poor quality. Due to the negative framing of the scheduling factors, a small amount of anecdotal evidence of harm can be used to permanently banish a substance to Schedule I.

Although two of the eight factors are neutral—evaluating "the scientific evidence regarding a substance's pharmacologic effects" and "the state of current scientific knowledge regarding the substance"—none of the eight factors are designed to evaluate the potential benefits of a substance, nor do they require the DEA to consider the potential positive effects of the substance on individuals or society and the harm that may result from removing the substance from the marketplace.

The negative framing of the rescheduling factors stacks the deck against substances from the start. Once they come under consideration for initial scheduling, the factors' negative slant creates a tendency for them to slide easily into a controlled substance schedule. Then, the scheduling factors often restrain them there indefinitely or facilitate their placement into even more restricted categories. When drugs are rescheduled, the tendency is for the DEA to move them to more restricted schedules instead of less restrictive categories.[128] The DEA has moved Schedule I drugs to Schedule II only five times,[129] and has descheduled a substance only twice.[130]

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current pattern of abuse of the substance; the scope, duration, and significance of abuse; the substance's potential risk to public health; the substance's psychic or physiological dependence liability; and whether the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act (CSA)).

126. Benedetto De Martino et al., *Frames, Biases, and Rational Decision-Making in the Human Brain*, 313 SCI. 684, 684 (2006).

127. 21 U.S.C. § 811(c)(6); *cf.* De Martino et al., *supra* note 126 (stating that humans often rely on simplifying heuristics as part of their decisionmaking when available information is incomplete or complex).

128. RICHARD LAWRENCE MILLER, THE ENCYCLOPEDIA OF ADDICTIVE DRUGS 116 (2002).

129. On May 25, 1984, the drug Sufentanil, a synthetic opioid estimated to be five to ten times stronger than fentanyl, was moved from Schedule I to Schedule II. *See* DRUG ENF'T ADMIN., U.S. DEP'T OF JUST., *Scheduling Actions: Alphabetical Order*, at 3–5, *in* LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS (2020), https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf. On May 13, 1986, Abbvie's THC drug, Marinol, was moved from Schedule I to Schedule II. *Id.* at 4. Thirteen years later, in 1999, it was moved a second time to Schedule III. *Id.* at 5.

130. David M. Wood et al., *Dissociative and Sympathomimetic Toxicity Associated with Recreational*

Understanding the history of the war on drugs and the CSA provides a possible explanation for why the factors were drafted this way. They may be well adapted to their intended purpose: to ensure that drugs can be easily scheduled based on little evidence to inflict as much damage as possible to certain segments of the population targeted by President Nixon's Administration. The eight factors make Schedule I a "regulatory black hole," a highly regulated category that has a low bar for entry and an extremely high bar for removal.[131]

Once an object or activity is relegated to a regulatory black hole, it can be exceptionally difficult to remove it.[132] For instance, once substances are sorted into Schedule I, they almost never come out due to large asymmetries between the quality and quantity of evidence required to place them in Schedule I—which is minimal—versus the quality and quantity of evidence required to take them out—which is extensive.[133] Although the same eight factors are used for scheduling and rescheduling, there are five additional factors that come into play when courts or the DEA decide whether to recategorize a Schedule I substance.[134]

Schedule I is unique because drugs in this category have no currently accepted medical use. Due to this defining characteristic, if a petitioner can establish that a drug in Schedule I has a currently accepted medical use, the DEA must reschedule it. Debates over rescheduling often turn on this issue. However, the CSA does not define currently accepted medical use. Accordingly, the DEA created a test for it in 1988, which has been refined by courts.[135]

In two cases, *Alliance for Cannabis Therapeutics v. DEA*[136] (ACT) and *Americans for Safe Access v. DEA*[137] (ASA), the U.S. Court of Appeals for the District of

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Use of 1-(3-Trifluoromethylphenyl) Piperazine (TFMPP) and 1-Benzylpiperazine (BZP), 4 J. MED. TOXICOLOGY 254, 255–56 (2008) (describing the removal of Dissociative and Sympathomimetic Toxicity Associated with Recreational Use of 1-(3-trifluoromethylphenyl) Piperazine (TFMPP) from the DEA's scheduling system following further review and in consideration of a lack of published information on toxicity of the drug).

131. Mason Marks, *Simulated Side Effects: FDA Uses Novel Computer Model to Guide Kratom Policy*, HARV. L.: BILL OF HEALTH (Feb. 8, 2018), https://blog.petrieflom.law.harvard.edu/2018/02/08/fda-uses-novel-computer-simulation-to-guide-kratom-policy/.

132. *Id.*

133. *Id.*

134. *Infra* note 142 and accompanying text.

135. Scheduling of 3, 4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act, 53 Fed. Reg. 5156, 5156–58 (Feb. 22, 1988) (to be codified at 21 C.F.R. pt. 1308).

136. 15 F.3d 1131(D.C. Cir. 1994).

137. 706 F.3d 438 (D.C. Cir. 2013).

Columbia clarified the scientific evidence required to establish "currently accepted medical use."[138] In ACT, the court adopted a five-part test.[139] In considering the petition for rescheduling marijuana, the DEA administrator had initially used an eight-part test. [140] However, the court determined that three of the eight requirements might be impossible for a Schedule I substance to meet.[141] After jettisoning those requirements, the court adopted a five-part test requiring: (1) that a substance's chemistry is known and reproducible; (2) that there are adequate safety studies; (3) that there are adequate and well-controlled studies proving efficacy; (4) that the drug is accepted by qualified experts; and (5) that the scientific evidence is widely available.[142] These requirements are very demanding and they significantly raise the barrier to rescheduling a Schedule I substance, enlarging the asymmetries between scheduling and rescheduling drugs in this category.

In ACT, the court layered this five-part test on top of the eight scheduling factors and remanded the case back to the DEA Administrator for reconsideration using the revised test. [143] The Administrator denied the petition, claiming that the evidence presented—which was largely anecdotal and consisted of patient reports of the therapeutic benefits from marijuana—did not satisfy the requirements of the five-part test.[144] The court cited the Administrator's ruling in which he claimed, "sick people are not objective scientific observers, especially when it comes to their own health."[145]

Times have changed since the ACT court issued its opinion. There is a trend toward acknowledging that individuals with lived experience can make valuable contributions to the advancement of medical science. The 21st Century Cures Act promotes patient-focused drug development, which the FDA defines as "a systemic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated

138. *All. for Cannabis Therapeutics*, 15 F.3d at 1135; *Ams. for Safe Access*, 706 F.3d at 440–41.

139. *All. for Cannabis Therapeutics*, 15 F.3d at 1135.

140. *Id.* at 1134.

141. The original eight-part test contained a fourth requirement that the substance and information regarding its use be generally available, a fifth requirement that its clinical use be recognized "in generally accepted pharmacopeia, medical references, journals or textbooks," and an eighth requirement that use of the substance be recognized "by a substantial segment of the medical practitioners in the United States." *Id.*

142. *Id.* at 1135.

143. *Id.* at 1137.

144. *Id.*

145. *Id.*

into drug development and evaluation."[146] Congress and the FDA recognize the importance of patient-focused drug development because they acknowledge that patients are a source of valuable information regarding the safety and efficacy of drugs under development. This perspective represents a significant departure from the DEA Administrator's belief, quoted in ACT, that the lived experience of people with medical conditions should be ignored because they cannot be trusted to be objective. In this respect, drug scheduling should be no different from drug development. Scheduling should evolve with the rest of medical science and include the voices of people with disabilities, mental health conditions, chronic pain, and substance use disorders in scheduling decisions by considering their needs—as they define them—within a revised set of scheduling factors.

In ASA, the court refined the five-part test introduced in ACT and focused on what constitutes "adequate and well-controlled studies proving efficacy."[147] The petitioners, Americans for Safe Access, interpreted this phrase to mean peer-reviewed, published studies, whereas the DEA interpreted it to mean studies similar to what the FDA requires for a New Drug Application (NDA), meaning evidence from Phase 3 clinical trials.[148] The petitioners heavily relied on an Institute of Medicine report stating that marijuana could offer relief to AIDS patients and people receiving chemotherapy.[149] However, the court accepted the DEA's interpretation of the report, viewing it as a call for additional studies on marijuana rather than an endorsement of its medical uses.[150]

The ASA court offered no clear resolution, concluding only that the DEA's construction of the phrase was reasonable and that, whatever the actual meaning of the phrase might be, it was certain that the petitioners had not met its requirements.[151] Despite offering no clear resolution, the opinion suggests that at a minimum, evidence from Phase 2 or Phase 3 clinical trials is likely required to meet the adequate and well-controlled studies proving efficacy requirement.[152] That is a very high bar, requiring randomized controlled trials with hundreds or thousands of participants.[153] These

146. *CDER Patient-Focused Drug Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development (Oct. 29, 2020).

147. *Ams. for Safe Access*, 706 F.3d at 450.

148. *Id.* at 451.

149. *Id.* at 450.

150. *Id.* at 450–51.

151. *Id.* at 451.

152. Marks, *supra* note 1, at 120.

153. *Id.* at 108.

requirements for rescheduling are far more stringent than the evidence required for initial scheduling, which can consist of observational studies, case reports, and other anecdotal evidence of potential harm. These lopsided requirements create the informational asymmetries of controlled substance scheduling and rescheduling.

The asymmetries trap Schedule I controlled substances in a regulatory black hole because the barriers to exiting Schedule I are much greater than the barriers to entry. They are problematic because as time goes by, science progresses, and courts and regulators have access to additional information, which may demonstrate that the evidence used to categorize an object or activity into a regulatory black hole was incomplete, incorrect, or biased. However, once the regulated item enters the black hole, there is no going back. Merely showing that the evidence used for scheduling was biased or incomplete is insufficient under the current system. The steep requirements for rescheduling, including those of ACT's five-part test, must be met. However, restrictions on scientific research created by a substance's Schedule I status handcuff researchers, impairing their ability to gather the evidence needed to meet those requirements. Unlike the eight scheduling factors, which negatively frame a substance and promote its banishment to Schedule I, the five parts of the currently accepted medical use test are overwhelmingly positive, making it nearly impossible for a substance in the depths of a regulatory black hole to meet the standard set. Because the DEA created the elements of the test for currently accepted medical use, this catch-22 may be a design feature of the system rather than a bug. The DEA's mission is squarely focused on enforcement and prosecution.[154] Thus, the agency has a vested interested in trapping substances in highly regulated categories, which keeps them under its jurisdiction and justifies the DEA's annual budget of nearly $3 billion.[155]

In addition to the ability to permanently schedule substances, the CSA gives the Attorney General the power to temporarily place a substance in Schedule I "to avoid an imminent hazard to public safety."[156] The CSA does not specify the quantity or quality of evidence necessary to establish that there is a risk to public safety, or that it is imminent.[157] However, it requires that the determination be based on three of the eight factors specified in 21

154. *DEA Mission Statement*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/mission (last visited Nov. 21, 2020).

155. *DEA FY 2020 Budget Request at a Glance*, U.S. DRUG ENF'T ADMIN., https://www.justice.gov/jmd/page/file/1142431/download (last visited Nov. 21, 2020) (reporting the DEA budget request of $2.976 billion for the 2020 fiscal year).

156. 21 U.S.C. § 811(h).

157. *Id.* § 811(h)(3).

U.S.C. § 811(c), including "actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution."[158] The Attorney General must specify the grounds on which the order for temporary scheduling is based by publishing a notice in the Federal Register.[159] Once implemented, temporary scheduling remains in effect for two years, and the Attorney General may extend it for one year.[160] When the DEA evaluates a substance for temporary scheduling, the factors the agency considers become even more negatively biased because only three of the § 811(c) factors are utilized, and all three of those factors are negatively biased.

In evaluating a drug for temporary scheduling, the DEA need not consider the positive impact of the substance, if any, and whether the public would be harmed by the substance's removal from both the market and scientific research. Moreover, further reflecting the asymmetries of federal drug control, there is no complimentary provision to temporarily reschedule or deschedule a drug. For example, there is no mechanism to temporarily remove substances from Schedule I if doing so might benefit society and avoid imminent hazards to public safety. If the purpose of the rescheduling factors is to objectively evaluate whether a substance should be scheduled or rescheduled, then they should be more balanced. Moreover, if scheduling procedures are intended to promote public safety, there should be mechanisms to temporarily deschedule substances because there is no reason to believe that temporary descheduling is any less important or any less likely to benefit society than temporary scheduling.

The closest thing to a temporary rescheduling measure is the EUA, which is discussed further below as a potential mechanism to make psilocybin and MDMA available on an emergency basis. Though not a means of rescheduling controlled substances, EUAs could allow the FDA Commissioner to make Schedule I substances available to treat conditions caused by chemical, biological, radiologic, and nuclear (CBRN) threats, including infectious agents such as COVID-19. This path toward availability is important because the evidence required to satisfy conditions for an EUA are relatively low—much lower than required to remove a substance from Schedule I. Therefore, during public health emergencies, an EUA could compensate for the evidentiary asymmetries of the scheduling system. However, EUAs would not apply in all circumstances. For instance, they would not be available to address public health emergencies that are not caused by CBRN agents, such as the opioid crisis and mental health crisis that existed prior to the pandemic. To address these types of emergencies, a more

158. *Id.*

159. *Id.* § 811(h)(4).

160. *Id.* § 811(h)(2).

permanent and widely applicable avenue for emergency use or temporary rescheduling of controlled substances should be implemented.

B. Legislative Rescheduling

Congress implemented the CSA, and it has the power to reschedule or deschedule controlled substances through two pathways: it can amend relevant portions of the CSA or pass new legislation that directly reschedules or deschedules a drug.[161] To date, Congress has proposed no legislation advocating for the rescheduling of psychedelics. However, last year, U.S. Representative Alexandria Ocasio-Cortez introduced a bill that would have reduced barriers to the scientific study of psychedelic compounds in Schedule I.[162] Specifically, the bill would have amended a large appropriations bill and eliminated a section that prohibits using federal dollars to fund "any activity that promotes the legalization of any drug or other substance in Schedule I."[163] The phrase "promotes the legalization of" has been interpreted to bar the use of federal funding to conduct research on psychedelic compounds.

In a debate on the House floor, Ocasio-Cortez referenced the catch-22 that psychedelics researchers currently face.[164] "[W]herever there is evidence of good, we have a moral obligation to pursue and explore the parameters of that good. Even if it means challenging our past assumptions or admitting past wrongs," she added, referencing the U.S. war on drug's stigmatization of psychedelics and its longstanding prohibition on their use and evaluation.[165]

Ocasio-Cortez also mentioned rising rates of suicide, the potential for psychedelics to reverse this trend, and a moral responsibility to explore and harness that potential:

> Thirty percent of all military veterans have considered suicide . . . . [I]f a Schedule I drug shows clinical promise in treating [suicidal thoughts] and in treatment resistant depression, perhaps it is not the drug we should say is morally wrong, but perhaps it is the law, the schedule, the statute [that is immoral].[166]

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161. *See* Hudak & Wallack, *supra* note 121.

162. Tom Angell, *AOC Pushes to Make It Easier to Study Shrooms and Other Psychedelic Drugs*, FORBES (June 8, 2019, 9:28 AM), https://www.forbes.com/sites/tomangell/2019/06/08/aoc-pushes-to-make-it-easier-to-study-shrooms-and-other-psychedelic-drugs/#7c8445c81002.

163. 165 CONG. REC. H4612 (daily ed. June 12, 2019) (statement of Rep. Alexandria Ocasio-Cortez).

164. *Id.* at H4613.

165. *Id.*

166. *Id.*

Representative Scott Perry spoke out against the proposed bill.[167] Appearing to conflate scientific study of psychedelics with endorsing their medical and recreational use, Perry asked: "Do we want the federal government telling our families and our children, take this [drug], it's good for you? Maybe it is. I sure don't think it is. I certainly don't want my kids taking it, and I don't want the government promoting it."[168] Perry's perspective ignores the growing body of evidence establishing the safety and efficacy of psilocybin and MDMA. It overlooks the fact that psychoactive drugs with nontrivial risks, such as SSRIs, benzodiazepines, and amphetamines (in the form of Ritalin and Adderall), are routinely prescribed to children to treat mental health conditions. Perry added, "I don't think this [Schedule I drug use] is what the government should be promoting, and I think we should have a lot more research before we tell our kids this is what they should be doing."[169] However, as pointed out by Ocasio-Cortez, the ban on federal funding for research of psychedelics impedes the scientific progress necessary to reschedule them under existing federal law.

Representative Lou Correa supported the bill, calling it a "lifesaving amendment" that is "both timely and very necessary."[170] According to Correa:

> We need legitimate, reliable research by universities and other institutions into the health benefits of cannabis and other substances . . . . As more Americans, including veterans, use cannabis and so-called 'magic mushrooms' to manage or treat their pain or other health conditions, it's important that doctors have the necessary information on the possible benefits, or not, of these substances."[171]

Correa then described how opioids are sometimes often used to treat PTSD, leading to dependence and death. He called for additional research on psychedelics, and other Schedule I drugs, to develop alternatives to opioids.[172]

Despite persuasive arguments by Ocasio-Cortez and Correa, the House rejected their proposed amendment.[173] Given congressional resistance to promoting federal funding of psychedelics research—a seemingly benign and narrow purpose—it appears unlikely that Congress would approve a bill to

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167. *Id.*

168. *Id.* at H4612–13 (statement of Rep. Scott Perry).

169. *Id.*

170. *Id.* at H4613 (statement of Rep. Lou Correa).

171. *Id.*

172. *Id.* at H4612.

173. Kyle Jaeger, *House Rejects AOC Amendment to Make It Easier to Study Psychedelic Drugs*, MARIJUANA MOMENT (June 13, 2019), https://www.marijuanamoment.net/congress-debates-aoc-amendment-to-make-it-easier-to-study-psychedelic-drugs/.

reschedule or deschedule psychedelics. In contrast, legislative rescheduling of marijuana seems more likely.[174]

On July 27, 2020, the Democratic National Committee's platform committee rejected an amendment that would have placed legalization of marijuana for adult use on the party's 2020 policy agenda.[175] Instead, the panel adopted a proposal that includes federal rescheduling, expunging marijuana-related convictions, legalizing medical marijuana, and permitting states to determine their own laws regarding adult use.[176] This approach appears to be a hybrid combining elements of decriminalization (regarding adult use) and legalization (with respect to medical use).

The following section provides an overview of proposed federal marijuana legislation. In the past four years, over a dozen bills have been introduced to Congress regarding marijuana rescheduling and decriminalization.[177] These bills are worth analyzing because they can serve as a road map for drafting psychedelics legislation.

Bills to reschedule marijuana are motivated in part by the negative impact prohibition has had on communities of color. One of the most recent proposals is Senate Bill 597, also called the Marijuana Justice Act of 2019, which would strike the words "marihuana" and "tetrahydrocannabinol" (THC), one of the physiologically active compounds in marijuana, from the CSA.[178] Earlier versions of the Act were introduced in 2017 and 2018.[179] According to one of its sponsors, U.S. Senator Cory Booker, "[t]he War on Drugs has not been a war on drugs, it's been a war on people, and

174. Kyle Jaeger, *Congress Planning Vote on Federal Marijuana Legalization Bill in September, Sources Say*, MARIJUANA MOMENT (July 24, 2020), https://www.marijuanamoment.net/congress-planning-vote-on-federal-marijuana-legalization-bill-in-september-sources-say/.

175. Kyle Jaeger, *Democratic Party Delegates Reject Marijuana Legalization Amendment to 2020 Policy Platform*, MARIJUANA MOMENT (July 27, 2020), https://www.marijuanamoment.net/democratic-party-delegates-reject-marijuana-legalization-amendment-to-2020-policy-platform/.

176. *Id.*; *see also* Kyle Jaeger, *Marijuana Legalization Excluded from Draft 2020 Democratic Party Platform*, MARIJUANA MOMENT (July 23, 2020), https://www.marijuanamoment.net/marijuana-legalization-excluded-from-draft-2020-democratic-party-platform/.

177. *See* Marijuana Justice Act of 2019, S. 597, 116th Cong. (2019); Marijuana Justice Act of 2018, H.R. 4815, 115th Cong. (2018); Marijuana Opportunity Reinvestment and Expungement (MORE) Act of 2019, H.R. 3884, 116th Cong. (2019); Marijuana Justice Act of 2017, S. 1689, 115th Cong. (2017); Compassionate Access Act, H.R. 715, 115th Cong. (2017); H.R. 2020, 115th Cong. (2017); Respect State Marijuana Laws Act of 2017, H.R. 975, 115th Cong. (2017); Legitimate Use of Medicinal Marihuana Act (LUMMA), H.R. 714, 115th Cong. (2017); Ending Federal Marijuana Prohibition Act of 2017, H.R. 1227, 115th Cong. (2017).

178. S. 597 § 2. "Marihuana" is a term commonly used to describe marijuana in older federal legislation.

179. S. 1689; H.R. 4815.

disproportionately people of color and low-income individuals."[180] To that end, the Marijuana Justice Act of 2019 contains social equity measures, some of which are modeled after similar measures implemented by state and local lawmakers.[181] However, marijuana social equity programs have been criticized for failing to achieve their goals of ensuring that communities most affected by the war on drugs have equal access to the thriving cannabis industry.[182] For example, critics allege that some programs have enabled nonminority investors to obtain licenses by partnering with Black entrepreneurs and subjecting them to predatory business practices.[183]

Despite imperfect implementation of state and local marijuana social equity programs, their goal of compensating for past injustice is noteworthy, and similar programs should be implemented in conjunction with psychedelics legislation. However, the social impact of marijuana prohibition differs from the impact of psychedelics prohibition. Accordingly, social equity programs that aim to address injustices associated with marijuana and psychedelics prohibition must be approached differently.

With respect to social equity, the Marijuana Justice Act of 2019 makes states ineligible to receive funds if they have a "disproportionate incarceration rate" for minority or low-income individuals arrested for marijuana-related offenses.[184] The Act would also create a Community Reinvestment Fund that channels funds into a grant program to benefit communities most impacted by the war on drugs.[185] Grants could be used to fund job training programs, community centers, health education programs, and other initiatives.[186]

A federal psychedelics decriminalization bill should contain similar social equity measures designed to address past injustices perpetrated against people with mental health conditions because of psychedelics prohibition.

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180. Press Release, Cory Booker, U.S. Sen., Booker, Lee, Khanna Introduce Landmark Marijuana Justice Bill (Feb. 28, 2019), https://www.booker.senate.gov/news/press/booker-lee-khanna-introduce-landmark-marijuana-justice-bill.

181. *Chart: Newer Marijuana Markets Embrace Social Equity Programs*, MARIJUANA BUS. DAILY (Aug. 6, 2019), https://mjbizdaily.com/chart-marijuana-social-equity-programs/.

182. Bart Schaneman, *California's Marijuana Social Equity Program, Rife with Corruption, Lives or Dies at Local Level*, MARIJUANA BUS. DAILY (July 23, 2020), https://mjbizdaily.com/local-level-key-to-california-cannabis-social-equity-program/.

183. Adam Elmahrek, *L.A.'s 'Social Equity' Program for Cannabis Licenses Under Scrutiny*, L.A. TIMES (June 23, 2020, 6:00 AM), https://www.latimes.com/california/story/2020-06-23/cannabis-licenses-social-equity-4th-mvmt.

184. S. 597, 116th Cong. § 3 (2019).

185. *Id.* § 4; Press Release, Kamala D. Harris, U.S. Sen., Harris Applauds House Comm. Passage of Marijuana Reform Legis. (Nov. 20, 2019), https://www.harris.senate.gov/news/press-releases/harris-applauds-house-committee-passage-of-marijuana-reform-legislation.

186. S. 597 § 4.

For example, whereas a federal marijuana social equity program may withhold federal funds from states that incarcerate a disproportionate number of racial minorities, a psychedelics social equity program might withhold funding from states that incarcerate a disproportionate number of people with mental health conditions or that lack programs to support this population. A portion of the taxes raised through psychedelics regulation could be invested in programs for trauma survivors, people with anxiety associated with life-threatening conditions, and people with other mental health conditions who have been impacted by the lack of effective drug therapies due to psychedelics prohibition. Further recommendations for these programs will be discussed in Part IV.

Like the Marijuana Justice Act of 2019, the Marijuana Opportunity Reinvestment Expungement (MORE) Act would remove marijuana and THC compounds (including THC and cannabidiol, which is also called CBD) from the CSA.[187] Within 180 days of its passage, the Act would require the U.S. Attorney General to finalize a rule removing these compounds from the controlled substances scheduling system.[188] Also like the Marijuana Justice Act of 2019, the MORE Act "aims to correct the historical injustices of failed drug policies that have disproportionately impacted communities of color and low-income communities."[189] To that end, it would implement a 5% sales tax on marijuana sales and invest those funds in an "Opportunity Trust Fund" that serves three goals through the Community Reinvestment Grant Program. The funds from the trust would provide job training, legal aid, literacy education, and substance use treatment to communities adversely impacted by the war on drugs.[190] Through the Cannabis Opportunity Grant Program, the funds from the trust would be used to provide loans to allow socially and economically disadvantaged groups to start small businesses in the marijuana industry.[191] Through the equitable licensing grant program, the trust would provide funds to "minimize barriers to cannabis licensing and employment for individuals most adversely impacted by the War on Drugs."[192] The MORE Act would also create a Cannabis Justice Office within the Office of Justice Programs, an agency of the DOJ.[193]

Some proposed federal legislation aims to remove marijuana from the controlled substances schedule without implementing social equity measures.

187. S. 2227, 116th Cong. § 2 (2019).
188. *Id.*
189. H.R. 3884, 116th Cong. § 2 (2019).
190. *Id.*
191. *Id.* § 4.
192. *Id.*
193. *Id.* § 5.

For instance, the Ending Federal Marijuana Prohibition Act of 2017 would have amended the CSA to remove marihuana and tetrahydrocannabinols from Schedule I and ensure that the CSA's regulatory controls and administrative, civil, and criminal penalties do not apply to marijuana.[194]

Other proposed federal marijuana legislation would reschedule marijuana instead of removing it from the controlled substances system. For example, H.R. 2020, which was introduced in 2017, would have ordered the U.S. Attorney General to move marijuana from Schedule I to Schedule III.[195] The Legitimate Use of Medicinal Marihuana Act (LUMMA) would have amended the CSA to move marijuana from Schedule I to Schedule II.[196] Further, it would have updated the CSA to ensure that none of its provision restrict activities that comply with state medical marijuana laws.[197]

The Compassionate Access Act, introduced in 2017, would have directed HHS to submit a recommendation to the DEA urging it to transfer marijuana from Schedule I to another controlled materials schedule.[198] Notably, unlike other rescheduling proposals, it would have allowed HHS to consider scientifically sound research conducted in states that allow medical marijuana, if conducted in accordance with state law, even if such research uses non-federally approved marijuana.[199] This provision highlights an important problem with U.S. marijuana and psychedelics research. Currently, U.S. scientists can only conduct research with marijuana that is grown by the federal government or with psychedelics that are produced by manufacturers licensed by the DEA.[200] Furthermore, in considering whether to reschedule substances, the FDA and DEA only consider evidence from within a narrow range of sources.[201]

Historically, the federal government produces marijuana at a farm on the campus of the University of Mississippi, and the quality of the product is notoriously poor.[202] For years, the DEA has promised to allow other growers

194. H.R. 1227, 115th Cong. § 3 (2017).

195. H.R. 2020, 115th Cong. § 1 (2017).

196. H.R. 714, 115th Cong. § 2 (2017).

197. *Id.*

198. H.R. 715, 115th Cong. § 1 (2017).

199. *Id.* § 3.

200. *See, e.g.*, Mason Marks, *DEA's Restrictive Cannabis Proposal Will Hinder Research and Favor Corporate Interests*, SEATTLE TIMES, https://www.seattletimes.com/opinion/deas-restrictive-cannabis-proposal-will-hinder-research-and-favor-corporate-interests/ (Sept. 13, 2019, 1:59 PM).

201. *See* Marks, *supra* note 1, at 120 (describing courts' and the DEA's requirement that evidence from Phase 2 or Phase 3 clinical trials be provided to establish that a currently accepted medical use for a controlled substance).

202. *Id.* at 126.

to produce marijuana for research, but it has failed to do so.[203] A similar problem hinders psychedelics research.[204] Only licensed individuals can produce psychedelics for research.[205] It is burdensome and expensive to obtain a license, and the DEA limits the number of licenses and the total mass of each psychedelic compound that can be produced each year (the aggregate production quota).[206] These restrictions severely limit the amount and quality of marijuana and psychedelics research that can be conducted in the United States. Drug expert David Nutt estimates that due to restrictive regulation, it is ten times more expensive to conduct research on Schedule I drugs than on drugs in less restricted categories.[207]

For 2021, the DEA has set the annual aggregate production quota for psilocybin at thirty grams and the quota for MDMA at fifty grams.[208] By comparison, the DEA set the quota for cocaine at 82,127 grams, the quota for fentanyl at 813,005, and the quota for amphetamine at 42,400,000 grams.[209] Granted, cocaine, fentanyl, and amphetamine have medical and scientific uses acknowledged by the DEA and FDA. However, their potential for diversion and problematic use is high—far greater than the risk associated with psilocybin and MDMA.

Current aggregate production quotas for psilocybin and MDMA are too low to facilitate scientific progress. In typical studies, a participant weighing 150 pounds might be administered psilocybin doses of 10 to 20 milligrams and MDMA doses of about 100 milligrams.[210] That means the DEA's 2020

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203. *Id.*

204. *Id.* at 128 (describing the impact of licensing and compliance requirements on psychedelics research).

205. *Id.* at 126.

206. *See* Terrance Woodworth, *How Will DEA Affect Your Clinical Study?*, 7 J. CLINICAL RSCH. BEST PRACS. 1, 1–5 (2011) (explaining the licensing guidelines, import export controls, quotas, security measures, and record-keeping requirements associated with studying Schedule I controlled substances).

207. David Nutt, *Illegal Drug Laws: Clearing a 50-Year-Old Obstacle to Research*, 13 PLOS BIOLOGY 1, 4 (2015).

208. Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020, 84 Fed. Reg. 48,170 (Sept. 12, 2019) (setting the aggregate production quota for psilocybin at thirty grams and setting the 2020 quota for psilocyn, a physiologically active metabolite of psilocybin, at fifty grams).

209. *Id.*

210. *See, e.g.*, Carhart-Harris et al., *supra* note 49, at 664–65 (discussing the results of experiments in which psilocybin is administered); Steven J. Lester et al., *Cardiovascular Effects of 3,4-Methylenedioxymethamphetamine: A Double-Blind, Placebo-Controlled Trial*, 133 ANNALS INTERNAL MED. 969 (2000).

aggregate production quotas allow for an estimated 150 to 300 doses of psilocybin and 500 doses of MDMA.[211] The aggregate production quotas must be raised if psilocybin and MDMA are to be investigated seriously by researchers or administered therapeutically as part of the medical response to COVID-19. Similarly, federal limits on marijuana production restrict legitimate scientific research.

If implemented, the research provision of the Compassionate Access Act would have been a step toward addressing these problems. By allowing research conducted using marijuana obtained from a wider variety of sources, and in accordance with state law, to be considered for the purposes of the rescheduling, the Act could have increased the diversity and quality of marijuana research and helped scientists remove it from Schedule I, a regulatory black hole. Similar provisions should be included in future marijuana and psychedelics legislation to leverage research that may be conducted in accordance with state and local laws, such as local decriminalization ordinances and Oregon's psilocybin legalization measure. Knowledge gained from research conducted by cities and states should not be discounted or swept under the rug.

In addition to expanding the variety of evidence that could be considered during rescheduling deliberations, the Compassionate Access Act would have required the Attorney General to delegate responsibility for registering marijuana researchers to an Executive Branch agency "that is not focused on researching the addictive properties of substances."[212] The agency would have been required to ensure adequate marijuana supply for medical research.[213] Whereas the DEA currently frustrates efforts to increase research on marijuana, the Compassionate Access Act would require a federal agency to facilitate marijuana research by ensuring an adequate supply of research material.[214]

States are generating useful information from their medical and adult use marijuana programs, and if approved, Oregon's psilocybin initiative could provide valuable data regarding the safety and efficacy of psilocybin, which could inform future federal legislation and regulation.[215] It would also help compensate for the prohibition on using federal funds to research Schedule

211. Estimates based on a research subject weighing 150 pounds, or sixty-eight kilograms.

212. H.R. 715, 115th Cong. § 3 (2017).

213. *Id.*

214. *Id.*

215. *See, e.g.*, Anuj Shah et al., *Impact of Medical Marijuana Legalization on Opioid Use, Chronic Opioid Use, and High-Risk Opioid Use*, 34 J. GEN. INTERNAL MED. 1419, 1424 (2019) (finding a modest decrease in opioid use in states where marijuana has been legalized).

I controlled substances. However, unless the DEA expands the range of evidence it will consider for federal rescheduling purposes, data from Oregon's program could not be used for that purpose.

In addition to lifting restrictions on research, the Compassionate Access Act contains the following provision:

> [N]o provision of the Controlled Substance Act . . . or Federal Food, Drug, and Cosmetic Act . . . shall prohibit or otherwise restrict . . . the prescription of marihuana by a physical for medical use . . . an authorized patient . . . caregiver . . . legally recognized guardian from obtaining, possessing, or transporting; an entity from producing, processing, manufacturing, or distributing; a pharmacy from dispensing; or a laboratory from testing medical marijuana or CBD in compliance with a state's medical marijuana law.[216]

This provision would require federal law enforcement to respect state marijuana laws.

Similarly, the Respect State Marijuana Laws Act of 2017 would have modified the CSA to ensure that anyone operating in compliance with state marijuana laws is immune from federal prosecution.[217] This protection would apply to medical and adult use of marijuana in states that allow it.[218] As state regulation of psychedelics became a reality in November 2020, Congress should make similar CSA amendments to ensure people acting in accordance with state and local psychedelics laws are not targeted by federal prosecutors. The prosecution of individuals using psilocybin in accordance with state and local laws would frustrate legitimate efforts to compensate for the lack of effective mental health therapies during the COVID-19 mental health crisis.

If psychedelics become legal in Oregon and other states, social equity programs should be implemented to reinvest funds raised through psychedelic sales into mental health research and provide housing, jobs, and other services to individuals impacted by the war on drugs. If the scientific investigations into psychedelics started in the 1950s had continued uninterrupted, then today, seventy years later, medical science might have developed pharmaceuticals based on those drugs that are safer and more effective than contemporary psychiatric drugs. By launching the war on drugs in 1970, President Nixon contributed to the suffering of millions. Contemporary state and federal drug law should aim to repair that damage and put the development of psychedelic therapies back on track.

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216. H.R. 715 § 2.

217. H.R. 975, 115th Cong. § 2 (2017).

218. *See id.*

In acknowledgement of the damage done by the war on drugs, in 2020, the Drug Policy Alliance proposed the Drug Policy Reform Act.[219] In addition to eliminating criminal penalties for possession of small quantities of controlled substances, and implementing many other measures to address the damage done by the war on drugs, the Act would shift control of drug scheduling and regulation from the DEA to the NIH.[220]

The following section discusses historical and contemporary cases that further illuminate the rescheduling process.

C. Judicial Rescheduling

If the DEA denies a petition to reschedule a substance, petitioners can challenge that decision in federal court. No federal cases have been brought to reschedule psilocybin or MDMA. However, numerous cases have been tried to determine whether marijuana should be rescheduled, and they are a rich source of information regarding the procedures associated with rescheduling.

As early as 1972, advocacy groups, such as the National Organization for the Reform of Marijuana Laws (NORML), argued for the reclassification of marijuana.[221] Since then, a total of five petitions to reschedule the substance have been submitted to the DEA.[222] However, the agency has denied them all. These denials have been litigated in a series of cases starting in 1974 with *NORML v. Ingersoll*.[223] At that time, President Nixon had not yet formed the DEA, and petitions were submitted to its predecessor, the Bureau of Narcotics and Dangerous Drugs (BNDD), which was led by John Ingersoll.[224]

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219. Press Release, Drug Pol'y All., Drug Policy Alliance Proposes Federal All-Drug Decriminalization, Releases New Legislative Framework (Aug. 6, 2020), https://www.drugpolicy.org/press-release/2020/08/DrugPolicyReformAct.

220. DRUG POL'Y ALL., DISMANTLING THE FEDERAL DRUG WAR: A COMPREHENSIVE DRUG DECRIMINALIZATION FRAMEWORK (THE DRUG POLICY REFORM ACT) 1 (2020), https://drugpolicy.org/sites/default/files/2020.08.06_dpa_decrim_model_0.pdf.

221. Gonzales v. Raich, 545 U.S. 1, 15 (2005).

222. All. for Cannabis Therapeutics v. Drug Enf't Admin., 15 F.3d 1131, 1135 (D.C. Cir. 1994); Ams. for Safe Access v. Drug Enf't Admin., 706 F.3d 438, 440 (D.C. Cir. 2013); JON GETTMAN, RESCHEDULING CANNABIS UNDER THE U.S. CONTROLLED SUBSTANCES ACT, SELECTED BIBLIOGRAPHY, TIME LINE, AND REFERENCE MATERIALS (2004), https://www.drugscience.org/NCCCT/JBG_NCCCT_04.pdf.

223. Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974).

224. Nat'l Org. for Reform of Marijuana Laws (NORML) v. Drug Enf't Admin., 599 F.2d 735, 737 (D.C. Cir. 1977) (explaining that the petition under consideration in the case was filed with the Bureau of Narcotics and Dangerous Drugs, which preceded the DEA).

NORML and other advocacy groups submitted a rescheduling petition to the Bureau on May 18, 1972, requesting that it remove marijuana from control under the CSA or transfer the substance from Schedule I to Schedule V.[225] Ingersoll, the Director of the BNDD, acting as the delegee of the U.S. Attorney General, refused to accept NORML's petition to either remove marijuana from federal control under the CSA or move it from Schedule I to Schedule V.[226] He concluded that 21 U.S.C. § 201(d) and § 811(d) gave him sole authority over the scheduling of substances controlled by treaty, without regard to the referral and rulemaking procedures.[227] Ingersoll refused to accept the petition claiming that he was barred from doing so by his obligations under the Single Convention.[228] According to Ingersoll, those obligations prevented him from considering NORML's rescheduling request.[229] The court was tasked with deciding whether those treaty obligations precluded Ingersoll from acting.[230]

The court held that Ingersoll had erred in dismissing NORML's petition outright and that a petition could only be rejected under very limited circumstances.[231] It said of Ingersoll's rejection: "It was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process."[232] The court interpreted § 201(d) of the CSA to authorize Ingersoll to determine which of the five schedules is most appropriate to ensure compliance with the Single Convention. However, "[t]he respondent [Ingersoll] seems to be saying that even though the treaty does not require more control than Schedule V provides, he can on his own say-so and without any reason insist on Schedule I. We doubt that this was the intent of Congress."[233] In other words, Ingersoll could not unilaterally decide that a substance must be categorized in Schedule I due to U.S. treaty obligations. This case is relevant to the scheduling of psilocybin and MDMA because, based on past litigation, if the scheduling of these substances was challenged in court, the DEA might claim that it cannot reschedule them due to U.S. treaty obligations under the Psychotropics Convention.

225. *NORML*, 497 F.2d at 655.
226. *NORML*, 599 F.2d at 741.
227. *Id.*
228. *NORML*, 497 F.2d at 656.
229. *Id.*
230. *Id.* at 657–58.
231. *Id.*
232. *Id.* at 659.
233. *Id.* at 660–61.

A second marijuana rescheduling case, *NORML v. DEA*,[234] was decided in 1977. Instead of refusing to consider NORML's petition, the respondent in this case, the DEA Administrator, refused to solicit the opinion of the Secretary of the Department of Health, Education, and Welfare (HEW), the agency that preceded HHS.[235] The DEA administrator used the same reasoning as *Ingersoll*, claiming that the DEA's treaty obligations under the Single Convention relieved him of the obligation to act on NORML's petition, in this case to seek HEW's scientific opinion.[236] The court concluded that "Section 201(d) must be read against this backdrop of intense concern with establishing and preserving HEW's avenue of input into scheduling decisions."[237] The court held that the DEA's "reading of Section 201(d) would destroy a balance of power created by a deliberate and conscientious exercise of the legislative process."[238] "[I]t enables him to place a substance in a CSA schedule—without regard to medical and scientific findings—only to the extent that placement in that schedule is necessary to satisfy United States international obligations."[239]

NORML v. DEA contains footnotes that describe historical turf battles over who should have the power to schedule and reschedule drugs.[240] These battles from the CSA's legislative history are of great relevance today. When the CSA was under consideration by a Senate committee, Senator Hughes of Iowa proposed amendments that would have limited the Attorney General's scheduling powers.[241] He initially proposed that HEW be given near total control over scheduling decisions. According to Hughes:

> Although [the Attorney General] does have, and should have, the right of research and development in the areas that are related directly to law enforcement, it would be better to leave the determining of dangerous substances and changing in schedules of classification up to the Department of Health, Education, and Welfare.[242]

However, the CSA's sponsors, Senators Dodd and Hruska, insisted that requiring the Attorney General to solicit nonbinding advice from HEW would compensate for the Attorney General's lack of scientific and medical

234. 599 F.2d 735 (D.C. Cir. 1977).
235. *Id.* at 738.
236. *Id.* at 737.
237. *Id.* at 746.
238. *Id.*
239. *Id.*
240. *Id.* at 745–46.
241. *Id.* at 745.
242. *Id.*

expertise.[243] They defeated Senator Hughes' amendment in a forty-six to thirty-six vote.[244]

Hughes fired back with a more modest proposal: The U.S. Attorney General could schedule or reschedule substances, but only after receiving the recommendation of HEW or a specially appointed "Scientific Advisory Committee."[245] Hughes stated:

> The provisions of this amendment do not make radical changes in the bill as reported. They do not transfer, as many have urged, the responsibility for such scientific determinations from the Department of Justice to the Department of Health, Education, and Welfare. All that they require is that in making decisions on essentially scientific and medical questions, the Attorney General act on the basis of recommendations from those agencies of the Government best qualified to make an expert judgment on the questions involved.[246]

Senators Dodd and Hruska fought back again and Hughes' second proposal was rejected, this time by a forty-four to thirty-nine vote.[247]

Congress eventually reached a compromise that created a division of labor between federal law enforcement and public health agencies.[248]

> This division of decisionmaking responsibility was fashioned in recognition of the two agencies' respective areas of expertise. Members of the House repeatedly stated that the Department of Justice should make judgements based on law enforcement considerations, while HEW should have the final say with respect to medical and scientific determinations.[249]

Looking back on this debate fifty years later, we can appreciate the concerns expressed by Senator Hughes and the other senators who supported his amendments. Resting control of U.S. drug policy, including scheduling decisions, in the hands of the DOJ and DEA has not decreased the rates of drug use or overdose. In the past two decades, U.S. rates of drug overdose death have soared.[250]

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243. *Id.*

244. *Id.*

245. *Id.* at 745.

246. *Id.*

247. *Id.*

248. *Id.*

249. *Id.* at 745–46.

250. HOLLY HEDEGAARD ET AL., NAT'L CTR. HEALTH STAT., U.S. DEP'T OF HEALTH & HUM. SERVS., DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1999–2018 (2020), https://www.cdc.gov/nchs/data/databriefs/db356-h.pdf.

D. Accelerated FDA Approval

In addition to DEA rescheduling, the FDA should accelerate its approval of therapies utilizing psilocybin and MDMA. In March, the FDA issued an EUA for the controversial antimalarial drugs chloroquine and hydroxychloroquine to treat COVID-19; in April, it issued an EUA for the antiviral drug remdesivir; and in August, it issued an EUA for convalescent plasma, which is plasma derived from the blood of people who have recovered from COVID-19.[251] The agency should issue similar authorizations for psilocybin and MDMA-assisted psychotherapy, which have already completed FDA-sanctioned clinical trials for safety and efficacy.[252] Unfortunately, during the 2020 U.S. presidential race, EUAs became heavily politicized, making their future and perceived legitimacy uncertain.[253] However, they remain an important tool that enables U.S. drug law to respond quickly to national emergencies.

Before describing the process for obtaining an EUA, it is worth discussing other potential pathways through which the availability of psilocybin and MDMA could be accelerated to make them available to mitigate the COVID-19 mental health crisis. The FDA has several ways to facilitate the availability of drugs by expediting clinical testing and approval. These methods for accelerating approval can be traced back to the 1980s AIDS epidemic.[254] Advocates for the HIV/AIDS community demanded quicker access to therapies and pressured the FDA to reform its approval process.[255]

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251. Dan Diamond, *FDA Issues Emergency Authorization of Anti-Malaria Drug for Coronavirus Care*, POLITICO, https://www.politico.com/news/2020/03/29/fda-emergency-authorization-anti-malaria-drug-155095 (Mar. 30, 2020, 5:56 AM); Arman Azad & Nicole Chavez, *FDA Issues Emergency-Use Authorization for Remdesivir to Treat Hospitalized Patients with Severe Covid-19*, CNN, https://www.cnn.com/2020/05/01/health/remdesivir-fda-authorization/ (May 1, 2020, 6:23 PM); Sanjay Gupta et al., *US FDA Announces Emergency Authorization for Convalescent Plasma to Treat Covid-19*, CNN, https://www.cnn.com/2020/08/23/health/covid-19-convalescent-plasma-eua-white-house/index.html (Aug. 23, 2020, 10:40 PM).

252. *See* Mithoefer et al., *supra* note 46; *see also* Michael P. Bogenschutz, *It's Time to Take Psilocybin Seriously as a Possible Treatment for Substance Use Disorders*, 43 AM. J. DRUG & ALCOHOL ABUSE 4 (2017).

253. *See* Amy Dockser Marcus & Thomas M. Burton, *Science Behind Convalescent Plasma for Covid-19 Is Clouded by Politics in FDA Authorization*, WALL ST. J., https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563 (Aug. 25, 2020, 6:46 PM).

254. Sheila R. Shulman & Jeffrey S. Brown, *The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked*, 50 FOOD & DRUG L.J. 503, 503–04 (1995).

255. Mary Dunbar, *Shaking Up the Status Quo: How AIDS Activists Have Challenged Drug Development and Approval Procedures*, 46 FOOD DRUG COSM. L.J. 673, 689–90 (1991).

There are four pathways for expediting FDA approval that are designed to expedite the development of drugs that address the unmet needs of people with serious or life-threatening conditions. They include priority review, accelerated approval, fast track designation, and breakthrough therapy designation.[256] These programs have different standards of review and require different types of evidence to justify and trigger accelerated approval.[257]

Priority review decreases the period between submitting a NDA after the completion of clinical trials and receiving FDA approval to market a drug.[258] A drug must be a significant improvement over previous treatments to qualify for priority review, which can reduce NDA processing time from ten months to six months.[259] However, priority review does not decrease the time required to complete clinical trials. In contrast, fast track designation, accelerated approval, and the breakthrough therapy can accelerate clinical trials and decrease the time to FDA approval.

The fast track designation was introduced in 1988.[260] It was inspired by the clinical evaluation and approval of zidovudine, an antiretroviral drug designed to treat AIDS.[261] Zidovudine was tested and approved in only two years with a single Phase 2 trial.[262] A drug can receive the fast track designation if it treats a serious condition and shows potential to address an unmet medical need.[263] This pathway has reduced the mean duration of clinical development from 8.9 to 6.2 years.[264]

Accelerated approval was implemented in 1992 to improve access to drugs that treat serious conditions and offer "a meaningful therapeutic benefit over

256. Erin E. Kepplinger, *FDA's Expedited Approval Mechanisms for New Drug Products*, 34 BIOTECH. L. REP. 15, 22 (2015).

257. *Id.* at 28–31.

258. *Priority Review*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm (Jan. 4, 2018).

259. *Id.*

260. Aaron S. Kesselheim et al., *Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987–2014: Cohort Study*, 351 BMJ 1, 2 (2015).

261. *Id.*

262. Jonathan J. Darrow et al., *New FDA Breakthrough-Drug Category—Implications for Patients*, 370 NEW ENG. J. MED. 1252, 1253 (2014).

263. *Fast Track*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track#:~:text=Fast%20track%20is%20a%20process,fill%20an%20unmet%20medical%20need.&text=Any%20drug%20being%20developed%20to,directed%20at%20an%20unmet%20need (Jan. 4, 2018). According to the FDA, filling an unmet medical need is defined as "providing a therapy where none exists or providing a therapy which may be potentially better than available therapy." *Id.*

264. *See* Darrow et al., *supra* note 262, at 1253.

existing treatments."[265] It could reduce the clinical investigation period of psychedelics if they are used to treat serious conditions, offer a meaningful benefit over traditional therapies, and can be shown to affect standard or surrogate markers of mental illness.[266] To date, no psychiatric drugs have received accelerated approval.

The breakthrough therapy designation was introduced in July 2012 with passage of the FDA Safety and Innovation Act.[267] It provides for expedited review of therapies for serious conditions that have an unmet need and represent a substantial improvement over other available therapy. [268] Though approval can be expedited through this pathway, treatments that obtain the breakthrough therapy designation must still undergo clinical testing, and the FDA expects preliminary evidence to come from Phase 1 or 2 clinical trials. [269] However, like the fast track pathway, the breakthrough therapy designation reduces the quantity of clinical evidence required. Drugs in this program have an average approval time of 4.2 years.[270]

Last year, the FDA designated psilocybin a breakthrough therapy for treating major depressive disorder.[271] In 2018, the agency granted psilocybin breakthrough status for use in treatment-resistant depression.[272] In 2017, the agency designated MDMA a breakthrough therapy for PTSD.[273] These designations reflect the FDA's confidence that psilocybin and MDMA are substantial improvements over existing mental health therapies.

Though having breakthrough status significantly decreases the time to FDA approval, the time to approval remains too long to provide needed therapies under emergency conditions, such as the COVID-19 pandemic. Experts estimate that even with the breakthrough designation, MDMA-

265. *See* Elizabeth A. Richey et al., *Accelerated Approval of Cancer Drugs: Improved Access to Therapeutic Breakthroughs or Early Release of Unsafe and Ineffective Drugs*, 27 J. CLINICAL ONCOLOGY 4398 (2009).

266. Marks, *supra* note 1, at 111.

267. *See* Darrow et al., *supra* note 262, at 1252.

268. *See id.*

269. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS – DRUGS AND BIOLOGICS 11 (2014), https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf.

270. *Id.* at 1253.

271. Rachel Feltman, *The FDA Is Fast-Tracking a Second Psilocybin Drug to Treat Depression*, POPULAR SCI. (Nov. 26, 2019), https://www.popsci.com/story/health/psilocybin-magic-mushroom-fda-breakthrough-depression/.

272. *Id.*

273. Janet Burns, *FDA Designates MDMA as 'Breakthrough Therapy' for Post-Traumatic Stress Disorder*, FORBES (Aug. 28, 2017, 3:58 PM), https://www.forbes.com/sites/janetwburns/2017/08/28/fda-designates-mdma-as-breakthrough-therapy-for-post-traumatic-stress/#6c759bf77460.

assisted psychotherapy will not be commercially available until 2022 at the earliest.[274] Before the pandemic, some speculated that psilocybin-assisted psychotherapy could be commercially available by 2021.[275] However, the pandemic has disrupted clinical trials and affected the pace at which scientific research is conducted.[276] As a result, the availability of MDMA and psilocybin-based therapies could be delayed by months or years. Approving psychedelic-assisted therapies in this timeframe may not benefit those affected by the COVID-19 mental health crisis.

Nevertheless, receiving a breakthrough designation reflects a drug's therapeutic potential because it must first complete Phase 1 or 2 clinical trials sanctioned by the FDA.[277] Thus, though far from conclusive evidence, the designations received by psilocybin and MDMA support their potential for safely treating depression and PTSD, respectively.

The following section describes the process through which the FDA may issue EUAs for unapproved drugs and medical devices. It will become apparent that even though psilocybin and MDMA are unapproved, Schedule I drugs, they should satisfy the requirements for receiving EUAs because the standards for issuing EUAs are significantly lower than the standards for establishing currently accepted medical use or FDA approval. The available evidence for these drugs should satisfy these relatively low requirements.

There are other potential avenues to make psychedelics available sooner, such as expanded access (sometimes called "compassionate use") and state and federal right-to-try laws.[278] However, these pathways will not be discussed further in this Article because unlike EUAs, they require patients to gain permission from healthcare providers and regulators on a case-by-case basis. Moreover, they may lack the capacity to support certain safety and data collection measures that can be built into EUAs by the FDA

274. *MDMA-Assisted Psychotherapy*, *supra* note 99.

275. Shelby Hartman, *Psilocybin Could Be Legal for Therapy by 2021*, ROLLING STONE (Nov. 9, 2018, 2:39 PM), https://www.rollingstone.com/culture/culture-news/psilocybin-legal-therapy-mdma-753946/.

276. Samik Upadhaya et al., *Impact of COVID-19 on Oncology Clinical Trials*, NATURE REVS. DRUG DISCOVERY (May 18, 2020), https://www.nature.com/articles/d41573-020-00093-1 (reporting that patient enrollment in active clinical trials for cancer therapies was severely affected by the COVID-19 pandemic during the survey assessment period).

277. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (Nov. 24, 2017).

278. *See Expanded Access*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/expanded-access (Apr. 27, 2020); *Right to Try*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try (Jan. 14, 2020).

Commissioner. Due to these and other limitations of expanded access and right-to-try programs, EUAs are more effective measures for a systematic, nationwide response to certain public health emergencies.

E. Emergency Use Authorization

The FDA Commissioner can issue EUAs to address health conditions resulting from CBRN threats.[279] Many COVID-19 diagnostic tests, numerous personal protective equipment products, and four medical treatments have been made available through this mechanism.[280] EUAs were introduced in 2004 with the passage of the Project BioShield Act, which amended the Food Drug and Cosmetic Act (FDCA) and empowered the FDA to authorize emergency use of unapproved drugs, medical devices, and other healthcare products such as diagnostic tests.[281] Under § 564 of the FDCA, the FDA Commissioner, using power delegated by the Secretary of HHS, can issue EUAs to treat or prevent serious or life-threatening conditions caused by CBRN agents when there are no adequate, approved, and available alternatives.[282]

Before the FDA can issue an EUA, the Secretary of HHS must issue an emergency declaration that justifies the authorization of the EUA.[283] The Secretary can issue the declaration if at least one of the following conditions is met: The Secretary of Homeland Security determines that there is a domestic emergency, or a significant potential for a domestic emergency,

279. *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (Nov. 21, 2020).

280. *Emergency Use Authorizations for Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices (July 29, 2020); *Personal Protective Equipment EUAs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas (Nov. 16, 2020); Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Ashley Rhoades, Manager, Regul. Affs., Gilead Scis., Inc. (Oct. 22, 2020) [hereinafter FDA Letter to Rhoades], https://www.fda.gov/media/137564/download.

281. Stuart L. Nightingale et al., *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1046 (2007).

282. *Id.* at 1048; 21 U.S.C. § 360bbb-3(b)(1); Notice of Emergency Use Authorization Declaration, 85 Fed. Reg. 17,335, 17,336 (Mar. 27, 2020).

283. 21 U.S.C. § 360bbb-3 (b)(1); *see also* U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATIONS OF MEDICAL PRODUCTS AND RELATED AUTHORITIES (2017), https://www.fda.gov/media/97321/download.

involving a heightened risk of attack with a CBRN agent;[284] the Secretary of Defense determines that there is a similar risk or potential risk to U.S. military forces;[285] or, the Secretary of HHS determines that there is "a public health emergency [under § 319 of the Public Health Service Act] that affects, or has a significant potential to affect, national security," and that involves a CBRN agent or agents, "or a disease or condition that may be attributable to such agent or agents."[286]

Following the HHS Secretary's declaration of emergency, the FDA Commissioner must satisfy additional conditions before issuing an EUA.[287] The Commissioner must consult, "to the extent feasible and appropriate given the circumstances" of the emergency, with the directors of NIH and the Centers for Disease Control and Prevention (CDC).[288] After consulting with these agencies, the FDA Commissioner may issue an EUA if he or she concludes that the CBRN agent specified in the HHS Secretary's emergency declaration "can cause a serious or life-threatening disease or condition;"[289] and "based on the totality of scientific evidence available . . . it is reasonable to believe that:"[290] "the product [that is the subject of the EUA] may be effective in diagnosing, treating, or preventing" that disease or condition;[291] that "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;"[292] and, that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition."[293]

Section 564(c)(2) only requires that the FDA Commissioner hold a reasonable belief that these conditions are met, which is a relatively low bar.[294] To issue an EUA, the Commissioner need not be certain that the conditions for issuance are met, nor must the preponderance of the evidence show that the conditions can be met. It need only be reasonable to conclude that the conditions are met based on the totality of the circumstances. Moreover, notice that § 564(c)(2)(A) requires only that the product that is being considered for an EUA "may be effective" for diagnosing, treating, or

284. 21 U.S.C. § 360bbb-3 (b)(1)(A).
285. *Id.* § 360bbb-3(b)(1)(B).
286. *Id.* § 360bbb-3(b)(1)(C).
287. *Id.* § 360bbb-3(c).
288. *Id.*
289. *Id.* § 360bbb-3(c)(1).
290. *Id.* § 360bbb-3(c)(2).
291. *Id.* § 360bbb-3(c)(2)(A).
292. *Id.* § 360bbb-3(c)(2)(B).
293. *Id.* § 360bbb-3(c)(3).
294. *Id.* § 360bbb-3(c)(2).

preventing serious or life-threatening diseases or conditions caused by the CBRN agent.[295] In other words, the effectiveness of the product need not be proven. Taken together, § 564(c)(2) and § 564(c)(2)(A) require only that the FDA Commissioner have a reasonable belief that that the product may be effective. This "may be effective" standard of evidence is far less stringent than the standards the FDA uses to approve pharmaceuticals under ordinary circumstances.[296]

The reasonableness standard of § 564(c)(2) also applies to the § 564(c)(2)(B) requirement regarding balancing of the product's risks and benefits. The Commissioner need only hold a reasonable belief that the benefits outweigh the risks. Moreover, according to FDA Guidance on EUAs, "[i]n determining whether the known and potential benefits of the product outweigh the known and potential risks, FDA intends to look at the totality of the scientific evidence to make an overall risk-benefit determination."[297] This part of the guidance suggests that evidence outside of clinical trials can be considered in weighing the risks and benefits. The phrase "totality of the evidence" suggests a far broader range of evidence than is typically considered for FDA approval, which consists of Phase 3 clinical trials having hundreds or thousands of participants.

The FDA's guidance specifies that for evaluating a potential EUA, relevant evidence "could arise from a variety of sources," and may include (but is not limited to): "results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, and *in vitro* data, available for FDA consideration."[298] Though not specifically identified by the guidance document, relevant evidence might also include case reports, public health surveys, and observational studies. According to the FDA's guidance, while balancing the risks, the agency "must take into consideration the material threat posed by the CBRN agent(s) identified in the HHS Secretary's declaration of emergency or threat of emergency, if applicable."[299] No further clarification is provided regarding the sources of evidence. However, concerning COVID-19 and its effects on the mental health, it would be prudent to consider rising rates of depression, anxiety, drug overdose, and suicide when contemplating the risks and benefits of an EUA for psilocybin and MDMA.

When evaluating whether there are adequate, approved, and available alternatives to the product being considered for an EUA, the FDA

295. *Id.* § 360bbb-3(c)(2)(A).

296. U.S. FOOD & DRUG ADMIN., *supra* note 283, at 5.

297. *Id.* at 8.

298. *Id.*

299. *Id.*

Commissioner need only have a reasonable belief that there are none. Though still a relatively low bar, this requirement may be the most challenging to meet because numerous alternatives to psilocybin and MDMA currently exist. The relevant question is whether they are adequate, approved, and available for treating mental health conditions associated with COVID-19.

According to FDA guidance, "[a] potential alternative product may be considered 'unavailable' if there are insufficient supplies of the approved alternative to fully meet the emergency need."[300] However, neither the guidance nor § 564 preclude other interpretations of the term "unavailable."[301] It might be equally reasonable to conclude that alternative products are unavailable if they are prohibitively expensive or available to some populations and not others. For example, should ketamine therapy be considered "available" for the purposes of responding to an emergency if a single dose costs over $500, multiple doses are required, and the treatment is not covered by insurance? It might be reasonable to conclude that these characteristics make the therapy unavailable to many people.

It is less clear what the term "adequate" means. The FDA guidance provides only one example:

> A potential alternative product may be considered "inadequate" if, for example, there are contraindicating data for special circumstances or populations (e.g., children, immunocompromised individuals, or individuals with a drug allergy), if a dosage form of an approved produce is inappropriate for use in a special population (e.g., a tablet for individuals who cannot swallow pills), or if the agent is or may be resistant to approved and available alternative products.[302]

The last phrase of this explanation, "or if the agent is or may be resistant to approved and alternative products," appears relevant to determining the adequacy of existing mental health therapies. Here, the term "the agent" should be interpreted broadly to include not only CBRN agents themselves but also the conditions and symptoms caused by those agents. Consider what would happen if that were not the case, and "agent" were interpreted to mean only the causative CBRN agent.

If a nuclear device is detonated and people suffer radiation sickness from its radioactive fallout, it would not make sense to say that the radiation is resistant to the treatment. It would be more accurate to say that the conditions and symptoms caused by the radiation are resistant to the treatment. Similarly, when considering mental health conditions caused by COVID-19, one might refer to the symptoms as being treatment resistant

300. *Id.*

301. *Id.*; 21 U.S.C. § 360bbb-3(c).

302. U.S. FOOD & DRUG ADMIN., *supra* note 283, at 8.

instead of the virus itself. This interpretation of the term agent is reasonable because it is the only interpretation that could be applied to all CBRN agents. For instance, conditions caused by COVID-19 can persist long after the virus is eradicated from a patient's body. At that point, it would be nonsensical to say that the virus is treatment resistant. Rather, the symptoms caused by the agent are treatment resistant.

When the term agent is construed broadly in this manner, it is reasonable to conclude that existing alternatives to psilocybin and MDMA, such as SSRIs and benzodiazepines, are not adequate under § 564 because a large percentage of mental health conditions caused by COVID-19 will be resistant to those approved and alternative products.

Similarly, it may be reasonable to conclude that alternative products are inadequate if they are relatively ineffective and associated with high risk. Should SSRIs be considered adequate if they leave up to 50% of those who try them without symptomatic relief? It might be reasonable to conclude that, given their high rate of ineffectiveness, SSRIs are not adequate to address COVID-19-related mental health conditions.

To date, no EUAs have been issued for drugs or devices that diagnose, prevent, or treat mental health conditions, and critics might argue that mental health conditions are not the types of conditions for which EUAs are intended. However, § 564 puts no limits on the scope of conditions for which EUAs may be issued.[303] It requires only that they be caused by CBRN agents. It has been documented that COVID-19 can enter the central nervous system and may affect one's mental health.[304] Even if it did not enter the nervous system, the virus can cause mental health conditions either directly—through physiologic effects—or indirectly—through social, economic, and psychological effects. Section 564 contains no limitations on what it means for a CBRN agent to cause a condition. This leaves room for an EUA to be issued for mental health conditions where COVID-19 infection is the proximate cause, for example by direct infection, and for conditions where COVID-19 causes a mental health condition by more indirect means, such as where a person becomes depressed due to working with COVID-19 patients, from the loss of a loved one due to COVID-19, or due to loss of housing or employment due to COVID-19. The existing and

303. § 360bbb-3(a)(1–2).

304. Ali A. Asadi-Pooya & Leila Simani, *Central Nervous System Manifestations of COVID-19: A Systemic Review*, 413 J. NEUROLOGICAL SCI. 1 (2020) (discussing COVID-19); Mario Gennaro Mazza et al., *Anxiety and Depression in COVID-19 Survivors: Role of Inflammatory Clinical Predictors*, 89 BRAIN, BEHAV., & IMMUNITY 594, 595 (2020); Nina Vindegaard & Michael Eriksen Benros, *COVID-19 Pandemic and Mental Health Consequences: Systematic Review of the Current Evidence*, 89 BRAIN, BEHAV., & IMMUNITY 531, 533 (2020).

potential adverse effects of COVID-19 on the mental health of various populations are well documented.[305]

To enhance safety of a product for which an EUA is issued, the FDA Commissioner can issue conditions of use alongside an EUA.[306] These conditions might resemble Risk Evaluation and Mitigation Strategies (REMS), which the FDA can require when it approves a drug or medical device.[307] One element of REMS, called Elements to Assure Safe Use (ETASU), can be implemented to mitigate a known serious risk associated with a drug.[308] Potential elements of ETASU include requiring hospitals, pharmacists, and healthcare providers who dispense or administer the drug to have special training.[309] With respect to EUAs for psilocybin and MDMA, the FDA might impose similar requirements, including that licensed healthcare providers administer the drugs in controlled settings. To decrease the risk of diversion, the Commissioner might require that only small amounts of the drug be stored at any given location, and to enhance safety, that patients be observed until the effects of the drugs have worn off.

Issuance of an EUA is not the end of the story; it is a starting point for gathering additional information on safety and efficacy. While EUAs are in effect, the FDA Commissioner can establish systems to collect and analyze safety and efficacy information on unapproved products. [310] If necessary, EUAs can be amended after they are issued.[311] If psilocybin and MDMA

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305. *See, e.g.*, Benjamin Y.Q. Tan et al., *Psychological Impact of the COVID-19 Pandemic on Health Care Workers in Singapore*, ANN. INTERNAL MED. (Aug. 18, 2020), https://www.acpjournals.org/doi/full/10.7326/M20-1083; Cuivan Wang et al., *A Longitudinal Study on the Mental Health of General Population During the COVID-19 Epidemic in China*, 87 BRAIN, BEHAV., & IMMUNITY 40, 42 (2020); Kim Mannemar Sønderskov et al., *The Depressive State of Denmark During the COVID-19 Pandemic*, ACTA NEUROPSCYHIATRICA, Apr. 10, 2020, at 1–2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7176490/pdf/S0924270820000150a.pdf; Naiara Ozamiz-Etxebarria et al., *Stress, Anxiety, and Depression Levels in the Initial Stage of COVID-19 Outbreak in a Population Sample in the Northern Spain*, 36 CADERNOS SAUDE PUBLICA, Apr. 2, 2020, at 4–5, https://www.scielo.br/pdf/csp/v36n4/en_1678-4464-csp-36-04-e00054020.pdf.

306. Nightingale et al., *supra* note 281, at 1049.

307. Jasmanda Wu & Juhaeri Johari, *The US Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) Program – Current Status and Future Direction*, 38 CLINICAL THERAPEUTICS 2526, 2526 (2016) ("[F]or most drugs, FDA-approved labeling is sufficient to ensure that the benefits of the drug outweigh the risks. However, for some drugs, additional risk mitigation measures beyond labeling are necessary.").

308. *Id.* at 2526–27.

309. *Id.* at 2527.

310. 21 U.S.C. § 360bbb-3(e)(2)(C).

311. Brooke Courtney et al., *Federal Legal Preparedness for Facilitating Medical Countermeasure Use During Public Health Emergencies*, J.L. MED. & ETHICS 22, 24 (2013).

were granted EUAs, the FDA could mandate that data be collected to monitor their safety and efficacy. If at any point safety became a concern, then the FDA Commissioner could amend or revoke the EUAs.

So far, the FDA has issued only three EUAs for medical treatments directed at COVID-19. Most COVID-19-related EUAs have been issued for diagnostic tests or personal protective gear, such as masks.[312] In 2020, the FDA issued an EUA for the antimalarial drugs chloroquine and hydroxychloroquine, for the antiviral drug remdesivir, and for convalescent plasma therapy.[313] In the letter issuing an EUA for chloroquine and hydroxychloroquine, the FDA recites the EUA threshold requirements and explains how they had been met; the Secretary of HHS had declared a public health emergency and concluded that the circumstances warranted authorizing the emergency use of drugs during the pandemic.[314] The letter then cited the scientific evidence supporting the emergency use of chloroquine and hydroxychloroquine for treating COVID-19: "Based upon limited *in-vitro* and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries . . . ."[315] The letter concluded that based on this evidence, the requirements for issuing an EUA had been met because COVID-19 can cause serious or life-threatening conditions, including severe respiratory illness; it was reasonable to believe, based on the totality of the evidence, that the drugs may be effective in treating COVID-19; when used under the conditions prescribed in the letter, "the known and potential benefits" of the drugs outweigh their known and potential risks; and there were no adequate, approved, and available alternatives.[316]

312. *Coronavirus Disease 2019 (COVID-19) Emergency Use Authorization for Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices (Aug. 3, 2020).

313. Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Dr. Rick Bright, Dir., Biomedical Advanced Rsch. & Dev. Auth. (Oct. 22, 2020) [hereinafter FDA Letter to Bright], https://www.fda.gov/media/136534/download; FDA Letter to Rhoades, *supra* note 280; Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID-19 Treatment, Another Achievement in Admin.'s Fight Against Pandemic (Aug. 23, 2020) [hereinafter FDA Press Release], https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment.

314. FDA Letter to Bright, *supra* note 313.

315. *Id.*

316. *Id.*

Notably, the FDA issued the EUA despite a serious known risk for heart abnormality.[317]

By comparison, the EUA issue letter for remdesivir contains more robust evidence. It cites a Phase 3 "randomized, double-blinded, placebo-controlled trial" conducted by the National Institute of Allergy and Infectious Disease (NIAID) and an open-label trial sponsored by remdesivir's manufacturer, Gilead.[318] This evidence is far more robust than the *in-vitro* data and anecdotal evidence the FDA relied on when issuing the chloroquine and hydroxychloroquine EUA.[319]

In June, the FDA withdrew its EUA for hydroxychloroquine, stating it was "unlikely to be effective in treating COVID-19."[320] However, this outcome should not be viewed as an indictment of the process for issuing EUAs. Instead, it is as an example in which the EUA process was working effectively.

In August, FDA Commissioner Stephen Hahn issued an EUA for using convalescent plasma to treat COVID-19.[321] Convalescent plasma is derived from the blood of people who have recovered from infection with the virus. It contains antibodies that might reduce morbidity and mortality in hospitalized patients. President Trump's announcement of the plasma EUA therapy sparked intense national debate.[322] The week prior to the announcement, experts from the CDC and NIAID urged Commissioner Hahn to hold off until more robust data could be collected through randomized controlled trials.[323] When Trump, Hahn, and HHS Secretary Alex Azar ignored their advice and announced the EUA during a press conference, it was met with a flurry of criticism from medical and public health experts.[324]

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317. QT prolongation is a potentially fatal heart conduction abnormality associated with chloroquine and hydroxychloroquine, particularly when they are administered with certain medications that promote QT prolongation. Mike Z. Zhai et al., *Need for Transparency and Reliable Evidence for Emergency Use Authorizations for Coronavirus Disease 2019 (COVID-19) Therapies*, 180 JAMA INTERNAL MED. 1145, 1145 (2020).

318. FDA Letter to Rhoades, *supra* note 280.

319. The FDA issued the remdesivir EUA before detailed results of the NIAID trial had been released. *Id.*

320. Lev Facher, *FDA Revokes Emergency Use Ruling for Hydroxychloroquine, Drug Touted by Trump as a Covid-19 Therapy*, STAT (June 15, 2020), https://www.statnews.com/2020/06/15/fda-revokes-hydroxychloroquine/.

321. FDA Press Release, *supra* note 313.

322. Gupta et al., *supra* note 251.

323. Noah Weiland et al., *F.D.A.'s Emergency Approval of Blood Plasma Is Now on Hold*, N.Y. TIMES, https://nyti.ms/2Q7q2BT (Aug. 28, 2020).

324. Gupta et al., *supra* note 251.

Some experts have leveled the following criticisms. EUAs can divert patients away from clinical trials, which can slow the accumulation of safety and efficacy information; EUAs influence the behavior of clinicians and encourage them to prescribe the authorized drugs even though an EUA does not constitute FDA approval; and EUAs cause surges in demand for the authorized treatment, resulting in widespread shortages that impact people who require the treatment for other indications.[325] These concerns are legitimate. When the FDA issued an EUA for chloroquine and hydroxychloroquine, some doctors stockpiled the drug for themselves, causing widespread shortages, and patients who required these drugs for treating other conditions, such as lupus, had difficulty obtaining them.[326]

Some experts appear to feel that nothing less than randomized controlled trials is acceptable, even under the exceptional circumstances of a pandemic.[327] However, not all the criticisms leveled against EUAs may be valid. Critics of the plasma EUA argue that the FDA should have waited for evidence from randomized controlled trials before it was issued.[328] But that would defeat its purpose. The EUA is designed for use in response to public health and military emergencies in which a CBRN threat is released and there are no adequate, approved, and available countermeasures. The idea is that there would be no time to conduct additional research before making a drug, device, or diagnostic test available. The Project BioShield Act specifies that, though they may be desirable, clinical trials are not required; let alone randomized controlled clinical trials (RCTs), which require hundreds or thousands of participants and a placebo control group. The requirements for issuing an EUA are intentionally low and the FDA Commissioner needs only a reasonable belief that the treatment will be effective. In the case of plasma therapy, the available data supported that conclusion. [329]

There may be some truth to the claim that making treatments available through EUAs might deter people from enrolling in clinical trials. However, that is not as bad of an outcome as critics contend. As prescribed by the FDCA, EUAs can also generate useful data safety and efficacy data.

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325. Zhai et al., *supra* note 317, at 1145–46.

326. Ellen Gabler, *States Say Some Doctors Stockpile Trial Coronavirus Drugs, for Themselves*, N.Y. TIMES, https://nyti.ms/2JeY1Vw (Apr. 9, 2020).

327. Weiland et al., *supra* note 323 (referring to the views of Dr. Anthony Fauci and Dr. Francis Collins, Dr. H. Clifford Lane told the New York Times, "[t]he three of us are pretty aligned on the importance of robust data through randomized control trials, and that a pandemic does not change that").

328. *Id.*

329. Michael J. Joyner et al., *Effect of Convalescent Plasma on Mortality Among Hospitalized Patients with COVID-19: Initial Three-Month Experience*, MEDRXIV, Aug. 12, 2020, at 2, https://www.medrxiv.org/content/10.1101/2020.08.12.20169359v1.full.pdf.

Some concerns are not applicable to EUAs for psilocybin and MDMA. Shortages of psilocybin and MDMA for other patient populations would not arise because these drugs are not used by existing patient populations. However, aggregate production quotas implemented by the DEA are a concern, and they would need to be lifted or shortages would occur almost immediately if the FDA issued an EUA.

Critics might argue that the FDA should not issue EUAs for psilocybin and MDMA-assisted therapy because they would be used to treat psychological symptoms, whereas the therapies authorized thus far for COVID-19 are used to treat physical symptoms. However, § 564 does not specify the types of medications that can receive EUAs or the types of symptoms they can treat. It only requires that they may be effective at treating conditions caused by a CBRN agent; that those conditions be serious or life-threatening; and that there be no adequate, approved, and available alternatives.[330] Determining whether psilocybin and MDMA qualify involves determining whether they meet these criteria.

The evidence supporting psilocybin's and MDMA's safety and efficacy is of higher quality than the evidence supporting the EUAs for hydroxychloroquine and convalescent plasma, which was largely anecdotal.[331] The evidence for psilocybin-assisted psychotherapy comes from a completed Phase 1 clinical trial and a partially completed Phase 2 trial.[332] The evidence for MDMA-assisted psychotherapy comes from completed Phase 1 and Phase 2 clinical trials and a partially completed Phase 3 trial.[333] There is also a large body of clinical and anecdotal evidence supporting the safety and efficacy of psilocybin and MDMA-assisted therapy.[334] Meanwhile, the public health risks associated with the COVID-

330. 21 U.S.C. § 360bbb-3(b)–(c)(1).

331. It is worth noting that hydroxychloroquine was already FDA-approved for treating conditions other than COVID-19, and it could be prescribed "off label" by physicians to treat symptoms caused by the virus. Andre C. Kalil, *Treating COVID-19—Off-Label Drug Use, Compassionate Use, and Randomized Clinical Trials During Pandemics*, 323 JAMA 1897, 1897 (2020).

332. *A Double-Blind Trial of Psilocybin-Assisted Treatment of Alcohol Dependence*, U.S. NAT'L LIB. MED., https://clinicaltrials.gov/ct2/show/NCT02061293 (Apr. 3, 2020).

333. *The MAPP Phase 3 Program Summary*, MULTIDISCIPLINARY ASS'N PSYCHEDELIC STUD., https://maps.org/research/mdma/ptsd/phase3 (last visited Nov. 21, 2020).

334. There is also a large body of clinical and anecdotal evidence supporting the safety and efficacy of psilocybin and MDMA-assisted therapy. *See, e.g.*, Press Release, Compass Pathways, Compass Pathways and King's College and London Announce Results from Psilocybin Study in Healthy Volunteers, (Dec. 12, 2019), https://compasspathways.com/compass-pathways-and-kings-college-london-announce-results-from-psilocybin-study-in-healthy-volunteers/ (concluding that in placebo-controlled trial there were "no serious adverse events" and "no

19 mental health crisis are significant. While rates of depression, anxiety, substance use, and suicide are rising, existing psychiatric drug treatments provide inadequate symptomatic improvement. Meanwhile, the risks associated with EUAs for MDMA and psilocybin-assisted therapy appear to be low.

III. STATE AND LOCAL REGULATION OF PSYCHEDELICS

Despite congressional and federal agency resistance to increasing access to psychedelics, three U.S. cities have taken the lead by decriminalizing them, and additional jurisdictions may decriminalize or legalize them this year. This Part describes those efforts and discusses how they may affect the COVID-19 mental health crisis and inform federal psychedelics policy and regulation.

In 2019, Denver became the first U.S. city to decriminalize mushrooms containing psilocybin.[335] In a historic vote, residents approved Ordinance 301, which has three main effects.[336] First, it mandates that prosecuting people who possess the mushrooms for personal use is the city's lowest law enforcement priority.[337] Second, it prohibits the city from spending funds to prosecute people over twenty-one who possess the mushrooms for personal use.[338] Third, it establishes the Psilocybin Mushroom Policy Review Panel,

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negative effects on cognitive and emotional functioning"); Robert S. Gable, *Toward a Comparative Overview of Dependence Potential & Acute Toxicity of Psychoactive Substances Used Nonmedically*, 19 AM. J. DRUG & ALCOHOL ABUSE 263 (finding psilocybin to be the least lethal and addictive drug of the twenty substances studied); Mason Marks, *Inside the Fight to Legalize Psilocybin Therapy in Oregon*, GIZMODO (Oct. 22, 2020, 11:15 AM), https://gizmodo.com/inside-the-fight-to-legalize-psilocybin-therapy-in-oreg-1845450885 (quoting expert, "it's almost impossible to overdose [on psilocybin]" and "it's been used in many hundreds of patients with few if any significant adverse effects"); Nicola Davis, *Ease Rules on Research into Psychedelic Drugs, Urges David Nutt*, GUARDIAN (Apr. 2, 2020 10:00 AM), https://www.theguardian.com/politics/2020/apr/02/ease-rules-on-use-of-psychedelic-drugs-in-research-urges-david-nutt ("Both the depression and tobacco smoking trials have shown that in some people psilocybin can produce clinical remission, in some cases persisting for years."); Ben Sessa et al., *A Review of 3, 4-methylenedioxymethamphetamine (MDMA)-Assisted Psychotherapy*, FRONTIERS PSYCH., Mar. 20, 2019, at 2 ("Further studies that control for confounding factors show no evidence of neurotoxicity with MDMA when used in isolation and no lasting neurocognitive impairments.").

335. Chavez & Prior, *supra* note 105.

336. *Id.*

337. CITY & CNTY. OF DENVER, COLO., DENVER PSILOCYBIN MUSHROOM DECRIMINALIZATION INITIATIVE (2018), https://www.denvergov.org/content/dam/denvergov/Portals/778/documents/PsilocybinFourthPetitionSample.pdf (last visited Nov. 21, 2020).

338. *Id.*

an eleven-member group convened to assess and report on the impact of Ordinance 301.[339]

The panel is the first of its kind, assembled to advise government officials and law enforcement on the implementation of psychedelics policies.[340] One of its first tasks was determining what types of information should be collected and reported regarding psilocybin arrests and prosecutions.[341] The panel held a series of online meetings to establish reporting criteria and submit recommendations to the city council.[342] According to panel member Kevin Matthews, who led the campaign to legalize psilocybin in Denver, some of the group's goals are keeping the city accountable to the local voters and making sure law enforcement is respecting the initiative and following the law.[343] He said concerns have been raised regarding what decriminalization should look like and how the city can best track psychedelic-related arrests involving people of color and other minorities.[344] The panel reviewed existing data on past cannabis activity showing that arrests for people of color went up after Denver implemented Amendment 64, which legalized recreational marijuana.[345] Therefore, the panel hopes to ensure that police are not targeting people based on race when it comes to psilocybin possession.[346] Accordingly, its members will track psilocybin arrests to ensure that law enforcement is respecting the will of Denver voters.[347]

Under Denver's system, cultivation and distribution of psilocybin-containing mushrooms remain criminal offenses. However, the city has effectively decriminalized their possession for personal use.

Weeks after Denver voters passed Ordinance 301, the Oakland, California City Council passed its own decriminalization measure,

339. *Id.*

340. *See* Alexander Lekhtman, *World's First Psilocybin Mushroom Policy Panel Starts Work in Denver*, FILTER MAG. (Jan. 2, 2020), https://filtermag.org/psilocybin-policy-panel-denver/; Kyle Jaeger, *Denver Government Psilocybin Panel Sets Criteria to Track Decriminalization's Impact*, MARIJUANA MOMENT (Mar. 24, 2020), https://www.marijuanamoment.net/denver-government-psilocybin-panel-sets-criteria-to-track-decriminalizations-impact/.

341. Jaeger, *supra* note 340.

342. The Society for Psychedelic Outreach, Reform, and Education, *Mushroom Panel Meeting #2*, FACEBOOK (Mar. 24, 2020), https://www.facebook.com/thesporeorg/videos/mushroom-panel-meeting-2/646980079181376/ (featuring Joe Montoya, Division Chief of Investigations at Denver Police Department, reporting that there were very few psilocybin-related investigations or arrests in Denver before the decriminalization of psilocybin in 2019).

343. *Id.*

344. *Id.*

345. *Id.*

346. *Id.*

347. *Id.*

Resolution 87731.[348] Unlike Denver's ordinance, Oakland's added other naturally occurring psychedelics, such as ayahuasca and peyote, to its list of decriminalized compounds.[349] According to the measure:

> [I]t shall be the policy of the City of Oakland that no department, agency, board, commission, officer or employee of the city, including without limitation, Oakland Police Department personnel, shall use any city funds or resources to assist in the enforcement of laws imposing criminal penalties for the use and possession of Entheogenic Plants by adults.[350]

However, like Denver's ordinance, the Oakland measure does not authorize manufacturing, distribution, or commercial sales.[351] Oakland has further resolved that it will urge state and federal lobbyists to work in support of decriminalizing all psychedelic plants and plant-based compounds that are categorized as Schedule I controlled substances by the federal government.[352] It requires the Alameda County District Attorney to stop prosecuting people for using Schedule I controlled substances, and asks the City Administrator to assess the community impact and benefits of decriminalization and provide a report to the City Council within a year.[353]

In 2020, Santa Cruz became the third city to decriminalize psilocybin and the second to decriminalize other naturally occurring psychedelics.[354] Resolution NS-29,623 is comparable to Oakland's Resolution and borrows much of its language and structure.[355] On September 21, 2020, the City

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348. Details on City Resolution No. 87731, CITY OF OAKLAND (June 4, 2019), https://oakland.legistar.com/LegislationDetail.aspx?ID=3950933&GUID=5E53E7F6-F79F-433D-B669-0D687786590F; Jon Blistein, *Oakland Decriminalizes Magic Mushrooms, Other Natural Psychedelics*, ROLLINGSTONE (June 5, 2019, 6:01 PM), https://www.rollingstone.com/culture/culture-news/oakland-decriminalize-magic-mushrooms-natural-psychedelics-844879/.

349. Blistein, *supra* note 348.

350. Memorandum from Noel Gallo, Councilmember, City of Oakland, to City Councilmembers and Members of the Pub. Safety Comm'n (June 5, 2019), https://www.decriminalizenature.org/media/attachments/2020/04/08/decriminilizing-entheogenic-plants_v1.2.pdf.

351. *Id.*

352. *Id.*

353. *Id.*

354. Alex Norcia, *Santa Cruz Is Decriminalizing Magic Mushrooms*, VICE (Jan. 29, 2020, 2:03 PM), https://www.vice.com/en_us/article/qjdvwx/santa-cruz-is-decriminalizing-magic-mushrooms.

355. *See Santa Cruz Resolution for Decriminalization of Entheogenic Plants and Fungi*, CHACRUNA INST. (Feb. 17, 2020), https://chacruna.net/santa-cruz-resolution-for-decriminalization-of-entheogenic-plants-and-fungi/(including text of passed resolution); Minutes from City Council

Council of Ann Arbor, Michigan, voted unanimously to decriminalize naturally-occurring psychedelics.[356] A similar resolution is under consideration in Chicago, where the City Council may decriminalize naturally occurring psychedelics and promote their use as alternative therapies for mental illness.[357] In June, a proposed psilocybin amendment was defeated during an Iowa House floor vote.[358]

In November 2020, Washington, D.C. voters approved a measure like those of Oakland and Santa Cruz.[359] On July 6, 2020, advocates from the group Decriminalize Nature D.C. submitted over 36,000 signatures from D.C. voters to put Initiative 81 on the ballot.[360] Also called the Entheogenic Plant and Fungus Policy Act, Initiative 81 will "make the investigation and arrest of adults for non–commercial planting, cultivating, purchasing, transporting, distributing, possessing and/or engaging in practices with entheogenic plants and fungi among the lowest law enforcement priorities for the District of Columbia."[361] The measure:

Meeting, City of Santa Cruz (Jan. 28, 2020), https://ecm.cityofsantacruz.com/OnBaseAgendaOnline/Meetings/ViewMeeting?id=747&doctype=2 (describing discussion and passage of Resolution Regarding Adult Personal Use and Personal Possession of Entheogenic Psychoactive Plants and Fungi).

356. Kaelan Deese, *Ann Arbor Lawmakers Vote to Decriminalize Psychedelic Mushrooms*, HILL (Sept. 22, 2020, 2:02 PM), https://thehill.com/homenews/state-watch/517581-ann-arbor-lawmakers-vote-to-decriminalize-psychedelic-mushrooms.

357. Josh McGhee, *Chicago City Council Quietly Begins Push to Decriminalize Psychedelics*, CHI. REP. (Oct. 24, 2019), https://www.chicagoreporter.com/chicago-city-council-quietly-begins-push-to-decriminalize-psychedelics/.

358. Kyle Jaeger, *Iowa GOP Lawmaker's Psilocybin Decriminalization Amendment Defeated in Floor Vote*, MARIJUANA MOMENT (June 23, 2020), https://www.marijuanamoment.net/iowa-gop-lawmakers-psilocybin-decriminalization-amendment-defeated-in-floor-vote/. The amendment's sponsor, State Representative Jeff Shipley made the following remarks: "Psilocybin . . . could open up Iowa to a whole new world of health and healing, revolutionizing our healthcare, revolutionizing mental health, where right now we have a system of treatments where a person has to take a pill, a synthetic pharmaceutical for an indefinite period of time, maybe for the rest of their life." *Id.* He added, "[t]hese treatments, at best, make a person's symptoms manageable." *Id.*

359. Justin Wm. Moyer, *D.C. Voters Approve Ballot Question to Decriminalize Psychedelic Mushrooms*, WASH. POST (Nov. 3, 2020, 8:24 PM), https://www.washingtonpost.com/local/dc-politics/dc-magic-mushrooms-result/2020/11/03/bb929e86-1abc-11eb-bb35-2dcfdab0a345_story.html.

360. Associated Press, *Activists Seek to Decriminalize 'Magic' Mushrooms in D.C.*, POLITICO (July 13, 2020, 12:36 PM), https://www.politico.com/news/2020/07/13/dc-decriminalizing-magic-mushrooms-359675.

361. *Initiative 81*, CAMPAIGN TO DECRIMINALIZE NATURE DC, https://decrimnaturedc.org/initiative-81/ (last visited Nov. 21, 2020); Ashraf Khalil, *Proposed Ballot Initiative Would*

> [C]all[s] upon the Attorney General of the District of Columbia and the United States Attorney for the District of Columbia to cease prosecution of residents of the District of Columbia for non-commercial planting, non-commercial cultivating, purchasing, transporting, distributing, engaging in practices with, and/or possessing entheogenic plants and fungi as defined in section 3 of this act.[362]

In November 2020, Oregon residents approved Measure 109—a ballot measure that goes further than previous psychedelics legislation in Colorado and California.[363] Measure 109 will apply statewide, and instead of merely decriminalizing psilocybin, it will establish a statewide licensing system for cultivation, distribution, and supervised administration of psilocybin.[364] In this respect, the system is analogous to cannabis licensing programs in over half the U.S. states.[365] However, unlike cannabis made available through medical and adult use programs, psilocybin produced in Oregon will be administered only by providers licensed by the Oregon Health Authority, the State's public health agency.[366] Measure 109's approval triggers a two-year development phase in which the state will develop a regulatory framework. The Governor will appoint a sixteen-member advisory board. Consumers will not be permitted to grow mushrooms or consume them. Psilocybin can only be manufactured, distributed, and administered by licensed producers, distributers, and facilitators. Criminal penalties will remain in effect statewide. However, there is a different ballot initiative, Measure 110, which Oregon voters also approved, that will decriminalize all illicit drugs in the state of Oregon.[367]

One drawback of state and local approaches to decriminalization is that psychedelics remain Schedule I controlled substances at the federal level, and individuals who use psychedelics are in violation of federal drug laws.[368] Considering the ongoing pandemic and the resulting mental health crisis, the DOJ should pledge not to enforce the CSA against individuals using psychedelics, such as psilocybin, in jurisdictions where they are legal.

Decriminalize 'Magic' Mushrooms, Other Psychedelics in DC, USA TODAY (July 3, 2020, 1:30 PM), https://www.usatoday.com/story/news/politics/elections/2020/07/13/magic-mushroom-decriminalization-washington-dc/5428673002/.

362. *Initiative 81*, *supra* note 361.

363. *Oregon Measure 109 Results*, *supra* note 22.

364. *Id.*

365. *Id.*

366. *Id.*

367. Max Dunat, *Oregon Ballot Initiative Would Decriminalize Low-Level Possession of All Drugs*, REASON (Aug. 21, 2020, 1:30 PM), https://reason.com/2020/08/21/oregon-ballot-initiative-would-decriminalize-low-level-possession-of-all-drugs/; *Oregon Measure 110 Results*, *supra* note 22.

368. Marks, *supra* note 1, at 74, 79.

In 2013, Deputy U.S. Attorney General James Cole issued a memorandum, *Guidance Regarding Marijuana Enforcement* (Cole Memorandum) to all U.S. state attorneys.[369] The Cole Memorandum explained that in light of the legalization of marijuana in several states, the DOJ had decided that its limited resources would be better spent on activities, such as stopping drug trafficking, preventing drug-related violence, and deterring marijuana consumption by minors, than on prosecuting adults using marijuana in accordance with state laws.

Because cities and states are now decriminalizing, and potentially legalizing, psychedelic therapy, the DOJ should issue an updated version of the Cole Memorandum instructing state attorneys general not to prosecute adults using psychedelics in accordance with state and local laws. In this manner, the agency could focus its efforts on drug trafficking, which poses far greater risks to the public than the personal use of psychedelics.[370]

IV. RECOMMENDATIONS

A. Short Term Recommendations

1. The DEA Should Deschedule Psilocybin and Reschedule MDMA by Moving It from Schedule I to Schedule IV

Given its safety profile, low potential to cause physical and psychological dependence, and therapeutic efficacy based on clinical trials and other evidence accumulated in the United States and abroad, the DEA should deschedule psilocybin and remove it from federal control. Compared to psilocybin, the substances in Schedule IV, such as benzodiazepines and hypnotics, have significant risks and high potential for dependence and diversion. Even Schedule V substances, such as over-the-counter cough medicines, can be more addictive than psilocybin, and their contents can be highly toxic.[371] Some Schedule V substances are routinely diverted for non-medical consumption.[372] Alcohol and nicotine, which are available over the

369. Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Just. to U.S. Att'ys (Aug. 29, 2020) [hereinafter Cole Memorandum], https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf.

370. Matthew P. Prekupec et al., *Misuse of Novel Synthetic Opioids: A Deadly New Trend*, 11 J. ADDICTION MED. 256, 258 (2017) (reporting that according to the DEA, the U.S. opioid crisis is fueled by fentanyl and related chemicals imported from Chinese laboratories).

371. *See, e.g.*, Victoria Hartley, *Overdose of Cough and Cold Remedies*, 10 EMERGENCY NURSE 20, 20, 21 (2003).

372. Marie Claire Van Hout, *Kitchen Chemistry: A Scoping Review of the Diversionary Use of Pharmaceuticals for Non-Medicinal Use and Home Production of Drug Solutions*, 6 DRUG TESTING ANALYSIS 778 (2014).

counter to adults of legal age, are more addictive than psilocybin and far more dangerous. They are responsible for over half a million deaths in the United States each year.[373]

When pharmaceutical scientists at Johns Hopkins University conducted an eight-factor analysis of psilocybin, they determined that the available data "supports the scheduling of psilocybin no more restrictively than Schedule IV."[374] However, their analysis did not consider over-the-counter medications.[375] The lethal dose of psilocybin in humans is estimated to be 1,000 times its therapeutic dose, which would likely be impossible for anyone to consume in its naturally occurring form.[376] By comparison, the lethal dose of acetaminophen, an unscheduled drug that may be purchased in any pharmacy or grocery store without a prescription, is estimated to be ten grams per day (2.5 times the maximum daily recommended dose of four grams).[377] Based on these observations, and the risks of psilocybin compared to those of Schedule IV, Schedule V, and many uncontrolled substances, psilocybin should be removed from the federal controlled substances list.

Compared to psilocybin, MDMA has a higher potential for physical and psychological dependence, and there is some evidence suggesting that it could be harmful if consumed chronically or at high doses. However, when administered in controlled settings, the risk of dependence, addiction, and toxicity can be minimized. Despite potential risks, evidence suggests that the risks are lower than those of benzodiazepines and may be comparable to those of substances in Schedule IV or Schedule V. Therefore, MDMA should be recategorized no more restrictively than Schedule IV.

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373. *See Alcohol Facts and Statistics*, NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM, https://www.niaaa.nih.gov/sites/default/files/AlcoholFactsAndStats.pdf (Feb. 2020) (reporting that an estimated 88,000 people die in the U.S. each year due to alcohol-related causes); *see also Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (May 21, 2020) (reporting that cigarette smoking causes 480,000 deaths each year in the United States).

374. Matthew W. Johnson et al., *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143, 161 (2018).

375. *Id.*

376. *Id.* at 150.

377. *See* Josh Bloom, *Is Tylenol 'By Far The Most Dangerous Drug Ever Made?'*, AM. COUNCIL SCI. & HEALTH (Sept. 11, 2017), https://www.acsh.org/news/2017/09/11/tylenol-far-most-dangerous-drug-ever-made-11711; *see also* Scott Saccomano, *Acute Acetaminophen Toxicity in Adults*, 14 NURSING CRITICAL CARE 10, 12 (2019) (reporting that acetaminophen toxicity has replaced viral hepatitis as the most common cause of acute liver failure in the United States); *TYLENOL Dosage for Adults*, TYLENOL, https://www.tylenol.com/safety-dosing/usage/dosage-for-adults#regular-strength-tylenol-tablets-dosing-chart (last visited Nov. 21, 2020).

2. *The FDA Should Issue EUAs for the Therapeutic Use of Psilocybin and MDMA-Assisted Psychotherapy*

To mitigate rising rates of depression, anxiety disorders, suicide, and substance use disorders associated with the COVID-19 pandemic, the FDA Commissioner should grant EUAs for psilocybin and MDMA-assisted psychotherapy. COVID-19 causes life-threatening conditions, and the pandemic has been linked to increasing rates of mental health conditions that are serious or life-threatening because they cause significant disability and increase the risk of suicide. The Secretary of HHS has issued an emergency declaration that justifies the issuance of EUAs, and a variety of EUAs have been issued based on relatively little clinical information, such as *in-vitro* studies, anecdotal cases reports, and non-randomized clinical trials. By comparison, there is ample evidence to support the safety and efficacy of psilocybin and MDMA-assisted psychotherapy to address treatment-resistant depression and anxiety disorders. Section 564(c)(2) of the FDCA requires only that the FDA Commissioner have a reasonable belief that, based on the totality of the scientific evidence, psilocybin and MDMA-assisted psychotherapy may be effective in treating or preventing depression, anxiety disorders, or suicide associated with the pandemic. This relatively low bar is met by the data acquired from completed Phase 1 and 2 clinical trials sanctioned by the FDA, numerous population studies, and trials conducted in the United Kingdom and other countries.

3. *The DEA Should Lift Annual Aggregate Production Quotas for Psilocybin and MDMA and Increase the Availability of Licenses to Conduct Research on Schedule I Controlled Substances*

To facilitate clinical research and the accessibility of psilocybin and MDMA, the DEA should lift its annual aggregate production quotas for these drugs. The current annual quotas of thirty grams for psilocybin and fifty grams of MDMA are inadequate to support adequate research, development, and distribution. The agency should also increase the availability of federal licenses required to produce and conduct research on Schedule I controlled substances.

4. *Congress and the DOJ Should Ensure that Individuals Acting in Accordance with State and Local Psychedelics Laws Are Not Prosecuted Under the CSA*

Considering the emerging mental health crisis and ongoing psychedelics legalization in cities and states throughout the country, Congress and the DOJ should ensure that individuals acting in accordance with state and local laws are not prosecuted for cultivating, possessing, or consuming psilocybin for personal use. In 2013, the Cole Memorandum instructed U.S. state

attorneys not to prosecute people in possession of small amounts of marijuana in accordance with state law.[378] The U.S. Attorney General should issue a similar memo exempting the personal use of psychedelics from the DOJ's and DEA's law enforcement agenda. Congress could pass psychedelics legislation comparable to the LUMMA, the Compassionate Use Act, or the Respect State Marijuana Laws Act, which would have amended the CSA to ensure that none of its provisions restrict intrastate activities that comply with state medical marijuana laws.

5. *Psychedelic Patent Holders Should Issue Open Intellectual Property Licenses for Their Inventions*

Though psychedelics can help mitigate the COVID-19 mental health crisis, there is a risk that private companies will patent psychedelic therapies, monopolize their use, raise prices, and restrict access to those who may benefit the most.[379] Naturally occurring psychedelics, including psilocybin, are not patent eligible because they fall within the judicially-created exceptions to patentability that include natural phenomena, abstract, ideas, and products of nature.[380] Similarly, preexisting synthetic psychedelics, such as MDMA, cannot be patented because they fail to meet the novelty requirement for patentability.[381] Nevertheless, drug makers have ways to work around these limitations by patenting processes that use these unpatentable compounds or patenting subtle variations of their molecular structure.[382] For instance, a company called COMPASS Pathways has a patent application pending on a crystalline formulation of psilocybin and a method of producing it.[383] In 2019, the company received a patent on "a method of treating drug resistant depression comprising orally administering" crystalline psilocybin.[384]

As the COVID-19 mental health crisis unfolds, corporations may attempt to capitalize on the pandemic to solidify their dominant positions in the marketplace.[385] In response to these concerns, federal legislators have outlined

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378. Cole Memorandum, *supra* note 369.

379. Marks, *supra* note 1, at 105–06.

380. *Id.*

381. *See* 35 U.S.C. § 102 (requiring novelty).

382. *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. BIOSCIENCES 590, 596 (2018).

383. Olivia Goldhill, *A Millionaire Couple Is Threatening to Create a Magic Mushroom Monopoly*, QUARTZ (Nov. 8, 2018), https://qz.com/1454785/a-millionaire-couple-is-threatening-to-create-a-magic-mushroom-monopoly/.

384. U.S. Patent No. 10,519,175 (filed Oct. 9, 2018).

385. Sharon Lerner, *Big Pharma Prepares to Profit from the Coronavirus*, INTERCEPT (Mar. 13, 2020, 2:46 PM), https://theintercept.com/2020/03/13/big-pharma-drug-pricing-coronavirus-profits/.

proposals to prevent corporations from capitalizing on the pandemic at the expense of the public.[386] One organization, the Open COVID Coalition, is urging patent holders to take its Open COVID Pledge.[387] Rightsholders who make the pledge agree to openly license their intellectual property to promote the development of technologies to address the COVID-19 pandemic.[388] Notable participants include Facebook, Amazon, AT&T, Intel, IBM, Uber, and Microsoft.[389] According to Facebook, "[t]he pledge allows people to use our patents to advance innovation that may help in ending the COVID-19 pandemic and minimizing the impact of the disease—without any uncertainty around intellectual property rights or fear of litigation."[390]

Holders of psychedelics-related patents should take the Open COVID Pledge or make similar arrangements to make their intellectual property available to those working to find solutions to the COVID-19 mental health crisis. Not everyone agrees.[391] Proponents of strong intellectual property rights argue that patents are prerequisites for innovation, and without their protection, the brightest minds will turn their efforts elsewhere.[392] However, some companies are making their patents open source. For instance, Tesla, the most profitable automotive company in history, has made its patents open source, and CEO Elon Musk claims that he hopes his competitors use Tesla's technology for society's benefit.[393] Musk's aerospace company, SpaceX, has broken world records and pushed the boundaries of engineering

386. Press Release, Rep. Jan Schakowsky, Congressional. Progressive Leaders Announce Principles on COVID-19 Drug Pricing for Next Coronavirus Response Package (Apr. 15, 2020), https://schakowsky.house.gov/media/press-releases/congressional-progressive-leaders-announce-principles-covid-19-drug-pricing.

387. Jeffrey D. Neuberger, *Open COVID Pledge Rolled Out to Make Patents and Other IP Available for COVID-19 Response*, NAT'L L. REV. (Apr. 21, 2020), https://www.natlawreview.com/article/open-covid-pledge-rolled-out-to-make-patents-and-other-ip-available-covid-19.

388. *Id.*

389. *Pledgers*, OPEN COVID PLEDGE, https://opencovidpledge.org/partners/ (last visited Nov. 21, 2020).

390. Kang-Xing Jin, *Keeping People Safe and Informed About the Coronavirus*, FACEBOOK (Oct. 5, 2020), https://about.fb.com/news/2020/08/coronavirus/.

391. Joseph Allen, *Stand Up to the Anti-Patent COVID-19 Narrative*, IPWATCHDOG (Apr. 30, 2020), https://www.ipwatchdog.com/2020/04/30/stand-anti-patent-covid-19-narrative/id=121197/.

392. *Id.*

393. Elon Musk, *All Our Patent Are Belong to You*, TESLA (June 12, 2014), https://www.tesla.com/blog/all-our-patent-are-belong-you; Sergei Klebnikov, *Tesla Is Now the World's Most Valuable Car Company with a $208 Billion Valuation*, FORBES (July 1, 2020, 12:58 PM), https://www.forbes.com/sites/sergeiklebnikov/2020/07/01/tesla-is-now-the-worlds-most-valuable-car-company-with-a-valuation-of-208-billion/#590daf6d5334.

and space flight; yet, it owns no patents.[394] These examples illustrate that patents are not necessarily pre-requisites for groundbreaking innovation.

B. Long Term Recommendations

1. Federal, State, and Local Legislators Should Implement Social Equity Programs in Conjunction with Psychedelic Decriminalization and Legalization Measures

When federal, state, and local governments legalize or decriminalize psychedelics, they should build social justice measures into the law. These measures could include programs that reinvest tax money saved or raised through regulation to support populations harmed by the war on drugs. Specifically, funds should be directed toward developing effective treatments for mental illness and supporting people living with mental health conditions.

2. The DEA and FDA Should Expand the Range of Evidence Considered During Rescheduling Deliberations.

Schedule I is a regulatory black hole because the evidence required to place a drug in this category need only be of low quality and quantity, while the evidence required to remove a drug from Schedule I must be abundant and of high quality. This asymmetry remains even if the information on which the initial classification was based is later brought into question or a situation arises in which a drug in Schedule I is shown to have great therapeutic promise. To prevent drugs that could be beneficial to society from becoming trapped in Schedule I, the DEA and FDA should broaden their conception of what constitutes currently accepted medical use. For instance, the agencies should consider a broader variety of sources of evidence, including case reports, population studies, and clinical trials conducted abroad, to determine whether a substance has a currently accepted medical use. Furthermore, they should consider evidence collected through research conducted in accordance with state law, which would allow cities and states that decriminalize or legalize MDMA and psilocybin to contribute to the scientific evidence regarding the risks, safety, and efficacy of these substances.

3. Congress Should Amend the Eight Scheduling Factors to Consider the Beneficial Effects of each Substance

The eight scheduling factors are biased; they frame each substance under consideration from a negative perspective. To promote an objective

394. Kim Bhasin, *ELON MUSK: 'If We Published Patents, It Would Be Farcical'*, BUS. INSIDER (Nov. 9, 2012, 11:58 AM), https://www.businessinsider.com/elon-musk-patents-2012-11.

evaluation of each substance, the factors should be amended to address the following questions:

a) Have trials been conducted in the United States or elsewhere that demonstrate the therapeutic potential of the substance?
b) Is the quality of the evidence from these studies strong or weak?
c) Will the substance have positive effects on the health of the general population, and how strong will those effects be?
d) Will the substance have positive effects on the health of marginalized groups, such as people with disabilities and mental health conditions, and how strong will those effects be?
e) Does the substance fill a societal role, such that if it was made permanently unavailable, there might be a negative impact on the health of the general population of the health of marginalized groups?
f) What harms and benefits do individuals with lived experience using the substance report?
g) Does the substance have potential to curtail existing substance use disorders?

4. *Congress Should Amend the CSA to Put Public Health Officials, Rather than Law Enforcement, in Control of U.S. Drug Regulation*

The DEA is not a scientific or medical organization, yet it is the primary agency responsible for controlled substance scheduling. Amid growing national scrutiny of law enforcement policies and procedures following numerous high-profile police shootings, Congress should reevaluate the DOJ's prominent role in U.S. drug policy. It has come to light that the war on drugs rests on a foundation of misinformation and racial animus, which has devasted communities of color. Moreover, due to restrictions on research and development, the drug war adversely impacts people with mental health conditions by depriving them of effective drug therapies. Accordingly, Congress should amend the CSA to shift drug control from law enforcement agencies to science and public health-oriented agencies, such as the FDA and the NIH. This restructuring of responsibilities would align federal controlled substance regulation with state drug control, which is overseen by public health agencies instead of law enforcement.

CONCLUSION

COVID-19 caught the United States off guard, and unless states, cities, and federal agencies act now, the nation will be equally unprepared for the mental health crisis that will follow in its wake. The healthcare system urgently needs new therapies to help Americans recover from the psychological effects of the

pandemic. Psilocybin and MDMA act quickly and are effective in those who fail to respond to traditional therapies. Moreover, their beneficial effects are often prolonged compared to those of traditional drug therapies. Accordingly, the DEA should reschedule MDMA and psilocybin, and the FDA should issue emergency authorizations for their use. To promote access, companies holding patents on psychedelic compounds should not enforce their rights for as long as the psychological effects of the pandemic persist. Finally, the DOJ should pledge to not prosecute individuals who use psychedelics in cities and states where they are decriminalized or legal.