Seton Hall University

eRepository @ Seton Hall

Student Works Seton Hall Law

2024

Cannabis and Psilocybin: Insurance Reimbursement, Legalization, and Rescheduling

Elena Athanas Markos

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship



Part of the Law Commons

Introduction

Forty states in 2023.¹ 5.4 million estimated patients.² 15.6 billion dollars in estimated medical sales by 2026.³ These are the macro level numbers of the United States' medical cannabis industry, but these numbers hardly tell the full story. Three hundred grand mal seizures in a week.⁴ Ten years of hope in new treatments.⁵ Seizures lasting two to four hours.⁶ One cannabis strain.⁷ These are the micro level numbers of a single individual whose life was forever changed by medical cannabis. At five years old, Charlotte Figi was diagnosed with a rare form of epilepsy, Dravet's syndrome.⁸ Charlotte suffered from 300 grand mal seizures a week that ravaged her tiny body, bound her to a wheelchair, and forced her into repeated cardiac arrest.⁹ At only three years old, Charlotte could not walk, talk, eat, or play like other children her age.¹⁰

With all known medical options exhausted, Charlotte's mother began calling medical cannabis stores in Colorado hoping she would find something that would help her daughter. ¹¹ Enter the Stanley brothers. The six brothers were crossbreeding strains of the cannabis plant that were very low in the psychoactive chemical tetrahydrocannabinol (THC) and high in the therapeutic cannabidiol (CBD). ¹² Together, the Stanley brothers, Charlotte's doctors, and the Figi family found the dose that worked best for her. ¹³ By taking the Stanley brothers' formulation twice a day, Charlotte was able to control her Dravet's syndrome seizures from 300

¹ Medical Marijuana Laws, NORML, https://norml.org/laws/medical-laws/ (last visited May 4, 2023).

² Medical Cannabis Patient Numbers, MARIJUANA POLICY PROJECT, https://www.mpp.org (last visited May 4, 2023).

³ US Cannabis Economic Impact, MJ BIZ DAILY, https://mjbizdaily.com/us-cannabis-sales-estimates/ (last visited May 4, 2023).

⁴ Minyvonne Burke, *Charlotte Figi, girl with severe seizures that inspired CBD treatments, dies at 13*, NBC NEWS, https://www.nbcnews.com (last visited May 4, 2023).

⁵ Charlotte Figi: The Girl Who Changed the World, CHARLOTTE'S WEB, https://www.charlottesweb.com/ (last visited May 4, 2023)

⁶ Marijuana stops child's severe seizures, CNN, https://www.cnn.com (last visited May 4, 2023).

⁷ Minyvonne Burke, s*upra*. note 4

⁸ *Id*.

⁹ *Id*.

¹⁰ *Id*.

¹¹ *Id*.

¹² *Id*.

¹³ *Id*.

times a week to three times a month in her sleep.¹⁴ The medication allowed Charlotte to become an active little girl and learn how to speak and feed herself for the first time at five years old.¹⁵

Charlotte's story is one story of many children in the United States who suffer from severe forms of epilepsy and have run out of conventional treatment options. Treatment of epilepsy with cannabis has been so successful that even pharmaceutical companies have created FDA approved medications for limited use. ¹⁶ Children are not the only beneficiaries of cannabis treatment. Cannabis has shown to be effective in patients with a broad spectrum of chronic diseases and disorders including ALS, chronic pain, cancer, panic disorder, post-traumatic stress disorder, and addiction. States with medical cannabis programs create a list of qualifying conditions that allow patients to access this alternative treatment. With the help of dispensary pharmacists, patients can begin a medical cannabis regimen that improves their disease symptoms and quality of life.

Medical use of cannabis has paved the way for conversations and research around psychedelic substances. Psilocybin is the main chemical found in several types of psychoactive mushrooms that has a hallucinogenic effect on people when ingested. Psilocybin is more commonly known as "magic mushrooms" for the hallucinogenic effects produced when the mushrooms are ingested. Magic mushrooms have been used as a recreational drug and religious practice for thousands of years, but the hallucinogenic effects produced have had a positive impact on modern patients. Currently, psilocybin is being evaluated for its clinical effectiveness to treat conditions including post-traumatic stress disorder (PTSD), treatment-resistant

¹⁴ *Id*.

¹⁶ FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), US FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/ (last visited May 4, 2023). The FDA has approved cannabis containing drugs Epidolex, Marinol, and Syndros for use in pediatric and adult patient populations.

¹⁷ Psychedelic and Dissociative Drugs, NIDA, https://nida.nih.gov/publications/drugfacts/hallucinogens (last visited May 4, 2023).

depression, and cancer related end of life anxiety. 18 With the current public health crisis of mental illness creating stress on the world's health and financial systems, it is important for psychiatrists to utilize the best treatment options for their patients. ¹⁹ Some clinicians have turned to psychedelics to offer their patients relief from various mental illnesses after conventional medications and therapy have failed.

Dr. Pradeep Bansal is a New York gastroenterologist who has long been skeptical of alternative therapies.²⁰ However, after receiving a cancer diagnosis that crushed him mentally, he decided to try psilocybin through a strictly controlled scientific trial.²¹ The week Dr. Bansal was to try the therapy, he underwent extensive screening including physical health exams, bloodwork, and questionnaires.²² Dr. Bansal received a dose of 25 milligrams that was "carefully calibrated" to induce a psychedelic experience for therapeutic benefit.²³ The experience was grueling leaving Dr. Bansal emotionally and physically drained, but with an intense sense of peace and meaning.²⁴ Dr. Bansal describes the psilocybin treatment as "the single most powerful experience of [his] life" that gave him a completely different perspective. 25 This treatment has allowed him to face his cancer battle with a renewed vigor.

In the United States, these new treatments are available to patients with extra money and through clinical trials. The barriers to obtaining cannabis and psilocybin are significant. There is no widespread insurance coverage for cannabis or psilocybin. While companies are making a significant profit from dispensaries, black people are still being significantly targeted for

¹⁸ Collin M. Reiff, MD, et al., Psychedelics and Psychedelic-Assisted Psychotherapy, 177 Am. J. of Psychiatry, 391-410

¹⁹ Thomas Insel, et al., Darkness Invisible: The Hidden Global Costs of Mental Illness, 94 FOREIGN AFFAIRS, 127-135 (2015). ²⁰ One Man's Psychedelic Journey to Confront His Cancer, WEBMD, https://www.webmd.com/mental-health/story/psychedelicpsilocybin-study-depression (last visited May 4, 2023). ²¹ *Id.*

²² *Id*.

²³ *Id*. ²⁴ *Id*.

²⁵ *Id*.

cannabis arrests.²⁶ This paper argues that private and public insurance programs should pay for medical cannabis and psilocybin treatment to alleviate a significant barrier of access to these effective treatments. This insurance coverage would be a significant step forward in righting the wrongs of the War on Drugs that has negatively impacted many individuals.

Part one of this paper provides background on cannabis and psilocybin in the United States by exploring racism and influential legislation. Part two of this paper discusses current efforts in the United States to legalize cannabis and psychedelic substances. This section also addresses current research and its barriers. Part three explores the intersection of cannabis with current health insurance schemes. Part four offers comparative examples from around the world including Uruguay, Czechia, Australia, and the United Kingdom. This section also offers a deep dive into a model system from Canada. Part five provides conclusions and recommendations.

Part I: Background of Cannabis and Psilocybin

Early History in the United States

In the late 1800s and early 1900s, there was general acceptance of cannabis as a medicine in the United States. Some of the largest growers and medical cannabis sellers were pharmaceutical companies that are now titans of their industry: Abbott Laboratories, Bristol Myers Squibb, Eli Lilly, and Pfizer.²⁷ The companies listed several cannabis products in their drug formularies that were available in a variety of forms such as powder, tablets, fluid extracts, and tinctures.²⁸ The cannabis products were used to help with illnesses and ailments such as epilepsy, reproductive health conditions, migraines, stomach worms, mental illness, and

²⁶ A Tale of Two Countries: Racially Targeted Arrests in the Era of Marijuana Reform, AMERICAN CIVIL LIBERTIES UNION, https://www.aclu.org/report/tale-two-countries-racially-targeted-arrests-era-marijuana-reform (last visited May 4, 2023).

²⁷ Debra Borchardt, *Pfizer, Eli Lilly Were the Original Medical Marijuana Sellers*, FORBES, https://www.forbes.com/ (last visited May 4, 2023).

²⁸ *Id*.

addiction.²⁹ Unfortunately, the companies discontinued growing cannabis when racism and legislation shifted public attitudes towards the plant.

Psychedelics, including psilocybin, have been utilized by ancient and indigenous cultures around the world from Mexico to Algeria, and Greece for thousands of years.³⁰ Researchers have found evidence that ancient and indigenous cultures frequently utilized the psychedelic substances as an element of spiritual practice.³¹ These practices have been carried on through the generations and are especially prevalent in South America with the psychedelic ayahuasca.³² Ayahuasca is generally consumed in healing ceremonies for its psychiatric and medicinal benefits.³³ Like cannabis, the public attitude towards psychedelic substances shifted, resulting in both substances being heavily restricted from the public.³⁴

Racism

It is impossible to discuss cannabis without addressing key points in its history to understand how the United States arrived at the position it is in today. The word "marijuana" stems from the Mexican word for the cannabis plant and was first introduced in the United States during the Mexican Revolution.³⁵ Unfortunately, the word has been tainted by a history of racist language. Beginning in the early 1900s, attitudes towards medical cannabis began to shift.³⁶ The public began to possess a negative view of cannabis associating it with various negative

²⁹ I

³⁰ David Nutt, et al., Psychedelics as Psychiatric Medications, OXFORD PSYCHIATRY LIBRARY (2023)

³¹ Id

³² Ede Frecska, et al., *The Therapeutic Potentials of Ayahuasca: Possible Effects against Various Diseases of Civilization*, FRONTIERS IN PHARMACOLOGY, (2016).

³ Id

³⁴ Psilocybin, US DRUG ENFORCEMENT AGENCY, https://www.dea.gov/factsheets/psilocybin (last visited May 4, 2023).

³⁵ Isaac Campos, *Mexicans and the Origins of Marijuana Prohibition in the United States: A Reassessment*, 32 Social History of Alcohol and Drugs (2018).

³⁶ *Id*.

stereotypes and racism. Early anti-cannabis legislation in the 1910s and 1920s specifically targeted Mexican Americans and migrants.³⁷

Harry Anslinger (Anslinger), Former Commissioner of the Federal Bureau of Narcotics of U.S. Government, was the forefather to the War on Drugs. Anslinger took discrimination to a new level by associating "marijuana" with racial slurs against people of color and calling them "satanic cultures." Anslinger was convinced societal acceptance and use of cannabis in the United States would cause "white women to associate with [people of color]." This language was used by Anslinger in testimony before Congress. Anslinger's campaign against cannabis culminated in the Marihuana Tax Act of 1937, which federally criminalized cannabis. Given the significant racist history surrounding the word "marijuana," this author will utilize the Latin word, "cannabis." Instances where "marijuana" is used instead of "cannabis" will be situations where various programs use the word or there are direct quotes.

Influential Legislation

The Marihuana Tax Act influenced subsequent legislation such as the Boggs Act of 1951 and the Narcotic Control Act of 1956, which increased legal penalties for possession of cannabis. Cannabis was removed from the United States Pharmacopedia in 1942. The restriction and racism surrounding cannabis was cemented when President Richard Nixon formally announced the War on Drugs. As a result of this declaration, cannabis and psilocybin were classified as Schedule 1 substances under the Controlled Substances Act of 1970. Classification of a drug,

³⁷ Isaac Campos, *supra*. note 35.

³⁸ Michael Schaller, *The Federal Prohibition of Marihuana*, 4 JOURNAL OF SOCIAL HISTORY, 61 (1970).

³⁹ *Id*.

⁴⁰ *Id*.

⁴¹ Id

⁴² Jamila Hodge, Fifty Years Ago Today, President Nixon Declared the War on Drugs, VERA, https://www.vera.org/news/fifty-years-ago-today-president-nixon-declared-the-war-on-drugs (last visited May 4, 2023).

⁴³ Id.

substance, or chemical under Schedule 1 means there is no currently accepted medical use and a high potential for abuse.⁴⁴ Other drugs in Schedule 1 include heroine, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, peyote, and psilocybin.⁴⁵

Part II: Current Steps to Legalize Cannabis

Cannabis has come a long way since 1970. Today thanks to state legislation, 40 states have an operational medical cannabis program, and 22 states have operational medical and adultuse cannabis programs. 46 Cannabis for any use is still federally illegal, but there are stirrings of change with the current Presidential administration. President Biden has issued Executive Orders to pardon non-violent federal cannabis possession convictions and promote equity in federal administrations as related to cannabis. 47 With states legalizing cannabis and the federal government maintaining its illegal status, there is significant tension between state and federal law that is unresolved.

The federal government is attempting to alleviate some of this legal tension through new legislative actions. Current pending legislation that would make a difference for cannabis consumption in the United States include banking, federal de-scheduling and de-criminalization, and veteran access. The Secure and Fair Enforcement Banking Act of 2021 (SAFE Act) was introduced to allow cannabis businesses to utilize major banking institutions without being penalized for selling a federally illegal substance.⁴⁸ This was a reversal of federal law that prohibited banking institutions from accepting money from illegal sources.⁴⁹ The passage of this

⁴⁴

⁴⁴ *Drug Scheduling*, US Drug Enforcement Agency, https://www.dea.gov/drug-information/drug-scheduling (last visited May 4, 2023).

⁴⁵ *Id*.

⁴⁶ NORML, *supra* note 1.

⁴⁷ Kyle Jaeger, *Biden Signs Equity-Focused Executive Order That Touts Marijuana Clemency Actions, Calling Criminalization A 'Failed Approach*,' MARIJUANA MOMENT, https://www.marijuanamoment.net/biden-signs-equity-focused-executive-order-that-touts-marijuana-clemency-actions-calling-criminalization-a-failed-approach/ (last visited May 4, 2023).

⁴⁸ SAFE Banking Act of 2021, H.R.1996, 117th Cong. (2021).

⁴⁹ *Id*.

bill would have protected banking institutions and insurers that chose to offer services to legitimate cannabis businesses operating under their respective state laws.⁵⁰ The bill has passed the House and was received by the Senate on April 20, 2021 and was referred to the Committee on Banking, Housing, and Urban Affairs.⁵¹

The Marijuana Opportunity, Reinvestment and Expungement Act of 2021 (MORE Act) was introduced to remove cannabis from the list of scheduled substances under the Controlled Substances Act and eliminate criminal penalties for an individual who manufactures, distributes, or possesses cannabis. ⁵² Notably, the Act would require all instances of "marijuana" or "marihuana" to be replaced with the plant's Latin name, cannabis to promote social justice and eliminate racist language. ⁵³ This sweeping legislation would have significantly changed the American landscape of cannabis by taking steps toward criminal justice reform and social justice, but it has stalled. ⁵⁴ MORE has passed the House and was received in the Senate on April 4, 2022 and referred to the Committee on Finance. ⁵⁵

The Veterans Equal Access Act was introduced to the House on June 23, 2022 and referred to the House Committee on Veterans' Affairs. ⁵⁶ The objective of the legislation is to authorize Veterans Affairs (VA) health care providers to facilitate and assist veteran participation in their respective state's cannabis programs. ⁵⁷ Under the current law, VA physicians are prohibited from discussing cannabis with their patients and veterans cannot obtain the necessary forms required to participate in their states' medical cannabis programs. ⁵⁸ The introduction of

⁵⁰ *Id*.

⁵² Marijuana Opportunity Reinvestment and Expungement Act, H.R.3617, 117th Cong. (2021).

⁵³ Id.

⁵⁴ *Id*.

⁵⁵ Id

⁵⁶ Veterans Equal Access Act, H.R.8197, 117th Cong. (2021).

⁵⁷ *Id*.

⁵⁸ *Id*.

these Acts is encouraging, but that excitement is tempered by the delays that are preventing change. For real societal change to happen in the United States, federal legislation must be passed that addresses barriers of access and social justice concerns.

Current Steps to Legalize Psychedelics

While cannabis is still establishing its place in modern American society, the plant has blazed the path for the fungus derived chemical—psilocybin. Law makers, researchers, and businesspeople alike are taking lessons from cannabis and applying these insights to psilocybin. With the recent and intense public interest in psychedelics, advocacy organizations have become more visible in conversations around psychedelics. The Multidisciplinary Association for Psychedelic Studies (MAPS) began in 1986, pushing for an end to psychedelic prohibition. The organization has become more influential, tackling research on Schedule 1 psychedelic substances and advocating for re-scheduling. Unlike cannabis, psilocybin is not available for retail purchase and consumption as a medicinal or recreational substance in every state except Oregon. Oregon became the first state to allow legal medicinal consumption of psilocybin under the supervision and direction of mental health professionals. As the state rolls out this revolutionary program, data and learnings will be critical to understanding success and addressing weak points. This information would provide insight to other states considering legalization of psilocybin.

Research and Rescheduling

As of the date of this writing, cannabis and psilocybin are Schedule 1 substances under the DEA's schedule scheme.⁶² Classifying cannabis and psilocybin as drugs with no accepted

⁵⁹ MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES, https://maps.org/ (last visited May 4, 2023).

⁶¹ Adults Can Now Use Magic Mushrooms with Supervision in Oregon, SMITHSONIAN MAGAZINE, https://www.smithsonianmag.com (last visited May 4, 2023).

⁶² US Drug Enforcement Agency, supra note 38.

medical use and a high likelihood for abuse has resulted in extreme barriers to studying the substances for their full breadth of medicinal purposes. The DEA has exclusive purview over research around cannabis and must be involved in all phases of research.⁶³ Out of 164 academic research institutions in the United States,⁶⁴ the DEA has authorized just one to research cannabis in partnership with the National Institute on Drug Abuse.⁶⁵ Notably, the thrust of this research is to study cannabis as a substance of abuse and not medicine.⁶⁶ To research the efficacy of cannabis and psilocybin, researchers must obtain permission from the federal government and a special license from the DEA.⁶⁷ In 2020 the DEA announced an effort to expand licenses for cannabis research through a rule making proceeding.⁶⁸ Three years later, the DEA has not issued new licenses to research institutions and has publicly stated the federal agency is still reviewing applications.⁶⁹

Researchers usually are not able to receive funding from the government and studies rely solely on independent funding.⁷⁰ Unlike pharmaceutical giants with significant budgets for funding studies, research on cannabis and psilocybin are conducted mostly by advocacy organizations, non-profits, and independent mental health therapists with constrained budgets.⁷¹

-

⁶³ DEA Continues to Prioritize Efforts to Expand Access to Marijuana for Research in the United States, US DRUG ENFORCEMENT AGENCY, https://www.dea.gov/stories/2021/2021-05/2021-05-14/dea-continues-prioritize-efforts-expand-access-marijuana-research (last visited May 4, 2023).

⁶⁴ The Top American Research Universities, THE CENTER FOR MEASURING UNIVERSITY PERFORMANCE, https://mup.umass.edu/Top-Universities (last visited May 4, 2023).

⁶⁵ The University of Mississippi is the only research institution approved by the federal government to study cannabis. *NIDA's Role in Providing Cannabis for Research*, NATIONAL INSTITUTE ON DRUG ABUSE, https://nida.nih.gov/research-topics/marijuana/nidas-role-in-providing-cannabis-research

⁶⁶ David Casarett & Donald I. Abrams, *Why Insurance Companies Should Pay for Medical Cannabis*, 4 THE AM. J. OF BIOETHICS 8, 8-10 (2019).

⁶⁷ Terrance Woodworth, *How Will DEA Affect Your Clinical Study?*, 7 J. CLINICAL RES. BEST PRACTICES 1, 1 (2011) (explaining the licensing guidelines, import export controls, quotas, security measures, and record-keeping requirements associated with studying controlled substances).

⁶⁸ US Drug Enforcement Agency, *supra*. note 57.

⁶⁹ Id.

⁷⁰ Multidisciplinary Association for Psychedelic Studies, *supra*. note 53.

⁷¹ Mason Marks, Psychedelic Medicine for Mental Illness And Substance Use Disorders: Overcoming Social And Legal Obstacles, 21 NYU J. of Legis. AND Pub. Policy, 69, 110 (2018)

These organizations almost exclusively rely on donor contributions to support their work. ⁷² Even without capital from the government, researchers must adhere to strict regulatory requirements that impose prohibitively expensive standards and extremely burdensome compliance conditions. ⁷³ For 50 years, the federal government did not award research grants for psychedelic drugs. That changed in 2021 when Johns Hopkins Medicine received the first federal grant for psychedelic treatment research to assess the potential impacts of psilocybin on tobacco addiction. ⁷⁴ The study enrollment has currently closed with research beginning in the summer of 2023. ⁷⁵

While researchers jump through hoops to create and complete trials of cannabis and psilocybin, initial published data has proven to be promising. A study from 2020 conducted at the Johns Hopkins Center for Psychedelic and Consciousness Research assessed the effects of psilocybin assisted therapy in major depressive disorder (MDD) through a randomized clinical trial. The trial assessed 24 participants finding that psilocybin with therapy was in fact efficacious to treat MDD. To In a 12 month follow up to the study, the researchers found patients had durable effects of psilocybin assisted therapy beyond the immediate antidepressant effects. Another study published in 2020, assessed the effects of methylenedioxymethamphetamine (MDMA) and psilocybin for treatment of mood and anxiety disorders, trauma and stress-related disorders, substance related and addictive disorders, and end of life care. Research for cannabis

7,

⁷² *Id*.

⁷³ Terrance Woodworth, *supra*. note 61.

⁷⁴ Johns Hopkins Medicine Receives First Federal Grant for Psychedelic Treatment Research in 50 years, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/news/newsroom/news-releases/johns-hopkins-medicine-receives-first-federal-grant-for-psychedelic-treatment-research-in-50-years (last visited May 4, 2023).

⁷⁵ QUIT SMOKING BALTIMORE, https://www.quitsmokingbaltimore.org/ (last visited May 4, 2023).

⁷⁶ Alan K. Davis et al., Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial, JAMA PSYCHIATRY. (2021)

⁷⁸ Alan K. Davis et al., *Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up*, 36 JOURNAL OF PSYCHOPHARMACOLOGY, 151-158 (2022)

⁷⁹ Collin M. Reiff, M.D. et al., *Psychedelics and Psychedelic-Assisted Psychotherapy*, 177 Am. J. of Psychiatry, 391-410 (2020).

has been slightly more established finding the substance is effective at reducing seizures for epilepsy patients.⁸⁰

For a substance to change schedules, there are two methods: through a legislative action or an administrative action. ⁸¹ Under the legislative action method, Congress can amend portions of the CSA to reschedule cannabis. ⁸² Through the administrative action method, there is involvement from multiple federal agencies with the process beginning by an initiation from the Attorney General by asking the department of Health and Human Services (HHS) to conduct an open and scientific review of a controlled substance. ⁸³ The process may begin outside of the Attorney General's office, but all requests will go through the Attorney General office and HHS, with an investigation from the FDA. ⁸⁴ The Attorney General conducts a parallel investigation by reviewing eight factors from the CSA. ⁸⁵ Courts have ruled to reschedule a substance, there must be a "currently accepted medical use" that meets specified factors. ⁸⁶ Courts who have considered rescheduling lawsuits have utilized the terms, "adequate and well-controlled studies proving efficacy" as helping to establish currently accepted medical use. ⁸⁷ According to the DEA, "to establish accepted medical use, the effectiveness of a drug must be established in well-

⁸⁷ *Id*.

⁸⁰ Tyler E. Gaston & Jerry P. Szaflarski, *Cannabis for the Treatment of Epilepsy: an Update*, 18 CURRENT NEUROLOGY AND NEUROSCIENCE REPORTS, 73 (2018)

⁸¹ Mason Marks, id.

⁸² Mason Marks, id.

⁸³ Mason Marks, id.

⁸⁴ Mason Marks, id.

⁸⁵ Mason Marks, *id.* (1) [i]ts actual or relative potential for abuse; (2) [s]cientific evidence of its pharmacological effect, if known; (3) [t]he state of current scientific knowledge regarding the drug or other substance; (4) [i]ts history and current pattern of abuse; (5) [t]he scope, duration, and significance of abuse; (6) [w]hat, if any, risk there is to the public health; (7) [i]ts psychic or physiological dependence liability; (8) [w]hether the substance is an immediate precursor of a substance already controlled under this subchapter.

⁸⁶ *Id.* (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.

controlled, well-designed, well-conducted, and well-documented studies, including a large number of patients."88

There are significant problems with these approaches. The terms used by courts have not been defined and are open to interpretation. The terms used by the DEA, "well-controlled, well-designed, well-conducted, and well-documented studies," have not been defined by the DEA and are open to interpretation. While the DEA requires "a large number of patients" for study participation, this is highly unlikely to happen because Schedule I substance studies are very expensive because of their heightened federal regulations and DEA involvement. These expenses likely limit the population researchers can support. With these barriers, and ambiguous standards, it seems almost impossible for researchers to produce enough information that will convince the DEA to reschedule cannabis and psilocybin. The DEA has moved a substance from Schedule I to Schedule II only five times in 40 years and removed a substance from Schedule I entirely only twice, which makes re-scheduling of cannabis and psilocybin a bit unlikely. These prohibitions on knowledge directly results in patient barriers to obtaining these substances for medical treatment. To better understand the full efficacy of cannabis and psilocybin, federal barriers to research must be removed and funding should be significantly increased.

Part III: Cannabis and Health Insurance

Giant professional industries like insurance, have not followed the momentum of medical cannabis. 90 The three most popular insurance coverage schemes in the United States are: private employer-sponsored health insurance, Medicare, and Medicaid. The most popular health insurance of these is private employer-sponsored health insurance offered to employees as a

⁸⁹ Ia

⁸⁸ Id.

⁹⁰ Id.

benefit for working at a company. These insurance plans have many options for employees to choose from including high-deductible health plans, preferred provider organization (PPO), point-of-service plan (POS), and health maintenance organizations (HMO).⁹¹ In the United States, insurance is run as a "for profit" model with insurance companies reporting billions of dollars of profits every year.⁹² With rising costs of insurance and motivation to maintain high profits, employees are paying more and more in premiums to help keep profits high.⁹³

As of the date of this writing, no major health insurer or government health plan provides coverage for medical cannabis in the United States. This means, patients with a recommendation for medical cannabis, must pay entirely out of pocket for their physician visit and product. Most insurers have provisions in their health plans stating the insurance company will not pay for health issues occurring, due to, or in association with voluntary involvement in an illegal act, which includes medical cannabis. Pather, insurance companies will only cover therapies listed on the health plan's drug formulary. Despite the increasing popularity of medical cannabis, most states with these programs prohibit insurers from covering medical cannabis through enacted statutes and case law. No state statute permits insurance claims or reimbursement for medical cannabis as a prescription.

As the landscape quickly changes, questions of whether cannabis may be covered by insurance are bringing up questions and lawsuits around whether workers compensation

_

⁹¹ 2022 Employer Health Benefits Survey, KAISER FAMILY FOUNDATION, https://www.kff.org/report-section/ehbs-2022-summary-of-findings/ (last visited May 4, 2023).

⁹² Jakob Emerson, *The House Always Wins: Insurers' record profits clash with hospitals' hardship*, BECKER'S PAYER ISSUES, https://www.beckerspayer.com/payer/the-house-always-wins-health-systems-face-worst-finances-in-decades-as-payers-rake-in-record-profits.html (last visited May 4, 2023).

⁹³ Frank Diamond, US Employers Brace for Healthcare Costs to Rise Next 3 Years, FIERCE HEALTHCARE, https://www.fiercehealthcare.com/payers/employers-expect-healthcare-costs-rise-next-3-years (last visited May 4, 2023).

⁹⁴ Alex Reger, *Illegal Act and Drug and Alcohol Exclusions in Health Insurance Policies*, OFFICE OF LEGIS. RESEARCH, https://www.cga.ct.gov/2016/rpt/pdf/2016-R-0138.pdf (last visited May 4, 2023).

⁹⁵ BLUE CROSS BLUE SHIELD OF ILLINOIS, https://www.bcbsil.com/medicare/pdf/2023/pdp-formulary-bas-il-2023.pdf (last visited May 4, 2023).

programs can cover medical cannabis. Until very recently, there was no legal precedent or statute requiring workers compensation plans to cover medical cannabis for injured workers. This issue has been heavily litigated with most state courts ruling the same way; medical cannabis is not covered or reimbursed by workers compensation plans. While there are 40 states with medical cannabis programs and no states allow health insurance reimbursement, reimbursement is permitted in just six states under a very narrow exception: workers compensation. He practice is also expressly permit workers compensation insurance reimbursement, the practice is also expressly prohibited by statute in six states. In 24 states, workers compensation insurance is not required to reimburse, or the statutes are silent on reimbursement. Despite express provisions allowing reimbursement, these situations are narrowly tailored requiring claimants to meet a certain set of criteria.

Current Steps to Insurance Coverage of Medical Cannabis

In New York state, patients may only receive Medicaid reimbursement for practitioner office visits related to patient evaluation and certification.⁹⁹ New York has clearly stated medical cannabis products are not available for coverage or reimbursement under the state's Medicaid program.¹⁰⁰ However, if New York State Senate Bill S8837 passes the Assembly and makes it to the Governor's desk, cannabis may be reclassified as a "prescription drug" allowing coverage under a number of public health insurance plans.¹⁰¹ The New York State Compassionate Care Act, which legalized medical cannabis, has no provision requiring medical cannabis to be

⁹⁶ John Howard et al., *Review of Cannabis reimbursement by workers compensation insurance in the US*, 64 Am. J. INDUSTRIAL MED., 989, 989-1001 (2021).

⁹⁷ Id.

⁹⁸ *Id*.

⁹⁹ New York State Medicaid Update, NEW YORK STATE, https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-06.htm#marijuana (last visited May 4, 2023). 100 Policy Clarification – Medical Cannabis Office Visits, New York STATE OFFICE OF CANNABIS MANAGEMENT,

https://cannabis.ny.gov/medical-cannabis-office-visits (last visited May 4, 2023).

An act to amend the public health law and the social services law, in relation to health coverage for medical marihuana, S8837, N.Y. Senate, (2022-2023).

reimbursed through private insurers. However, there is also no provision that prevents insurers from including medical cannabis as a covered medication. This leaves open the possibility that private insurers may reimburse patients for medical cannabis if they choose to. It is very unlikely this coverage would come from large multi-state insurers and more likely coverage would come from smaller private state-based insurers. For individuals seeking workers compensation reimbursement, NY CLS Cannabis § 34(12) permits reimbursement for the cost of medical cannabis if the patient meets a specified list of criteria. 104

In New Jersey, the Jake Honig Compassionate Use Medical Cannabis Act does not require a government medical assistance program or private health insurer to reimburse a person for costs associated with the medical use of cannabis. New Jersey courts have considered whether medical cannabis should be covered in an injured workers' claim and have overwhelmingly ruled in favor of the employee. 106 In these cases the New Jersey courts have reasoned medical cannabis is a legitimate medical expense employers must reimburse injured workers for. The courts in these cases reasoned there was no tension between the Controlled Substances Act and New Jersey's Compassionate Use Medical Marijuana Act because employers are not required to possess, manufacture, or distribute cannabis. 108

¹⁰² N.Y. CLS Pub Health § 3368.

¹⁰³ Id.

¹⁰⁴ *Id.* "The patient is certified to use medical marijuana by a registered practitioner who is authorized by the WCB under the New York Workers' Compensation Law; the medical marijuana is used to treat a condition authorized under the provisions of the New York Public Health Law and applicable New York Department of Health regulations; the condition for which the patient is certified is related to an established site of injury in a workers' compensation claim; the treating practitioner has obtained a variance if the condition is addressed in the applicable WCB medication treatment guidelines (MTGs) OR the treating medical provider has obtained a C4AUTH approval if the medical marijuana cost exceeds \$1,000 and the treatment is for a body part or condition not covered by the MTGs and; the claimant submits a request for medical marijuana reimbursement as a Medical & Travel (M&T) reimbursement request."

¹⁰⁵ N.J. Stat. § 24:6I-14.

 ¹⁰⁶ Steven McNeary v. Freehold Township; Watson v. 84 Lumber, NJ DOL, Division of WC, Claim Petition No. 2009-15740 (2017); Hager v. M&K Const., 2020 N.J. Super. LEXIS 4 –
 107 Id

¹⁰⁸ *Id*.

In Pennsylvania, the Medical Marijuana Act states that nothing must be construed to require an insurer or a health plan, whether paid for by Pennsylvania funds or private funds, to provide coverage for medical marijuana. However, this changed very recently with two cases where two judges ruled injured workers were to be reimbursed for medical cannabis as part of the reasonable treatment for their injuries. The two courts reasoned that there was no statutory language prohibiting insurers from reimbursing claimants who lawfully used medical marijuana to treat an accepted work injury when such treatment was medically reasonable and necessary. The courts also held that failing to reimburse for a work-related injury was a violation of the Workers' Compensation Act.

Lack of insurance coverage or reimbursement creates a significant barrier of access for individuals who can benefit from medical cannabis. These barriers are particularly high for low-income or fixed-income individuals who participate in Medicare and Medicaid. Registering for a patient card to access medical cannabis is expensive in many states with very few discounts. In Pennsylvania, an evaluation for a new medical cannabis patient cost is \$150 and an evaluation for an existing patient cost is \$100.¹¹³ Once evaluated, a patient pays for their medical marijuana ID card, which costs \$50.¹¹⁴ The state specifies that some patients who are part of Medicaid may be eligible for fee reductions.¹¹⁵ In total, it costs a Pennsylvania patient approximately \$200 to obtain a medical marijuana patient ID card. Unlike Pennsylvania, New York State has waived all application fees associated with a medical cannabis patient card, but charges a 7% tax on each

_

¹⁰⁹ 35 Pa. Stat. Ann. § 10231.2102

¹¹⁰ Fegley v. Firestone Tire & Rubber (Workers' Comp. Appeal Bd.), 2023 Pa. Commw. LEXIS 26.; Appel v. GWC Warranty Corp. (Workers' Comp. Appeal Bd.), 2023 Pa. Commw. LEXIS 25.

¹¹¹ *Id*.

¹¹² Id

¹¹³ Pennsylvania, CANNA CARE DOCS, https://cannacaredocs.com/pennsylvania/ (last visited May 4, 2023).

 ¹¹⁴ Getting Medical Marijuana, COMMW. PA., https://www.pa.gov/guides/pennsylvania-medical-marijuana-program/#PayforanIDCard (last visited May 4, 2023).
 115 Id.

sale. While Pennsylvania does not impose sales tax on medical cannabis products, cannabis products are very expensive. For example, a pain relief balm that is 15 milliliters costs a patient at least \$45 or \$3 per one milliliter. Without reimbursement or coverage from insurance, patients pay a significant amount of money out of pocket for their treatment. As of the time of this writing, patients may only receive legal psilocybin through clinical trials or by paying thousands of dollars out of pocket in certain states, including Oregon.

Part IV: Comparative Examples

Model Cannabis Program: Canada

Medical Cannabis in Canada

The United States would do well to model insurance coverage of medical cannabis on Canada's programs. Canada's approach to medical cannabis has been very different from the United States. While some legislative moves from the United States have influenced Canada, the nation has made decisions independent of the United States. In 1923, Canada took the measure of making cannabis illegal, 117 14 years before the United States did through the Marihuana Tax Act of 1937. While President Nixon was declaring a War on Drugs in 1972 that dominated Western democracy policy for decades, Canada was researching cannabis. The Royal Commission of Inquiry into the Non-Medical Use of Drugs developed an enormous body of research that produced four reports. One revolutionary recommendation came in 1972 and urged the government to repeal the offense of cannabis possession. 119 Ironically, the 1972 Shafer

¹¹⁶ Doctor Solomon's pain relief balm starts at \$45 and is price dependent on the dispensary. LEAFLY, https://www.leafly.com/brands/dr-solomon-s/products/dr-solomon-s-rescue-transdermal-balm-lotions (last visited May 4, 2023).

¹¹⁷ BRUCE A. MACFARLANE ET AL., CANNABIS LAW (2d ed. 2021)

¹¹⁸ Marijuana Tax Act of 1937, 552, 75th Cong. (1937).

¹¹⁹ BRUCE A. MACFARLANE, id.

Commission appointed by President Nixon, presented the same recommendation that cannabis possession should not be an offense at the federal or state level.¹²⁰

In 2002, conversations around cannabis began changing. The Canadian Houses of Parliament advocated for legislative change to existing cannabis laws such as decriminalization of possession for less than 30 grams. ¹²¹ In addition to legislative change, there were medical cannabis cases being heard in Canada's courts. The case that changed everything for Canada was *R. v. Parker* heard by the Ontario Court of Appeal. ¹²² Mr. Parker (Parker) was a patient with epilepsy who managed his seizures with cannabis. ¹²³ Parker sued the federal government alleging the laws of possession and cultivation of medical cannabis were so prohibitive they infringed on his rights of liberty and security of the person conferred under the Canadian Charter of Rights and Freedoms. ¹²⁴ The Ontario Court of Appeal sided with Parker and instead of appealing, the federal government introduced a medical cannabis regulatory scheme. ¹²⁵ After this ruling, the courts have attempted to secure patients' right of access to medical cannabis by establishing a body of caselaw. ¹²⁶

The Cannabis Act was introduced with the election of Prime Minister Justin Trudeau to protect young persons, prevent illicit activities, reduce the burden on the criminal justice system, and ensure a quality-controlled supply of cannabis. 127 The Cannabis Act enabled additional rules and regulations, including the codification of patients' access to medical cannabis. 128 Under Canada's Cannabis Regulations, Part 14 lays out the necessary provisions related to patients'

1.

¹²⁰ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1749335/

¹²¹ BRUCE A. MACFARLANE, id.

¹²² R. v. Parker (2000), 146 C.C.C. (3d) 193 (Ont. C.A.)

¹²³ *Id*.

¹²⁴ *Id.* (the Canadian Charter of Rights and Freedoms is the Canadian equivalent of the United States Constitution and Bill of Rights)

¹²⁵ *Id*.

¹²⁶ BRUCE A. MACFARLANE, id.

¹²⁷ https://laws-lois.justice.gc.ca/eng/acts/c-24.5/

¹²⁸ https://laws-lois.justice.gc.ca/eng/regulations/sor-2018-144/

"Access to Cannabis for Medical Purposes." The overall legislation covers aspects of medical cannabis from licensing, packaging, to document retention and reporting. Under Medical Access, patients' rights have limits to ensure patient protection and program legitimacy. The Act specifies that patients who want medical cannabis need to obtain authorization in the form of a medical document from their health care provider. Once a patient is given the medical document, the patient selects a licensed producer of medical cannabis that is registered with the government. Notably, if the patient wants to switch providers, the patient must go through the whole process again by obtaining a new medical document from the patients' health care practitioner, cancellation of registration with current licensed producer, and registration with new licensed producer.

Canadian Insurance Landscape

Canada's health insurance scheme is very different from the United States as it is not a giant for profit industry. Through the Canada Health Act, Canada created Medicare, which is a publicly funded health care system. This public health care system ensures all Canadians have reasonable access to medically necessary health services without paying out-of-pocket. Medicaid scheme, the Canadian federal government delegates the management, organization, and delivery of health care to the 13 provinces and territories. Each provincial and territorial plan must meet the standards prescribed by the federal government in

_

¹²⁹ Canada Cannabis Regulation, SOR/2018-144, Fed. Gov. of Canada, (2022)

¹³⁰ *Id*.

¹³¹ *Id*.

¹³² Accessing cannabis for medical purposes from a licensed producer, GOV. OF CANADA, https://www.canada.ca/en/health-canada/services/getting-cannabis-from-licensed-producer/accessing-from-licensed-producer.html (last visited May 4, 2023).

¹³³ **Location**

134 **Location**

135 **Location**

136 **Location**

137 **Location**

137 **Location**

138 **Location**

138 **Location**

139 **Location**

139 **Location**

130 **Location**

130 **Location**

130 **Location**

131 **Location**

133 **Location**

133 **Location**

133 **Location**

134 **Location**

135 **Location**

135 **Location**

136 **Location**

137 **Location**

137 **Location**

138 **Location**

138 **Location**

139 **Location**

130 **Location**

130 **Location**

130 **Location**

131 **Location**

131 **Location**

132 **Location**

133 **Location**

133 **Location**

133 **Location**

134 **Location**

135 **Location**

135 **Location**

136 **Location**

137 **Location**

137 **Location**

138 **Location**

138 **Location**

139 **Location**

130 *

¹³⁴ *Id*.

¹³⁵ Canada Health Care System, HEALTH CANADA, https://www.canada.ca/en/health-canada/services/canada-health-care-system.html (last visited May 4, 2023)

¹³⁷ *Id.* Provinces and territories include Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Quebec, Saskatchewan, and Yukon.

the Canada Health Act.¹³⁸ The federal government is in charge of setting and administering national standards, providing funding support for the provincial and territorial health plans, supporting delivery of health care services to specific groups, and other health-related functions.¹³⁹ In addition to publicly funded health care, Canadians may elect to have private insurance coverage through employers.¹⁴⁰ Generally, private insurance covers services not covered under Canadian Medicare such as vision, dental, outpatient prescription drugs, rehabilitation services, and private hospital rooms.¹⁴¹

Canadian Medical Cannabis and Insurance

A significant facet of Canada's insurance policies include reimbursement for medical cannabis. In a document from the Canada Revenue Agency, there is an extensive outline of claims for reimbursement patients can make, including for medical cannabis. ¹⁴² The document specifies patients may receive reimbursement for cannabis, cannabis oil, cannabis plant seeds, or cannabis products purchased for medical purposes. ¹⁴³ Notably, there is not a monetary limit on how much patients may submit for insurance reimbursement from Health Canada. ¹⁴⁴ The only restrictions on reimbursement are for the cost of growing cannabis, which includes pots, soil, nutrients, and grow lights. ¹⁴⁵ Data is not publicly available to gauge how much the government has reimbursed patients for medical cannabis. Under private insurance schemes, patients may

-

¹³⁸ I.A

¹³⁹ *Id.* Specific groups include First Nations people living on reserves, Inuit, serving members of the Canadian Forces, eligible veterans, inmates in federal penitentiaries, and some groups of refugee claimants.) (Other federal health related functions include the regulation of products including food and pharmaceuticals, supporting health research and disease monitoring and prevention, in addition to tax support for health-related costs.

¹⁴⁰ International Health Care System Profiles: Canada, THE COMMONWEALTH FUND, https://www.commonwealthfund.org/international-health-policy-center/countries/canada (last visited May 4, 2023). ¹⁴¹ Id.

¹⁴² Medical Expenses, CANADA REVENUE AGENCY, https://www.canada.ca/en/revenue-agency/services/forms-publications/rc4065/medical-expenses.html (last visited May 4, 2023).

¹⁴³ *Id*.

¹⁴⁴ *Id*.

¹⁴⁵ *Id*.

"opt-in" to coverage of medical cannabis at the group level. Patients may obtain reimbursement subject to pre-authorized medical conditions, annual dollar caps, and other administrative requirements. Covered medical conditions include cancer, multiple sclerosis, rheumatoid arthritis, HIV/AIDS, palliative care, pediatric epilepsy, spasticity related to spinal cord injury, and chronic neuropathic pain. Other plans are broader allowing patients to obtain medical cannabis when prescribed by a physician as medically required.

Canada widely reimburses their Veteran population for medical cannabis, a practice that began in 2007. ¹⁵⁰ From 2021 to March 31, 2022, Canada reimbursed 18,388 Veterans for medical cannabis totaling \$153,780,985. ¹⁵¹ Canada has noted the health and well-being of its Veterans is a top priority for the Government of Canada, which it has prioritized through the Veteran medical cannabis program. ¹⁵² The numbers reported show medical cannabis is very popular with veterans and estimates popularity will only increase. ¹⁵³ It is postulated that Veteran access to medical cannabis is a contributing factor of decreased Veteran suicide rates, ¹⁵⁴ but this claim is not substantiated by available data. ¹⁵⁵ By all appearances, Canada encourages Veteran populations to access medical cannabis despite the lack of research available. There have been

¹⁴⁶ A Patient's Guide to Reimbursement Options for Medical Cannabis, SPECTRUM THERAPEUTICS, https://www.spectrumtherapeutics.com/content/dam/canada-new/downloads/Guide%20to%20Reimbursement%20of%20Medical%20Cannabis.pdf (last visited May 4, 2023).

¹⁴⁷ *Id*.

¹⁴⁸ *Id*. ¹⁴⁹ *Id*.

¹⁵⁰ Cannabis for Medical Purposes, GOVERNMENT OF CANADA, https://www.veterans.gc.ca/eng/about-vac/research/researc

¹⁵² *Id*.

¹⁵³ Lee Berthiaume, *Ottawa on track to spend \$200-Million per year on cannabis for veterans*, THE GLOBE AND MAIL, https://www.theglobeandmail.com/canada/article-ottawa-on-track-to-spend-200-million-per-year-on-cannabis-for-veterans/ (last visited May 4, 2023).

¹⁵⁴ Kyle Jaeger, *As Canada Reimburses Medical Marijuana for Military Veterans, The U.S. Keeps Failing Those Who Served (Op-Ed)*, MARIJUANA MOMENT, https://www.marijuanamoment.net/as-canada-reimburses-medical-marijuana-for-military-veterans-the-u-s-keeps-failing-those-who-served-op-ed/ (last visited May 4, 2023).

^{155 2021} Report on Suicide Mortality in the Canadian Armed Forces (1995 to 2020), GOVERNMENT OF CANADA, https://www.canada.ca/en/department-national-defence/corporate/reports-publications/health/2021-report-on-suicide-mortality-in-the-caf-1995-to-2020.html#toc10 (last visited May 4, 2023).

calls for more research and clinical support on cannabis as a treatment for mental health to better understand its efficacy and use in Veteran patient populations.¹⁵⁶

Additional situations in which Canadian medical cannabis patients can receive reimbursement include workers compensation and tax credits. Medical cannabis patients are able to obtain reimbursement through workers compensation programs. ¹⁵⁷ Covered conditions include spasticity due to spinal cord injury, chemotherapy-induced nausea and vomiting, HIV/AIDS loss of appetite, palliative care, and chronic neuropathic pain. ¹⁵⁸ Notably on a case-by-case basis, medical cannabis may be used on a trial basis for opioid and narcotic harm reduction. ¹⁵⁹ Medical cannabis patients are also eligible for income tax credits as an allowable medical expense. ¹⁶⁰ To be eligible for these tax credits, medical cannabis must be prescribed by a qualified healthcare professional and purchased from a legal source (licensed producers). ¹⁶¹

Psilocybin

While cannabis is fully legal and available for reimbursement in Canada, psilocybin remains a restricted illegal substance. Under Canada's Controlled Drugs and Substances Act (CDSA), psilocybin is illegal to sell, possess, or produce. Psilocybin is also regulated under Canada's Food and Drug Act (FDA), which ensures the quality, efficacy, and safety of health products. There are limited exceptions and situations that allow an individual to possess and use psilocybin. Similar to the United States where patients may access investigational treatment

¹⁵⁶ Veterans and their Families want better research and clinical support on cannabis as a treatment for mental health, MENTAL HEALTH COMMISSION OF CANADA, https://www.newswire.ca/news-releases/veterans-and-their-families-want-better-research-and-clinical-support-on-cannabis-as-a-treatment-for-mental-health-814527400.html (last visited May 4, 2023).

¹⁵⁷ Spectrum Therapeutics, *supra*. note 140.

¹⁵⁸ *Id*.

¹⁵⁹ *Id*.

¹⁶⁰ Cannabis in Canada and Taxes, INTUIT TURBOTAX, https://turbotax.intuit.ca/tips/cannabis-in-canada-and-taxes-11208 (last visited May 4, 2023).

¹⁶¹ La

¹⁶² Psilocybin and psilocin (Magic Mushrooms), GOVERNMENT OF CANADA, https://www.canada.ca/en/health-canada/services/substance-use/controlled-illegal-drugs/magic-mushrooms.html (last visited May 4, 2023).

¹⁶³ Regulating health products, GOVERNMENT OF CANADA, https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-regulates-1/health-products.html (last visited May 4, 2023).

options through the Right to Try Act, ¹⁶⁴ Canadians may access drugs through Health Canada's Special Access Program. ¹⁶⁵ This program allows Canadians to access therapies that have shown promise in clinical trials or been approved in other countries that are not yet authorized for sale in Canada. ¹⁶⁶ Similar to the United States, patients with serious or life-threatening conditions that have failed to respond to conventional therapies may try these drugs. ¹⁶⁷ Through this program, health care providers may request psilocybin treatment for their patient, prompting Health Canada conduct a fact based analysis to evaluate available evidence of safety, efficacy of the drug, and the patient's condition. ¹⁶⁸ Patients may also access psilocybin under section 56(1) of the CDSA, which grants discretionary power to the Minister of Health to exempt persons or a class of persons or controlled substances for a purpose that is in the public interest. ¹⁶⁹ As with the Special Access Program, the Minister of Health assesses each request on the facts presented in the request including but not limited to the medical condition for which psilocybin is to be used, existing scientific evidence for the use of psilocybin in the treatment of the condition, conventional therapies tried, support of a health care practitioner, and risk. ¹⁷⁰

Canada's approach to medical cannabis and psilocybin may be considered radical in some circles, but based on available data, the country appears to be carefully and thoughtfully responding to public sentiment, lawsuits, and the latest scientific research. As Canada continues to enforce these programs, there are insights to be gained that are applicable to other countries considering similar legislation. Reported negative impacts of medical and adult-use cannabis

¹⁶⁴ Right to Try, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try (last visited May 4, 2023).

¹⁶⁵ Government of Canada, *supra*. note 156.

¹⁶⁶ Id

¹⁶⁷ *Id*.

¹⁶⁸ *Id*.

¹⁶⁹ *Id*.

¹⁷⁰ *Id*.

include an increase in drug-impaired driving, road accidents, and little to no involvement of pharmacists in administering cannabis.¹⁷¹ While these concerns are legitimate, Canada permits the sale of alcohol which is estimated to contribute to 1,250 to 1,500 deaths and 63,000 instances of injury related to impaired driving.¹⁷² This evidence suggests no matter the impairment inducing substance, there will still be risk associated with a substance's use. Increased governmental involvement in the regulation and distribution of all impairing substances may reduce risk but not eliminate risk entirely.

Additional International Approaches: Uruguay, Czechia, Australia, and United Kingdom

Each of the countries discussed has a unique approach to medical cannabis, which may be harder to replicate in the United States. However, there are a few common themes. Under public health insurance schemes, some countries permit public health insurance coverage of medical cannabis, while others allow for coverage in extremely narrow situations. In the private insurance industry, some private insurers permit coverage of medical cannabis and are not prohibited from covering cannabis based on government statutes. These approaches are dissimilar from the United States where the only opportunity for medical cannabis patients to receive reimbursement from public or private insurer is through workers compensation programs in medically legal states.

In 2013, Uruguay became the first country in the world to legalize cannabis for recreational use. ¹⁷³ Uruguay's healthcare system has two sectors: government public hospitals

¹⁷¹ Jacob Ablin, et al., *Medical Use of Cannabis Products: Lessons to be Learned from Israel and Canada*, SCHWERPUNKT (2015).

¹⁷² The Rate of Impaired Driving in Canada, MOTHERS AGAINST DRUNK DRIVING CANADA, https://madd.ca/pages/impaired-driving/overview/statistics/ (last visited May 4, 2023).

¹⁷³ Simon Maybin, *Uruguay*: *The World's Marijuana Pioneer*, BBC https://www.bbc.com/news/business-47785648 (last visited May 4, 2023).

and privately-owned hospitals.¹⁷⁴ All citizens are eligible for public healthcare through the Administracion de los Servicios de Salud del Estado (ASSE).¹⁷⁵ According to research, it appears that more economically advantaged individuals receive insurance coverage through private insurers instead of the government universal healthcare.¹⁷⁶ Uruguay has reimbursement available for medical cannabis, but the government does not regulate it.¹⁷⁷

Czechia, more commonly known to English speaking countries as the Czech Republic, has legalized cannabis for medical use. Notably, the country openly states insurance reimbursement is available for medical patients. ¹⁷⁸ In 2020, patients in Czechia are entitled to insurance coverage of 90% of the retail price of cannabis for 30 grams of flower per month for medical use. ¹⁷⁹ The country does not impose limitations on reimbursement based on THC content. ¹⁸⁰ Czechia has a universal healthcare system with coverage available to all citizens. ¹⁸¹

Australia has legalized medical cannabis and controls the production and distribution very tightly. ¹⁸² Insurance available to citizens of Australia includes public and private insurance schemes. As of the date of this writing, the public governmental health insurance does not provide coverage or reimbursement for medical cannabis. ¹⁸³ However, most private health insurers cover medical cannabis for patients. ¹⁸⁴ For example, the Health Insurance Fund of

¹⁷⁴ Rifat Atun et al. Universal health coverage in Latin America: Health-system reform and universal health coverage in Latin America, Lancet (2015)

¹⁷⁵ ADMINISTRACION DE LOS SERVICIOS DE SALUD DEL ESTADO, https://www.asse.com.uy/home (last visited May 4, 2023).

¹⁷⁶ Pamela Bernales-Baksai, *Tackling segmentation to advance universal health coverage: analysis of policy architectures of health care in Chile and Uruguay*, International Journal for Equity in Health (2020).

¹⁷⁷ Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs, PHARMA BOARDROOM, https://pharmaboardroom.com/legal-articles/cannabinoid-drugs-medicinal-cannabis-and-opioid-drugs-uruguay/ (last visited May 4, 2023).

¹⁷⁸ Alfredo Pascual, *Czech Medical Sales Show Timid Growth Despite Insurance Coverage*, MJ Biz Dailly, https://mjbizdaily.com/czech-medical-cannabis-sales-show-timid-growth-despite-insurance-coverage (last visited May 4, 2023).

¹⁸⁰ Id.

¹⁸¹ Lucie Bryndová et al., Czechia: Health System Review, 25 HEALTH SYSTEMS IN TRANSITION 1 (2023).

¹⁸² Medicinal Cannabis, HEALTH DIRECT, https://www.healthdirect.gov.au/medicinal-cannabis (last visited May 4, 2023).

¹⁸³ Does Health Insurance Cover Medical Cannabis?, ALTERNALEAF, https://www.alternaleaf.com.au/post/does-health-insurance-cover-medical-cannabis (last visited May 4, 2023).

¹⁸⁴ Id.

Australia will cover between \$80 and \$200 for medical cannabis depending on the plan held by the patient. 185

United Kingdom has made medical cannabis available to citizens. 186 Insurance is available to all citizens of the United Kingdom through the National Health System (NHS). 187 While medical cannabis is available for purchase, the NHS generally does not provide reimbursement except in rare cases. 188 A situation where the NHS has reimbursed a patient for medical cannabis was for a "debilitating but common condition." This patient was the first individual to obtain reimbursement for medical cannabis in 2023, five years after medical cannabis was legalized. 190 The patient declined to share more details about their condition.

Medical cannabis is a larger international market than psilocybin with only a few countries permitting legal consumption. Some countries are more liberal, permitting consumption of psilocybin more recently and others have a deep history of indigenous peoples utilizing the substance for religious or cultural practices carried through to the modern era. The countries that permit consumption of psilocybin and psychedelics are the United States, the Netherlands, Jamaica, Bahamas, Brazil, Nepal, Mexico, Peru, and Portugal. 191 As previously discussed, in the United States psilocybin is still considered a Schedule 1 substance but consumption is permitted in Oregon under recent state legislation. In Portugal, all illegal drugs were decriminalized in 2000. 192 The goal of this legislation was to promote public health rather

¹⁸⁵ Id.

¹⁸⁶ Michael Anderson et al., United Kingdom Health System Review, 24 HEALTH SYSTEMS IN TRANSITION 1 (2022)

¹⁸⁸ Sarah Sinclair, NHS Reimburses Cost of Unlicensed Cannabis Treatment in 'Rare' Adult Case, CANNABISHEALTH, https://cannabishealthnews.co.uk/2023/01/25/nhs-reimburses-cost-unlicensed-cannabis-treatment-in-rare-adult-case (last visited May 4, 2023).

¹⁸⁹ Id.

¹⁹¹ James Hallifax, Five Countries Where Psychedelics are Legal, PSYCHEDELIC SPOTLIGHT, https://psychedelicspotlight.com/5countries-where-psychedelics-are-legal/ (last visited May 4, 2023).

¹⁹² Ximene Rego et al., 20 years of Portuguese drug policy - developments, challenges and the quest for human rights, SUBSTANCE ABUSE TREATMENT, 16 PREVENTION, AND POLICY 59 (2021).

than policing of the public.¹⁹³ Reception and outcomes of this policy are varied, but it is one of the most liberal drug policies in the world. Jamaica legalized psilocybin and has been capitalizing on this with revenue generated from tourism.¹⁹⁴ As previously discussed, drug tourism has increased in recent years with citizens from countries where the substances are illegal traveling to countries where psychedelic substances are legally consumable.

Part V: Conclusions and Recommendations

Insurance Reimbursement of Cannabis and Psilocybin

States with medical cannabis programs should expressly allow insurance reimbursement for patients by amending the statutes that establish the medical cannabis program. While the body of research around cannabis for various conditions continues to be built, insurers can cover treatment that is supported by evidence for conditions such as seizures and pain, while ensuring the safe use of cannabis. Insurance coverage of medical cannabis would reduce upfront costs to patients and medical cannabis would function more akin to prescription drugs by being included on insurance drug formularies. Insurance companies do not have to eliminate cost sharing measures if they cover medical cannabis—patients can still pay a co-pay for the prescription. In some instances, medical cannabis should be fully covered such as palliative care, cancer treatment, pediatric seizures, and for low-income individuals. This would help fixed income and low-income individuals access a medical treatment that is beneficial to their health. Insurance coverage to reduce patient costs may also decrease diversion and patients obtaining cannabis from the unregulated market. Despite the prevalence of dispensaries in the United States, people still obtain their cannabis from legacy dealers who can offer lower prices. Diversion is a

¹⁹³ Id.

¹⁹⁴ Max Berlinger, All-Inclusive Magic Mushroom Retreats Are the New Luxury Trips, BLOOMBERG, https://www.bloomberg.com/news/articles/2021-08-19/all-inclusive-magic-mushroom-ayahuasca-retreats-are-new-luxury-trips (last visited May 4, 2023).

significant concern for cannabis businesses whether the diversion is from employees or through dispensary break-ins. Covering medical cannabis may result in decreased diversion and increase in use by low-income populations. By covering these alternative therapies, insurers may spend less on patients over time, because these treatments could replace more expensive therapies like anti-depressants that have a long list of side effects.

Insurers can contribute to research around cannabis by facilitating and collecting data from patient outcomes with the treatment under their coverage. Contributing to this body of research would help ensure patient therapeutic success by further understanding situations when cannabis is therapeutically successful. These insights would be gathered from wide patient population that researchers are currently struggling to obtain from formalized clinical trials. As previously discussed, Schedule 1 trials are very restricted in their patient population because of financial restraints. Involvement of a larger body of individuals from insurance coverage would significantly increase available data and accelerate data collection.

Finally, insurance coverage of medical cannabis would facilitate productive conversations between patients and their health care providers. These conversations would influence a patient's use of cannabis in a way that is more transparent and considers their overall health. Many patients use medical cannabis but may not disclose it to their health care provider for fear of stigmatization. This means a provider does not have a whole picture of their patient when trying to develop a treatment plan. By not disclosing their use, patients may be harming themselves. For example, if a patient is on a specific medication that has an interaction with cannabis, the patient may be experiencing side effects that are detrimental to their health and reducing the effectiveness of the two therapies. Insurance coverage of medical cannabis and health care appointments related to medical cannabis would remove some of the stigma around

cannabis use and promote treatment transparency for patients. It is likely that if patients feel stigmatized about their cannabis use, the patient will not disclose their use to a doctor. A patient may insist to their doctor that they do not smoke, but their blood work may tell a different story. Lack of disclosure can result in negative health effects such as negative effects from smoking cannabis. Therefore, insurance coverage of medical cannabis would contribute to data collection and patient health improvement.

Oregon should offer financial incentives to patients paying out of pocket to access psilocybin for medical treatment as the program becomes established. This is because Oregon is the first state to legalize psilocybin and all states that legalize psilocybin will take their lessons and data from Oregon. As there isn't a significant body of research available to patients, patients should have incentive to take on the risk of participation. When research illuminate's conditions where psilocybin is effective, insurance companies should begin covering these therapies. This would help facilitate safe consumption, reduce diversion, and facilitate patient-physician conversations similar to cannabis.

Unlike Canada, United States veterans cannot obtain medical cannabis through the

United States Department of Veterans Affairs Health Care because cannabis is an illegal

Schedule I Controlled Substance. Like other Americans, veterans need to go through the

costly application process to receive a medical cannabis patient card. Luckily for veterans, if they

obtain medical cannabis through a state approved program, veterans will not be denied VA

benefits because of cannabis use. The inability to access medical cannabis through VA

benefits has led to the creation of advocacy organizations such as Disabled American Veterans

_

¹⁹⁵ VA and Marijuana – What Veterans Need to Know, U.S. DEPARTMENT OF VETERANS AFFAIRS, https://www.publichealth.va.gov/marijuana (last visited May 4, 2023).

(DAV) and Veterans Cannabis Project. The two organizations are working hard to make cannabis accessible to veterans in an effort to help with pain and mental health. ¹⁹⁷ Their goals include coverage of medical cannabis through VA benefits already available to veterans. This would ensure veterans do not need to pay more out of pocket for medical cannabis and facilitate conversations with their health care providers. As the VA is not allowed to discuss cannabis use with veterans, removing this barrier would ensure effective treatment.

Reschedule Cannabis and Psilocybin

Cannabis and psilocybin should be rescheduled from Schedule I to Schedule III. The Schedule I designation is for drugs and substances that have no currently accepted medical use, but as this paper has explored, there is accepted medical use for cannabis and psilocybin. As researchers continue to build the body of credible information around these substances, there are legitimate therapeutic uses for these substances: cannabis for epilepsy, spasticity, and pain and psilocybin for major depressive disorder. The initial data around these substances is very positive with few side effects. While Schedule I is for drugs that have a high possibility for abuse (addiction), there is not sufficient evidence to show cannabis or psilocybin are addictive, but rather evidence shows the substances help with addiction issues. By using cannabis and psilocybin to treat addiction, specifically opioid addiction, may decrease overdoses. A very common treatment of opioid addiction is treatment with another opioid. Cannabis and psilocybin can help addiction treatment because these substances are more natural and less dangerous than opioids. Unlike opioid overdose, cannabis and psilocybin overdoses rarely result in death because their mechanism of action is very different, namely they are not a central nervous system depressant.

¹⁹⁷ DAV, https://www.dav.org/ (last visited May 4, 2023); VETERANS CANNABIS PROJECT, https://www.vetscp.org/ (last visited May 4, 2023).

If the DEA does not wish to reschedule cannabis and psilocybin, the agency must adjust guidelines and protocols to reduce barriers to research. The DEA has claimed there is not enough evidence to support medical use of these substances, but the agency has built barriers that make it almost impossible to obtain evidence. The prohibition on knowledge and understanding must be removed for researchers to understand and utilize cannabis and psilocybin as legitimate medical treatments where the substances have shown promise. Until the DEA removes these barriers, it is nearly impossible for researchers to develop a meaningful body of research to inform uses and insurance coverage.

Federal Legalization of Cannabis and Psilocybin

The federal government should legalize cannabis and psilocybin by amending portions of the CSA or through judicial rulings. Psilocybin should at the very least be de-criminalized to allow researchers to better understand how the substance works. By legalizing psilocybin, the government would remove significant financial and procedural barriers to studying and understanding the use of this substance. While states are legalizing cannabis and the federal government continues to prohibit it, all state cannabis laws are in significant tension with the CSA placing these programs at risk. While some state judges claim the state cannabis laws are not preempted by the CSA, other state judges argue the state cannabis laws are preempted by the CSA. This is a significant split since it effects 40 of the 50 states. This tension should be resolved to ensure states will not be federally penalized for creating medical cannabis programs that benefit their citizens. The federal government should also remove individuals harmed by the War on Drugs from prison. While cannabis is legal in states, no individual should be in prison from minor cannabis infractions or have cannabis infractions on their permanent record. The MORE Act is a step in the right direction to ensure these goals of legalization and social justice.

Congress should act on this legislation to eliminate tension between federal and state law and bring justice to those harmed by punitive drug laws.

Conclusion

Cannabis and psilocybin should be covered by insurance, rescheduled, decriminalized, and federally legalized in the United States to promote understanding, increase population health, and resolve significant tension in the law. At a minimum, the government should eliminate financial and procedural barriers to research so cannabis and psilocybin may be better understood. After these steps are taken, public and private insurance companies should cover these treatments to remove barriers for low-income populations and contribute to the body of research on cannabis and psilocybin. The United States cannot come to a greater understanding of these substances and right the harm from the War on Drugs without rescheduling, federally legalizing, and understanding cannabis and psilocybin from a scientific and legal perspective.