TAKE THE GATEKEEPERS TO COURT: HOW MARIJUANA RESEARCH UNDER A BIASED FEDERAL MONOPOLY OBSTRUCTS THE SCIENCE-BASED PATH TO LEGALIZATION

I. INTRODUCTION

Meet Irvin.[1] At age 10, Irvin was diagnosed with exostosis,[2] a very rare bone disorder that causes severe and debilitating pain from tumors that grow on most long bones in his body.[3] Irvin has made a life for himself as a respected stockbroker, trading tens of thousands of stock market dollars each day for his clients,[4] and he even continues to play softball every Sunday despite medical predictions that he would not make it past his teens.[5] As he puts it, "I am able to do this because I have the right medicine."[6] Irvin's case is a curious one: the federal government directly provides him with a drug to treat his disease but publicly denies that this drug has any legitimate medical value. That is, Irvin is a federally approved marijuana smoker.[7]

This schizophrenic treatment of marijuana by the federal government stems from the now-abolished Compassionate Investigational New Drug program established in 1978 that granted a limited number of patients

1. Evan Halper, *Pot-Smoking Stockbroker Has a Steady Supplier: The Feds*, L.A. TIMES (Mar. 12, 2015, 3:00 AM), http://www.latimes.com/nation/great-reads/la-na-c1-government-pot-smoker-20150312-story.html; Daniel Oberhaus, *The US Government Has Sent This Guy 300 Joints Each Month for 34 Years*, VICE (Sept. 8, 2016, 9:00 PM), https://www.vice.com/en_us/article/the-us-government-has-sent-this-guy-300-joints-each-month-for-34-years; NEWS21, *Florida: America's Second Medical Marijuana Patient*, VIMEO (Aug. 6, 2015), https://vimeo.com/135585787.

2. Oberhaus, *supra* note 1.

3. NEWS21, *supra* note 1.

4. Halper, *supra* note 1.

5. NEWS21, *supra* note 1.

6. *Id.*

7. Halper, *supra* note 1.

access to marijuana as medicine.[8] Irvin is one of only four surviving participants in this program,[9] and unlike the regular medical marijuana patient, he gets his supply directly from the Drug Enforcement Agency ("DEA"),[10] the arm of the executive branch which has functioned as the main obstacle to lifting the federal ban on the drug.[11] The government's discomfort with this aberration in DEA policy is reflected in the observation by drug policy reform advocate Rick Doblin that "[t]he government was never comfortable with this program . . . They are just waiting for all the people in it to die."[12]

Although seemingly absurd at first, this opposite treatment of marijuana makes absolute sense in the context of the modern American administrative state.[13] Agencies like the DEA, CIA, and NSA are given wide latitude in exercising their delegated powers under the highly deferential standard applied to administrative actions established by the seminal case *Chevron v. Natural Resources Defense Council*.[14] Fortunately for legalization advocates like Irvin[15] and Rick Doblin,[16] the very *Chevron* analysis that gives such great latitude to these agencies also contains the power to take it away at the very first sight of arbitrary and capricious behavior.[17] When we observe how the DEA grows, packages, and delivers 300 tightly rolled joints to Irvin's doorstep every twenty-five days via FedEx,[18] we realize that this very same agency stymies advocates and

8. Craig Patrick, *Two Floridians Get Free Marijuana For Life—From the Feds*, FOX 5 (Nov. 2, 2015), http://www.fox5dc.com/news/43872602-story.

9. *Who Are the Patients Receiving Medical Marijuana through the Federal Government's Compassionate IND Program?*, ProCon.org, https://medicalmarijuana.procon.org/view.answers.php?questionID=000257 (last updated July 19, 2012); Russell Goldman, *Irvin Rosenfeld Has Received Over 115,000 Joints from the Federal Government*, ABC NEWS (Nov. 24, 2009), http://abcnews.go.com/Business/man-sets-marijuana-record-smokes-115000-joints-provided/story?id=9159281.

10. Halper, *supra* note 1.

11. *See* Craker v. DEA, 714 F.3d 17 (1st Cir. 2013); Ams. for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013).

12. Halper, *supra* note 1.

13. *See generally* George Will, *Battling the Modern American Administrative State*, WASH. POST (Nov. 27, 2015), https://www.washingtonpost.com/opinions/battling-the-modern-administrative-state/2015/11/27/a1c639ba-9392-11e5-8aa0-5d0946560a97_story.html?utm_term=.167d04dd85ba.

14. *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).

15. Goldman, *supra* note 9.

16. *See* Catherine Saint Louis, *D.E.A. Keeps Marijuana on List of Dangerous Drugs, Frustrating Advocates*, N.Y. TIMES (Aug. 11, 2016), https://www.nytimes.com/2016/08/12/health/dea-keeps-marijuana-on-list-of-dangerous-drugs-frustrating-advocates.html?_r=0.

17. *Chevron*, 467 U.S. at 842-44.

18. Goldman, *supra* note 9; Harper, *supra* note 1.

researchers attempting to establish a science-based path toward federal legalization of marijuana.[19]

This Note argues that the Drug Enforcement Agency does not deserve *Chevron* deference when it unjustly handicaps the marijuana legalization movement through an arbitrary and capricious interpretation of the Controlled Substances Act ("CSA"). Part II provides a brief history of marijuana regulation in the United States and reveals how *Chevron* gives the DEA an almost unfettered discretion to say when a drug will be rescheduled under the CSA. Part III explores the process behind researching marijuana and explains how the current federal monopoly on the supply of research marijuana obstructs the very studies the DEA requires because of a bias against applications for medical use research. Part IV argues that this bias against medical use research constitutes arbitrary and capricious behavior that does not deserve judicial deference, justifying a change in the DEA's administration of the Act that would allow for more research into the medical value of marijuana.

II. *CHEVRON* DEFERENCE AND THE DEA'S UNFETTERED DISCRETION IN THE CONTEXT OF MEDICAL MARIJUANA

A. Marijuana Has Been Used as a Medicine for Centuries

As a preliminary note, several sources point to the use of marijuana as medicine for thousands of years notwithstanding its Schedule I status in the United States.[20] In ancient times pre-dating the start of the Common Era, marijuana was used to treat such conditions as rheumatism, constipation, dysentery, and malaria.[21] In Ancient India, marijuana was consumed to aid appetite, digestion, and sleep.[22] More recently, the National Academy of Sciences, Engineering, and Medicine published a January 2017 report surveying over 10,000 studies on the effects of marijuana on human health and found strong evidence of marijuana's ability to reduce pain for those suffering from multiple sclerosis and chemotherapy-induced nausea and vomiting.[23] In that same report, researchers nevertheless acknowledged that

19. *See infra* Part IV.

20. Elena Quattrone, *The "Catch-22" of Marijuana [Il]legalization*, 22 B.U. J. SCI. & TECH. L. 299 (2016).

21. Peter J. Cohen, *Medical Marijuana: The Conflict Between Scientific Evidence and Political Ideology*, 2009 UTAH L. REV. 35 (2009). As Professor Cohen points out, there are accounts of medical marijuana use in ancient China as far back as 2700 B.C. *Id.*

22. Quattrone, *supra* note 20.

23. Patti Neighmond, *Marijuana's Health Effects? Top Scientists Weigh In*, NPR (Jan. 12, 2017), http://www.npr.org/sections/health-shots/2017/01/12/509488977/marijuanas-health-

there is still a lack of "conclusive" evidence about marijuana's positive medical effects due partly to its federal prohibition as a Schedule I substance.[24]

B. A Brief History of Marijuana Regulation and the Role of Chevron Deference

Urban legends that suggest the original drafts of the Declaration of Independence and Constitution were written on hemp paper reflect marijuana's prevalence in the United States since the nation's founding.[25] In fact, a survey of the history of drug legislation in America reveals that using criminal law to regulate the use, sale, and manufacture of psychoactive substances did not become the norm for American legislatures until well into the twentieth century.[26] As Professor Deborah Ahrens points out, passing criminal laws to control the spread of marijuana and other drugs was hardly based on evidence-based dialogue.[27] Rather, such laws were motivated by a political desire to target the socially disfavored groups associated with them, oftentimes delineated on racial lines.[28]

When the CSA was passed in 1970, any ambiguity regarding marijuana's illicit status in the eyes of the federal government was settled when it, along with MDMA, LSD, and psilocybin, was classified as a Schedule I substance alongside heroin and GHB.[29] Of the five schedules that a drug may be classified under the CSA, Schedule I is deemed by the U.S. government to be the most restricted category[30] and, most pertinent to the argument here, is defined in part as having "no currently accepted medical use."[31] Professor Alex Kreit, an expert on marijuana law, offers one major critique to this categorical approach to drug legislation, namely, a

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effects-scientists-weigh-in.

24. *Id.*

25. John Vigorito, *Creating Constitutional Cannabis: An Individual State's Tenth Amendment Right to Legalize Marijuana*, 46 U. TOL. L. REV. 221 (2014).

26. Deborah Ahrens, *Drug Panics in the Twenty-First Century: Ecstasy, Prescription Drugs, and the Reframing of the War on Drugs*, 6 ALB. GOV'T L. REV. 397, 400-01 (2013).

27. *Id.* at 401.

28. *Id.* Professor Ahrens has developed an extensive body of research discussing this trend, citing examples that include the association of "Demon rum" with Irish and Italian immigrants in the 1800s, opium with Chinese immigrants in the early 1900s, and crack cocaine with urban African-Americans in the late 1980s. *Id.*

29. *See* Chemerinsky et al., *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74, 82 (2015).

30. *See id.*

31. 21 U.S.C. §812(b) (2012). As a result, Schedule I substances are the only category of drugs that doctors may never prescribe.

resulting "schedule first, study later" mentality wherein a drug with a demonstrated potential for medical value like marijuana can be placed in Schedule I without any prior opportunity to prove it does not belong there in the first place.[32]

Although a drug may be rescheduled through Congressional action, this occurs very rarely.[33] Consequently, advocate groups such as the National Organization for the Reform of Marijuana Laws ("NORML") and, more recently, Americans for Safe Access have taken it upon themselves as citizens to rally together and pursue an alternate route to rescheduling provided in the CSA, namely, initiating an administrative action as "interested parties"[34] by filing a petition with the DEA and, if necessary, taking them to court.[35] These attempts, however, have proven largely unfruitful as time and time again the D.C. Circuit, where many of these cases arise and where the DEA's main operations take place, has sided with the DEA and its staunch position against rescheduling marijuana by entitling it to what is known as *Chevron* deference.[36]

Under the holding of *Chevron v. Natural Resources Defense Council*, courts will defer to an administrative agency's interpretation of a statute that the agency is responsible for administering—as the DEA is responsible for the CSA—unless that interpretation is either (1) manifestly contrary to an express Congressional intent or (2) an arbitrary and capricious interpretation.[37] When Congress fails to define a particular phrase in a statute, a reviewing court will accept and condone an agency's interpretation of that phrase so long as it satisfies the rather low bar of "a permissible construction of the statute."[38] Giving such deference stems from the premise that courts should not substitute their judgment for that of an agency despite a clear disagreement with its conclusions because the agency has the fact-finding power and expertise on which to make sound administrative decisions.[39]

Congress failed to define the phrase "currently accepted medical use" when enacting the CSA, resulting in the great deference given to the DEA

32. Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 353-54 (2013).

33. Kevin A. Sabet, *Much Ado About Nothing: Why Rescheduling Won't Solve Advocates' Medical Marijuana Problem*, 58 WAYNE L. REV. 81, 85 (2012).

34. *Id.* at 84.

35. Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974); Ams. for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013).

36. *See Ingersoll*, 497 F.2d 654; *Ams. for Safe Access*, 706 F.3d 438.

37. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-44 (1984).

38. *Id.* at 843.

39. *See id.* at 844.

in cases against marijuana advocate groups like those mentioned above.[40] With this deference, the agency wields sole authority to craft a multi-part test used to determine whether a drug has a proven "medical use" under the statute.[41] *Chevron* does not mandate a reviewing court's blind or absolute adherence to an agency's judgments,[42] but marijuana and many other Schedule I substances with support from medical practitioners across the country nevertheless remain illegal under federal law because no advocate group has successfully overcome the following five-part test[43] used by the DEA in determining whether a psychoactive substance has a "currently accepted medical use:"[44]

1) The drug's chemistry is known and reproducible;
2) Adequate safety studies have been conducted;
3) Adequate and well-controlled studies proving efficacy have been conducted;
4) The drug is accepted by qualified experts;
5) The scientific evidence is widely available.

All five parts must be satisfied before the DEA will find that a substance has an accepted medical use.[45]

The requirement of "adequate and well-controlled studies proving efficacy" (hereafter, "efficacy studies") is the main obstacle to the rescheduling movement and has been the most litigated.[46] In 2013, for instance, Americans for Safe Access and various other marijuana advocate organizations petitioned the DEA to initiate proceedings to reschedule marijuana.[47] The DEA denied the petition, and the D.C. Circuit granted review.[48] The plaintiffs argued that the denial was arbitrary and capricious and therefore not entitled to *Chevron* deference because the DEA was choosing to ignore "numerous peer-reviewed scientific studies" offered as evidence of marijuana's medical benefit.[49] In rejecting this argument, the

40. Kreit, *supra* note 32, at 333. In fact, the term United States "is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA[.]" *Id.* at 343.

41. *Id*. at 350.

42. U.S. Lines, Inc. v. Fed. Mar. Comm'n, 584 F.2d 519, 535 (D.C. Cir. 1978) (existence of judicial review negates notion of absolute deference).

43. All. for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991); All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994); Ams. for Safe Access v. DEA, 706 F.3d 438, 439-442 (D.C. Cir. 2013).

44. *Ams. for Safe Access*, 706 F.3d at 449.

45. *Id.*

46. *See All. for Cannabis Therapeutics*, 930 F.2d at 938; *All. for Cannabis Therapeutics*, 15 F.3d at 1135; *Ams. for Safe Access*, 706 F.3d at 441.

47. *Ams. for Safe Access*, 706 F.3d at 439.

48. *Id.*

49. *Id.* at 440.

Court made clear that peer-reviewed studies do not qualify as efficacy studies, reasoning that "'scientists understand that peer review per se provides only a minimal assurance of quality, and that the public conception of peer review as a stamp of authentication is far from the truth.'"[50] Finding the DEA's construction of its own regulation "eminently reasonable," the Court felt obliged to defer to the agency's interpretation of "currently accepted medical use" as requiring more than what the plaintiffs offered as evidence and, therefore, denied their claim.[51]

As a matter of public policy, it is reasonable for an administrative agency to require scientific studies of any drug that will be introduced and sold to the public for human consumption in order to prevent needless deaths from "bad" medicine. But we must keep in mind that there is a clear distinction between the DEA's interpretation of the CSA and how it chooses to enforce it. That is, though it is reasonable for the DEA to require efficacy studies, the process it offers to fulfill these studies may nevertheless be unreasonable and, therefore, open to challenges by citizens in the federal courts. This issue stems from the federal monopoly model the federal government has used to regulate research into Schedule I substances, and as the discussion below reveals, marijuana serves as a prime example of how this form of regulation can constitute arbitrary and capricious behavior. An overview of the process of acquiring marijuana for research sheds further light on the problem.

III. THE FEDERAL MONOPOLY MODEL TO RESEARCHING MEDICAL MARIJUANA

A. The Federal Process Behind Acquiring Research Marijuana Protects Against Criminal Prosecution

Since marijuana remains a Schedule I substance, the federal government retains full authority to prosecute anyone involved in its use, sale, or manufacture regardless of marijuana's legal status under state laws.[52] *Gonzales v. Raich* represents the first time the federal government directly violated a state law permitting the use of medical marijuana when it entered state bounds to seize and destroy all six of the plaintiffs' cannabis

50. *Id.* at 452 (quoting Charles Jennings, *Quality and Value: The True Purpose of Peer Review*, NATURE.COM (2006), http://www.nature.com/nature/peerreview/debate/nature 05032.html).

51. *Ams. for Safe Access*, 706 F.3d at 452.

52. *See* United States v. McIntosh, 833 F.3d 1163 (9th Cir. 2016); Chemerinsky et al., *supra* note 29, at 82-83 (discussing the criminal aspect behind Schedule I status).

plants possessed in compliance with California's Compassionate Use Act.[53] The Supreme Court held that homegrown marijuana intended strictly for personal, medical use was so closely tied to interstate commerce that it fell within Congress's power to regulate.[54] Justices O'Connor, Rehnquist, and Thomas joined in dissent.[55] They argued the majority's ruling disrupted fundamental principles of federalism that should require respect for the role of the States to serve as laboratories.[56] As Justice Thomas wrote, "Our federalist system, properly understood, allows California and a growing number of other States to decide for themselves how to safeguard the health and welfare of their citizens."[57] But this argument did not win the day, and the Court condoned the federal destruction of state-authorized medicinal cannabis.[58]

The high risk of prosecution under the CSA is the reason it is so difficult for researchers to access a supply of marijuana for research. Despite the Obama Administration's proclaimed "hands off" policy regarding state-based legalization of medical marijuana,[59] no rule of law bound his or any future president's administration to honor such a policy.[60] As reported by *Rolling Stone*, Obama's Department of Justice ("DOJ") was on the path to outpace the George W. Bush Administration in 2012 in the number of medical marijuana raids throughout the country.[61] Between 2009 and 2013, Obama's Administration outspent the previous administration by $100 million in its efforts to take down medical dispensaries.[62] And in 2016, judicial intervention by the Ninth Circuit was required to halt the prosecution of medical marijuana industry workers in California because, despite a Congressional act barring the DOJ from using any federal funds to

53. *See* Gonzales v. Raich, 545 U.S. 1, 7, 11 n.14 (2005).

54. *Id.* at 9, 17-19.

55. *Id.* at 42.

56. *Id.*

57. *Id.* at 74 (Thomas, J., dissenting).

58. *Id.* at 9.

59. Frank Robison & Elvira Strehle-Henson, *Cannabis Laws and Research at Colorado Institutions of Higher Education*, 44-OCT. COLO. LAW. 73, 75 (2015) ("Specifically, in 2009, the [DOJ] issued a memorandum stating that medical marijuana operations in medical marijuana states are not a prosecutorial priority, arguably promoting the first major expansion of marijuana-inspired entrepreneurial activities.").

60. *See* United States v. McIntosh, 833 F.3d 1163 (9th Cir. 2016).

61. Marc Zilversmit, *Obama's Iran-Contra*, SUN SENTINEL (Apr. 28, 2016, 1:34 PM), http://www.slate.com/articles/news_and_politics/.

62. Nick Lindsey, *Dispensary Raids Rise Under Obama Regime*, GREEN RUSH DAILY (Feb. 24, 2016), https://www.greenrushdaily.com/2016/02/24/dispensary-raids-rise-obama-regime/.

target lawful participants in a state-approved medical marijuana program,[63] U.S. attorneys still tried to prosecute.[64] Although such evidence may be used to critique President Obama for reneging on promises made on the campaign trail, Obama as president responded with a valid point: in the capacity of top enforcer of the law, he cannot "nullify congressional law" which continues to classify marijuana as an illegal Schedule I substance.[65]

In order to avoid criminal penalties, then, the burgeoning marijuana researcher seeking to study the drug's medical benefits must undergo what many deem a very onerous and frustrating application and licensing process.[66] Various administrative entities, each requiring their own individual stacks of paperwork, must give their approval.[67] Professor Kreit aptly describes the high hurdle this process poses to researchers by comparing the relative ease with which 31% of teenagers in a 2012 survey said they could obtain marijuana "within a day" to the several years it may take for a researcher to navigate through the CSA's requirements to get a supply for research.[68] Thus, although medical marijuana dispensaries across the nation may offer a cornucopia of high quality marijuana to America's roughly 1.2 million medical marijuana patients,[69] not one ounce of this bountiful supply can be used to conduct efficacy studies aimed at marijuana rescheduling because of the federal prohibition.[70]

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63. Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, §542, 129 Stat. 2242, 2332-2333 (2015).

64. *McIntosh*, 833 F.3d at 1179; Associated Press, *Court Bars Feds from Prosecuting Medical Marijuana Cases*, DENVER POST (Aug. 17, 2016, 1:26 AM), http://www.denverpost.com/2016/08/17/court-bars-feds-from-prosecuting-medical-marijuana-cases/.

65. Byron Tau, *Obama Clarifies His Stance on Medical Marijuana*, POLITICO44 BLOG (Apr. 25, 2012, 10:12 AM), http://www.politico.com/blogs/politico44/2012/04/obama-clarifies-his-stance-on-medical-marijuana-121598.

66. Robison & Strehle-Henson, *supra* note 59, at 77 ("Dissatisfaction with the federal marijuana research scheme is decades old."); *see also* Kreit, *supra* note 32, at 354-55 (citing letter from researcher that "dealing with [NIDA] has been the worst experience of my career!").

67. *Marijuana Research with Human Subjects*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/newsevents/publichealthfocus/ucm421173.htm (last updated Feb. 28, 2017).

68. Kreit, *supra* note 32, at 356-57.

69. *Number of Legal Medical Marijuana Patients*, PROCON.ORG, http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889 (last updated Mar. 3, 2016).

70. *See* Shaunacy Ferro, *Why It's So Hard For Scientists To Study Medical Marijuana*, POPULAR SCI. (Apr. 18, 2013), http://www.popsci.com/science/article/2013-04/why-its-so-hard-scientists-study-pot.

B. The Role of the National Institute on Drug Abuse in Deciding What Research Gets the Green Light

Once a researcher has received approval from all the necessary administrative agencies, the next step is to secure an actual supply of federally sanctioned marijuana for research,[71] which is the step of most concern to this Note. Under the Single Convention on Narcotic Drugs, an international treaty the U.S. has signed and which the CSA requires federal drug policy to abide by,[72] the U.S. must create "a government agency" that is in charge of controlling the distribution and growth of marijuana for research.[73] The National Institute on Drug Abuse ("NIDA") is this agency,[74] and for nearly 50 years, it granted the only contract to legally produce marijuana to a single grower at the University of Mississippi.[75]

Legal scholars have described and critiqued this arrangement between NIDA and the University of Mississippi as a so-called "federal monopoly" on research marijuana.[76] Health law attorney Alexander Campbell has characterized it as a "medical marijuana Catch-22," that is, a situation in which the DEA requires researchers to perform efficacy studies but obstructs their attempts to do so by giving the only supply of federally-approved research marijuana to an institution with a clear and admitted bias against studies on medical use.[77] The strength of this federal grip on research was affirmed in 2009 when the DEA officially denied the 2001 application of Dr. Lyle E. Craker, a professor of plant sciences at the University of Massachusetts, to register as a private marijuana manufacturer outside of the NIDA monopoly.[78] Again, in 2013, the monopoly was protected when the First Circuit affirmed the DEA's decision to deny Dr. Craker's application on appeal.[79] These two decisions weigh even heavier considering the DEA's own Administrative Law Judge recommended that Dr. Craker's application be granted.[80] As Dr. Craker told the *Washington*

71. Alexander W. Campbell, *The Medical Marijuana Catch-22: How the Federal Monopoly on Marijuana Research Unfairly Handicaps the Rescheduling Movement*, 41 AM. J.L. & MED. 190, 200 (2015).

72. 21 U.S.C. §811(d) (2012).

73. Robison & Strehle-Henson, *supra* note 59, at 74.

74. *NIDA's Role in Providing Marijuana for Research*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research (last updated Mar. 2017).

75. *Id.*

76. *See generally* Campbell, *supra* note 71; Quattrone, *supra* note 20.

77. Campbell, *supra* note 71, at 192.

78. Lyle E. Craker, Denial of Application, 74 Fed. Reg. 2101 (Jan. 14, 2009).

79. Craker v. DEA, 714 F.3d 17, 18 (1st Cir. 2013).

80. *Id.* at 21.

Post, "Working with medical marijuana seems so similar to the work we're doing with other medicinal plants that I've never understood the DEA's big problem with it."[81]

It turns out the DEA's "big problem" with breaking up the NIDA monopoly has been the risk of diversion of federally grown marijuana into illicit markets.[82] In the case against Dr. Craker, both the DEA and the First Circuit cited §823(a)(1)-(6) of the CSA, known as the "public interest" factors,[83] to determine that his application should be denied.[84] Under the CSA, the Attorney General is allowed to approve an application for a private manufacturer only if it is "consistent with the public interest," which means that approval of the application will not disrupt the "maintenance of effective controls against diversion."[85] The DEA successfully argued that because NIDA offered an "adequate" supply of marijuana for research, approving Dr. Craker's application would only increase the chance of federally grown marijuana ending up on illicit markets by virtue of having more of the substance created outside the government's control.[86] The First Circuit was persuaded and sided with the DEA.[87]

Despite a story like Dr. Craker's, which took nearly 10 years to receive a final denial of his petition,[88] the DEA has evidenced some willingness to break up the NIDA monopoly by opening the doors for private manufacturers to produce marijuana for research albeit, in typical DEA fashion, through a non-binding commitment made in August 2016.[89] In a policy statement from former DEA Administrator Chuck Rosenberg, the DEA finally acknowledged the inadequate supply of marijuana provided through the NIDA monopoly in light of the "greater public interest in

81. Marc Kaufman, *Researchers Press DEA to Let Them Grow Marijuana*, WASH. POST (May 24, 2007), http://www.washingtonpost.com/wp-dyn/content/article/2007/05/23/AR2007052301451.html.

82. *Craker*, 714 F.3d at 22 (agreeing with the Administration's reading of legislative history of the CSA that the addition of new manufacturers increases diversion risks).

83. 21 U.S.C. § 823(a)(1)-(6) (2012).

84. *Craker*, 714 F.3d at 21.

85. 21 U.S.C. § 823(a)(1) (2012); *Craker*, 714 F.3d at 19.

86. *Craker*, 714 F.3d at 22.

87. *Id.* at 28.

88. Steven Nelson, *DEA Ends Half-Century Pot Monopoly, But Withholds Big Prize for Reformers*, U.S. NEWS & WORLD REP. (Aug. 11, 2016, 4:35 PM), https://www.usnews.com/news/articles/2016-08-11/dea-ends-half-century-pot-monopoly-but-withholds-big-prize-for-reformers.

89. Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,848 (Aug. 12, 2016) (to be codified at 21 C.F.R. pt. 1301).

expanding marijuana-related research."[90] In fact, not only can applicants register to conduct academic research, but the DEA is now allowing applications "for strictly commercial endeavors funded by the private sector and aimed at drug product development," a possibility that was not available under the historical NIDA monopoly system.[91]

This statement is a far cry from a man who was put under fire in November 2015 for stating to reporters that smoking marijuana is "a joke" and cannot be called medicine.[92] But it does highlight how the Agency's initial concern with Lyle Craker's application to become a manufacturer outside of the secure NIDA monopoly has diminished in light of increased pressure by the public to press the DEA to recognize its medical value. It is worth mentioning that although this statement might be welcome news to marijuana advocates, a non-binding statement is just that: the federal government is not obligated by law to approve any applications it receives.[93] Reporter Andrew Joseph has pointed out that, as of July 2017, the DEA has yet to approve any additional grow operations in the United States.[94] As Professor Kreit observed in one interview, "It could be that two years from now, we still only have one registrant."[95] That one registrant is and may continue to remain the University of Mississippi under its contract with NIDA.

IV. THE NIDA MONOPOLY'S BIAS AGAINST MEDICAL USE CONSTITUTES ARBITRARY AND CAPRICIOUS BEHAVIOR

The DEA opens itself up to challenges in the federal courts when it uses a biased federal monopoly model[96] to regulate Schedule I research as it has with marijuana. Advocate groups should target this monopoly on research marijuana to persuade courts that the DEA's administration of the

90. *Id.* at 53,846.

91. *Id.*

92. Paula Reid & Stephanie Condon, *DEA Chief Says Smoking Marijuana As Medicine "Is a Joke,"* CBS NEWS (Nov. 4, 2015, 3:10 PM), http://www.cbsnews.com/news/dea-chief-says-smoking-marijuana-as-medicine-is-a-joke/.

93. Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,848 (Aug. 12, 2016) (to be codified at 21 C.F.R. pt. 1301).

94. Andrew Joseph, *DEA Solicited Applications to Grow Marijuana for Research. It Hasn't Approved One*, STAT (July 24, 2017), https://www.statnews.com/2017/07/24/dea-marijuana-licenses-research/.

95. Andrew Joseph, *The DEA Is Looking for Candidates to Grow Marijuana for Research—But Will it Find Any Takers?*, STAT (Aug. 31, 2016), https://www.statnews.com/2016/08/31/marijuana-research-dea-growers-permits/.

96. *See supra* Section III-B.

CSA does not deserve judicial deference because it handicaps the very research that the DEA requires.[97] The Supreme Court has spoken to what normally leads to a finding that an agency decision is "arbitrary and capricious," and "entirely fail[ing] to consider an important aspect of the problem" is one way to meet this standard.[98] In the case of restrictions imposed on marijuana research under the CSA specifically, the DEA has entirely failed to consider the crippling effect that the federal monopoly has on fulfilling a prerequisite to rescheduling, namely, the performance of efficacy studies.

A. A Biased Federal Monopoly Hinders the Science-Based Path to Legalization

A federal monopoly is crippling when the institution reviewing applications has a bias against medical research. In the case of marijuana research under the NIDA monopoly, the drug supply continues to be solely in the hands of a federal institute with a mandate dedicated to studying drug abuse.[99] NIDA's mission statement is clear: "to advance science on the causes and consequences of drug use and addiction."[100] This prerogative naturally leads NIDA to favor approving research aimed at studying drug abuse over those focused on medical use. For instance, as a spokesperson for NIDA once told the *New York Times*, "As the National Institute on Drug Abuse, our focus is primarily on the negative consequences of marijuana use . . . we generally do not fund research focused on the potential beneficial medical effects of marijuana."[101] In the words of the director of

97. D.C. Circuit precedent shows us that the DEA has already changed its interpretation of "currently accepted medical use" in the past when the court found certain factors in its multi-factor test seemingly impossible to satisfy and, therefore, not presumptively entitled to *Chevron* deference. All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1134-35 (D.C. Cir. 1994). More recently, in *Ams. for Safe Access v. DEA*, the court left open the possibility that the DEA's federal monopoly could justify challenging the DEA's administration of its own regulation but declined to address this issue because the petitioners in that case did not properly raise it with the DEA. Ams. for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013).

98. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

99. NAT'L INST. ON DRUG ABUSE, *About NIDA*, https://www.drugabuse.gov/about-nida (last visited Feb. 16, 2018).

100. *Id.*

101. Gardiner Harris, *Researchers Find Study of Medical Marijuana Discouraged*, N.Y. TIMES (Jan. 18, 2010), http://www.nytimes.com/2010/01/19/health/policy/19marijuana.html.

the NIDA marijuana program, Mahmoud ElSohly, "It's not that NIDA would take it upon itself to investigate the medical aspects of cannabis . . . It's not the charge of NIDA."[102]

Disparities in federal funding demonstrate this bias at work. In a 2015 study conducted out of Arizona State University, reporters gathered data on federal grants from the National Institute of Health for marijuana research between 2008 and 2014.[103] They calculated a nearly $1 billion discrepancy between abuse-related research and studies that were focused on therapeutic use, the lion share of the funding going to abuse-related research.[104] Of course, the Supreme Court has made clear that federal agencies are allowed to fund certain projects at the expense of others without risking a court overturning their decisions to do so.[105] But the greater significance of this nearly $1 billion funding gap is the strong evidence it offers of a bias against medical use applications. When considered in conjunction with the negative public statements made by NIDA officials and NIDA's own governmental mandate, this funding disparity further points to a biased research process.

Researchers, advocate groups, and lawyers have heavily critiqued the NIDA monopoly for hindering research into the drug's medical use.[106] The Drug Policy Alliance and the Multidisciplinary Association for Psychedelic Studies ("MAPS"), advocate groups at the forefront of the marijuana movement, argue that this monopoly "systemically impede[s] scientific research"[107] by not only referencing lengthy delays and refusals in providing researchers with materials[108] but also the inferior quality of marijuana provided by NIDA which only reaches a highest potency of 7%

Thanks to Alexander Campbell for pointing me to this article. In 2015, for instance, NIDA funded 281 marijuana studies but only 17% looked at medical applications. Beth Mole, *Studying Marijuana Remains a Drag*, ARSTECHNICA (Nov. 5, 2016, 6:00 AM), http://arstechnica.com/science/2016/11/studying-marijuana-remains-a-drag/.

102. Jayson Chesler & Alexa Ard, *Government Restrictions, Lack of Funding Slow Progress on Medical Marijuana Research*, NEWS21 (Aug. 15, 2015), http://weedrush.news21.com/government-restrictions-lack-of-funding-slow-progress-on-medical-marijuana-research/#researchmap.

103. *Id.*

104. Out of $1.4 billion in federal support, $1.1 billion was provided for abuse-related research, leaving the remaining $297 million for studies on therapeutic use. *Id.*

105. Nat'l Endowment for the Arts v. Finley, 524 U.S. 569, 585 (1998).

106. *See* Campbell, *supra* note 71, at 192; Kreit, *supra* note 32, at 354-55; Karen O'Keefe, *State Medical Marijuana Implementation and Federal Policy*, 16 J. HEALTH CARE L. & POL'Y 39, 42 (2013).

107. DRUG POL'Y ALL. & MAPS, THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE 2 (June 8, 2014), https://www.drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf.

108. *Id.* at 9.

THC compared to the 15 to 24% THC levels smoked by legal patients in medical marijuana states.[109] Karen O'Keefe, Director of State Policies at the Marijuana Policy Project, has also pointed to evidence that researchers with approved DEA registrations were still prevented from conducting their research because NIDA refused to provide the supplies necessary to perform the studies.[110] Professor Kreit provides an illustration of the frustration researchers face navigating this biased regulatory scheme with a letter that AIDS researcher Donald Abrams wrote to NIDA stating, "I must tell you that dealing with your Institute has been the worst experience of my career!"[111] Headlines like "Researchers Find Study of Medical Marijuana Discouraged"[112] and "Feds Limit Research on Marijuana for Medical Use"[113] have circulated the media as reporters look to give voice to the strong frustration felt by researchers and advocate groups confronting a government that repeatedly frustrates their efforts to establish a science-based path for marijuana's federal legalization.

Finally, the DEA itself has even acknowledged the negative impact the federal monopoly has had on the progress of medical use science. In August 2016, the DEA released a policy statement opening the doors to private manufacturing applications for medical research.[114] Despite having approved nearly 1,000 National Institute of Health-supported research projects on medical marijuana between 2008 and 2015, the DEA still refuses to recognize that marijuana has any medical benefit to this day.[115] In order to accommodate the growing public interest in seeing marijuana rescheduled, the DEA determined that the best solution was to finally break up the NIDA monopoly and provide private manufacturers a pathway to offering researchers the marijuana they need to perform the required efficacy studies.[116] Though this statement was explicitly non-binding as made clear in a provision directly preceding Chuck Rosenberg's signature,[117] it underscores the DEA's own understanding that its federal monopoly model over research marijuana has failed to consider an

109. *Id.* at 10.

110. O'Keefe, *supra* note 106, at 42.

111. Kreit, *supra* note 32, at 355.

112. Harris, *supra* note 101.

113. Chesler & Ard, *supra* note 102.

114. Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 156, 53,846 (Aug. 12, 2016).

115. Chesler & Ard, *supra* note 102.

116. Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. at 53,846.

117. *Id.* at 53,848.

important aspect of the problem, namely, the inadequate supply of marijuana it would provide for medical research purposes.

B. Alternative Interpretations of the Controlled Substances Act Can Redress the DEA's Arbitrary and Capricious Behavior

In this context, a federal monopoly is arbitrary and capricious when the federal government has entirely failed to consider that placing such a monopoly in the hands of an agency biased against medical use unfairly handicaps research into a Schedule I substance with great potential to help patients, like Irvin,[118] deal with debilitating illnesses. The DEA could take two possible actions to redress its behavior. First, the DEA can do what it has already offered to do in the case of medical marijuana research: break up the monopoly. By giving Dr. Lyle Craker a license to privately manufacture marijuana for research (as he tried to attain to no avail over the course of a decade),[119] researchers could rest assured that, given all other administrative requirements being met, a supply would be ready for them to use. The key difference now would be requiring this decision take the form of a regulation with the force of law and not a non-binding policy statement that can be discarded at will. In this way, the DEA ensures that the only supply of a substance is not discriminately apportioned among studies with objectives diametrically opposed to one another.

A second, less dramatic option would be to maintain a federal monopoly but place it in the hands of an agency without bias, that is, one that looks just as favorably on medical use applications as any others. The National Institute on Mental Health, for example, could serve as a potential candidate for this responsibility. Former director Dr. Thomas R. Insel has stated: "I'm personally biased in favor of these types of studies . . . If it proves useful to people who are really suffering, we should look at it. Just because it is a psychedelic doesn't disqualify it in our eyes."[120] This option would continue to protect the government's interest against diversion of Schedule I substances into illicit markets while removing the bias, which is the concern of this discussion. In either case, the DEA would offer a fair and unobstructed path to rescheduling that honors a commitment to a science-based approach to federal drug regulation.

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118. Halper, *supra* note 1; Oberhaus, *supra* note 1; NEWS21, *supra* note 1.

119. Nelson, *supra* note 88.

120. Michael Pollan, *The Trip Treatment*, THE NEW YORKER (Feb. 9, 2015), http://www.newyorker.com/magazine/2015/02/09/trip-treatment.

C. The CSA's Scheduling Scheme Inhibits Effective Responses to Modern Public Health Issues

A final policy consideration supporting an unbiased regulation of research into substances like marijuana, MDMA, and psilocybin is the fact that, unlike other drugs that may be placed in Schedule I, all three of these substances have proven to have at least a potential for useful medical applications.[121] Professor Kreit's description of the CSA's "schedule first, research later (or never)" approach to drug legislation suggests that a drug's Schedule I status derives not from any affirmatively known and recorded danger to society, but from a lack of a "currently accepted medical use."[122] This leads to the problematic situation in which, as he describes it, a substance that has been studied over 1,000 times with results pointing to no medical value has "no currently accepted medical use" just as equally as a substance that has never been studied at all.[123]

A current example of how such a draconian system lacks the foresight necessary to prevent a drug from being trapped in Schedule I status resides in the growing body of research demonstrating that medical marijuana provides hope for counteracting what the Center for Disease Control has proclaimed an "opiate epidemic"[124] in the United States.[125] Overdose deaths caused by prescription opiates like Vicodin and OxyContin have quadrupled in America since 1999.[126] As NIDA points out, this public health concern goes beyond the individual patients consuming these substances given the growing number of infants born with defects caused by drug use during pregnancies.[127] As Professor Deborah Ahrens observes,

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121. *Id.*; Zoe Cormier, *Magic Mushroom Drug Lifts Depression in Human Trial*, SCI. AM. (May 17, 2016), https://www.scientificamerican.com/article/magic-mushroom-drug-lifts-depression-in-human-trial1/#; Olivia Solon, *'My Therapist Gave Me a Pill': Can MDMA Help Cure Trauma?*, THE GUARDIAN (Sept. 16, 2016), https://www.theguardian.com/society/2016/sep/16/mdma-ptsd-therapy-trauma-maps-medical-study.

122. Kreit, *supra* note 32, at 353.

123. *Id.*

124. *Legalizing Marijuana Decreases Fatal Opiate Overdoses, Study Shows*, DRUGABUSE.COM, http://drugabuse.com/legalizing-marijuana-decreases-fatal-opiate-overdoses/ (last visited Feb. 16, 2018); *see Understanding the Epidemic*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/ (last updated Aug. 30, 2017).

125. Marcus A. Bachhuber et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010*, 174 JAMA INTERNAL MED. 1668 (2014) [hereinafter *Opioid Study*].

126. *Prescription Opioid Overdose Data*, CTR. FOR DISEASE CONTROL & PREVENTION (last updated Aug. 1, 2017), http://www.cdc.gov/drugoverdose/data/overdose.html.

127. Nora D. Volkow, *What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?*, NAT'L INST. ON DRUG ABUSE (May 1, 2015), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/what-federal-government-doing-to-combat-

many prescription pill addictions start from the "erroneous impression" that taking these pills in the first place is not dangerous since these drugs have been legally prescribed to those taking them.[128] Recent studies have offered a glimmer of hope in curbing this national epidemic in the form of medical marijuana.[129]

In one recent study, researchers collected death certificate data in all 50 states between the years 1999 and 2010.[130] They soon discovered that the rates of fatal overdoses from opiates declined significantly in states with medical marijuana laws on the books compared to those without such laws. In these states, the rates dropped from roughly 20% less deaths just after one year of the medical marijuana laws taking effect to a 33% drop in deaths six years later.[131] In another study, researchers looked at federal car crash data and found that drivers in medical marijuana states were less likely to test positive for opioids immediately following a fatal accident compared to drivers in other states.[132] Although it is too early to establish an exact causal link, an increased willingness of patients to "substitute marijuana for opioids in the treatment of severe or chronic pain" seems a plausible explanation.[133]

What we risk with a "schedule first, research later (or never)" regime of drug regulation is the chance to counteract an epidemic like the one we are currently experiencing with opiates because a substance that may serve as an alternative, such as marijuana, has been criminalized decades before citizens are able to realize they can truly benefit from access to it. And yet, this story of a therapeutic substance trapped within Schedule I status is not unique to marijuana. Several recent studies reveal that MDMA ("ecstasy"), LSD ("acid"), and psilocybin ("magic mushrooms"), all of which are

opioid-abuse-epidemic. Moreover, in 2015, 276,000 adolescents between the ages of 12 to 17 years old were found to be current nonmedical users of pain relievers, and over a third of these minors suffered from clinical addiction to these substances despite exhibiting no legitimate grounds for a prescription. *Opioid Addiction 2016 Facts & Figures*, AM. SOC'Y OF ADDICTION MED., http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf (last visited Feb. 19, 2018).

128. Ahrens, *supra* note 26, at 418.

129. *See generally Opioid Study*, *supra* note 125.

130. *Opioid Study*, *supra* note 125, at 1668-69.

131. Melissa Healy, *Medical Marijuana Could Reduce Painkiller Abuse, Study Suggests*, L.A. TIMES (Aug. 25, 2014, 7:02 PM), http://www.latimes.com/nation/la-sci-medical-marijuana-20140826-story.html; *Opioid Study*, *supra* note 125, at 1668.

132. *Study of Fatal Car Accidents Shows Medical Marijuana May Help Curb Opioid Use*, MAILMAN SCH. OF PUB. HEALTH (Sept. 16, 2016), https://www.mailman.columbia.edu/public-health-now/news/study-fatal-car-accidents-shows-medical-marijuana-may-help-curb-opioid-use.

133. *Id.*

categorized as Schedule I substances,[134] have a great potential to offer tremendous psychological relief to patients suffering from Post-Traumatic Stress Disorder ("PTSD") triggered by the horrors of war and the violence of rape.[135]

In one remarkable case, Alice, who suffered from severe PTSD caused by years of physical and sexual abuse by a drug-dealing father, was assessed on the clinician-administered PTSD scale, or "CAPS," an extensive questionnaire known as the "gold standard" in PTSD assessment.[136] Any individual who reaches a score over sixty is ranked as a "severe" case.[137] For Alice, who reported being unable to even answer the phone let alone step outside her own home before undergoing MDMA therapy, the results were striking: her score went from 106 to zero, signaling that her PTSD had been cured.[138] Describing her experience, Alice reported on a base level of peacefulness despite the experience not always being an easy one: "I had the first few minutes of peace I've had in years . . . I was always able to come back to feeling good."[139] Despite such positive results reported today, physicians cannot prescribe MDMA in the U.S. because of its hasty placement in Schedule I decades earlier.

Psilocybin offers another example of a substance that has fallen victim to the CSA's "schedule first, research later" approach to regulation. Psilocybin is the main psychoactive component in "hallucinogenic" or "magic mushrooms,"[140] and it has shown preliminary success in treating obsessive-compulsive disorder,[141] addiction,[142] and PTSD.[143] The Heffter

134. *See* Chemerinsky et al., *supra* note 29, at 82.

135. MULTIDISCIPLINARY ASS'N FOR PSYCHEDELIC STUD., *MDMA-Assisted Psychotherapy*, http://www.maps.org/research/mdma (last visited Feb. 17, 2018); Solon, *supra* note 121.

136. Examples of questions included on this assessment are: "In the past month, have you had any unwanted memories of (event) while you were awake, so not counting dreams?" and "Have there been times when you felt emotionally numb or had trouble experiencing feelings like love or happiness?" *Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)*, U.S. DEP'T OF VETERAN AFF., http://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp (last visited Feb. 16, 2018).

137. Solon, *supra* note 121.

138. *Id.*

139. *Id.*

140. Cormier, *supra* note 121.

141. Solon, *supra* note 121.

142. Maia Szalavitz, *'Magic Mushroom' Drug Shows Promise in Treating Addictions and Cancer Anxiety*, TIME (Dec. 7, 2012), http://healthland.time.com/2012/12/07/magic-mushroom-drug-shows-promise-in-treating-addictions-and-cancer-anxiety/.

143. Tom Shroder, *'Acid Test': The Case for Using Psychedelics to Treat PTSD, Depression*, WASH. POST (Sept. 4, 2014), https://www.washingtonpost.com/lifestyle/magazine/acid-test-the-case-for-using-psychedelics-to-treat-ptsd-depression/2014/09/04/03c3c222-0e01-11e4-8c9a-923ecc0c7d23_story.html.

Research Institute, a non-profit organization, has focused its energies on psilocybin applications for cancer-related emotional distress[144] and has produced success stories like that of Patrick Mettes, a TV news director in his mid-fifties whose cancer diagnosis followed soon after his wife observed the whites of his eyes turn the color yellow.[145]

Although Patrick had never taken a hallucinogenic before, his experience in the Phase II trial study was encouraging: despite a strong belief that death was imminent at the beginning of the study, Patrick reported "feeling the happiest in his life" in a follow-up discussion two months after therapy.[146] Patrick only lived seventeen more months post-treatment, but his wife described to the *New Yorker* a newfound zest for life she had never seen in her husband during those last months, "[He] had a sense of patience he had never had before . . . Now it was about being with people, enjoying his sandwich and the walk on the promenade. It was as if we lived a lifetime in a year."[147] British researchers have used fMRI technology to demonstrate psilocybin's effect of cutting activity to key nodes in the brain associated with self-consciousness and depression, offering one possible theory on why the drug is so successful in helping patients combat end-of-life anxiety.[148]

Director of NIDA, Dr. Nora Volkow, has spoken on psilocybin directly, stating:

> [T]he main concern we have at NIDA in relation to this work is that the public will walk away with the message that psilocybin is a safe drug to use. In fact, its adverse effects are well known . . . . Progress has been made in decreasing use of hallucinogens, particularly in young people. We would not want to see that trend altered.[149]

Here, we have another clear statement by a top NIDA official demonstrating a stronger concern over a substance's negative rather than positive attributes, suggesting an unwillingness to produce a supply for Phase III trials based on the premise that allowing large-scale production of these substances for medical research may lead to an increase in their recreational abuse.[150] But as Heffter Research Institute founder Mark Geyer has observed, such logic tends to have a discriminate impact on medical

144. HEFFTER RES. INST., *Psilocybin for Cancer-Related Emotional Distress*, https://heffter.org/cancer-distress/ (last visited Feb. 16, 2018).

145. Pollan, *supra* note 120.

146. *Id.*

147. *Id.*

148. Szalavitz, *supra* note 142.

149. Pollan, *supra* note 120.

150. *See id.*

research despite no intention of doing so, "The goal wasn't to stop scientists, the goal was to stop street use . . . but the side effect of that was that even legitimate research was curtailed."[151]

The federal government has a legitimate interest in preventing these substances from getting into the hands of illicit dealers, but the strength of this argument diminishes in light of the wide degree of availability these drugs already experience on the black market.[152] In the 2014 Global Drugs Survey, one out of five U.S. participants reported they had used MDMA in the past year.[153] In the words of one individual working on the American music festival circuit where illicit supplies of these drugs have reportedly been easy to find, "All I had to do was text a friend."[154] As Professor Kreit points out, even the worst diversion problems at research labs handling a Schedule I substance like MDMA, psilocybin, or marijuana would likely have a negligible impact at best on the amount already widely available to Americans, resulting in a wash under a cost benefit analysis.[155] In fact, with reports like that of the Drug Abuse Warning Network noting a 123% increase in the number of emergency room visits involving MDMA, there is a strong public interest in performing thorough research on MDMA and other Schedule I substances as quickly as these rates continue to rise to counteract any consequences that may result from recreational use of impure mixtures of the substances found on the black market.[156]

The positive results stemming from various studies conducted on the medical benefits of marijuana and various psychedelics should flag these substances in a manner that overcomes the stigma attached to Schedule I status. One way to ensure this stigma does not play a deterring role in the research of promising Schedule I substances like marijuana is to avoid placing a monopoly of the research supply in the hands of a government agency automatically inclined to disfavor applications into their medical use.

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151. Shaunacy Ferro, *Why Doctors Can't Give You LSD (But Maybe They Should)*, POPULAR SCI. (Apr. 16, 2013), http://www.popsci.com/science/article/2013-04/new-science-lsd-therapy.

152. Kreit, *supra* note 32, at 357.

153. DRUG POL'Y ALL., *How Many People Use MDMA?*, http://www.drugpolicy.org/drug-facts/mdma-ecstasy-molly/how-many-people-use-mdma#five (last visited Feb. 16, 2018).

154. Marina Csomor, *There's Something (Potentially Dangerous) About Molly*, CNN (Aug. 16, 2012), http://www.cnn.com/2012/08/16/health/molly-mdma-drug/index.html.

155. Kreit, *supra* note 32, at 357.

156. NAT'L INST. ON DRUG ABUSE, *Drug-Related Hospital Emergency Room Visits*, https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/drugfacts_hospitalvisits.pdf (last updated May 2011).

V. CONCLUSION

Although $297 million is a considerable amount of money to have invested in medical marijuana research,[157] it also represents the high cost we have paid for marijuana to remain a Schedule I substance at a time when nearly half the nation and the District of Columbia provide over a million citizens access to it for medical use.[158] The so-called medicinal research "Catch-22"[159] highlights a serious flaw in American drug regulation: the creation of a categorical system in which illegality is easy to fall into and potentially impossible to escape. A change in the DEA's administration of the phrase "currently accepted medical use" that does away with a biased monopoly would open the doors to medical marijuana research and truly honor a science-based path to federal legalization.

Jasen B. Talise∗

157. Chesler & Ard, *supra* note 102.

158. PROCON.ORG, *Number of Legal Medical Marijuana Patients*, *supra* note 69.

159. Campbell, *supra* note 71.

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