

NOTE

THE “CATCH-22” OF MARIJUANA [IL]LEGALIZATION

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INTRODUCTION

On February 28, 2014, Brian and Meghan Wilson decided to move their family cross-country from New Jersey, a state with a modest, restrictive medical marijuana program, to access the robust program in Colorado with one goal in mind: to ensure the survival of their three-year old daughter, Vivian.¹ Vivian suffers from Dravet syndrome, an aggressive and deadly form of epilepsy, triggered by sunlight exposure, temperature fluctuations, and geometric patterns.² The Wilson family heard about the positive effects of cannabis treatments on children with Dravet syndrome; treatments, which so far have not been validated by the U.S. Food and Drug Administration (“FDA”), because marijuana is an illegal drug under federal law.³ Vivian, like thousands of other medical refugees who have flocked to Colorado, has found solace and improvement in her medical condition due to treatment with medical marijuana.⁴ Her mother attests, “[Vivian] didn’t have any quality of life last year Her life is better because we added cannabis.”⁵

Stories like Vivian’s are becoming increasingly common. Even though states are legalizing marijuana for medicinal and recreational purposes, the U.S. Congress remains steadfast in refusing to acknowledge its potential medicinal benefit, and refuses to legalize it. The FDA fuels this stance through its own public statements. As recently as June 2015, the FDA commented that it “[has]

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¹ Susan K. Livio, *Medical Marijuana: N.J. Child Improves as Family Finds Fewer Roadblocks in Colorado*, NJ.COM (Sept. 21, 2014, 7:00 AM), http://www.nj.com/politics/index.ssf/2014/09/medical_marijuana_nj_child_improves_as_family_finds_fewer_roadblocks_in_colorado.html [<http://perma.cc/BXL8-FXSR>].

² *Id.*

³ *Id.*

⁴ *Id.* (Vivian’s family reports that she takes two anti-seizure drugs, and two kinds of cannabis oil administered four times a day).

⁵ *Id.*

not approved a marketing application for a drug product containing or derived from botanical marijuana, and has not found any product to be safe and effective for any indication.”⁶

Despite the FDA’s stance against marijuana legalization, states and international markets are moving forward in researching and developing treatments based on the medicinal benefits of plant-based cannabis.⁷ As their efforts increase the availability of the product generally, access is limited to the states that have legalized it for medical or recreational use. Access to international products is altogether blocked due to federal prohibitions. Marijuana’s classification has a chain reaction of negative effects: researchers must jump through hoops to access marijuana for research, which limits research on the efficacy and safety of the product, while consumers in states where marijuana is legalized use marijuana-based products without federally approved scientific evidence of its efficacy or safety. The federal illegalization of marijuana creates a catch-22: the bans on marijuana prevent its legalized use because it is stigmatized as dangerous, and having no medical benefit, but the current regulations as they stand prevent researchers from showing consumers why marijuana *is* dangerous, and has no medical benefit.

This paper asserts that the barriers to researching the benefits of plant-based cannabis must be eliminated to facilitate research on its therapeutic effects. This can most easily be achieved through the rescheduling of marijuana from its current status as a Schedule I banned substance.⁸ Rescheduling marijuana would increase its availability for research, create a less attenuated relationship between the state and federal view of marijuana, and expand the market for domestic and international marijuana-based products, which are deemed effective in treatment. This paper will conclude that rescheduling marijuana is a necessary step to determine whether plant-based cannabis has medicinal effects

⁶ U.S. FOOD AND DRUG ADMINISTRATION, FDA AND MARIJUANA: QUESTIONS AND ANSWERS, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#notapproved> [<https://perma.cc/V4KB-2ZQ9>].

⁷ *Welcome to the Center for Medicinal Cannabis Research*, UNIV. OF CAL., SAN DIEGO, CENTER FOR MEDICINAL CANNABIS RESEARCH, <http://www.cmc.ucsd.edu/index.php/2015-11-20-20-49-13> [<https://perma.cc/3VZ4-AK9H>] (Some individual states are funding clinical trials that demonstrate the medical benefit of marijuana. For instance, in California, the Center for Medicinal Cannabis Research (“CMCR”) oversees objective, high-quality medical research that aims to “enhance understanding of the efficiency and adverse effects of marijuana as a pharmacological agent,” with research centered on studying the potential medicinal benefits of cannabis for diseases and conditions); Brennan Linsley, *Colorado to spend millions on medical marijuana research*, CBS NEWS (Dec. 17, 2014, 5:51 PM), <http://www.cbsnews.com/news/colorado-to-spend-millions-on-medical-marijuana-research/> [<https://perma.cc/5MV9-SMPM>] (“Colorado will spend more than \$8 million researching marijuana’s medical potential. . .”).

⁸ For a full explanation of the Schedule categorizations as encompassed in the Controlled Substances Act, see *infra* text accompanying notes 21-26.

warranting its federal legalization in the United States.

I. EXPLANATION OF MEDICAL CANNABINOIDS

A. History of Using Marijuana as Medicine

Using marijuana as medicine is by no means a novel concept. It has been recognized as a therapeutic agent across many cultures for over 5,000 years.⁹ The ancient Chinese used marijuana for healing, and the Chinese still use it today as an appetite enhancer, and as relief for diarrhea and dysentery.¹⁰ Ancient Indian culture recognized the healing potential of marijuana by using it to improve sleep, enhance appetite, and help with digestion.¹¹ In Western culture, marijuana was prescribed in 1830s Ireland to treat muscle spasms and pain.¹² Even in the U.S. in 1860, physicians “reported success in using marijuana to treat chronic cough, gonorrhea, pain,” and other ailments.¹³ By the turn of the 20th century pharmaceutical companies such as Parke-Davis (now known as Pfizer), and Eli Lilly researched the development of painkillers and sedatives featuring marijuana extracts to treat epilepsy and migraines.¹⁴ Indeed, marijuana was included in the United States Pharmacopeia from 1850 until 1942 when it was removed “because it was believed to be a harmful and addictive drug that caused psychoses, . . . and violent behavior.”¹⁵ Marijuana’s removal from the U.S. Pharmacopeia followed passage of the first federal law against it, the Marihuana Tax Act of 1937.¹⁶ The Act “required anyone producing, distributing, or using marijuana for medical purposes to register and pay a tax . . . which effectively prohibited [its] nonmedical use.”¹⁷ Once it was removed from the

⁹ *Historical Timeline: History of Marijuana as Medicine – 2900 BC to Present*, PROCON.ORG, <http://medicalmarijuana.procon.org/view.timeline.php?timelineID=000026> [<https://perma.cc/EW2U-GP7U>].

¹⁰ Melanie Reid, *The Quagmire that Nobody in the Federal Government Wants to Talk About: Marijuana*, 44 N.M. L. REV. 169 (2014). See also *Historical Timeline supra* note 9.

¹¹ *Historical Timeline, supra* note 9. See also ALISON MACK & JANET JOY, MARIJUANA AS MEDICINE? THE SCIENCE BEHIND THE CONTROVERSY 14 (2001).

¹² Reid, *supra* note 10, at 169-170.

¹³ *Id.* at 170.

¹⁴ Debra Borchardt, *Pfizer, Eli Lilly Were the Original Medical Marijuana Sellers*, FORBES (Apr. 8, 2015) <http://www.forbes.com/sites/debraborchardt/2015/04/08/pfizer-eli-lilly-were-the-original-medical-marijuana-sellers/> [<https://perma.cc/F9SP-QJY4>].

¹⁵ INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 14 (Janet E. Joy et al., eds., 1997), http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf [<https://perma.cc/Z8X2-QZ4G>].

¹⁶ *Medical Use of Marijuana-History*, USLEGAL, INC., <http://medicalmarijuana.uslegal.com/medical-use-of-marijuana-history/> [<https://perma.cc/R3YV-5JW2>].

¹⁷ INSTITUTE OF MEDICINE, *supra* note 15, at 14.

Pharmacopeia marijuana “lost its remaining mantle of therapeutic legitimacy.”¹⁸

Central to understanding the full complexity of the marijuana controversy is an understanding of the categorization of controlled substances as promulgated in the Controlled Substances Act (“CSA”). The CSA was passed in 1970 as part of President Richard Nixon’s Comprehensive Drug Abuse and Prevention Act.¹⁹ It was intended to classify drugs based on medical and scientific evidence, and as such, groups drugs into five classifications, or schedules, taking into account a drug’s potential for abuse, its potential toxicity and harm, and any medical benefits.²⁰ Drugs listed as Schedule I, including heroin, LSD, PCP, and marijuana, are deemed to have a “high potential for abuse,” possess “no currently accepted medical value or use in treatment in the United States,” and “a lack of accepted safety for the use of the drug . . . under medical supervision.”²¹ Drugs listed in Schedules II through V are considered to have some medical value, but are grouped according to their potential for abuse.²² A Schedule II drug is recognized as having a high potential for abuse, may demonstrate some medical use in treatment, and includes cocaine, methamphetamine, and OxyContin.²³ Schedule III (Vicodin, acetaminophen with codeine), Schedule IV (valium, Xanax), and Schedule V (codeine cough syrup) drugs, typically have a lower potential for abuse than that of Schedule I or Schedule II drugs, and have a “currently accepted medical use in treatment in the United States.”²⁴

Though some physicians may see a medicinal power in marijuana, practitioners cannot prescribe it under federal law, and though they may prescribe marijuana legally under state law, they may still be prosecuted under the CSA due to its Schedule I designation.²⁵ Additionally, providers who prescribe marijuana do so even though it is not approved as a safe and effective drug.²⁶ The American Medical Association, the Minnesota Medical Association,

¹⁸ *Historical Timeline*, *supra* note 9. See Reid, *supra* note 10; see generally Appendix-C, THE UNITED STATES PHARMACOPEIA, <http://antiquecannabisbook.com/Appendix/AppendixC.htm> [<https://perma.cc/A8F9-YR5R>].

¹⁹ DRUG POLICY ALLIANCE, THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE 3, https://www.drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf [<https://perma.cc/XPK4-6ZTD>].

²⁰ See *id.* at 3-4; see also 21 U.S.C. § 812(a)-(b)(1) (2012) (“There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V.”).

²¹ 21 U.S.C. § 812(b)(1).

²² *Drug Scheduling*, DEA, <http://www.dea.gov/druginfo/ds.shtml> [<https://perma.cc/KU66-EM2P>].

²³ *Id.*

²⁴ 21 U.S.C. § 812(b)(3)-(5).

²⁵ Alexander W. Campbell, *The Medical Marijuana Catch-22: How the Federal Monopoly on Marijuana Research Unfairly Handicaps the Rescheduling Movement*, 41 B.U. AM. J. L. MED. 190, 205 (2015).

²⁶ *Id.* at 206.

and the American Society of Addiction Medicine, among others, have all issued statements opposing the medicinal use of marijuana because of the lack of research demonstrating its medical benefits.²⁷ The American Academy of Pediatrics has stated that while cannabinoids may have potential as therapy for a number of medical conditions, they do not recommend prescribing them until more research is done.²⁸ There is a demand in the medical community for more research, but significant hurdles make researching marijuana with federal support highly problematic as discussed *infra*.

B. Brief Explanation of Marijuana's Pharmacology

“Marijuana” is the Mexican colloquial name for a plant known to botanists as *Cannabis Sativa*.²⁹ It is a hemp plant that contains cannabinoids, chemicals that initiate physiological effects when they bind to cannabinoid receptors in the brain.³⁰ It has approximately 525 known components, and at least eighty-five different known cannabinoids can be derived from it.³¹ However, the most common plant-derived cannabinoids, and the ones most at issue in this paper, are Phytocannabinoid tetrahydrocannabinol (“THC”), and Cannabidiol (“CBD”).³² THC ingestion is most often associated with psychological effects such as euphoria, analgesia, sedation, cognitive impairment, and appetite

²⁷ ASAM Staff, *New York Times Calls for Legalization of Marijuana, ASAM Strongly Objects*, AM. SOC'Y ADDICTION MED. (July 28, 2014), <http://www.asam.org/magazine/read/article/2014/07/28/new-york-times-calls-for-legalization-of-marijuana-asam-strongly-objects> [https://perma.cc/2ATG-9LBL]; Christopher Snowbeck, *Minnesota Medical Association Does Not Support Legalizing Pot*, TWINCITIES.COM (Mar. 17, 2014), <http://www.twincities.com/2014/03/17/minnesota-medical-association-does-not-support-legalizing-pot/> [https://perma.cc/93CB-RPAU] (“The Minnesota Medical Association does not support a bill to legalize medical marijuana in the state. [It] wants more studies of the medicinal potential in marijuana.”).

²⁸ *American Academy of Pediatrics Reaffirms Opposition to Legalizing Marijuana for Recreational or Medical Use*, AM. ACAD. PEDIATRICS (Jan. 26, 2015), <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/American-Academy-of-Pediatrics-Reaffirms-Opposition-to-Legalizing-Marijuana-for-Recreational-or-Medical-Use.aspx> [https://perma.cc/48EK-MV75].

²⁹ Eric Schlosser, *Reefer Madness*, THE ATLANTIC (August 1994), <http://www.theatlantic.com/magazine/archive/1994/08/reefer-madness/303476/> [https://perma.cc/L87R-BHJQ].

³⁰ *See generally* KENNETH MACKIE, THE SCIENTIFIC SIDE OF MEDICAL MARIJUANA (Natl. Assn. Bds. of Pharm. Fall Symposium, 2009), <http://www.medicinalgenomics.com/wp-content/uploads/2011/04/Ken-Mackie.pdf> [https://perma.cc/ZD2G-U4XM].

³¹ Abir T. El-Alfy et al., *Antidepressant-like effect of Δ9-tetrahydrocannabinol and other cannabinoids isolated from Cannabis sativa L*, PHARMACOLOGY BIOCHEMISTRY AND BEHAV. 95(4): 434–42 (2011), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866040/> [https://perma.cc/TNA8-ERUP].

³² *Id.*

stimulation.³³ CBD is the cannabinoid most often associated with healing.³⁴ Among other potential health benefits, CBD has been shown to relieve convulsion, inflammation, anxiety, and nausea; prevent short-term memory loss; and inhibit cancer cell growth in breast cancer.³⁵

Evidence has shown that CBD on its own is not psychoactive.³⁶ Indeed, CBD has been shown to mitigate the “high” produced by THC, and has been studied as a potential antipsychotic and anti-seizure drug.³⁷ High-CBD (and low-THC) based marijuana treatments have been used to treat severe forms of pediatric epilepsy in children at more effective levels than alternative treatments.³⁸ Additionally, research demonstrates that marijuana can mitigate chronic neuropathic pain. In a 2010 clinical trial led by researcher Mark Ware, M.D., at McGill University in Montreal, Canada, a placebo was compared with three different doses of cannabis.³⁹ The study’s results, which are published in the *Canadian Medical Association Journal*, provide evidence that “low doses of inhaled cannabis containing approximately 10% THC, smoked as a single inhalation three times daily over five days offer modest pain reduction in patients suffering from neuropathic pain.”⁴⁰ Additionally, in a 2013 FDA-approved trial that assessed the impact of vaporized cannabis on neuropathic pain, researchers showed that “even low doses of THC ‘provided statistically significant 30% reductions in pain intensity when compared with placebo.’”⁴¹

³³ *Id.*

³⁴ Raphael Mechoulam et al., *Cannabidiol – Recent Advances*, CHEMISTRY & BIODIVERSITY, 4(8): 1678–92 (Aug. 2007), <http://www.ncbi.nlm.nih.gov/pubmed/17712814> [<https://perma.cc/HL2N-CMUK>].

³⁵ *Id.* at 1680, 1682-1688. See Arran Frood, *Key Ingredient Staves Off Marijuana Memory Loss*, NATURE.COM, (Oct. 1, 2010), <http://www.nature.com/news/2010/101001/full/news.2010.508.html> [<http://perma.cc/F66S-S2LJ>]; Joseph I. Sirven, MD, Patricia O. Schafer, RN, MN, *Medical Marijuana and Epilepsy*, EPILEPSY.COM (April, 2015), <http://www.epilepsy.com/learn/treating-seizures-and-epilepsy/other-treatment-approaches/medical-marijuana-and-epilepsy> [<http://perma.cc/F7QE-8R4D>].

³⁶ *Taking A Science-informed Approach to Medical Marijuana*, NAT’L INST. ON DRUG ABUSE: NORA’S BLOG (Apr. 28, 2015), <https://www.drugabuse.gov/about-nida/noras-blog/2015/04/taking-science-informed-approach-to-medical-marijuana> [<https://perma.cc/9L6N-LGZ9>].

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Research demonstrates benefits of medical cannabis as a treatment for chronic pain*, MCGILL UNIV.: CHANNELS (Aug. 30, 2010), <https://www.mcgill.ca/channels/news/research-demonstrates-benefits-medical-cannabis-treatment-chronic-pain-166555> [<https://perma.cc/7NU7-5QHM>].

⁴⁰ *Id.*

⁴¹ Barth Wilsey et. al., *Low-dose vaporized cannabis significantly improves neuropathic pain*, 14:2 J. OF PAIN 136, 145 (2013).

C. Pharmaceuticals that Feature Cannabinoids

Despite the federal government's current stance on marijuana, there are two FDA approved drugs on the market that feature synthetic cannabinoids.⁴² The two FDA-approved synthetic THC-based medications available for consumer use are Marinol, which features the synthetic cannabinoid dronabinol, and Cesamet, which contains the synthetic cannabinoid nabilone.⁴³ Marinol, a Schedule III drug,⁴⁴ was approved in 1985 to treat nausea and vomiting associated with cancer, and again in 1992 to treat anorexia associated with AIDS related weight-loss.⁴⁵ Cesamet, a Schedule II drug, was approved for treating nausea and vomiting associated with chemotherapy in 1985.⁴⁶ The FDA has stated that these specific products have “undergone FDA’s rigorous approval process, and have been determined to be safe and effective for their respective indications and dosing, and demonstrate views of the IOM [Institute of Medicine] that the future of marijuana as a potential medicine lies in classical pharmacological drug development.”⁴⁷ Considering that the FDA has already approved two drugs featuring the synthetic version of marijuana, why is the United States government so reluctant to recognize the medicinal benefit of the

⁴² *Pharmaceutical Products Already Exist; they are called Marinal & Cesamet*, DEA, http://www.dea.gov/divisions/sea/in_focus/marinol-cessmet.pdf [<http://perma.cc/CSL2-BPQN>]. See also Andrea Rael, *What is Synthetic Marijuana and How Does it Compare to Traditional Marijuana?*, HUFFINGTON POST (Sept. 11, 2013, 5:40PM), http://www.huffingtonpost.com/2013/09/11/synthetic-marijuana_n_3908171.html [<https://perma.cc/R4E7-H2LQ>]; *Synthetic Drugs*, OFFICE OF NAT’L DRUG CONTROL POLICY, <https://www.whitehouse.gov/ondcp/ondcp-fact-sheets/synthetic-drugs-k2-spice-bath-salts> [<https://perma.cc/28EN-F8PT>] (Synthetic cannabinoids were developed by John W. Huffman at Clemson University in 1984 to study cannabinoid receptors in the brain. They were manufactured to mimic the effects of THC, and by 2012 more than 158 synthetic cannabinoids and related substances had been identified).

⁴³ *FDA and Marijuana: Questions and Answers*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm> (last updated Sept. 30, 2015) [<https://perma.cc/3UBK-6RTC>] (“The FDA has approved Marinol for therapeutic uses in the U.S., including for the treatment of anorexia associated with weight loss in AIDS patients”).

⁴⁴ See 21 U.S.C. § 812(b)(1)-(5) (2012); *Marinol NDA*, FDA (Sept. 2004), <http://www.fda.gov/ohrms/dockets/dockets/05n0479/05N-0479-emc0004-04.pdf> [<https://perma.cc/D8SE-7YYJ>].

⁴⁵ *Marinol NDA*, FDA (Sept. 2004), <http://www.fda.gov/ohrms/dockets/dockets/05n0479/05N-0479-emc0004-04.pdf> [<https://perma.cc/D8SE-7YYJ>].

⁴⁶ See 21 U.S.C. § 812(b)(1)-(5); *Cesamet Description*, DRUGS.COM, <http://www.drugs.com/pro/cesamet.html> [<https://perma.cc/MF37-LLEA>].

⁴⁷ *Cannabidiol: Barriers to Research and Potential Medical Benefits: Hearings before the Caucus on Int’l Narcotics Control of the U.S. Senate* (June 24, 2015) (statement of Douglas C. Throckmorton), <http://www.fda.gov/NewsEvents/Testimony/ucm453989.htm> [<https://perma.cc/DD5T-NMTK>].

botanical product?

II. BACKGROUND REGARDING THE PROBLEM

A. History of Marijuana Illegality in the United States

The answer to the question posed is primarily rooted in ignorance and the morality-based notions of regulation. Though marijuana was not officially deemed a banned substance until the passing of the CSA in 1970, fear associated with the use of marijuana began in the early 20th century.⁴⁸ Marijuana's illegality and criminalization were largely associated with the hysteria surrounding prejudice and racism.⁴⁹ In 1910, Mexico erupted in a civil war known as the Mexican Revolution, which resulted in fighting for over two decades.⁵⁰ During this time, the U.S. saw an influx of Mexican immigrants who brought with them their traditional means of intoxication, smoking marijuana.⁵¹ Racism against this population ensued, and prompted the belief that marijuana and the people who used it were dangerous.⁵²

Spearheading the passage of these regulations was the first commissioner of the Federal Bureau of Narcotics, Harry J. Anslinger, appointed in 1930.⁵³ Anslinger vehemently pursued a nationwide marijuana prohibition.⁵⁴ Indeed, in

⁴⁸ Reid, *supra* note 10, at 170.

⁴⁹ *Marijuana Timeline*, PBS, <http://www.pbs.org/wgbh/pages/frontline/shows/dope/etc/cron.html> [https://perma.cc/MWH8-E3XM].

⁵⁰ *Mexican Revolution*, PBS, <http://www.pbs.org/opb/historydetectives/feature/mexican-revolution/> [https://perma.cc/9UE4-Z9TP].

⁵¹ Matt Thompson, *The Mysterious History of 'Marijuana'*, NPR (July 22, 2013, 11:46 AM), <http://www.npr.org/sections/codeswitch/2013/07/14/201981025/the-mysterious-history-of-marijuana> [https://perma.cc/X27X-QTGC].

⁵² *Marihuana Makes Fiends of Boys in 30 Days: Hasheesh Goads Users to Blood-Lust*, SF EXAMINER (1923), <http://www.druglibrary.org/mags/examiner23.htm> [https://perma.cc/47PN-SW3S]; Schlosser, *supra* note 29 (“Police officers in Texas claimed that marijuana incited violent crimes, aroused a ‘lust for blood,’ and gave its users ‘superhuman strength.’ Rumors spread that Mexicans were distributing this ‘killer weed’ to unsuspecting American schoolchildren. In New Orleans newspaper articles associated the drug with African-Americans, jazz musicians, prostitutes, and underworld whites”); Tia Ghose, *Marijuana: Facts About Cannabis*, LIVESCIENCE (Jan. 13, 2015, 11:49 PM), <http://www.livescience.com/24559-marijuana-facts-cannabis.html> [https://perma.cc/Y4PX-569D] (Strong propaganda campaigns supported the hysteria with broadcasted news articles featuring headlines like the 1933 Los Angeles Examiner’s article, “Deadly Marihuana Dope Plant Ready for Harvest That Means Enslavement of California Children”).

⁵³ Anslinger, Harry Jacob, and U.S. Drug Policy, ENCYCLOPEDIA.COM, <http://www.encyclopedia.com/doc/1G2-3403100057.html> [https://perma.cc/6KAW-S98H] (Anslinger served in this position until 1962).

⁵⁴ Schlosser, *supra* note 29 (Anslinger made public statements about marijuana, asserting “that the use of this ‘evil weed’ led to killings, sex crimes, and insanity”).

1937 Anslinger “testified before Congress in the hearings that would result in the introduction of federal restrictions on marijuana.”⁵⁵ His testimony included a letter sent to him from Floyd K. Baskette, editor of the Alamosa, Colorado, *Daily Courier*, which informed Anslinger about a “sex-mad degenerate” who had “brutally attacked a young Alamosa girl” while under the influence of marijuana.⁵⁶ Anslinger further called the authors of a research report from the New York Academy of Medicine “dangerous” and “strange” when in 1944, after years of research, they released a report concluding that “marijuana use did not cause violent behavior, provoke insanity, lead to addiction, or promote opiate use.”⁵⁷

The first U.S. ordinance directly banning the sale or possession of marijuana was passed in 1914 in El Paso, Texas, which led other states to follow suit.⁵⁸ By 1937 all forty-eight states had some law restricting the use of marijuana, and thirty-five states had criminalized its use.⁵⁹ In addition to the Marihuana Tax Act of 1937, Congress enacted the Boggs Act in 1952, and the Narcotics Control Act in 1956, “which set mandatory sentences for drug-related offenses, including marijuana.”⁶⁰

As a means of justifying the criminalization of marijuana Anslinger categorized marijuana as a stepping-stone to narcotics addiction, a concept that became widely accepted among legislators.⁶¹ During Congressional debates regarding passage of the Narcotic Control Act of 1956, Texas Senator Price Daniel, Chairman of the Senate subcommittee that investigated the drug, characterized marijuana utilizing the stepping stone theory, stating “[marijuana is] a drug that starts most addicts in the use of drugs. [It] is a dangerous drug, [and] can lead to some of the worst crimes committed by those who are addicted to the habit. [I]ts use leads to the heroin habit, and then to the final destruction of the persons addicted.”⁶² However, scientific researchers point out that “the

⁵⁵ Thompson, *supra* note 51.

⁵⁶ Allen Best, *77 Years Later, Here Comes the Pot*, HIGH COUNTRY NEWS (Feb. 19, 2014), <http://www.hcn.org/wotr/77-years-later-here-comes-pot> [<https://perma.cc/PAW2-HCEK>].

⁵⁷ Schlosser, *supra* note 29.

⁵⁸ *Id.*

⁵⁹ Richard J. Bonnie & Charles H. Whitebread, II, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry Into the Legal History of American Marijuana Prohibition*, 56 VA. L. REV. 971, 1034 (1970).

⁶⁰ *Marijuana Timeline*, *supra* note 49 (Under these laws, a first-offense marijuana possession carried a minimum sentence of two to ten years with a fine up to \$20,000. “An example of criminalization includes: 57 year old Samuel Caldwell who was convicted of selling three marijuana cigarettes in Denver and was ordered to serve two years in prison”).

⁶¹ Schlosser, *supra* note 29. *See also* INSTITUTE OF MEDICINE, *supra* note 15, at 99 (The stepping stone theory is one of two theories (the second being the gateway theory) that legislatures have used to warrant its prohibition. It is the idea that progression from marijuana to other drugs arises from pharmacological properties of marijuana itself. The gateway theory suggests that the “legal status of marijuana makes it a gateway drug.”).

⁶² Bonnie & Whitebread, *supra* note 59, at 1079.

stepping stone hypothesis applies to marijuana only in the broadest sense . . . [and] many of the factors associated with a willingness to use marijuana are . . . the same as those associated with a willingness to use other illicit drugs.”⁶³

Then, in 1970, President Richard Nixon signed into law the CSA, the federal statute that regulates the manufacture and distribution of controlled substances discussed *supra*,⁶⁴ under which marijuana was categorized as a Schedule I banned substance.⁶⁵ During the drafting of the CSA “the Assistant Secretary of Health, Dr. Roger O. Egeberg, recommended that . . . marijuana . . . be classified as a Schedule I substance” until more research was done on the effects of the substance “since there [was] still a considerable void in our knowledge of the plant and effects of the active drug contained in it.”⁶⁶ So began the catch-22 of marijuana legalization: classifying marijuana as a Schedule I substance, not because of evidence of its potential for danger, but because of the absence of any such evidence.

In response, President Nixon formed The National Commission on Marijuana and Drug Abuse (“NCMDA”), called the Schafer Commission, to which he “appointed a bipartisan commission to study marijuana.”⁶⁷ The Commission’s report, entitled “Marihuana, A Signal of Misunderstanding,” advocated for the decriminalization of marijuana for personal use.⁶⁸ Researchers found that “looking only at the effects on the individual there is little proven danger of physical or psychological harm from the experimental or intermittent use of . . . cannabis. The risk of harm lies instead in the heavy, long-term use of the drug, particularly of the most potent preparations.”⁶⁹ Despite the findings of the Schafer Commission, President Nixon and Congress rejected their

⁶³ INSTITUTE OF MEDICINE, *supra* note 15, at 99 (“There is no evidence that marijuana serves as a stepping stone on the basis of its particular physiological effect”).

⁶⁴ See generally *supra* text accompanying notes 19-24.

⁶⁵ *Id.*

⁶⁶ Sanjay Gupta, *Why I Changed My Mind on Weed*, CNN (August 8, 2013), <http://www.cnn.com/2013/08/08/health/gupta-changed-mind-marijuana/> [<https://perma.cc/7KUY-T64L>] (“Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marijuana be retained within Schedule I at least until the completion of certain studies now underway to resolve the issue”).

⁶⁷ Schlosser, *supra* note 29 (the Schafer Commission was headed by Commissioner, Raymond P. Schafer).

⁶⁸ *Id.*; RAYMOND P. SHAFER, REPORT OF THE NAT’L COMMISSION ON MARIHUANA AND DRUG ABUSE (1972), <http://www.druglibrary.org/schaffer/library/studies/nc/ncmenu.htm>.

⁶⁹ SHAFER, *supra* note 68 (The Commission concluded that “Society should seek to discourage use, while concentrating its attention on the prevention and treatment of heavy, and very heavy use. [T]he criminalization of possession of marihuana for personal [use] is socially self-defeating as a means of achieving this objective. We believe our recommended scheme will permit society to exercise its control and influence in ways most useful and efficient, meanwhile reserving to the individual American his sense of privacy . . . and, his options to select his own life style, values, goals, and opportunities”).

recommendations.⁷⁰ The states, however, did not. In response, in the 1970s eleven states decriminalized marijuana, and other states reduced their prohibitions and penalties against it.⁷¹

Nonetheless, in the 1970s and 1980s, federal support for prohibitions against marijuana raged on.⁷² Parent-based groups like the Parents' Resource Institute for Drug Education, and the National Federation of Parents for Drug-Free Youth emerged as strong organizations that were supported by top officials at the National Institute on Drug Abuse ("NIDA"), and the Drug Enforcement Administration ("DEA").⁷³ President Reagan signed an executive order in 1982 establishing the Drug Abuse Policy Office, headed by Carlton Turner, who believed marijuana was an extremely dangerous drug.⁷⁴ Following the creation of this office, three major laws were passed in the 1980s: "the Comprehensive Crime Control Act of 1984, the Anti-Drug Abuse Act of 1986, and the Anti-Drug Abuse Amendment Act of 1988, which raised federal penalties for marijuana possession, cultivation, and trafficking."⁷⁵ These laws firmly established the federal government's stance on prohibitions against the legalization of marijuana.

Prohibitive laws against marijuana were established with no scientific evidence supporting the assertion that marijuana is dangerous, and has no medicinal benefit. Indeed, in 1997 the IOM "after a comprehensive study of the medical efficacy of cannabis therapeutics [concluded] that cannabis is a safe and effective medicine, patients should have access, and the government should expand avenues for research and drug developments."⁷⁶ Again, the federal government ignored the IOM's recommendations. And again, states acted in accordance with them. In 1996, California became the first state to allow for the sale and medical use of marijuana, which was the first step in marijuana legalization in the United States.⁷⁷

B. The State of Marijuana Legalization

Despite marijuana's unwavering Schedule I designation at the federal level,

⁷⁰ Schlosser, *supra* note 29.

⁷¹ *Marijuana Timeline*, *supra* note 49.

⁷² Schlosser, *supra* note 29.

⁷³ *Id.* (These government organizations have tremendous influence over the nation's drug policies).

⁷⁴ *Id.*

⁷⁵ *Marijuana Timeline*, *supra* note 49. ("In conjunction with the Comprehensive Crime Control Act of 1984, the new law raised federal penalties for marijuana possession and dealing, basing the penalties on the amount of the drug involved. Possession of 100 marijuana plants received the same penalty as possession of 100 grams of heroin. A later amendment to the Anti-Drug Abuse Act established a "three strikes and you're out" policy, requiring life sentences for repeat drug offenders, and providing for the death penalty for "drug kingpins").

⁷⁶ *Medical Use of Marijuana-History*, *supra* note 16; *see also* Joy et al., *supra* note 15.

⁷⁷ *See Marijuana Timeline*, *supra* note 49.

as of December 2015, four states—Washington and Colorado in 2012, and Alaska and Oregon in 2014—have legalized the recreational use of marijuana, with varying provisions regarding possession, cultivation, and transportation of the drug.⁷⁸ In 2014, the District of Columbia passed a more limited measure that legalized the possession and home cultivation of marijuana.⁷⁹ Additionally, twenty-three states have legalized its medicinal use.⁸⁰ Due to the statewide recognition of medical marijuana’s legality, approximately 275 million Americans are living in states where medicinal marijuana is an option for treatment.⁸¹

Many wonder how states may legalize marijuana while it remains illegal at the federal level. Due to its Schedule I designation, the manufacture, distribution, or possession of marijuana is a criminal offense under federal law.⁸² The CSA, then, is an exercise of express Congressional power to regulate interstate commerce, as granted in the Commerce Clause of the U.S. Constitution.⁸³ Additionally, these laws could be preempted under the Supremacy Clause of the U.S. Constitution. Federal preemption “occurs when a state law or regulation conflicts with a Federal law or regulation.”⁸⁴ The Supremacy Clause states that the laws of the U.S. Federal government “have supremacy over state constitutions and laws, so that if a state law is in conflict with federal law, [the] federal law trumps.”⁸⁵

Conflicting state and federal laws regarding marijuana were considered in the 2005 Supreme Court case *Gonzales v. Raich*. In *Gonzales*, California’s

⁷⁸ *State Marijuana Laws Map*, GOVERNING, <http://www.governing.com/gov-data/state-marijuana-laws-map-medical-recreational.html> [<http://perma.cc/8VRG-BUN4>].

⁷⁹ Press Release, Drug Pol’y Alliance, Marijuana Legalization in Washington: One-Year Status Report (July 6, 2015), <http://www.drugpolicy.org/news/2015/07/marijuana-legalization-washington-state-one-year-status-report> [<https://perma.cc/S6W9-AR3J>].

⁸⁰ *23 Legal Medical Marijuana States and DC*, PROCON.ORG (March 14, 2016, 4:52 PM), <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> [<http://perma.cc/97H7-82DW>].

⁸¹ Steph Sherer, *10 Reasons Why Federal Marijuana Prohibition is about to Go Up in Smoke*, HUFFPOST POLITICS (July 23, 2015, 1:46 PM), http://www.huffingtonpost.com/steph-sherer/10-reasons-why-federal-me_b_7851642.html [<https://perma.cc/Q23P-ZNNQ>].

⁸² *Gonzales v. Raich*, 545 U.S. 1, 3 (2005).

⁸³ David B. Rivkin, Jr. & Elizabeth Price Foley, *Federal Antidrug Law Goes Up In Smoke*, WALL ST. J. (Dec. 28, 2014), <http://www.wsj.com/articles/david-b-rivkin-jr-and-elizabeth-price-foley-federal-antidrug-law-goes-up-in-smoke-1419810742> [<http://perma.cc/3EJD-YZFT>]. See also 21 U.S.C. § 801(3) (2012) (As stated in the CSA, “a major portion of the traffic in controlled substances flows through interstate and foreign commerce,” and therefore, even locally grown and sold drugs have a substantial impact on interstate commerce).

⁸⁴ Heather Gray, *Commentary: Federal Preemption of State Laws Regarding Medical Marijuana*, PARTNERSHIP FOR DRUG-FREE KIDS (Jan. 21, 2015), <http://www.drugfree.org/join-together/commentary-federal-preemption-state-laws-regarding-medical-marijuana/> [<https://perma.cc/7QHF-DNE5>].

⁸⁵ *Id.*; see also U.S. CONST. art. VI, § 2.

Compassionate Use Act permitted California residents to cultivate their own marijuana for medicinal purposes.⁸⁶ Notwithstanding the state law, DEA officials seized and destroyed cannabis plants Respondents had been growing for their medicinal use, even though their behavior was legal under California law.⁸⁷ The Court held that the DEA agents' actions were permissible since the CSA is a valid exercise of federal power, and that there was no violation of the Commerce Clause.⁸⁸

Though *Gonzalez* has yet to be overturned, its holding does not preempt states from legalizing marijuana as they deem appropriate, since as Randy Barnett, the attorney who represented the Respondents in *Gonzalez* explains “this would amount to unconstitutional commandeering.”⁸⁹ According to Barnett, *Gonzalez* did not imply that “Congress had the power to compel state legislatures to exercise their police power to criminalize the possession of marijuana, or to maintain their previous legislation criminalizing such behavior.”⁹⁰ Such a preemption theory is in direct conflict with the Supreme Court’s holdings in *New York v. United States*⁹¹, and *Printz v. United States*,⁹² in which the Supreme Court held that “Congress may not use its commerce . . . powers to ‘commandeer’ the sovereign power of state legislatures to enact laws, or to commandeer state . . . officials to enforce federal law[s].”⁹³ Though federal laws may criminalize or prohibit substances, states cannot be compelled to criminalize or prosecute such activity under state law.⁹⁴ Therefore, the state is not compelled to pass laws that align with federal prohibitions, even though the federal government may enforce its prohibition within a state.⁹⁵

However, the Supreme Court held in the 2012 case *Arizona v. United States*, “when the federal government does not enforce its own laws, states still ‘may

⁸⁶ *Gonzales*, 545 U.S. at 6-7.

⁸⁷ *Id.*

⁸⁸ *Id.* at 9.

⁸⁹ Josh Blackman, *Federal Law Does Not Preempt State Marijuana or Gun Laws*, JOSH BLACKMAN’S BLOG (Jan. 5, 2015), <http://joshblackman.com/blog/2015/01/05/federal-law-does-not-preempt-state-marijuana-or-gun-laws-in-colorado/> [https://perma.cc/7A4J-2FN8.http] (“The federal Controlled Substances Act ‘in no way preempts states from ceasing to prohibit marijuana, as this would amount to unconstitutional commandeering’”).

⁹⁰ *Id.* (“It certainly never hinted . . . that a congressional power to prohibit intrastate activity somehow required states to criminalize such behavior or ‘preempted’ states from ceasing to prohibit it.”).

⁹¹ *New York v. United States*, 505 U.S. 144 (1992), Randy Barnett, *Another Misbegotten Reliance on Gonzales v. Raich*, WASH. POST (Dec. 31, 2014), <https://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/12/31/another-misbegotten-reliance-on-gonzales-v-raich/> [https://perma.cc/PT3Q-2N6N].

⁹² *Printz v. United States*, 521 U.S. 898 (1997).

⁹³ Blackman, *supra* note 89.

⁹⁴ Barnett, *supra* note 90.

⁹⁵ *Id.*

not pursue policies that undermine federal law.”⁹⁶ As applied to state marijuana legalization, because a state’s decision to regulate and legalize the sale of marijuana increases the substance’s availability in interstate commerce, it in effect undermines the CSA.⁹⁷ This exact issue is currently being litigated in Colorado, a state that has legalized the recreational use of the substance.⁹⁸ In March 2015, law enforcement officials from Colorado, Kansas, and Nebraska filed a lawsuit against the Governor alleging that the state law allowing the recreational use of marijuana is preempted by the CSA.⁹⁹ The complainant alleges that Amendment 64, which legalized marijuana in Colorado, pursues a goal that directly opposes the CSA’s scheduling of marijuana as a banned substance.¹⁰⁰

Despite the conflicts, in August 2013, the Department of Justice (“DOJ”) announced its decision to suspend enforcement of the CSA.¹⁰¹ In its memorandum issued to U.S. law enforcement, the DOJ advised law enforcement “to refrain from using ‘limited investigative and prosecutorial resources’ to pursue marijuana-related violations of the CSA in states that chose to regulate

⁹⁶ Rivkin & Foley, *supra* note 83 (quoting *Arizona v. United States*, 132 S. Ct. 2492, 2511 (2012)).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Michael D. Hornback, *Do Federal Drug Laws Preempt State Laws Legalizing Marijuana? We’ll See*, WYATT EMP’T L. BLOG (Mar. 17, 2015), <http://www.lexology.com/library/detail.aspx?g=829fd137-370e-4cb9-9f96-3ca3292fc307> [perma.cc/WTH8-Z8HU]; Complaint, *Smith v. Hickenlooper*, No. 1:15-cv-00462, 2 (D. Colo. 2015).

¹⁰⁰ *Hickenlooper*, No. 1:15-cv-00462, at 2-3. On Feb. 26, 2016, however, Senior District Judge, Daniel Y. Wiley for the U.S. District Court of Colorado granted the defendant’s motion to dismiss finding that the plaintiffs’ lack standing to bring the suit, and that the CSA does not create a private right of action warranting that the suit be brought. *Smith v. Hickenlooper*, 2016 U.S. Dist. LEXIS 23889. *See also Nebraska and Oklahoma v. Colorado*, SCOTUS BLOG, <http://www.scotusblog.com/case-files/cases/nebraska-and-oklahoma-v-colorado/> [perma.cc/UNY5-RJZF]; Ricardo Baca, *Professor: Why Nebraska, Oklahoma have a right to kill Colorado’s legal pot*, (June 26, 2015, 10:30 AM), <http://www.thecannabist.co/2015/06/26/nebraska-oklahoma-colorado-marijuana-pot/36873/> [http://perma.cc/WAJ5-M6S4] (A similar case, which was pending petition in the Supreme Court, in which the neighboring states to Colorado, Nebraska and Oklahoma allege that the CSA preempts Colorado’s marijuana law. They are concerned since, as neighboring states, Colorado’s legalization of marijuana has resulted in an influx of marijuana through their borders, and has burdened their criminal justice system. On March 21, 2016, Nebraska and Oklahoma’s petition for *certiorari* was denied). *See also Nebraska v. Colorado*, 577 U.S. ___, 4 (2016).

¹⁰¹ Memorandum from James M. Cole, Deputy Attorney General, for all United States Attorneys, *Guidance Regarding Marijuana Enforcement* (Aug. 29, 2013), <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> [perma.cc/4A8B-3KQ3].

marijuana businesses.”¹⁰² The memo outlined eight priority areas for federal prosecutors to focus their efforts on when dealing with marijuana legalization, including preventing the sale of marijuana to minors, preventing the revenue from marijuana sales to contributing to crime enterprises, and preventing violence and use of firearms in association with the cultivation and distribution of marijuana.¹⁰³ Indeed, Deputy Attorney General James Cole stated in the memo that the DOJ’s “guidance . . . rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those laws could pose to public safety, public health, and other law enforcement interests.”¹⁰⁴

As states continue to recognize the legalization of marijuana, and the DOJ authorizes marijuana enforcement consistent with the Deputy Attorney General’s memorandum,¹⁰⁵ federal courts remain deferential to administrative agencies when considering cases regarding the decriminalization of the substance.¹⁰⁶ For instance, in the 2015 federal district court case, *United States v. Pickard*,¹⁰⁷ sixteen individuals were indicted for conspiracy to manufacture at least 1,000 marijuana plants in violation of federal law.¹⁰⁸ Mr. Pickard moved to dismiss his indictment, alleging that the federal government’s disparate treatment of the marijuana legalization as compared with the states was a direct violation of the equal sovereignty doctrine promulgated by the Tenth Amendment.¹⁰⁹ After considering the varying expert testimony regarding the benefits and dangers of marijuana, federal Judge Kimberly Mueller concluded that the issues raised in the case are policy issues for Congress to address and concluded that the court does not have authority to “second-guess the DOJ’s enforcement policy.”¹¹⁰

A decision like *Pickard*, in conjunction with the wide variances and contradictions of states writing their own laws regarding the legality of marijuana highlights the need for Congressional intervention to reschedule marijuana from a Schedule I substance, and ultimately advance research on the medicinal benefits and healing potential of marijuana.¹¹¹

¹⁰² *Id.*; Rivkin & Foley, *supra* note 83.

¹⁰³ Cole, *supra* note 101.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ Arielle Pardes, *Marijuana is Still a Schedule I Drug, Judge Rules*, VICE (April 15, 2015), <http://www.vice.com/read/marijuana-is-still-a-schedule-i-drug-judge-rules-415> [perma.cc/9UKD-QKQK].

¹⁰⁷ *U.S. v. Pickard*, 100 F. Supp. 3d 981 (E.D. Cal. 2015).

¹⁰⁸ 21 U.S.C. §§ 846, 841 (1970); *Pickard*, 100 F. Supp. 3d at 988-89.

¹⁰⁹ *Pickard*, 100 F. Supp. 3d at 989.

¹¹⁰ *Id.* at 989, 999-1001, 1012.

¹¹¹ Katie Campbell et al., *Wide Variety On How States Handle Medicinal Marijuana: News21 Report*, IOWAWATCH.ORG (Aug. 19, 2015), <http://iowawatch.org/2015/08/19/wide->

III. RESEARCHING WITH MARIJUANA TODAY

A. FDA Drug Approval Process

In considering the expansion of research regarding marijuana's medicinal benefits, "[t]he question is not whether marijuana can be used as a herbal remedy, but rather how well this remedy meets today's standards of efficacy and safety."¹¹² The FDA is the federal agency responsible for bringing drugs to market.¹¹³ It protects the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), and ensuring that drugs intended for use in humans are safe and effective for their intended uses.¹¹⁴ Before a new drug may be lawfully marketed and sold in the United States the FDA must first approve it through the new drug approval process.¹¹⁵ The new drug approval process typically involves the following steps: preclinical investigation, clinical trials, submission and review of the New Drug Application ("NDA"), and post-marketing.¹¹⁶

The goals of the first step, preclinical investigation, are to (1) identify the potential effects in the body of the chemical substance being investigated, and (2) to gather enough evidence on the potential new drug to determine whether it would be safe to test on humans.¹¹⁷ Then researchers may begin testing a potential new drug in people through clinical trials, which requires formal notification to the FDA in the form of submitting an Investigational New Drug application ("IND").¹¹⁸ If the FDA does not object to the IND within thirty days, researchers may begin clinical trial testing of the new drug.¹¹⁹

Clinical trials are divided into three phases.¹²⁰ Phase I trials assess safety and tolerability, and "ordinarily involve the initial administration of the drug to a small number (twenty to eighty) of healthy test subjects."¹²¹ Phase II trials

variety-on-how-states-handle-medicinal-marijuana-news21-report/ [https://perma.cc/4B8N-RSTY] ("For example, in Vermont, a medical marijuana patient is allowed only two mature plants and two ounces of marijuana. By contrast, in Washington state, a patient can have 15 plants and 24 ounces of prepared marijuana.").

¹¹² INSTITUTE OF MEDICINE, *supra* note 15, at 17.

¹¹³ JARILYN DUPONT, U.S. FOOD AND DRUG ADMIN., FDA OVERVIEW 4, 8 (2011), <http://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM283299.pdf>.

¹¹⁴ *Id.*

¹¹⁵ Geoffrey M. Levitt, *The Drugs/Biologics Approval Process*, in A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION 124 (Kenneth R. Piña & Wayne L. Pines eds., 4th ed., 2012).

¹¹⁶ *Id.* at 123, 125.

¹¹⁷ *Id.* at 125.

¹¹⁸ *Id.* at 125, 127.

¹¹⁹ *Id.* at 127.

¹²⁰ *Id.*

¹²¹ *Id.*

involve an expanded patient group (up to several hundred patients) and examine the efficacy of drugs for a particular indication, while also determining potential short-term side effects.¹²² Finally, Phase III studies typically include a much larger sample size of human subjects, and aim to explore, demonstrate, or confirm the therapeutic efficacy and benefit to patients for a particular indication.¹²³

Because of marijuana's Schedule I designation, these studies are much more difficult to conduct. Indeed, as of January 2015, no large-scale clinical trials have been conducted on marijuana, preventing the existence of evidence from adequate and well-controlled clinical trials of whether marijuana has medicinal benefit.¹²⁴

B. Conducting Federally Supported Research on Marijuana

Complicating the process for demonstrating the medicinal benefits of marijuana is the process for conducting federally approved research on marijuana. Because of its Schedule I classification, conducting clinical research on marijuana requires approval from three federal agencies: the FDA, the DEA, and NIDA, which is part of the Department of Health and Human Services ("HHS"), the parent to NIH.¹²⁵ Researchers must: (1) submit an Investigational New Drug application and research protocol to the FDA, (2) obtain investigation registration and site licensure from the DEA, and (3) obtain marijuana from NIDA.¹²⁶ Each step presents equally challenging hurdles.

First, the researcher must have an active-status IND on file with the FDA, which contains the research protocol the FDA evaluates for safety and effectiveness.¹²⁷ The FDA determines whether the intended study is deemed safe enough to proceed to clinical trial testing.¹²⁸ The researcher must also apply to

¹²² *Id.*; Throckmorton, *supra* note 47.

¹²³ *Americans for Safe Access v. DEA*, 706 F.3d 438, 451 (2013); 21 C.F.R. § 312.21 (2015).

¹²⁴ *Americans for Safe Access*, 706 F.3d at 451 (As of 2013 there have been no Phase II or Phase III trials on marijuana. A drug efficacy study is considered 'adequate and well-controlled' when it follows clinical trial protocols as approved by the FDA.). *See also* German Lopez, *Study: Medical Marijuana May Literally Save Lives*, VOX (July 16, 2015), <http://www.vox.com/2015/7/16/8974965/medical-marijuana-prescription-painkillers> [<https://perma.cc/6LD9-T4RM>].

¹²⁵ *FDA and Marijuana*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm> (Feb. 9, 2016) [<https://perma.cc/Z4AB-LU9M>].

¹²⁶ *Marijuana Research with Human Subjects*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421173.htm> [<https://perma.cc/SEF2-AN8U>].

¹²⁷ Campbell, *supra* note 25, at 200.

¹²⁸ Suzanne White Junod, *FDA and Clinical Drug Trials: A Short History*, FDA (July 7, 2014), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm>

the DEA for registration to conduct research using a Schedule I substance, so that the researcher may receive, possess, and handle marijuana without fear of prosecution.¹²⁹ In order to receive such registration, “a researcher must first be determined by HHS to be qualified and competent, and the proposed research must be determined by HHS to have merit.”¹³⁰ Despite the Secretary’s determination, the DEA may still withhold a certificate for research if “he/she determines that the certificate of registration should be denied on a ground specified in §304(a) of the [CSA] (21 U.S.C. §824(a)).”¹³¹

Once these steps are completed, and proper authorizations are received, the researcher must contact NIDA to obtain research grade marijuana, since NIDA is the designated agency responsible for overseeing marijuana cultivation for medicinal research through the NIDA Drug Supply Program.¹³² NIDA provides research-grade marijuana for scientific study through cultivation conducted at a facility at the University of Mississippi.¹³³ Marijuana crops are grown, harvested, and stored on a secured plot of land, with varying strengths, potencies, and forms for ingestion depending on their need in research.¹³⁴ The University of Mississippi is the only facility authorized to produce marijuana legally for FDA-approved research, and no other Schedule I substance is available from

[<https://perma.cc/QTH7-M9KR>].

¹²⁹ 21 C.F.R. § 1301.13(e) (2015) (All researchers who will work on the study must apply for registration under a specific group of “controlled substances activities.” Any researcher who engages in more than one group of controlled substances activities must obtain a separate registration for each group of activities, in this case, Research, Schedule I. A Research, Schedule I registration allows the registrant to: manufacture or import the basic class of substance or substances for which registration was issued, and to distribute such class to persons registered or authorized to conduct research with such class of substances, or to conduct chemical analysis with controlled substances.)

¹³⁰ *Announcement of the Dept. of HHS’s Guidance on Procedures for the Provision of Marijuana for Medical Research*, NIH (May 21, 1999), <https://grants.nih.gov/grants/guide/notice-files/not99-091.html> [<https://perma.cc/3J2R-4PJC>] [hereinafter *HHS Guidance*].

¹³¹ Campbell, *supra* note 25, at 201; 21 U.S.C. § 824(a) (2012) (stating that the DEA can deny, revoke, or suspend registration if it finds that a manufacturer, distributor, or dispenser of controlled substances violates any one of five criteria promulgated in the statute).

¹³² *See* Campbell, *supra* note 25 (This authority is granted pursuant to the Single Convention on Narcotic Drugs, which was signed in 1961 to combat global drug abuse through a coordinated international effort).

¹³³ *Marijuana Research at NIDA*, NIH (Jan. 2014), <https://www.drugabuse.gov/drugs-abuse/marijuana/marijuana-research-nida> [<https://perma.cc/V5KQ-4S89>]; *NIDA’s Role in Providing Marijuana for Research*, NIH (June 2015), <https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research> [<https://perma.cc/AP4K-2C2K>] (As of June 2015, the University of Mississippi was the only facility that had been issued a license for the cultivation of marijuana for research in the U.S.).

¹³⁴ *Id.*

only one governmental source for research purposes.¹³⁵

Accessing marijuana through the NIDA Drug Supply Program requires fulfillment of specific criteria.¹³⁶ If a researcher is accessing marijuana for non-NIH funded human research an applicant must (1) demonstrate scientific validity and ethical soundness through review by the FDA's IND process, and (2) possess a DEA registration for marijuana.¹³⁷ If a researcher is accessing marijuana for NIH-funded projects an applicant must: (1) demonstrate scientific validity and ethical soundness through the NIH grant review process consisting of three steps: (i) the NIH peer review system, which assesses the scientific and technical merit of all grant applications, (ii) the National Advisory Council of the funding institute, and (iii) the funding institute's Director, who makes the final funding decision on the merit of an application, based on peer review, public health significance, and institute priorities.¹³⁸

NIDA has stated that it is generally not in the business of funding or supporting research on the medicinal effects of marijuana.¹³⁹ Indeed, in 1999 "HHS issued guidelines for the provision of NIDA's marijuana to privately-funded studies."¹⁴⁰ The guidelines explicitly state, "if the goal of the research is to develop the marijuana plant into an FDA-approved prescription medicine, then NIDA's marijuana is not to be provided."¹⁴¹

This bias against medical marijuana research is reflected in its historical approval of federal funding. In 2003 NIDA reportedly granted less than \$6 million in funds among twenty-two studies researching marijuana.¹⁴² Although in 2012 NIDA reported granting more than ten times as much funding to finance sixty-nine marijuana-related research projects, the majority of these studies only

¹³⁵ DRUG POLICY ALLIANCE, *supra* note 19, at 3.

¹³⁶ HHS Guidance, *supra* note 130.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ Campbell, *supra* note 25, at 192.

¹⁴⁰ DRUG POLICY ALLIANCE, *supra* note 19, at 9.

¹⁴¹ *Id.* ("The goal of this program must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the FDCA for commercial marketing of a medical product. As the IOM report stated, 'The purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems'").

¹⁴² Rob Hotakainen, *Feds Accused of Steering Funding to Anti-Pot Researchers*, McClatchyDC (Mar. 19, 2014, 3:36 PM), <http://www.mcclatchydc.com/news/nation-world/national/economy/article24765427.html> [<https://perma.cc/D4CL-JFGK>]; Matt Ferner, *Colorado Funds Multiple Studies on Marijuana's Medical Possibilities*, HUFFPOST POLITICS (Dec. 19, 2014, 5:10 PM), http://www.huffingtonpost.com/2014/12/17/medical-marijuana-research_n_6342552.html [<https://perma.cc/R2WJ-VCYQ>]. ("Since 2003 hundreds of grants for marijuana-related studies have received federal approval, but only a fraction of those have examined the potential medical benefits of marijuana").

focused on marijuana's negative effects.¹⁴³ Steven Gust, special assistant to the director at NIDA has stated, “[w]e’ve been studying marijuana since our inception [in 1974]. The large majority of that research has been on . . . the harmful effects.”¹⁴⁴ Additionally, NIDA has funded only a few projects examining marijuana's possible medical benefits.¹⁴⁵ However, NIDA reported that as of January 31, 2015 they issued twenty-eight active grants related to researching the therapeutic benefits of marijuana.¹⁴⁶

Some groundbreaking steps have been taken towards advancing research on marijuana's potential therapeutic benefits. In June 2015, the government removed a long-standing hurdle to marijuana research established in May 1999. The initial process “required that all privately funded marijuana studies in the U.S. submit a study proposal to the [FDA] review board, [which also] had to be reviewed by the Public Health Service (PHS) to determine the ‘scientific and ethical soundness’ of the study.”¹⁴⁷ The second step, requiring PHS review, was removed because it shared similar goals with the required FDA review, and since no other Schedule I substance had been required to go through this extra step.¹⁴⁸ Additionally, in April 2015 the DEA proposed a massive increase in marijuana production to meet the increasing demands of researchers studying the medicinal effects of the drug.¹⁴⁹ This increase in production follows the federal government's announcement that it would grant as much as \$70 million over the next five years to the University of Mississippi for marijuana research.¹⁵⁰

Though these changes demonstrate a positive step towards marijuana research reform, more can be done to streamline the process of obtaining needed data about marijuana's medicinal benefits. As Tom Angell, founder of Marijuana Majority, stated, “[t]he next step should be moving marijuana out of Schedule I to a more appropriate category, which the administration can do without any further Congressional action.”¹⁵¹

¹⁴³ Hotakainen, *supra* note 142 (Indeed, NIDA reported granting more than \$30 million in marijuana-related research projects).

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *NIDA Research on the Therapeutic Benefits of Cannabis and Cannabinoids*, NIDA (March 2016), <http://www.drugabuse.gov/drugs-abuse/marijuana/nida-research-therapeutic-benefits-cannabis-cannabinoids> [<https://perma.cc/PMM3-7P82>].

¹⁴⁷ Connor Bland, *Fed. Govt. Reduces Cannabis Research Hurdles*, WHAXY (June 22, 2015), <https://www.whaxy.com/news/united-states-reduces-cannabis-research-barriers> [<https://perma.cc/VVU5-JCU4>].

¹⁴⁸ *Id.*

¹⁴⁹ Matt Ferner, *DEA Wants to Triple Production of Govt. Marijuana for Research*, HUFFINGTON POST (Apr. 8, 2015, 9:40 PM), http://www.huffingtonpost.com/2015/04/08/dea-government-marijuana-research_n_7027730.html [<https://perma.cc/TPH9-7AX2>].

¹⁵⁰ *Id.*

¹⁵¹ Bland, *supra* note 146.

IV. SOLUTION

A. Rescheduling Marijuana Will Remove Hurdles to Researching Medicinal Potential

In order to best facilitate the expansion of medical marijuana research the federal government should first reschedule marijuana from a Schedule I substance. As demonstrated, the complexity involved in conducting research on marijuana demonstrates the catch-22 of legalization: “it likely needs a large-scale clinical trial to be rescheduled, but those studies are much harder to conduct until it is reclassified.”¹⁵² Rescheduling marijuana will help eliminate the procedural hurdles blocking expansive research on its medicinal benefits.

The rescheduling of marijuana also has budding legislative support. In March 2015, a bi-partisan bill was introduced to the United States House of Representatives and the United States Senate called the Compassionate Access, Research Expansion, and Respect States Act of 2015 (“CARERS Act”).¹⁵³ The CARERS Act would provide access to medical marijuana, and further enable research into the medicinal properties of the drug.¹⁵⁴ Some recommendations of the CARERS Act include (a) rescheduling marijuana from a Schedule I to a Schedule II controlled substance; (b) excluding CBD from the definition of marijuana when it contains no greater than 0.3% THC; and (c) promoting research by allowing experts to access the drug to conduct tests and clinical trials.¹⁵⁵

As of Spring 2015, the Senate assigned the bill to a committee with sixteen sponsors.¹⁵⁶ In the House, the bill has the bipartisan support of seventeen sponsors.¹⁵⁷ However, both bills seem to be languishing in committee, as

¹⁵² German Lopez, *Poll: The Only Drug Americans Want to Legalize is Marijuana*, VOX (March 15, 2016, 9:00 AM), <http://www.vox.com/2016/3/15/11224500/marijuana-legalization-war-on-drugs-poll> [<http://perma.cc/WH4X-KHTC>].

¹⁵³ Compassionate Access, Research Expansion, and Respect States Act of 2015, S. 683, 114th Cong. (2015), <https://www.congress.gov/bill/114th-congress/senate-bill/683> [<https://perma.cc/AHS5-6MY2>].

¹⁵⁴ *Id.*

¹⁵⁵ S. REP. NO. 114-161, No. 40, at S1385-86 (2015), <https://www.congress.gov/congressional-record/2015/03/10/senate-section/article/S1385-1> [<https://perma.cc/MJB8-RGMW>].

¹⁵⁶ S. 683: *CARERS Act of 2015*, GOVTRACK.US (Mar. 10, 2015), <https://www.govtrack.us/congress/bills/114/s683> [<https://perma.cc/47MS-JCW7>]; The Editorial Board, *Congress and Obama are Too Timid on Marijuana Reform*, N.Y. TIMES (Aug. 8, 2015), http://www.nytimes.com/2015/08/09/opinion/sunday/congress-and-obama-have-been-too-timid-on-marijuana-reform.html?_r=1 [<https://perma.cc/5JCJ-KRLP>].

¹⁵⁷ The Editorial Board, *Congress and Obama are Too Timid on Marijuana Reform*, N.Y. TIMES (Aug. 8, 2015), http://www.nytimes.com/2015/08/09/opinion/sunday/congress-and-obama-have-been-too-timid-on-marijuana-reform.html?_r=1 [<https://perma.cc/5JCJ-KRLP>].

Congress has not yet scheduled for a hearing or a vote.¹⁵⁸ Though passing the CARERS Act would not repeal the federal ban on marijuana, “it is a big step in the right direction.”¹⁵⁹

B. *The DEA’s Ability to Reschedule Marijuana*

Another option to advance research on the medicinal benefits of marijuana would be to leverage the DEA to reschedule it. Under the CSA, the Attorney General may initiate proceedings to add, delete, or change the schedule of a drug or substance if evidence shows that it does not fit the Schedule to which it has been assigned.¹⁶⁰ However, in determining whether to reschedule a drug the DEA must consider, “scientific evidence of the drug’s pharmacological effect, if known,” and “the state of current scientific knowledge regarding the drug or other substance.”¹⁶¹ Indeed, in April 2016, the DEA released a letter to United States senators, signed by acting DEA Administrator, Chuck Rosenberg, that it plans to decide on whether marijuana should be reclassified in the first half of 2016.¹⁶² Such a decision is spawned by the FDA’s review of medical evidence surrounding the safety and effectiveness of marijuana, and its rescheduling recommendation made to the DEA, which is not yet available for public review.¹⁶³ DEA action to reschedule marijuana in 2016 would be a historical change to its previous position.

For instance, in the 2013 case, *Americans for Safe Access v. DEA*, the Coalition to Reschedule Cannabis petitioned the DEA to reschedule marijuana to a Schedule III, IV, or V drug.¹⁶⁴ The Court of Appeals for the D.C. Circuit held that not enough evidence existed to reschedule marijuana, despite some evidence of its medical potential, and the court upheld the DEA’s denial of the petitioner’s request.¹⁶⁵ The court deferred to the agency’s judgment in deciding that marijuana does not have a “currently accepted medical use,” which requires

¹⁵⁸ *Id.*

¹⁵⁹ The Editorial Board, *A Sensible Bill on Medical Marijuana*, N.Y. TIMES (March 11, 2015), http://www.nytimes.com/2015/03/11/opinion/a-sensible-bill-on-medical-marijuana.html?_r=0 [https://perma.cc/X3JT-ZFK3].

¹⁶⁰ 21 U.S.C. § 811(a) (2012).

¹⁶¹ 21 U.S.C. § 811 (c)(2)-(3).

¹⁶² Matt Ferner, *DEA Plans to Decide Whether to Reschedule Marijuana by Mid-Year*, HUFFPOST POLITICS (April 5, 2016, 10:46 PM), http://www.huffingtonpost.com/entry/dea-marijuana-reschedule_us_5704567de4b0537661881644 [https://perma.cc/L2GK-9PX3].

¹⁶³ *Id.*

¹⁶⁴ *Americans for Safe Access v. DEA*, 706 F.3d 438, 440 (D.C. Cir. 2013) (“The CSA permits the DEA to reclassify drugs to less restrictive schedules according to various statutory criteria, and interested parties can petition the DEA for such action”). *See also* Steven Wishnia, *Is Marijuana Close to being Legalized?*, SALON (Oct. 15, 2012), http://www.salon.com/2012/10/15/is_marijuana_close_to_being_legalized/ [https://perma.cc/CR47-W7K6].

¹⁶⁵ *Americans for Safe Access*, 706 F.3d at 441.

“adequate and well-controlled studies proving efficacy.”¹⁶⁶

To assess whether a “currently accepted medical use” exists the court requires consideration of five factors: (1) The drug’s chemistry must be known and reproducible; (2) it must have adequate safety studies; (3) adequate well-controlled studies proving efficacy must exist; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.¹⁶⁷ A drug’s effectiveness must be established in “well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients.”¹⁶⁸ As the court in *Safe Access* clarifies, peer-reviewed studies are not enough to establish that a study is also “adequate and well-controlled.”¹⁶⁹

C. Opposition to Marijuana Legalization

Critics fear that federally recognizing the medical benefit of marijuana will increase addiction rates, and increase injuries and deaths from impaired cognition, especially while driving.¹⁷⁰ However, many of the FDA’s most effective medications are also dangerous and highly addictive. For instance, opiates, such as morphine and codeine, are both abused and used to great medical benefit.¹⁷¹ Though opioids are subject to strict regulation, “including quotas on the amount that can be legally manufactured,” and “signals to physicians that a drug has abuse potential” they are demonstratively more dangerous than marijuana.¹⁷²

Since the late 1990s, the number of people dying from opioid painkillers has steadily risen, with more than 16,000 deaths reported in 2013.¹⁷³ Additionally, a 2015 study by the CDC found 45% of people who used heroin were also addicted to prescription painkillers.¹⁷⁴ Interestingly, states that have legalized medicinal

¹⁶⁶ *Id.* at 440-41. *See* Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). *See also* MD Pharma., Inc. v. DEA, 133 F.3d 8, 16 (D.C. Cir. 1998) (“We will not disturb the decision of an agency that has ‘examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made’”).

¹⁶⁷ *Americans for Safe Access*, 706 F.3d at 441.

¹⁶⁸ *Id.* at 450.

¹⁶⁹ *Id.* at 451-52 (“[W]here the court reasons that peer-reviewed, published studies, suggesting marijuana’s medical efficacy do not past muster to be considered “adequate and well-controlled”).

¹⁷⁰ *Top Ten Reasons Not to Legalize “Medical” Marijuana*, DRUG FREE AMERICA FOUNDATION, <http://dfaf.org/assets/docs/Top%20Ten%20Reasons%20Not%20to%20Legalize%20color%20block%20style.pdf> [<https://perma.cc/26YE-6NLG>].

¹⁷¹ INSTITUTE OF MEDICINE, *supra* note 15, at 101.

¹⁷² *Id.* at 102.

¹⁷³ Lopez, *supra* note 123.

¹⁷⁴ *Today’s Heroin Epidemic*, CDC (July 7, 2015),

marijuana have seen a 25% reduction in deaths caused by prescription painkillers, a statistic that is largely attributed to people choosing marijuana instead of harsher alternatives.¹⁷⁵ Such statistics provide further support for advancing research on the medicinal benefits of marijuana: If it can be proven that marijuana can relieve pain, it can substitute opioid painkillers.¹⁷⁶

The FDA also has concerns regarding developing medicines derived from botanicals. For instance, in deciding whether an investigational drug meets the requisite safety and efficacy standards for approval, manufacturers must demonstrate that a drug may be consistently manufactured and dosed.¹⁷⁷ There are specific challenges that arise when a drug is derived from a botanical source, such as the variance with which the product may be developed, and whether the source is from a single plant or a combination of different plants.¹⁷⁸ Therefore, in accordance with the IOM's recommendations for advancing marijuana research, the FDA recognizes that clinical trials involving marijuana should be conducted with the goal of developing appropriate dose levels, and safe delivery systems as an alternative to smoking marijuana.¹⁷⁹

Proper dosing, and potency of cannabis-based treatments is of great concern even in states where medical marijuana is legal. Even Colorado passed a law in 2014 that barred licensed labs from testing marijuana products unless they came from a commercial grower or seller.¹⁸⁰ Therefore, home-growers, like Brian Wilson mentioned *supra*¹⁸¹ who buys and cooks his daughter's cannabis oil with recipes shared from other patients is "flying blind" without the ability to test its potency.¹⁸² Without FDA approved products, developers are left in a mix of trial and error to figure out what variance of botanical product works best.

<http://www.cdc.gov/vitalsigns/heroin/index.html> [<https://perma.cc/P45P-2MFA>].

¹⁷⁵ Marcus A. Bachhuber et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010*, 174 JAMA INTERNAL MEDICINE 1668-73 (2014), <http://archinte.jamanetwork.com/article.aspx?articleid=1898878> [<https://perma.cc/SBE7-4Q7V>]; Sandra Young, *Medical marijuana laws may reduce painkiller overdoses*, CNN (Aug. 26, 2014, 3:24 PM), <http://www.cnn.com/2014/08/25/health/medical-marijuana-overdose-deaths/> [<https://perma.cc/Z3AT-2>]; Jackson Marciana et al., *Medical Marijuana States See Painkiller Drops by 25%*, COUNTER CURRENT NEWS (Aug. 11, 2015, 9:15 PM), <http://countercurrentnews.com/2015/08/medical-pain-drop-by-25-percent/#> [<https://perma.cc/AB52-7349>].

¹⁷⁶ Lopez, *supra* note 123.

¹⁷⁷ Throckmorton, *supra* note 122.

¹⁷⁸ *Id.*; see generally U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY BOTANICAL DRUG PRODUCTS (2004), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070491.pdf> [<https://perma.cc/JWF8-22QA>].

¹⁷⁹ Throckmorton, *supra* note 122; see generally U.S. FOOD & DRUG ASS'N, *supra* note 178.

¹⁸⁰ Livo, *supra* note 1.

¹⁸¹ See *id.*

¹⁸² *Id.*

Researching and subsequently developing products effective in treatment would alleviate these concerns.

As demonstrated, many critics disagree with the categorization of marijuana as a Schedule I substance, and deplore the consequences of this categorization on research.¹⁸³ For instance, Dan Riffle, the Director of Federal Policies at the marijuana Policy Project, has commented that recognizing marijuana as being as dangerous as the drugs that share its Schedule I connotation is “ludicrous.”¹⁸⁴ Despite the assertion by Rosenberg in August 2015 that “heroin [a Schedule I substance] is clearly more dangerous than marijuana,” the DEA has yet to entertain the idea of rescheduling marijuana, until now in 2016.¹⁸⁵ Tamar Todd, a staff attorney for the Drug Policy Alliance, argues “the DEA [says] that marijuana needs FDA approval to be removed from Schedule I, but . . . they are obstructing that very research. While there is a plethora of scientific evidence establishing marijuana’s safety and efficacy, the specific clinical trials necessary to gain FDA approval [are] obstructed by the government.”¹⁸⁶

V. CONCLUSION

As demonstrated, the current process for how federally supported research must be conducted on marijuana creates a catch-22 in regard to discovering evidence of marijuana’s potential healing effects. “The DEA has argued for decades that there is insufficient evidence to support rescheduling marijuana, or the medical use of marijuana. At the same time, it has along with the National

¹⁸³ Christopher Ingraham, *The Government Is Stifling Medical Marijuana Research, Major Think Tank Declares*, THE WASHINGTON POST (Oct. 20, 2015), <https://www.washingtonpost.com/news/wonk/wp/2015/10/20/the-federal-government-is-stifling-medical-research-major-think-tank-declares/> [<http://perma.cc/8TPS-2A8Q>]; see also Jacob Sullum, *More Than Zero: Reclassifying Marijuana Could Have a Significant Impact on Drug Policy*, FORBES (Feb. 7, 2014, 7:00 AM), <http://www.forbes.com/sites/jacobsullum/2014/02/07/more-than-zero-reclassifying-marijuana-would-have-a-significant-impact-on-drug-policy/> [<https://perma.cc/SE3S-U984>] (“Rescheduling marijuana might make it easier to conduct research on the plant’s medical utility, which could lead to cannabis-derived medications that would past muster with the FDA”).

¹⁸⁴ Pardes, *supra* note 106.

¹⁸⁵ Matt Ferner, *New DEA Chief: ‘Heroin is Clearly More Dangerous Than Marijuana,’* HUFFPOST POLITICS (Aug. 5, 2015, 4:49 PM), http://www.huffingtonpost.com/entry/dea-chief-marijuana-heroin-danger_55c25079e4b0f7f0bebb4ef5 [<https://perma.cc/M4EL-YXF4>]; but see Michael Harthorne, *DEA Chief in Hot Water After Calling Pot a ‘Joke,’* Newser (Nov. 20, 2015, 4:17 PM), <http://www.newser.com/story/216404/dea-chief-in-hot-water-after-calling-medical-pot-a-joke.html> [<https://perma.cc/TZQ7-WTQX>]. Ferner, *supra* note 162.

¹⁸⁶ P. Smith, *DC Appeals Court Denies Marijuana Rescheduling*, STOP THE DRUG WAR (Jan. 23, 2013, 9:00 PM), http://stopthedrugwar.org/chronicle/2013/jan/23/dc_appeals_court_denies_marijuan [<https://perma.cc/448K-M26F>].

Institute on Drug Abuse acted in a manner intended to systematically impede scientific research.”¹⁸⁷ However, the FDA acknowledges the considerable interest among its constituents regarding the use of botanical marijuana to treat medical illnesses.¹⁸⁸ Accordingly, the FDA’s attitude towards the medical benefits of marijuana is shifting. In June 2015 Dr. Douglas C. Throckmorton, Deputy Director for Regulatory Programs at the FDA’s Center for Drug Evaluation and Research spoke before the Senate’s Caucus on International Narcotics Control about the FDA’s role in regulating cannabinoid research for potential medical uses.¹⁸⁹ He indicated that “the drug approval process [is] the best way to help ensure that new medicines, including . . . medicines derived from cannabidiol . . . are appropriately reviewed” and consistent with the FDA’s requirements.¹⁹⁰

Though the FDA has yet to recognize the medicinal benefit of botanical marijuana it is not completely unresponsive of advancing research on its medicinal benefits.¹⁹¹ Especially considering the reasons behind marijuana’s prohibition, and its possible healing potential, leveraging lawmakers to reschedule marijuana from a Schedule I substance, and to subsequently remove the hurdles impeding research will create the opportunity to properly discover whether there is true medicinal potential in marijuana for which U.S. citizens may benefit.

¹⁸⁷ DRUG POLICY ALLIANCE, *supra* note 19, at 2.

¹⁸⁸ *See generally id.*

¹⁸⁹ Throckmorton, *supra* note 122.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*