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Reclassifying Cannabis as a Schedule III Drug

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This essay explores the statutory framework of the federal Controlled Substances Act (CSA) and its classification of cannabis as a Schedule I drug. It is impossible to discuss the federal prohibition cannabis without discussing its United States drug control history. Cannabis did not become an alleged social problem until around 1910, when reports emerged that Mexican immigrants and African Americans in Texas and New Orleans, Louisiana, respectively, were using the drug.[1] The name "cannabis" was shifted to "marijuana" in order to associate the drug with Mexican immigrants.[2] The history of cannabis in the U.S. is tied to music, specifically jazz musicians.[3] There was a fear that the jazz musicians would use the drugs to seduce white women.[4] In the 1920s to 1930s the states started to outlaw cannabis.[5]

Federal prohibition of cannabis starts with Harry J. Anslinger, who was the first head of the Federal Bureau of Narcotics (FBN). Anslinger was a racist that associated "dangerous" drug use with minoritized Americans.[6] He facilitated a large disinformation campaign to advance the narrative that cannabis caused people to go crazy.[7] Following Anslinger's lead, government officials ignored science and research on cannabis out of fear of the American culture becoming "blackened."[8]

FBN advocated for the Uniform Narcotic Drug Act of 1932 and facilitated the enactment of the Marijuana Tax Act of 1937.[9] These laws were the precursors to federal prohibition of cannabis.[10] FBN worked alongside the National Conference of the Commissioners on Uniform

[1] GRASS IS GREENER (Netflix 2019).
[2] *See id*.
[3] *See id*.
[4] *See id*.
[5] GRASS IS GREENER, *supra* note 1.
[6] *See id*.
[7] *See id*.
[8] *See id*.
[9] DOUGLAS A. BERMAN. & ALEX KREIT, MARIJUANA LAW AND POLICY 139-140 (2020).
[10] *See id*.

State Laws (NCCUSL)[11] to draft the Uniform Narcotic Drug Act.[12] The annual proceedings of the Commissioners show that the Commission did not undertake a scientific study of any kind to inform the cannabis section of the Uniform Narcotic Drug Act.[13] In their 1970 law review article, Richard J. Bonnie and Charles H. Whitebread II, suggest that Congress was "hoodwinked" into passing the Marijuana Tax Act by the FBN and its campaign of public hysteria surrounding cannabis.[14]

Congress outlawed cannabis with the passage of the CSA in 1970 as part of the War on Drugs.[15] President Nixon, who signed the CSA into law, feared social and political movements of the time were a threat to his presidency.[16] He created the DEA by executive order and expanded law enforcement for crimes related to illegal drugs.[17]

The CSA classifies controlled substances into one of five schedules.[18] Schedule I drugs are banned illegal substances that cannot be used outside a federally-approved research study.[19] Schedule II-V drugs have legitimate medical uses and, as such, can be prescribed by a physician for use.[20] Nixon commissioned a report, called the Shafer Report, to assess the dangerousness of cannabis.[21] The results of the report were so controversial that members of the Shafer Commission held a televised event to discuss their findings.[22] During this event, the members of the Commission explained there the public had been inundated with widespread cannabis

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[11] James J. White, *Symposium: One Hundred Years of Uniform State Laws: Ex Proprio Vigore*, 89 MICH. L. REV. 2096, 2096 (1991).
[12] MARIJUANA LAW AND POLICY, *supra* note 9.
[13] *See id*.
[14] *See id*.
[15] *See* GRASS IS GREENER, *supra* note 1.
[16] *See id*.
[17] Jeff Karberg, *Note: Progress in the Challenge to Regulate Online Pharmacies*, 23 J.L. & HEALTH. 113, 121 (2010).
[18] MARIJUANA LAW AND POLICY, *supra* note 9.
[19] *See* GRASS IS GREENER, *supra* note 1.
[20] *See id*.
[21] *See id*.
[22] *See id*.

misinformation and that they wanted to "demythologize" the drug.[23] The Commission members reported that occasional marijuana use does not do any physical harm and may not do any psychological harm.[24] As such, the report ultimately recommended decriminalizing small amounts of cannabis.[25] Nixon and his administration, however, ignored that proposal and, instead, doubled down on cannabis criminalization.[26] Nixon made it clear that he would continue to thwart efforts to legalize cannabis and push for harsh penalties for cannabis possession and use.[27]

This paper proceeds in six parts. Part I discusses the rescheduling process that needs to take place in order to reschedule drugs listed in the CSA. Part II describes what criteria is used to determine how drugs are scheduled on the Schedule I drug list in the CSA, as well as the misplacement of cannabis on the Schedule I list. As the section details, cannabis has a low potential for abuse; cannabis has known and accepted medical uses, and there are even FDA approved drugs derived from cannabis; the DEA medical use factors are satisfied as applied to cannabis; there is accepted safety for use of the drug under medical supervision. Therefore, cannabis does not belong on Schedule I of the CSA.

Part III describes what criteria is used to determine the placement of a drug on the Schedule III list of the CSA and why cannabis belongs on Schedule III. Part IV looks at the Marijuana Opportunity Reinvestment and Expungement Act (MORE) and its implications for full cannabis legalization. Part V argues that rescheduling cannabis will allow for increased medical usage and greater opportunities for research. This section also discusses why the FDA, as a regulatory body, is more suited to handle the rescheduling process of the CSA, rather than

[23] *See id.*
[24] *See id.*
[25] *See id.*
[26] *See id.*
[27] *See id.*

the DEA. This Article concludes arguing for removal of cannabis as a Schedule I drug as the first step towards full legalization. This paper does not argue that cannabis should not be fully decriminalized in time, but rather, rescheduling cannabis is the first step in the process to full legalization.

I. The Rescheduling Process

The DEA controls the scheduling and rescheduling of drugs on the CSA schedules.[28] There is, however, shared authority between the Food and Drug Administration (FDA), the DEA, the Secretary of Health and Human Services (HHS), and the Attorney General (AG) in the scheduling decision process.[29] The process starts with either an interested outside party or the Secretary of HHS filing a petition to reschedule the drug or substance with the AG.[30]

Before the AG can reschedule any controlled substance it must request a scientific and medical evaluation and scheduling recommendation from the Secretary.[31] The CSA requires the consideration of eight statutory factors to determine the appropriate schedule for a substance.[32] The DEA has narrowed this analysis to five factors, and this paper will discuss those factors in its Schedule I analysis.[33] The CSA also requires the Secretary to make a scheduling recommendation, which in turn means the FDA (on behalf of the Secretary) must, provide its

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[28] *The Controlled Substances Act*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/csa#:~:text=S.C.,The%20manufacturer%20of%20a%20drug (last visited April 5, 2022).
[29] Rebecca S. Eisenberg & Deborah B. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD DRUG L.J., 246, 256-257 (2019).
[30] John Hudak and Grace Wallack, *How to reschedule marijuana, and why it's unlikely anytime soon*, BROOKINGS., (Feb. 13, 2015) https://www.brookings.edu/blog/fixgov/2015/02/13/how-to-reschedule-marijuana-and-why-its-unlikely-anytime-soon/
[31] Leiderman, *supra* note 29 at 256-258.
[32] *See id*. There are eight statutory factors to be considered with the rescheduling of a drug: (1) Its actual or relative potential for abuse; (2) Scientific evidence of its pharmacological effect, if known; (3) The state of current scientific knowledge regarding the drug or other substance; (4) Its history and current pattern of abuse; (5) The scope, duration, and significance of abuse; (6) What, if any, risk there is to the public health; (7) Its psychic or physiological dependence liability; (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.
[33] *See id*.

evaluation of whether a substance has a currently accepted medical use in the United States.[34] The AG will then review the FDA's recommendations to determine if a drug should be rescheduled .[35] The AG will initiate a rulemaking proceeding for rescheduling if it finds that there is substantial evidence that the given drug should be rescheduled.[36]The FDA has recently approved multiple drugs whose active ingredients are synthetic cannabinoids and this paper discusses those products in the following section.

II. Cannabis as a Schedule I Drug

According to the CSA, "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance."[37] To place a drug on Schedule I, the findings required are as follows: (1) the drug or other substance has a high potential for abuse; (2) the drug or other substances has no currently acceptable medical uses in treatment in the United States; (3) there is a lack of accepted safety for use of the drug or other substance under medical supervision. This section explores why these elements are not satisfied as applied to cannabis.

The first prong of the required findings describes a Schedule I substances as drugs that have a "high potential for abuse."[38] There is substantial disagreement, however, whether cannabis has a high potential for abuse. Much like the Shafer Report, the case law acknowledges that there is mass misinformation about cannabis and its dangers.[39] Studies demonstrate that heavy use of cannabis does not result in physical dependence on tetrahydrocannabinol (THC) [40],

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[34] *See id*.
[35] Wallack, *supra* note 30.
[36] *See id*.
[37] 21 U.S.C. § 812(b); DOUGLAS A. BERMAN. & ALEX KREIT, MARIJUANA LAW AND POLICY 56 (2020).
[38] *See id*.
[39] United States v. Kiffer, 477 F.2d 355-357 (2d Cir. 1973).
[40] Annaliese Smith, *Comment: Marijuana as a Schedule I Substance: Political Ploy or Accepted Science?*, 40 SANTA CLARA L. REV. 1137, 1143 (2000).

the chemical in cannabis responsible for psychoactive reactions.[41] Scholars have observed that marijuana is not associated with death like other drugs.[42] In fact, there has never been a recorded death from a cannabis overdose.[43] A cannabis user needs to ingest cannabis at thousands of times the average dose in order to overdose.[44] Marijuana use can cause an increase in heart rate or blood pressure but these cardiovascular effects are unlikely to be of clinical significance.[45]

The *American Journal of Emergency Medicine* reported that lifetime use of marijuana is rarely associated with emergency room visits.[46] For the few marijuana users that do develop THC dependence, such dependence appears to be less severe than dependence on other drugs.[47] The World Health Organization has taken the position that the risks of marijuana are small and unlikely to produce public health problems of the scale of other drugs like alcohol and tobacco.[48]

A 2005 University of Oxford study determined that there is little evidence that long term cannabis use causes permanent cognitive impairment.[49] Similar to this finding, researchers have suggested that marijuana can induce acute memory-related brain inhibition, but that does not necessarily mean that memory loss will persist after a period of abstinence.[50] Some studies suggest that about a month of abstinence can reverse cognitive deficiencies in chronic cannabis users.[51]

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[41] Susan R.B. Weiss et al., *Building Smart Cannabis Policy from the Science Up*, INT'L J DRUG POLICY 39, 42 (2017).
[42] Peter J. Cohen, *Symposium: Drugs, Addiction, Therapy, and Crime: Medical Marijuana: The Conflict Between Scientific Evidence and Political Ideology*, 2009 UTAH L. REV. 35, 55 (2009).
[43] DOUGLAS A. BERMAN. & ALEX KREIT, MARIJUANA LAW AND POLICY 48 (2020).
[44] *See id*.
[45] *See id*.
[46] *Id*. at 49.
[47] *See id*.
[48] *Id*. at 48.
[49] *See id*.
[50] Cohen, *supra* note 42 at 58.
[51] Weiss et al., *supra* note 41 at 49.

There are, however, contradictory studies that suggest that cannabis has a potential for abuse. Leigh v. Panlilio et al., suggest in their article, *Screening and Evaluation of Medications for Treating Cannabis Use Disorder*, that there is a lack of attention on cannabis dependency due to the devastating effects of other abusive drugs like opioids or nicotine.[52] Also, marijuana dependence is often kept a secret.[53] Cannabis withdrawal syndrome is classified as a mental disorder.[54] This classification highlights the fact that cannabis relapse is associated with greater withdrawal symptoms.[55] Only a subset of cannabis users will develop Cannabis Use Disorder.[56] Cannabis activates the brain chemical dopamine, which is a chemical that makes people feel happy.[57] For young people, it is possible to feel withdrawal from this dopamine hit, and such withdrawal could lead to lower self-esteem and negative mood swings thereby creating cannabis dependance.[58]

Approximately 9% of individuals that have reported using cannabis develop dependence or addiction.[59] In juxtaposition, between 8% to 12% of people who take prescription opioids develop opioid use disorder.[60] In the mid-2010s, tens of thousands of people overdosed from heroin and other opioids.[61] There are more people admitted to emergency rooms for cocaine use

[52] Leigh V. Panlilio, *Screening and Evaluations of Medications for Treating Cannabis Use Disorder*, INT'L REV. NEUROBIOLOGY 87, 92 (2016).
[53] Shivika Datta et al., *Wonder or evil?: Multifaceted health hazards and health benefits of Cannabis sativa and its phytochemicals*, SAUDI JOURNAL OF BIOLOGICAL SCIENCES 7291, 7307 (2021).
[54] Panlilio, *supra* note 52 at 94.
[55] *Id*.
[56] Weiss et al., *supra* note 41 at 46.
[57] *Id*. at 11.
[58] Datta et al. *supra* note 53.
[59] Weiss et al. *supra* note 41 at 46.
[60] *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE (March 11, 2021), https://nida.nih.gov/drug-topics/opioids/opioid-overdose-crisis#:~:text=Between%208%20and%2012%20percent,develop%20an%20opioid%20use%20disorder.
[61] MARIJUANA LAW AND POLICY, *supra* note 9 at 59.

than any other drug.[62] Opioids and cocaine, however are classified CSA Schedule II drugs while cannabis remains on Schedule I.[63]

Ingestion of high doses of cannabis can produce an acute psychotic reaction, which resolves once the intoxication wears off.[64] Studies are inconsistent when it comes to the association between adverse mental outcomes and cannabis use.[65] While links between cannabis and schizophrenia have been replicated, the evidence suggests that most cannabis users do not develop schizophrenia.[66]

Scientists conduct rodent research to mimic periodic adolescent use of cannabis.[67] The results of those studies indicate that adult rates with low to moderate THC exposure during adolescence exhibit enhanced heroin self-administration.[68] The researchers noted, however, that vulnerability to THC exposure can be explained from certain high-risk genotypes.[69] In other words, individuals with certain genes may be predisposed to having addictive traits.

Medical cannabis participants report reduced use of prescription opioids in individuals with opioid use disorder (OUD).[70] These findings have prompted a push for medical cannabis for patients with OUD, but more research needs to be conducted.[71] In sum, cannabis research teaches that the potential for cannabis abuse is moderate when compared to other drugs, including drugs that are lower on the federal schedule.

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[62] *Addiction statistics*, ADDICTION CTR., (November 23, 2021), https://www.addictioncenter.com/addiction/addiction-statistics/
[63] MARIJUANA LAW AND POLICY, *supra* note 9 at 57.
[64] Cohen, *supra* note 42 at 58-59.
[65] *Id*.
[66] Weiss et al., *supra* note 41 at 47.
[67] Arthur Robin Williams, *Cannabis as a Gateway Drug for Opioid Use Disorder*, J LAW MED ETHICS, 268, 272 (2020).
[68] *Id*.
[69] *See id*.
[70] *See id* at 273.
[71] *See id*.

The second prong of the CSA Schedule I criteria is that the drug at issue have "no accepted medical use in treatment in the United States."[72] This is significant because cannabis has many known and accepted medical uses.[73] As such, this prong does not apply to cannabis. The Drug Enforcement Agency (DEA) has developed a list of five criteria that it considers when evaluating whether a drug has an accepted medical use.[74] Those factors are whether: (1) the drug's chemistry is known and reproducible; (2) there are adequate safety studies; (3) there are adequate and well-controlled studies proving efficacy; (4) the drug is accepted by qualified experts; and (5) the scientific evidence is available.

A. The Drug's Chemistry Must be Known and Reproducible

A potential problem with satisfying first component of the five-factor test—that the drug's chemistry must be known and reproducible—is the difficulty with reproducing cannabis.[75] The drug's chemical properties, however, are known and well documented.[76]

A recent article published by the Multidisciplinary Publishing Institute (MPI) gives an overview of the chemical makeup of cannabis.[77] It explains that, "Cannabis sativa, a member of herbaceous Cannabaceae family of plants, produces more than 568 unique compounds, of which more than 100 belong to the unique class of phytocannabinoids. These are organic molecules with a polyphenolic structure."[78] The article goes on to describe what phytocannabinoids are,

[72] MARIJUANA LAW AND POLICY, *supra* note 9 at 56.
[73] *Id*. at 413-421
[74] Smith, *supra* note 40 at 1154.
[75] Leiderman, *supra* note 29 at 263.
[76] Yi Yank et al., *Bioactive Chemical Composition of Cannabis Extracts and Cannabinoid Receptors.* MULTIDISCIP PUB INST., 3466, 3467 (2020).
[77] Yank, *supra* note 75.
[78] *See id*.

"such as, tetrahydrocannabinol (THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCA), and cannabidiolic acid (CBDA)".[79]

The problem is that different compositions of phytocannabinoids have widely varying ranges of biological and psychological responses.[80] An example of this variation would be that the THC content in cannabis can range from 0.14% to more than 25% depending on the concentration of phytocannbinoids from plant to plant.[81] Moreover, the pharmacological responses produced by cannabis or cannabis extracts are different from those of a single phytocannabinoid.[82]

A possible way to circumvent this issue is to point to the use of cannabinoids in treating epilepsy. In June 2018, the FDA approved Epidiolex, which is a cannabidiol oral solution that treats Lennox-Gastaut Syndrome (LGS) and Dravet syndrome (DS).[83] LGS and DS are rare epileptic disorders.[84]

Epidiolex is the first FDA-approved drug that contains a purified substance derived from cannabis.[85] Well-controlled clinical studies supported Epidiolex's approval to treat epilepsy.[86] The FDA contends that prescribers, "can have confidence in the drug's uniform strength and consistent delivery that appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes."[87]

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[79] *See id*.
[80] *See id*.
[81] *See id*.
[82] *See id*.
[83] Rhys H Thomas et al., *Cannabis and epilepsy: what you need to know*, PRACT NEUROL., 465, 466 (2018).
[84] Doven Lazaridis et al., *Treatment of Seizures Associated with Lennox-Gastaut and Dravet Syndromes: A Focus on Cannabidiol Oral Solution*, PT, 255, 255 (2019).
[85] Thomas et al., *supra* note 81 at 467.
[86] *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy*, U.S. FOOD AND DRUG ADMIN., (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms
[87] *Id*.

Besides Epidolex, the FDA has approved three cannabis-related drug products:[88] Marinol, Syndros, Cesamet.[89] These products are synthesized from cannabinoids, meaning that they are man-made to mimic the structure of cannabis chemicals.[90] These mimics, however, do not always produce the same effects as natural cannabis.[91] Marinol and Syndros contain dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC).[92] Both drugs are used to treatment anorexia associated with weight loss in AIDS patients.[93] Cesamet contains nabilone, which a synthetically derived substance similar to THC.[94] Cesamet treats nausea and vomiting associated with cancer chemotherapy.[95]

B. There Must be Adequate Safety Studies; There Must be Adequate and Well-Controlled Studies Proving Efficacy

These two factors in the medical use analysis are grouped together because they are inextricably intertwined.[96] The DEA has explained that, "a determination that a drug is ineffective is tantamount to a determination that it is unsafe."[97]

Research proves that cannabis has neuroprotective properties, which means it protects brain cells from harm.[98] Studies demonstrate that cannabis can reduce the likelihood of head and

[88] *FDA Regulation of Cannabis and Cannabis-Derived Products Including Cannabidiol (CBD)*, U.S. FOOD AND DRUG ADMIN. (Jan, 1, 2022), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#:~:text=Cannabis%20is%20a%20plant%20of,)%20and%20cannabidiol%20(CBD).
[89] *Id*.
[90] *Synthetic Cannabinoids (K2/Spice) Drug Facts*, NAT'L INST. ON DRUG ABUSE, https://nida.nih.gov/publications/drugfacts/synthetic-cannabinoids-k2spice (last visited April 28, 2022).
[91] *Id*.
[92] *Clinical Pharmacy Program Guidelines for Cesamet, Marinol, Syndros*, UHC PROVIDER, 1, 1 (2020).
[93] *See id*.
[94] *See id*.
[95] *See id*.
[96] Leiderman, *supra* note 29 at 258.
[97] *Id*.
[98] MARIJUANA LAW AND POLICY, *supra* note 9 at 48.

neck cancer.[99] The drug also is effective in reducing nausea, vomiting, and muscle spasms.[100] The most common conditions for which medical cannabis is used are pain, spasticity associated with multiple sclerosis, post-traumatic stress disorder, cancer, epilepsy, cachexia, cachexia glaucoma, HIV/AIDS, and degenerative neurological conditions.[101]

The National Academies of Sciences, Engineering, and Medicine (NAS) reported findings from thirty-seven studies assessing the efficacy for cannabis or cannabinoids.[102] The NAS concluded that cannabis is an effective method of treatment for a number of medical ailments.[103]

Congress presupposed that cannabis had no therapeutic medical uses when it placed the drug on Schedule I in 1970.[104] Ironically, classifying a drug as a Schedule I list makes researching it potential medical uses exceedingly difficult.[105] Researchers who want to conduct research on cannabis have to navigate a series of review processes.[106]

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[99] *Id*.
[100] Smith, *supra* note 40 at 1158.
[101] MARIJUANA LAW AND POLICY, *supra* note 9 at 413.
[102] *Id*.
[103] *See id*. at 413-421. There is substantial evidence that cannabis is an effective treatment for chronic pain in adults. There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting. There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS. There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity. There is limited evidence that THC capsules are an effective treatment for improving symptoms of Tourette syndrome. There is limited evidence that cannabinoids are ineffective treatments for improving the symptoms associated with dementia. There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma. There is limited evidence of a statistical association between cannabinoids and better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage. There is limited evidence that cannabidiol is an effective treatment for the improvement of anxiety symptoms, assessed by a public speaking test, in individuals with social anxiety disorders. There is moderate evidence that cannabinoids, primarily nabiximols, are an effective treatment to improve short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, and multiple sclerosis. There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder.
[104] GRASS IS GREENER, *supra* note 1.
[105] THE NAT'L ACADEMIES OF SCIENCES, ENG., AND MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH, 378 (2017).
[106] *Id*.

These processes begin with a researcher submitting an investigation new drug (IND) application to the FDA.[107] In the next step, the investigator may contact the National Institute on Drug Abuse (NIDA), an important source of research-grader cannabis, to obtain an administrative letter of authorization (LOA).[108] An LOA describes the manufacturer's facilities and the availability and relevant characteristics of the desired cannabis product.[109] These characteristics include, strains quality, strength pharmacology, toxicology, etc.).[110] To safeguard against the acquisition of cannabis for non-research purposes, researchers also have to apply to the DEA for registration and site licensure before conducting any studies with cannabis or cannabis derived substance.[111] The researcher has to submit the IND and LOA to the FDA and the DEA for review.[112]

After submitting the applications, the researcher must wait at least 30 days before initiating research.[113] During this time the FDA reviews the application to ensure that the research participants will not be exposed to unreasonable risk.[114] If the FDA does determine that the proposed research would expose study participants to unreasonable risk or that there is another deficiency in the IND application, the research project can be put on hold.[115] The researcher will not be to be able to continue the research project until the deficiencies are resolved.[116]

In some states, researchers also have to apply for and receive a controlled substance certificate from a state board of medical examiners or a controlled substance registration from a

[107] *See id*. at 379.
[108] *See id*.
[109] *See id*.
[110] *See id*.
[111] *See id*.
[112] *See id*.
[113] *See id*.
[114] *See id*.
[115] *See id*.
[116] See id.

department of the state government.[117] The researchers can only apply for DEA registration and site licensure when the necessary approvals[118] have been secured from the state.[119]

Additionally, researchers need to submit a research protocol to the DEA that includes details regarding the security provisions for storing and dispensing the cannabis.[120] To ensure that the cannabis will be stored and accessed in accordance with the DEA security requirements, DEA officials may perform a preregistration inspection of the facility where the research will take place.[121] Researchers need to bear the costs of meeting these security requirements.[122]

There is yet another obstacle that researchers need to overcome in order to research cannabis, which is approval to conduct a human clinical trial.[123] The researchers need to get approval by an institutional review board showing the board that they have an appropriate plan to protect the rights and welfare of the human subjects.[124] If a study is being conducted in a clinical research center, a separate review may be required by this entity's medical or research advisory committee.[125]

These substantial layers of bureaucracy that emerge from trying to research a Schedule I substance have discouraged a number of cannabis researchers from apply for grant funding or pursuing additional research efforts.[126]

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[117] *See id*. at 380
[118] *See id*. Some state governments require additional approval, like California, that requires that all trials involving Schedule I or Schedule II controlled substances be registered with and approved by the Research Advisory Panel of California.
[119] *See id*.
[120] *See id*. at 381
[121] *See id*. DEA security requirements include storing cannabis in a safe, steel cabinet, or a vault, and limiting access to the storage facility to an absolute minimum number of specifically authorized employees.
[122] *See id*.
[123] *See id*.
[124] *See id*.
[125] *See id*.
[126] *See id*.

As a result, and although the NAS reported that cannabis's effectiveness in treatment for certain conditions was backed my "substantial evidence," cannabis's efficacy regarding the vast majority of the medical conditions discussed is suffered from "insufficient or no evidence upon which to base conclusion about therapeutic effects."[127] Consequently. the NAS stressed the need for more substantial research to provide comprehensive and conclusive evidence on the therapeutic effects of cannabis and cannabinoids.[128]

The NAS is not the only scientific enterprise that has called for more additional marijuana research. The Institute of Medicine published a report demanding more rigorous and systematic research into the potential medical benefits of cannabis.[129] Leading medical organizations, including the American Medical Association and the American Cancer Society, also have advocated for more research into the potential benefits of cannabis.[130]

Cannabis's classification as a Schedule I drug, in conjunction with the numerous unique federal rules regulating cannabis research, have long precluded large-scale scientific research as to the drug's therapeutic effects in the United States.[131] Scholars contend that rescheduling cannabis to at least Schedule II would make it possible for large pharmaceutical companies to conduct research on cannabis, including clinical trial.[132] It is possible for researchers to apply to the FDA and DEA for access to drugs on the Schedule I drugs.[133] The problem is that researchers must obtain the cannabis they study from a single federal facility created to legally cultivate cannabis for research studies[134] at the University of Mississippi.[135] Researchers argue that this

[127] MARIJUANA LAW AND POLICY, *supra* note 9 at 421-422.
[128] *See id*. at 422.
[129] *See id*.
[130] *See id*.
[131] *See id*.
[132] *See id*.
[133] *See id*.
[134] *See id*.
[135] *See id*.

limitation on cannabis supply has dramatically impeded legitimate research in the United States.[136]

In May 2021, the DEA announced that it is in the process of registering several additional American companies to produce cannabis for medical and scientific research.[137] Scientists will nonetheless continue to be proscribed under federal law, a notoriously slow process[138], from simply using the cannabis available at state-license dispensaries for their research.[139]

Dr. Lyle Craker, a prominent plant biologist, applied to grow cannabis for research purposes, and his application languished for years without approval.[140] He had to engage in a long court battle with the DEA in order to obtain the license. Another researcher, Dr. Sue Sisley, also received preliminary DEA approval to grow cannabis.[141] Dr. Sisley has observed that there are many varieties of cannabis that produce different clinical effects, and that variety is not available from the government supply of cannabis.[142]

The lone facility authorized to produce cannabis for research in Mississippi also has failed to produce a quality product. That cannabis has been described as "anemic" green powder that is very diluted.[143] Researchers do not have access to cannabis with varying concentrations of CBD and THC, or in different forms, like edibles and oils.[144] This is important because it means

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[136] *See id*.
[137] Will Stone, *After 50 Years, U.S. Opens the Door to More Cannabis Crops for Scientists*, NPR, https://www.npr.org/sections/health-shots/2021/05/30/1000867189/after-50-years-u-s-opens-the-door-to-more-cannabis-crops-for-scientists#:~:text=After%2050%20Years%2C%20U.S.%20Opens,More%20Cannabis%20Crops%20For%20Scientists&text=Angerer%2FGetty%20Images-,More%20than%2030%20states%20have%20medical%20marijuana%20programs%20%E2%80%94%20yet%20scientists,more%20growers%20to%20the%20mix (last visited April 3, 2022).
[138] *Id*.
[139] *See id*.
[140] *See id*.
[141] *See id*.
[142] *See id*.
[143] *See id*.
[144] *See id*.

that the research conducted on cannabis in the United States often does not translate to the kind of cannabis products that are used in the real world.[145] Scholars suggests that the biggest leap forward for research would be the down scheduling of cannabis from Schedule I.[146]

In fact, the United States House of Representatives recently passed bipartisan legislation, the Medical Marijuana Research Act, to permit scientists to access cannabis from state-legal dispensaries.[147] This Act removes barriers for researchers approved to study cannabis.[148] It sets clear deadlines for when federal agencies need to act on research applications and makes it easier for scientists to modify their research protocols without having to seek federal approval.[149] Proponents of the Act on both sides of the political aisle contend that its provisions will advance our understanding of the medical benefits of cannabis.[150]

There is also bipartisan agreement that the DEA has inhibited cannabis research through its inefficient application process.[151] As a result, the House Act mandates that the DEA license more growers and eliminates any restrictions on the number of additional entities that the DEA can registered to cultivate cannabis for research purposes.[152] It also eases the registration process.[153]

The Act further delegates to HHS and the AG the creation of rules to process facilitations between marijuana manufacturers and researchers.[154] It also requires HHS to submit a report to

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[145] *See id*.
[146] *See id*.
[147] Kyle Jaeger, *House Passes Bipartisan Marijuana Research Bill to Let Scientists Study Dispensary Products, Days After Legalization Vote*, MARIJUANA MOMENT, https://www.marijuanamoment.net/house-passes-bipartisan-marijuana-research-bill-to-let-scientists-study-dispensary-products-days-after-legalization-vote/#:~:text=The%20U.S.%20House%20of%20Representatives,products%20from%20state%2Dlegal%20dispensaries (last visited April 6, 2022).
[148] *Id*.
[149] *See id*.
[150] *See id*.
[151] *See id*.
[152] *See id*.
[153] *See id*.
[154] *See id*.

Congress within five years that assesses new research so that Congress can determine whether to reschedule cannabis rescheduling.[155] Federal prohibition continues to pose research obstacles but this Act promises to make the process much easier going forward.[156]

The Senate has passed similar legislation called the Cannabidiol and Marihuana Research Expansion Act.[157] The major difference between the House and Senate Bills is that the House Bill allows researchers to obtain cannabis from state-legal dispensaries whereas the Senate Bill continues to require researcher to obtain cannabis from the sole federally authorized facility (the University of Mississippi).[158]

In terms of safety, the FDA-approved drug Epidiolex, which is discussed above, has shown the consistent and safe reproduction of a product using a chemical derived from cannabis.[159] Studies also indicate that cannabis is safe and effective therapeutic but there is a significant need for additional research. Even assuming the House and Senate reconcile their competing bills and enact a new cannabis research law, cannabis's ongoing classification as a Schedule I drug will continue to inhibit scientific research.[160]

C. The Drug Must be Accepted by Qualified Experts.

Besides FDA's approval of Epidiolex, there is a swath of evidence that cannabis is accepted by qualified experts as a viable therapeutic. One need look no further than the medical marijuana legalization states to find that evidence.[161] States with active medical cannabis laws

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[155] *See id*.
[156] *See id*.
[157] Kyle Jaeger, *Senate Passes Marijuana Research Bill One Week After House Approves Similar Legislation*, MARIJUANA MOMENT, https://www.marijuanamoment.net/senate-passes-marijuana-research-bill-one-week-after-house-approves-similar-legislation/ (last visited April 6, 2022).
[158] *Id*.
[159] U.S. FOOD AND DRUG ADMIN, *supra* note 86.
[160] THE NAT'L ACADEMIES OF SCIENCES, ENG., AND MED., *supra* note 105.
[161] Ben Adlin, *States With Medical Marijuana Laws Saw 20% Drop in Some Opioid Prescriptions*, MARIJUANA MOMENT, https://www.marijuanamoment.net/states-with-medical-marijuana-laws-saw-20-drop-in-some-opioid-prescriptions/ (last visited April 6, 2022).

(MCLs) have seen opioid prescriptions drop nearly 20% compared to prohibition states.[162] Columbia University's Irving Medical Center lead a research project analyzing the correlation between medical marijuana and opioid prescriptions.[163] The research data they collected showed that, "State MCLs were associated with a statistically significant reduction in aggregate opioid prescribing of 144,000 daily doses (19.7% reduction) annually."[164] Most state medical marijuana programs require a physician's recommendation.[165] Given the sheer number of Americans that have obtained such recommendations, its near impossible to contend that qualified federal and state experts have not accepted cannabis as a therapeutic.[166]

D. The Scientific Evidence Must be Widely Available

The third prong of the Schedule I criteria is that a drug "lack . . . accepted safety for use . . . under medical supervision."[167] This factor only applies to drugs that do not have new drug application (NDA) approval.[168] "NDA-approval" means a drug that has been approved by the FDA.[169] Arguably, the FDA's approval of Epidiolex, whose active ingredient is a non-synthesized cannabis derived chemical, means that at least one natural cannabinoid is NDA approved. Thus, the FDA has made it widely known, through its approval, that there is scientific evidence of cannabis's safety.[170]

However, long before the FDA approval of Epidiolex, medical officials felt confident enough in the scientific evidence of cannabis's medical use that they would recommend their

[162] *Id*.
[163] *See id*.
[164] *See id*.
[165] MARIJUANA LAW AND POLICY, *supra* note 9 at 439.
[166] Martha Rosenthal et al., *Demographics, Perceptions, and Use of Medical Marijuana among Patients in Florida*, 4 MED CANNABIS CANNABINOIDS 13, 13 (2021).
[167] MARIJUANA LAW AND POLICY, *supra* note 9 at 56.
[168] Leiderman, *supra* note 29 at 259.
[169] *Id*.
[170] U.S. FOOD AND DRUG ADMIN, *supra* note 86.

patients take it under the relevant circumstances.[171] State medical marijuana regimes follow what is known as the prescription/recommendation dichotomy.[172] This dichotomy involves a physician giving a recommendation to a patient, rather than a prescription, to obtain medical marijuana.[173] The physician gives the recommendation knowing full well that the patient will use the recommendation as a means of obtaining marijuana, which is still illegal under federal law, but is distinguished from a formal prescription.[174] The distinction, in a recommendation vs. a prescription, was relied on heavily in the Ninth Circuit case, *Conant v. Walters*.[175]

In *Walters*, the court enjoined the federal government from either revoking a physician's license to prescribe controlled substances or conducting an investigation of a physician that might lead to such a revocation where the basis for the government's action was solely the physician's professional "recommendation" to use medical cannabis.[176] The *Walters* court was careful to distinguish between a physician's treatment recommendation and physician prescribing.[177] *Walters* is clearly protective of doctors who recommend cannabis to their patients. The case leaves open the possibility, however, that a physician who actually prescribed cannabis to a patient may well be in violation of federal law.[178]

Since *Walters*, no serious effort has been made by federal authorities to prosecute doctors.[179] There are currently thirty states that have medical marijuana programs.[180] Each state has its own unique laws defining who can access medical marijuana.[181] These laws typically

[171] MARIJUANA LAW AND POLICY, *supra* note 9 at 431.
[172] *Id*. at 439.
[173] *See id*.
[174] MARIJUANA LAW AND POLICY, *supra* note 9 at 439.
[175] *Id*. at 431-435
[176] *See id*.
[177] *See id*.
[178] MARIJUANA LAW AND POLICY, *supra* note 9 at 439.
[179] *See id*.
[180] Leiderman, *supra* note 29 at 249.
[181] MARIJUANA LAW AND POLICY, *supra* note 9 at 454.

include some list or criteria of medical conditions eligible for the state's medical marijuana program.[182]

III. Cannabis as a Schedule III Drug

Schedule III drugs must satisfy the following criteria: (1) they must have a potential for abuse less than other substances in schedules I and II; (2) they must have a currently accepted medical use in treatment in the U.S.; and (3) their abuse may lead to moderate or low physical dependence or high psychological dependence.[183]

Cannabis satisfies the first component here because it has a lower potential of abuse than several Schedule I and II drugs, including heroin, cocaine, and methamphetamine.[184] It also meets the second component for several reasons.

First, the drugs chemistry is known and reproducible, as the chemical makeup for cannabis is well documented[185], and the cannabis-derived drug Epidiolex can be successfully reproduced.[186]

Second, there has been adequate safety studies and adequate well-controlled studies proving the efficacy of cannabis.[187] Studies prove that cannabis has neuroprotective properties[188], has the potential to reduce the likelihood of head and neck cancer[189], and can effectively reduce

[182] *Id*.
[183] MARIJUANA LAW AND POLICY, *supra* note 9 at 56.
[184] ADDICTION CTR, *supra* note 62.
[185] Yank, *supra* note 75.
[186] U.S. FOOD AND DRUG ADMIN, *supra* note 86.
[187] MARIJUANA LAW AND POLICY, *supra* note 9 at 413-421.
[188] MARIJUANA LAW AND POLICY, *supra* note 9 at 48.
[189] *Id*.

nausea, vomiting, and muscle spasms.[190] The NAS has concluded, after assessing thirty-seven studies, that cannabis is an effective method of treatment for a number of medical ailments.[191]

Third, the drug is accepted by qualified experts.[192] Again, the FDA has approved a cannabis-derived drug and has noted the safety of its use.[193]Additionally, most state medical marijuana programs require a physician's recommendation[194], and there have been a substantial number of Americans who have obtained these recommendations, signifying the federal and state acceptance of cannabis as a therapeutic.[195]

Fourth, the scientific evidence is widely available.[196] The FDA has made the evidence of cannabis medicinal use widely available by approving Epidiolex.[197]Also, in the last 20 years there has been no serious efforts from federal authorities to prosecute doctors in the thirty states that have medical marijuana programs, an implicit acceptance of the scientific evidence of cannabis efficacy.[198]

Cannabis also satisfies the third component because there is a chance that cannabis leads to moderate physical dependence and possible psychological dependence in a small group of people.[199]

IV. The Marijuana Opportunity Reinvestment and Expungement Act (MORE)

[190] Smith, *supra* note 40 at 1158.
[191] MARIJUANA LAW AND POLICY, *supra* note 9 at 413-421.
[192] U.S. FOOD AND DRUG ADMIN, *supra* note 86
[193] *Id*.
[194] MARIJUANA LAW AND POLICY, *supra* note 9 at 439.
[195] Rosenthal, *supra* note 166.
[196] U.S. FOOD AND DRUG ADMIN, *supra* note 86.
[197] *Id*.
[198] MARIJUANA LAW AND POLICY, *supra* note 9 at 439.
[199] Weiss et al., *supra* note 41 at 46.

The MORE Act, which has been introduced in both chambers of Congress, removes cannabis from list of federally banned drugs under the CSA.[200] It also includes provisions about prison sentences, criminal reform, taxes on cannabis, and legalization on the state level.[201] The House of Representatives recently passed the MORE Act and it is currently pending in the Senate.[202] If the Senate passes the Act and the President signs it into law, there will be no need to down schedule cannabis to Schedule III because it will be entirely de-scheduled and the objectives of this paper will be fulfilled.

V. Proposal

This paper is certainly not the first to propose the down scheduling of cannabis, and it likely will not be the last. Advocates have fought for the rescheduling cannabis through many different means over the last five decades. In the 1973 case, *United States v. LaFroscia*,[203] a defendant brought the first constitutional challenge to the scheduling of cannabis.[204] There, the court refused to address the defendant's rescheduling claim because he had not exhausted administrative procedures that Congress established to challenge a scheduling determination.[205]

Even when advocates have used the correct administrative procedures to challenging the scheduling of cannabis, they have failed. The National Organization for the Reform of Marijuana Laws (NORML) filed a rule-making petition in 1972 with the U.S. Court of Appeals for the D.C.

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[200] Kyle Jaeger, *House Approves Federal Marijuana Legalization Bill for Second Time in History*, MARIJUANA MOMENT, from https://www.marijuanamoment.net/house-begins-final-debate-on-federal-marijuana-legalization-bill-with-floor-vote-imminent/ (last visited April 6, 2022).
[201] *Id*.
[202] *See id*.
[203] United States v. LaFroscia, 354 F. Supp. 1338, 1340 (S.D.N.Y. 1973).
[204] Smith, *supra* note 40 at 1149.
[205] *Id*.

Circuit requesting that cannabis be removed from the CSA entirely or transferred to Schedule V. The court, however, rejected the petition.[206]

On remand, the court found that the placement of cannabis on Schedule I did not only flow from the lack of currently accepted medical uses, but required the balancing of possible medical uses with the potential for abuse.[207] The court did acknowledge that there were possible treatment uses for cannabis and that further studies should be conducted.[208] The court remanded the case again for further findings with the Secretary of Health, Education, and Welfare (HEW).[209] After a long delay HEW recommended that cannabis remain on the Schedule I drug list and the DEA denied NORML's petition to reschedule cannabis.[210]

NORML then filed a third request with the U.S. Court of Appeals, and the court, in turn, ordered the DEA to review the petition in its entirety.[211] In the mid-1980s the DEA called for public hearing on cannabis's proper classification.[212] The administrative judge ruled that cannabis should be transferred from Schedule I to Schedule II, based on the evidence of a small group of respective physicians that accepted the medical use of cannabis.[213] However, based on an eight-factor test the DEA Administrator rejected this recommendation requiring a greater showing to prove currently accepted medical use before approving such a rescheduling.[214]

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[206] *See id*. at 1151.
[207] *See id*. at 1152.
[208] *See id*.
[209] *See id*. at 1152-1153.
[210] *See id*. at 1153.
[211] *See id*.
[212] *See id*.
[213] *See id*.
[214] Smith, *supra* note 40 at 1153-1154. The Administrator based his rejection of a currently accepted medical use on an eight-factor test, under which a drug has a currently accepted medical use if the following factors can be shown: (1) Scientifically determined and accepted knowledge of its chemistry; (2) The toxicology and pharmacology of the substance in animals; (3) Establishment of its effectiveness in humans through scientifically designed clinical trials; (4) General availability of the substance and information regarding the substance it s use; (5) Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks; (6) Specific indications for the treatment of recognized disorders; (7) Recognition of the use of the substance by organizations or

This rejection was challenged by the Alliance for Cannabis Therapeutics (ACT) and NORML together.[215] After showing evidence that that the DEA Administrator unreasonably rejected the petition, the court remanded the petition to the Administrator.[216] The Administrator, again, upheld the rejection of the petition.[217]This rejection was appealed by the NORML to the D.C. Circuit court, who also upheld the Administrator's objection, but established a new five-part test to determine whether a substance has a currently accepted medical use.[218] The five-part test was analyzed in the medical use analysis of this paper. The new test was, interestingly, focused on adequate controlled studies to determine efficacy and safety of cannabis.[219] In sum, the DEA has fought fervently to stop the rescheduling of cannabis.[220]

Annaliese Smith's law review comment, *Marijuana as a Schedule I Substance: Political Ploy or Accepted Science?,* also makes the argument that cannabis should classified as a Schedule III drug.[221] Smith's comment points out the mistakes made by prior petitioners who have sought to have cannabis down scheduled: the failure to present sufficient evidence to establish that cannabis does not have a high potential for abuse and has known and accepted medical uses.[222]

This paper also aims to further that goal, and, in order to avoid past petitioning mistakes, it is important to be clear about why cannabis ought to be moved to Schedule III. It is also important to note the difficulty in establishing sufficient evidence of cannabis's medical uses due

associations of physicians; and (8) Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.
[215] *Id*. at 1154.
[216] *See id*.
[217] *See id*.
[218] *See id*. at 1155-1156.
[219] *See id*. at 1156.
[220] *See id*. at 1149-1156.
[221] *See id*. at 1167-1168.
[222] *See id*. at 1149-1156.

to the drug's placement on Schedule I. Through the rescheduling regulations, the DEA is essentially asking for us to open a locked box, and the key is in the box.

The DEA can, and must, reschedule cannabis to Schedule III. Moving cannabis to Schedule III will open up important research opportunities. This is particularly critical should the MORE Act not get enacted. That stated, the Cannabidiol and Marihuana Expansion Act, and the Medical Marijuana Research Act, demonstrate that there is near unanimous support in Congress that more research needs to be done into cannabis for medical purposes.[223]

Rescheduling cannabis is the first step to full federal legalization and will facilitate the short-term goal of making cannabis more readily available for research purposes. Congress should amend, or enact legislation similar to, the Cannabidiol and Marihuana Expansion Act and the Medical Marijuana Research Act, that mandates that the DEA and FDA approve two federal facilities in every state to manufacture cannabis for research purposes. The bill also should stipulate that these facilities need to make quality grade medical marijuana with the chemical components of THC and CBD that are common to Cannabis Sativa rather than hemp.[224] It should further ensure that there are variety of different cannabis strains available so researchers can test how different chemical combinations react with the human body.

There should also be a shift in regulatory power from the DEA to the FDA when it comes to scheduling decisions. The DEA is a law enforcement agency[225] that has always aired on the side of caution when it comes to scheduling decisions, evidenced by the fact that it has never down-scheduled any controlled substance.[226] The DEA has also aggressively fought against the

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[223] MARIJUANA MOMENT, *supra* note 147.
[224] Stone, *supra* note 137.
[225] *Mission*, U.S. DRUG ENFORCEMENT ADMIN, https://www.dea.gov/about/mission#:~:text=The%20mission%20of%20the%20Drug,members%20of%20organizations%2C%20involved%20in (last visited April 6, 2022).
[226] 21 U.S.C. § 812 (1970)- 21 U.S.C. § 812 (2022).

rescheduling of cannabis despite evidence of medical use.[227] In juxtaposition the FDA is a scientific public health agency[228] that has recently approved four cannabis drug applications, and has seriously considered the medical uses of cannabis as they relate to the tenants of the CSA.[229] The FDA should have authority over rescheduling decisions as well as applications for growing facilities. The FDA should be a given a time constraint on responses to grower applications, to avoid the pervading issue of delayed applications.

VI. Conclusion

Under the DEA's own guidelines, cannabis ought to be removed from Schedule I. It has known and accepted medical uses and there is accepted safety for use of cannabis under medical supervision. The drug also does not have a high potential for abuse. The first step to federal legalization is to down-schedule cannabis to Schedule III so that more research can be conducted concerning the drug's therapeutic uses. In the alternative, or in conjunction with this proposal, Congress needs to shift power from the DEA to the FDA to analyze the medical viability of Schedule I drugs, as the DEA has only acted in their policing capacity while ignoring the tide of mounting evidence surrounding the medical viability of cannabis.

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[227] Smith, *supra* note 40 at 1156.

[228] *What We Do*, U.S. FOOD AND DRUG ADMIN, https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Basics-,FDA%20Mission,and%20products%20that%20emit%20radiation. (last visited April 6, 2022).

[229] U.S. FOOD AND DRUG ADMIN, *supra* note 88.