GETTING BACK ON SCHEDULE: FIXING THE CONTROLLED SUBSTANCES ACT

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Federal drug policy has been the subject of much debate over the last decade, as the Obama Administration pushed for both executive and legislative branch changes[1] that scrambled typical partisan allies in Congress and reinvigorated a debate that had been happening mostly out of the spotlight. As the Trump Administration has moved to reverse and halt these changes, Congress has begun to show signs of life through attempts to address some of the numerous inefficiencies and shortcomings that have developed in the almost fifty years since the adoption of the Controlled Substances Act.[2] This Note analyzes the legislative backbone of federal drug policy and argues for legislative and administrative changes that would lead to a more efficient, transparent, and standardized regime.

I. INTRODUCTION

In 1970, Congress passed the Controlled Substances Act (CSA).[3] Signed by President Richard Nixon, the bill was designed as part of an omnibus package addressing the scattershot regulatory and administrative approach the federal government had taken to

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[1] *See* Kasey C. Phillips, *Drug War Madness: A Call for Consistency Amidst the Conflict*, 13 CHAP. L. REV. 645, 670–71 (2010) (discussing efforts made by the Obama Administration to change the federal government's drug policy).

[2] *See* James Cooper, *The United States, Mexico, and the War on Drugs in the Trump Administration*, 25 WILLAMETTE J. INT'L L. & DISP. RESOL. 234, 284–85 (2018).

[3] Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970).

address narcotics in the first half of the twentieth century.[4] Today, drug policy in the United States is run jointly through the Food and Drug Administration (FDA), which is part of the agency now known as the Department of Health and Human Services (HHS), and the Drug Enforcement Agency (DEA), which is part of the Department of Justice (DOJ).[5] Though the bill was not initially designed as a purely punitive piece of legislation, most of the bill's administrative teeth comes by way of enforcement actions brought by the DOJ and DEA.[6] In fact, Title I of the omnibus bill was full of public-health initiatives, such as funding for mental health centers, increased research funding, and privacy protections for research subjects.[7] The Controlled Substances Act came second, as Title II of the bill.[8]

However well-intentioned the public-health aspects of the larger omnibus bill were, their ultimate effect has paled in comparison to the heart of the bill, the substance regulation provisions, which over the last fifty years have become overbearing, burdensome, and in some cases nonsensical. The CSA established a method for the regulation of potentially dangerous substances which is based on whether the substance has a currently accepted medical use, the relative potential for abuse of the substance, and the likelihood of causing dependence when abused.[9] The bill grants the Attorney General rule-making power to "schedule" new substances or re-schedule already controlled substances to a different level.[10] The five levels of regulation run from most to least regulated: Schedule I substances are entirely prohibited, while Schedule V drugs are those of the lowest potential for abuse and "consist of preparations

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4 *See* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 334 (2013). *See also* David T. Courtwright, *The Controlled Substances Act: How a "Big Tent" Reform Became a Punitive Drug Law*, 76 DRUG & ALCOHOL DEPENDENCE 9, 10 (2004).

5 Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U.L. Rev. 586, 605 (1973). The Department of Justice delegated scheduling authority to the Drug Enforcement Agency in 1973. 28 C.F.R. § 0.100 (1973).

6 *See* Courtwright, *supra* note 4, at 12.

7 Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

8 Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970).

9 *See* 21 U.S.C. § 812(b)(1)(A–C) (2012); U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMIN., *Practitioner's Manual: An Informational Outline of the Controlled Substances Act* 5 (2006), https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf. [hereinafter *Practitioner's Manual*].

10 *See* 21 U.S.C. § 811(a) (2012).

containing limited quantities of certain narcotics."[11] Because the government has classified Schedule I substances as having "no currently accepted medical use,"[12] research on such substances is only allowed in accordance with the CSA's strict controls.[13]

As we rightfully worry about the perils of drug usage and overdoses across the country, it's worth taking stock of exactly how those substances come to be regulated by the government if for no other reason than to ensure that public policy reflects our goals of preventing abuse and providing assistance to those in need. Increasingly, America's federal drug policy does not achieve these purposes.

As the result of legislative and executive actions like the adoption of the CSA, federal drug policy in the United States currently consists of a maze-like structure of statutory and administrative rules centered around a scheduling system that is virtually impossible to understand. Though this system provides a method for regulators to differentiate between more dangerous substances, the individuals making those scheduling determinations are often law enforcement officials and government bureaucrats applying multiple, multi-level factor tests.

Unfortunately, the tests that have developed over the years since the passage of the CSA have created numerous deficiencies with their inconsistent application, leading to public policy subject to political pressures as opposed to sound decision making. In order to determine a substance's schedule, the DOJ, in coordination with HHS, uses an eight-factor statutory test to determine whether control is appropriate.[14] Once they decide that control of a substance is appropriate, the CSA outlines three factors to determine exactly what schedule the substance should be placed on.[15] Finally, in order to interpret one of these three factors, the DEA has developed its own five-part test.[16] Many of the factors amongst these tests are duplicative and others are at

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[11] *Drug Scheduling*, DRUG ENFORCEMENT ADMIN., https://www.dea.gov/druginfo/ds.shtml (last visited Jan. 23, 2019).

[12] *See* 21 U.S.C. § 812(b)(1)(B).

[13] *See* Kreit, *supra* note 4, at 336. *See also* Practitioner's Manual, *supra* note 10, at 9.

[14] *See* 21 U.S.C. § 811(c).

[15] *See* Ams. for Safe Access. v. Drug Enf't Admin., 706 F.3d 438, 449 (D.C. Cir. 2013).

[16] *See id.*

times at odds with each other (if not in their explicit language, then at least in their application).[17] If that sounds overly burdensome, that's because it is.

Over the years, this confusing method of deciding when and to what extent a substance should be controlled has caused a variety of issues. Perhaps most tangibly, it has caused the research of substances that are placed on Schedule I to be restricted in such a way that has limited the number of scientific studies on those substances to virtually zero.[18] It has given the government, and specifically law enforcement, license to immediately regulate substances that are deemed dangerous or similar in composition to an already scheduled substance. The DEA is not immune to political pressure. As a result, the priority by which substances get scheduled can be more the result of political pressure than overwhelming scientific evidence. Finally, the statutory scope of the regulations, without regular reevaluation, has caused our regulators to fall behind general public sentiment in regard to certain substances, most notably marijuana.

There is a better way. A new, amended CSA could refocus federal drug policy on the health side of the equation. Instead of having the majority of the power in the hands of law enforcement officials, controlled substance conclusions should be made by public health officials and scientists. This Note does not suggest that law enforcement should not remain a part of controlled substance review. Rather, it intends to suggest only that eliminating some of the inefficiencies by centralizing analysis and lifting restrictions that have burdened citizens will, on the whole, lead to better federal drug policy.

Part I of this Note discusses the CSA's scheduling scheme and the difficulties determining how a substance should be listed, as well as the draconian research restrictions inherent in the bill. Part II considers ancillary issues that have arisen in recent years as a result of the Scheduling scheme the CSA adopted, such as the development of synthetic substances, enforcement priority changes across administrations, and shifts in marijuana laws. Part III outlines potential solutions to these issues by revising the current sentencing scheme with a multifaceted approach, led by legislative reform complimented by certain regulatory changes.

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[17] *See* Kreit, *supra* note 4, at 350 n.103.

[18] *See* Shelly B. DeAdder, *The Legal Status of Cannabidiol Oil and the Need for Congressional Action*, 9 BIOTECHNOLOGY & PHARMACEUTICAL L. REV. 68, 83–85 (2016).

a. Scheduling Substances Under the CSA

Scheduling under the CSA is more of an art than science–one federal court noted that the criteria "cannot logically be read as cumulative in all situations,"[19] while another noted that "classifications at times cannot be followed consistently."[20] Federal administrators are subject to strong lobbying campaigns from members of Congress, seeking to get drugs ravaging their districts scheduled and off the streets as quickly as possible.[21] Sometimes, the legislators get their way.[22] On the other hand, such administrative scheduling-by-fire has caused hand wringing among critics and patient populations who say that some drugs being scheduled or re-scheduled are important to pain management and shouldn't be subject to the additional restrictions that come with a higher schedule.[23] Scheduling these substances as Schedule I or Schedule II can relegate patients seeking treatment with them into a virtually impossible bureaucratic maze that some argue limits treatment options.[24] For example, the debate around medical marijuana has caused consternation for government agencies for some time now.[25] Advocates claim that the chemicals in marijuana can assist in calming seizures and mitigating pain in patients with epilepsy and chronic pain

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19 United States v. Maiden, 355 F.Supp. 743, 748 n.4 (D. Conn. 1973).

20 Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F.Supp. 123, 140 (D.D.C. 1980).

21 *See* Mike Hedeen, *Schumer: New Synthetic Drugs Making Kids Sick*, SPECTRUM NEWS BUFF. (Feb. 16, 2015, 9:45 PM), http://www.twcnews.com/nys/buffalo/news/2015/02/16/warning-from-schumer-about-cloud-9.html.

22 *See* Press Release, Joe Manchin, U.S. Senator, Manchin Applauds DEA's Final Rule to Reschedule Hydrocodone (Aug. 21, 2014) https://www.manchin.senate.gov/newsroom/press-releases/manchin-applauds-deas-final-rule-to-reschedule-hydrocodone.

23 *See* Aaron Doll, *Putting the Fox in Charge of the Chicken Coop: An Examination of the Controlled Substances Act and the Reclassification of Hydrocodone*, 41 U. DAYTON L. REV. 421, 436–37 (2016).

24 *See* DeAdder, *supra* note 18, at 70–72; Ethan B. Russo, *Cannabinoids in the Management of Difficult to Treat Pain*, 4 THERAPEUTICS & CLINICAL RISK MGMT. 245, 245 (2008).

25 *See* Press Release, Drug Enforcement Admin., DEA Announces Actions Related to Marijuana and Industrial Hemp (Aug. 11, 2016) https://www.dea.gov/divisions/hq/2016/hq081116.shtml (noting DEA administrators recently denied two petitions for rescheduling but changed other regulations surrounding marijuana).

disorders.[26] Marijuana has consistently garnered controversy for its placement on Schedule I since the beginning of the CSA's regulatory scheme,[27] and it appears it will continue to be a subject of debate as more states vote to legalize the drug in defiance of federal law.[28]

While marijuana may be unique, it is certainly not alone—the CSA scheduling method is also fraught with issues as applied to other substances. The stated difference between Schedule I and Schedule II is "established medical use."[29] However, if this were truly the only difference, it would render the other two elements listed in 21 U.S.C. § 812(b) superfluous—"potential for abuse" and the dependency profile of the substance would essentially be written out of the statute on the DEA's interpretation.[30] Marijuana is the clearest example of a substance that has fallen victim to such an application of the law. The DEA has repeatedly stated it has no accepted medical use. On the other hand, marijuana has been proven to cause minimal harm, especially in comparison to alcohol and tobacco,[31] and has minimal potential for abuse, yet has been listed as a Schedule I drug since the passage of the CSA in 1970.[32] Conversely, having no accepted medical use does not automatically consign a substance to Schedule I,[33] though the DEA appears to believe so.[34] Both poppy straw and poppy straw concentrate, substances with no accepted medical use, are listed as Schedule II substances.[35]

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[26] *See* DeAdder, *supra* note 18, at 69. *See also* Russo, *supra* note 24, at 245.

[27] Nat'l Org. Reform of Marijuana Laws v. Drug Enf't Admin, 559 F.2d 735, 737 (D.C. Cir. 1977).

[28] *See* Samuel Stebbins, et.al., *Pot Initiatives: Predicting the Next 15 States to Legalize Marijuana*, USA TODAY, (Nov. 14, 2017) https://www.usatoday.com/story/money/ 2017/11/14/pot-initiatives-predicting-next-15-states-legalize-marijuana/860502001/.

[29] Nat'l Org. Reform of Marijuana Laws, 559 F.2d at 748.

[30] *Id.*

[31] Christopher Ingraham, *Marijuana May be Even Safer than Previously Thought, Researchers Say*, WASH. POST: WONKBLOG (Feb. 23, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/ 02/23/marijuana-may-be-even-safer-than-previously-thought-researchers-say/?utm_term=.802f6eebd42f.

[32] Harrison Jacobs, *The DEA Treats Heroin and Marijuana as Equally Dangerous Drugs*, BUSINESS INSIDER, (May 22, 2016, 5:54 PM) https://www.businessinsider.com/us-drug-scheduling-system-heroin-marijuana-2016-5.

[33] Kriet, *supra* note 4, at 341.

[34] *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (Dep't of Justice, July 8, 2011).

[35] *See* DEA, *Lists of: Scheduling Actions, Controlled Substances, Regulated Chemicals*, U.S. DEP'T OF JUSTICE, at 15 (Dec. 10, 2018),

If "accepted medical use" was the only criterion causing issues with the classification scheme of the CSA, or if the three § 812(b) factors were the only basis for the DEA to determine the schedule of a substance, the problem might be easily remedied.[36] However, in § 811(c), the CSA lists eight additional factors for the DEA to consider before scheduling a substance, many of which are more specific than the "potential for abuse" and dependency profile criteria laid out in § 812(b).[37] For example, "scientific evidence of [the substance's] pharmacological effect," "the state of current scientific knowledge," and "whether the substance is an immediate precursor of a substance already controlled" are all potential considerations for the Attorney General.[38] Even the government has labeled these factors as "redundant" and "circular" in internal memorandum.[39] Additionally, because of the overlapping jurisdiction between the FDA/HHS and DEA/DOJ, conclusions can vary between agencies. Under the CSA, the Secretary of HHS recommends whether or not a substance should be scheduled or remain scheduled.[40] Even though according to the statute the Attorney General (and thereby the DEA Administrator) is bound by the Secretary's scientific findings,[41] in practice the two agencies work together to determine whether a substance should be controlled, and the DEA has significant input on the recommendation that comes to them.[42]

In addition to the broad statutory authority granted to the executive branch by the CSA, courts have given significant discretion to the government when it comes to scheduling. In 1987,

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https://www.deadiversion.usdoj.gov/schedules/orangebook/ orangebook.pdf.

[36] *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767, 53768 (Dep't of Justice, Aug. 12, 2016).

[37] *See id.* at 53767–72, 53777–78, 53781–85.

[38] 21 U.S.C. § 811(c).

[39] United States v. Pastor, 419 F. Supp 1318, 1339 n.6 (S.D.N.Y. 1975).

[40] 21 U.S.C. § 811(b).

[41] *Id.*

[42] *See* Douglas C. Throckmorton, *Re-scheduling Prescription Hydrocodone Combination Drug Products: An Important Step Toward Controlling Misuse and Abuse*, U.S. FOOD & DRUG ADMIN: FDA VOICE (Oct. 6, 2014), https://blogs.fda.gov/fdavoice/index.php/2014/10/re-scheduling-prescription-hydrocodone-combination-drug-products-an-important-step-toward-controlling-misuse-and-abuse/ (noting that the DEA requested the scientific and medical recommendation from FDA regarding a substance that was eventually reclassified); Doll, *supra* note 23, at 429, 435 (noting that in a case where DEA didn't get a recommendation from HHS that they liked, they quickly moved for a re-evaluation, and the drug was eventually rescheduled).

the First Circuit considered a challenge to the DEA's scheduling of MDMA.[43] The court held that the DEA's determination of MDMA's potential for abuse was not arbitrary and capricious, even though the DEA "articulated no standard" to warrant placement on Schedule I.[44] So long as the Administrator can compare the substance to others already scheduled, they may reach conclusions as to the substances' potential abuse.[45] Though the scheduling order was reversed on other grounds in *Grinspoon*, the DEA was eventually able to reschedule MDMA as a Schedule I substance once it provided reasoning other than that the lack of FDA interstate marketing approval constituted a lack of "accepted medical use."[46]

In order to determine whether a substance has a currently accepted medical use under § 812(b), the DEA employs a five-part test (developed in response to *Grinspoon* and its progeny) and only concludes a substance has a sufficient use if it has demonstrated all five elements.[47] First, "the drug's chemistry must be known and reproducible. . . ."[48] This is easy enough to discern with modern science. The latter four requirements have proven to be more problematic: "(2) [t]here must be adequate safety studies; (3) [t]here must be adequate and well-controlled studies proving efficacy; (4) [t]he drug must be accepted by qualified experts; and (5) [t]he scientific evidence must be widely available."[49] Unlike the various factors specifically outlined in the CSA for determining the schedule of a substance, these five factors were developed by the DEA as the result of repeated litigation into the classification of marijuana and MDMA as Schedule I substances.[50] Without a legislative definition of "accepted medical use," citizens are stuck with the initial interpretation of the uber-cautious and pro-regulatory executive branch.

In order to reschedule a drug, the FDA first must recommend such a move to the DEA after conducting analysis in accordance

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43 Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 882 (1st Cir. 1987).

44 *Id.* at 893.

45 *Id.*

46 See *id.* at 891.

47 Denial, 76 Fed. Reg. at 40,579 (July 8, 2011).

48 Am. for Safe Access. v. Drug Enf't Admin., 706 F.3d 438, 449 (D.C.Cir. 2013).

49 *Id.*

50 *See, e.g.*, Grinspoon v. Drug Enf't Admin., 828 F.2d 882, 884 (1st Cir. 1987); Alliance for Cannabis Therapeutics v. Drug Enf't Admin., 930 F.2d 936, 939 (D.C. Cir. 1991).

with the § 811(c) eight factor test.[51] Then the FDA, the National Institute on Drug Abuse (NIDA) and the Assistant Secretary of Health in HHS make a recommendation for scheduling.[52] Finally, HHS transfers the recommendation to the DEA, and the DEA considers that recommendation before publishing in the federal register the notice for rulemaking (or lack thereof).[53] Between the § 811(c) eight factor test, the three § 812(b) factors and the DEA's own five part definition of "accepted medical use," determining the schedule of a substance has become a bureaucratic mess that leads to federal agency slow walking and delayed scheduling and rescheduling.

b. Research Issues

The ability for the federal government to quickly and affirmatively address the drug crisis is necessary to help stem the spread of dangerous drugs like synthetic cannabinoids. On the other hand, when the government uses its authority to take rapid steps to combat what might be a drug crisis today,[54] the DEA may be cutting off the ability of researchers to solve the problems of tomorrow.[55] The CSA grants the Secretary of HHS (in consultation with the Attorney General) the authority to develop procedures for practitioners attempting to engage in research of Schedule I substances, specifically differentiating Schedule I from Schedule II, III, IV or V.[56] This broad grant of authority has spawned an entire Part of the Code of Federal Regulations.[57] The procedures that have developed as the result of the distinction in the CSA

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51 *Researching the Potential Medical Benefits and Risks of Marijuana: Hearing Before the Subcomm. on Crime and Terrorism of the S. Comm. on the Judiciary*, 114th Cong. (2016) (statement of Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs, Food and Drug Administration).

52 *Id.*

53 *Id.*

54 *See, e.g.*, Christopher Ingraham, *Congress is Considering a Bill that Would Expand Jeff Sessions's Power to Escalate the War on Drugs*, WASH POST: WONKBLOG (June 16, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/06/16/congress-is-considering-a-bill-that-would-expand-jeff-sessions-power-to-escalate-the-war-on-drugs/?utm_term=.d8252d6566da.

55 Such rapid enforcement measures also have been linked to increased abuse of substitute drugs. *See* SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC (2016) (following addicts' transition from prescription opioid abuse to heroin throughout the United States).

56 *See* 21 U.S.C. § 823(f) (2018).

57 21 C.F.R. § 1301 (2019).

between Schedule I and the other four levels have led to restrictions on research that fly in the face of the five-part test the DEA has established to find a substance has a "currently accepted medical use."

Under the CSA, a potential researcher of a controlled substance must submit an application to the DEA.[58] However, in order to research a Schedule I substance, researchers must wade even deeper through the quagmire of bureaucracy. For example, just because a substance a public researcher wants to study is Schedule I, the researcher must submit an additional form, detailing their study, their protocols and the reasons for it.[59] Currently there are five factors the Attorney General has to consider when determining whether to approve research of Schedule II, III, IV or V substances.[60] However, § 823(f) operates differently for Schedule I substances. Any application for a Schedule I substance is required by statute to be reviewed first by the Secretary of HHS (or by designation the FDA Commissioner) who "shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol."[61] In making this determination, HHS is explicitly required to consult with DOJ,[62] which in practice leads to DEA involvement in the approval process. If HHS, in consultation with DOJ determines that an applicant is qualified for research, the Attorney General can only then deny the application for reasons listed in 21 U.S.C. § 824(a).[63] This may seem like reason for increased research in comparison to the other levels. However, since the Attorney General is consulted by HHS on "effective procedures" for diversion of the substances,[64] the DEA and DOJ have ample ability to deny applications before they are formally received from HHS.

The burdensome research application submission process actually begins even before the DEA scrutinizes a potential

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58 *See* DIVERSION CONTROL DIV., DRUG ENF'T ADMIN., APPLICATION FOR REGISTRATION UNDER CONTROLLED SUBSTANCES ACT OF 1970, https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf (last visited Jan. 31, 2019).

59 DEA Research Protocol, 21 C.F.R. § 1301.18 (2010); *DEA Form 225 – New Application for Registration*, DRUG ENFORCEMENT ADMIN., DIVERSION CONTROL DIVISION, https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm (last visited Feb. 13, 2018).

60 21 U.S.C. § 823(f).

61 21 U.S.C. § 823(f).

62 21 U.S.C. § 823(f).

63 21 U.S.C. § 824(a) (2018).

64 21 U.S.C. § 823(f).

applicant. Getting DEA approval is in fact much harder than just submitting an application. There first must be approved manufacturing of the substance in question. Manufacturing of Schedule I substances is within the discretion of the Attorney General based on a six-factor test to determine whether production is within the public interest.[65] Again, marijuana is a case study for DEA policies in this regard. As of August 2016, after nearly fifty years of challenges to its Schedule I listing, the DEA had approved just one entity to produce and supply researchers with marijuana in the entire United States.[66] The DEA works in tandem with NIDA and the FDA in making the drug accessible to researchers, setting a yearly quota on the amount of marijuana produced. Overseeing the project, NIDA coordinates the distribution of marijuana to researchers that have jumped through all the hoops required for Schedule I researchers.[67] As of August 2017 there were at least twenty-five additional applications to grow marijuana that the DEA had not acted on.[68] If there are no approved manufacturers, there can be no approved research.

This problem is exacerbated by the difference between recreational drugs, such as marijuana, and substances developed by pharmaceuticals. Drugs like synthetic cannabinoids and opioids, which are concededly causing deaths in many areas around the country,[69] can be subject to fierce public scrutiny[70] and accelerated executive actions to limit supply. Once placed on Schedule I however, any public research into those substances

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65 21 U.S.C. § 823(a).

66 Press Release, Drug Enf't Admin., DEA Announces Actions Related to Marijuana and Industrial Hemp (Aug. 11, 2016), https://www.dea.gov/press-releases/2016/08/11/dea-announces-actions-related-marijuana-and-industrial-hemp.

67 *See supra* Part I (b).

68 Matt Zapotosky & Devlin Barrett, *Justice Department at Odds with DEA on Marijuana Research, MS-13*, WASH. POST, (Aug. 15, 2017), https://www.washingtonpost.com/world/national-security/justice-department-at-odds-with-dea-on-marijuana-research-ms-13/2017/08/15/ffa12cd4-7eb9-11e7-a669-b400c5c7e1cc_story.html?utm_term=. 2dba62c298d1.

69 *See* Katie Zezima, *Study: Despite Decline in Prescriptions, Opioid Deaths Skyrocketing Due to Heroin and Synthetic Drugs*, WASH. POST (Apr. 10, 2018), https://www.washingtonpost.com/news/post-nation/wp/ 2018/04/10/study-despite-decline-in-prescriptions-opioid-deaths-skyrocketing-due-to-heroin-and-synthetic-drugs/?utm_term=.37b483b8929d.

70 *See Synthetic Cannabis Cases Spike; Lawndale Store Shut Down*, CBS CHICAGO (Mar. 28, 2018, 6:09 PM), http://chicago.cbslocal.com/2018/03/28/synthetic-cannabis-cases-spike-lawndale-store-shut-down/.

must be run through the DEA.[71] Meanwhile, pharmaceutical companies can develop their own drugs, then submit them to the FDA with the company's initial proposal for scheduling.[72] Unlike substances pushed into Schedule I by statute or by DOJ's emergency scheduling powers, this gives large pharmaceutical corporations a chance to shape regulators thought process for scheduling their developed substances.[73] Additionally, when prescription medications fail to relieve symptoms, patients sometimes turn to substances like marijuana for relief.[74] Unfortunately, because of its listing as a Schedule I substance, there is little verifiable data speaking to its effectiveness.

Perhaps most problematic is the CSA's prescribed purpose for these research restrictions. Though the language in the statute would seem to indicate that the potential danger of the substance is the most important factor,[75] even with the limited research available we know this not to be the case. Amongst Schedule II substances, drugs such as cocaine, oxycodone and hydrocodone all have been shown to cause significantly more overdose deaths than those of marijuana, listed as a Schedule I substance.[76] Cocaine, abused regularly across college campuses,[77] was once used as a numbing medication, hence its listing as a Schedule II drug.[78] As the years have passed however, substances with similar chemical

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71 DEA Research Protocols, *supra* note 59.

72 21 C.F.R. § 314.50(d)(5)(vii) (2012).

73 *See* QUINONES, *supra* note 55, 125–27.

74 Russo, *supra* note 24.

75 *See* 21 U.S.C. § 823(f)(5) ("The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion. . . .").

76 *Compare* NAT'L INST. ON DRUG ABUSE, NAT'L INST. OF HEALTH, OVERDOSE DEATH RATES (2018), https://www. drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (indicating overdose rates for cocaine and prescription opioids), *with* COMM. ON THE HEALTH EFFECTS OF MARIJUANA, NAT'L ACADS.' OF SCI., ENG'G, & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 236 (2017), https://www.ncbi.nlm.nih.gov/books/NBK423845/pdf/Bookshelf_NBK423845.pdf) (concluding "[t]here is insufficient evidence to support or refute a statistical association between cannabis use and death due to cannabis overdose").

77 *See* Kasperski et al., *College Students' Use of Cocaine: Results from a Longitudinal Study*, 36 ADDICTIVE BEHAVIORS 408, 408 (2011) (indicating 36% of college students had been offered cocaine at least once by the fourth year of school).

78 *See* Gerald T. McLaughlin, *Cocaine: The History and Regulation of a Dangerous Drug*, 58 CORNELL L. REV. 537, 544–45 (1973).

structures yet smaller potential for abuse such as Novocain and other local anesthetics became available for the same procedures.[79] One wouldn't have to jump too far to infer that research into cocaine helped develop these less abusive substances.

Marijuana is not the only longtime Schedule I substance to face research issues. Another Schedule I drug, MDMA (or ecstasy) has also shown potential medicinal value,[80] but because of its classification as a Schedule I controlled substance and the research limitations that come with it, any medicinal value will almost certainly take significantly longer to be realized than a Schedule II-V substance would.[81] In *Grinspoon*, the Harvard professor challenging the scheduling action explicitly noted the potential adverse effects that the DEA's action might have on MDMA research.[82] In 2012, a study noted the potential medical benefits the drug might have on veterans with post-traumatic stress disorder.[83] Unfortunately, Schedule I restrictions will make further Phase II and Phase III studies harder to come by, resulting in a slower development of research and a smaller likelihood of rescheduling should the substance actually prove to have substantial medical value.

Adding to the confusion is the accessibility of these drugs on the black market. Heroin, a drug that has in the last several years regained popularity and that is widely seen as one of the most dangerous substances on the market in terms of deaths and overdoses,[84] remains widely accessible irrespective of its classification as a Schedule I substance,[85] as does marijuana.[86] Why keep such a tight lid on valuable medical research when the drugs are so commonly available on the streets?

On the whole, the result of a Schedule I classification on availability for research is nonsensical. Since the CSA was enacted into law in 1970, just thirteen substances have been removed from

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79 QUINONES, *supra* note 55, at 78.

80 Benedict Carey, *A 'Party Drug' May Help the Brain Cope with Trauma*, N.Y. TIMES (Nov. 19, 2012), http://www. nytimes.com/2012/11/20/health/ecstasy-treatment-for-post-traumatic-stress-shows-promise.html?page–wanted=all.

81 Kreit, *supra* note 4, 352–56.

82 Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 896 (1stCir. 1987).

83 *See* Carey, *supra* note 80.

84 DRUG ENF'T ADMIN., U.S. DEP'T OF JUSTICE, NATIONAL DRUG THREAT ASSESSMENT 45 (2017), https://www.dea. gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf [hereinafter NATIONAL DRUG THREAT ASSESSMENT]

85 *See* QUINONES, *supra* note 55.

86 NATIONAL DRUG THREAT ASSESSMENT, *supra* note 84 at 99.

Schedule I into a less regulated classification, and only two since 1990.[87] As a result, research is almost always permanently limited on substances once they are listed under Schedule I. Combined with the lack of a coherent structure for identifying and classifying a new substance, the CSA's model for scheduling substances is woefully outdated. Advanced medical research can provide a more detailed study of substances as they arise today than research in 1970 could, but research into longtime scheduled substances is limited by the current regulatory scheme.[88] Assessing the potential medical usage of drugs, whether new, old, dangerous or harmless should not be made impossible by an enforcement agency. Restricting access to controlled substances to save lives from overdoses is a valuable goal, but currently, it also may be costing other victims theirs. We should not be forced to choose between one life saved from prevention and another from research.

II. METASTATIC GROWTH

a. Analogue Substances

Over the years, the CSA's enforcement provisions were enhanced by the government's "War on Drugs," as amendments passed by subsequent Congresses took a hardline stance towards illicit substances. As originally written, the statute prevents a drug from being "placed in any schedule unless the findings required for such a schedule are made."[89] In 1984, the Comprehensive Crime Control Act created an exception, granting the Attorney General emergency scheduling power, allowing the Department to skip formalized review.[90] This legislation granted DEA the authority to schedule what are thought to be dangerous substances such as MDMA and, more recently, substances that bear substantial similarities to previously scheduled substances, commonly known as synthetic drugs.[91] This has created another whole set of problems, as advocates of stronger DEA authority cite

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87 DRUG ENF'T ADMIN., U.S. DEP'T OF JUSTICE, *Scheduling Actions: Chronological Order, in* LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS (2018), https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf.

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

89 21 USC § 812(b) (2012).

90 Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, § 508, 98 Stat. 1976, 2071 (1984).

91 *See* United States v. Kelly, 874 F.3d 1037, 1043–44 (9th Cir. 2017).

the need to address criminals' ability to slightly alter chemical composition to avoid running afoul of the CSA, while critics worry it could limit positive uses of these substances.[92]

In 1986, Congress passed the Controlled Substance Analogue Enforcement Act, which formally prohibited any substance "substantially similar" to a controlled substance listed in Schedule I or Schedule II by treating the substance as if it was scheduled as its sister chemical is.[93] This was mostly done in response to the explosion of "designer" or "synthetic" drugs that manufacturers (in many cases, chemists in small laboratories)[94] developed in order to skirt federal drug statutes. Designers simply had to tweak the chemical structure of a controlled substance to avoid being subject to CSA restrictions.[95] Spurred on by academic drug research that promoted testing and altering combinations, new discoveries and substances quickly found their way onto the black market.[96] Congressional action created a new enforcement mechanism for law enforcement to use against drug manufactures, but that too has not come without its pitfalls. Not only has the Department of Justice had a difficult time enforcing these laws, [97] but law enforcement has difficulty keeping up with the rapid changes in the chemical composition of substances abused throughout the country.[98]

In the years since its passage, exactly what constitutes a "substantially similar" substance within the Analogue Act has remained murky.[99] Every few years, a new synthetic emerges that

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92 Christopher Ingraham, *Congress is Considering a Bill that Would Expand Jeff Sessions's Power to Escalate the War on Drugs*, WASH POST: WONKBLOG (June 16, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/ 06/16/congress-is-considering-a-bill-that-would-expand-jeff-sessions-power-to-escalate-the-war-on-drugs/?noredirect=on&utm_term=.89f75dfe71e.

93 Pub. L. No. 99–570, § 1203, 100 Stat. 3207, 3213–14 (codified as amended at 21 U.S.C. § 802 (1986)).

94 Gregory Kau, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*, 156 PENN. L. REV. 1077, 1079 (2008).

95 *Id.*

96 *Id*. at 1083–84.

97 *See* McFadden v. United States, 135 S. Ct. 2298, 2307 (2015) (remanding a conviction for harmless error analysis when District Court improperly instructed jury on *mens rea* requirement for a prosecution under the Analogue Act); United States v. Forbes, 806 F. Supp. 232, 233 (D. Colo. 1992) (noting the concerns of prosecutors in regard to the difficulty proving whether a chemical compound is substantially similar to the relevant controlled substance).

98 *See* Ingraham, *supra* note 92 (discussing legislation that would make it easier for the Department of Justice to react to small tweaks to compositions).

99 *See* United States v. Lawton, 84 F.Supp.3d 331, 337 (D. Vt. 2015) (holding

ravages users for a period, only to be eclipsed by the next substance. This, combined with the statutory requirement that the substance be "intended for human consumption,"[100] has led to a game of whack-a-mole by the federal law enforcement, as they rush to schedule new substances as Schedule I or Schedule II drugs. This type of reactionary scheduling leads to scattershot policymaking and mediocre law enforcement.[101] This is not to say that there haven't been successful prosecutions,[102] but rather that they are so few and far between, and the statute is applied so unevenly, that the Analogue Act is no longer workable. On October 24th, 2018, President Trump signed the "SUPPORT for Patients and Communities Act" into law, a comprehensive opioid bill that contained one notable change to federal synthetic policy.[103] A version of the Synthetic Abuse and Labeling of Toxic Substances Act of 2017, or "SALTS" Act, was included, which codifies a set of nonexclusive factors to be considered in the government's determination that a drug is intended for human consumption.[104] Proponents of the bill argue that codifying these factors will make it harder for distributors of synthetic substances to deceptively market their drugs as "not for human consumption" and escape prosecution.[105]

The federal government's rush to prevent the abuse of synthetic drugs is also indicative of another, larger issue that lies within the CSA. By placing these substances on the Schedule I list of prohibited compounds, the government is declaring that they have

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that although the Analogue Act is not unconstitutionally vague for failure to define "substantially similar," the determination of a drug's similarity to a controlled substance is a question for the jury).

100 21 U.S.C. § 813 (2017).

101 *See* Michael H Andreae et al., *An Ethical Exploration of Barriers to Research on Controlled Drugs*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. 2–3, 9 (Apr. 1, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849133/pdf/nihms-778176.pdf (describing how the seemingly arbitrary scheduling of drugs allows research on a substance that may benefit some patients but limits or prohibits research on a substance that, due to differing circumstances, may benefit other patients).

102 *See* United States v. Washam, 312 F.3d 926, 928 (8th Cir. 2002).

103 Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 (2018).

104 *See id.* at ch.5, sec. 3241, 57 (2018).

105 *See* Press Release, Senator Amy Klobuchar, Klobuchar and Bipartisan Group of Senators Introduce Legislation to Help Fight Synthetic Drugs (Jan. 25, 2017), https://www.klobuchar.senate.gov/public/index.cfm/2017/1/klobuchar-and-bipartisan-group-of-senators-introduce-legislation-to-help-fight-synthetic-drugs.

"no currently accepted medical use."[106] However, the emergency scheduling power of the DEA effectively stops any public research in its tracks by treating the substance as a Schedule I drug for 21 U.S.C. § 823(f) purposes.[107] As soon as a substance is scheduled, any public research requires DEA approval.[108] It is true that many of these compounds are dangerous and have led to deaths of citizens all around the country;[109] however, it is also possible that we may not be aware of a potential medical use of a substance that is listed on Schedule I precisely because the DEA so strictly restricts public research. Although perhaps the need for research is more pressing for newly developed/scheduled substances, this "schedule first, study later"[110] policy is exacerbating the problem over time, effectively prohibiting research on quickly scheduled substances that then remain scheduled for decades. A substance placed in Schedule I is put there because it "has no currently accepted medical use,"[111] not because it is dangerous to potential public researchers. Public researchers have shown the ability to safely research dangerous substances for years. For example, AIDS research involves the study of a dangerous disease that HHS has developed controlled research procedures for going as far back as 1984.[112]

b. Marijuana

Marijuana is an example of the problems that can arise from being listed as a Schedule I substance for an extended period of time. The United States official position on marijuana is that it is a dangerous drug with no currently accepted medical use.[113] However, individual states seem to have rapidly moved away from that position in the last decade. As of March 2016, twenty-three

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106 21 U.S.C. § 812(b)(1).

107 *See supra* notes 58–59, 93 and accompanying text.

108 *See supra* note 62 and accompanying text.

109 *See, e.g.*, Courtney Astolfi, *FDA Head Details Plans to Curb Shipments of Synthetic Opioids into Ohio*, CLEVELAND.COM (Mar. 28, 2018), https://www.cleveland.com/metro/index.ssf/2018/03/fda_head_talks_to_clevelandcom.html).

110 *See* Kreit, *supra* note 4, at 353–56.

111 21 U.S.C. § 812(b)(1).

112 Office for Human Research Protections, *AIDS Research, Guidance for IRBs (1984)*, HHS (Dec. 26, 1984), https://www.hhs.gov/ohrp/regulations-and-policy/guidance/aids-research-guidance-for-irbs/index.html.

113 *See* 21 U.S.C. § 812(c) (listing marijuana as a Schedule I substance).

states had recognized "medical marijuana" in some capacity, four states and the District of Columbia had approved the use of recreational marijuana, and thirteen states had passed statutes recognizing the medical value of cannabinol (CBD).[114] In November 2016, an additional four states legalized recreational use.[115] In addition, twenty-one states and the District of Columbia have decriminalized certain amounts of marijuana possession.[116] The rapid expansion of legalized marijuana has forced the federal government to reconcile the tension between these new state laws and the CSA. The DEA has reluctantly recognized a "potential therapeutic utility of cannabinoids,"[117] but because no studies "involve successively larger groups of patients" that are "designed primarily to explore and to demonstrate or confirm therapeutic efficacy and benefit in patients,"[118] they have repeatedly denied rescheduling.[119] For a new drug in development, this wouldn't be a problem, because the manufacturer could order the study. On the other hand, for a substance already listed as a Schedule I compound, the § 823(f) research restrictions kick in and cut off potential public studies.[120]

Though Congress has thus far taken extremely limited steps to address the discrepancy between federal and state marijuana laws,[121] the executive branch has. In 2013, Deputy Attorney General James Cole published a memorandum to United States Attorney's nationwide, updating federal enforcement policy.[122] The

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114 Douglas C. Throckmorton, *FDA Regulation of Marijuana: Past Actions Future Plans*, FOOD AND DRUG ADMIN. (Apr. 12, 2016), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM498077.pdf.

115 Ben Gilbert, *4 States Just Voted to Make Marijuana Completely Legal – Here's What we Know*, BUSINESS INSIDER (Nov. 9, 2016, 8:52 AM), http://www.businessinsider.com/marijuana-states-legalized-weed-2016-11.

116 *See States That Have Decriminalized*, NORML, http://norml.org/aboutmarijuana/item/states-that-have-decriminalized (last visited Apr. 6, 2018).

117 Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,580 (Jul. 18. 2011) (to be codified at 21 C.F.R. Chapter II).

118 *Id.* at 40,567.

119 *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12, 2016) (to be codified at 21 C.F.R. Chapter II).

120 21 U.S.C. § 823(f).

121 *See* Jasun C. Molinelli, *AG Sessions Fails to Deter Congress From Extending the Rohrabacher Farr Amendment*, ARCHERNORRIS: THE GREEN ENTERPRISE (Mar. 23, 2018), https://www.archernorriscannabisblog.com/2018/03/ag-sessions-fails-deter-congress-extending-rohrabacher-farr-amendment/.

122 Memorandum from James Cole, Deputy Attorney General, on Guidance

"Cole Memo" reiterated certain priorities such as "preventing the diversion of marijuana from states where it is legal under state law in some form to other states,"[123] while noting that other than the listed priorities, "the federal government has traditionally relied on states and local law enforcement agencies to address marijuana activity."[124] In effect, the memo signaled that the administration would ignore the listing of marijuana as a Schedule I substance for enforcement purposes, avoiding a potentially politically sensitive clash between the federal and state governments. Unfortunately for marijuana advocates, this guidance was issued in the form of a memorandum, not a legally binding regulation. Therefore, a future administration could immediately rescind the memo and begin prosecuting local marijuana dispensaries as distributors of a Schedule I controlled substance – which is exactly what looks to be happening under the current administration. In fact, in 2018 Attorney General Sessions not only rescinded the Cole Memo but also repeatedly opined on the dangers of marijuana and the need to enforce existing federal drug laws.[125] As a result, many state and local officials are concerned about potential changes in enforcement.[126] A new, clearer scheduling scheme would alleviate some, if not all of these concerns.

III. REFORM

The United States needs to take drastic steps to overhaul our approach to federal drug policy. The system no longer reflects current needs and is administered in a ham-handed fashion that leads to many different upsetting results. This starts with rethinking the current federal scheduling scheme. The three findings of § 812(b) and eight factors in § 811(c), combined with the five factor DEA test determining whether a substance has an "accepted medical use" is unwieldy, and in the government's own

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regarding marijuana enforcement to all United States Attorneys (Aug. 29, 2013) https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf. [hereinafter *Cole Memo*].

123 *Id.*

124 *Id.*

125 Josh Gerstein, *Sessions announces end to policy that allowed legal pot to flourish*, POLITICO, (Jan. 4, 2018 9:31 AM), https://www.politico.com/story/2018/01/04/jeff-sessions-marijuana-policy-us-attorney-enforcement-324020.

126 *Id.*

words, "redundant."[127] Barring a drastic change in the judiciary's approach to administrative law,[128] Congress will need to take substantial steps via legislation in order to fix a problem of this magnitude. Though change will also require a shift in regulatory and administrative application of federal statutes, at the end of the day, the detailed restrictions inherent within the text of the CSA will necessitate large scale legislative reform.

a. Legislative Options

Because any regulatory reform faces a potential reversal that may come with a new administration, legislative reform is the most appropriate way to address our federal drug policy. While comprehensive CSA reform would produce the most holistic change to the system, a methodical piecemeal method could accomplish many of the same goals.

Any changes to federal policy should begin with an adjustment to the current federal scheduling system. The classification system is overbearing and inconsistent. To fix it, Congress should start anew, and reassess what the most important factors in determining whether a substance should be controlled really are. The reasons for this are threefold. First, changing the classification scheme is necessary to standardize the federal governments approach to controlled substances. Second, such changes will have downstream effects on the problems discussed *supra*, specifically in regard to research, where Schedule I substances are heavily regulated. Finally, a wholesale revamp of the scheduling system that includes changes to the way analog substances are treated will temper the consequences political and public pressure have on good policymaking.

The current three findings of § 812 and eight factor test in § 811 that go into a scheduling determination create a duplicative analysis that provides no real guidance for regulators, and that's

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[127] United States v. Pastor, 419 F. Supp 1318, 1339 n.6 (S.D.N.Y. 1975).

[128] One might argue that Congress failed to articulate an "intelligible principle" when assigning the executive branch the job of scheduling controlled substances, or more specifically, in determining whether a substance has a currently accepted medical use. This would violate the non-delegation doctrine, a legal theory that the Supreme Court has only ever found statutes in violation of in two instances, both over 80 years ago. The Supreme Court has already ruled that the delegation of temporary scheduling authority to the Attorney General is appropriate even if Congress is required to be more specific when delegating authority defining criminal conduct. *See* Touby v. United States, 500 U.S. 160, 165–66 (1991).

before considering the DEA's five-part test for accepted medical use under § 812(b). Instead, Congress should set a clear benchmark by making potential for abuse the only factor for a DEA recommendation on what schedule to place a substance under, a recommendation that may be altered by NIDA consideration of subsequent factors. This would immediately create an even playing field amongst drugs like cocaine, oxycodone and marijuana. In practice, placing such a heavy weight on "accepted medical use" has led to discrepancies such as cocaine being listed as a Schedule II, while less dangerous drugs have been placed in Schedule I. As scholars have noted, a substance with no currently accepted medical use but also with a low potential for abuse would currently be placed in Schedule I.[129] Instead of focusing solely on currently accepted medical use, Congress should consolidate both the three findings of § 812(b) and eight factor test of § 811(c) in favor of a test with mitigating factors.

The fundamental flaw with the current scheduling system isn't the five-level set up; rather, it's the factors going into each individual determination. A new CSA could keep the five levels but should dramatically reduce the DEA's involvement in the initial scheduling process. The DEA should be limited to making determinations on potential for abuse. Each substance should receive a publicized score, from one to ten, with each third rank requiring a higher scheduling *recommendation* from DEA. This recommendation could then be considered by NIDA scientists along with the other factors outlined in a new § 811(c).

Congress should eliminate the superfluous multi-factor tests that exist in § 811(c) and § 812(b) in favor of a single test. Instead, new language could be inserted to § 811(c):

When considering whether a substance should be controlled and the schedule to be assigned to it, the National Institute on Drug Abuse should consider:

(1) It's actual or relative potential for abuse, as recommended by the Attorney General.

(2) Scientific evidence of its pharmacological effect, if known.

(3) State of current scientific knowledge regarding the drug or related substances.

(4) Any currently accepted medical uses.

(5) Its psychic or physiological dependence liability.

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[129] Kreit, *supra* note 4, at 343.

(6) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(7) What, if any, risk the substance presents to the public health. [130]

This new, seven-part test would not alleviate all scheduling issues; however, if § 812 then requires that the substances are to be placed on schedules I-V in accordance with the factors outlined in § 811(c), it would remove some of the extraneous language and highlight the factors that are truly important, while making the scheduling process more transparent for the judiciary and citizenry alike.[130]

Congress should be also more specific in defining "currently accepted medical use" in their new test, either directly in the text or in committee reports. One possibility would be to adopt a standard similar to one courts are familiar with applying. The *Daubert* standard[131] for the admittance of expert testimony is admittedly a loose standard that weighs in favor of admittance, but as it would only be one part of the NIDA consideration, its use could address experimental treatments and cutting-edge science and would promote additional research. This test could be easily adopted to "accepted medical use" and could be litigated in courts, which all have experience dealing with the *Daubert* standard.

In addition to creating a more transparent scheduling system, all substances should be subject to annual government testing by NIDA, to allow for faster response times to changes in public policy and increased medical advances around the country. The general public should also be able to petition DEA for additional research on substances viewed as dangerous, which could lead to an updated rating of the drug on the one through ten scale detailed above. If a drug that is listed as a Schedule II-V substance is

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[130] *Schedule of Controlled Substances: Mainting Marijuana in Schedule 1 of the Controlled Substances Act*, U.S. DEP'T OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION, Jul. 2016, https://www.deadiversion.usdoj.gov/schedules/marijuana/Maintaining%20Marijuana%20in%20Schedule%20I%20of%20the%20Controlled%20Substances%20Act.pdf

[130] For a more generalized theory on delegating scheduling authority, see Doll, *supra* note 23, at 440–41.

[131] The *Daubert* factors are (1) whether the theory or technique employed is generally accepted in the scientific community; (2) whether it has been subjected to peer review and publication; (3) whether it can be and has been tested; (4) whether the known or potential rate of error is acceptable; and (5) whether the research was conducted independent of the potential litigation at hand. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593, 594 (1993).

believed to be leading to abuse, DEA research (published publicly) could quickly lead to a new recommendation to NIDA on whether the substance should remain in its current schedule or move up to Schedule I. This recommendation should again be made solely on the potential for abuse.

These changes will alleviate some of the concerns that stem from 21 U.S.C. § 823. Lifting research restrictions legislatively will both provide the necessary relief and grant scientists some measure of certainty. By changing the way substances are scheduled, policy makers can enable some increased level of research, as any new method will hopefully lead to both only legitimately dangerous substances being placed on Schedule. If a full rewrite of § 811 and § 812 fails, revision of 21 U.S.C. § 823 is the next logical step. As currently written, the law requires the HHS Secretary and the Attorney General to prioritize "effective controls of diversion" when considering research applications.[132] This encourages minimal research approvals and does not properly consider the need for research of Schedule I substances. Congress should not stop by simply lifting the DEAs research restrictions.

It is unlikely that the DEA will willingly cede their regulatory gatekeeping power over controlled substances to the FDA and NIDA – instead, targeted legislation granting uniform, sole authority to the NIDA to vet and approve researchers will allow for quicker approval processes and for increased research on Schedule I substances. NIDA's number one goal is to advance addiction science,[133] unlike the DEA's, which is to enforce the controlled substances laws.[134] This difference in priorities should enable increased research. By empowering NIDA exclusively to handle all research applications and distribution of Schedule I substances, researchers may finally gain access to drugs like MDMA that have been restricted since the late 1980s. DEA's repeated (and sometimes warranted) exercise of emergency scheduling authority has prevented outside research on substances that could, one day, provide some medical benefits. In 1970, no one foresaw the potential benefits of marijuana on

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132 21 U.S.C. § 823(a)(1).

133 *2016-2020 NIDA Strategic Plan*, NIDA, https://www.drugabuse.gov/about-nida/strategic-plan/nidas-mission (last visited Apr. 12, 2018).

134 *DEA Mission Statement*, DRUG ENFORCEMENT ADMIN., https://www.dea.gov/about/mission.shtml (last visited Apr. 12, 2018).

children with epilepsy or those with chronic pain,[135] and it has taken nearly fifty years to recognize any progress on this measure. Congress should learn from the problems these restrictions have caused for the general welfare of the citizenry and consolidate research approval and distribution within NIDA. There is no reason for DEA involvement in research facilities. Should NIDA suspect that one of their applicants is misusing the substance provided to them, they could then refer the matter to DEA for appropriate enforcement.

In an attempt to remedy some of the issues that have arisen since states began legalizing marijuana, Senators Kirsten Gillibrand (D-NY), Corey Booker (D-NJ) and Rand Paul (R-KY) have introduced the Compassionate Access, Research Expansion and Respects States (CARERS) Act.[136] One of the most interesting ideas put forward in the CARERS Act is to essentially outsource marijuana law to the states. The bill does this by inserting a provision negating its effect on any individual "in compliance with state law."[137] Though this would be a difficult way to regulate drug policy more generally, this idea of a waiver might be applicable in certain specific contexts. For instance, if the DEA is insistent on maintaining some level of control over Schedule I research applications, it would make sense for Congress to provide the states with a waiver process. If state governments decide that they wish to regulate research of Schedule I drugs differently than the federal government, they should be able to apply through the DEA to obtain waivers for public research done in accordance with state law. This would be one way to alleviate enforcement concerns without completely ceding all government oversight.

Additionally, addressing the Attorney General's emergency scheduling authority has become a major concern in light of the ability of illegal manufacturers to create synthetic substances.[138] Congress should increase the Attorney General's authority to schedule chemically similar compounds by creating a structure similar to that proposed by Senators Grassley and Feinstein through the Stop the Importation and Trafficking of Synthetic

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135 DeAdder, *supra* note 18; Russo, *supra* note 24.

136 Press Release, Senator Cory Booker et al., The Compassionate Access, Research Expansion and Respect States (CARERS) Act (Jul. 15, 2017) https://www.booker.senate.gov/?p=press_release&id=613 doc/2017%20CARERS%20One%20Pager1.pdf.

137 S. 1374, 115th Cong. (2017).

138 *See supra* Part II (a).

Analogues Act of 2017 (SITSA).[139] SITSA creates a new schedule for "substantially similar" substances and allows the Attorney General to schedule the substance without analysis of the substance's drug abuse record and risk to public health.[140] However, where the authors of SITSA err is allowing such a substance to be effectively banned for five years without any further analysis. The Attorney General should be allowed to immediately schedule a substance – but should have to substantiate such a finding within 120 days and provide reports to Congress reaffirming the need for temporary scheduling every year, which would include scientific reports conducted by NIDA. If NIDA concludes that there is not a legitimate basis for the emergency scheduling, the drug should be immediately removed from the list of controlled substances.

Reapportioning the distribution of power in the constant pull between HHS and DOJ is also vital for the government adjust to drug use in the twenty first century. Enforcement resources vastly outnumber other federal prevention and treatment methods. The 21st Century Cures Act, passed in November 2016, provides funding for physician training, development of state prescription drug monitoring programs (PDMPs) and other prevention activities.[141] Similar steps in resource shifting from enforcement to treatment related solutions need to be a continued part of efforts to decrease drug abuse throughout the country; such steps include the recently passed SUPPORT for Patients and Communities Act, which provides funding for certain provisions in the 21st Century Cures Act and focuses more squarely on treatment than enforcement measures.[142] On the other hand, from an executive branch perspective, it unfortunately appears that the current administration favors the time-tested (and failed) policy of increased enforcement.[143]

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139 S. 1327, 115th Cong. sec 2, § 2, sec. 3 (2017).

140 *See* Ingraham, *supra* note 92.

141 Pub. L. No. 114-255, 130 Stat. 1033, sec. 1003(c) (2016).

142 *See* Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 (2018).

143 *See* Jacqueline Alemany, *Trump Focuses on Law Enforcement Side of Opioid Rollout*, CBS NEWS (Oct. 24, 2018, 11:36 AM), https://www.cbsnews.com/news/trump-focuses-on-law-enforcement-side-of-opioid-rollout.

a. Regulatory Recourse

If legislative reform fails to gain traction, that should not mean the end for changes to the federal scheduling system. Regulatory reform might also be used in order to relieve some of the major headaches presented in the previous sections. Though the language in § 823 is fairly restrictive, the FDA and DEA can take steps to lift certain research restrictions through regulatory reform. The executive branch could also remove marijuana from the list of controlled substances, but unfortunately the mandatory scheduling considerations in § 811 and § 812 leave little room for non-legislative reform.

21 C.F.R. § 1301.32 details the actions the executive branch must take after receiving an application for research of a Schedule I. It states that when the HHS Secretary determines the applicant for research is qualified and competent and the research protocol is meritorious, the DEA Administrator should issue a certificate of registration within ten days.[144] The DEA should act immediately in accordance with 21 C.F.R. § 1301.32 to approve additional research on Schedule I substances.

Moreover, the DEA should move to adopt new regulations that ease the bureaucratic burdens on potential applicants for research. The DEA could strengthen protections laid out in § 1301.32(d) for applications where agency action hasn't been taken in a certain period of time[145] C.F.R. § 1301.18 lays out the research protocols necessary to gain approval of a Schedule I substance application, and the DEA could relax some of the requirements necessary, such as lowering application fees for manufacturing or lengthening the registration period for those looking to obtain a DEA registration number. As it stands, it costs over $3,000 per year to be registered to manufacture a Schedule I substance.[146] In regards to marijuana, for example, in 2016 the DEA decided to increase the number of DEA-registered marijuana manufacturers in an attempt to facilitate research.[147] Unfortunately, until this most recent policy change there had been only *one* authorized entity in the *entire country* that was allowed to produce marijuana for researchers.[148]

144 21 C.F.R. § 1301.32(c) (2018).

145 21 C.F.R. § 1301.32(d) (2018).

146 *See* 21 C.F.R. § 1301.13(e)(i) (2018).

147 Policy Statement, 81 Fed. Reg. 53846 (Aug. 12, 2016).

148 Matt Zapotosky & Devlin Barrett, *Justice Department at Odds with DEA on Marijuana Research, MS-13*, WASH. POST (Aug. 15, 2017), https://www.washingtonpost.com/world/national-security/justice-department-at-

Moreover, the new policy was effectively reversed by Attorney General Sessions in 2017.[149] Approving additional growers to promote research would require no change in rules or regulations and no legislative changes.

A streamlined/deregulated application approval process is necessary in order to provide researchers with the ability to do the work that they need while still ensuring citizen safety. The DEA, by requiring independent approval of Schedule I research, is intruding on what should be the exclusive role of NIDA and the FDA. Instead, DEA should focus their efforts on enforcement while allowing the scientists to vet fellow scientists. Ambitious regulatory reform would consolidate approval power under one roof, suggested here as NIDA.

IV. CONCLUSION

Overall, in order to bring transparency and common sense back into federal drug policy, it is necessary to rethink the Controlled Substances Act and its approach to controlled substances. Updating an outdated scheduling system with byzantine regulations on research and substances that no longer require such strict regulation should be among the priorities of the 116th Congress. A streamlined and more transparent CSA would be easier for all parties to navigate – from citizens, to researchers, to judges and juries. With these types of changes, and continued support for treatment-style measures like the SUPPORT for Patients and Communities Act, the United States can get federal drug policy back on schedule.

odds-with-dea-on-marijuana-research-ms-13/2017/08/15/ffa12cd4-7eb9-11e7-a669-b400c5c7e1cc_story.html?utm_term=.f9b8d25e9ebc (noting the University of Mississippi's monopoly on marijuana production for research).

149 *Id.*