

**Before the
DRUG ENFORCEMENT ADMINISTRATION
Arlington, VA 22202**

In the Matter of)
Schedules of Controlled Substances: Rescheduling of Marijuana) Docket No. DEA-1362
Notice of Proposed Rulemaking)
)

**COMMENTS OF
SMART APPROACHES TO MARIJUANA**

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INTRODUCTION

This proposed rulemaking could lead to the most significant rescheduling decision in the history of the Controlled Substances Act (the “Act” or “CSA”). 21 U.S.C. § 801 *et seq.* Marijuana has been controlled under Schedule I since Congress itself placed marijuana under Schedule I when it passed the Act in 1970. There has been no failure to revisit that judgment in the more than five decades since. The Drug Enforcement Administration (DEA), acting under delegated authority from the Attorney General, and the Department of Health and Human Services (HHS)¹ have previously considered requests to reschedule marijuana no fewer than nine times, as early as 1972 and as recently as 2016, after numerous states had already attempted to circumvent federal restrictions on the trafficking and use of marijuana.² On each occasion, after applying the criteria specified in the Act, DEA and HHS have rejected the rescheduling request and determined that marijuana must remain controlled under Schedule I. Significantly, HHS agreed on each occasion that, under the criteria set by the Act, marijuana must remain controlled under Schedule I.

To change course now and reschedule marijuana, DEA (or the Attorney General) would have to provide a detailed justification explaining why the consistent analysis of the government over the past five decades holding that the statutory criteria require controlling marijuana under Schedule I is no longer accurate or applicable. It is well settled that when an agency changes

¹ This authority was originally delegated to the Department of Health, Education, and Welfare, but is now exercised by HHS and for ease of reference this Comment refers solely to HHS. *See* Department of Education Organization Act, Pub. L. No. 96-88, §§ 301, 509, 93 Stat. 668, 677-79, 695 (1979).

² *See* 81 Fed. Reg. 53,767 (Aug. 12, 2016); 81 Fed. Reg. 53,688 (Aug. 12, 2016); 76 Fed. Reg. 40,552 (July 8, 2011); 66 Fed. Reg. 20,038 (Apr. 18, 2001); 57 Fed. Reg. 10,499 (Mar. 26, 1992); 54 Fed. Reg. 53,767 (Dec. 29, 1989); 44 Fed. Reg. 36,123 (June 20, 1979); 40 Fed. Reg. 44,164 (Sept. 25, 1975); 37 Fed. Reg. 18,097 (Sept. 7, 1972).

course, it must provide a reasoned explanation for the change. *See, e.g., FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003) (“[A]gency action is arbitrary and capricious if it departs from agency precedent without explanation.”). In particular, “a reasoned explanation is needed for disregarding facts and circumstances that underlay” a prior decision on the same subject. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016).

Here, DEA would have to explain that evidence it previously found compelling relating to statutory factors such as marijuana’s potential for abuse, its likelihood for leading to physical or psychological dependence by users, and its adverse health effects (both on users and the public more broadly), no longer warrants maintaining marijuana under Schedule I. For example, DEA would have to point to new studies or new scientific evidence overturning its prior findings under the statutory criteria specified by the CSA that marijuana is properly listed in Schedule I. In addition, DEA would have to provide evidence of a sea change in the approach of physicians with respect to marijuana to establish that marijuana now has a “currently accepted medical use” (CAMU) in the United States. A finding as to a CAMU is critical, because marijuana cannot be moved out of Schedule I unless DEA finds that it has a CAMU.³

Nothing in the record, however, provides any basis for DEA to change its prior conclusions on these points. If anything, recent research confirms the serious adverse health effects of using marijuana. To give just one example, marijuana has been shown to have serious negative effects

³ The critical distinction between Schedule I drugs and drugs in Schedules II to V is that drugs classified in Schedule I lack a “currently accepted medical use,” and lack an “accepted safety for use . . . under medical supervision.” 21 U.S.C. § 812(b)(1). If a drug has a CAMU, it is placed in Schedules II to V, depending on the potential for abuse of the drug, and the propensity of the drug to lead to physical or psychological dependence. *Id.* § 812(b)(2)-(5).

on the neurological development of adolescents, producing cognitive deficits that persist indefinitely. *See infra* Part II.A.1.a.i. That is particularly concerning given the high and increasingly heavy usage rate of marijuana among teenagers and the increasing potency of botanical marijuana available in the United States. In the past 30 years average concentrations of THC in botanical marijuana have increased over five-fold: from 3% in 1991 to 17% today, and some strains are as potent as 35% THC. Other concentrated products, like oils and dabs, can contain 99% THC. In addition, it remains the case that not a single professional organization of physicians in the United States recommends the use of marijuana for treating *any* condition. In short, nothing about the *facts* concerning marijuana with respect to the relevant statutory criteria has changed in any way in the last eight years to suggest that relaxed restrictions under the CSA are warranted.

Nevertheless, HHS has, for the first time, recommended rescheduling marijuana to Schedule III. *Memorandum for DEA, from HHS, Re: Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act* [hereinafter “HHS Recommendation”] 5 (Aug. 29, 2023). The NPRM rightly concludes that HHS’s recommendation is not binding on DEA and that DEA must make its own independent assessment of rescheduling under the criteria set by the Act. *Rescheduling of Marijuana* [hereinafter “NPRM”], 89 Fed. Reg. 44,597, 44,599 (May 21, 2024). In conducting that analysis, the Administrator should reject HHS’s recommendation, because HHS’s analysis is wholly inadequate to justify such an extraordinary about-face in applying the terms of the Act. As explained further below, HHS has completely failed to provide a reasoned explanation for multiple changes in its analysis that were necessary to yield the novel recommendation for rescheduling marijuana to Schedule III. For example, HHS simply ignored multiple health effects of marijuana that were previously an important part of both

DEA's and HHS's analysis of the proper scheduling of marijuana under the Act. To give just one example, in 2016, both DEA and HHS discussed the deleterious effects of marijuana on neurological development in adolescents as a serious health impact that supported continued regulation under Schedule I.⁴ In its current recommendation, however, HHS fails even to *mention* the effects of marijuana on neurological development. HHS does not purport to explain that prior studies were faulty or that newer studies have established that marijuana poses a lesser risk to the cognitive development of adolescents. Instead, it simply ignores the issue entirely. That is the height of arbitrary and capricious decision making. Such a “failure to come to grips with conflicting precedent constitutes an inexcusable departure from the essential requirement of reasoned decision making.” *Ramaprakash*, 346 F.3d at 1125 (quotation omitted). Here, HHS failed to provide any explanation for departing from its prior analysis examining such health effects.

As for the critical finding concerning a CAMU, HHS does not even pretend that the facts have changed sufficiently to support a conclusion that marijuana now somehow has a CAMU under the test that both DEA and HHS have applied since the 1990s—a test that has expressly been found consistent with the CSA by the D.C. Circuit. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994). Instead, HHS simply invented an entirely new test for determining whether a CAMU exists—a test that conveniently waters down the standard so that the agency can find a CAMU even though no organization of physicians has ever approved the use of marijuana for treating any condition. It could hardly be clearer that HHS deliberately changed its analysis to arrive at a preordained outcome supporting the rescheduling of marijuana.

⁴ *See* 81 Fed. Reg. 53,767, 55,830 (Aug. 12, 2016).

HHS’s unexplained and unjustified changes to its analysis—and its failure even to address health effects that it previously found compelling—are particularly suspect given the unprecedented genesis of this proceeding. Unlike every prior rescheduling proceeding, this rulemaking was not initiated by a petition from a private party purporting to have evidence that warranted reconsidering the proper scheduling of marijuana under the Act. Instead, it was initiated by the current Administration based on nothing more than a policy preference—a policy preference that some believed would be advantageous to them politically. On October 6, 2022, President Biden declared that, in his view, no one should go to prison for possession of marijuana. *See* The White House, Statement from President Biden on Marijuana Reform (Oct. 6, 2022), <https://perma.cc/LVF6-344M>. He then provided a blanket pardon to every person convicted of a federal offense of marijuana possession and directed the Attorney General and the Secretary of HHS to examine rescheduling marijuana under the CSA. As that announcement made clear, the President was not calling for a reconsideration of the proper scheduling of marijuana based on new evidence about the health effects or potential for abuse of marijuana or based on new developments in its medical use. Instead, the announcement was based solely on the Biden Administration’s political desire to be able to declare a massive relaxation of federal restrictions on access to the most widely used (and abused) illicit recreational drug in an election year.

Needless to say, the policy preferences of the current incumbent of the White House and his desire to loosen restrictions on a controlled substance because he believes that will be popular are not relevant criteria that DEA is permitted to consider under the Act. The DEA’s “core mission” is “enforcing the nation’s drug laws and enhancing public health, safety, and national security.”⁵

⁵ See DEA, Core Values, <https://perma.cc/NH6H-CG3F>.

That includes applying the statutory criteria set by Congress and ensuring that the American people are protected from substances that have a high potential for abuse, have a deleterious effect on health, and lack a CAMU. For DEA to abandon the analysis it has consistently followed in the past and accept a recommendation from HHS that wholly fails to explain a change in approach would be a craven abdication of the Administrator's responsibility to the American people under the Act. History would judge the Administrator harshly for ignoring undisputed scientific evidence about the health effects of marijuana and abandoning America's youth to the effects that marijuana will have in impairing their cognitive development and leaving them with life-long cognitive deficits, all in the name of supporting the short-term political preferences of a particular Administration.

For all the reasons set out below, the Administrator should reject HHS's faulty recommendation and maintain marijuana under Schedule I of the Act.

INTEREST OF SMART APPROACHES TO MARIJUANA IN THE PROCEEDING

Smart Approaches to Marijuana (SAM) is a nonpartisan organization that advocates for a health-first approach to marijuana policy. It is comprised of medical doctors, lawmakers, treatment providers, preventionists, teachers, law enforcement officers and others who seek a middle road between incarceration and legalization. SAM's mission is to equip policymakers with commonsense proposals, based in reputable science, to promote public health and decrease marijuana use and its consequences. SAM opposes the transfer of marijuana into Schedule III.

BACKGROUND

A. Statutory and Regulatory Background

Congress enacted the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, as a revision to previous anti-drug laws and the national implementing legislation for the UN Single Convention on Narcotic Drugs. The CSA is "a comprehensive statute designed to rationalize

federal control of dangerous drugs.” *Nat’l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977). Under the CSA, substances are categorized into a series of five schedules. Schedule I drugs have a “high potential for abuse,” lack a “currently accepted medical use” (CAMU), and lack an “accepted safety for use . . . under medical supervision.” 21 U.S.C. § 812(b)(1). If a drug has a CAMU, it is placed in Schedules II to V, depending on the potential for abuse of the drug, and the propensity of the drug to lead to physical or psychological dependence. *Id.* § 812(b)(2)-(5).

Whether a drug has a CAMU is a significant distinction separating a Schedule I from the other schedules. For example, cocaine, methamphetamine, and fentanyl are highly addictive and dangerous narcotics. Nevertheless, they are placed in Schedule II rather than Schedule I because they also have a CAMU and can be prescribed by a doctor: cocaine has use as a local anesthetic during surgeries,⁶ methamphetamine is used to treat severe ADHD,⁷ and fentanyl is used to treat patients with severe pain.⁸ Comparably less deadly drugs like peyote are nonetheless placed in Schedule I because they lack a CAMU.⁹

In enacting the CSA, Congress classified marijuana as a Schedule I drug. *Id.* at § 812(c), Schedule I(c)(10). Federal law defines marijuana as the plant “*Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every

⁶ *Position Statement: Medical Use of Cocaine*, American Academy of Otolaryngology-Head and Neck Surgery, <https://perma.cc/8TWM-B2BW>.

⁷ *Methamphetamine (Oral Route) Description*, Mayo Clinic, <https://perma.cc/56S6-6S7H>.

⁸ *Fentanyl DrugFacts*, National Institute on Drug Abuse (June 2021), <https://perma.cc/C38V-8GFP>.

⁹ Unlike cocaine, methamphetamine, and fentanyl, DEA does not even discuss peyote in its discussion of drug threats for 2024. DEA, National Drug Threat Assessment 2024 (May 9, 2024), <https://perma.cc/42ZW-W5LH>.

compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.” 21 U.S.C. § 802(16)(A). Due to its placement in Schedule I, federal law prohibits the possession, manufacture, and distribution of marijuana, 21 U.S.C. §§ 841, 844, except for marijuana cultivated by persons licensed by the DEA for purposes of research, *see* 21 C.F.R. pt. 1301.

Congress authorized the Attorney General to amend Congress’s initial scheduling placement. 21 U.S.C. § 811. “[B]efore initiating proceedings” to add, remove, or transfer a drug between schedules, the Attorney General “shall request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance.” 21 U.S.C. § 811(b). When recommending or determining that a drug should be placed in a different schedule, the Secretary and the Attorney General must consider eight factors listed in 21 U.S.C. § 811(c). These factors are:

- (1) marijuana’s potential for abuse;
- (2) scientific evidence of its pharmacological effects;
- (3) the state of current scientific knowledge regarding marijuana;
- (4) marijuana’s history and current pattern of abuse;
- (5) the scope, duration, and significance of that abuse;
- (6) the risks marijuana poses to the public health;
- (7) marijuana’s psychic or psychological dependence liability; and
- (8) whether marijuana is an immediate precursor of a substance already controlled under the CSA.

Id. § 811(c); *see also id.* § 811(b) (directing HHS to consider the eight factors). Prior to the issuance of the NPRM, HHS’s findings as to “scientific and medical matters” are “binding.” *Id.* § 811(b). If the Attorney General proposes rescheduling, rulemaking proceedings shall be “on the

record after opportunity for a hearing.” *Id.* at § 811(a). During the formal rulemaking process, HHS’s findings are no longer binding. *See Questions Related to the Potential Rescheduling of Marijuana*, 48 Op. O.L.C. ___, *24 (Apr. 11, 2024).

The successive rescheduling proceedings addressing Marinol provide a good example of how this process normally unfolds. Marinol contains synthetic dronabinol, a Schedule I substance that is an isomer of delta-9-tetrahydrocannabinol (THC). In 1985, the FDA approved Marinol, which consists of “specified quantities of dronabinol in sesame oil and encapsulated in round soft gelatin capsules.” 50 Fed. Reg. 42,186 (Oct. 18, 1985). The following year, relying on an evaluation by HHS and the FDA’s approval of Marinol, DEA transferred Marinol to Schedule II. 51 Fed. Reg. 17,476 (May 13, 1986). In 1999, after over a decade on Schedule II and after the FDA expanded the indications for which Marinol was an approved drug, DEA transferred Marinol to Schedule III. *See* 64 Fed. Reg. 35,928 (July 2, 1999). For the first time, a chemically standardized, synthetic drug with specified doses of THC was controlled under Schedule III.

B. The DEA Has Repeatedly Rejected Efforts to Reschedule Marijuana.

The DEA has never transferred a drug directly from Schedule I to Schedule III in one rulemaking, and it has never rescheduled *any* drug out of Schedule I without an FDA-approved medical application.

Over the last fifty years, during both Republican and Democratic administrations, DEA has rejected petitions to reschedule marijuana no fewer than nine times. *See* 81 Fed. Reg. 53,767 (Aug. 12, 2016); 81 Fed. Reg. 53,688 (Aug. 12, 2016); 76 Fed. Reg. 40,552 (July 8, 2011); 66 Fed. Reg. 20,038 (Apr. 18, 2001); 57 Fed. Reg. 10,499 (Mar. 26, 1992); 54 Fed. Reg. 53,767 (Dec. 29, 1989); 44 Fed. Reg. 36,123 (June 20, 1979); 40 Fed. Reg. 44,164 (Sept. 25, 1975); 37 Fed. Reg. 18,097

(Sept. 7, 1972). DEA has considered this issue as recently as 2016 and 2011 and both times concluded that marijuana belongs in Schedule I.

In 2011, DEA denied a petition to reschedule marijuana submitted by the Coalition for Rescheduling Cannabis. 76 Fed. Reg. 40,552 (July 8, 2011). DEA concluded that marijuana belonged in Schedule I because of its high potential for abuse, lack of a CAMU, and lack of accepted safety for use under medical supervision. With respect to its high potential for abuse, DEA found that marijuana “had the highest levels of past year dependence and abuse.” *Id.* at 40,584. With respect to marijuana’s use in medicine, the DEA, quoting HHS’s evaluation, explained that the lack of “a consistent concentration of [THC] in botanical marijuana from diverse sources complicates the interpretation of clinical data using marijuana.” *Id.* at 40,558. Based on the available data, there was no “consensus of medical opinion concerning medical applications of marijuana.” *Id.* at 40,560. The DEA also emphasized that the majority of new users of marijuana were “less than 18 years of age.” *Id.* at 40,567. The DEA also considered petitioners’ suggestion that state-level medicinal marijuana practice had a bearing on how marijuana should be scheduled, concluding that this “is contrary to the CSA’s statutory scheme,” and the CSA “precludes the argument that state legislative action can establish accepted medical use under the CSA.” *Id.* at 40,579.

DEA rejected two petitions to reschedule marijuana in 2016. *See* 81 Fed. Reg. 53,767 (Aug. 12, 2016) (denying petitions of Governors Chaffe and Gregoire to remove marijuana from Schedule I); 81 Fed. Reg. 53,688 (Aug. 12, 2016) (denying petition of Mr. Krumm, CNP to move marijuana to Schedule II). DEA again found that marijuana was “the most abused and trafficked illicit substance in the United States” and “was mentioned in 36.4% of illicit drug-related emergency department (ED) visits, corresponding to 455,668 out of approximately 1.25 million

visits.” 81 Fed. Reg. at 53,839. With respect to marijuana’s status as medicine, DEA reiterated that marijuana “has hundreds of cultivars containing variable concentrations of [THC],” *id.* at 53,778; that “state-level ‘medical marijuana’ laws do not provide evidence” towards a CAMU, *id.* at 53,836; and that “neither adequate safety studies nor adequate and well-controlled studies prov[e] marijuana’s efficacy” as medicine, *id.* at 53,780. DEA’s analysis also showed that the use of marijuana by adolescents was increasing, from 21.4% of 12th graders in 2011, 76 Fed. Reg. at 40,571 to 22.7% in 2016, 81 Fed. Reg. at 53,770. DEA also found that marijuana use “can lead to physical dependence . . . as well as psychic or psychological dependence.” *Id.* at 53,821. DEA also found that marijuana use disorder was increasing. *Id.* at 53,758.

C. At President Biden’s Request, HHS and the Attorney General Initiated the Administrative Review of Marijuana’s Status as a Schedule I Controlled Substance.

In October 2022, President Biden took the unprecedented step of directing the Attorney General and the Department of Health and Human Services to, once again, “initiate the administrative process to review” marijuana’s status as a Schedule I narcotic. *See* The White House, Statement from President Biden on Marijuana Reform (Oct. 6, 2022), <https://perma.cc/LVF6-344M>. The President asserted that Schedule I was only “meant for the most dangerous substances,” also noting that marijuana is currently classified in the “same schedule” as “heroin and LSD,” and in a more restrictive schedule than “fentanyl and methamphetamine.” *Id.*

In its evaluation of marijuana behind closed doors and without any input from the public, interested parties, or presumably outside experts, HHS proposed a 180-degree reversal from its conclusions published just eight years ago (when President Biden served as the Vice President). HHS’s recommendation, provided to the DEA in August, 2023, consists of a memorandum analyzing cannabis under the eight statutory factors listed in the CSA, *see Memorandum for DEA,*

from HHS, *Re: Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act* [hereinafter “HHS Recommendation”] (Aug. 29, 2023), and a separate memorandum prepared by the Food and Drug Administration’s Center for Drug Evaluation and Research, *see Food & Drug Admin., Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act* [hereinafter “FDA Memo”] (Aug. 28, 2023). In contrast to the 2011 and 2016 Decisions, HHS’s Recommendation omits any discussion of the harms marijuana poses to the developing brains of adolescent users. It also treated alcohol as a comparator drug, even though Congress expressly exempted alcohol from scheduling under the CSA and it has never been used to evaluate a scheduling determination. Additionally, in further departures from its consistent analysis in the past:

- HHS now claims that State-level marijuana programs do provide evidence that marijuana has a CAMU, HHS Recommendation 2;
- HHS now claims that the existence of hundreds of chemovars of marijuana with varying THC levels does not preclude generalizations about the medical use of cannabis, *id.* at 21;
- HHS fails to consider state-level diversion data, despite acknowledging its relevance in 2016;
- HHS fails to discuss the scope and significance of the effect of marijuana on pregnant women and unborn children;
- HHS fails to discuss marijuana’s impacts on drivers and the increase in automobile crashes that would accompany rescheduling;
- HHS ignores the link between marijuana use and psychosis;

- HHS fails to consider the respiratory harms of marijuana use;
- HHS fails to acknowledge the grave public health risks posed by the increasing frequency of use by adolescents.

Most significant, HHS abandons the five-part test that DEA has previously determined is necessary under the CSA and the last five presidential Administrations have traditionally used to establish whether a drug without FDA approval has a CAMU.

In response to HHS’s recommendation, the Attorney General issued an NPRM proposing to transfer marijuana to Schedule III. *See Rescheduling of Marijuana* [hereinafter “NPRM”], 89 Fed. Reg. 44,597 (May 21, 2024).¹⁰ The NPRM notes that HHS’s recommendations are not binding after the rulemaking is initiated, and this of course is correct. *See infra* Part I. Accordingly, DEA must now make its own independent assessment based on evidence in the record and must adequately explain any departure from its own prior analysis. The NPRM also makes clear that DEA has not reached a conclusion.

In a video, President Biden praised the NPRM as “a major step to reclassify marijuana from a Schedule I drug to a Schedule III drug” adding that reclassifying marijuana is “an important move toward reversing longstanding inequities.” *See White House, President Biden Discusses Taking the Next Step to Reclassify Marijuana*, YouTube (May 16, 2024), <https://tinyurl.com/2s42rk62>. President Biden did not claim that rescheduling was justified to address breakthroughs in medical science or that there was any statutory basis to support his policy view.

¹⁰ Although the head of the DEA (or Director of Bureau of Narcotics and Dangerous Drugs) appears to have signed all prior notices of proposed rulemaking to reschedule a controlled substance and all nine denials of requests to reschedule marijuana, the head of the DEA did not sign the NPRM here.

ANALYSIS

I. OLC Correctly Concluded That HHS’s Recommendation Is Not Binding On the Attorney General After Issuance of the NPRM To Consider Rescheduling a Controlled Substance.

As OLC recognized, once the Attorney General initiates formal rulemaking to reschedule a controlled substance, HHS’s scientific and medical findings are no longer binding. *See Questions Related to the Potential Rescheduling of Marijuana* [hereinafter “OLC Memo”], 48 Op. O.L.C. ___, *24 (Apr. 11, 2024). The Attorney General has authority to follow the evidence presented during the comment and on-the-record-hearing and depart from HHS’s recommendations where appropriate.

“[B]efore initiating proceedings” to consider rescheduling a drug, the CSA directs the Attorney General to “request from the Secretary [of HHS] a scientific and medical evaluation” of the controlled substance at issue along with the Secretary’s “recommendation[.]” as to the ultimate scheduling determination. 21 U.S.C. § 811(a). Traditionally, neither the Attorney General’s request nor HHS’s findings are made public until after the issuance of a denial of a rulemaking petition or issuance of an NPRM—unless suspecting members of the public file a FOIA request. In this case, HHS did not initiate any form of public engagement or openly solicit input from interested parties, outside experts, or otherwise work in a manner transparent to the American people. At this stage of the proceeding, the Secretary’s “recommendations” by statute “shall be binding on the Attorney General as to such scientific and medical matters.” *Id.*

As OLC correctly concluded, whatever the status of HHS’s closed-door assessment before formal rulemaking, HHS’s recommendation cannot carry binding authority into the formal rulemaking process. *See* OLC Memo at *24. The decision to transfer a drug to a different schedule must be made “on the record after opportunity for a hearing.” 21 U.S.C. § 811. Once the Attorney General initiates proceedings by publishing an NPRM, HHS’s nonpublic findings cannot have

binding effect. “[W]hile Congress intended the recommendation of HHS to have significant weight in the decisionmaking process, it also intended that there be an opportunity for a meaningful hearing *after* receipt of the HHS report.” *Grinspoon v. DEA*, 828 F.2d 881, 890 (1st Cir. 1987); *see also Reckitt & Colman, Ltd. v. Adm’r, DEA*, 788 F.2d 22, 27 n.8 (D.C. Cir. 1986) (noting that if HHS’s findings were binding “it is difficult to see what purpose the agency’s on-the-record hearing served in this case”). It would be manifestly inconsistent with Congress’s decision to demand a formal rulemaking process if the Attorney General were bound by conclusions that were reached by HHS without any transparency or public input.

As explained below, given that HHS’s recommendation here significantly changed the rescheduling analysis and ignored important parts of the inquiry, it should not be afforded any deference.

II. The CSA’s Eight Factor Test Cannot Support Rescheduling Marijuana to Schedule III.

The CSA identifies eight factors for the Attorney General to consider when scheduling or rescheduling a substance. 21 U.S.C. § 811(c). Specifically, the statute directs the Attorney General to consider:

- (1) marijuana’s potential for abuse;
- (2) scientific evidence of its pharmacological effects;
- (3) the state of current scientific knowledge regarding marijuana;
- (4) marijuana’s history and current pattern of abuse;
- (5) the scope, duration, and significance of that abuse;
- (6) the risks marijuana poses to the public health;
- (7) marijuana’s psychic or psychological dependence liability; and

(8) whether marijuana is an immediate precursor of a substance already controlled under the CSA.

A careful review of these factors plainly establishes that marijuana is properly listed in Schedule I based on its high potential for abuse, the scope and significance of abuse, the risks it poses to public health, and its liability for creating physical and psychological dependence. Each time the DEA and HHS have previously considered these factors, they have readily found that they require placing marijuana under Schedule I. In coming to a different conclusion in this proceeding, HHS did not invoke new evidence in the form of new scientific studies or data that fundamentally changed the assessment of marijuana under these factors. There has not been some sea change in the science understanding marijuana in the past eight years. Instead, as explained further below, HHS was able to come to a different conclusion here only by significantly changing *the way it analyzed these factors*. In other words, it changed the analysis so that it could reach a different result.

For example, in assessing marijuana's potential for abuse, the HHS Recommendation assessed evidence that individuals were taking marijuana in amounts sufficient to cause harm to their health or to create a hazard to others by comparing marijuana use to a different set of comparator drugs than has ever been used in the past. HHS compared marijuana to heroin, fentanyl, oxycodone, hydrocodone, cocaine, ketamine, benzodiazepines, zolpidem, tramadol, and alcohol. These comparators are substances that have notably high risks of overdose leading to severe consequences, including death. When marijuana is compared to that carefully curated list of substances that have high risks of such severe outcomes, it is possible for HHS to conclude that marijuana is not "among the substances producing the most frequent incidence of adverse outcomes." NPRM, 89 Fed. Reg. at 44,603 (describing HHS conclusion). To put it bluntly, if one

compares the number of people killed by heroin to the number of people killed by marijuana, marijuana does not look so bad. *Cf. id.* at 44,614 (describing HHS conclusion that, “[f]or overdose deaths, marijuana is always ranked the lowest among comparator drugs,” and explaining HHS’s interpretation that therefore the risk to public health posed by marijuana “is relatively lower than that posed by most other comparator drugs”).

But that has never been the narrow focus of analysis that HHS (or the DEA) has used when considering the factors under the CSA. Instead, both HHS and DEA have compared marijuana to other similar substances (*i.e.*, hallucinogens), that are also restricted under Schedule I and have considered health outcomes beyond the most severe consequences of an overdose. And that prior approach makes sense. A drug like marijuana can impair neurological development and cause long-lasting deficits for those who use it at an early age. That necessarily means that it can have an extraordinarily serious impact on public health even if it does not lead to a large number of overdose deaths. As both HHS and DEA recognized in the past, emergency room visits, poison control calls, and overdose deaths alone are not the be all and end all of public health analysis for a controlled substance.

HHS, moreover, has provided no satisfactory rationale to explain why it has changed its method of analysis in this rescheduling proceeding. When an agency changes course, it must provide a reasoned explanation to justify its change in analysis. *See, e.g., FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). “Agencies are free to change course as their expertise and experience may suggest or require, but when they do so they must provide a ‘reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.’” *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003) (quoting *Greater Bos. Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)). Here, HHS failed to provide any explanation to

justify its changed method of analysis. Such an “unexplained inconsistency” in an agency’s approach is “a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

Similarly, throughout its analysis of the public health effects of marijuana, HHS ignored health effects that both HHS and the DEA considered in prior rescheduling proceedings. To give just one example, both HHS and DEA previously pointed to studies showing that marijuana impaired neurological development in adolescents and likely had impacts that could lead to long-term deficits in neurological development and IQ. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,767, 53,774 (Aug. 12, 2016) (2016 Decision); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,555 (July 8, 2011) (2011 Decision). In this proceeding, HHS failed to mention those health effects entirely. It did not provide any explanation as to why those health effects were important when rescheduling was considered eight years ago but were not worth considering now. Instead, it simply ignored them without any explanation whatsoever. Once again, that is the height of arbitrary and capricious decision making. “[A]gency action is arbitrary and capricious if it departs from agency precedent without explanation.” *Ramaprakash*, 346 F.3d at 1124. And ““a reasoned explanation is needed for disregarding facts and circumstances that underlay”” a prior decision on the same subject. *Encino Motorcars, LLC*, 579 U.S. at 222 (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515-16). Here, HHS failed to provide any explanation for departing from its prior analysis examining such health effects. DEA cannot follow HHS on that erroneous path.

As explained below, a straightforward analysis of the factors under the CSA—not an analysis that has been deliberately altered to support a pre-determined outcome—leads to the conclusion that marijuana cannot be removed from Schedule I.

A. Factor 1: Marijuana Has a High Potential for Abuse.

While the CSA does not define the term “abuse,” prior scheduling decisions by both the DEA and HHS have considered the following four subfactors to determine whether a substance has a high potential for abuse:

1. Whether there is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community;
2. Whether there is a significant diversion of the drug or drugs containing such a substance from legitimate drug channels;
3. Whether individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; and
4. Whether the drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

See 2011 Decision, 76 Fed. Reg. at 40,553; 2016 Decision, 81 Fed. Reg. at 53,769.

As detailed below, a review of these four subfactors demonstrates that marijuana has a high potential for abuse. First, marijuana use poses a serious risk to the health of users and to the health and safety of the community—a fact that HHS masked by altering the focus of its analysis in this proceeding compared to prior rescheduling proceedings. HHS focused almost exclusively on acute consumption risks—mainly the risk of overdose hospitalization or death—and completely ignored other significant health effects, including the harm marijuana inflicts on developing brains, the

lifelong consequences of prenatal exposure, respiratory impacts from smoking marijuana, increased rates of automobile crashes, and marijuana's causal role in the development of psychosis. Second, marijuana is regularly diverted from state-authorized use, and moving marijuana to a lower schedule will only exacerbate that problem. Third, data show that individuals frequently use marijuana on their own initiative, rather than on the basis of legitimate medical advice, further increasing the risk of abuse. Finally—as further evidence of its risk for abuse—two of the three most pharmacologically similar drugs to marijuana are restricted under Schedule II and the third, which is restricted under Schedule III, was only moved to Schedule III because it carries a dramatically lower risk of abuse than marijuana.

1. Marijuana Is Hazardous to the Health of Both Users and to the Safety of the Community.

The analysis of health impacts in the HHS Recommendation marks an extraordinary departure from the analysis that both HHS and the DEA performed in prior rescheduling proceedings in 2011 and 2016. In their prior decisions, both HHS and DEA considered a wide range of health impacts, including developmental impacts on adolescents, risks from prenatal exposure, harm to users' respiratory systems, automobile crash risk, and the association between marijuana use and psychosis. 2011 Decision, 76 Fed. Reg. at 40,555-58, 40,568, 40,575-77, 40,582-83; 2016 Decision, 81 Fed. Reg. at 53,774-76, 53,830-32, 53,837-38. Both HHS and DEA also assessed the risks of marijuana by comparing marijuana to a group of Schedule I drugs with low rates of overdose death but with myriad other health impacts: namely MDMA, GHB, LSD, and PCP, among other hallucinogens and inhalants. 2011 Decision, 76 Fed. Reg. at 40,561, 40,571; 2016 Decision, 81 Fed. Reg. at 53,782, 53,825. Based on this analysis, HHS determined that “individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. 2016 Decision, 81 Fed. Reg. at 53,770; *see also*

2011 Decision, 76 Fed. Reg. at 40,568 (“Indeed, marijuana is abused in amounts sufficient to create hazards to public health and safety[.]”).

Without even acknowledging that it was changing course, HHS abandoned the comprehensive public health inquiry it used in both 2011 and 2016 and the conclusion it reached the last time it considered this question. In its place, HHS provided only a perfunctory analysis, plainly designed to support a preordained conclusion that marijuana should be rescheduled.

HHS’s new analysis proceeds by: (1) focusing almost exclusively on the risk of acute consumption, (2) comparing marijuana to a limited, newly selected group of drugs that have high risks of overdose hospitalization and death (mainly opiates and depressants), and (3) relying on marijuana’s comparatively lower risk of hospitalization and death to argue that marijuana carries a low risk of the “greatest adverse consequences” and therefore belongs in Schedule III. *See* HHS Recommendation 45-57. That analysis paints a misleading picture of the substantial public health risks posed by marijuana, and DEA cannot rely on it to justify rescheduling marijuana. In particular, as a matter of law, DEA cannot follow HHS and change its method for assessing the public health effects of marijuana without providing a clear explanation and justification for any changed analysis. *See, e.g., Encino Motorcars, LLC*, 579 U.S. at 222; *Ramaprakash*, 346 F.3d at 1124.

a. The HHS Recommendation Wrongly Ignores, Without Explanation, Health Risks that Were Considered and Were Essential in the Denial of Rescheduling in Both 2011 and 2016.

The HHS Recommendation departs dramatically from the extensive health analysis that HHS conducted in both 2011 and 2016. For example, in 2011 HHS cited studies showing that adolescent marijuana use was associated with reductions in IQ and measures of attention. 2011 Decision, 76 Fed. Reg. at 40,555. In 2016, HHS cited additional studies showing deficits in

attention, impulse control, general executive functioning, and general neuropsychological performance and persistent reductions in IQ among adolescent users. 2016 Decision, 81 Fed. Reg. at 53,774-75. Based on these studies, DEA has previously concluded that “adolescents may be particularly vulnerable to the long-lasting deleterious effects of marijuana on cognition.” 2011 Decision, 76 Fed. Reg. at 40,577. In both 2011 and 2016, HHS discussed studies showing that children exposed to marijuana in utero scored worse on abstract and visual reasoning tasks, worse on verbal measures, worse on memory measures, worse on impulse control, and had a reduced ability to maintain attention. 2011 Decision, 76 Fed. Reg. at 40,556; 2016 Decision, 81 Fed. Reg. at 53,775. Based on those studies, DEA concluded that “Prenatal exposure to marijuana was linked to children’s poorer performance in a number of cognitive tests.” 2011 Decision, 76 Fed. Reg. at 40,568.

HHS also closely examined respiratory impacts in both its 2011 and 2016 analyses. 2011 Decision, 76 Fed. Reg. at 40,557-58; 2016 Decision, 81 Fed. Reg. at 53,776. In 2011, HHS found that “chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer and lung damage[.]” 2011 Decision, 76 Fed. Reg. at 40,575, and in 2016, HHS noted that “lung cancer cases have been reported in young marijuana users with no tobacco smoking history or other significant risk factors[.]” 2016 Decision, 81 Fed. Reg. at 53,776.

In its prior analyses, HHS also considered the risk of automobile crashes in depth and discussed studies showing that marijuana impairs motor skills generally, impairs performance in simulated driving situations, results in increased stopping distances, and increases the risk of accident in real-world situations. 2011 Decision, 76 Fed. Reg. at 40,555, 40,582; 2016 Decision, 81 Fed. Reg. at 53,774, 53,783. Finally, HHS extensively analyzed the evidence linking marijuana

use to increased occurrences of psychosis and schizophrenia in both 2011 and 2016. 2011 Decision, 76 Fed. Reg. at 40,555-56; 2016 Decision, 81 Fed. Reg. at 53,775-76.

These health impacts were all core parts of both HHS's and DEA's analysis in both 2011 and 2016 when those agencies determined that individuals were taking marijuana in amounts sufficient to harm their health as well as the health and safety of others in the community. 2016 Decision, 81 Fed. Reg. at 53,770; *see also* 2011 Decision, 76 Fed. Reg. at 40,568.

In marked contrast, the current HHS Recommendation contains no discussion of risks to adolescents, no discussion of prenatal exposure, no discussion of respiratory impacts, and no discussion of marijuana's causal association with psychosis. Although the NPRM does discuss automobile crashes, that discussion consists of three sentences that astonishingly omit any indication that driving under the influence of marijuana increases the risk of an accident. NPRM, 89 Fed. Reg. at 44,614. The NPRM simply notes that the number of drivers testing positive for marijuana after a collision has increased in recent years, without any mention of marijuana's causal role in those crashes. *See id.* Each of these risks—risks to adolescents, risks of prenatal exposure, respiratory impacts, the risk of automobile crashes, and marijuana's causal association with psychosis—will be discussed in more detail below.

i. Marijuana Causes Lasting Harm to Adolescent Users.

HHS's new-found approach to assessing the health risks associated with marijuana systematically ignored health effects that previously formed a central part of the analysis used by both HHS and DEA in assessing rescheduling. Perhaps most significant, the HHS recommendation failed to address at all the lasting harmful effects that marijuana has on adolescent users, particularly with respect to neurological development. Both information that DEA

previously relied on and new studies performed since 2016 strongly confirm that marijuana use can have a significant deleterious impact on neurological development in adolescents.

In both 2011 and 2016, HHS considered the risk of developmental harm to adolescent marijuana users in depth. For example, in 2011 HHS cited studies showing that adolescent marijuana use was associated with reductions in IQ and measures of attention. 2011 Decision, 76 Fed. Reg. at 40,555. In 2016, HHS cited additional studies showing deficits in attention, impulse control, general executive functioning, and general neuropsychological performance and persistent reductions in IQ among adolescent users. 2016 Decision, 81 Fed. Reg. at 53,774-75. Based on these studies, DEA has previously concluded that “adolescents may be particularly vulnerable to the long-lasting deleterious effects of marijuana on cognition.” 2011 Decision, 76 Fed. Reg. at 40,577.

Abundant evidence confirms these concerns. The human brain undergoes extensive changes in adolescence and neuromaturation continues into early adulthood. 2011 Decision, 76 Fed. Reg. at 40,577; *see also, e.g.,* Joanna Jacobus & Susan F. Tapert, *Effects of Cannabis on the Adolescent Brain*, 20 *Current Pharm. Design* 2,186 (2014). Development changes during this period include myelination, synaptic pruning, cortical thinning, and decreased cerebral volumes. *E.g.,* Jacobus & Tapert, *supra*. Thus, “results on the long-lasting cognitive effects of marijuana use in adults cannot necessarily generalize to adolescent marijuana users.” 2011 Decision, 76 Fed. Reg. at 40,577.

Marijuana use during adolescence has been linked to changes in brain structure in users. In particular, it has been associated with changes in cortical thickness, with different impacts in different locations. *See, e.g.,* Joanna Jacobus et al., *Cortical thickness in adolescent marijuana and alcohol users: A three-year prospective study from adolescence to young adulthood*, 16

Developmental Cognitive Neuroscience 101 (2015); Jodi M. Gilman et al., *Cannabis Use Is Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users*, 34 J. Neuroscience 5,529 (2014); Melissa P. Lopez-Larson et al., *Altered Prefrontal and Insular Cortical Thickness in Adolescent Marijuana Users*, 220 Behavioral Brain Research 164 (2011). One study found that changes in grey matter volumes can be caused by one or two instances of using marijuana during adolescence. Catherine Orr et al., *Grey Matter Volume Differences Associated with Extremely Low Levels of Cannabis Use in Adolescence*, 39 J. Neuroscience 1817 (2019). Studies have linked adolescent marijuana use to changes in white matter structures as well. Jacobus & Tapert, *supra*. The differences in white matter integrity associated with marijuana use predict future risky, aggressive, and delinquent behaviors. *Id*.

These impacts are not only observable on brain scans: studies show that adolescent marijuana use has negative effects on cognition. A longitudinal study of long-term marijuana users who began using marijuana during adolescence showed dramatic decreases in IQ over time, with the most persistent users losing an average of 8 IQ points between ages 13 and 38. Madeline H. Meier et al., *Persistent cannabis users show neuropsychological decline from childhood to midlife*, 109 Proceedings Nat'l Acad. of Scis. U.S. 2657 (2012). As HHS pointed out in 2011, a longitudinal study assessing IQ in 9-12 year olds, before marijuana, and again at 17-20, found that "current heavy marijuana users showed a 4-point reduction in IQ in later adolescence compared to those who did not use marijuana." 2011 Decision, 76 Fed. Reg. at 40,555 (citing Peter Fried et al., *Current and former marijuana use: preliminary findings of a longitudinal study of effects on IQ in young adults*, 166 Canadian Med. Ass'n J. 887 (2002)). IQ decreases have been shown to persist for at least one year after abstinence from marijuana in subjects who started using marijuana in adolescence. 2016 Decision, 81 Fed. Reg. at 53,774 (citing Meier, *supra*).

Adolescent users of marijuana also have a reduced ability to maintain attention, worse memory, and worse planning and sequencing ability, even after a month of abstinence. Krista Lisdahl Medina et al., *Neuropsychological functioning in adolescent marijuana users: subtle deficits detectable after a month of abstinence*, 13 *J. Int'l Neuropsychology Soc'y* 807 (2007). Studies also show individuals who start using marijuana during adolescence have reduced impulse control, ability to sustain attention, and general executive functioning. Maria Alice Fontes et al., *Cannabis use before age 15 and subsequent executive functioning*, 198 *Brit. J. Psychiatry* 442 (2011). These effects are correlated with age of onset of use, dosage, and frequency of use. Staci A. Gruber et al., *Age of onset of marijuana use and executive function*, 26 *Psychol. Addictive Behaviors* 496 (2012); Natalie Castellanos-Ryan et al., *Adolescent cannabis use, change in neurocognitive function, and high-school graduation: A longitudinal study from early adolescence to young adulthood*, 29 *Dev. & Psychopathology* 1253 (2017). And these impacts are substantial: one recent study found that “cannabis is associated with more concurrent and long-term consequences on adolescent cognitive functions than alcohol”—specifically working memory, perceptual reasoning, delayed memory recall, inhibitory control. Jean-François G. Morin et al., *A Population-Based Analysis of the Relationship Between Substance Use and Adolescent Cognitive Development*, 176 *Am. J. Psychiatry* 98 (2019).

Adolescent marijuana use also has negative impacts on life outcomes. There are “clear and consistent associations and dose-response relations between the frequency of adolescent cannabis use and [] adverse young adult outcomes,” including failure to complete high school or obtain a degree, future cannabis dependence, use of other illicit drugs, and future suicide attempts. Edmund Silins et al., *Young adult sequelae of adolescent cannabis use: an integrative analysis*, 1 *Lancet Psychiatry* 286 (2014); see also Castellanos-Ryan et al., *supra* (age of first use and frequency of

use associated with lower graduation rates). A 2021 study of twins from age 11 into adulthood found that individuals who used marijuana had lower grade point averages, reduced academic motivation, additional disciplinary problems at school, and lower socioeconomic attainment later in life. Jonathan D. Schaefer et al., *Associations between adolescent cannabis use and young-adult functioning in three longitudinal twin studies*, 118 *Proceedings Nat'l Acad. of Scis. U.S.* 1 (2021), <https://tinyurl.com/3vncfz2b>. The study's lead author, Jonathan Schaefer, explained, "[b]ecause these twins shared the same genetics and family backgrounds, differences in adult outcomes between twins were more likely to be specifically attributable to differences in their earlier cannabis use rather than other factors, such as their family's socioeconomic status." *Cannabis use in adolescence leads to poorer school performance, lower socioeconomic attainment, study suggests*, University of Minn. (Mar. 31, 2021), <https://perma.cc/K3B9-RZ7H>.

While research on this point is still developing, these impacts are especially worrisome given the increasing potency of marijuana products. Crucially, THC levels in the botanical marijuana available in the United States have increased over five-fold in the past 30 years. Marijuana strains are "shifting, as breeding of different strains are yielding plants and resins with dramatic increases in THC content," rising from ~3% in the mid-2000s to 12-16% by 2016. Bertha K. Madras, *Cannabis and Medicinal Properties* 4 (July 13, 2016), <https://perma.cc/T9Y3-AMZQ> (hereinafter "Madras 2016 Testimony"). HHS concedes that the THC concentration in marijuana samples seized by DEA has increased from 3% in 1991 to 17.1% in 2017. HHS Recommendation 11. According to one analysis of over 8,500 herb cannabis products, from a variety of chemovars offered at 653 dispensaries, "the average THC concentration in these products were consistently above 15%" and in medical programs could be as high as 35%. See Mary Catherine Cash et al.,

Mapping cannabis potency in medical and recreational programs in the United States, 15 PLOS One 5, 14 (2020), <https://perma.cc/NBQ8-FR8S>.

Despite this mountain of evidence establishing the deleterious effects of marijuana on neurological development in adolescents, the HHS Recommendation fails to address the health effects of marijuana on neurological development *at all*. HHS did not provide any explanation for ignoring what it had previously identified as an important consideration relating to the health effects of marijuana. Instead, it just dropped any discussion of that point without any justification. The DEA cannot follow a recommendation based on that approach, and it cannot follow the same approach of ignoring the effects of marijuana on neurological development that it previously identified in 2011 and 2016. It is well settled that DEA would have to provide a reasoned explanation for such a change in its analysis, *see, e.g., Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016), and there is no good explanation for such an approach here. Following HHS's approach would be the height of arbitrary and capricious rulemaking.

ii. Prenatal Exposure Poses a Serious Risk to Public Health.

HHS's novel analysis also ignores the risks of prenatal exposure to marijuana. In 2011 and 2016, both DEA and HHS acknowledged the particular health risks raised by prenatal exposure to marijuana. In so doing, HHS discussed studies showing that children exposed to marijuana in utero scored worse on abstract and visual reasoning tasks, worse on verbal measures, worse on memory measures, worse on impulse control, and had a reduced ability to maintain attention. 2011 Decision, 76 Fed. Reg. at 40,556; 2016 Decision, 81 Fed. Reg. at 53,775. Based on those studies, DEA concluded that "Prenatal exposure to marijuana was linked to children's poorer performance in a number of cognitive tests." 2011 Decision, 76 Fed. Reg. at 40,568. Evidence showing long-term harm from prenatal exposure has only increased since 2016. Nonetheless, HHS simply

chose—without explanation—to ignore another one of the key health effects of marijuana that had been important to its analysis in the past.

THC passes the placental barrier, J. Idanpaan-Heikkila et al., *Placental transfer of tritiated-1-delta-9-tetrahydrocannabinol*, 281 *New Eng. J. of Med.* 330 (1969), resulting in fetal blood concentrations that closely resemble those found in the mother's blood, Rebecca Thompson et al., *Marijuana Use in Pregnancy: A Review*, 74 *Obstetrical & Gynecological Survey* 415 (2019). A systemic review of studies investigating the impact of prenatal marijuana exposure on health outcomes found that children exposed to prenatal marijuana are more likely to be admitted to the neonatal intensive care unit at delivery. J. K. L. Gunn et al., *Prenatal exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis*, 6 *Brit. Med. J. Open* 5 (2016), <https://perma.cc/A8RL-QUX2>. Prenatal exposure is also associated with reduced birth weights. *See id.* at 1.

Studies also show long-term impacts from maternal marijuana use. Three-year-old children of maternal marijuana users have poorer abstract/visual reasoning skills. D.R. Griffith et al., *Three-year outcome of children exposed prenatally to drugs*, 33 *J. Am. Academy of Child & Adolescent Psychiatry* 20 (1994). Four-year-old children of mothers who were heavy marijuana users during pregnancy have deficits in memory, verbal, and quantitative reasoning measures. P.A. Fried & B. Watkins, *36- and 48-month neurobehavioral follow-up of children prenatally exposed to marijuana, cigarettes and alcohol*, 11 *J. Developmental & Behavioral Pediatrics* 49 (1990). In utero exposure to marijuana is negatively associated with executive function tasks that require impulse control, visual analysis, and hypothesis testing in nine-to-twelve-year-old children. P.A. Fried & B. Watkinson, *Differential effects on cognitive functioning in 9- to 12-year olds prenatally exposed to cigarettes and marihuana*, 20 *Neurotoxicology & Teratology* 293

(1998). A study of fourteen-year-old children of maternal marijuana users found increased delinquent behavior and decreased achievement test scores. Lidush Goldschmidt et al., *School achievement in 14-year-old youths prenatally exposed to marijuana*, 34 *Neurotoxicology & Teratology* 161 (2012). Based on these concerns, the American College of Obstetricians and Gynecologists recently recommended that women who are pregnant or contemplating becoming pregnant “should be encouraged to discontinue marijuana use,” including medical marijuana use, and that OBGYNs “should be discouraged from prescribing or suggesting the use of marijuana for medicinal purposes during preconception, pregnancy, and lactation.” American College of Obstetricians and Gynecologists, Committee on Obstetric Practice, *Marijuana Use During Pregnancy and Lactation* (July 2015, reaffirmed 2021), <https://perma.cc/HR8U-NYGA>.

The rising potency of marijuana products poses a risk that future data will show even more dramatic effects. *See supra* p. 27.

iii. Marijuana’s Harmful Respiratory Impacts.

In its analysis in 2011, HHS found that “chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer and lung damage[.]” 2011 Decision, 76 Fed. Reg. at 40,575, and in 2016, HHS noted that “lung cancer cases have been reported in young marijuana users with no tobacco smoking history or other significant risk factors[.]” 2016 Decision, 81 Fed. Reg. at 53,776. The American Lung Association puts it more bluntly: “Smoking marijuana clearly damages the human lung.” *Marijuana and Lung Health*, American Lung Association, <https://perma.cc/F5JF-W6WF>. They explained that “smoking marijuana causes chronic bronchitis and marijuana smoke has been shown to injure the cell linings of the large airways, which could explain why smoking marijuana leads to symptoms such as chronic cough, phlegm production, wheeze, and acute bronchitis.” *Id.*; *see also* Mark J. Pletcher

et al., *Association between marijuana exposure and pulmonary function over 20 years*, 307 JAMA 173 (2012) (same). HHS’s Recommendation does not mention respiratory impacts.

Although marijuana smoke may ultimately be less likely to cause lung cancer than cigarette smoke, marijuana smoke contains several of the same carcinogens and co-carcinogens as tobacco smoke. M. D. Roth et al., *Airway inflammation in young marijuana and tobacco smokers*, 157 Am. J. Respiratory & Critical Care Med. 928 (1998). One study has found that users with over 10.5 joint-years¹¹ of exposure to marijuana smoke have a significantly increased risk of developing lung cancer, even after accounting for over 300 different controls. S. Aldington et al., *Cannabis use and risk of lung cancer: a case-control study*, 31 Euro. Respiratory J. 280 (2008). Based on these findings, the study’s authors concluded that long-term cannabis use increases the risk of lung cancer in young adults. *Id.* Multiple studies have confirmed that marijuana smoke can prompt pre-cancerous inflammatory changes in bronchial cells. *See, e.g., Roth, supra.*

The rising potency of marijuana products poses a risk that future data will show even more dramatic effects. *See supra* p. 27.

iv. The Increasing Availability of Marijuana Has Caused an Increase in Automobile Crashes.

In 2011 and again in 2016, both HHS and the DEA engaged in extensive analyses of marijuana’s impacts on drivers, and both concluded that marijuana impairs psychomotor performance, making it “inadvisable” for anyone who has recently used marijuana to operate motor vehicles. 2011 Decision, 76 Fed. Reg. at 40,561; 2016 Decision, 81 Fed. Reg. at 53,783.¹²

¹¹ The study defined a “joint year” as smoking one joint per day for a year.

¹² Along these same lines, DOJ recently told the Eleventh Circuit that marijuana so alters users’ “perception of time” and so “impair[s] perception and motor skills” that allowing marijuana users to possess firearms “endanger[s] public safety” because users are more likely to mishandle

As part of those analyses, HHS and DEA considered studies showing that marijuana impairs motor skills generally, impairs performance in simulated driving situations, results in increased stopping distances, and increases the risk of accident in real-world situations. 2011 Decision, 76 Fed. Reg. at 40,555, 40,582; 2016 Decision, 81 Fed. Reg. at 53,774, 53,783, 53,837-38. In contrast, HHS's Recommendation does not discuss a single study relating to driving risk. The NPRM fares little better: although it references information from DEA showing an increase in the number of drivers testing positive for marijuana use, it studiously avoids discussing the causal link between marijuana use and risk of accident. *See* NPRM, 89 Fed. Reg. at 44614. A full review of the literature plainly demonstrates that increased societal marijuana use increases the risk and number of automobile crashes. *See, e.g.,* Charles M. Farmer et al., *Changes in Traffic Crash Rates After Legalization of Marijuana: Results by Crash Severity*, 83 J. Studies on Alcohol & Drugs 494 (2022).

Marijuana use causes slowed reaction times, an inability to maintain concentration, and lapses in attention. L.D. Chait & J. Pierri, *Effects of smoked marijuana on human performance*, in *Marijuana/Cannabinoids. Neurobiology & Neurophysiology* 387 (Laura Murphy & Andrzej Bartke, eds., 1992). Studies involving simulated driving consistently find that marijuana impairs users' ability to safely operate a motor vehicle. R. Andrew Sewell et al., *The effect of cannabis compared with alcohol on driving*, 18 Am. J. on Addictions 185 (2009). Subjects administered even a low dose of marijuana (one 3.95% THC cigarette) show increased disequilibrium and increased breaking distances. A. Liguori, *Effects of marijuana on equilibrium, psychomotor performance, and simulated driving*, 9 Behavioral Pharmacology 599 (1998). An NHTSA

firearms. Supplemental Br. of Appellees at 9, *Cooper v. Att'y Gen.*, No. 22-13893 (11th Cir. July 12, 2024).

simulated driving study found that marijuana reduced subjects' ability to drive steadily within a lane and to maintain a safe distance while following other vehicles. Hendrik W. J. Robbe & James F. O'Hanlon, U.S. Dep't of Transportation, *Marijuana, alcohol and actual driving Performance* (1999), <https://perma.cc/5EEY-JNM5>.

The risks of crash from driving while impaired by marijuana have been further confirmed by more recent data developed since DEA last rejected a rescheduling of marijuana in 2016. For example, one recent study found that users lack the ability to recognize the deficits caused by marijuana. In that study, 69% of subjects believed that they were no longer affected by an administered dose of marijuana after 90 minutes and believed they were, as a result, able to drive safely. Thomas D. Marcotte et al., *Driving Performance and Cannabis Users' Perception of Safety: A Randomized Clinical Trial*, 79 *JAMA Psychiatry* 201 (2022). When those same subjects were placed in a driving simulator, they showed significant impairment 90 minutes after administration—in fact, their degree of impairment was virtually identical to that demonstrated by subjects tested 30 minutes after administration. *Id.* Fig. 2. Current field sobriety tests are also inadequate to identify impaired drivers and reliably get them off the road. *See, e.g.*, Thomas D. Marcotte et al., *Evaluation of Field Sobriety Tests for Identifying Drivers Under the Influence of Cannabis*, 80 *JAMA Psychiatry* 914 (2023).

The driving deficits identified above are not limited to the realm of studies and simulations—data show they result in an increased number of accidents in the real world. Four recent studies analyzing crash rates in states that have legalized marijuana have all found substantial increases in crash rates. For example, Aydelotte et al. found that states that allow commercial marijuana sales have 1.9 additional deaths per billion motor vehicle miles traveled (BVMT) when compared to states without commercial sales. Jayson D. Aydelotte et al., *Fatal*

crashes in the 5 years after recreational marijuana legalization in Colorado and Washington, 132 *Accident Analysis & Prevention* (2019). Kamer et al., using a slightly different methodology, found that states with commercial sales had 2.1 additional deaths per BVMT. Russel S. Kamer, *Change in Traffic Fatality Rates in the First 4 States to Legalize Recreational Marijuana*, 180 *JAMA Internal Medicine* 1119 (2020). Adhikari et al. found 2.22 additional deaths per BMVT. Kusum Adhikari et al., *Revisiting the effect of recreational marijuana on traffic deaths*, 115 *International J. Drug Pol’y* (2023). Similarly, another recent study found that legalization of marijuana and subsequent onset of retail sales within a state is associated with a 5.8% increase in injury crash rates and a 4.1% increase in fatal crash rates. *See Farmer, supra.*

Studies that assess relative crash risks by considering the rate at which drivers involved in crashes test positive for THC or report marijuana use also consistently find an increased risk of crash. These studies, however, consistently understate the strength of the association between driving under the influence of marijuana and crash risk when compared to other methods of analysis, in part because marijuana use at some unspecified point in the past is a poor proxy for intoxication and impairment. *See, e.g.* Ed Wood, *What Level of THC in Blood Causes Impairment, We Save Lives*, <https://perma.cc/5J56-UMHY>. Nonetheless, two recent meta-analyses of such studies have found that marijuana use is associated with a doubled risk of a motor vehicle crash. Li et al., found an odds ratio (OR) of 2.66 for a crash after marijuana use. Mu-Chen Li et al., *Marijuana Use and Motor Vehicle Crashes*, 34 *Epidemiologic Reviews* 65 (2012). Asbridge et al., used a slightly different methodology and found OR of 1.92 for crashes generally and an OR of 2.10 for fatal crashes. Mark Asbridge et al., *Acute cannabis consumption and motor vehicle collision risk: systematic review of observational studies and meta-analysis*, 344 *BMJ* 536 (2012). A more conservative recent meta-analysis found that marijuana is associated with a 20 to 40

percent increase in the risk of a crash. Ole Rogeberg & Rune Elvik, *The effects of cannabis intoxication on motor vehicle collision revisited and revised*, 111 *Addiction* 1348 (2016). Additionally, a 2007 study of drivers who tested positive for cannabis but negative for alcohol found that marijuana use resulted in a 30 to 40 percent increase in the chances a driver involved in a fatal crash undertook an unsafe driving action (e.g., speeding) in relation to the crash. Michel Bedard et al., *The impact of cannabis on driving*, 98 *Canadian J. of Pub. Health* 6 (2007).

Driving under the influence of marijuana becomes even more dangerous when users are also under the influence of alcohol. Robbe & O'Hanlon found that drivers operating under the influence of marijuana and alcohol performed worse on simulated driving tasks than drivers operating only under the influence of marijuana. Robbe & O'Hanlon, *supra*. A recent meta-analysis of prior studies examining the effects of marijuana on drivers found that marijuana and alcohol had an additive (negative) impact on users' ability to drive steadily in their lane. Rebecca L. Hartman et al., *Cannabis Effects on Driving Lateral Control With and Without Alcohol*, 154 *Drug & Alcohol Dependence* 154 (2015). These deficits result in a real-world increase in the risk of crash: one study found that drivers who tested positive for both alcohol and marijuana were dramatically more likely to be involved in, and culpable for, a crash than drivers who tested positive for marijuana or alcohol alone. Olaf H. Drummer et al., *The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes*, 36 *Accident Analysis & Prevention* 239 (2004).

Increasing rates of driving under the influence of marijuana, coupled with the increasing potency of marijuana, intensify these risks. For example, in 2022, 20.64% of past-year marijuana users over the age of 16 drove under the influence of marijuana, compared to 8.9% of past-year alcohol users over the age of 16 who drove under the influence of alcohol, according to the

NSDUH.¹³ In other words, marijuana users are more than twice as likely to drive under the influence of marijuana as alcohol users are likely to drive under the influence of alcohol.

Data from the Youth Risk Behavior Surveillance System shows that high school students are driving under the influence at an even higher rate. Among high school students, 53% of past month marijuana users reported driving under the influence of marijuana in the past month, and 21% reported driving under the influence at least six times in that time span. HHS Recommendation 50. This is notably higher than the share of drinkers who reported driving under the influence—only 16% of past month alcohol users reported driving under the influence in that same data set. *Id.* Data from NSDUH shows that 20.4% of past-year users over age 16—a group that inherently uses marijuana less frequently than the past-month users discussed above—report driving under the influence of marijuana. Substance Abuse and Mental Health Services Administration, Results from the 2022 National Survey on Drug Use and Health (National Survey 2022), Tables 1.1A, 8.35A (2022), <https://tinyurl.com/nnjx2x3c>. In comparison, only 8.9% of past-year drinkers in that sample reported driving under the influence of alcohol. *Id.* These findings suggest a particular hazard to the public health given two documented trends related to marijuana use in the United States. The first is the rising share of the population that uses marijuana—the share of past-month users increased from 6% of the population in 2004 to 15% in 2022. Substance Abuse and Mental Health Services Administration, Results from the 2018

¹³ According to Table 8.35A of the 2022 National Survey, in 2022 12,491,000 people aged 16 or older drove under the influence of marijuana and 15,569,000 drove under the influence of alcohol. Table 1.7A shows that 60,693,000 aged 16 or older used marijuana in the past year (1,738,000 between the ages of 16 and 17, and 58,955,000 aged 18). Table 2.8A estimates that 175,227,000 aged 16 or older used alcohol in the past year (2,552,000 between the ages of 16 and 17, and 172,675,000 aged 18 or older). In total, the percentage of past-year marijuana users who drove under the influence of marijuana was 20.6% (12,491,000/60,693,000). The total number of past-year alcohol users who drove under the influence of alcohol was 8.9% (15,569,000/175,227,000). 2022 National Survey, <https://tinyurl.com/57x6kbyj>.

National Survey on Drug Use and Health, Table 7.3B (2018), <https://perma.cc/MU35-C88M>; Substance Abuse and Mental Health Services Administration, Results from the 2022 National Survey on Drug Use and Health, Table 1.1B, *supra*. The second is the increasing concentration of THC in marijuana. *See supra* p. 27.

v. Marijuana Use Increases the Risk of Developing Psychosis.

As with all the health risks discussed above, in 2011 and again 2016, HHS and DEA extensively analyzed the evidence linking marijuana use to increased occurrences of psychosis and schizophrenia. 2011 Decision, 76 Fed. Reg. at 40,555-56, 40,576; 2016 Decision, 81 Fed. Reg. at 53,775-76, 53,831. Since that time, new research has firmly established a causal link between marijuana use and the development of psychosis and schizophrenia. The HHS Recommendation, however, wholly ignores this entire topic. DEA must take this risk into account.

Psychosis is a generic description of a group of severe mental illnesses characterized by the presence of delusions, hallucinations, and other associated cognitive and behavioral impairments. The term covers both acute psychotic episodes and chronic conditions such as schizophrenia. In a 2017 report on the health effects of cannabis, the National Academies of Sciences, Engineering, and Medicine found a “strong and consistent association between cannabis use and the subsequent development of psychosis and psychotic disorders” across the literature. Nat’l Acads. of Scis., Eng’g, & Med, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* [hereinafter “NAS Rep.”] 295 (2017), <https://perma.cc/A8LT-RDVP>; *see also, e.g.*, Arianna Marconi et al., *Meta-analysis of the Association Between the Level of Cannabis Use and Risk of Psychosis*, 42 *Schizophrenia Bull.* 1262 (2016) (systemic review); Theresa H. M. Moore et al., *Cannabis use and risk of psychotic or affective mental health outcomes: a systematic review*, 370 *Lancet* 319 (2007).

In addition to the strong association between marijuana use and psychosis, generally, marijuana use is also associated with increased relapse rates, more hospitalizations and pronounced positive symptoms in psychotic patients. Alkomiet Hasan et al., *Cannabis use and psychosis: a review of reviews*, 270 Euro. Archives of Psychiatry & Clinical Neuroscience 403 (2020). As DOJ recently confirmed in a brief filed with the Eleventh Circuit, marijuana users also “pose a higher risk of suicide than ordinary citizens.” Supplemental Br. of Appellees at 10, *Cooper v. Att’y Gen.*, No. 22-13893 (11th Cir. July 12, 2024) (citing NAS Rep. 311-12). Marijuana use by adolescents is also strongly associated with suicidality. Gabriella Gobbi et al., *Association of Cannabis Use in Adolescence and Risk of Depression, Anxiety, and Suicidality in Young Adulthood: A Systematic Review and Meta-analysis*, 76 JAMA Psychiatry 426 (2019).

While researchers continue to investigate the reason for this strong association between marijuana use and psychosis, there is an emerging consensus that marijuana use plays a causal role in the development of psychosis and schizophrenia in some cases. *See, e.g.*, Moore, *supra*; Jose Maria Pelayo-Teran et al., *Gene-environment interactions underlying the effect of cannabis in first episode psychosis*, 18 Current Pharm. Design 5024 (2012); John McGrath et al., *Association between cannabis use and psychosis-related outcomes using sibling pair analysis in a cohort of young adults*, 67 Archives of Gen. Psychiatry 440 (2010). Several factors support this conclusion.

First, several studies have found increased regional rates of psychosis occurring alongside increases in marijuana use and access. A 2022 study found that hospital discharges for marijuana-associated psychosis were higher in states with legal marijuana. Lauren V. Moran et al., *Geographical variation in hospitalization for psychosis associated with cannabis use and cannabis legalization in the United States*, 308 Psychiatry Res. (2022). Another study found a positive association between the number of cannabis dispensaries and county-wide emergency

department visits for psychosis in Colorado after legalization. George Sam Wang et al., *Impact of cannabis legalization on healthcare utilization for psychosis and schizophrenia in Colorado*, 104 Int'l J. of Drug Pol'y (2022). Specifically, the authors found that emergency room visits for psychosis increased 24% after legalization. *Id.* The increase in emergency department visits was smaller in localities that had a greater number of medical dispensaries pre-legalization, *id.*, indicating that medicinal use had already caused a partial increase in psychosis cases in those areas. More generally, as marijuana use has increased across the United States, the incidence of self-reported psychosis has also increased. Ofir Livne et al., *Association of Cannabis Use-Related Predictor Variables and Self-Reported Psychotic Disorders: U.S. Adults, 2001–2002 and 2012–2013*, 179 Am. J. Psychiatry 36 (2021). From 2003 to 2013, the rate of past-year self-reported psychosis among U.S. adults increased from 0.33% to 0.80%. *Id.*

Second, the dose-dependent relationship between marijuana intake and the risk of psychosis implies a causal relationship. Marconi et al. found a large increase (OR of 3.40, 95% CI = 2.55–4.54) in psychosis risk among the top 20% of marijuana users. Marconi, *supra*. Another study, restricting its analysis to frequent users, also found a strong association (aOR of 2.09; 95% CI = 1.54–2.84). Moore, *supra*. Use of high potency marijuana is associated with an increased risk of psychosis, as is daily use. Marta Di Forti et al., *The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study*, 6 Lancet Psychiatry 427 (2019); *see also, e.g.*, Kat Petrilli et al., *Association of cannabis potency with mental ill health and addiction: a systematic review*, 9 Lancet Psychiatry 736 (2022). Daily users of 10% THC marijuana (or higher) are nearly five times more likely to develop a psychotic disorder than nonusers. Di Forti, *supra*. Based on these results, Di Forti et al. estimated that 12% of first-episode psychosis could be eliminated if high-potency cannabis was

no longer available. *Id.* Another recent study found that, assuming causality, one-fifth of schizophrenia cases among males could be prevented by averting cannabis use disorder. Carsten Hjorthoj et al., *Association between cannabis use disorder and schizophrenia stronger in young males than in females*, 53 *Psychol. Med.* 7322 (2023). In addition, patients with early-onset psychotic symptoms are more likely to report early marijuana use, a fact that the authors of a 2010 study found supported their hypothesis of marijuana use playing a causal role in the development of psychosis. McGrath, *supra*; see also, e.g., Sarah Kanana Kiburi, *Cannabis use in Adolescence and Risk of Psychosis: Are there Factors that Moderate this Relationship? A Systematic Review and Meta-Analysis*, 42 *Substance Abuse* 527 (2021).

Third, longitudinal studies show a strong association between marijuana use and the later development of psychosis, indicating that marijuana use is influencing psychotic symptoms and not the other way around. For example, a long-term study of Swedish conscripts found a positive association between marijuana use at induction and the development of schizophrenia over the following fifteen years. S. Andreasson et al., *Cannabis and schizophrenia. A longitudinal study of Swedish conscripts*, 2 *Lancet* 1483 (1987). A follow up study involving those same conscripts at 35 years also found a positive association between marijuana use at induction and the later development of psychosis and schizophrenia. E. Manrique-Garcia et al., *Cannabis, schizophrenia and other nonaffective psychoses: 35 years of follow-up of a population-based cohort*, 42 *Psychol. Med.* 1321 (2012).

Finally, studies controlling for genetic factors have also found an association between marijuana use and the risk of psychosis. A 2010 study of marijuana-using and marijuana-abstinent siblings found a statistically significant increase in psychosis among marijuana users. McGrath, *supra*. A 2012 study investigating a potentially confounding gene associated with both marijuana

use and schizophrenia found that marijuana use resulted in an increase in measured schizotypy. Marco Colizzi et al., *Interaction Between Functional Genetic Variation of DRD2 and Cannabis Use on Risk of Psychosis*, 41 *Schizophrenia Bull.* 1171 (2015).

b. The HHS Recommendation Minimized the Health Risks of Marijuana by Comparing Marijuana to an Artificially Constrained Set of Substances with Notably High Overdose Risks.

Not only does the HHS Recommendation fail to consider many known health risks of marijuana but, in a transparent attempt to downplay the health risks it does consider, the HHS Recommendation compares marijuana to a hand-picked list of substances known for their high risk of hospitalization and death,¹⁴ specifically: fentanyl, cocaine, oxycodone, hydrocodone, tramadol, heroin, ketamine, benzodiazepines, zolpidem, and alcohol. NPRM, 89 Fed. Reg. at 44,603.

Neither HHS nor DEA saw fit to use any of these drugs as comparators in either the 2011 or 2016 Decisions. Instead, they compared marijuana to drugs such as MDMA, GHB, LSD, and PCP, among other hallucinogens and inhalants. 2011 Decision, 76 Fed. Reg. at 40,561, 40,571; 2016 Decision, 81 Fed. Reg. at 53,782, 53,825. Other than ketamine, a Schedule III drug, the NPRM does not compare marijuana to any hallucinogens, many of which are in Schedules I and II. Psilocybin (mushrooms), LSD, peyote, mescaline, MDMA (ecstasy), and DMT are Schedule I substances; PCP is Schedule II. *See Controlled Substances by CSA Schedule*, U.S. Department of

¹⁴ In 2022, data from CDC's WONDER database for drug overdose deaths in which a drug was specified shows that fentanyl and tramadol are among the class of drugs most commonly identified in drug overdose deaths, cocaine is the third most-identified class, alcohol fourth, oxycodone and hydrocodone belong to the fifth most identified class of drugs, heroin is sixth, and zolpidem belongs to the seventh most common. *Current Final Multiple Cause of Death Data*, CDC WONDER (2022).

Justice, <https://perma.cc/HFG7-T7FX>. All these drugs are included in the annual National Survey on Drug Use and Health (NSDUH), which is the primary database on which HHS relied for its data, meaning that they easily could have been included in HHS’s review. Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration (2022), <https://perma.cc/5G8V-B65D>. Apart from DMT, all of these substances have higher use rates than ketamine, 2022 NSDUH Results, App’x B, Table 1.108B, <https://perma.cc/RWK4-XAV5>, making ketamine an odd choice for inclusion as the only hallucinogen used as a comparator. Indeed, it seems clear that ketamine was chosen since, after adjusting for use rates, it results in a notably high rate of poison control cases and those cases are more likely to result in serious medical outcomes than most of the other comparators. NPRM, 89 Fed. Reg. at 44,612.

If other or additional hallucinogens had been included as comparators, the comparison would have shown that marijuana poses a much higher relative risk to public health. As part of its analysis here, HHS found that

Out of 1.4 million admissions documented in the 2020 TEDS dataset [for substance abuse facility admissions], the most frequently reported primary drug of admission was alcohol (31%, n= 442,014 admissions), followed by heroin (21%, n=292,126 admissions), marijuana (10%, n=139,481 admissions), and cocaine (5%, n=71,725 admissions). Other comparator drugs, including oxycodone, benzodiazepines, hydrocodone, ketamine, or tramadol, were each reported as the primary drug less than 2% of admissions.

Id. at 44,611. Because HHS artificially limited the comparators it used, it omitted the fact that “hallucinogens”—a group that includes over forty Schedule I substances—were the primary substance for only 1,899 substance abuse facility admissions, or 0.13% of all admissions. There were 73 times more admissions for marijuana. Moreover, the CDC’s WONDER database indicated there were 25 overdose deaths that listed either LSD (ICD-10 code: T40.8) or “Other and

unspecified psychodysleptics [hallucinogens]” (T40.9) as a contributing cause of death in 2021. LSD is a Schedule I substance, and the “other and unspecified psychodysleptics” covered in T40.9 include dozens of additional Schedule I substances, meaning that this group of substances, combined, were only listed alongside 25 overdose deaths. In comparison, “cannabis derivatives” (T40.7) were listed alongside 1,159 overdose deaths.

HHS’s deliberate—and wholly unexplained—decision to change its public health analysis by excluding other hallucinogens as comparators led to distorted conclusions. HHS decided that “[t]he risks to the public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological databases for ED visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths” and that “although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator drugs.” NPRM, 89 Fed. Reg. at 44,601, 44,614. If HHS had followed the same type of analysis it used in 2011 and 2016, and if it had used the same comparator drugs, it could not have reached those conclusions.

Finally, the HHS recommendation also departed dramatically from past rescheduling assessments under the CSA by using alcohol as a general comparator for marijuana in assessing risk. HHS Recommendation 5. DEA should not follow that approach. Because alcohol is expressly exempted from scheduling, 21 U.S.C. § 802(6), its relative health risks are not relevant under the CSA for determining how another substance should be scheduled. Accordingly, no prior scheduling decision has *ever* used alcohol as a general comparator when assessing health risks. The fact that HHS took the unprecedented step of using alcohol as a comparator—without providing any explanation for its novel analysis—shows once again that the HHS recommendation depends on cherry-picking data and novel departures from settled analysis under the CSA to reach

a pre-ordained (and politically motivated) outcome. The DEA should not accept HHS's novel analysis of health and safety risks.

2. Marijuana Has a High Risk of Diversion.

The second subfactor used to assess potential for abuse is whether “there is a significant diversion of the drug . . . from legitimate drug channels.” *See* 2011 Decision, 76 Fed. Reg. at 40,553; *accord* 2016 Decision, 81 Fed. Reg. at 53,769. In 2011 and again in 2016, DEA and HHS found that an absence of data on this factor was *not* indicative of a lack of abuse, but rather reflected the very limited legitimate channels for marijuana authorized by federal law. In both years, DEA and HHS looked to other factors as indicative of abuse potential. In 2023, however, HHS changed course entirely, without explanation.

“Legitimate drug channels” is not specifically defined. Both the 2011 Decision and the 2016 Decision acknowledge that the extremely restricted nature of permissible channels for using marijuana under federal law offer very limited potential for diversion. 2011 Decision, 76 Fed. Reg. at 40,568; 2016 Decision, 81 Fed. Reg. at 53,822. As a result, in both years, DEA and HHS explained that diversion from legitimate *federally authorized* channels was not a meaningful metric to assess marijuana's potential for abuse, and examined instead other metrics to quantify the extent of illicit use of marijuana such as domestic seizures. *Id.*

For example, HHS's 2011 Basis for Recommendation explained that “the lack of significant diversion of [federal] investigational supplies may result from the ready availability of illicit cannabis of equal or greater quality.” 2011 Decision, 76 Fed. Reg. at 40,553. HHS went on to explain that “[t]he magnitude of the demand for illicit marijuana is evidenced by DEA/Office of National Drug Control Policy (ONDCP) seizure statistics” with the total federal seizures of marijuana in 2003 amounting to 2,700,282 pounds, “represent[ing] nearly a doubling of marijuana

seizures since 1995, when 1,381,107 pounds of marijuana were seized by federal agents.” *Id.* Consistent with HHS’s 2011 finding, DEA concluded that “marijuana is the most commonly abused illegal drug in the United States.” *Id.* at 40,568. Similarly, in 2016, HHS again pointed to “the widespread availability of illicit marijuana” and domestic drug seizure statistics (573,195 kg in 2011), as factors establishing high potential for abuse. 2016 Decision, 81 Fed. Reg. at 53,770.

In short, the 2011 and 2016 DEA and HHS analyses utilized domestic seizure statistics as a substitute metric for diversion, given the lack of legitimate federal channels for using marijuana. That approach, of course, did not foreclose analyzing data on diversion from *non-federal* channels. To the contrary, in 2016, HHS noted that “legitimate channels” could include use in state-authorized medical marijuana programs, but it found a paucity of data. 81 Fed. Reg. 53,770. HHS explained that “[n]umerous states and the District of Columbia have state-level medical marijuana laws,” but noted that “state-level drug channels do not have sufficient collection of data” related to the safety of those programs. *Id.* HHS again reiterated, marijuana “has long been widely trafficked in the United States” and, as such, “the lack of data indicating diversion . . . from legitimate channels to the illicit market is not indicative of a lack of potential for abuse of the drug.” 81 Fed. Reg. 53,822.

Today, unlike in 2011 and 2016, there is a plethora of state-level diversion data. Despite the availability of that data, however, HHS completely failed to analyze or even so much as acknowledge this data in its 2023 Recommendation. Instead, HHS began its analysis with a boilerplate statement repeating the 2011 and 2016 findings about lack of known diversion from federally authorized channels. HHS Recommendation 8. Rather than turning to state-level channels, as HHS did in 2016, and rather than otherwise referring to illicit trafficking statistics, HHS ended its analysis there. It stated summarily that “there are significant additional sources of

marijuana in the United States, both from illicit cultivation and production, illicit importation from other countries, and from state programs that permit dispensing of marijuana for medical use and, in some states, recreational adult use.” HHS Recommendation 8.

In short, HHS not only failed to *analyze* state-level diversion data. It *failed to even acknowledge that such data exists*. This approach is legally infirm. It is well settled that an agency may not “entirely fail to consider an important aspect of the problem when deciding whether regulation is appropriate.” *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (brackets, quotations omitted); *see also, e.g., Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem.”).

a. The HHS Recommendation Wrongly Ignores, Without Explanation, State-Level Data On Diversion.

Numerous studies have been published in recent years—all of which are readily accessible on the Internet and therefore available to HHS—establishing significant diversion from “legitimate” state-level channels for authorized use of marijuana. “The illegal markets are thriving in legal marijuana states and the legal market drives products found on the illegal market.” Report of Bertha Madras 12 (July 22, 2024) (“Madras Rep.”) (attached). Diversion is common across the country and across age ranges, as “[u]nderage persons obtain marijuana/THC products from diverted legal products and the illegal market.” *Id.* at 12.

To start, minors commonly obtain marijuana illicitly diverted from medical use. The 2020 Illinois Youth Survey found that 11% of 12th graders, 9% of 10th graders, and 9% of 8th graders who used marijuana in the prior year in suburban Chicago obtained it through “*someone else’s medical marijuana prescription*.” 2020 Illinois Youth Survey: Suburban Chicago, Illinois Department of Human Services 29, <https://perma.cc/7CED-EE2F>. This increased to 15% of 12th

graders in other urban and suburban counties, 2020 Illinois Youth Survey: Other Urban/Suburban, Illinois Department of Human Services 29, <https://perma.cc/4EYK-Q9YA>, and 18% of 12th graders in rural counties, 2020 Illinois Youth Survey: Rural, Illinois Department of Human Services 29, <https://perma.cc/ALG6-NJLC>.

In Arizona, 18.3% of 12th graders, 13.0% of 10th graders, and 10.2% of 8th graders that used marijuana in 2022 obtained it “from someone with a medical marijuana card.” 2022 Arizona Youth Survey, Arizona Criminal Justice Commission 52, <https://perma.cc/C8BM-BH3Q>.

In Massachusetts, a 2022 study tracked trends following marijuana legalization. It found that “[a]mong at-risk youth in Massachusetts, use of diverted medical cannabis *increased* after medical cannabis legalization.” Maddie O’Connell et al., *Trends in Cannabis-Related Attitudes and Behaviors among Cannabis-Using Adolescent and Young Adult Outpatients following Medical Cannabis Legalization in Massachusetts*, 43 *Substance Abuse* 328 (2022). More specifically, “[t]hree years following the 2013 passage of Massachusetts’ [medical marijuana law], [the researchers] observed a significantly increased rate of diverted medical cannabis use in [their] sample of cannabis-using youth.” *Id.*

Moreover, the results suggest that diversion was not simply the direct result of greater availability within that state. Instead, the study found that “nearly one in four obtained medical cannabis through non-Massachusetts sources, including those in non-bordering states, reflecting diffusion or ‘contamination’ from other states with more established cannabis policies.” *Id.* (citing Xinguang Chen, *Information Diffusion in the Evaluation of Medical Marijuana Laws’ Impact on Risk Perception and Use*, 106 *Am. J. Pub. Health* e8 (2016); Xinguang Chen et al., *Medical Marijuana Laws and Marijuana Use Among U.S. Adolescents: Evidence From Michigan Youth Risk Behavior Surveillance Data*, 48 *J. Drug Educ.* 18 (2018).

This finding is not limited to Massachusetts. The 2022 study noted that its results “are consistent with two studies with similar populations in Colorado, which found substantial rates of medical cannabis diversion reported by adolescent outpatients of a substance use treatment center (49% in one study, and 74% in the other).” *Id.* (citing Stacy Salomonsen-Sautel et al. *Medical Marijuana Use among Adolescents in Substance Abuse Treatment*, 51 *J. Am. Acad. Child Adolescent Psych.* 694, (2012); and Christian Thurstone et al., *Medical marijuana diversion and associated problems in adolescent substance treatment*, 118 *Drug Alcohol Depend.* 489 (2011).

Illicit direct sale to minors from dispensaries is also a significant issue: state-level data from Arizona shows that “[d]ispensaries, just like drug dealers, sell to thousands of minors every year.” Connor Kubeisy, *The Drug Review: Marijuana Dispensaries Sell to Thousands of Minors Every Year*, Foundation for Drug Policy (Mar. 11, 2024), <https://perma.cc/9DJN-UBJ4>. While minors in Arizona “can legally purchase marijuana from a dispensary with a doctor-approved medical marijuana card,” “according to the Arizona Department of Public Health, there were only 105 medical marijuana patients below the age of 18 in June 2022.” *Id.* At the same time, “[d]ispensaries were estimated to have sold to more than 5,000 students in 12th, 10th, and 8th grades, after adjusting for usage rates, the percentage of users that bought from dispensaries in Arizona, and school enrollment for the 2021–2022 school year.” *Id.* And these numbers do “not include students in any other grade, suggesting the actual number of K-12 customers is closer to 10,000.” *Id.*

The diversion data is similarly concerning among young adults. A longitudinal study of young adults ages 18 to 26 in Los Angeles, California, where medical marijuana is legal, found that “[n]on-patients without access to legal marijuana were nonetheless able to access marijuana intended for those with doctors’ recommendations.” Megan Reed et. al, *Marijuana sources in a*

medical marijuana environment: dynamics in access and use among a cohort of young adults in Los Angeles, California, 27 *Drugs: Educ. Prev. Pol’y* 69 (2019). Patient and non-patient users of marijuana reported commonly getting the drug from family and friends, and the majority reported that the marijuana originated at a dispensary. *Id.* Further, “[f]or many non-patients, a *majority* of marijuana was sourced from a friend or family member, who often possessed a medical marijuana recommendation and then purchased marijuana for them at a dispensary.” *Id.* (emphasis added). The illicit trade also traced back to the dispensaries themselves. In multiple cases, non-patients reported being able to purchase marijuana directly from dispensaries that did not check for medical recommendations. *Id.*

Diversion is also common among older adults. For example, in a 2020 study of adults aged 35 and 55, “[m]ore than two thirds of medical marijuana users reported that all the medical marijuana they had used was medically recommended for others, indicating a substantial degree of diversion.” Yvonne M. Terry-McElrath et al., *Diversion of Medical Marijuana to Unintended Users Among U.S. Adults Age 35 and 55, 2013–2018*, 81 *J. Stud. Alcohol Drugs* 604, 608 (2020). According to the same study, among past-year medical marijuana users who were age 35, 72.9% of their marijuana was diverted from a different medical marijuana user; among those aged 55, 64.3% used diverted marijuana. *Id.* Indeed, “only one quarter of respondents who had used medical marijuana in the prior year reported using it solely recommended for themselves.” *Id.* at 609.

HHS’s failure to acknowledge the data is especially troubling because diverted marijuana poses unique risks. According to the 2020 Terry-McElrath Report, “[t]o whatever degree diverted medical marijuana is used medically, concerns exist related to ‘loaning’ and/or ‘borrowing’ medication for health purposes.” *Id.* at 210. “Such behaviors are associated with negative

consequences from abuse/disorder, and loss of medical warnings and instructions, which leads to increased risk of incorrect dosing and lack of effectiveness, overdose, side effects, etc.” *Id.* In addition to “loaning” and “borrowing” behaviors, “it is estimated that a majority of people using marijuana for medical purposes also use the drug to get high.” Madras Rep.” 5.

In 2016, HHS did not consider state-level diversion because it found there was insufficient data. Over the past eight years, numerous studies have been conducted to fill that gap. Yet, in its 2023 Recommendation HHS refused to even acknowledge the existence of these studies. The only rational conclusion is that HHS deliberately sought to hide from data that would have undermined its pre-determined conclusion.

b. The HHS Recommendation Wrongly Ignores, Without Explanation, Data on The Magnitude of Domestic Demand for Marijuana.

Even though HHS pointed to domestic marijuana seizure statistics in its 2011 and 2016 Recommendations, *see* 2011 Decision, 76 Fed. Reg. at 40,553 (finding that seizures doubled between 1995 and 2003), 2016 Decision, 81 Fed. Reg. at 53,770 (noting significant 2011 seizure rates), and concluded that the data established significant abuse of marijuana, 2011 Decision, 76 Fed. Reg. at 40,568 (“marijuana is the most commonly abused illegal drug in the United States”), in its 2023 Recommendation HHS made no mention of seizure statistics in its analysis of diversion, nor did it draw any conclusions as to how seizure statistics factor into assessing marijuana’s potential for abuse.

HHS’s failure to address data on this score is inexplicable. Indeed, the HHS Recommendation never discusses law enforcement drug seizure rates, except for one passing discussion of drugs *submitted to forensic laboratories for analysis*, with the unsurprising

conclusion that there has been a modest decrease in marijuana sent for laboratory analysis from 2015 to 2021. HHS Recommendation 43-44.

Importantly, the decriminalization of marijuana in numerous states has *not* quelled criminal activity. According to the DEA’s 2024 National Drug Threat Assessment, despite state level “decriminalization” for recreational use in 24 states and DC and for “medical” use in 38 states and DC, “the black market for marijuana continues, with substantial trafficking by Mexican cartels, and Chinese and other Asian organized crime groups profiting from illegal cultivation and sales, as well as exploitation of the ‘legal’ market.” 2024 DEA National Drug Threat Assessment 37, <https://perma.cc/42ZW-W5LH>. Indeed, “[t]he price of marijuana in illegal U.S. markets has remained largely stable for years, even as the potency of marijuana has increased exponentially.” *Id.*

The 2024 National Drug Threat Assessment also found that “[b]lack-market marijuana cultivation, processing, and trafficking is expanding, as criminal organizations exploit loopholes in the laws and regulations governing the marijuana ‘industry’ to establish large cultivation sites and reap huge profits from the sale of marijuana and other THC products.” *Id.* at 40. What’s more, it is Chinese cartels dominating the market. Sebastian Rotella et al. “Gangsters, Money and Murder: How Chinese Organized Crime Is Dominating America’s Illegal Marijuana Market,” ProPublica (Mar. 14, 2024), <https://perma.cc/VHZ5-W7UL>. China has invested significant resources into purchasing American farmland, which in many cases is used for illegally growing marijuana. Chinese nationals and organized crime mostly run these farms in states where marijuana is legal. By using the legal market as cover, illegal operators can hide in plain sight. *Illegal Chinese Marijuana Farms*, Smart Approaches to Marijuana (May 2024), <https://perma.cc/AW3A-V8KU>.

This illegal activity correlates with significant seizure statistics. Between 2018 and 2022, according to the ONDCP, the number of seized marijuana plants increased 102%, from 2,817,986 to 5,681,839. 2022 DEA Final Domestic Cannabis Eradication/Suppression Program Statistical Report, <https://perma.cc/6X2R-DR7U>; 2018 DEA Final Domestic Cannabis Eradication/Suppression Program Statistical Report, DEA, <https://perma.cc/GYU7-MRD2>. Between 2020 and 2022, the number of kilograms of marijuana seized by the High Intensity Drug Trafficking Areas program increased 23.5%, from 1,923,487 to 2,356,467. 2022 Report to Congress, High Intensity Drug Trafficking Areas Program, White House Off. Nat. Drug Control Pol’y 21, <https://perma.cc/Q7EJ-A343>; 2024 Report to Congress, High Intensity Drug Trafficking Areas Program, White House Off. Nat. Drug Control Pol’y 21, <https://perma.cc/J8EM-HKGJ>. Additionally, the number of outdoor marijuana plants that were seized increased by 59%, from 590,344 to 939,733. National Drug Control Strategy, 2020 Data Supplement, White House Off. Nat. Drug Control Pol’y 167, <https://perma.cc/GM63-U25S>; *Domestic Cannabis Eradication / Suppression Program*, DEA, <https://perma.cc/543D-Q7GH>. The number of indoor marijuana plants that were seized increased by 35%, from 234,972 to 316,299. *Id.*

As in 2011 when DEA denied a marijuana rescheduling petition, marijuana remains the most abused illegal drug in the United States. *Cannabis Facts and Stats*, CDC (Feb. 22, 2024), <https://perma.cc/473B-AJ7S>.

As HHS explained in 2011 and again in 2016, data showing large seizures of illegal marijuana supports the conclusion that marijuana has a high potential for abuse. The stark absence of any similar discussion of seizure rates in HHS’s 2023 Recommendation is inexplicable. It shows, once again, a sharp departure from past analysis by HHS without any sufficient rationale to justify the agency’s change in course.

c. The Rewarding Effects of Marijuana Contribute to Its Significant Non-Medical Use.

Although many states have provided authorization under state law for the “medical” use of marijuana, the fact remains that the vast majority of marijuana use in the United States is for nonmedical purposes. According to the 2022 National Survey on Drug Use and Health, a mere 16.4% of past-year marijuana users said that at least some of their marijuana use was recommended by a doctor—meaning that nearly 84% of past-year marijuana users, or more than 50,000,000 users, are using it solely for recreational purposes.¹⁵

The reason for overwhelming nonmedical use is straightforward. As HHS has acknowledged: “There is ample epidemiological evidence that marijuana is self-administered by humans because of its ability to produce rewarding psychological effects, such as euphoria.” HHS Recommendation 58. For example, a 2016 study found that “acute THC administration causes increased dopamine release.” Michael A. P. Bloomfield et al., *The Effects of Δ9-tetrahydrocannabinol on the dopamine system*, 539 *Nature* 369 (2016). As HHS noted, “[t]he rewarding responses observed in humans are consistent with the prevalence of nonmedical use of marijuana, which includes abuse of the substance.” HHS Recommendation 18.

In summary, data on diversion of use from “legitimate” state-level channels indicates alarming statistics on medically prescribed marijuana making its way into the hands of individuals other than those for whom it was prescribed. Moreover, the more lax the state laws, the higher incidence of diversion. These recent statistics, together with the sustained domestic demand and

¹⁵ 2022 National Survey, Public-use Data, <https://tinyurl.com/523tcwmf> (utilizing crosstab variables Row: During the past 12 months, at least some marijuana use was recommended by a doctor (MJANYMEDYR_RECODE); Column: During the past 12 months, if they used marijuana - recoded (MRJYR); Weight: Final person-level sample weight - revised (ANALWT2_C)), *result available here*: <https://tinyurl.com/mr2csvhx> (2022 National Survey Data Query Comparing Medical and Non-Medical Use).

high rates of seizure, coupled with the known science on the rewarding effects, establish not only a high potential for abuse, but also show that greater availability for “medical” use correlates with significant non-medical use, including illicit sales by dispensaries to minors.

d. The Significant Tax Consequences of a Schedule III Designation will Greatly Increase Diversion.

As established above, diversion from “medical” marijuana programs is a significant source for illicit marijuana. This problem will increase exponentially if marijuana is placed on Schedule III—the tax implications of such a rescheduling will make the “medical” marijuana business significantly more lucrative, increasing supply.

Section 280E of the Internal Revenue Code “disallows all deductions or credits for any amount paid or incurred in carrying on any trade or business that consists of illegally trafficking in a Schedule I or II controlled substance within the meaning of the federal Controlled Substances Act.” News Release, *IRS: Marijuana remains a Schedule I controlled substance; Internal Revenue Code Section 280E still applies*, IRS (June 28, 2024), <https://perma.cc/P9SY-7SRK>. “Because the provision applies only to activities involving substances in Schedule I or II, moving marijuana from Schedule I to Schedule III would allow marijuana businesses to deduct business expenses on federal tax filings.” Joanna R. Lampe, *Legal Consequences of Rescheduling Marijuana*, Congressional Research Services (May 1, 2024), <https://tinyurl.com/3udabtfx>.

The ability to claim credits and deductions for ordinary business expenses incurred in operating a marijuana dispensary will, of course, encourage the opening of more marijuana dispensaries. In turn, that will incentivize additional advertising and marketing, which in turn will encourage use by young people. The effectiveness of advertisements on young people is well established. For example, a study of young people in the U.S. aged 15 to 26 found that young people consumed *1% more alcoholic drinks per month for each additional ad seen per*

month. Leslie B. Snyder et al., *Effects of Alcohol Advertising Exposure on Drinking Among Youth*, 160 *Archives Pediatric Adolescent Med.* 18 (2006). They consumed 3% more alcoholic beverages per month with each additional dollar spent per capita on alcohol ads in their media market. *Id.* In turn, more alcohol advertisements in a given market showed increased consumption for young people in their late 20s in that same market. By contrast, alcohol use “plateaued in the early 20s for youth in markets with fewer advertisements.” *Id.*

In sum, there is likely to be a direct connection between rescheduling and further diversion and abuse.

3. Individuals Frequently Use Marijuana on Their Own Initiative, Rather Than on the Basis of Legitimate Medical Advice.

There can be no dispute that individuals frequently use marijuana—indeed, they primarily use marijuana—on their own initiative rather than on the basis of medical advice. According to the 2022 National Survey on Drug Use and Health, 61.9 million people over age 12 reported using marijuana in the past year, and marijuana was the most commonly used illegal drug. Substance Abuse & Mental Health Servs. Admin., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* 14 (2023), <https://perma.cc/5G8V-B65D>. According to the 2022 Monitoring the Future survey, marijuana is used by a large percentage of American adolescents and is the most commonly used illicit drug among American youth. Among students surveyed in 2022, 11.0% of 8th graders, 24.2% of 10th graders, and 38.3% of 12th graders reported that they had used marijuana in their lifetime. In addition, 8.3%, 19.5%, and 30.7% of 8th, 10th, and 12th graders, respectively, reported using marijuana in the past year. Lloyd D. Johnston et al., *Monitoring the Future, National Survey Results on Drug Use 1975-2022: 2022 Overview, Key Findings on Adolescent Drug Use* 89 (2022), <https://perma.cc/B8E9-Q7QV>.

Based on enrollment data from the National Center for Education Statistics, this equates to approximately 340,000 8th grade, 830,000 10th grade, and 1,179,000 12th grade students reporting past year use.¹⁶

As DOJ has previously recognized, the existence of federal and state laws limiting the legal use of marijuana, coupled with its high rate of use, support the conclusion that “the majority of individuals using marijuana do so on their own initiative rather than on the basis of medical advice from a licensed practitioner.” 2016 Decision, 81 Fed. Reg. at 53,770. Survey data also supports this conclusion. In NSDUH 80% of people who reported past-year marijuana use in 2022 reported nonmedical use. HHS Recommendation 37. In survey data from CDC’s Behavioral Risk Factor Surveillance System, 75% of individuals with past-30 days marijuana use reported nonmedical use. *Id.*

4. FDA’s Treatment of Similar Drugs Shows that Marijuana Does Not Belong in Schedule III.

This factor, which asks whether the drug is a “new drug[] so related in [its] action to . . . drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs,” is of limited applicability to an already-scheduled drug like marijuana, which has been a Schedule I substance since the CSA was enacted in 1970. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, tit. II, sec. 202(c), 84 Stat. 1236, 1249 (1970); 21 U.S.C. § 812(c), Schedule I(c)(10); *see also* 21 C.F.R.

¹⁶ Private school enrollment data for 2022 is not yet available. As a result, these figures were calculated using a combination of 2022 public school enrollment data, *Enrollment in public elementary and secondary schools, by level and grade, Selected years, fall 1980 through fall 2023*, Nat’l Center for Educ. Statistics, <https://perma.cc/TQ3G-XSG8>, and 2021 private school enrollment data, *Private elementary and secondary school enrollment, percentage distribution of private school enrollment, and private enrollment as a percentage of combined enrollment in public and private schools, by school orientation and grade: Selected years, fall 1999 through fall 2021*, Nat’l Center for Educ. Statistics, <https://perma.cc/2HQ9-2A9E>.

§ 1308.11(d)(23). The primary compound in marijuana responsible for its abuse potential is THC. NPRM, 89 Fed. Reg. at 44,602. However, to the extent this factor impacts the analysis, it shows that marijuana does not belong in Schedule III.

FDA has approved two drug products containing dronabinol and one containing nabilone, a structurally related cannabinoid. *See id.*; 2016 Decision, 81 Fed. Reg. at 53,822-23. All three are scheduled under the CSA.

First, Marinol is an FDA-approved medicine containing a synthetic, standardized dose of THC. Marinol was originally placed in Schedule II, but later downgraded to Schedule III “because of low numbers of reports of abuse *relative to marijuana*.” 2016 Decision, 81 Fed. Reg. at 53,770-71 (emphasis added). For some reason this context was omitted from the NPRM. *See* NPRM, 89 Fed. Reg. at 44,602-03. Understood in that context, Marinol’s placement in Schedule III indicates that marijuana, which has an extremely high rate of abuse, should be placed in a more restrictive schedule.

Second, Syndos, another dronabinol product containing synthetic THC, is currently located in Schedule II. 21 C.F.R. § 1308.12(f)(2).

Finally, Cesamet, a drug product containing nabilone, is currently listed in Schedule II. *Id.* § 1308.12(f)(1).

The Schedule designations of Marinol, Syndos, and Cesamet confirm that botanical marijuana, which is much more subject to abuse, should not be moved to Schedule III and that such a rescheduling decision would be inconsistent with treatment of these other drugs with the same active ingredient. Unlike these drugs, crude marijuana is not approved by the FDA, cannot be prescribed by a doctor, and contains wildly variant doses of THC. It cannot be the case that these FDA-approved drugs and crude marijuana belong in the same CSA schedule.

B. Factor 2: Marijuana’s Pharmacological Effects Result in Numerous Dangers to the Public Health.

Marijuana’s pharmacological effects are well known and pose substantial dangers to public health. As discussed above, marijuana harms adolescent brain development, resulting in long-term cognitive impacts, and has similar negative effects on children exposed to marijuana in utero. *See* Parts II.A.1.a.ii, *supra*. Marijuana smoke contains many of the same carcinogens and co-carcinogens that are in cigarette smoke and causes pre-cancerous inflammatory damage to bronchial cells. *See* Part II.A.1.a.iii, *supra*. It also impairs users’ psychomotor control, judgment, and ability to focus, all of which increase the risk of automobile crashes. *See* Part II.A.1.a.iv, *supra*. Finally, marijuana plays a causal role in the development of psychosis. *See* Part II.A.1.a.v, *supra*. HHS largely ignores these impacts in its pharmacological discussion in its recommendation, but they were key factors in both HHS’s and DEA’s analysis of this factor in both 2011 and 2016. 2011 Decision, 76 Fed. Reg. at 40,554-58; 2016 Decision, 81 Fed. Reg. at 53,771-77. A complete discussion of these effects is set out in Part II.A.1, *supra*.

C. Factor 3: Current Scientific Knowledge Shows That Marijuana Is A Dangerous Psychoactive Substance.

Marijuana is one of the most-researched drugs in the world. Despite its status as a Schedule I substance, there have been tens of thousands of studies on cannabis conducted in America. According to one recent estimate published in the *Journal of Cannabis Research*, between 1829 and 2021 there have been nearly 30,000 “scholarly journal publications on the topic of cannabis and cannabinoid research,” most submitted in the last 20 years. *See* Jeremy Y. Ng & Nathan Chang, *A bibliometric analysis of the cannabis and cannabinoid research literature*, *J. of Cannabis Research* 4:25 at 3, 7 (2022). The study finds that the United States was responsible for producing over 12,000 publications or about 41 percent of the entire literature base. *Id.* at 4. That research increasingly shows that cannabis is chemically variable; dose ranges for beneficial effects are

unknown; and use of cannabis for psychoactive effects is unsafe and leads to negative health outcomes.

Marijuana is a flowering herb. There are three recognized subspecies: *cannabis sativa* L., *cannabis indica*, and *cannabis ruderalis*.¹⁷ Cannabis, the dried flowering tops of the marijuana plant (especially the *sativa* and *indica* subspecies), contains at least “750 chemicals, among which are some 104 different cannabinoids.” See Madras 2016 Testimony 2. Cannabinoids are substances that have mind-altering properties when they interact with certain receptors in the central nervous system. Cannabinoids from the cannabis plant are classified as “phytocannabinoids,” and they are distinct from (i) “endocannabinoids,” the “neurotransmitters produced in the brain or in peripheral tissues,” and (ii) “synthetic cannabinoids,” created in a laboratory. The most active cannabinoids in botanical cannabis are “cannabidiol” (CBD) and “delta-9-tetrahydrocannabinol” (THC). *Id.* From cross breeding cannabis *sativa* and *indica*, there are now at least 700 distinct cultivars, colloquially called “strains,” of cannabis. See David Gloss, “An Overview of Products and Bias in Research,” 12 *Neurotherapeutics* 731, 732 (2015).

Cannabis is too chemically variegated to be medically analyzed as a single substance. As the DEA recognized in 2016, “[d]ifferent marijuana samples derived from various cultivated strains may have very different chemical constituents, including [THC] and other cannabinoids.” 2016 Decision, 81 Fed. Reg. at 53,771 (quoting Appendino et al., *Cannabinoids: occurrence and*

¹⁷ While the CSA defined “marihuana” with reference to “*Cannabis sativa* L.,” 21 U.S.C. 802(16)(a), federal courts have consistently held that the CSA’s prohibitions apply to all varieties and subspecies of cannabis. See *United States v. Walton*, 514 F.2d 201, 204-05 & n.12 (D.C. Cir. 1975) (holding the CSA “meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC” and “[e]very federal appeals court which has considered the point has reached a similar conclusion.”) (collecting cases); accord *United States v. Rothberg*, 480 F.2d 534, 536 (2d Cir. 1973); *United States v. Moore*, 446 F.2d 448 (3d Cir. 1971).

medicinal chemistry, 18 *Curr. Med. Chem.* 1085-99 (2011)). “[B]ecause of the variations in chemical composition,” distinct “[c]annabis strains cannot be considered collectively.” *Id.* at 53,833. Cannabis may also vary “due to growing conditions and processing of the plant after harvesting.” *Id.*

This problem has only become worse since the DEA last considered rescheduling marijuana. The “chemical composition” of botanical cannabis “is constantly changing.” Madras 2016 Testimony 4. A 2018 study of 36 different “medical” cannabis strains found that “no two Cannabis samples has the same phytocannabinoid profile . . . most pairs of samples differed by more than 71% of the phytocannabinoid components.” Paula Berman, et al., *A new ESI-LC/MS approach for comprehensive metabolic profiling of phytocannabinoids in Cannabis*, *Scientific Reports* 8:14280 (2018). Many of these have been developed to increase the “ratio of THC to CBD, so as to minimize the putative THC antagonism by CBD.” Madras 2016 Testimony 4.

The current state of scientific research shows that marijuana contains numerous health hazards, *supra* Part II.C, and carries significant risk of physical dependence, *infra* Part II.G. The meta-analyses are increasingly equivocal about the benefits of cannabis, and the evidence of harm is becoming stronger. *See* Madras Rep. 9-14, 16-17. And as summarized in *infra* Part III.B, marijuana does not have a currently accepted medical use.

D. Factor 4: Marijuana’s History and Current Pattern of Abuse.

The HHS Recommendation attempts to move the goal posts—or, more aptly, to change the entire playing field—in its analysis on Factor Four, just as it has done in Factor One. In particular, HHS grounds its conclusions about the significance of the history and current patterns of abuse for marijuana in *comparisons to alcohol*. That approach is contrary to the CSA, which expressly excludes alcohol from comparative treatment to other drugs as a matter of policy choice by

Congress. And it is a stark departure from the precedent set by the analysis used by both DEA and HHS in past rescheduling proceedings. It is transparently obvious, moreover, that the only reason for HHS's novel approach is its belief that comparisons to alcohol can support the preordained outcome that HHS sought to reach: rescheduling marijuana. Indeed, HHS's focus on a statutorily *sui generis* substance underscores it cannot reach the conclusion it sought to reach by engaging in appropriate and relevant comparisons. The use of alcohol as a comparator also distracts from more important statistics, including that daily marijuana use reached its peak in 2021, that laxer marijuana laws are correlated with higher rates of marijuana use, and that the rate of abuse by youth is higher for marijuana than for other drugs.

1. Alcohol Is Not an Appropriate Comparator.

Alcohol is expressly exempted from scheduling under the CSA, 21 U.S.C. § 802(6), and as such there is no basis for using alcohol as a comparator in scheduling determinations. It is meaningless to point to data about alcohol as an indicator of how another substance should be treated under the Act because, by congressional directive, alcohol is in a unique category and never has been (and never can be without amending the statute) a controlled substance. Accordingly, neither DEA nor HHS has *ever* used alcohol as a general comparator before in a rescheduling analysis, including the 2011 and 2016 proceedings concerning marijuana. *E.g.* 2011 Decision, 76 Fed. Reg. at 40,560-61 (only passing references to alcohol in 2011 HHS Recommendation on Factors Four and Five); 2011 Decision, 76 Fed. Reg. at 40,581-82 (no mention of alcohol in 2011 DEA Decision on Factors Four and Five); 2016 Decision, 81 Fed. Reg. at 53,781-83 (no mention of alcohol in 2011 HHS Recommendation on Factors Four and Five); *id.* at 53,836-37 (no mention of alcohol in 2011 DEA Decision on Factors Four and Five).

Despite the lack of statutory basis and any historical precedent, the HHS Recommendation prominently features alcohol as a relevant comparator for assessing the pattern of marijuana abuse. HHS Recommendation 37. For example, HHS noted, as its very first substantive finding, that “[f]rom 2015 to 2019, NSDUH data show that the prevalence of past-year use of alcohol was 5-6 times greater than nonmedical use of marijuana.” *Id.* HHS concludes: “These data show that use of marijuana for medical and nonmedical purposes is extensive in the United States, but that its prevalence of use is less than that of alcohol and significantly more than that of other drugs of abuse that are scheduled under the CSA.” *Id.*

One is left to wonder the relevance of the alcohol abuse comparison. Except, of course, to distract attention from the fact that the use of marijuana for nonmedical purposes is “significantly more than that of other drugs of abuse that are scheduled under the CSA.” *Id.* Even if alcohol-related data were relevant, the durability of that comparator as favoring rescheduling is highly suspect because “the prevalence of marijuana use disorder is rapidly approaching that of alcohol.” Madras Rep. 4. At bottom, there is one statistic that must control the conclusion on history and pattern of abuse. Namely, HHS’s admission that the prevalence of marijuana use is “significantly more than that of other drugs of abuse that are scheduled under the CSA.” *Id.*

2. Peak Figures for Past-Year, Past-Month, And Daily Marijuana Use.

In 2011 and 2016, DEA’s evaluation of Factor Four prominently included marijuana use statistics, 2011 Decision, 76 Fed. Reg. at 40,561, 2016 Decision, 81 Fed. Reg. at 53,867, as well as the factors fueling the high consumption of marijuana, *id.* In 2023, HHS’s Recommendation discounted the significance of the overall use statistics by emphasizing that marijuana is used less frequently than alcohol. HHS Recommendation 37. Setting that irrelevant fact aside, the overall prevalence of use bears emphasizing.

Marijuana use remains disturbingly high. The percentage of the population using marijuana (past-year) rose to 18% in 2019. HHS Recommendation 33. Meanwhile, according to NSDUH data, during the 2015 to 2017 time period, among individuals who used marijuana within the past year, 89% did so without a recommendation from a healthcare provider. *Id.* This number has varied slightly over time, down to 84% in 2020, and back up to 86% in 2021. *Id.*; *see* 2022 National Survey Data Query Comparing Medical and Non-Medical Use (calculating nonmedical use at 84%).

Additionally, use frequency has skyrocketed. In 2022, “[p]ast-year, past-month, and daily marijuana use (use on 20 or more occasions in the past 30 days) reached the highest levels ever recorded since these trends were first monitored in 1988.” News Release, *Marijuana and hallucinogen use among young adults reached all time-high in 2021*, NIH (Aug. 22, 2022) (2022 NIH Release), <https://perma.cc/4CSK-9C6D>. According to the National Institutes of Health-supported study, “[t]he proportion of young adults who reported past-year marijuana use reached 43% in 2021, a significant increase from 34% five years ago (2016) and 29% 10 years ago (2011).” *Id.* In turn, past-month use was reported by 29% of young adults in 2021, compared to 21% in 2016 and 17% in 2011. *Id.* Likewise, the prevalence of daily marijuana use reached its highest level reported in 2021, at 11 percent of Americans aged 12 or older. This number is up three points from 2016 (8%) and up 5 points from 2011 (6%). *Id.*¹⁸

¹⁸ According to the National Survey on Drug Use and Health, there were 15.07 million daily marijuana users in 2022 (based upon past-year use), up 13% from 13.30 million in 2021 and 182% from 5.35 million in 2012. 2022 National Survey, Table 8.3A (2022 and 2021 data), <https://tinyurl.com/mryjmh92>; 2012 National Survey, Table 7.19A (2012 data), <https://tinyurl.com/467emjcv>. In 2022, this corresponded to 5.3% of Americans aged 12 or older. *See* Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2020 to July 1, 2023 (nc-est2023-syasexn), Census Bureau, (total population over age 12 in 2022 was 286,159,223), <https://tinyurl.com/3tbz4j2e>.

Similarly, among past-year users, marijuana users used marijuana on an average of 142.1 days per year, compared to hallucinogen users for an average of 15.3 days; inhalant users for an average of 33.6 days; cocaine users for an average of 41.5 days; alcohol users for an average of 89.1 days; crack users for an average of 98.8 days; methamphetamine users for an average of 153.0 days; and heroin users for an average of 173.8 days. 2022 National Survey, Table 8.1B <https://tinyurl.com/49cc5sru>.

In summary, recent data shows that marijuana usage is steadily increasing, reaching a staggering 43% of the young adult population in 2021. 2022 NIH Release. The vast majority of users, moreover, admit that their use is recreational and not at the recommendation of any healthcare provider. HHS Recommendation 33. And according to 2020 National Survey on Drug Use and Health, up to 1 in 3 past-month marijuana users meets the criteria for cannabis use disorder. Deborah S. Hasin et al., *Prevalence and correlates of DSM-5 cannabis use disorder, 2012–2013: findings from the national epidemiologic survey on alcohol and related conditions – III*, 173 Am. J. Psych. 588 (2016); Deborah S. Hasin et al., *Prevalence of marijuana use disorders in the United States between 2001-2002 and 2012-2013*, 72 JAMA Psych. 1235 (2015) (together, Hasin Studies). Meanwhile, in 2022, approximately 61 million people reported past-year marijuana use. 2022 National Survey, Table 1.27A, <https://tinyurl.com/5n7a8exx>. These staggering numbers suggest that up to 20 million Americans could have a marijuana substance abuse disorder.

3. Laxer State Restrictions Are Correlated with Increased Use

Also absent from HHS's 2023 Recommendation is any recognition of the correlation between increased access to marijuana dispensaries and increased recreational use of marijuana. For example, a 2020 study from Los Angeles establishes that increased sources of marijuana is

correlated with destigmatization: “Overall, consistent access to marijuana regardless of source, as well as the emergence of new sources such as marijuana conferences, points to broader destigmatization and normalization of marijuana in this sample of young adults.” Megan Reed, et. al, *Marijuana sources in a medical marijuana environment: dynamics in access and use among a cohort of young adults in Los Angeles, California*, *Drugs: Education, Prevention and Policy* (Jan. 16, 2019); <https://perma.cc/YT4R-VKF8>. The report found that “accessibility is a key dimension of normalization” namely, “the ease with which participants acquired marijuana and the emergence of novel sources over the course of the study suggest increased normalization of marijuana use among this sample of young adults.” *Id.*

In Los Angeles, the mere existence of medical marijuana dispensaries near where young adults lived was associated with “greater expectations of marijuana’s positive benefits.” Regina A. Shih, et al., *Associations between young adult marijuana outcomes and availability of medical marijuana dispensaries and storefront signage*, *114 Addiction* 2162, 2162 (Dec. 2019). Even more specifically, “medical marijuana dispensaries with signage show stronger associations with number of times used each day and positive expectancies.” *Id.* Notably, only 9% of study participants held medical marijuana cards. *Id.* For those with medical marijuana cards, the density of dispensaries had lesser effects on per-month and per-day use. *Id.* In other words, a fair conclusion is that the existence of dispensaries is correlated with illicit use. “A higher concentration of dispensaries is associated with higher rates of youth/young adult use.” Madras Rep. 12.

Youth studies show a significant percentage of minors purchasing marijuana from dispensaries, even though that is prohibited under the state programs. When high school users in Arizona were asked how they obtained marijuana, 21.0% of 12th graders, 13.1% of 10th graders,

and 8.2% of 8th graders said they “bought it from a dispensary within Arizona.” 2022 Arizona Youth Survey, Arizona Criminal Justice Commission, p. 52, <https://perma.cc/4YFS-2V8X>. Similarly, the 2021 Washington State Healthy Youth Survey found that 12% of 12th graders, 6% of 10th graders, and 3% of 8th graders who obtained marijuana in the past month answered, “Bought at store.” 2021 Washington State Youth Health Survey, Data Sheet Prompt: 2021 Survey Year, State Sample, Marijuana Use, 6th, 8th, 10th, and 12th Grades, <https://perma.cc/HP2X-PWBL>. The 2021 Massachusetts Youth Health Survey found that 4.3% of high school students who used marijuana in the past month answered, “I bought it from a store.” Results Of The Massachusetts Youth Health Survey 2021, Massachusetts Dept. of Health (Oct. 6, 2022), <https://tinyurl.com/2byjp52n>. And in Colorado, when past-month high school users were asked to identify the *one source* where they “usually” obtained marijuana, 4.9% answered, “I bought it at a marijuana store or center.” Marijuana Behaviors: Obtainment, *Healthy Kids Colorado Survey 2021*, Colorado Department of Health & Environment, <https://tinyurl.com/4n67bp6w>.

4. Young People Abuse Marijuana With Greater Frequency than Any Other Drug.

Finally, young people abuse marijuana more than other scheduled substances. According to the 2022 National Study, past-month marijuana users between the ages of 12 and 17 used marijuana on an average of 11.6 days. In comparison, hallucinogen users in this age group used it on an average of 2.7 days and inhalant users used it on an average of 4.8 days (cocaine, heroin, and meth were not reported due to low precision in this age group). 2022 National Survey, Table 8.2B, <https://tinyurl.com/363z6fvd>. Additionally, among this age group, cigarette users used cigarettes on an average of 5.9 days and alcohol users used alcohol on average of 2.9 days. *Id.* In other words, even if alcohol use were an appropriate comparator, for youth ages 12 to 17, those

who used marijuana in the past month used it with twice the frequency that alcohol users consumed alcohol.

Expanding the sample to all individuals 12 and older, past-month marijuana users used marijuana on an average of 16.2 days, compared to cocaine users at 6.4 days, crack users at 11.4 days, hallucinogen users at 2.8 days, heroin users at 20.3 days, and meth users at 18.6 days. *Id.* Here, per-month marijuana use was exactly double per-month alcohol use, which came in at 8.1 days.

E. Factor 5: The Scope, Duration, and Significance of Marijuana Abuse.

The Fifth Factor is scope, duration, and significance of Abuse. In crafting its recommendation, HHS analyzed various datasets that ranked heroin and cocaine (as well as alcohol) as having the greatest adverse medical consequences over the 2015 to 2020 period, including for serious medical outcomes and death. NPRM, 89 Fed. Reg. at 44,613. Once again, this mode of analysis is new. In neither the 2011 nor the 2016 rescheduling considerations did HHS discuss, much less focus extensive attention on, the relative acute negative health outcomes for marijuana vis-à-vis other scheduled drugs. 2016 Decision, 81 Fed. Reg. at 53,783 (HHS 2016 Recommendation focusing on gross use statistics, frequency of use, and ED visits); 2011 Decision, 76 Fed. Reg. at 40,561 (same focus for HHS 2011 Recommendations).

Put simply, if you define the “significance” of abuse in terms of how many emergency room visits, poison control calls, or severe outcomes (like death) have occurred, then it is possible to paint marijuana as less of a societal problem than heroin. But that is never the mode of analysis HHS or DEA have used. Instead, they have examined and credited other outcomes from abuse of the substance that are also hugely significant, even if they do not lead to death. Rather than focus on comparative studies, in 2011 and 2016 DEA’s conclusions focused on the nature of marijuana

abuse itself. For example, in its 2016 decision, DEA noted the “widespread and significant” abuse of marijuana; cited lifetime use statistics and the significant increase in past-month use since 2013; and emphasized that in 2014, a staggering 18.5% of past month marijuana users age 12 or older “used marijuana on 300 or more days within the past 12 months.” 81 Fed. Reg. at 53,837. Likewise, DEA noted in 2016 evidence that THC percentages had increased overtime and that higher percentages “are associated with greater psychoactive effects.” *Id.* In conclusion, in 2016 DEA found that “marijuana continues to be the most commonly used illicit drug, with large incidences of heavy use and dependence in teenagers and young adults.” *Id.*

Similar to 2016, in 2011 DEA’s conclusions with respect to Factor Five focused on the significance of use of marijuana itself. As a relevant summary, DEA concluded that “Marijuana use is associated with dependence and addiction.” 2011 Decision, 76 Fed. Reg. at 40,582. In particular, “current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning,” while “large epidemiological studies indicate that marijuana use may exacerbate symptoms in individuals with schizophrenia, and may precipitate schizophrenic disorders in those individuals who are vulnerable to developing psychosis.” *Id.*

The current HHS Recommendation offers no findings that counter these previously established findings. For example, HHS does not deny that “marijuana use may exacerbate symptoms in individuals with schizophrenia, and may precipitate schizophrenic disorders in those individuals who are vulnerable to developing psychosis.” *Id.* HHS does not contend with the fact that, “at the population level, assuming causality, one-fifth of cases of schizophrenia among young males might be prevented by averting [marijuana abuse].” Madras Rep. 10. Instead, the HHS Recommendation *fails to even mention schizophrenia*. And while HHS’s 2023 Recommendation acknowledges that “in the past 30 years, the potency of marijuana with regard to Δ 9-THC has

increased dramatically,” HHS Recommendation 11, it offers no analysis whatsoever of the impact of higher THC levels on the scope, duration, or significance of abuse, *id.* at 37-45.

As to the scope of abuse, marijuana is by far the most used illicit drug. In 2022, 70.34 million Americans aged 12 or older used an illicit drug, of which 61.90 million used marijuana. In comparison, 8.51 million used hallucinogens, 5.27 million used cocaine, 1.05 million used heroin, and 2.64 million used methamphetamine. 2022 National Study, Table 1.1A, <https://tinyurl.com/57w3fb5a>. Meanwhile, according to the National Institute on Drug Abuse, the average potency of marijuana increased from 3.96% THC in 1995 to 15.34% in 2021. Cannabis Potency Data, National Institutes of Health (Nov. 3, 2022), <https://perma.cc/ZFP9-GSFS>.

The significance of this abuse comes to bear in numerous ways. Marijuana is shown to be associated with use of other drugs. It harms pregnant women and their children. It impairs neurological development in adolescents (as discussed in *supra* Part II.A.1.a.i). And it contributes to traffic fatalities, among other harms.

1. Marijuana is Associated with Use of Other Drugs.

According to the 2022 National Survey on Drug Use and Health, past-year marijuana users were 31 times more likely to have used a hallucinogen in the past year, compared to non-marijuana users (12.40% vs. 0.40%).¹⁹ Similarly, past-year marijuana users were 18.5 times more likely to have used cocaine in the past year, compared to non-marijuana users (7.40% vs. 0.40%); 12.3 times more likely to have used methamphetamine in the past year, compared to non-marijuana users

¹⁹ 2022 National Survey, Public-use Data, <https://tinyurl.com/5czw8a7y> (scroll to “marijuana,” then click “recommended variables,” then click “During the past 12 months, if they used marijuana - recoded (MRJYR).” Select “column” and “add to crosstab.” Follow these steps again for the comparison variable, such as for example the past-year use of hallucinogens, which should be added as the “row.” Once variables are selected, click “run crosstab,” which will provide the results.) (2022 National Survey Data Query Assessing Use Correlation Among Substances).

(3.70% vs. 0.30%); 11 times more likely to have used heroin in the past year, compared to non-marijuana users (1.10% vs. 0.10%); 8 times more likely to have used illegally made fentanyl in the past year, compared to non-marijuana users (0.80% vs. 0.10%); 3.0 times more likely to have smoked cigarettes in the past year, compared to non-marijuana users (36.90% vs. 12.50%); and 1.5 times more likely to have used alcohol in the past year, compared to non-marijuana users (85.80% vs. 56.20%). *Id.* As summarized by a 2021 University of Queensland study, “[b]y the mid-30s, both young-adult and adolescent-onset regular users [of cannabis] were more likely than . . . non-users . . . to have used other illicit drugs, . . . be a high-risk alcohol drinker, . . . smoked daily, . . . and less likely to be in relationships.” Gary C. K. Chan et al., *Young-adult compared to adolescent onset of regular cannabis use: A 20-year prospective cohort study of later consequences*, 40 *Drug & Alcohol Rev.* 627, 627 (May 2021) (“Queensland Study”); see Madras Rep. 12 (“By their mid-30s, young-adult or adolescent-onset regular users compared with minimal/non-users, are 20 times more likely to have used other illicit drugs, 3.7 times more likely to be a high-risk alcohol drinker, 7 times more likely to smoke daily, and are much less likely to be in relationships.”).

Today, the United States faces the “deadliest drug threat” it has ever seen. 2024 NDTA at 1. This deadliest threat comes from fentanyl, which killed “nearly 38,000 Americans in the first six months of 2023 alone.” *Id.* In particular, “[f]entanyl manufactured by the Mexican cartels is the main driver behind the ongoing epidemic of drug poisoning deaths in the United States.” *Id.* at 20.

Regular marijuana use correlates with fentanyl use, as “regular cannabis use . . . strongly predicted . . . illicit drug use.” Queensland Study at 635. In particular, marijuana users are *8 times more likely* to have used illegally made fentanyl in the past year. 2022 National Survey Data Query

Assessing Use Correlation Among Substances, *supra* n.16. In the midst of this unprecedentedly deadly crisis, it is deeply disturbing that the federal government is considering loosening restrictions on a drug—marijuana—which correlates with use of the fentanyl, the main driver behind our unprecedented drug crisis.

In addition to destroying the lives of young people, tearing families apart and fracturing communities, the market for fentanyl feeds a host of other national and transnational criminal activities, particularly through Mexican cartels. The Sinaloa and Jalisco Cartels—the primary and most dangerous drug cartels in Mexico—are both involved in the illicit fentanyl trade. 2024 NDTA at 4, 12. Utilizing Chinese manufactured precursors, *id.* at 7, the cartels reap profits which feed other criminal activities, including “arms trafficking, money laundering, migrant smuggling, sex trafficking, bribery, extortion, and a host of other crimes.” *Id.* at 1. These cartel activities “have a global reach extending into strategic transportation zones and profitable drug markets in Europe, Africa, Asia, and Oceania.” *Id.*

Rescheduling marijuana will bolster business for the cartels. It will do so directly—decriminalization of marijuana has not ended the black market for marijuana but has instead allowed criminal organizations to profit from illegal cultivation and sales. *See supra* Part II.A.2.b. And it will do so indirectly by increasing demand for marijuana, *supra* Part II.D.3 (Laxer State Restrictions Are Correlated with Increased Use), and in turn boosting demand for other illicit drugs like fentanyl, which is an unprecedented scourge on the Nation.

2. Widescale Marijuana Availability Negatively Effects Pregnant Women.

According to the Substance Abuse and Mental Health Services Administration, “Marijuana use during pregnancy can be harmful to a baby’s health and cause many serious problems, including stillbirth, preterm birth, and growth and development issues.” Marijuana and Pregnancy,

Substance Abuse and Mental Health Services Administration (June 6, 2024), <https://perma.cc/9ZXC-5925>. “Pregnant marijuana users had a higher rate of cesarean delivery, a high risk of delivering a small for gestational age infant with smaller head circumference, a higher risk of requiring entry into neonatal intensive care units, and higher risk of supplemental oxygen use at birth.” Madras Rep. 14. Moreover, “THC and other chemicals in marijuana can be passed to a baby through breast milk, increasing the baby’s risk for problems with brain development.” *Id.* These are serious risks, yet HHS chose to ignore them completely. This, again, marks a dramatic change in course in HHS’s 2023 Recommendation, and is out of step with 2011 and 2016.

For example, in 2011 HHS noted that “Chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer, lung damage, *and poor pregnancy outcome.*” 2011 Decision, 76 Fed. Reg. at 40,561 (emphasis added). Going a step further, in 2016 HHS included a section in its Recommendation titled “Behavioral Effects of Prenatal Exposure.” 2016 Decision, 81 Fed. Reg. at 53,830. Among other things, HHS noted that “some evidence suggests an association between heavy prenatal marijuana exposure and deficits in some cognitive domains.” *Id.* Specifically, HHS found in 2016 that “[i]n both 4-year-old and 6-year-old children, heavy prenatal marijuana use is negatively associated with performance on tasks assessing memory, verbal reasoning, and quantitative reasoning.” *Id.* (internal citations omitted). Likewise, “heavy prenatal marijuana use is associated with deficits in measures of sustained attention in children at the ages of 6 years and 13-16 years” whereas, “[i]n 9- to 12-year-old children, prenatal marijuana exposure is negatively associated with executive functioning tasks that require impulse control, visual analysis, and hypothesis.” *Id.* (internal citations omitted).

HHS fails to provide any rationale for ignoring that same evidence. There has not been any change in the data showing negative effects from marijuana on the unborn. According to the

most recent statement from the CDC, “studies suggest that marijuana use by persons during pregnancy could be linked to problems with attention, memory, problem-solving skills, and behavior in their children later in life.” Cannabis and Pregnancy, U.S. Centers for Disease Control and Prevention (Feb. 15, 2024), <https://perma.cc/74HH-CX5Z>. The FDA “strongly advises against the use of cannabidiol (CBD), tetrahydrocannabinol (THC), and marijuana in any form during pregnancy or while breastfeeding.” What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding, U.S. Food and Drug Administration (Oct. 16, 2019), <https://tinyurl.com/3fvnt5r9>. Moreover, a new study conducted by Duke Health found that marijuana use during pregnancy is linked to increases in childhood cancers. Sarah Avery, “Survey Finds Link Between Drug/Cannabis Use During Pregnancy and Certain Childhood Cancers,” Duke Health, (Jan. 12, 2024), <https://perma.cc/YZX5-2X6W>.

According to the NSDUH, the percentage of pregnant women between the ages of 15 and 44 that used marijuana in the past month increased from 7.1% in 2021 to 7.9% in 2022. In comparison, it reported cocaine at 0.0%, heroin at 0.0%, LSD at 0.0% (any hallucinogen at 0.4%), opioids at 0.8%, and alcohol at 11.0%—again highlighting how the inclusion of alcohol changes the frame of reference. 2022 National Survey, Table 8.28B, <https://tinyurl.com/yc67tnau>. Of particular concern, the NSDUH also found that 15.3% of pregnant women between the ages of 18 and 25 used marijuana in the past month. *Id.*

To put a fine point on it, one recent study shows that the prevalence of marijuana “retail” stores is associated with increased marijuana use among pregnant women. Kelly C. Young-Wolff, et al., *Association of Cannabis Retailer Proximity and Density With Cannabis Use Among Pregnant Women in Northern California After Legalization of Cannabis for Recreational Use*, JAMA Network Open (March 4, 2021), <https://perma.cc/WC6N-F8PH>.

HHS’s omission of data related to the scope and significance of marijuana abuse in terms of its effects on pregnant women and unborn children is yet another unexplained and flagrant departure from HHS’s own past analysis.

3. Widescale Marijuana Availability Increases Traffic Fatalities.

Separately, HHS downplays the significance of marijuana abuse on traffic fatalities. According to the HHS Recommendation, “[t]he prevalence of driving under the influence of a drug when all individuals over the age of 16 are combined was 4% for marijuana and 5% for alcohol, with less than 1% for cocaine and for heroin.” HHS Recommendation 51. This statistic is misleading because it did not adjust for usage rates. HHS should have reported the percentage of past-year users of a substance who drove under the influence of the substance, rather than the share of the entire population—which raises the relative share of alcohol because it has a higher rate of use. For example, in 2022, 20.4% of past-year marijuana users over the age of 16 drove under the influence of marijuana, compared to 8.9% of past-year alcohol users over the age of 16 who drove under the influence of alcohol, according to the NSDUH.²⁰ In other words, marijuana users are *more than twice as likely to drive under the influence of marijuana* as alcohol users are likely to drive under the influence of alcohol. That data necessarily shows that marijuana abuse is worse in terms of creating risks for traffic accidents and fatalities.

Likewise, the HHS Recommendation failed to consider traffic fatalities due to drivers under the influence of marijuana. This is despite DEA’s 2016 finding that impaired driving from marijuana abuse is a risk to public health. 81 Fed. Reg. at 53,820. According to a 2021 study, “there is unanimous agreement across studies that acute cannabis use significantly increases the risk for car crashes and impairs specific driving skills.” Ulrich W. Preuss, et al., *Cannabis Use and*

²⁰ 2022 National Survey, *supra* n.13 (data comparing driving under the influence).

Car Crashes: A Review, Front Psychiatry (May 28, 2021), <https://perma.cc/5DC9-7RJA>. “High quality culpability studies (SIGN) noted that there is a dose effect of higher THC blood concentrations with increased risk for fatal crashes and those with injuries.” *Id.*

A 2022 report from the NTSB noted that marijuana is the second most detected substance after alcohol in arrests for impairment and crashes—it is more often detected than stimulants, sedatives, and prescription drugs. News Release, Report Finds Alcohol and Cannabis Are Primary Drugs Detected in Impaired Drivers, NTSB (Jan. 12, 2023), <https://perma.cc/WU4D-WJAQ>. Moreover, since recreational marijuana was legalized in Colorado in 2013, traffic deaths where drivers tested positive for marijuana increased 138% while all Colorado traffic deaths increased 29%. Rocky Mountain High Intensity Drug Trafficking Area Program, *The Legalization of Marijuana in Colorado: The Impact*, 118 Mo. Med. 534 (2021). And the increase in fatal motor vehicle accidents involving marijuana is not unique to the United States. Madras Rep. 14. It is inexplicable and inexcusable that these topics are nowhere to be found in HHS’s 2023 Recommendation. The statute requires more.

The negative effects of marijuana use are difficult to overstate. It is undisputed that marijuana negatively affects cognitive development in adolescents. *See supra* Part II.A.1.a.i. Significant marijuana use by teenagers can lead to persistent cognitive deficits. *Id.* Teenagers who use marijuana regularly are likely to do more poorly in school and never reach their full potential. *Id.*; Queensland Study at 627 (“Cannabis users who began regular use in their teens had poorer later life outcomes than non-using peers.”). Even if marijuana does not kill a teenager or send him to the emergency room,²¹ it may set his entire life on a trajectory for lower achievement, unfinished

²¹ Of course, marijuana does destroy the lives of some young people. The tragic death of Johnny Stack is recounted in Yale School of Medicine News. *See* Isabella Backman, “Not Your

education, and poor employment prospects. According to Dr. Bertha Madras, while an estimated “25-30% of people who use cannabis regularly will develop [cannabis use disorder (“CUD”)] over time” the risk for youth is “twice the rate of adults.” Madras Rep. 10. This means that up to more than 50% of youth who use marijuana regularly will develop CUD. And given the staggering numbers for use of marijuana by teenagers, that outcome from marijuana abuse has an enormous public health significance for our country. In 2022, 1.6 million teenagers used marijuana in the last month,²² and of those 285,000 reported using it 300 days in the past year²³—that is, almost every day. And when that is combined with the dramatic increases in potency, that means that more teenagers are getting more hallucinogen stunting their cognitive development than at any time in our history.

And the data from state programs also shows that relaxing restrictions on marijuana while supposedly keeping it in a restricted program simply does not work. Wherever states permit medical marijuana, teenagers *report* that getting marijuana from that program (either directly or through a person who shares the marijuana with them) is a major source of marijuana reaching school-age adolescents. *See supra* Part II.D.4.

F. Factor 6: Marijuana Poses Serious Risks to the Public Health.

Marijuana poses numerous substantial risks to the public health, most of which the HHS Recommendation completely fails to address, including long-term damage to brain development

Grandmother’s Marijuana: Rising THC Concentrations in Cannabis Can Pose Devastating Health Risks,” Yale School of Medicine News (Aug. 30, 2023), <https://perma.cc/LK4N-LSR3>. Other tragic marijuana-related deaths are collected at SAM’s website, <https://perma.cc/XD6X-T3YW> and at MomsStrong.org, <https://perma.cc/7TYC-S4AG>.

²² 2022 National Survey, Table 1.28A, <https://tinyurl.com/ceyxvk52>.

²³ 2022 National Survey, Table 8.3A, <https://tinyurl.com/44hf7kdw>.

in adolescent users, lifelong developmental impacts from prenatal exposure, respiratory impacts, increased rates of automobile crashes, increased rates of psychosis and schizophrenia, and acute consumption risks similar to those posed by other Schedule I substances like hallucinogens. As Madras explains, individuals who began regular marijuana use in their teenage years “had poorer later life outcomes than non-users.” Madras Rep. 13. “Youth marijuana users are more likely to have suicidal thoughts and attempted suicide in young adulthood” and “are [] more likely to develop psychosis and have earlier age of onset of schizophrenia.” *Id.* A complete discussion of these risks can be found in *supra* Part II.A.1.a.v.

One statistic that bears additional discussion is emergency department (ED) visits. HHS’s Factor Six conclusion fundamentally misleads the reader into believing that marijuana-related ED visits are not a significant public health risk. Specifically, HHS states that the “risks to the public health posed by marijuana *are low compared to other drugs of abuse* (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological databases *for ED visits*, hospitalizations, unintentional exposures, and most importantly, for overdose deaths.” HHS Recommendation 57 (emphasis added). A fair takeaway from this sentence would be that ED visits for marijuana are low compared to heroin, *cocaine, and benzodiazepines*. That is false.

“Cannabis-involved emergency department mentions have risen dramatically over the past decade.” Madras Rep. 6. For example, as even HHS even otherwise acknowledges, “[m]arijuana had the second-highest utilization-adjusted rate of estimated ED visits from 2016 to 2020.” *Id.* at 42. Meanwhile, a 2022 DAWN study placed marijuana as nearly-tied-for-second with opioids as the substance most involved in drug-related ED visits. Specifically, alcohol came in at 45.0%, opioids at 12.7%, marijuana at 11.9%, methamphetamines at 8.2%, cocaine at 5.8%, and benzodiazepines at 2.7%. 2022 Findings from Drug-Related Emergency Department Visits, Drug

Abuse Warning Network 52 (2023), <https://perma.cc/6S4A-HUDB>. To put a finer point on it, in 2022 DAWN found that marijuana-related ED visits were *four-and-a-half times more likely* than for benzodiazepines, *two times more likely* than cocaine, and *one and a half time more likely* than methamphetamines. *Id.*

The 2022 data thus show that marijuana leads to more ED visits than cocaine, meth, and benzodiazepines. In light of that fact, HHS cannot credibly claim that “risks to the public health posed by marijuana are low compared to other drugs of abuse” based on ED visits as a factor. ED visit data establishes that marijuana poses a serious risk to public health.

G. Factor 7: Marijuana Poses Serious Psychic and Physiological Dependence Liability.

The Seventh Factor for consideration is the psychic or physiological dependence liability of marijuana. 21 U.S.C. § 811(c)(7). In both 2011 and 2016, HHS found that marijuana users suffered from both psychic and physical withdrawal symptoms. For example, in its 2011 Recommendation HHS noted that “[l]ong-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.” 2011 Decision, 76 Fed. Reg. at 40,584. In 2016, HHS reinforced its prior assessment concerning the prevalence of psychic and physiological dependence of marijuana, as tied to the drug’s “psychoactive effects.” 2016 Decision, 81 Fed. Reg. at 53,785. The 2016 Recommendation stated that “[p]sychoactive responses to marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking.” *Id.* (internal quotation omitted). “Moreover, high levels of psychoactive effects, notably positive reinforcement, are associated with increased marijuana use, abuse, and dependence.” *Id.* (internal quotation omitted). In other words,

the pleasurable response to marijuana (*i.e.*, its rewarding effect) feeds abuse and dependence.²⁴ The length and frequency of use are correlated with physical dependence and withdrawal symptoms.

Following these conclusions, in its 2023 Recommendation HHS acknowledges that “[p]hysical dependence may occur in up to 40-50% of individuals who use marijuana on a regular basis.” HHS Recommendation 61. Moreover, “90% of individuals who use marijuana who were diagnosed with CUD also reported marijuana physical dependence.” *Id.* These are staggering figures: physical dependence in 40-50% of regular users and 90% physical dependence for those diagnosed with CUD. In 2022, 5.7 million young adults in America (ages 18-25) and 1.3 million teenagers (ages 12-17) are reported as having substance use disorder for marijuana. 2022 National Survey, Table 5.1A, <https://tinyurl.com/bdhut6c7>. These numbers translate into 5.1 million young adults with physical dependence, and 1.17 million teenagers with physical dependence.

In turn, for individuals diagnosed with CUD, “the severity and duration of withdrawal symptoms associated with marijuana discontinuation are greater” than in those without such a diagnosis. *Id.* HHS concluded that “[t]his may be a function of individuals with CUD having a more extensive exposure to marijuana.” *Id.* Taken together, the psychoactive, rewarding response of marijuana is associated with increased use, abuse, and dependence. In turn, the higher the frequency (or intensity) of use, the more serious the physical and psychological dependence.

As established in the preceding sections, the rates of monthly and daily use of marijuana have increased ever since tracking data began to be collected in 1988. 2022 NIH Release.

²⁴ As HHS States in the concluding paragraph of its Recommendation, addressing the Section 812(b)(3)(C) factor, “[t]he ability of marijuana to produce psychic dependence is shown through its ability to produce rewarding effects that underlie its nonmedical use and epidemiological outcomes related to abuse.” *Id.* at 64.

According to the 2022 National Survey, 24.4% of past-year marijuana users were daily or almost daily users.²⁵ 2022 National Survey, Table 8.3B <https://tinyurl.com/49cc5sru>. It follows that physical and psychological dependence have increased as well, particularly with the increase in THC potency in marijuana over the past decade.²⁶

These statistics lead to a natural conclusion that greater availability over time, together with greater potency and more frequent use, all exacerbate the problem of dependency. HHS diverts attention to a more favored narrative in its 2023 Recommendation. It states that symptoms associated with both psychic and physical dependence “are relatively mild for most individuals,” *id.* at 61, while adding that “the severity may be greater with increased exposure, *id.*” HHS once again abandons its prior analysis and diverts attention to the low probability of severe outcomes (such as death, *id.* at 60) from using marijuana, and the fact that milder withdrawal symptoms are connected to more casual use.

²⁵ In contrast, 0.4% of past-year hallucinogen users were daily users; 0.6% of past-year inhalant users were daily users; 2.2% of past-year cocaine users were daily users; 6.6% of past-year crack users were daily users; 6.6% of past-year alcohol users were daily users; 22.3% of past-year methamphetamine users were daily users; and 26.0% of past-year heroin users were daily users. *Id.*

²⁶ In its 2011 Decision, DEA noted at least “one study showing that higher levels of Δ 9-THC in the body are associated with greater psychoactive effects, which can be correlated with higher abuse potential.” 2011 Decision, 76 Fed. Reg. at 40,581 (internal citations omitted). Today, according to Dr. Bertha Madras:

Studies show that high THC, more potent products are associated with more use-related harm among adolescents, college age students, and adults, specifically: (i) more regular marijuana use, more use problems, more use of other drugs, more tobacco dependence, more alcohol use disorder, more academic problems; more addiction, more psychosis, perception deficits, and more distorted thinking, perception, dizziness among older adults.

Madras Rep. 15 (internal citations omitted).

However, given the trend toward heavier use, the focus on infrequent use is mistaken. Indeed, correlating to the trend toward heavier use, recent studies indicates that CUD may be significantly underdiagnosed. According to the 2020 National Survey on Drug Use and Health, 1 in 3 past-month users met the criteria for cannabis use disorder. Hasin Studies, *supra*. Similarly, a 2023 study found that “CUD was common (21%) among primary care patients who use cannabis in a state with legal recreational use, with patients using for nonmedical reasons most at risk of moderate to severe CUD.” Gwen T. Lapham et al., *Prevalence of Cannabis Use Disorder and Reasons for Use Among Adults in a U.S. State Where Recreational Cannabis Use is Legal*, 6 JAMA Open 7 (2023). The researchers concluded that “[a]s legal recreational cannabis use among adults continues to increase across the US, the results here underscore the importance of assessing patient cannabis use and CUD symptoms in medical settings.” *Id.*

According to Dr. Bertha Madras, “it is estimated that 25% or more of patients using marijuana as medicine have a cannabis use disorder.” Madras Rep. 5. This proportion “is far higher than pain patients using prescription opioids.” *Id.* Moreover, as noted above, an estimated “25-30% of people who use cannabis regularly will develop CUD over time, with youth developing CUD at *twice the rate of adults.*” *Id.* at 10.

The increased importance of assessing CUD symptoms is likewise highlighted by the statistics showing that “90% of individuals who use marijuana who were diagnosed with CUD also reported marijuana physical dependence.” HHS Recommendation 61. One report found that “most patients with severe CUD did not receive diagnosis or treatment” and “[t]he probability of CUD diagnosis and treatment could be even lower in other settings without routine cannabis assessment.” Theresa A. Matson et al., *Association Between Cannabis Use Disorder Symptom*

Severity and Probability of Clinically-Documented Diagnosis and Treatment in a Primary Care Sample, 251 *Drug & Alcohol Dependence* 110946 (2023).

Likewise, the Canadian Government's HHS counterpart has warned that "[c]ontrary to popular belief, people *can* become addicted to cannabis." *Addiction to cannabis*, Health Canada, <https://perma.cc/KAK2-MRJJ>. "Continued, frequent and heavy cannabis use can cause physical dependency and addiction," while "[a]ddiction can develop at any age, but youth are especially vulnerable because their brains are still developing." *Id.*

Moreover, a 2022 study of marijuana card holders in the greater Boston area showed that "using cannabis products to treat pain, anxiety and depression failed to improve these symptoms while *doubling the risk of developing the addictive symptoms of cannabis use disorder.*" Press Release, *Marijuana for medical use may result in rapid onset of cannabis use disorder*, Mass. Gen. Hospital (Mar. 18, 2022), <https://perma.cc/UG2B-5NQH>; Jodi Gilman, et al., *Effect of Medical Marijuana Card Ownership on Pain, Insomnia, and Affective Disorder Symptoms in Adults*, 5 *JAMA Network Open* e222106 (2022). The Gilman study concluded that "people seeking cannabis to treat symptoms of anxiety and depression were at greatest risk of CUD." *Id.*

Given the data showing such a high incidence of CUD among heavy users, it would be an error for DEA to focus on the relatively mild dependence associated with occasional marijuana use. And that is especially the case given the data showing growing frequency of use among the population as restrictions are loosened, and where the data shows an ever-increasing THC concentration.

H. Factor 8: Marijuana is Not An Immediate Precursor of a Substance Already Controlled Under the CSA.

As DEA noted in its 2016 Decision, marijuana is not an immediate precursor of substance already controlled under the CSA. 81 Fed. Reg. at 53,839.

III. Marijuana Indisputably Continues to Meet the Criteria for Remaining Exactly Where Congress Placed It: in Schedule I.

A. Marijuana Has a High Potential For Abuse.

As explained above in Part II.D, marijuana has a high potential for abuse.

B. The Proposed Redefinition of “Currently Accepted Medical Use” Does Not Justify Rescheduling Marijuana.

To reschedule marijuana, DEA must also conclude that marijuana has a “currently accepted medical use in treatment in the United States.” 21 U.S.C. § 812(b)(1)(B). For three decades, DEA, HHS, and FDA have consistently determined that marijuana lacks a CAMU. HHS came to a contrary conclusion for this rulemaking only by replacing the five-factor test that DEA has relied upon for decades and that the D.C. Circuit has found compliant with the Act. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994). In its place, HHS recommends, and the Attorney General has proposed adopting, a two-part inquiry that asks first whether there is “(1) widespread current experience with medical use of the substance in the United States by licensed health care practitioners (HCPs) operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” FDA Memo 2. If there is, part two asks whether there is “scientific support for at least one of these medical uses of a substance.” *Id.*

That test is unmoored from the language of the CSA because it would permit a finding that there is a CAMU for a controlled substance even where there is only marginal use of the substance by doctors and that use is supported by mixed and inconclusive scientific data. Moreover, marijuana would fail even under HHS’s new permissive test.

1. The Proposed Redefinition of “Currently Accepted Medical Use” Is Unlawful.

The novel test developed by HHS for this rulemaking does not conform with the statutory requirement that a substance have a “currently accepted medical use.” 21 U.S.C. § 812(b)(1)(B). The first part of the test put forward by HHS violates the Act because it subordinates medical science and consensus in the medical community to the vague “experience” of marijuana being authorized to treat medical conditions at the state level. These state programs authorizing medical marijuana use are so underregulated that they can scarcely be called the practice of medicine, let alone serve as a proxy for the medical consensus required by statute. Step two of the revised CAMU standard does not alleviate this problem because it asks merely whether an alleged medical use for a controlled substance has *any* “scientific support”—which is apparently satisfied once a favorable study or two are published. That check-box inquiry is no substitute for actual medical science.

Congress directed the Administrator to examine the “scientific evidence of [the drug’s] pharmacological effect” and the “state of current scientific knowledge regarding the drug.” 21 U.S.C. § 811(c)(2), (3). This scientific knowledge informs whether a controlled substance has a “currently accepted medical use in treatment.” 21 U.S.C. § 812(b). To have a “medical” use, the substance must have utility in “the practice of medicine” by physicians. *Stedmans Medical Dictionary* 1076-77 (27th ed. 2000) (tracing etymology of “medical” from the Latin *medicus* meaning “physician”). A medical use is “accepted” if it is “widely used, recognized, or approved.” *American Heritage Dictionary* (5th ed. 2022). To have a CAMU, then, the purported health benefits of a controlled substance must have widespread approval by medical practitioners who have expertise in the scientific knowledge and pharmacology of that substance.

Statutory history fortifies that reading. “A century before the Controlled Substances Act was enacted, the determination of what drugs to accept as medicine was totally democratic and totally standardless.” 57 Fed. Reg. 10,499, 10,503 (Mar. 26, 1992) (“1992 Decision”). As a result, “opium, morphine, codeine and cocaine” were “spooned regularly into children” and adults through “wonder-working medicants [such] as Mrs. Winslow’s Soothing Syrup, Dr. Cole’s Catarrh Cure and Perkins’ Diarrhea Mixture.” *United States v. Moore*, 486 F.2d 1139, 1217-18 (D.C. Cir. 1973) (en banc) (Wright, J., dissenting). Widespread use of these pseudo-medicines led Congress to pass federal legislation regulating the interstate drug market, *see, e.g.*, Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), culminating in the Food, Drug and Cosmetic Act. 21 U.S.C. § 301 *et seq.* These laws, as DEA Administrator Bonner summarized, marked a shift “away from uninformed opinions of lay persons and local doctors to expert opinions of specialists trained to evaluate the safety and effectiveness of drugs, and away from totally democratic decision-making to oversight by the Federal Government.” 1992 Decision at 10,503. Under the FDCA, drugs for human use met federal safety standards and could be marketed nationally if they (i) obtained New Drug Application approval by the FDA or (ii) were “GRASE drugs”—that is, “‘generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective,’ based on substantial scientific evidence.” *Id.*²⁷ The statutory phrase “currently accepted medical use” in CSA, 21 U.S.C. § 812(b), was enacted against that backdrop of well-developed standards for determining “whether drugs have accepted medical uses.” 1992 Decision at 10,503.

²⁷ Certain “very old” drugs were also grandfathered into the new regime without regard for whether they met “modern standards for safety and effectiveness.” *Id.*

To be sure, FDA-approval is not a prerequisite to have a CAMU. *Grinspoon v. DEA*, 828 F.2d 881, 888 (1st Cir. 1987). As Administrator Bonner acknowledged, *Grinspoon* “was correct” because Congress placed GRASE drugs, which lacked FDA approval, into Schedules II to V. 1992 Decision at 10,503-04. But since the drugs Congress initially listed in Schedules II to V (and hence had a CAMU) had either FDA approval, GRASE status, or were grandfathered by the FDCA, and drugs listed in Schedule I did not have such recognition, the DEA concluded that “Congress equated the term ‘currently accepted medical use in treatment in the United States’ as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use.” 1992 Decision at 10,503. The D.C. Circuit affirmed this decision in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1134 (D.C. Cir. 1994).

That is why DEA maintained that a consensus of “qualified experts” was a prerequisite to finding CAMU. Specifically, DEA has interpreted CAMU to mean that a “consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder.” 81 Fed. Reg. at 53,836 (quoting 57 Fed. Reg. 10,499, 10,506). Remarkably, HHS and DEA have maintained that “state-level ‘medical marijuana’ laws’ do not provide evidence of such a consensus among qualified experts.” *Id.* Moreover, “a material conflict of opinion among experts precludes a finding of consensus.” *Id.* While that inquiry is normally packaged as the fourth element in DEA’s five-element CAMU test, it is necessarily derived from the plain language of § 812. Only experts in the science of drug safety and effectiveness can determine if a controlled substance has a “medical use,” and only upon consensus (not a minority report) of such experts can it be said the drug has an “accepted” medical use. Nothing in the NPRM suggests that marijuana is supported by a consensus of qualified experts.

So HHS changed the test to change the answer. The novel test put forward by HHS and adopted in the NPRM violates § 812(b) because it jettisons the requirement of a consensus by qualified experts in favor of (1) the state-level experience with using the drug as treatment for a particular indication and (2) any credible scientific support. In combination, both factors create a permissive test that has nothing to do with CAMU as written in § 812(b).

a. Step One of the Revised CAMU Standard Erroneously Equates Widespread Experience With a Medical Consensus.

Step One of the HHS test rests on the illogical premise that “widespread current experience with medical use” at the state level with a controlled substance is indicative of whether the substance enjoys widespread *acceptance* as medicine. The problem with this standard is that state medical marijuana programs are not a reliable proxy for the standard of medical practice.

For starters, HHS’s test counts not just physicians but lumps together all “licensed health care providers” in determining whether a substance has achieved accepted status as medicine. But that is misguided, because many persons are licensed under the catch-all label “health care providers” (like psychologists, social workers, and chiropractors) but are not licensed to practice medicine and therefore are not relevant in determining medical use. *See, e.g.*, Ohio Revised Code § 4743.10 (counselors and social workers are “medical practitioners”); Code of Virginia § 8.01-581.1 (psychologists, social workers and chiropractors are “health care providers”); Nevada Rev. Stat. § 629.031 (music therapist). On its face, the new CAMU standard is out of step with the language of § 812.

Far from being a special case warranting an exception, state-run marijuana programs illustrate why HHS’s CAMU standard violates § 812(b). Medical marijuana may be widespread in that a majority of states have authorized certain providers to recommend cannabis to patients, but only a small percentage of doctors in those states ever do so. Only about 3.4% of active

physicians in New York publicly participate in the state medical marijuana programs.²⁸ Just 3.6% of active physicians in Florida are approved to order medical marijuana.²⁹ In Colorado, it is reported that “just under 2 percent” of all licensed doctors issue marijuana recommendations. *See* Sophie Quinton, “Where Doctors can Recommend Marijuana to Replace Opioids, Stateline (Aug. 13, 2019), <https://perma.cc/6V43-HYKB>. Leading medical organizations like the American Medical Association do not support the legalization of cannabis for “medicinal use.” *See* Am. Med. Assoc., Cannabis Legalization for Medicinal Use D-95.969 (2023), <https://perma.cc/CD65-BT5F>. The American Psychiatric Association uses even stronger language: “There is no current scientific evidence that cannabis is in any way beneficial for the treatment of any psychiatric disorder,” accordingly “[t]he APA does not endorse cannabis as medicine.” Am. Psychiatric Assoc., Position Statement in Opposition to Cannabis as Medicine (May 2019), <https://perma.cc/CSB7-SUEA>. The medical utility of botanical cannabis therefore remains marginal and controversial. It is not commonly used by physicians and certainly not “currently accepted.”

The coterie of health care providers that do write marijuana recommendations participate in a system that bears little resemblance to the practice of medicine. These state programs, Dr.

²⁸ This percentage is estimated by dividing the number of active physicians as of 2022, <https://tinyurl.com/23hst43c> (78,362) by the number of doctors who have consented to be a publicly listed participant in New York’s medical cannabis program, <https://tinyurl.com/5n6c5cba> (2,669).

²⁹ This percentage was conservatively calculated dividing the number of doctors approved to order marijuana, *see* <https://tinyurl.com/mtez27tw> (listing 2,067 physicians), by the most recent estimate of the number of physicians providing direct patient care, *see* Florida Health, 2023 Florida Physician Workforce Annual Report 2 (Nov. 1, 2023), <https://perma.cc/8PEZ-DJ94> (56,769 physicians). Since it may be possible that Florida physicians recommending marijuana are not classified as providing direct patient care, the true percentage may much lower.

Keith Humphreys of Stanford University explains, “have given marijuana the status of medicine with none of the standards.” See Sophie Quinton, “Where Doctors can Recommend Marijuana to Replace Opioids, Stateline (Aug. 13, 2019), <https://perma.cc/LXE6-TWNE>. If marijuana is “a medical drug, it is the least regulated medical drug in the U.S.” See Chelsea L. Shover & Keith Humphreys, *Six policy lessons relevant to cannabis legalization* 3 (HHS public access author manuscript), 45 Am. J. Drug Alcohol Abuse 698 (2019), <https://tinyurl.com/54r5vv7t>. There are at least eight ways state-level “medical” marijuana programs are a significant departure from traditional medical practice, and therefore have no bearing on whether marijuana has CAMU.

First, virtually no health care provider *prescribes* botanical cannabis. Instead, they certify that a person has a medical condition that might qualify them for medical marijuana under state law. In some states, the form explicitly states that the physician is *not* authorizing the use of cannabis but is only attesting to an underlying condition. See, e.g., Letter from Brian L. Strom and Vicente Gracias, Provider Guidance Document Regarding Medical Cannabis, Rutgers Health (Aug. 26, 2020), <https://perma.cc/U3F3-37ER> (New Jersey). As a result, in nearly all jurisdictions, marijuana “recommendation letters cannot specify dose, frequency, route of administration, strength, or any other attribute.” See K. Humphreys & Chelsea L. Shover, *Recreational cannabis legalization presents an opportunity to reduce the harms of the US medical cannabis industry*, 19 World Psychiatry 191 (2020).³⁰

³⁰ Colorado is the exception that proves the rule. In 2022, Colorado passed legislation requiring that medicinal marijuana providers specify (among other things) a maximum THC concentration level and the daily authorized quantity. See *Regulating Marijuana Concentrates* H.B. 1317 (2021). At least one marijuana clinic closed its doors because of the law’s heightened standards. See Thy Vo, “Colorado aimed to crack down on youth access to cannabis concentrates. Doctors say their jobs are being threatened instead,” *The Colorado Sun* (Feb. 7, 2022), <https://perma.cc/38ER-RAE7>.

Second, because doctors are not issuing written prescriptions, users usually get their “medical” marijuana from a dispensary rather than a pharmacy. “Even though pharmacists are understood to be medication experts, they are not required in most states to participate in or oversee the dispensing process.” See Leah Sera Pharm.D., M.A. & Nakia Duncan Pharm.D., *Medical cannabis: Roles, responsibilities, and challenges for clinical pharmacists*, 6 J. Am. Coll. Clin. Pharm. 732, 733 (2023).³¹ Dispensaries are mainly staffed by salespersons called “budtenders,” apparently a play on the term “bartender.” Unlike a pharmacist, no formal education or training is necessary before becoming a budtender. As a consequence, budtenders are not prepared to advise users about ways cannabis can trigger allergies or interact with other drugs that the user may be taking. According to one alarming survey conducted in 2018, 69% of 400 cannabis dispensaries in Colorado recommended marijuana to a pregnant woman to alleviate first-trimester morning sickness. Betsy Dickson et al., *Recommendations From Cannabis Dispensaries About First-Trimester Cannabis Use*, 131 *Obstetrics & Gynecology* 1031, 1031 (2018). Moreover, dispensaries rather than pharmacies would likely continue to play an essential role even if marijuana were rescheduled. Pharmacies would have great difficulty filling prescriptions for crude marijuana because they must dispense drugs to immune compromised individuals and cannot intermingle pharmaceuticals with an organic compound like marijuana that can be contaminated by deadly bacteria, pesticides, and fungi. For instance, a UC Davis patient with a winnable cancer battle was killed by fungal infection after taking medical marijuana with mold and fungus strains.

³¹ Rare exceptions do exist. Minnesota requires that a pharmacist make the final approval for medical marijuana distribution, Minn. Stat. Ann. § 342.51 subd. 3, New York requires an on-site pharmacist supervising the dispensary, 10 CRR-NY 1004.12. Pennsylvania requires a pharmacist at least be available by synchronous communication, 35 Pa. Stat. Ann. § 10231.801, and Arkansas requires each dispensary to have a pharmacist consult, Ark. Const. amend. XCVIII, § 8. The vast majority of states have no such requirements. See Natalie Schmitz & Lucas Richert, *Pharmacists and the future of cannabis medicine*, 60 JAPhA 207, 210 (2020).

See “Fungus In Medical Marijuana Eyed As Possible Cause In California Man’s Death” CBS News (Feb. 6, 2017 9:02 AM PST), <https://perma.cc/BC9E-RB6V>.

Third, because marijuana is not dispensed by prescription, states are not constrained to limit recommending authority to licensed physicians. Many states allow providers of alternative medicine to officially recommend “medical” marijuana to their patients. Naturopathic physicians can issue “written certifications” for persons to use “medical” marijuana in Washington D.C., Arizona, and Washington State. *See* D.C. Mun. Regs. tit. 22-C, § 800; Ariz. Rev. Stat. §§ 32-1581, 36-2801; Wash. Rev. Code § 69.51A.010. New Mexico authorizes chiropractors to provide written certification for “medical” cannabis, *see* N.M. Stat. § 26-2B-3(L); N.M. Code R. § 16.4.15.11, and at least one “licensed Cannabis Chiropractor” offers examinations and promises a cannabis card can be granted in as little as 24 hours. *See* Winds of Choice, <https://perma.cc/Y8AQ-RCG3>.

Fourth, even when the marijuana consultation is performed by a licensed physician, there often is not a bona fide doctor-patient relationship. As the DEA itself has explained, “for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship” consisting of at least four elements: (i) a “patient has a medical complaint” (ii) a “medical history has been taken” (iii) a “physical examination has been performed” and (iv) “[s]ome logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.” *See* Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 21,181, 21,182 (Apr. 27, 2001). But these combined elements are rarely present when a patient wants marijuana to treat a health condition. As previously explained, only a tiny fraction of doctors in a medical marijuana state actually participate in the program, so the overwhelming majority of patients are usually not getting a “medical” marijuana recommendation from their primary care physician. Instead, most patients meet with a doctor

whose business model is writing marijuana recommendations. As Dr. Kenneth Finn recounts, when he investigated Colorado’s medical marijuana program by participating as a patient, he was diagnosed with chronic “severe pain” after just 60-seconds during a telehealth appointment. Finn Decl. ¶ 6. The physician “never asked about prior treatments, about what medication I may be on, if I have had any imaging of my knee, and if I did what the results were. She never asked whether I had minimal, mild, moderate, or severe pain.” *Id.* Such an examination is not a bona-fide doctor-patient relationship.

Unsurprisingly, in many states, the practice of providing certifications for medical marijuana is concentrated in a mere a handful of practitioners who write thousands of medical marijuana recommendation letters each year. In 2023, ten providers (less than one tenth of one percent of licensed doctors) in Colorado wrote 39,000 marijuana recommendations—more than 55% of all recommendations in the state that year. Finn Decl. ¶ 8; *see also* Medical Marijuana Registry Annual Legislative Report 10 (Jan. 2024). In Florida, a jurisdiction HHS highlights for its monitoring checks, FDA Memo 4, 89 doctors issued 95,000 recommendations for marijuana in just 6 months. *See* Tampa Bay Times, “A small number of Florida doctors are approving thousands of medical marijuana patients,” (Sept. 4, 2019), <https://perma.cc/YB9X-WWA3>. Nine doctors in Oregon “approved half [of] the 56,531 marijuana patients and pending applicants,” usually as treatment for pain, even though none of those nine doctors “specializes in addiction treatment or pain management.” Noelle Crombie, “Medical marijuana: A few high-volume doctors approve most patients,” *The Oregonian* (Dec. 29, 2012, 8:27 PM), <https://perma.cc/WFD8-7F4W>. In Pennsylvania, a doctor issued over 27,000 marijuana cards in less than five years. *See* Paul Van Osdol, “Some doctors issuing thousands of medical marijuana cards have disciplinary history involving drugs,” *Pittsburg Action News* (May 6, 2024 6:56 PM EDT),

<https://tinyurl.com/yc2dws4>. One Philadelphia doctor personally issued more than “43,000 cards” for medical marijuana. *Id.*

Fifth, medical marijuana can be recommended for any condition and without the formality of a physical examination or conducting tests verified by lab work. “In most medical marijuana states,” Doctor Reese explains, “doctors can recommend medical marijuana for almost any condition.” *See* “Marijuana Use: What Parents Need to Know,” Debbie P. Reese, MD Pediatrics (last modified May 14, 2024 12:21:26 PM), <https://tinyurl.com/3hzjecvc>. In other jurisdictions, like the District of Columbia, individuals over 21 can self-certify their medical condition “in lieu of securing a recommendation from a healthcare provider.” *See* Medical Cannabis Patient 21+ Self Certification Guidance, DC ARBA, <https://perma.cc/GB45-QXXP>. (July 6, 2022).

Sixth, in contrast to the practice with other controlled substances that have legitimate medicinal use, providers do not have to document the failure of other treatments before recommending marijuana. *See* Abraham M. Nussbaum et al., “*But my Doctor Recommended Pot*”: *Medical Marijuana and the Patient-Physician Relationship*, 26 J. Gen. Intent. Med. 1364 (2011). Marijuana can be the first and only part of a treatment plan. *See id.* at 1366.

Seventh, state programs do not require physicians to identify which patients could be harmed by marijuana. There are no agreed upon or standardized contraindications for “medical” use of marijuana. *Id.*

Eighth, there is some evidence that some marijuana doctors do not keep adequate medical records. *See* Madras Rep. 19. As Dr. Finn explains, seeking medical records from doctors who issue written marijuana recommendations is difficult because patients usually have no record of the name of the recommending physician. Finn Decl. ¶ 10. On the one occasion when a patient had remembered the issuing physicians’ name, Finn was unable to obtain any medical records

despite repeated faxes and phone calls. *Id.* He was also told by one marijuana practice that “we are not required to maintain medical marijuana records.” *Id.*

None of that is standard medical practice. These state programs are not establishing cutting-edge medicine. Rather they are providing a superficial veneer associating marijuana with medical providers while largely medicalizing the recreational use of marijuana.

SAM does not doubt that there are users of medical marijuana who have been led to believe (despite the lack of any high-quality evidence from controlled studies) that marijuana can help relieve their symptoms from a real medical condition. The fact remains, however, that most “medical” marijuana users are young adult males with a prior history of consuming cannabis recreationally. See Thomas J. O’Connell & Che B. Bou-Matar, *Long term marijuana users seeking medical cannabis in California (2001–2007): Demographics, social characteristics, patterns of cannabis and other drug use of 4117 applicants*, 4 Harm Reduct. J. 16 (2007). And yet HHS concludes that the widespread distribution of marijuana for medical-sounding reasons satisfies the first part of its test. When the facts surrounding these programs are properly understood, they clearly have no bearing on whether marijuana has a currently accepted medical use.

Worst of all, HHS’s revised CAMU test turns the CSA on its head. It perversely incentivizes state-level programs to act in open and ongoing defiance of the CSA to manufacture evidence that a drug has a CAMU. Under this approach, if enough states run roughshod over the restrictions of the CSA, then (according to HHS’s theory) that becomes evidence of medical use. Such an outcome is manifestly at odds with the purpose of the CSA.

b. Step Two of the Revised CAMU Standard Erroneously Conflates Bare “Scientific Support” With a Medical Consensus.

Compounding the problem, Step Two of HHS’s test lowers the burden of proof as to what constitutes “accepted medical use.” Step Two gives the mantle of accepted medicine to any

treatment that Step One showed to be widespread in the states if it has “some credible scientific support.” HHS Recommendation 24. But having “some credible scientific support” is a far cry from having an “accepted medical use.” The scientific support could be “credible” but low quality due to a lack of adequate controls (double-blind, placebo, or randomization). The scientific support might be a lone island in a sea of contrary evidence of equivalent or greater quality. And this new-found test strategically ignores the position statements by professional medical organizations with subject-matter expertise. In short, Step Two of HHS’s test can establish only whether a drug warrants further investigation and experimentation; it has nothing to do with whether a drug has a “currently accepted medical use” under the plain meaning of those terms.

HHS’s evaluation of cannabis confirms that Step Two is an entirely toothless factor that is satisfied even when a “review of the available information identified mixed findings of effectiveness across indications.” HHS Recommendation 25.

Start with the evidence for marijuana as treatment for pain. A systematic review of the literature by the University of Florida—a report that apparently has never been published in any peer-reviewed journal but which HHS discusses at length—“identified some data supporting effectiveness of marijuana” but “ultimately concluded the results are inconclusive or mixed.” *Id.* at 26. The National Academies of Sciences also published a review of the literature and found that there was “substantial evidence” that cannabis was effective for treating chronic pain—but also substantial evidence that there was a statistical association between cannabis and “respiratory problems” (when smoked), car crashes, and “schizophrenia or other psychoses.” NAS Rep. at 13, 16-17, 19. HHS also discussed the systematic review published by the Agency for Healthcare Research and Quality. HHS Recommendation 26. That report found “some support for the use of marijuana-related products in the treatment of pain, but overall concluded these effects were small

and the increased risk of dizziness, nausea, and sedation may limit the benefit.” *Id.* HHS does not grapple with the safety and health concerns identified by NAS and AHRQ and amazingly states that “[n]one of the evidence from the systematic reviews . . . identified any safety concerns that would preclude the use of marijuana in the indications for which there exists some credible scientific support.” *Id.*

Cannabis fares no better as treatment for other conditions like anorexia or nausea. While the UF report found “low- to moderate-quality evidence supporting the use of marijuana as medical treatment for outcomes in anorexia, nausea and vomiting, and PTSD,” the HHS Recommendation candidly concedes that the FDA’s review of the literature “showed mixed results for these indications.” *Id.* The HHS Recommendation ends its analysis by also conceding that the “vast majority of professional organizations did not recommend the use of marijuana in their respective specialty” and the American Psychiatric Association “specifically recommended against it.” *Id.* at 27.

With only mixed or inconclusive evidence, and without citing any express support (even conceding some opposition) from leading professional medical organizations, HHS still concludes that cannabis has a “currently accepted medical use.” That conclusion flouts the plain language of § 812(b). It effectively strikes out the language that marijuana be an “accepted” treatment since, in HHS’s hands, that standard is satisfied even if there is no widespread acceptance by qualified experts, no acceptance by any organization of specialists, and the scientific data behind the use is inconclusive.

Indeed, it is difficult to see what Schedule I narcotic could not eventually satisfy HHS’s new test. Take heroin. England has allowed doctors to prescribe heroin as a drug addiction treatment for over one hundred years. *See Tom Carnwath, Heroin prescription for heroin addiction*

– *an English view*, 16 *Acta Neuropsychiatrica* 275-80 (2004). If states adopted “medical heroin” programs so HCPs can certify users for crude heroin as treatment for drug addiction,³² there is surely at least some “credible scientific evidence” that could be marshaled in support to justify rescheduling heroin. HHS’s permissive CAMU standard could be used to effectively reschedule any hard narcotic if there is the political will in some states to make the narcotic broadly available.

* * *

HHS’s revised CAMU standard violates § 812(b). It relies on a sleight-of-hand in which “widespread experience” in state programs that have little in common with the actual practice of medicine combined with a modicum of widely disputed evidence is enough to deem cannabis to have CAMU.

2. Marijuana Fails Even HHS’s Unlawfully Permissive CAMU Test.

Having erroneously changed the meaning of “currently accepted medical use,” HHS goes wrong again in concluding that marijuana satisfies its own new test. The contention that marijuana is medicine is a fiction: marijuana is an impure, organic compound and it is largely unregulated with respect to potency and quality. These variables make generalized conclusions about marijuana’s efficacy impossible. And the thin evidence supporting marijuana use under laboratory settings has not persuaded any leading professional medical societies to endorse its use. Marijuana therefore does not have a CAMU and lacks “an accepted safety for use under medical supervision.” 21 U.S.C. § 812(b)(1).

³² This suggestion is not unrealistic as prescription heroin was recently approved in Canada, *see* Susan Scutti, “Prescription heroin gets green light in Canada,” CNN (Sept. 14, 2016 9:15 PM EDT), <https://perma.cc/29DC-GXE9>, and at least one prominent think tank proposes adopting this policy in America, *see* Elana Goron, “Is America Ready For Prescription Heroin?” NPR (Dec. 6, 2018 12:36 ET), <https://perma.cc/2GJB-VJ98>.

a. Marijuana’s Chemical Composition and Its Various Modes of Consumption Are Too Variable to Permit Generalized Conclusions.

HHS fails to show that there is any credible scientific support that marijuana has a CAMU because marijuana is a non-chemically uniform drug and can be consumed in many different ways. Moreover, dispensary marijuana suffers persistent product integrity problems—containing high levels of metals, as well as occurrences of mold, and fungi—that would never be tolerated for real medicine handed through a pharmacy window. As a result, the findings in any marijuana study are limited to the particular strain of marijuana, THC level found in that marijuana, and mode of consumption involved in that study—they do not provide any results that can be applied to marijuana generally. No study cited by HHS attempts to replicate its findings across a range of doses and with a variety of delivery methods. These studies, then, are probative medical evidence only of the potential benefits that occur at the THC dosage and delivery mechanism from that study.

Cannabis-based medicines like Epidiolex and Dronabinol use a synthetic THC that permits a standardized oral dosage. Because the chemical composition is known, it is possible for clinical trials to measure the efficacy of these drugs and make safety assessments for the public. In marked contrast, marijuana is an organic substance. Unprocessed, botanical, or dispensary marijuana varies in its “composition, purity, bioavailability, pharmacokinetics and pharmacodynamics.” *See* Madras, *supra*, at 2. According to Bertha Madras, Professor of Psychobiology at Harvard Medical School, the average chemical composition is also changing over time: between 2005 and 2016, “the number of cannabinoids identified in the whole plant increased from 70 to 104, and other known compounds in the plant increased from ~400 to ~650.” *Id.* at 4.

As explained above, *supra* p. 27, THC concentration in marijuana has increased by 500% in the past 30 years. HHS concedes that the THC concentration in marijuana samples seized by DEA has risen from 3% in 1991 to 17.1% of 2017. HHS Recommendation 11. Today, “the average THC concentration” is “consistently above 15%” and, depending on the chemovar, can be as high as “35%”—an over 40% increase in potency. *See* Cash et al., *supra*, at 5, 14.

Another variable that complicates extrapolating medical benefits is that marijuana can be consumed in multiple ways—*i.e.*, “smoke inhalation, vaporization, liquids, foods, [and] creams.” Madras, *supra*, at 2. The effects of marijuana also vary significantly by the means of preparation. “Inhalation by smoking or vaporization releases maximal levels of THC into blood within minutes,” but can take 2-3 hours with “[o]ral ingestion.” *Id.* No study or report cited by HHS attempts to control all these variables.³³

Finally, dispensary marijuana—the kind that is sold in the state medical marijuana programs—lacks product integrity. Marijuana is an organic compound so “factors such as soil quality, bacterial and fungal contamination, the use of herbicides, pesticides, insecticides, . . . animal waste, insects, toxic chemicals, active compounds, heavy metals, bear on marijuana quality.” *Id.* at 4. In Oregon, “only 3% of retailers and 32% of growers” had been inspected for contaminants, leading the state audit report to conclude that “Oregon’s marijuana testing program cannot ensure that . . . products are safe.” *See* Ore. Liquor Control Comm’n, Oregon’s *Framework*

³³ To the extent they are provided, THC labels on dispensary marijuana are notoriously inaccurate. *See* Ryan Vandrey et al., Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products, 313 JAMA 2491 (2015) (“Of 75 products purchased (47 different brands), 17% were accurately labeled, 23% were underlabeled, and 60% were overlabeled with respect to THC content.”); Michelle Rindels, “State: Sparks marijuana testing lab yielded ‘inaccurate and misleading’ results on pot potency,” *The Nevada Indep.* (Nov. 18, 2019 2:27 PM), <https://perma.cc/693P-VBZC>.

for Regulating Marijuana Should Be Strengthened to Better Mitigate Diversion Risk and Improve Laboratory Testing 1 (Jan. 2019). In California, “just 5-percent of cannabis products . . . are tested for safety. And some experts believe as much as half the pot being grown is contaminated with potentially dangerous chemicals or bacteria.” Natash Zouves, “Labs warn of dangerous, contaminated pot at dispensaries,” ABC 7 News (Apr. 20, 2018), <https://perma.cc/KXA6-W6ZM>.³⁴ Pesticide contamination has sent some medical marijuana users to the emergency room with “serious neurological symptoms.” See Joel Grover and Matthew Glasser, “Pesticides and Pot: What’s California Smoking?” NBC4 (February 22, 2017), <https://perma.cc/UB8Y-YFH8>. According to an audit by the NBC4 investigation team in partnership with Steep Hill Labs, 43 out of 44 (93%) of retail marijuana products tested positive for pesticides. *Id.* Medical marijuana contaminated with toxic molds and fungi have caused deaths in cancer patients. See “Fungus In Medical Marijuana,” *supra*. Fungicides used to prevent these contaminations are also unsafe, particularly myclobutanil, which releases cyanide gas upon combustion and poses a particular risk for smoked marijuana. Zouves, “Labs warn of dangerous, contaminated pot at dispensaries,” *supra*. Metal contamination from poor quality controls may be why marijuana users on average have 27% higher levels of lead and 22% higher levels of cadmium in their blood. See Nate Seltenrich, “Untested, Unsafe? Cannabis Users Show Higher Lead and Cadmium Levels,” 131 *Environ. Health Prospect* 094001-1 (Sept. 2023). If any medicine had these problems, it would be pulled off the shelves immediately.

³⁴ And even the testing that does occur can be falsified. After one California marijuana lab was caught falsifying pesticide test results, 10,000 pounds of marijuana were recalled. See Sacramento laboratory fakes pesticide test results, thousands of pounds of marijuana recalled,” *Food Safety Magazine* (Jan. 15, 2019), <https://perma.cc/78KW-H2MS>.

Because marijuana is variegated, can be consumed in a variety of ways, and lacks product integrity, it is impossible to determine a safe therapeutic window for marijuana. HHS cannot infer that the results of any one marijuana study provide any support for marijuana as a whole. HHS's conclusion thus that botanical marijuana is accepted medical treatment for pain, nausea, and anorexia reduces to a part-to-the-whole fallacy: HHS infers that botanical marijuana may be effective by relying on tests that do no more than show inconclusive evidence that one particular strain of marijuana consumed in a particular way *may* be effective.

b. None of the Literature Cited by HHS Provides Credible Scientific Support that Marijuana Is Pain Medicine.

No study analyzed in the FDA Memo concludes that general use of marijuana and other cannabis products, regardless of THC content, chemovar, or mode of consumption, is a safe or effective treatment for pain. Indeed, the lack of evidence in this area is why organizations like International Association for the Study of Pain (IASP) “does not currently endorse general use of cannabis and cannabinoids for pain relief . . . There is not enough high-quality human clinical safety and efficacy evidence to allow IASP to endorse the general use of cannabis and cannabinoids for pain at this time.” *See* IASP, “Cannabinoid Non-technical Summary,” (2021), <https://perma.cc/X46G-JL6J>.³⁵ Nevertheless, based on “FDA’s review of the available information,” the NPRM asserts that “[t]he largest evidence base for effectiveness exists for marijuana use within the pain indication.” NPRM, 89 Fed. Reg. at 44,618. The three systematic

³⁵ Many other medical associations specializing in pain also do not endorse cannabis as medicine. *See The British Pain Society position statement on the use of medical cannabis and cannabis-based products in the management of chronic pain*, The British Pain Soc’y (Nov. 25, 2019), <https://perma.cc/H87C-B2QG>; *Prescribing medical cannabis for chronic non-cancer pain*, Australian and New Zealand College of Anaesthetists (March 2022), <https://perma.cc/7SSK-QZPU>; *Medical Cannabis*, New Zealand Pain Soc’y (Dec. 9, 2016).

reviews that the FDA draws upon have significant limitations, and HHS’s conclusion that marijuana has a CAMU for treating pain is unsound.

Start with the NAS Report. *See* HHS Recommendation 26; FDA Memo 73; NPRM, 89 Fed. Reg. at 44,618. The chapter of the report addressing marijuana’s potential as treatment for pain concludes there is “substantial evidence” supporting the use of cannabis products to treat pain. All of the underlying studies, however, involve either cannabis-based medicines with synthetic THC or low-dose THC cannabis grown in a lab. None of these studies provides scientific evidence that cannabis products as a whole are effective or safe as a means to treat pain.

The NAS report is based on five systematic reviews, and it concludes that the best review is Penny F. Whiting et al., “Cannabinoids for Medical Use: A Systematic Review and Meta-analysis,” 313 JAMA 2456-73 (2015) [hereinafter “Whiting 2015 Review”]. The Whiting 2015 Review analyzed 79 different studies, of which 28 assessed how different cannabis products could mitigate pain. It concludes that any improvement from cannabinoids “did not reach statistical significance.” *Id.* at 2456. Moreover, of the *entire review*, only four studies involved smoked cannabis and of these just one—involving THC levels of merely 3.5%—found marijuana had a beneficial effect for pain. *See* D. I. Abrams et al., “Cannabis in painful HIV-associated sensory neuropathy,” *Neurology* (2007). Twenty of the other chronic pain studies in the Whiting 2015 Review evaluated inapposite products like nabiximols (a standardized drug made by GW pharmaceuticals and which is unavailable in the United States); and nabilone and dronabinol (FDA-approved drugs). The NAS report conceded “many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level . . . [and] very little is known about the efficacy, dose, routes of administration, or

side effects of commonly used and commercially available cannabis products.” NAS Rep. at 89-90.

The other four systematic reviews also have little to no bearing on whether botanical cannabis has a medical use. The second review NAS evaluated “did not include any studies that used cannabis” and only identified one study using FDA-approved dronabinol. The third and fourth reviews “did not contribute unique studies or findings.” NAS Rep. at 88.

The fifth review upon which NAS based its findings also misses the mark. *See* Michael H. Andrae et al., “Inhaled Cannabis for Chronic Neuropathic Pain: A Meta-analysis of Individual Patient Data,” 16 *J. of Pain* (2015) [hereinafter “Andrae 2015”]. This review examined just five Randomized Controlled Trials (RCTs), all with substantial limitations.³⁶ None of the trials evaluated more than 50 subjects (two evaluated fewer than 30) and none spanned more than six weeks. Most important, none of these trials analyzed the effects of cannabis from a state-authorized medicinal marijuana dispensary or with THC level greater than 10% (and two trials did not evaluate cannabis with a higher THC dose than 3.5%). These trials, all over a decade or two old, have no bearing on marijuana today, which now boasts an average 17% THC with some cannabis products like dabs, oils, and edibles as high as 99% THC. *See* Isabella Backman, “Not Your Grandmother’s Marijuana,” *supra*; Ashley Priest, “THC Distillate: What It Is and How to Use It,” Veriheal (May 14, 2024), <https://perma.cc/8UJD-VBL5> (explaining “THC distillate”

³⁶ *See* Barth Wilsey et al., *Low Dose Vaporized Cannabis Significantly Improves Neuropathic Pain*, 14 *J. Pain* 136-48 (2013); Mark A. Ware et al., *Smoked cannabis for chronic neuropathic pain: a randomized controlled trial*, 182 *CAMJ* E694-E701 (2010); Ronald J. Ellis et al., *Smoked medicinal cannabis for neuropathic pain in HIV: a randomized, crossover clinical trial*, 34 *Neuropsychopharmacology* 672-80 (2009); Barth Wilsey et al., *A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain*, 9 *J Pain* 506-21 (2008); D. I. Abrams, *Cannabis in painful HIV-associated sensory neuropathy: a randomized placebo-controlled trial*, 68 *Neurology* 515-21 (2007).

“typically contains 90 to 99% THC”). These trials do not provide credible evidence that there are reliable medicinal benefits for marijuana generally.

After the NAS review, FDA highlights research conducted by the Agency for Healthcare Research and Quality. *See* Chou R. Ahmed et al., “Living Systematic Review on Cannabis and Other Plant-Based Treatments for Chronic Pain: 2023 Update—Surveillance Report 3, AHRQ Publication No. 24-EHC018 (April 2024) [hereinafter “AHRQ Review”]. In its summary, HHS claims this review found “some support for the use of marijuana-related products in the treatment of pain.” HHS Recommendation 26. But the only “marijuana-related products” that the review found had *any* potential effect to alleviate pain was a THC oromucosal spray and products with a high dose of synthetic THC ingested orally. AHRQ Review at 3-4 tbl. 3. The report concluded there was “no evidence” of a pain benefit from using “Whole-Plant Cannabis.” *Id.* In other words, the study provided no evidence whatsoever that would support medical use of the controlled substance at issue here.

Finally, FDA cited a review conducted by the University of Florida in partnership with the FDA. *See* FDA Memo 30-71 (summarizing review). While the full text of the review is apparently not public, the summary provided by FDA shows that the *majority* of the RCTs included in the review showed no improvement for pain symptoms. The outcomes of these RCTs, organized by subject area, is provided in the Table below:

Total RCTs	Focus area	Effect on Subject Pain – #RCTs
27	Pain as primary outcome (on VAS, NRS, SPID, BPI rating scales)	Improvement – 8 No improvement – 18 Worsening – 1
3	Neuropathic pain and fibromyalgia pain	Improvement – 1 No improvement – 2
3	Sleep quality	Improvement – 2 No improvement – 1

Understandably, given that most of the RCTs found that cannabis had no effect on pain, FDA summed up its findings as “mixed or inconclusive.” FDA Memo 67. Moreover, FDA graded for evidence quality each pain-related RCT and deemed *every one* a “high concern” for the “Generalizability” domain, meaning that it is difficult to predict whether the conclusions from those studies apply to more than the population studied.

None of the literature cited by HHS comes anywhere close to establishing that combusting crude marijuana as a cigarette is medicine for pain.

c. None of the Literature Cited by HHS Provides Credible Scientific Support that Crude Marijuana Can Effectively Treat Anorexia, Nausea, or Vomiting.

HHS also concluded that some scientific evidence supported marijuana as treatment for “anorexia related to a medical condition” and “nausea and vomiting (e.g., chemotherapy-induced).” HHS Recommendation 28. Careful parsing of the underlying evidence again shows that this claim is overstated.

The UF review compiled a grand total of six studies that bear on whether marijuana is a potential treatment for anorexia. FDA Memo 33. Of these, three were discarded because each was rated as having “a critical risk of bias.” *Id.* That left three RCTs, two provided “low quality evidence that cannabis increased body weight” and one “showed no benefit compared with [the] placebo.” *Id.* at 36.

The UF review found still less evidence that marijuana is a potential treatment for nausea. Just three RCTs met the eligibility criteria for consideration. Of these, one was conducted in Australia and analyzed the effects of a cannabis-extract capsule administered over five days. *See* P. Grimison et al., “Oral THC:CBD cannabis extract for refractory chemotherapy-induced nausea and vomiting: a randomised, placebo-controlled, phase II crossover trial,” 31 *Annals of Oncology*

1553-60 (2020). It is not clear what THC dose was given in the capsule and FDA grades this study “high concern” on the generalizability domain. Another RCT evaluated just seven subjects who were given Nabiximols, a prescription medication with standardized formula and approved as treatment in Spain, where the study was conducted. *See* Marta Duran et al., “Preliminary efficacy and safety of an oromucosal standardized cannabis extract in chemotherapy-induced nausea and vomiting,” *British J. of Clinical Pharmacology* (2009). Researchers in third study intravenously administered THC but the trial “was stopped” due to “negligible effect” on nausea and “instead showed substantial side effects that are not tolerable in the perioperative setting.” *See* Maren Kleine-Brueggeney et al., “Intravenous Delta-9-Tetrahydrocannabinol to Prevent Postoperative Nausea and Vomiting: A Randomized Controlled Trial,” *121 Anesthesia & Analgesia* 1157-64 (2015). Not one of these studies provide information about the THC dosages involved, nor do they involve crude marijuana.³⁷

C. Marijuana Lacks Accepted Safety For Use Under Medical Supervision.

To move a substance out of Schedule I, the Administrator must also conclude that the substance has an “accepted safety for use of the drug or other substance under medical supervision.” 21 U.S.C. § 812(b)(1)(C). Neither the NPRM nor HHS provide a unique assessment of marijuana under subsection (C). Rather, the NPRM (relying on the HHS Recommendation 63-64) casually asserts that subsection (C) is met for the same indications for which marijuana has a CAMU. NPRM, 89 Fed. Reg. at 44,616. That is plainly inadequate. In the past, the government

³⁷ Of course, even if some forms of marijuana provided a medical benefit to a narrow class of patients, that would supply no reason to move marijuana into Schedule III. It would only justify moving marijuana into Schedule II alongside other dangerous drugs that have highly limited medical application like Adderall or oxycodone—especially since marijuana has a much higher abuse potential than other schedule III drugs. *See supra* Part II.D.

maintained that marijuana *did* lack an accepted safety under medical supervision because doctors had no “assurance of a consistent and predictable potency” nor “proof that the substance is free of contamination.” 66 Fed. Reg. 20,038, 20,052 (Apr. 18, 2001); *see also* 44 Fed. Reg. 36,123, 36,126 (June 20, 1979) (marijuana lacks accepted safety under medical supervision due to “the variability of THC content in natural [marijuana] plant materials”); *accord NORML v. Bell*, 488 F. Supp. 123, 140 (D.D.C. 1980) (same). Here too the NPRM concedes that marijuana still suffers from “high variability” and that this is a “major consideration for the potential variability of drug effects and safety,” NPRM, 89 Fed. Reg. at 44,606, but decides (without explanation) that marijuana is nonetheless has “accepted safety for use under medical supervision,” *id.* at 44,616. DEA’s failure to analyze § 812(b)(1)(C), particularly given the change the government’s position, would be arbitrary and capricious. *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020) (“An agency’s wholesale failure to address past practice and formal policies regarding an issue, let alone to explain its reversal of course . . . is arbitrary and capricious.” (ellipsis original; brackets and quotations omitted)).

D. Abuse of Marijuana Leads to Moderate to High Levels of Physical Dependence.

As explained in *supra* Part II.G, marijuana use has serious risks of psychic and physiological dependence.

CONCLUSION

HHS has not provided any sound justification for rescheduling marijuana under the criteria established by the Act, and the Administrator should conclude that marijuana must stay in Schedule I.

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