UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 26-96**

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW BY SMART APPROACHES TO MARIJUANA AND THE OPPOSED STATES

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Pursuant to 21 C.F.R. § 1316.64 and this Tribunal's Order of July 16, 2026, Designated Parties Smart Approaches to Marijuana (SAM) and Idaho, Indiana, and Nebraska (the Opposed States) submit this Post-Hearing Brief of Proposed Findings of Fact and Conclusions of Law with respect to the proposed rescheduling of marijuana under the Controlled Substances Act.

INTRODUCTION

Marijuana has been controlled under Schedule I of the Controlled Substances Act since 1970.[1] The Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS)[2] have previously considered rescheduling marijuana no fewer than nine times, most recently in 2016. On each occasion, after reviewing the available scientific evidence and applying the criteria specified by the Controlled Substances Act, the Government determined that marijuana must remain in Schedule I because it (i) has a high risk of abuse, (ii) has no currently accepted medical use, and (iii) cannot be used safely under medical supervision.

Under those same statutory standards, the Government can reverse its prior determinations only by showing that marijuana (i) has a risk of abuse lower than that of relevant comparator drugs, (ii) has a use in medical treatment that is accepted by established medical authorities, and (iii) can be used safely under medical supervision and its dependency risks are limited to moderate to low physical dependence or high psychological dependence. But as the recent Hearing showed, all the evidence is to the contrary. The non-medical use of marijuana is more prevalent today than it was ten years ago, with rates of abuse exceeding those of all other controlled substances. Nor is marijuana more accepted as a form of medical treatment: As of today, no major medical

[1] 21 U.S.C. § 812.

[2] The original agency was the Department of Health, Education, and Welfare, but its role was transferred to HHS in 1979. *See* Department of Education Organization Act, Pub. L. No. 96-88, §§ 301, 509, 93 Stat. 668, 677–79, 695 (1979).

organization accepts marijuana as a medicine, and the American Psychiatric Association recommends against it. And the prevalence of dependency is higher now than ever before, with rates of use disorder approaching 30 percent of all marijuana users.

On these facts, marijuana cannot be rescheduled and must remain in Schedule I. So the Government now proposes to reschedule marijuana *not* based on the facts, but rather based on new and different standards—standards that are *not* found in the Controlled Substances Act, that run contrary to previous HHS and DEA practices, and that were devised solely for purposes of this rescheduling. In its new recommendation, HHS replaces its previous analysis of abuse with a newfound focus on overdose risk, asserting that marijuana belongs in Schedule III merely because it is not as lethal as cocaine and opioids, a comparison that HHS previously *rejected* as "inappropriate" when it was proposed during the last rescheduling proceeding in 2016. On the question whether marijuana has a currently accepted medical use, HHS abandons the five-part test that it previously used for decades, replacing it—on the fly, no less—with a new test that allows the agency to find a "currently accepted medical use" based on use by "health care practitioners" rather than physicians, with no acceptance by any major medical organization, and in the face of conflicting scientific data. And as to marijuana's potential for dependency, HHS ignores the ever-increasing rate of addiction and instead focuses on the severity of withdrawal symptoms, an analysis it has never before undertaken.

This Tribunal should reject the Government's attempt to supplant the standards of the Controlled Substances Act and decades of agency precedent with newfound standards dreamt up only for this proceeding. Under the established legal standards, the evidence points in only one direction: Marijuana must remain in Schedule I.

BACKGROUND

A. Legal Framework.

Congress passed the Controlled Substances Act of 1970 (CSA), 21 U.S.C. § 801 *et seq.,* to establish a "comprehensive regime to combat the international and interstate traffic in illicit drugs." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). The CSA divides controlled substances into five schedules, 21 U.S.C. § 812, "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body," *Gonzalez*, 545 U.S. at 13. Schedule I is the most restrictive and is reserved for substances with no currently accepted medical use and a high potential for abuse. Upon enacting the CSA, Congress placed marijuana in Schedule I. 21 U.S.C. § 812(c).

The CSA also established detailed procedural requirements for adding, removing, or transferring substances between Schedules. *Id.* § 811. To move a drug from Schedule I to Schedule III, the Attorney General must find that the drug (i) has a potential for abuse less than substances in Schedules I and II; (ii) has a currently accepted medical use in treatment in the United States; and (iii) risks, at most, moderate-to-low physical dependence or high psychological dependence. *Id.* § 812(c). In making the ultimate scheduling determination, the Attorney General must consider the eight factors enumerated in § 811(c): (1) the drug's "actual or relative potential for abuse"; (2) "[s]cientific evidence of its pharmacological effect, if known"; (3) "[t]he state of current scientific knowledge regarding the drug or other substance"; (4) "[i]ts history and current pattern of abuse"; (5) "[t]he scope, duration, and significance of abuse"; (6) "[w]hat, if any, risk there is to the public health"; (7) "[i]ts psychic or physiological dependence liability"; and (8) "[w]hether the substance is an immediate precursor of a substance already controlled under this subchapter." *Id.* § 811(c).

B. Previous Rescheduling Proceedings for Marijuana.

In nine separate instances over the past 50 years, DEA has rejected petitions to reschedule marijuana, concluding that marijuana belongs in Schedule I because of its high potential for abuse, lack of currently accepted medical use, and inability to be used safely under medical supervision.[3]

Before 2023, DEA's most recent review of marijuana was in 2016. Based on a 2015 HHS recommendation, *see* SAM Ex. 11 (2015 Recommendation), DEA found that marijuana was "the most abused" illicit substance in the United States and that using it can lead to both physical and psychological dependence, SAM Ex. 13 at 73 (2016 Decision); *see id.* at 55. DEA considered a wide range of health impacts, including the association between marijuana use and psychiatric conditions like psychosis and schizophrenia. *Id.* at 8–10, 64–66, 71–72. Also of concern was the increased risk that marijuana poses to adolescent users in terms of diminished neurological functioning and reduced IQ. *Id.* at 8–9. Furthermore, DEA considered the "diversion" of marijuana—that is, the redirecting of a legally-obtained substance to illegal purposes, typically recreational use—as evidence of abuse, invoking data on domestic seizures of marijuana by law enforcement as evidence of substantial illicit use. *Id.* at 3–4, 7, 54–62.

To assess marijuana's abuse potential against that of other drugs, both DEA and HHS compared marijuana to a diverse range of Schedule I and Schedule II substances. They noted that marijuana was more frequently involved in hospital emergency department visits than all other major illicit drugs except cocaine, including ecstasy (MDMA), LSD, and PCP. *Id.* at 16, 59; *accord* SAM Ex. 11 at 36 (2015 Recommendation). But DEA and HHS expressly rejected the suggestion

[3] *See* 81 Fed. Reg. 53767 (Aug. 12, 2016) (cited herein as SAM Ex. 13); 81 Fed. Reg. 53688 (Aug. 12, 2016) (cited herein as SAM Ex. 12); 76 Fed. Reg. 40552 (July 8, 2011); 66 Fed. Reg. 20038 (Apr. 18, 2001); 57 Fed. Reg. 10499 (Mar. 26, 1992); 54 Fed. Reg. 53767 (Dec. 29, 1989); 44 Fed. Reg. 36123 (June 20, 1979); 40 Fed. Reg. 44164 (Sept. 25, 1975); 37 Fed. Reg. 18097 (Sept. 7, 1972).

that marijuana's abuse profile could be gauged by comparing its "effects" to those of cocaine and opioids, stating that comparisons between marijuana and cocaine, amphetamines, or opioids were "inappropriate" because such drugs have "differing mechanism(s) of action . . . and adverse effect profiles." SAM Ex. 13 at 4–5 (2016 Decision); *accord* SAM Ex. 11 at 8 (2015 Recommendation).

To ascertain whether marijuana has a currently accepted medical use (CAMU), DEA and HHS each applied the five-part test the D.C. Circuit approved in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).[4] Both agencies found that marijuana failed as to each factor, because (i) marijuana is a highly variable substance (and thus lacks standardization for dosing purposes) (factor 1); (ii) use of marijuana was not supported by adequate safety or efficacy studies (factors 2 and 3); (iii) treatment with marijuana had no support whatsoever among authoritative bodies like the American Medical Association (factor 4); and (iv) scientific evidence of any strain of cannabis capable of reliably producing standardized doses was not available (factor 5). SAM Ex. 13 at 13–15 (2016 Decision); *accord* SAM Ex. 11 at 26, 30–33 (2015 Recommendation). While noting the increased prevalence of state "medical marijuana" programs throughout the United States, DEA and HHS refused to consider such programs as part of its analysis, stating that "state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder." SAM Ex. 13 at 14 (2016 Decision); *accord* SAM Ex. 11 at 32 (2015 Recommendation).

[4] Under the longstanding five-part test, "(1) [t]he drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available." *All. for Cannabis Therapeutics v. DEA*, 15 F.3d at 1135 (citing 57 Fed. Reg. at 10506 (Mar. 6, 1992)).

C. State Medical Marijuana Programs.

In 1996, California became the first state to decriminalize possession of marijuana for "medical" purposes. Other states followed suit. By 2023, at least 43 U.S. jurisdictions—38 states, four territories, and the District of Columbia—had similar medical marijuana programs. Gov. Ex. 3 at 82 & tbl. 1 (2023 Recommendation).

The extent of actual *medical* oversight in these programs varies considerably. In nearly all state "medical" marijuana programs, the health care providers who can authorize marijuana use by providing a "recommendation" need not be licensed physicians. The result is that fewer than half of the providers who recommend marijuana as medicine are actual doctors. SAM Ex. 3 at 19 ("Madras Report"); *see id.* at 21 tbl. 3. Moreover, only 21 of the 43 jurisdictions with medical marijuana programs in 2023 required that a board of "qualified experts" preapprove medical conditions for treatment with marijuana. Gov. Ex. 3 at 82 & tbl. 2a (2023 Recommendation). And fewer jurisdictions still—only 17 of 43 in 2023—conduct a medical or scientific review as part of the condition-approving process. *Id.*; *see also* Tr. 461:9–15 (Chiapperino).[5] Thus, in the majority of U.S. jurisdictions with medical marijuana programs, whether a particular condition can be treated with marijuana is in the hands of nonphysicians.

D. The August 2023 HHS Recommendation and the Present NPRM.

The current rescheduling began in October 2022, when President Biden ordered the review of marijuana's Schedule I status in the first-ever rescheduling request initiated by the Government. *See* The White House, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), perma.cc/LVF6-344M. The President cited no new medical data to justify rescheduling marijuana,

[5] Only *six* of the 17 jurisdictions with a medical review process have ever rejected the use of marijuana in treating a particular condition. *See* Gov. Ex. 3 at 87–91 tbl. 2a.

but instead simply asserted that Schedule I is meant "for the most dangerous substances," mentioning heroin and LSD as examples. *Id.*

HHS began its review of marijuana that same October and completed its eight-factor analysis ten months later in August 2023.[6] In its 2023 Recommendation to DEA, the agency took an approach markedly different from prior rescheduling proceedings. In assessing marijuana's abuse profile, HHS ignored the drug's diversion from state-authorized medical programs, asserting that scientific research was the only "legitimate" marijuana channel under federal law and that diversion solely from *that* narrow channel was effectively non-existent. And HHS gave no consideration to seizure data as it had before. Gov. Ex. 3 at 9 (2023 Recommendation).[7] That approach conveniently allowed HHS to ignore the seizure data it had previously considered. Even more strikingly, HHS made scant mention of the risks of chronic marijuana use that had featured prominently in its prior analysis. There was no mention whatsoever of the causal relationship between marijuana use and psychiatric illness, notwithstanding that the scientific data linking marijuana to psychosis was significantly *stronger* than eight years earlier. *See* SAM Ex. 7 at 56–57 (DEA Report).

HHS's 2023 Recommendation noted marijuana's high prevalence of non-medical use, finding that it is "the most frequently abused federally illicit drug in the United States." Gov. Ex. 3 at 63. But its analysis of marijuana's abuse potential was focused not on its overall societal effects in absolute terms. Instead, HHS focused on marijuana's comparative effects on a user-adjusted basis in the specific category of acute harms, particularly overdose deaths and emergency

[6] Before initiating a rulemaking proceeding to consider rescheduling, DEA must receive a recommendation from HHS addressing the scientific and medical factors. 21 U.S.C. § 811(b).

[7] Puzzlingly, HHS stated in its point heading, "There **is** significant diversion of the substance from legitimate drug channels." Gov. Ex. 3 at 9 (emphasis added). This was likely simply copied from the 2015 analysis, which—in its rush to complete the analysis—HHS neglected to change.

room visits. *Id.* at 28. Moreover, HHS introduced a wholly new set of comparator substances strongly associated with overdoses—*e.g.*, heroin, fentanyl, oxycodone, hydrocodone, and cocaine—several of which it had expressly rejected as "inappropriate" in 2015. *Compare id.* (identifying cocaine, fentanyl, oxycodone, etc. as "several comparator substances"), *with* SAM Ex. 11 at 8 (2015 Recommendation). HHS concluded that marijuana's risk for the severest outcomes was low *when compared to that select list* of high-overdose drugs—and thus that marijuana had a lower abuse potential than at least some drugs from Schedules I and II. Gov. Ex. 1 at 7 (2024 NPRM) (describing HHS conclusion); Gov. Ex. 3 at 9, 63 (2023 Recommendation).

Even more significant changes occurred in HHS's analysis of whether marijuana has a currently accepted medical use. At the time that review began in October 2022, the only test that HHS had ever used to assess "currently accepted medical use" was the above-noted five-part test endorsed by the D.C. Circuit in *Alliance for Cannabis Therapeutics*. In July 2023, however, two months before FDA researchers analyzing marijuana finished their review,[8] the HHS Secretary "directed" the FDA team to employ a substantially less demanding two-part test. Tr. 412:17–413:22 (Chiapperino). Under that test, a drug could have a CSA-sufficient "currently accepted medical use" if there was:

1. "widespread current experience with medical use of marijuana in the United States by licensed HCPs [*i.e.*, health care providers] operating in accordance with implemented state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions"; and

2. "some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied."

Gov. Ex. 1 at 21 (2024 NPRM).

[8] The scientific and medical analysis in the 2023 HHS Recommendation was supplied by FDA's Center for Drug Evaluation and Research. Gov. Ex. 3 at 99 (2023 Recommendation).

For Part 1, HHS's Office of the Assistant Secretary for Health (OASH) undertook a review of state medical marijuana programs and the conditions being treated with marijuana in those state programs. Although HHS had eschewed consideration of those state medical marijuana programs in its 2015 analysis—and continued to eschew them in 2023 when analyzing diversion—OASH nonetheless used them as a basis to claim that, across the United States, "more than 30,000 HCPs [*i.e.*, health care practitioners] . . . are authorized to recommend the medical use of marijuana for more than six million registered patients for at least 15 medical conditions." Gov. Ex. 3 at 79 (2023 Recommendation); *accord id.* at 84. And on that basis, OASH determined that marijuana met the Part 1 standard of "widespread current experience" with "medical use" as to the 15 conditions it had identified. *Id.* at 84.[9]

Thereafter, the Part 2 analysis was conducted by FDA. FDA tasked a team of University of Florida (UF) epidemiologists and, separately, FDA's own medical staff to review the scientific and medical literature for seven of the 15 conditions identified in Part 1 to see whether "some" scientific support existed for marijuana as a treatment.[10] *See* Gov. Ex. 3 at 26–29, 113–14. FDA's interpretation of what this meant was lenient: In FDA's view, "some" scientific support could be shown even where the data was in conflict. That is, if there were only "a couple of studies" for a

[9] The 15 conditions were ALS, autism, cachexia, cancer, chronic pain, Crohn's disease, epilepsy, glaucoma, HIV/AIDS, multiple sclerosis, Parkinson's, muscle spasm, nausea, PTSD, and spasticity. Gov. Ex. 3 at 26 n.9 (2023 Recommendation); *id.* at 83 (OASH Part 1 Analysis).

[10] As Dr. Chiapperino testified, while the body of evidence for Part 2 encompassed "five buckets" of information—including national surveys, state safety surveys, and select FDA-approved cannabinoid drugs—FDA's conclusions concerning scientific support largely rested on just two buckets, namely the separate scientific literature reviews conducted by UF and FDA. Tr. 488:7–22 (FDA "primarily reli[ed] on the literature review conducted by the University of Florida" and the "review conducted by the medical officer team at FDA.").

particular condition, one of which showed marijuana to have positive effect and the other of which did not, FDA credited the former and found the standard met. Tr. 376:8–15 (Chiapperino).

Even under this lenient standard, FDA concluded that no scientific support existed as to four of the seven conditions under review (and, indeed, that marijuana was actually harmful for at least one condition it was being used to treat, *i.e.*, PTSD). *See* Gov. Ex. 3. at 29 (2023 Recommendation). As to the remaining three, the UF and FDA scientists disagreed as to whether the data showed that marijuana could help. *Id.* As to pain, FDA summarized their competing views as follows:

> In the pain indication, the UF analysis found inconclusive results; however, numerous other systematic reviews concluded that there exists some level of evidence supporting the use of marijuana for pain.

Id. at 200. And as to anorexia and nausea/vomiting, FDA wrote:

> UF found there is low to moderate quality evidence supporting the effectiveness of marijuana as medical treatment for outcomes in anorexia related to certain medical conditions, [and] nausea and vomiting . . . ; however, FDA review of systematic reviews showed mixed results, mostly in support of synthetic forms or evidence only in observational studies with high risk of bias, which are not relevant to this discussion.

Id. To resolve these disputes among the competing scientific teams, FDA simply went with whichever team had the rosier view of the data. As the FDA representative at the hearing testified:

> Q. As to each of these three indications, did you resolve the doubts in favor of an interpretation that favored a finding of currently accepted medical use?
>
> A. We favored the finding listed as the conclusion from the medical officer reviewing these. Yeah.
>
> Q. Which in this case was, there is a currently accepted medical use?
>
> A. Yes.

Tr. 512:8–17. Thus, FDA favored its own scientific team's view in one case (pain), and UF's view in the other two (anorexia and nausea/vomiting), and on that basis found the Part 2 standard met. *See* Gov. Ex. 3 at 29 (2023 Recommendation).

Based on these findings, HHS concluded that marijuana met the criteria for placement in Schedule III and recommended that it be rescheduled. Ten months later, the Attorney General issued a Notice of Proposed Rulemaking proposing to transfer marijuana to Schedule III. *See* Gov. Ex. 1 at 1 (2024 NPRM). The 2024 NPRM correctly noted that HHS's recommendations were not binding once rulemaking began, and that DEA would have to make its own assessment based on an evidentiary hearing. *Id.* at 5.

E. DEA's Eight-Factor Analysis Under § 811(c).

The 2024 NPRM solicited "additional information" relevant to certain scheduling factors that were not covered by HHS's 2023 Recommendation.[11] The DEA's Drug and Chemical Evaluation Section[12] (the "Section") responded by undertaking an independent review of the scientific literature. In December 2024, the Section provided a 96-page eight-factor analysis titled "Marijuana Scientific Knowledge," *see* SAM Ex. 7 at 3–4 (Akinfiresoye Declaration), that in the Section's view, filled "gaps" in HHS's 2023 Recommendation, *see* Tr. 1391:1–13 (Akinfiresoye).

The Section's report noted "widespread" abuse of marijuana, SAM Ex. 7 at 46, making it the "most widely used illicit drug in the United States," *id.* at 12. On this point, the DEA Report

[11] Specifically, the 2024 NPRM solicited information concerning: (i) seizures of marijuana by law enforcement and cannabis-related ED visits, Gov. Ex. 1 at 6; (ii) diversion from state programs and DEA-registered manufacturers to the illicit market, *id.*; (iii) marijuana's pharmacological effects, *id.* at 9; (iv) marijuana's pattern of abuse, *id.* at 14; (v) public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of delta-9-THC potency, *id.* at 18; and (vi) epidemiological survey data on adverse outcomes related to nonmedical use of marijuana and comparator drugs, *id.* at 6.

[12] The DEA Evaluation Section is a unit within the Diversion Control Division responsible for chemical evaluation of controlled substances. Tr. 1340:1–6 (Akinfiresoye).

cited extensive evidence of diversion from state medical marijuana programs (including seizure data), concluding that increased access through state-authorized channels had increased rather than reduced illicit use. *Id.* at 15, 17–18, 48–49. As to marijuana's health effects, the report cited data showing that chronic use posed grave psychiatric risks—including cognitive impairment, psychosis, and other mental health disorders—and that the prevalence of psychotic incidents had increased in jurisdictions with medical marijuana programs. *Id.* at 27–28, 49, 61. The report emphasized that adolescents and young adults were particularly susceptible to these effects because of ongoing brain development, and that increasing THC concentrations in modern cannabis products may increase the likelihood and severity of adverse outcomes. *Id.* at 20, 46, 56.

As to marijuana's currently accepted medical use, the Section eschewed HHS's recently devised two-part test and instead used the established five-part test upheld in *Alliance for Cannabis Therapeutics*, finding the latter to be "more comprehensive." Tr. 1359:6–1360:21 (Akinfiresoye); *see* SAM Ex. 7 at 36–37 (DEA Report). The Section concluded that marijuana failed as to each prong of that test, noting that

- marijuana had no known and reproducible chemistry, because it "is not a single chemical and does not have a consistent and reproducible chemical profile with predictable or consistent clinical effects,"
- adequate safety studies on marijuana did not exist, and there was extensive evidence of "high potency" (and thus unsafe) THC products dominating the market;
- there were no adequate and well-controlled studies to establish marijuana's efficacy as a treatment for any medical indication;
- marijuana was not accepted by qualified experts, and its use by ordinary medical practitioners (who have not evaluated its chemistry, pharmacology, or toxicology) did not equate to expert endorsement; and
- scientific evidence of marijuana was not sufficiently available.

SAM Ex. 7 at 37–40.

In this vein, the report gave significant attention to very recent clinical studies on marijuana as a treatment for pain. *Id.* at 41–42. As the Section observed, each of those studies—nine in all, dating from 2018–24, some of which were missed by HHS—showed that marijuana provided no benefit as pain medicine or, in some cases, actually made the condition worse. *See id.* As the author of the report testified: "There wasn't clear data to support the use of marijuana for the treatment of chronic pain." Tr. 1372:13–14; *see also* Tr. 1372:15–18 (Dr. Akinfiresoye agreeing that the studies she found "showed that in some cases [marijuana] actually made chronic pain worse"). And these findings were not the result of a tendentious or selective review of the literature, as the author of the report was *not* trying to find only negative studies. Tr. 1372:19–23, 1375:1–8 (Akinfiresoye).

Finally, the Section's analysis of state medical marijuana programs took a much more skeptical view than HHS's. It cited extensive data showing that dispensary workers ("budtenders") frequently gave advice that was harmful to the customers or contrary to medical advice from their physicians. SAM Ex. 7 at 41.

F. Public Comments and the Evidentiary Hearing.

The public submitted over 43,000 comments in response to the 2024 NPRM. Although an evidentiary hearing on the rescheduling was initially scheduled to begin in January 2025, the proceedings were suspended that same month. *See* Order, Hr'g Dkt. No. 24-44 (Jan. 13, 2025). The hearing itself was ultimately canceled a year later. 91 Fed. Reg. 22778 (Apr. 28, 2026).

In April 2026, the acting Attorney General signed an order directly transferring the following two categories of marijuana to Schedule III, without an evidentiary hearing: (i) marijuana in an FDA-approved product (a null set) and (ii) marijuana licensed under a state medical program. DUID Ex. 5 at 1–2 (AG Rescheduling Order). A new hearing was then set to address the rescheduling of any marijuana not already covered, *e.g.*, recreational and illicit

marijuana, unlicensed bulk products or extracts, and other products outside the medical programs covered by the AG Rescheduling Order. 91 Fed. Reg. 22777 (Apr. 28, 2026) (Hearing Order). The Tribunal captured this narrowed focus in both its Preliminary Order, ALJ Ex. 20 at 2, and its remarks on the record during the hearing itself: "The issue in this case, again, is whether marijuana . . . other than those products already in Schedule III, should be moved to Schedule III." Tr. 2497:8–19.

The hearing commenced on June 29. Over 11 days, seven Designated Parties and the Government presented testimony from 14 witnesses. The Government presented two:

- **Dr. Dominic Chiapperino**, the director of the Controlled Substance Staff at FDA's Center for Drug Evaluation and Research. Tr. 37:2–8. Having overseen FDA's evaluation of marijuana for HHS's 2023 Recommendation, he testified as a fact witness to the process that led to HHS's ultimate endorsement of marijuana for transfer to Schedule III. *See* Tr. 43:22–44:12, 50:14–17.
- **Dr. Corey Burchman**, a New Hampshire-based physician who specializes in anesthesiology and pain medicine. Tr. 549:20–21. Dr. Burchman was tendered as an expert in pain medicine, and he testified concerning his experiences treating patients with marijuana, and in particular marijuana's putative effectiveness in reducing opioid use. Tr. 541:16–20, 560:5–8.

SAM also presented two expert witnesses:

- **Dr. Bertha Madras**, a Harvard Medical School psychobiologist who studies the effect of drugs on the brain. Tr. 1190:19–21, 1284:4–9. She testified extensively to marijuana's addictive properties and link to psychotic disorders such as schizophrenia. *See, e.g.*, Tr. 1252:8–20, 1262:18–21.

- **Dr. Luli Akinfiresoye**, a DEA Drug and Chemical Evaluation Section pharmacologist and the principal author of the above-mentioned 2024 DEA Report. Tr. 1344:5–1345:1. In her testimony, she stood by the 2024 DEA Report and discussed it at length. Tr. 1351:3–6.

The Opposed States also presented two expert witnesses:

- **Dr. Deepak D'Souza**, a Veterans Affairs staff psychiatrist, Yale Medicine psychiatry professor, and the inaugural director of the Yale Center for the Science of Cannabis and Cannabinoids. He testified to marijuana's devastating effects on the chemistry of the human brain, abuse potential, and link to psychosis and schizophrenia. *See* Tr. 2216:1–6, 2263:10–12, 2274:10–13, 2279:19–23.
- **Sheriff William Honsal** of Humboldt County, California, which has long had "worldwide notoriety" for its marijuana production. Tr. 2389:7–9, 2426:2. Sheriff Honsal testified to how loosening marijuana restrictions fuels a black market in marijuana and, with it, crime. Tr. 2457:9–20, 2474:15–18.

In addition, the National Drug and Alcohol Screening Association (NDASA) called **Patrice Kelly**, formerly of the U.S. Department of Transportation, and **Mary Jo McGuire**, executive director of NDASA. Tr. 1020:21–23. **Ed Wood**, founder and president of DUID Victim Voices, testified for that organization. Tr. 1428:18–19. **Dr. Kenneth Finn**—a specialist in, among other things, pain management and pain medicine—testified on his own behalf and also called to the stand **Laura Stack**, who testified to the severe effects of marijuana use on a family member. Tr. 1580:12–17, 1679:20. **Erica Stephens**, assistant special agent in charge of the Tennessee Bureau of Investigation's Dangerous Drugs Task Force, testified for the Tennessee Bureau of Investigation. Tr. 1796:13–15. Finally, **Dr. Phillip Drum** testified on his own behalf and called

to the stand **Dr. Karen Randall**, a Colorado-based emergency medicine physician who spoke about marijuana's especially deleterious consequences for young people. Tr. 2062:17, 2065:10–12, 2153:6–13.

The Designated Parties were thereafter permitted to submit post-hearing proposed findings of fact and conclusions of law.

PROPOSED FINDINGS OF FACT

I. PROPOSED FINDINGS RELATED TO MARIJUANA'S RISK OF ABUSE AND DEPENDENCE LIABILITY.

The 2024 NPRM states, "In 2016, HHS found that many factors indicated marijuana's high abuse potential, 'including the large number of individuals using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use.'" Gov. Ex. 1 at 19 (quoting SAM Ex. 12 at 19 (2016 Decision)); *accord* SAM Ex. 13 at 55–62 (2016 Decision); SAM Ex. 11 at 43 (2015 Recommendation); *see also* 21 U.S.C. § 812(b) (requiring placement of drugs with a "high potential for abuse" in Schedule I or II). By the accounts of all witnesses and documentary evidence at the hearing, every single one of those factors applies equally today. In fact, the abuse of marijuana and its related health effects have only become graver and more pronounced problems since 2016.

A. Marijuana Abuse and Dependence, and Their Related Health Effects, Have Worsened Since the Last Rescheduling Proceeding in 2016.

Just as it was in 2016, marijuana is today the "most frequently abused" illicit drug in the United States. Gov. Ex. 3 at 63 (2023 Recommendation); *see also* Tr. 520:3 (Chiapperino).

The non-medical use of marijuana has only increased since 2016, and more Americans today are using marijuana for pleasure than ten years ago. Tr. 407:7–408:1 (Dr. Chiapperino agreeing that "since 2015 . . . the prevalence of non medical marijuana use in the United States has gone up"); Gov. Ex. 3 at 34 (2023 Recommendation noting "an increase in the prevalence of

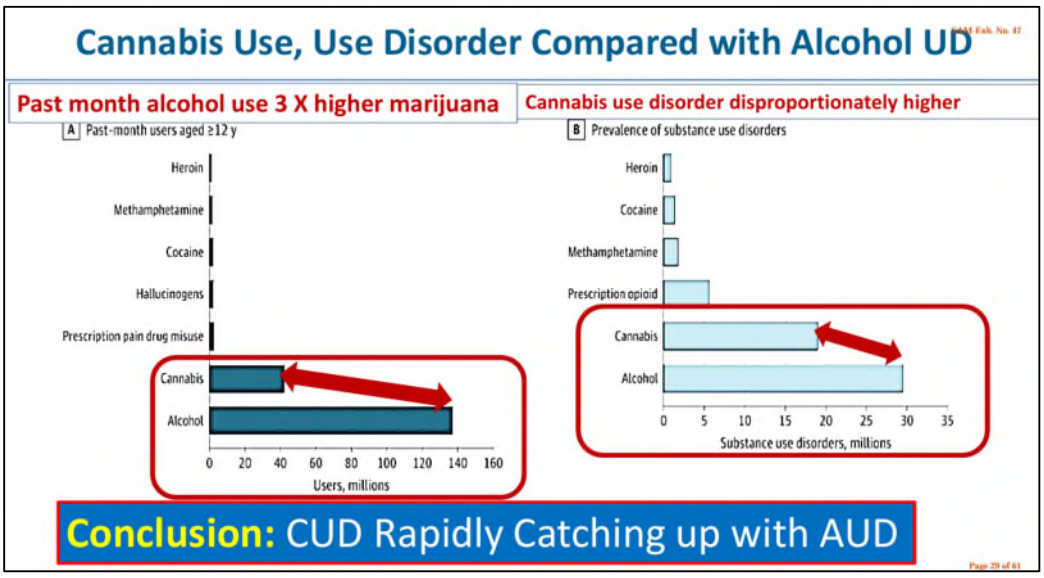
overall nonmedical use of marijuana"). Such use of marijuana—use intended to achieve rewarding effects (*i.e.*, to get high)—constitutes abuse. That is the view of HHS, which "treat[s] all non-medical use as abuse." Tr. 523:11–15 (Chiapperino); Gov. Ex. 3 at 58–59 (2023 Recommendation).

The potency of marijuana has also increased, as the percentage content of THC, the psychoactive cannabinoid component of marijuana, has gone up considerably. Tr. 407:23–408:1 (Chiapperino). This increase is in no way a new development, but rather the continuation of a long trend of ever-increasing THC content since marijuana was first scheduled in 1970. The change has been dramatic. As HHS's 2023 Recommendation showed, the THC content of marijuana averaged 17.1 percent in 2017, an increase of almost 500 percent since 1991. Gov. Ex. 3 at 12. The result is that "high-THC products" now "dominate[ ]" the market. Tr. 1366:16–1367:22 (Akinfiresoye), 1841:7–15 (Stephens), 2232:17–-2233:10 (D'Souza). This is critical both to abuse *and* dependence potential, as it is THC that gives marijuana its rewarding effect and induces withdrawal symptoms when use stops. *See* Gov. Ex. 3 at 63, 65 (2023 Recommendation). As DEA has observed, "[H]igher levels of Δ9-THC in the body are associated with greater psychoactive effects, which can be correlated with higher abuse potential." 76 Fed. Reg. at 40581 (2011 Decision) (internal citations omitted). Indeed, "high THC, more potent products are associated with . . . more regular marijuana use, more use problems . . ., more addiction, [and] more psychosis." SAM Ex. 3 at 16 (Madras Report) (internal citations omitted).

Because the potency of marijuana is directly related to a drug's potential to create dependence, the rate of Cannabis Use Disorder (CUD) has increased as well. Tr. 1246:20–1247:10 (Madras: CUD "skyrocketing"). All experts who touched this subject, including Government witness Dr. Burchman, agreed that the rate of CUD presently stands at 30 percent of past-year

users. Tr. 593:7–8 (Burchman), 1246:20–25 (Madras), 1397:17–20 (Akinfiresoye). Given marijuana's overall prevalence of use, this means that Cannabis Use Disorder is the most common use disorder of any controlled substance. Tr. 290:1–13 (Chiapperino), 1246:17–1247:10 (Madras), 1397:12–20 (Akinfiresoye).

Indeed, as Dr. Madras' chart (pictured below) shows, the prevalence of use disorder for marijuana far exceeds that of other illicit drugs, and is even more common than alcohol use disorder (AUD) on a utilization-adjusted basis (*i.e.*, as a percentage of users).[13] Tr. 1251:17-1252:20 (Madras). The result is that CUD is now the "number one" reason for addiction treatment for Americans under 20. SAM Ex. 10 at 163 (2026 National Drug Control Strategy); *see also* Tr. 1398:9–11 ("19.2 million" persons in United States meet criteria for "lifetime cannabis dependence").



[13] As a percentage of past-month users, the prevalence of CUD is around 45 percent (roughly 19m CUD cases divided by about 42 million past-month cannabis users), whereas the prevalence of AUD is only around 21 percent (about 29 million AUD cases divided by 137 million past-month alcohol users). Note that the above-cited 30 percent CUD rate is calculated based on past-*year* users, rather than past-*month* users.

SAM Ex. 47 at 29 (Madras Slides). Marijuana's potential to induce dependence was confirmed by HHS as well. As the 2023 Recommendation states, "Physical dependence may occur in up to 40-50% of individuals who use marijuana on a regular basis," and "90% of individuals who use marijuana who were diagnosed with CUD also reported marijuana physical dependence." Gov. Ex. 3 at 61.

With the rise in cannabis abuse and dependence, the number of Americans hospitalized for CUD is also greater than it was ten years ago. Tr. 407:12–22 (Chiapperino); Gov. Ex. 3 at 43–44 (2023 Recommendation). The same is true of the annual number of emergency department visits attributable to marijuana. *Compare* Tr. 407:12–22 (Chiapperino), *with* SAM Ex. 3 (Dr. Madras report) at 7 ("Cannabis-involved emergency department mentions have risen dramatically over the past decade."). This increasing trend has placed marijuana second only to cocaine among drugs most likely to be involved in emergency department (ED) visits on a utilization-adjusted basis. According to HHS: "Marijuana had the second-highest utilization-adjusted rate of estimated ED visits from 2016 to 2020 . . . ." Gov. Ex. 3 at 43 (2023 Recommendation). And on an absolute basis, the number of ED visits attributable to marijuana far exceeds cocaine. *Id.*

The Government has sought to minimize marijuana's dependence liability by emphasizing that its ordinary withdrawal syndrome is less acutely severe than withdrawal from opioids. Dr. Burchman supplied the most vivid version of that comparison, describing opioid withdrawal as a "dumpster fire" and marijuana withdrawal as the "dying glowing ember of a campfire." Tr. 596:24–597:2. But that analogy proves considerably less than the Government suggests. Dr. Burchman was comparing the acute clinical intensity of withdrawal, not the overall prevalence or severity of marijuana dependence. Moreover, his testimony was merely observational, not

scientific, as he is "not an addictionologist" and does not generally read the addiction-medicine literature. Tr. 848:14–15; *see also* Tr. 850:20–23, 869:1–6.

More fundamentally, the broader record shows that cannabis withdrawal is serious. Dr. D'Souza testified that regular users who stop may experience withdrawal disturbances in sleep, appetite, and mood, and that withdrawal is "often a reason why people go back to using cannabis and are unsuccessful to remain quit." Tr. 2263:3–12. The record also identifies a substantially more serious withdrawal consequence that the Government's opioid comparison obscures: As Dr. Finn testified, a 2025 study established that cannabis withdrawal can "precipitate first-episode psychosis or aggravate or relapse a preexisting psychosis." Tr. 1649:10–18 (discussing Finn Ex. 22 (Chesney (2025)). In sum, cannabis withdrawal "isn't just headaches and lack of sleep" but "can actually cause psychosis." Tr. 1649:19–22. Thus, the fact that typical marijuana withdrawal may be less acutely painful than opioid withdrawal does not establish a modest dependence liability; the record instead shows physical dependence, a recognized withdrawal syndrome that helps perpetuate continued use, substantial rates of cannabis use disorder, and potentially grave psychiatric consequences upon cessation.

B. Marijuana Causes Psychosis and Schizophrenia, and Is a Greater Contributor to Mental Illness than Any Other Illicit Drug.

When considering marijuana's appropriate scheduling a decade ago, HHS gave extensive consideration to the potential psychiatric effects of marijuana use, citing numerous studies and medical articles on the association between marijuana and psychosis.[14] SAM Ex. 11 at 20–21

[14] Psychosis describes a group of severe mental illnesses characterized by delusions, hallucinations, and other associated cognitive and behavioral impairments. *See* SAM Ex. 10 at 172 (2026 National Drug Control Strategy) ("Psychosis is a symptom of disturbances of thinking, perception and emotions.")

(2015 Recommendation).[15] But the 2015 Recommendation was careful to observe that no more than an association could be shown, because the data at that time was insufficient to establish causation. *Id.* at 20.

That is no longer the case. Since the last rescheduling proceeding, new research has firmly established a causal link between marijuana use and the development of psychosis and schizophrenia. Dr. Akinfiresoye testified that this link "has been established." Tr. 1399:12–14; *see also* Tr. 1400:4–12, 1401:5–13. Dr. D'Souza agreed that "marijuana contributes in a causal way to the onset of schizophrenia or psychosis." Tr. 2274:10–13. And Dr. Madras testified in no uncertain terms that "the majority of psychiatrists . . . that have published[] say that cannabis is a component cause of schizophrenia, not just an association." Tr. 1265:4–8; *see also* SAM Ex. 3 at 10 (Madras Report). Indeed, on this point, all relevant experts agreed.[16]

The only dissenting voice was that of Dr. Burchman, who testified that when the studies on marijuana and psychosis are closely examined, the relationship between them is revealed to be mere "correlation," not causation. Tr. 938:11–23.[17] But by his own admission, Dr. Burchman is no expert on the subject, and indeed he begged off most questions on marijuana's psychiatric effects. Tr. 762:11–20 ("Well, sir, my domain is not psychiatry, and I have to say I'm not really

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[15] *See also* 81 Fed. Reg. at 53774–76, 53830–32, 53837–38, 53775–76.

[16] 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* 295 (2017), perma.cc/A8LT-RDVP (NASEM Report) (incorporated via Finn Ex. 6); Gov. Ex. 3 at 18, 239–40 (2023 Recommendation); *see also* SAM Comment Letter at 38–41.

[17] Dr. Burchman provided a colorful example of correlation, namely the relationship between cheese consumption and death by bed-sheet strangulation. Tr. 936:18–938:10 ("[N]o one's going to say that eating more cheese is going to cause you to die by being strangled in your bed sheets.").

familiar with the statements with respect to the American [Psychiatric Association] . . . ."); *see also* Tr. 869:1–7 ("I'm not a psychiatrist . . ., so it's not really the sphere in which I deal."). In this vein, he had "no understanding or comment" on the verifiable fact that "of all drugs, marijuana has the highest rate of transition from psychosis to schizophrenia." Tr. 791:4–20; *see* SAM Ex. 10 at 173 (2026 National Drug Control Strategy: "[M]arijuana has the highest conversion rate from psychosis to schizophrenia and bipolar disorder."). But most importantly, Dr. Burchman did not discuss—by name or otherwise—any of the studies that he was purportedly refuting through his claims about correlation, and instead merely commented generally on "many, the majority, of marijuana articles in the medical literature." Tr. 938:11–15.

The strong causal link between marijuana and psychosis manifests itself in critical problems in the public health, including through increased suicide risk and the transition from psychosis to outright schizophrenia. Indeed, on this point, it is an established fact that marijuana is more harmful than any other controlled substance. The evidence on this point was undisputed, as it came directly from the 2026 report of the Office of National Drug Control Policy:

> In a study of 11363 records, marijuana use was associated with an 11-fold risk of psychosis for individuals aged 12 to 19. . . . **While all drugs carry some level of risk, marijuana has the highest conversion rate from psychosis to schizophrenia and bipolar disorder**. Drug use is also associated with suicide, **and the number one drug found in toxicology reports of people who died from suicide** under the age of 25 in Colorado and San Diego **was marijuana, more than alcohol or any other drug**.

SAM Ex. 10 at 172–73 (emphasis added) (footnotes omitted); *see also* Tr. 2281:3–9 (Dr. D'Souza testifying that "the rate of conversion to a chronic psychotic disorder such as schizophrenia . . . [is] highest for cannabis relative to the other drugs that are known to induce psychosis").[18]

[18] *See* Supp. Br. of DOJ at 10, *Cooper v. Att'y Gen.*, 148 F.4th 1307 (11th Cir. 2024) (No. 22-13893) (citing NASEM Report, *supra*, at 311–12) (marijuana users "pose a higher risk of suicide than ordinary citizens").

The record thus establishes that marijuana use can cause psychosis and schizophrenia, and that the resulting public-health consequences are exceptionally serious. The evidence has advanced substantially since HHS last considered the issue. What the scientific literature could once establish only as an association is now recognized as a causal relationship. Marijuana is associated with an extraordinarily high rate of progression from drug-induced psychosis to schizophrenia and bipolar disorder, as well as substantial suicide risk among young people. The expert testimony and scientific evidence on these points were overwhelming and, in all material respects, undisputed.

C. Marijuana Has a High Risk of Diversion.

"Diversion" denotes taking a quantity of drug obtained through legal channels and using it for illegal purposes. *See, e.g.*, Gov. Ex. 3 at 7 (2023 Recommendation); *see also* Tr. 1391:22–23 (Dr. Akinfiresoye defining diversion as using a drug for a purpose "other than what it was intended for"). Under DEA and HHS criteria, diversion is a highly relevant consideration in evaluating a drug's potential for abuse. SAM Ex. 7 at 15 (DEA Report noting that diversion "indicat[es] that the substance has a potential for abuse").

In its 2023 Recommendation, HHS determined that diversion was *not* a problem for marijuana by limiting its analysis to diversion from federally authorized investigational drug research—the only "legitimate" channel for using marijuana, according to HHS—and thereby excluding channels authorized by *state* law, such as medical marijuana programs. *See* Gov. Ex. 3 at 9. As the hearing evidence showed, however, diversion of marijuana from state channels is, in fact, a very pronounced problem and contributes significantly to marijuana abuse and related criminal activity.

Key testimony on this point came from DEA's own Dr. Akinfiresoye. Without impeachment or contradiction by any other witness, she agreed that the very "state medical

marijuana programs" that HHS relies on to show widespread "medical" use are "a significant source of diversion of marijuana in the United States." Tr. 1391:25–1392:5. This was entirely consistent with the 2024 report of Dr. Bertha Madras, who observed that "illegal markets are thriving in legal marijuana states and the legal market drives products found on the illegal market." SAM Ex. 3 at 12–13. HHS's wholesale omission of state medical marijuana programs from its diversion analysis, Dr. Akinfiresoye further agreed, was a significant "gap" in the agency's overall evaluation of the drug's abuse potential. Tr. 1393:12–1394:14.

Importantly, the problem of diversion from state programs is not limited to increased recreational use and/or abuse by individual users. It also includes the rising rate of criminal activity that follows the drug's increased availability. As the DEA's 2024 National Drug Threat Assessment noted:

> Black-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.

TBI Ex. 12 at 40. This is not limited to small-time crime. A significant amount of illicit marijuana trafficking is carried out by domestic and transnational criminal organizations, including the dangerous Sinaloa and Jalisco New Generation cartels and Chinese, Bulgarian, and Russian crime families. Tr. 2476:13–2478:6 (Honsal).[19] These criminal organizations operate in states where marijuana is legal, using the legal market as cover for their illegal operations. Tr. 2477:9–15 (Honsal); *see* Tr. 2460:1–2461:5 (same). Drug trafficking organizations use "both legal and

[19] *See also* SAM Comment Letter at 51 (citing Sebastian Rotella et al., *Gangsters, Money and Murder: How Chinese Organized Crime Is Dominating America's Illegal Marijuana Market*, ProPublica (Mar. 14, 2024), perma.cc/VHZ5-W7UL).

illegal" marijuana grow operations, which makes "it more difficult for law enforcement to detect the illicit material." Tr. 1832:4–9 (Stephens).

To the point of this proceeding, Special Agent Erica Stephens explained that relaxed marijuana restrictions would "increase the number of available channels for individuals and drug trafficking organizations to divert marijuana." Tr. 1820:19–25; *accord* Tr. 1833:20–1833:2. The uptick in the illegal marijuana trade that attends to increased legal availability, moreover, is not a matter of speculation; it is confirmed by seizure statistics. *See, e.g.*, Tr. 1815:2–3 (Stephens: "Marijuana is consistently the number one drug seized by TBI annually . . . .").

D. Marijuana Is a "Variable Organic Plant" That Can Be Consumed in Different Preparations Through "Different Routes of Administration."

The HHS recommendation acknowledges that "marijuana has hundreds of chemovars containing variable concentrations of Δ9-THC, cannabinoids, and other compounds" and so "is not a single chemical with a consistent and reproducible chemical profile or predictable and consistent clinical effects." Gov. Ex. 3 at 21. This inherent variability "raises concerns related to safety, quality, and consistency." *Id.*; *accord* Tr. 211:1–25 (Chiapperino); *cf.* Tr. 2243:6–9 (D'Souza). The NPRM recognized that marijuana's "high variability" is a "major consideration for the potential variability of drug effects and safety." Gov. Ex. 1 at 10. In the past, DEA has concluded that marijuana lacked an "accepted safety for use under medical supervision," *see* 21 U.S.C. § 812(b), because physicians could not be assured of "a consistent and predictable potency" or that the substance was "free of contamination," 66 Fed. Reg. 20038, 20052 (Apr. 18, 2001); *see also* 44 Fed. Reg. 36123, 36126 (June 20, 1979) (concluding no accepted safety for use under medical supervision because of "the variability of THC content in natural [marijuana] plant materials").

E. The Government's Comparison of Marijuana to Cocaine and Opioids for Severe Acute Harms, on a Utilization-Adjusted Basis, Was Not Methodologically Sound.

The principal basis for HHS's conclusion that marijuana had a comparatively low abuse potential (and thus warranted transfer to Schedule III) was its observation that marijuana was less likely, on a per-user basis, than certain other drugs in Schedules I and II to produce certain adverse outcomes. Gov. Ex. 3 at 63. This was what Dr. Chiapperino called the "risk ratio," Tr. 76:2–13, and it was a central point of the NPRM:

> HHS emphasized that an evaluation of various epidemiological databases of adverse outcomes from 2015 to 2021 involving marijuana or comparator drugs that are used nonmedically showed that the utilization-adjusted rate of adverse outcomes involving marijuana was consistently lower than the utilization adjusted rates of adverse outcomes involving heroin, cocaine, and, for certain outcomes, other comparators, including alcohol.

Gov. Ex. 1 at 5. HHS also zeroed in on the gravest acute outcomes, most importantly overdose deaths, comparing marijuana against a select list of overdose-prone drugs, namely cocaine, heroin, oxycodone, and other opioids:

> HHS also concluded that the public health risks posed by marijuana are lower compared to those posed by other drugs of abuse (*e.g.*, heroin, oxycodone, cocaine), based on . . . emergency department (''ED'') visits, hospitalizations, unintentional exposures, and most importantly, overdose deaths. The rank order of the comparators in terms of greatest adverse consequences typically ranked heroin, benzodiazepines, and cocaine first or in immediately subsequent positions, with marijuana in a lower place in the ranking, especially when HHS adjusted for utilization.

Id.; *see also* Gov. Ex. 3 at 63.

The evidence presented at the hearing established, however, that HHS's own definition of "abuse" is much broader than acute injury or overdose. As Dr. Chiapperino testified, Tr. 523:12–16, HHS classifies "abuse" to encompass all instances of non-medical use—not merely those that cause harm, let alone severe, acute, physical harms, Tr. 531:4–9. Consistent with this, as Dr. Chiapperino further acknowledged, the Schedule I and II categories—both of which are for drugs

with a high potential for abuse[20]—contain many substances which, like marijuana, do not have a high overdose risk and are not prone to severe adverse effects in acute doses. Peyote and psilocybin, for example, are both in Schedule I, notwithstanding the fact that they have no realistic overdose risk. Tr. 532:22–533:1–6.

And the hearing evidence also called into question the "risk ratio" or utilization-adjusted focus of HHS's analysis. Prior analyses of abuse have given heavy weight to a drug's overall societal impact, which necessarily considers the number of people using it, not merely how heavily it affects them individually. The NPRM itself is crystal clear on this point:

> In 2016, HHS found that many factors indicated marijuana's high abuse potential, "including the large number of individuals using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use."

Gov. Ex. 1 at 19 (quoting SAM Ex. 12 at 19 (2016 Decision)); *accord* SAM Ex. 13 at 55 (2016 Decision). The NPRM further states that the abuse analysis considers the "safety of other individuals" and "the community," not merely the health hazards to the users themselves, which makes a drug's absolute impact, not its utilization-adjusted impact, more important. Gov. Ex. 1 at 5 (NPRM).

The hearing evidence also cast grave doubt on the comparators that HHS chose as the premise for its low-abuse-potential conclusion. As Dr. Chiapperino testified, comparator selection is a critical consideration, and HHS's ordinary approach is to assess a drug's abuse potential by comparison to drugs from the same pharmacological class, because such drugs usually have a similar mechanism of action to the subject drug:

[20] As Dr. Chiapperino testified, the only difference between Schedules I and II is that Schedule II drugs have a currently accepted medical use. Tr. 487:6–9; *see also* 28 U.S.C. § 812.

Q Am I right . . . that when you're assessing the abuse potential of a drug, that selecting appropriate comparators is very important?

A Yes.

Q And that when you're looking for appropriate comparators, ideally, you look to drugs in the same pharmacological class, correct?

A Yes.

Q Okay. Which, in the case of marijuana, is hallucinogens, correct?

A It is controlled under the CSA paragraph for hallucinogens, yes.

Tr. 534:24–535:12 (Chiapperino). The very same point appears in the 2023 Recommendation, wherein HHS states that, for scheduling purposes, the assessment of a drug's harm potential considers the class of the drug, not merely where the drug stands in the overall hierarchy of overdose risk:

> [T]he rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.

Gov. Ex. 3 at 64 (2023 Recommendation).

HHS's 2015 Recommendation was entirely consistent with this, as it expressly rejected the suggestion to weigh the "comparative effects" of marijuana against those of Schedule II cocaine and opioids, finding that comparison "inappropriate," for the same reasons that Dr. Chiapperino testified to during the hearing:

> The mechanism(s) of action of the above Schedule II substances are wholly different from one another, and they are different from tetrahydrocannabinol (THC) and marijuana as well. For example, Schedule II stimulants [cocaine] typically function by increasing monoaminergic tone via an increase in dopamine and norepinephrine (Schmitt et al., 2013). In contrast, opioid analgesics function via mu-opioid receptor agonist effects. These differing mechanism(s) of action result in vastly different behavioral and adverse effect profiles, making comparisons across the range of pharmacologically diverse C-II substances inappropriate.

SAM Ex. 11 at 8; *see* Tr. 534:18–535:24 (Chiapperino). Dr. Madras's testimony confirmed that this was the right approach, as marijuana, cocaine, and opioids all act through different pharmacological systems and thus produce materially different patterns of harm. Tr. 1280:3–11 (Madras). Whereas marijuana "acts on the cannabinoid system," "[c]ocaine acts specifically on the dopamine" and heroin "on the opioid system." Tr. 1280:3–7 (Madras). That is a distinction with a difference, as drugs' "consequences depend on the type of signals that they are attacking, and modulating, and affecting, and causing to adapt." Tr. 1280:9–11 (Madras); *accord* Tr. 1280:16–18 (Madras).

No witness at the hearing explained why the particular drugs used by HHS for purposes of the abuse-potential analysis were selected, or why that selection was appropriate or consistent with ordinary agency principles for selection of comparators.

II. PROPOSED FINDINGS RELATED TO WHETHER MARIJUANA HAS A CURRENTLY ACCEPTED MEDICAL USE.

A. Marijuana Does Not Pass the Five-Part CAMU Test That HHS and DEA Have Always Applied.

Marijuana has flunked the five-part test for CAMU at least four times since *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994). *See* SAM Ex. 12 (2016 Decision); SAM Ex. 13 (2016 Decision); 76 Fed. Reg. 40552 (July 8, 2011); 66 Fed. Reg. 20038 (Apr. 18, 2001); *cf.* Tr. 405:25–406:3 (Chiapperino). The only reason that marijuana did not flunk the test a fifth time, the evidence showed, was that HHS pulled the plug on the analysis midstream. As Dr. Chiapperino testified, several months after commencing their evaluation, he and his team were "directed" by the Assistant Secretary for Health to apply the recently devised two-part test instead. Tr. 412:13–25. And that was not because HHS or FDA lost confidence in the five-part test; to the contrary, the five-part test is still used today in the evaluation of all drugs other than marijuana. Tr. 413:23–414:2.

The Government's gambit to avoid a fifth consecutive failure did not succeed. Both witnesses who evaluated the drug on Government time—Dr. Chiapperino at FDA and Dr. Akinfiresoye at DEA—testified that marijuana would have flunked the five-part test again. Dr. Chiapperino testified that marijuana is "a variable substance" and so does not have "known and reproducible" chemistry. Tr. 427:13–18, 430:7. "[O]n the basis of the first element alone," he explained, marijuana "[w]ould not have passed" the five-part test. Tr. 437:6–15. Nor does it have the "acceptance of qualified experts." Tr. 478:3–479:12. As HHS's 2023 Recommendation observes, leading medical organizations like the American Medical Association do not endorse the medical use of cannabis, and, indeed, the American Psychiatric Association actively opposes it for making psychiatric conditions worse. Gov. Ex. 3 at 28–29, 116, 198–99; *see also* Gov. Ex. 1 at 23 (2024 NPRM).

Dr. Akinfiresoye went further, testifying that marijuana flunked all five factors of the five-part test. She testified that marijuana (i) does not have known and reproducible chemistry, Tr. 1365:11–1366:6; (ii) is not supported by "adequate safety studies," Tr. 1367:18–21; and (iii) lacks "the third factor of well-controlled and sufficient studies to prove it's efficacious," Tr. 1368:15–17. Like Dr. Chiapperino, she also testified that (iv) marijuana "did not pass" the criterion of "the acceptance of qualified experts." Tr. 1376:7–11. And lastly, she acknowledged that (v) marijuana lacked widely available evidence "sufficient to address [its] chemistry, pharmacology, toxicology, and effectiveness" as a drug. Tr. 1377:17–24, 1378:6–16. These findings were not just her opinion, moreover, but "the consensus view of . . . the Drug and Chemical Evaluation Section" at DEA. Tr. 1376:14–18.

B. Marijuana Does Not Pass the Less Rigorous Two-Part CAMU Test That Was Made Up for This Proceeding.

The two-part test is less rigorous than the five-part test, as it eliminates multiple requirements and is thus easier to pass. As Dr. Chiapperino testified, it does not require a showing of reproducible chemistry, Tr. 409:16–19; acceptance by a body of experts, Tr. 409:23–410:8; or the same degree of scientific support to establish a drug's safety and efficacy, Tr. 431:2–4, 496:23–497:3.

In place of those longstanding requirements, the two-part test asks only:

(i) whether there is "widespread current experience" with the "medical use" of the drug under the auspices of a state medical authority (Part 1), and

(ii) whether there exists "some" credible scientific support for the particular use(s) identified under the first prong (Part 2).

Even assuming *arguendo* that this new test is consistent with Controlled Substances Act—and it is not—the evidence introduced at the hearing showed that marijuana does not pass either prong.

1. There Is No Evidence of "Widespread Current Experience" with "Medical Use," for Any Particular Condition, That Is "Recognized" by a Medical Regulatory Authority.

The Government's evidence on the "widespread current experience" prong boiled down to two things: (i) the "Part 1 Analysis" performed by the Office of the Assistant Secretary for Health (OASH), which analyzed state medical marijuana programs and the conditions being treated with marijuana in those programs, Gov. Ex. 3 at 79–98; Tr. 444:18–23 (Dr. Chiapperino testimony that OASH, not FDA, undertook Part 1 analysis), and (ii) the testimony of Dr. Burchman about his clinical pain practice in New Hampshire.[21] With no disrespect to Dr. Burchman, the isolated, anecdotal experiences of one doctor in one state cannot meet the standard of "widespread," and

[21] By his own account, Dr. Burchman did not use marijuana as a treatment in other locations earlier in his career. Tr. 559:20–560:7, 644:1–3, 648:14–21.

thus the Government's case as to Part 1 effectively rested entirely on the written record of the OASH Part 1 Analysis.[22]

The sum and substance of OASH's evidence—which was repeated multiple times both in the broader HHS 2023 Recommendation and the separate Part 1 Analysis that was attached to it—was the sheer number of health care providers and patients that are using marijuana as a treatment across the United States as a whole. This was clear on the first page:

> To assist in the determination of whether marijuana has a CAMU in the United States, OASH conducted an analysis evaluating Part 1 and confirmed that more than 30,000 HCPs across 43 U.S. jurisdictions are authorized to recommend the medical use of marijuana for more than six million registered patients for at least 15 medical conditions. OASH's Part 1 analysis, therefore, supports the finding that marijuana has at least one CAMU in the United States.

Gov. Ex. 3 at 79; *see also id.* at 25.

This evidence does not suffice for multiple reasons.

i. State Medical Marijuana Programs Do Not Show "Medical" Use of Marijuana.

The evidence showed that the state programs relied on by OASH for its Part 1 showing do not represent "medical use." The persons recommending marijuana ("HCPs" or "health care providers") in state programs need not be physicians, and more than half of them are not. SAM Ex. 3 at 19 (Madras Report); *see id.* at 21 tbl. 3. In most states, no physical exam is required to obtain a marijuana recommendation, Tr. 1238:18–20 (Madras), nor must there be an actual "ongoing relationship" between recommender and patient, Tr. 1238:20–22 (Madras); SAM Ex. 3

[22] OASH did not have a representative witness at the hearing, so its methods and conclusions were presented entirely by Dr. Chiapperino. And because Dr. Chiapperino does not work at OASH and was not involved in its analysis, he was unable to present any insight on Part 1 beyond the written report that OASH created. Tr. 164:11–16 ("[OASH] provided that [Part 1] memo to us already completed . . . . So, I don't think I could answer how they interpreted current healthcare practitioner experience.").

at 5–6 (Madras Report). Moreover, the marijuana recommendations themselves are unlike ordinary prescriptions in that they do not specify dose, frequency, route of administration, strength, or any other attribute. *See, e.g.*, Tr. 2138:3–2140:18 (Randall).

Nor are the persons who dispense marijuana trained in medicine. As the evidence showed, in most states, the person selecting the product for the patient is not a doctor or a pharmacist but a "budtender." As Dr. Akinfiresoye testified, budtender "advice" is "not medical," Tr. 1385:12–16, and her review of the relevant literature showed that budtenders give advice that "is actually harmful" to their customers, Tr. 1386:2–4; *see also* SAM Ex. 7 at 41 (DEA Report) (budtenders did not acknowledge "harms associated with marijuana" such as "addictiveness"). The only dissenting testimony was from Dr. Burchman, who testified that the budtenders at the dispensaries where he is involved acknowledge the addictiveness of marijuana. Tr. 743:1. But his anecdotes do not undermine Dr. Akinfiresoye's point, which is based on several pieces of peer-reviewed research, SAM Ex. 7 at 41 (DEA Report). The same limitations apply to his testimony about the safety practices observed in New Hampshire's medical marijuana program. By Dr. Burchman's own account, his knowledge of the practices and programs in other states is limited. *See, e.g.*, Tr. 644:3–5 ("My pain practice . . . was restricted to the State of New Hampshire."), 914:23–25 (answering "Nope" when asked "Do you know anything about Vermont?").

Due to the lack of medical oversight, there are numerous conditions being treated with marijuana despite the lack of any scientific basis to believe that marijuana will be effective. Dr. Chiapperino's testimony on this point was clear: There are "more than 100[ ] conditions around the United States being treated in medical marijuana programs that . . . never passed the Part 2 test" of even "some" credible scientific support. Tr. 466:19–467:1. He was not an outlier on this

point: Other experts agreed that, as to most of the conditions currently being treated with marijuana in state programs, there is effectively zero scientific support suggesting it is effective.[23]

Worse still, FDA's analysis in support of the 2023 Recommendation showed that some conditions are being treated with marijuana despite scientific evidence showing that the drug is more likely to be harmful than helpful as to that condition. As Dr. Chiapperino testified:

> Q And in fact, some of those conditions that have been authorized in state marijuana programs have actually been recommended against, correct?
>
> A Yes.
>
> . . .
>
> Q . . . [Y]ou agree with me that based on the review of the data, that PTSD, or post-traumatic stress disorder, is a condition for which people are taking medical marijuana under state medical marijuana programs, correct?
>
> A Yes.
>
> Q And you reviewed that as part of your Part 2 analysis, did you not?
>
> A We did.
>
> Q And you concluded that the risks of adverse events from taking medical marijuana, according to the science, outweighed the benefits of taking it, correct?
>
> A Yes. That was our finding, I think.

Tr. 467:2–24.

[23] Dr. Madras explained many states permit "medical" cannabis for "any medical condition that the doctor may deem worthwhile," which is in practice "arbitrary" and unsupported by science. Tr. 1239:1–5. "[A]s a clinician scientist," Dr. D'Souza explained, "[t]here's no common pathophysiology that would explain why one product should be beneficial for all these 60 conditions." *Id.* at 2299:20–2300:3. Dr. Madras was blunt: "The science behind these indications is, in most indications, close to absolute zero." *Id.* at 1228:6–9.

These facts demonstrate that state authorization of marijuana as medicine is a poor proxy for either medical acceptance or scientific validity, and thus cannot, without more, carry the Government's burden to establish CAMU.

ii. OASH's Nationwide Figures Do Not Show Medical Use in States Where "Use is Recognized by Entities That Regulate the Practice of Medicine."

The figures cited by OASH in support of its Part 1 finding of "widespread current experience"—*i.e.*, 30,000 health care providers and six million patients—are nationwide figures, derived from all 43 jurisdictions in the United States where medical marijuana programs exist.

Most of the states with medical marijuana programs that are lumped into OASH's nationwide figures, however, are states that do **not** qualify under the Part 1 standard. That is, they are not states where the particular uses of marijuana have been "recognized by entities that regulate the practice of medicine." As the OASH Part 1 Analysis states, just 21 of the 43 medical-marijuana jurisdictions have an expert board that reviews and approves particular medical uses of marijuana as a precondition to treatment. Gov. Ex. 3 at 82 & tbl. 2a (2023 Recommendation). And even in those 21 states, the "'reviewing/recommending bodies' are not necessarily the same entities that regulate the practice of medicine more generally." *Id.* at 81.

The record is devoid of evidence of how many providers or patients are using marijuana as a treatment in the few states where the medical uses of marijuana are recognized by a medical regulatory board, which are the only ones pertinent to the Part 1 test.

iii. OASH's Nationwide Figures Do Not Show "Widespread Current Experience" to Treat Any Particular Condition.

The 30,000-provider and six-million-patient figures cited by OASH also represent the numbers using marijuana across all medical conditions, with no breakdown as to the number of providers or patients using marijuana to treat any particular condition.

Although the OASH Part 1 Analysis does identify, for each medical condition, the number of ***jurisdictions*** (states) in which that condition may be treated with marijuana, *see, e.g.*, Gov. Ex. 3 at 94 (40 jurisdictions recognize pain as a condition treatable with marijuana), it provides no specifics as the number of providers, state-wise or nationally, who are using marijuana to treat that condition. This is true for each of the 15 conditions that purportedly passed the Part 1 analysis, as well as all three of the conditions that purportedly passed both Part 1 and Part 2.

To focus on just the three conditions that purportedly passed both Part 1 and Part 2—pain, anorexia, and nausea/vomiting—the record before this Tribunal stands as follows. There is evidence of just ***two*** health care providers, in the entire United States, who have ever recommended marijuana as a treatment for pain: Dr. Burchman, who testified that it worked, and Dr. Finn, who testified it did not. And as to the conditions of anorexia and nausea/vomiting, there is simply no evidence of the number of health care providers in the United States (or any state therein) who have ever recommended marijuana as treatment. It could be zero.

2. HHS Cannot Meet the Standard of "Some" Credible Scientific Support for Any Indication.

Part 2 was the scientific component of the two-part test, in which FDA inquired whether there was "some" credible scientific evidence to support any of the uses of the drug identified as "widespread" in Part 1. FDA did not undertake this inquiry for each of the 15 conditions identified in Part 1, but instead chose the seven most likely to have been the subject of scientific study. Tr. 465:7–12 (Chiapperino). Four of the seven selected by FDA failed the test of even "some" credible scientific support, meaning they had none at all. Gov. Ex. 3 at 185 (anxiety), 186–87 (PTSD), 187–88 (inflammatory bowel disease), 189 (epilepsy) (2023 Recommendation).

As to the remaining three conditions—pain, anorexia, and nausea/vomiting—FDA claimed to have found the standard met, but it did so, as noted above, in the face of conflicting views of

the data between the UF scientists and FDA's own medical team. The evidence introduced at the hearing showed that the only way FDA was able to find scientific support in the face of conflicting views was to cherry-pick favorable studies, ignore unfavorable ones, and thus disregard the scientific method altogether.

i. The Evidence Does Not Demonstrate Credible Scientific Support for the Use of Marijuana for Pain.

Of all medical conditions treated with marijuana, pain was studied most extensively and thus had the broadest base of material to review. *See* Tr. 62:7–8 (Chiapperino: "Pain was the indication for which there were the most available studies."); Gov. Ex. 1 at 22 (2024 NPRM); Gov. Ex. 3 at 200 (2023 Recommendation). After reviewing the universe of available information—a total of 47 studies, including 39 randomized controlled trials and eight observational studies—the UF epidemiologists concluded that marijuana failed the Part 2 test for lack of scientific support. As FDA put it:

> Although a large literature base was identified for the pain indication, with a number of RCTs [*i.e.*, randomized controlled trials] showing benefit and their meta-analysis showing a small but significant effect for marijuana on the NRS [*i.e.*, Numeric Rating Scale] outcome measure, UF concluded the data were too inconsistent to provide a conclusive statement on the benefit of marijuana for the treatment of pain.

Gov. Ex. 3 at 180 (2023 Recommendation). Other than Dr. Burchman, every expert who addressed this subject at the hearing reached the same conclusion or an even more negative one. *See, e.g.*, Tr. 1231:13–1235:20 (Madras); Tr. 1370:12–23; 1372:6-14 (Akinfiresoye); Tr. 1624:23–1625:2 (Finn); Tr. 2294:23–2295:19 (D'Souza). The same goes for the International Association for the Study of Pain (IASP), which (as FDA admitted) did ***not*** find scientific support for marijuana as pain medicine. Gov. Ex. 3 at 199 (2023 Recommendation) (noting IASP conclusion that "the evidence base . . . fails to reach the threshold").

To overcome this evidence and explain how marijuana could still meet the test of scientific support as a treatment for pain, the Government relied on (i) Dr. Chiapperino, who testified (as a fact witness only) that FDA's medical team found scientific support in the narrower endpoint of neuropathic pain, and (ii) Dr. Burchman, who testified about his personal experience as a pain physician and marijuana's utility in reducing opioid use. Neither witness's testimony sufficed to overcome the shared views of UF, the IASP, and every other expert called.

Dr. Chiapperino's Testimony and the Neuropathic Pain Endpoint. Neuropathic pain is pain caused by damage to, or dysfunction of, the patient's nervous system (as opposed to injury to non-neural tissue). This narrower indication was critical to FDA's affirmative conclusion on pain: As Dr. Chiapperino admitted, when asked whether the data on pain in general—*i.e.*, without the neuropathic endpoint—would otherwise have satisfied FDA's credible-scientific-support standard, Dr. Chiapperino could not say that they would:

> Q Okay. I think I understand what you're saying, is that without the neuropathic pain data, you don't know whether or not you would have been able to make a finding that pain was a currently accepted medical use for marijuana. Is that correct?
>
> A I think that's fair, yes.

Tr. 499:15–21.

Despite acknowledging the critical significance of the neuropathic pain data to FDA's overall conclusion, Dr. Chiapperino was remarkably general as to what that data was: He testified only to the existence of "at least one study with a moderate quality of evidence" and then, later, to the "living survey" of pain patients by the Agency for Healthcare Research and Quality (AHRQ). Tr. 62:24–63:1, 63:10. As he put it:

> Overall, when the pooled data were considered, there was a small margin of benefit. There were also some adverse events reported. However, in a more narrow category of neuropathic pain, the studies were more supportive of a

> therapeutic benefit for patients with neuropathic pain. ***I think there was at least one study with moderate quality of evidence showing benefit***.

Tr. 62:18–63:1 (emphasis added). And:

> We also brought in results from AHRQ's living survey of -- or living study, systematic review of people using pain. That study has, I believe, evidence of some benefit to patients, and our own medical officer looked at the literature and had similar findings with U of F.

Tr. 63:19–25. He did not identify any other evidence that supposedly demonstrated scientific support for the neuropathic pain indication, either on direct or cross-examination.

To be sure, in outlining its review of the relevant literature, FDA cited fourteen systematic reviews and meta-analyses that discuss neuropathic pain in one way or another. *See* Gov. Ex. 3 at 181–85. None of them, however, is a "study with a moderate quality of evidence." These systematic reviews are rather amalgamations of dozens of studies, all of varying qualities and varying conclusions. Thus, it appears that Dr. Chiapperino was referring to one of the three neuropathic pain trials that UF reviewed and ultimately found insufficient to support the pain indication. Those three trials are itemized at Table 45 of the FDA Part 2 Memorandum, as shown below (Gov. Ex. 3 at 173):

Table 45. Quality of Evidence Rating for Pain Scores Assessed Via Neuropathic-Specific Pain Scales, Certainty Rating by Study and Overall

Domain Assessed	(Nurmikko et al. 2007)	(Wilsey et al. 2016a)	(Selvarajah et al. 2010)	Overall Certainty Rating Across Studies Assessing That Outcome
Certainty	Moderate concern	Low concern	Moderate concern	Moderate concern
Imprecision	Moderate concern	Low concern	Moderate concern	Moderate concern
Inconsistency				Moderate concern
Generalizability	High concern	High concern	High concern	High concern
Publication bias				Low concern
Overall quality of evidence rating				Moderate quality

Source: Consortium for Medical Marijuana Clinical Outcomes Research in Partnership with the Sentinel Initiative. Medical Literature and Data on Cannabis Use. Project 2/1B Report dated July 7, 2023.

As the FDA memorandum states, one of those three studies did, in fact, show a positive finding for the neuropathic pain endpoint:

> [T]hree RCTs assessed neuropathic pain and fibromyalgia pain using neuropathic pain-specific outcome assessment tools. One of the three RCTs reported an improvement in pain, and the others reported mixed results, or no change based on a moderate quality of evidence rating (Table 45).

Gov. Ex. 3 at 172. This was sufficient, as Dr. Chiapperino explained, because FDA's methodology in the Part 2 analysis allowed for the cherry-picking of favorable data. As he testified:

> Q . . . [A favorable study] doesn't have to be repeatable, correct?
>
> A Correct.
>
> Q Okay.
>
> A There might only be a couple of studies. If one was positive and one was not, we would still consider the results in the first study.

Tr. 376:8–15.

Relying on one trial and disregarding two others is not science. Cherry-picking studies simply because they support a preferred outcome is anathema to the scientific method, and the mere fact that FDA was apparently willing to ignore data in pursuit of policy goals does not make it scientifically permissible to do so. "Courts have consistently excluded expert testimony that 'cherry-picks' relevant data, because such an approach does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science.'" *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018) (citations and quotations omitted). Such testimony is properly excluded under the *Daubert* standard as "unreliable." *Id.* at 645; *see, e.g.*, *In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 247 (S.D.N.Y. 2018) (excluding epidemiologist for, among other things, "selective use of case report data"). To grasp this, one need look no further than the testimony of the Government's other witness, Dr. Burchman, who testified:

> Q Okay and, in fact, good science as to marijuana or any other pharmaceutical has to take into account all the evidence, both favorable and unfavorable, for any course of treatment, correct?
>
> A Yes, sir.

Tr. 781:15–20.

The only other piece of evidence that Dr. Chiapperino cited to support the neuropathic pain endpoint—"AHRQ's living survey," Tr. 63:20—reveals nothing that would explain why Dr. Chiapperino thought it supported marijuana as a treatment. The few marijuana-related products that the survey found to have *any* potential effect to alleviate pain were THC sprays, not botanical marijuana. Gov. Ex. 3 at 182–83. And as to botanical "whole-plant cannabis," the survey found that evidence of a chronic pain benefit was "insufficient." *Id.* at 182 (emphasis added).

The weakness of FDA's relied-upon evidence on neuropathic pain was highlighted in the publications of other scientific organizations. A 2018 systematic review published in the highly regarded *Cochrane Database of Systematic Reviews* excluded most of the underlying trials used in the meta-analyses relied upon by FDA, and ultimately reached a conclusion exactly the opposite of FDA's:

> There is a lack of good evidence that any cannabis-derived product works for any chronic neuropathic pain.

See SAM Ex. 45 at 4 (Mücke (2018)). Dr. Chiapperino confirmed that the *Cochrane* review was available at the time of FDA's medical-officer review, Tr. 500:22–501:1, but it is not mentioned in the FDA bibliography. It appears the agency never reviewed it.

Dr. Burchman's Testimony and the "Opioid-Sparing" Endpoint. Dr. Burchman is an anesthesiologist and pain management physician who retired from clinical practice in 2019. Tr. 549:20–21, 750:23–25, 751:14–17. He began recommending botanical marijuana to pain patients in the later years of his career (approximately 2016–2019) while practicing at Dartmouth Hospital in New Hampshire. Tr. 559:21–560:8. In his opinion, marijuana is "extremely helpful in chronic pain patients," Tr. 581:23–24, particularly in reducing their use of opioids, *see* Tr. 579:4–21, 580:2–5, 587:6–588:4. The basis for these opinions was largely Dr. Burchman's clinical experience, namely, his claim to have treated between 200 to 400 pain patients with marijuana.

Tr. 565:5–8, 582:1–10. He also cited certain medical literature, including (i) the NASEM 2017 study, Tr. 584:18–21; (ii) a paper by Dr. Ethan Russo, Tr. 582:21–24; and (iii) his own co-authored study on marijuana and opioid dependence, Tr. 583:12–20. Despite Dr. Burchman's personal accomplishments, no aspect of his testimony supports the Part 2 standard of "some credible scientific evidence" for the medical use of marijuana as a treatment for pain. That is so for multiple reasons.

Start with Dr. Burchman himself. Scientific research must be dispassionate, and Dr. Burchman is "not a researcher" (his own words, Tr. 884:20), much less a dispassionate one. Since 2019, Dr. Burchman has held multiple positions in the cannabis industry, including Chief Medical Officer of Acreage Holdings, one of the largest cannabis suppliers in the United States.[24] Tr. 752:23–754:4 (Burchman); Gov. Ex. 6 at 2 (Burchman C.V.). As he testified, his income from cannabis-related sources amounts to $30,000 to $40,000 annually. Tr. 816:16–17. While working for the cannabis industry, moreover, Dr. Burchman advocated for marijuana as a treatment for a wide range of psychiatric conditions—*e.g.*, PTSD, depression, and anxiety, Tr. 760:9–21—all of which are well outside his area of expertise, and some of which, FDA's analysis noted, would likely be worsened rather than helped by marijuana, Tr. 517:10–13 (Dr. Chiapperino confirming that for PTSD, "risks of adverse events outweigh the benefits" of marijuana). Dr. Burchman's enthusiasm for marijuana as pain treatment, therefore, must be taken with a grain of salt.

[24] Indeed, as Dr. Burchman's lawyer explained in a podcast shortly after he testified, the marijuana "industry was very up in arms" at not being allowed to formally participate at the hearing "until it was announced" that Dr. Burchman would be a witness "on behalf of the industry." *See* @CultivatedMedia, "It May Be a Kangaroo Court — But For Once, We're the Kangaroo" | Gary Kaminsky, YouTube (July 8, 2026), tinyurl.com/yc65cs9s; *id.* (video "Description" indicating that Kaminsky "helped with [Burchman's] witness prep").

But even taking Dr. Burchman's opinions at face value, his observations from clinical experience are, by definition, clinical rather than scientific in nature. He never attempted to write up his observations into an article for peer review, one of the key indicators of scientific rigor. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993). More importantly, every patient to whom he recommended marijuana (whether to reduce opioid use or for another reason) ***knew*** that he or she was getting marijuana, so there was zero control for the placebo effect or other confounding factors. These controls are critical, Dr. D'Souza explained, to curb natural biases: "[I]f a researcher is anti- or pro-cannabis, those unconscious biases might interfere with their assessments if they know that the person did or did not receive cannabis or placebo." Tr. 2245:18–20. As a matter of sound science, therefore, Dr. Burchman's uncontrolled clinical observations cannot establish that marijuana caused any patient-reported reduction in pain.

Nor did the literature Dr. Burchman referenced cure the weakness in his testimony. Asked for the strongest scientific support for his position, he identified a "landmark" review by Dr. Ethan Russo. Tr. 582:21–24. But Dr. Russo himself also had ties to the cannabis industry, Tr. 780:23–781:3 (Burchman), and the paper Dr. Burchman relied upon was sponsored by GW Pharmaceuticals, Tr. 779:14–18.[25] As to the paper that Dr. Burchman co-authored, that paper was merely a survey of dispensary customers, selected entirely from people who already use marijuana and believe that it helps them—not a scientific experiment. Indeed, the authors of the study concede that the "retrospective design does not allow for inferences of causal relationship." Brian

[25] GW Pharmaceuticals is the manufacturer of cannabis-based drug Sativex. *See Sativex (Nabiximols) for the Treatment of Multiple Sclerosis, Europe*, Clinical Trials Arena (Mar. 15, 2024), perma.cc/NUS4-L2T8.

J. Piper et al., *Substitution of Medical Cannabis for Pharmaceutical Agents for Pain, Anxiety, and Sleep*, 31 J. Psychopharmacology 569, 574 (2017).[26]

More to the point, Dr. Burchman made no claim that he had undertaken a thorough or comprehensive review of the scientific literature, much less any effort to analyze it in writing as an expert ordinarily would. Thus, like FDA and Dr. Chiapperino, he simply cited the data that supported his views without mentioning the rest. That, again, is cherry-picking, not sound science. *See, e.g.*, *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (opinion reached by "first identifying [a] conclusion . . . and then cherry-picking observational studies that support [the] conclusion and rejecting or ignoring the great weight of the evidence that contradicts [the] conclusion . . . does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science'"); *Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc.*, 55 F. Supp. 2d 1024, 1039 (N.D. Cal. 1999) ("The Ninth Circuit has upheld the exclusion of expert testimony where the expert selectively chose his support from the scientific landscape." (citing *Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996)).

Contrast Dr. Burchman's perfunctory review with the work of the other experts at the hearing who undertook full literature reviews and concluded that marijuana did *not* have an opioid-sparing effect. Dr. Akinfiresoye reviewed no fewer than "nine different studies" concerning marijuana's potential to reduce reliance on opioids. Tr. 1374:5–6. She concluded that marijuana "did not work in reducing opioid overdose deaths," Tr. 1374:11–13, and agreed that some studies found "that marijuana did not work in reducing opioid use," Tr. 1374:19–22. Indeed, the Section's

[26] He claimed the NASEM report had "extreme confidence" that marijuana treated pain. Tr. 584:22–24. But as Dr. Madras explained, NASEM's analysis of pain was "deeply flawed" because it depended on trials using "isolated cannabinoids" and "nabiximols." Tr. 1231:5–1234:12; *see also* Tr. 1627:7–1629:10 (Finn).

report identified evidence that marijuana may actually "serve as an initiator for opioid use," not a means to reduce it. SAM Ex. 7 at 43. And Dr. Akinfiresoye identified evidence that marijuana could make chronic pain "worse." Tr. 1372:16–18.

Dr. Madras likewise testified that the epidemiological evidence does not establish an opioid-sparing effect. To the contrary, she identified evidence associating marijuana use with increased opioid-related risks. Youth "who use marijuana before the age of 18," she explained, are at "the highest risk for developing opioid use disorder," and marijuana users are "more likely to drop out of treatment" for opioid-use disorder. Tr. 1237:7–12. She further testified that there was no epidemiological evidence demonstrating an opioid-sparing effect and that, if anything, states adopting medical-marijuana laws subsequently experienced an increase in "opioid overdoses." Tr. 1237:16–19.

Dr. Finn, an expert in pain medicine and the public health effects of marijuana, reached a similar conclusion from both his clinical experience and the scientific literature. He testified that a recent meta-analysis—Hsu (2025)—is the "most recent comprehensive review of the literature," and it "found that cannabis and cannabinoids really aren't helping" and "did not support" using cannabis for chronic pain. Tr. 1629:17–1630:13 (discussing Finn Ex. 5). He noted that, HHS's analysis of pain was "not credible" because, of the "27 randomized controlled trial[s]" it reviewed, "18 of them" or "two thirds of the studies they looked at showed no benefit in pain." Tr. 1624:19–1625:2. As for his clinical practice, he testified that "the vast majority of, nearly 100 percent" of pain patients he encountered who used marijuana reported that it "wasn't doing what it was supposed to do" and yet declined to taper their opioids. Tr. 1587:6–20 (Finn). More importantly, he cited scientific literature finding that cannabis users were more likely to develop opioid-use disorder or misuse prescription opioids. Tr. 1641:1–4, 1642:14–17.

ii. The Evidence Does Not Demonstrate Credible Scientific Support for the Use of Marijuana for Anorexia Related to a Medical Condition or Nausea/Vomiting.

As to the other two indications that met HHS's Part 2 standard of scientific support—anorexia and nausea/vomiting—the universe of available medical evidence was far smaller than for pain, and hence the literature review was much more limited. Despite the narrowed field, however, the UF team and the FDA medical team again disagreed as to whether scientific support could be found, but this time their respective viewpoints were reversed: For both conditions, UF thought the evidence supported marijuana's use as a treatment, whereas FDA identified only "mixed results." Gov. Ex. 3 at 200. As HHS's 2023 Recommendation states:

> UF found that there is low- to moderate-quality evidence supporting the use of marijuana as medical treatment for outcomes in anorexia, nausea and vomiting, and PTSD. However, FDA review of systematic reviews showed mixed results for these indications.

Id. at 27. Just like for the pain indication, therefore, the Government's task at the hearing was to explain how it reconciled UF's and FDA's conflicting viewpoints to arrive at an affirmative conclusion of scientific support for each indication.

To address this point (and thereby carry its burden), the Government tendered no expert testimony. It instead relied solely on fact-witness testimony from Dr. Chiapperino. As to both indications, Dr. Chiapperino took the same approach as he did for pain, pointing to the existence of studies showing positive findings—again, without discussing or even identifying any specific study—and ignoring negative ones. As he characterized the finding of support for anorexia:

> It was based on, I think, three clinical trials, and in one of those clinical trials, there was evidence of benefit, and the study was rated to have a moderate quality of evidence. "Moderate quality of evidence" in these systematic reviews means that the true effect of marijuana is probably similar to the observed result or reported effect.

Tr. 61:9–17. And as to the finding of support for nausea/vomiting:

> Similar, there was a handful of studies available, and in some of those studies, [the] benefit was identified with a moderate quality of evidence.

Tr. 61:25–62:3.

It is, again, completely contrary to the scientific method to cherry-pick one study out of three (or a "handful," or "some") simply because it favors a preferred outcome and then ignore the remainder because they do not. Any scientist taking such an approach would be expected, at minimum, to explain *why* the favored study is more reliable than the ignored ones. But Dr. Chiapperino did no such thing, and, indeed, he did not even identify *which one* of the three anorexia studies covered by UF suggested a benefit. Nor is the answer apparent in the FDA memorandum itself, as it merely describes quality of evidence produced by the three studies and certain of their observations, but not which way they ultimately point. The same is true with respect to the nausea/vomiting indication: There are, in fact, a "handful" of inconsistent studies of that endpoint, Tr. 61:25 (Chiapperino), but neither Dr. Chiapperino nor the FDA memorandum itself identifies which was which. *See Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001) (upholding under *Daubert* the exclusion of an expert who "did not adequately explain why he ignored certain facts and data, while accepting others," and rather "cherry-picked the facts he considered to render an expert opinion").

Compounding the need for further explanation, Dr. Madras' slide on clinical trial results explains that "[c]annabinoids should not be utilized as a first-line treatment for nausea and vomiting." SAM Ex. 47 at 13; *accord* SAM Ex. 2 at 16 (Madras 2016 Report). That is not to mention that use of marijuana can itself cause nausea and vomiting, such that the "cure" may be worse than the disease. *See* SAM Ex. 32 at 3 (Madras & Larkin (2025)); *accord* Finn Ex. 99 at 66 (Canada Information for Health Care Professionals (2018)) ("important to note" cannabis use "has been reported to paradoxically trigger a chronic cyclic vomiting syndrome"); *accord* SAM Ex. 7

at 24 (DEA Report) (listing nausea as a "common" effect of marijuana use); *see also* SAM Ex. 25 (Young-Wolff (2025)).

The same is true for anorexia-cachexia, where the few studies of marijuana's effect have "small sample sizes." SAM Ex. 47 at 13 (Madras Slides). Assessing cancer cachexia, the Government of Canada concluded that "evidence for cannabinoids (e.g., dronabinol) in the treatment of this condition is low." Finn Ex. 99 at 70 (citing Mantovani (2010)). It noted, for instance, a phase III trial of advanced cancer patients finding that neither cannabis extract nor THC "provided any statistically significant benefit compared to placebo" on quality-of-life measures. *Id.* at 65 (citing Strasser (2006)).

PROPOSED CONCLUSIONS OF LAW

Under the Controlled Substances Act, 21 U.S.C. § 812(b)(3), the Attorney General (*i.e.*, the Government) can transfer a controlled substance to Schedule III only when, after considering the eight factors that inform all scheduling decisions, he finds that (i) the substance's potential for abuse is less than that of substances in Schedules I and II, (ii) it has a currently accepted medical use in treatment in the United States, and (iii) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence. *See* 21 U.S.C. §§ 811(b), 812(b). The Government bears the burden of proving that each of those three criteria is met. *See* 5 U.S.C. § 556(d); 21 C.F.R. § 1316.56.[27]

[27] In this regard, HHS's recommendation carries some weight, but it does not 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"); *see also Questions Related to the Potential Rescheduling of Marijuana*, 2024 WL 2412009, at *16 (O.L.C. Apr. 11, 2024) (same).

Here, the relevant substance is marijuana,[28] but it is *not* the undifferentiated category that HHS reviewed in 2022–23. Rather, as this Tribunal observed on the record,[29] it is the category of marijuana that has not *already* been transferred to Schedule III by the AG Rescheduling Order. *See* ALJ Ex. 20 at 2 (Preliminary Order); DUID Ex. 5 at 10 (AG Rescheduling Order). That residual category consists exclusively of marijuana that is *not* being used under a licensed state program, which is to say, illicit marijuana and marijuana that is being used recreationally. Such residual marijuana should remain in Schedule I, where it has always been, as the evidence taken at the hearing shows that it meets none of the statutory criteria for placement in Schedule III.

I. MARIJUANA HAS A HIGH POTENTIAL FOR ABUSE AS COMPARED TO SCHEDULE I AND II SUBSTANCES.

The first statutory factor in any controlled substance scheduling determination is its "potential for abuse." Schedules I and II are reserved for those substances with a "high potential for abuse," and Schedule III is appropriate only for those substances with a "potential for abuse less than the drugs or other substances in Schedules I and II." 21 U.S.C. § 812(b). As discussed above, in 2016—as well as in all other rescheduling considerations over the past half century—HHS and DEA concluded that marijuana had a ***high*** abuse potential and thus should remain in Schedule I. *See* Gov. Ex. 1 at 24. Those prior analyses considered marijuana's impact on an absolute basis across a wide range of harms, giving substantial weight to diversion from state programs, associated crime, widespread use, availability, and overall public-health consequences, including cognitive and psychiatric harms. *See* Gov. Ex. 1 at 19 (NPRM) (noting prior finding of "high abuse potential" based on, inter alia, "the large number of individuals using marijuana.").

[28] 21 U.S.C. § 802(16) (statutory definition); *see also* Tr. 928:2–25; *accord* Tr. 1288:16–25; Tr. 1409:12–1410:10; Tr. 1507:3–13; Tr. 1671:24–1672:17.

[29] Tr. 2497:8–19.

The hearing evidence showed that, under that mode of analysis, marijuana unquestionably has a high potential for abuse. As Dr. Chiapperino acknowledged during cross-examination, the facts indicating abuse that were crucial to marijuana's Schedule I status a decade ago have only become more pronounced. *See* Tr. 407:7–408:1. Since 2015, when FDA concluded that marijuana has a high potential of abuse, the potency of marijuana, the prevalence of marijuana, and the number of emergency department visits and hospitalizations involving marijuana disorder have all gone up. *Id.* Marijuana is still "the most frequently abused illicit drug in the United States." Tr. 519:23–520:4 (Chiapperino); *accord* Tr. 1395:3–8 (Akinfiresoye); Tr. 1814:18–22 (Stephens). It also "has the highest conversion rate from psychosis to schizophrenia and bipolar disorder." SAM Ex. 10 at 173 (2026 National Drug Control Strategy). Marijuana users have the highest risk of developing schizophrenia relative to other drugs. Tr. at 2275:13–15 (D'Souza); *accord* Tr. 2280:23–2281:9. Indeed, the evidence of marijuana's causal relationship with various psychiatric harms is stronger than ever before. Tr. 2296:17–22. There is, in other words, no new and more favorable data suggesting that marijuana is *less* prone to abuse—or less abused in fact—than it was in any previous rescheduling where Schedule I was upheld. Every one of those prior findings is as true today as it was in 2016.

Given these established facts, the *only* basis on which the Government has urged a finding of a lower abuse profile—or, at least, low enough to move marijuana to Schedule III—was to depart from its usual mode of analysis. Specifically, the Government emphasized a user-adjusted analysis of harm (rather than on an absolute basis), with a focus on severe and acute harms (rather than across-the-board harms), by comparison to a select few substances of disparate pharmacological classes notorious for high overdose risk (rather than comparators from the same class or otherwise pharmacologically appropriate). Tr. 75:22–78:22 (Chiapperino). This new

mode of analysis is inconsistent with both the statutory standards that the Government must apply as well as with prior agency practice, and for those reasons it must be rejected.

First, on the issue of a "utilization-adjusted" analysis, the abuse potential of a drug cannot be viewed in isolation from the number of individuals using the drug. Under HHS's own criteria, the "public health risks" that factor into abuse potential are *not* limited to the risks affecting those who *use* the drug, but also those affecting society in general, *i.e.*, "other individuals" and "the community." Gov. Ex. 1 at 5 (NPRM). The more prevalent a drug is, therefore, the greater its abuse potential. For this very reason, previous analyses of marijuana's abuse potential have given heavy weight to the sheer number of persons who use it, and have not focused myopically on the impact that it has on individual users in particular instances. As the NPRM itself states:

> In 2016, HHS found that many factors indicated marijuana's high abuse potential, "including the large number of individuals using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use.

Id. at 19 (quotations omitted). If evaluated with "absolute numbers," Dr. Chiapperino acknowledged, the amount of harm caused by marijuana, "due to high prevalence . . . was high." Tr. 76:2–8 (Chiapperino).

Second, and wholly separate from the question of utilization-adjusted versus absolute effects, the concept of "abuse" goes well beyond "overdose" or "acute harm." As Dr. Chiapperino testified, HHS generally classifies "abuse" to encompass all instances of non-medical use, Tr. 523:12–16 (Chiapperino), not merely those that cause harm, let alone severe acute harms, Tr. 531:5–9 (Chiapperino). Moreover, the types of harm that merit consideration when assessing abuse potential are not limited to acute ones. Consistent with this, the Schedule I and II

categories—both of which are for drugs with a *high* potential for abuse[30]—contain many substances which, like marijuana, do *not* have a high overdose risk and are *not* prone to severe adverse effects in acute doses. *See* 21 U.S.C. § 812(c). Peyote and psilocybin, for example, are both in Schedule I, notwithstanding that they have no realistic overdose risk. Tr. 532:22–533:6.

Third, even assuming that HHS acted soundly by focusing on acute harms on a per-user basis when assessing abuse potential, its analysis was distorted the comparison to a handpicked list of substances notorious for overdose risk. The statutory standard for placement in Schedule III is a potential for abuse "less than the drugs or other substances in Schedules I and II," 21 U.S.C. § 812(b), and those schedules contain many other drugs besides the high-lethality drugs that HHS used here, *see id.* § 812(c) & scheds. I & II. Given this range of options, HHS's ordinary approach is to assess a drug's abuse potential by comparison to drugs from the same pharmacological class. Tr. 535:5–9 (Chiapperino). But HHS did not do that here, instead relying on comparator drugs that it had previously described as "inappropriate**"** for direct comparison with marijuana. Tr. 534:19–24.

No witness at the hearing explained why cocaine and opioids are appropriate comparators for marijuana now when they were not appropriate comparators a decade ago. The only explanation that appears anywhere in the record, in fact, is HHS's mention that "***some*** of the comparator substances"—not all—are "approved for use in conditions similar to the indications for which marijuana was evaluated in the CAMU analysis," mentioning opioids for pain and benzodiazepienes for anxiety. Gov. Ex. 3 at 28 (2023 Recommendation) (emphasis added). Putting aside that marijuana ***failed*** the CAMU test as to the anxiety indication for lack of medical

[30] As Dr. Chiapperino testified, the only difference between Schedules I and II is that Schedule II drugs have a currently accepted medical use. Tr. 487:6–10; *see also* 28 U.S.C. § 812.

support, the CAMU analysis and the use-in-treatment logic have nothing to do with the pharmacological similarity that has always governed the analysis before. Indeed, were HHS's newfound logic sufficient—*i.e.*, if the agency could overlook pharmacological class when substances are used to treat the same conditions—its analysis in 2015 would have come out the opposite way, as both cocaine and opioids have recognized uses for pain treatment.

It is black-letter law that when an agency reverses "prior policy," it must provide "a more detailed justification than what would suffice for a new policy created on a blank slate." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009). This is especially true when "a new policy rests upon factual findings that contradict those which underlay its prior policy." *Id.* HHS's recommendation violates these principles. Put simply, "agency action is arbitrary and capricious if it departs from agency precedent without explanation." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003). An "unexplained inconsistency" with prior agency practice is itself "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) (citation modified) (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)). HHS did not mention—let alone analyze and defend—its about-face on assessing marijuana's abuse profile, and DEA cannot cure that defect by simply adopting HHS's flawed analysis.

II. MARIJUANA HAS NO CURRENTLY ACCEPTED MEDICAL USE IN THE UNITED STATES.

To transfer marijuana out of Schedule I—whether to Schedule III or any other—DEA must conclude that marijuana has a "currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3)(B). This proceeding, however, explicitly *excludes* consideration of medical marijuana. *See* ALJ Ex. 20 at 2 ("Importantly, the scope of this hearing is not to discuss the rescheduling of ***medical*** products approved by the Food and Drug Administration that contain

marijuana and of ***medical*** marijuana products already regulated by the states, which has already occurred. Accordingly, no evidence or testimony will be received on that matter." (emphases added)). As this Tribunal has made clear, "[t]he narrow issue in this matter is whether the ***remainder*** of marijuana . . . should be" rescheduled. *Id.* (emphasis added). At the risk of stating the obvious, it would be a paradox to conclude that ***non-medical*** marijuana has a commonly accepted ***medical*** use.

That glaring threshold defect aside, marijuana simply has no CAMU. For three decades, DEA, HHS, and FDA have consistently determined that marijuana lacks a currently accepted medical use based on the five-factor test that the D.C. Circuit approved in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994). As the evidence at the hearing showed—without disagreement or dispute—marijuana has never passed, and could not *now* pass, this established five-part test.

In its place, HHS recommends, and the Attorney General has proposed adopting, a new two-part inquiry—one which was developed specifically for marijuana, and which did not exist when the scientific review began in 2022—that could find a "currently accepted medical use" based on (i) "widespread current experience" by "healthcare providers" in certain state programs, and (ii) "some credible scientific evidence" supporting the uses by those providers. Gov. Ex. 3 at 79 (2023 Recommendation). As a matter of both law and fact, this test and the evidence offered in support of it fail to establish—and, indeed, *cannot* establish—that marijuana has a currently accepted medical use as the statute requires for rescheduling.

A. HHS's Two-Part Test Is Contrary to the Statutory Standard of "Currently Accepted Medical Use" and Prior Agency Practice.

To have a "medical use," a substance, procedure, practice, or other thing must have utility in "the practice of medicine," which is to say, by *physicians*. *Stedman's Medical Dictionary* 1076–

77 (27th ed. 2000) (tracing etymology of "medical" from the Latin *medicus* meaning "physician"). As applied to a controlled substance, therefore, the plain meaning of "currently accepted medical use" is a use in treatment that is accepted by some contingent—putting aside the question of how large a contingent—of actual medical doctors.

The new two-part test, however, does not depend on use or approval (widespread or otherwise) by physicians at all. The test itself (as articulated by HHS) makes no mention of physicians or doctors, and instead would allow a finding of CAMU to be premised on the experience and use of a drug by "HCPs" or "health care providers" (HCPs). To be sure, the category of "healthcare providers" *includes* physicians, but it is not limited to them, and also includes many other species of providers with *no* medical training, like psychologists, social workers, and chiropractors. *See, e.g.*, Ohio Rev. Code § 4743.10 (counselors and social workers are "medical practitioners"); Va. Code § 8.01-581.1 (psychologists, social workers and chiropractors are "health care providers"); Nev. Rev. Stat. § 629.031 (music therapist). It is a very strange test of "currently accepted medical use" that can be satisfied without considering the practices of even *one* licensed physician, let alone a consensus.[31]

In addition, and setting aside the statutory standard, the two-part test is in no way consistent with the way HHS has approached the CAMU question over the last 50 years. As noted above, it has always applied—and, to this day, continues to apply—the recognized five-part test for scheduling evaluations of all other drugs besides marijuana. That test, in other words, has not fallen out of favor, but was simply bypassed for the evaluation of marijuana in 2023. The only reason tendered for that temporary departure from longstanding agency practice—which was not

[31] The term "healthcare provider" appears only in Part 1 of the two-part test, but Part 2 does not cure the problem, as it looks only to "scientific support," not clinical practice. There is thus no aspect of the two-part test that requires an analysis of the practices of actual physicians.

articulated in the HHS 2023 Recommendation itself, but only backfilled later by DEA in the subsequent NPRM—was that:

> [The five-part test] left no room for an evaluation of (1) whether there is widespread medical use of a drug under the supervision of licensed health care practitioners under State authorized programs and, (2) if so, whether there is credible scientific evidence supporting such medical use.

Gov. Ex. 1 at 21.

That is certainly not a reasoned critique of the five-part test. For one thing, if the five-part test were defective, the agency would have discontinued that test rather than continuing to apply it to all other drugs. *See* Tr. 414:14–17 (Chiapperino). Moreover, the DEA's putative explanation does nothing more than recite the standards of the two-part test—without stating why those standards are preferable or more consistent with the statutory text—and thus the assertion that the five-part test "left no room" for an evaluation of the two-part standards is merely an observation that the five-part test ***is not the same thing*** as the two-part test. That is a tautology, not a rationale. The agency cannot just pivot to a new test without explaining its reason for doing so. *See Encino Motorcars, LLC*, 579 U.S. at 222; *Ramaprakash*, 346 F.3d at 1124. It has not.

B. The Evidence Does Not Satisfy the Two-Part Test.

Even if the two-part test were consistent with the statutory standard for CAMU and previous agency practices (and it is not), marijuana still would not have a "currently accepted medical use," as the proof offered by the Government in fulfillment of that test fell well short of what the test requires, as to both prongs.

1. The Government Cannot Satisfy the Part 1 Test with Nationwide Figures Not Broken Down by State or Medical Condition.

As discussed above in the Findings of Fact, the Government's only evidence of "widespread current experience" consists of aggregated figures showing that approximately 30,000 health care providers and six million patients currently treating with marijuana across all

jurisdictions and all medical conditions. Those figures do not satisfy Part 1 because they do not show the extent of provider experience in the particular states where a medical board determines appropriate uses, which the Part 1 test requires. In addition, because those figures are not broken down by medical condition, the Tribunal cannot determine the extent of provider experience with the three medical conditions that supposedly passed the Part 2 analysis and that the Government has offered in support of CAMU (pain, anorexia, and nausea/vomiting).

Part 1 of the two-part test asks

> whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented state-authorized programs, **where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions**.

Gov. Ex. 3 at 3, 25, 112 (emphasis added). Given this last clause, the only "medical use" that counts toward "widespread current experience" is use in a state where particular uses of marijuana are "recognized by entities that regulate the practice of medicine." *Id*. The point of this requirement is to distinguish state programs where particular uses of marijuana are recognized by a state medical body from those where uses are recognized by some other means, such as ballot initiatives. That is a sensible distinction, because approval by legislation is not indicative of medical practice or experience. Given this distinction, the test of "widespread current experience" with a particular use can be satisfied *only* by evidence from states where the "recognition" of that use is conferred by the entity regulating the practice of medicine.

That is nowhere near all 43 jurisdictions with medical marijuana programs, and thus the 30,000-provider and six-million-patient figures do not apply. As the OASH Part 1 Analysis states, there are just 21 medical-marijuana states that provide for "a board of qualified experts to evaluate the inclusion of additional qualifying conditions." *Id.* at 81. While the *total* number of providers and patients (*i.e.*, not broken out by medical condition) in those states could, in theory, be

determined from Table 4 in the OASH Part 1 Analysis, OASH does not bother to identify which states they are, nor has HHS asserted that the figures limited to those states—whatever they are—would meet the standard of "widespread current experience." *See id.* at 96–97 tbl. 4. In addition, and even more fundamentally, the OASH Part 1 Analysis concedes that the "reviewing/recommending bodies" that evaluate particular conditions for inclusion in state medical marijuana programs "are not necessarily the same entities that regulate the practice of medicine more generally." *Id.* at 81. Thus, the data that the Government has provided as to the Part 1 test does not align with the standard that it must meet.

A similar and equally fatal problem arises from the fact that OASH's "widespread experience" figures are not broken down by medical condition. The two-part test contemplates that the medical conditions evaluated in Part 1 will move on to Part 2 only if they "satisf[y]" the Part 1 test. *Id.* at 3. That concept is meaningless if the test of "widespread experience" is applied on an *en masse* basis rather than condition-by-condition basis just like the Part 2 test was. Indeed, without a condition-by-condition analysis of provider experience, there is no way to tell how any medical condition evaluated in Part 2 "satisfied" the Part 1 test, or what threshold of provider experience it had to meet to do so. *Id.* Nor is there any alignment between the two parts of the test, and, indeed, on the present record, the Tribunal has no idea whether the conditions that purportedly have "credible scientific support" under Part 2 are the same ones with which providers supposedly have "widespread current experience" under Part 1.

To be sure, OASH Part 1 Analysis does provide a condition-by-condition breakdown of the states in which particular uses of marijuana are recognized, but—according to the plain language of the test and OASH's own analysis—the Part 1 prong of "widespread current experience" is satisfied only by the number of HCPs who are using marijuana for particular uses, not the number

of states where the use is authorized. Here again, therefore, the data that the Government has provided as to the Part 1 test does not align with the standard it is required to meet.

2. State Medical-Marijuana Programs Do Not Supply the Medical or Scientific Acceptance Necessary to Establish CAMU.

The Government cannot establish a currently accepted medical use merely by pointing to the existence or scale of state medical-marijuana programs. Those programs do not operate like ordinary medical practice in several respects that matter to the CAMU inquiry. The persons authorized to recommend marijuana need not be physicians, and in many jurisdictions they are not; recommendations may issue without a physical examination or an ongoing physician-patient relationship; and the recommendation itself generally does not specify the dose, strength, frequency, route of administration, or other features ordinarily associated with a medical prescription. *See* SAM Ex. 3 at 19, 21 tbl. 3; Tr. 1238:18–23 (Madras); Tr. 2138:3–2140:18 (Randall). Nor is product selection necessarily supervised by trained medical professionals: Dr. Akinfiresoye testified that dispensary "budtender" advice is "not medical," Tr. 1385:12–16, and that the literature she reviewed documented advice that could be affirmatively harmful, Tr. 1386:2–4; *see also* SAM Ex. 7 at 41. Whatever those programs may demonstrate about legal access or consumer demand, they do not, without more, demonstrate acceptance of marijuana as medicine ***by the medical profession***.

The disconnect between state authorization and scientific support is even more pronounced. Dr. Chiapperino acknowledged that more than one hundred conditions are being treated with marijuana in state programs even though they never satisfied HHS's Part 2 requirement of "some credible scientific support." Tr. 466:19–25. Other experts described the same problem in starker terms: Dr. Madras testified that some states permit marijuana for essentially any condition a provider deems appropriate and that, for most such indications, the

science is "close to absolute zero." Tr. 1228:6–9; *see also* Tr. 1239:1–5. And Dr. D'Souza observed that there is no common pathophysiological basis that would explain why the same product should be effective across the dozens of conditions for which state programs authorize it. Tr. 2299:20–2300:3.

Finally, it bears repeating that HHS's reliance on state medical marijuana programs as proof of legitimate medical practices flies in the face of its approach to diversion. As discussed above, when HHS was considering diversion for purposes of its abuse analysis—and plainly sought low statistics on diversion to suggest a low potential for abuse—it turned a blind eye to rampant diversion from state medical marijuana programs by suggesting that federal programs were the only "legitimate" channel. But when HHS needed to data to support the idea of "widespread current experience" for CAMU purposes, the same state programs it disregarded as *not* "legitimate" suddenly became the sole focus of its analysis. The agency cannot have it both ways.

For CAMU purposes, therefore, state authorization cannot substitute for the very medical and scientific acceptance the test is supposed to measure. A regime in which nonphysicians may recommend an unspecific product, dispensary employees may effectively guide product selection, and scores of authorized conditions lack even HHS's minimal scientific support does not itself establish that marijuana has become an accepted medical treatment. At most, the state programs show that marijuana is widely permitted and widely used under state law; they do not establish that its use is accepted in the medical sense relevant to the federal scheduling inquiry.

3. Marijuana Fails Part 2 of the Two-Part Test.

The second part of the two-part test concerns the scientific component, for which HHS adopted a standard of "some credible scientific support." As discussed above, the Government's

evidence does not satisfy even that self-defined threshold. Whatever "some" may mean, the word **scientific** must impose at least one irreducible requirement: The evaluation must be conducted in a manner consistent with the scientific method. That means the evidence must be assessed as a whole, including both favorable and unfavorable results, rather than by isolating positive studies and disregarding conflicting ones. *See In re Lipitor*, 892 F.3d at 634 (4th Cir. 2018) (cherry-picking data "not good science" (quotations omitted)); *In re Bextra*, 524 F. Supp. 2d at 1176 (same).

The record shows that FDA did not follow that basic principle. Dr. Chiapperino acknowledged that a favorable result need not be repeatable and that, where two studies conflict, FDA may still rely on the positive one: "There might only be a couple of studies. If one was positive and one was not, we would still consider the results in the first study." Tr. 376:8–15. That approach is not a method for determining what the body of scientific evidence demonstrates; it is a rule that permits an affirmative finding whenever some favorable evidence can be extracted from a mixed record—in a word, cherry-picking. The Government's own witness Dr. Burchman concurred with the opposite—and elementary—scientific principle: that "good science" concerning marijuana, as with any pharmaceutical, "has to take into account all the evidence, both favorable and unfavorable." Tr. 781:15–20. Dr. D'Souza likewise explained why scientific safeguards like blinding and placebo controls exist in the first place: to prevent researcher and subject expectations from distorting results. Tr. 2245:12–24. A methodology that affirmatively permits selective reliance on favorable findings cannot establish "credible scientific support."

That defect was outcome-determinative. For pain—the indication with by far the largest evidentiary record—the UF review found the evidence too inconsistent to support a conclusion of benefit, and Dr. Chiapperino conceded that FDA's contrary conclusion depended on the narrower

neuropathic-pain endpoint. Tr. 499:3–21. Yet even there, only one of three randomized controlled trials reported improvement, while the others produced mixed results or no change. Gov. Ex. 3 at 172–73. The same pattern recurred for anorexia and nausea/vomiting, where Dr. Chiapperino relied on the existence of one favorable trial out of three, or "some" favorable studies out of a "handful," without reconciling the contrary results. Tr. 61:9–17, 61:25–62:3. Meanwhile, experts who reviewed broader bodies of evidence reached materially different conclusions. *See, e.g.*, Tr. 1372:1–14, 1374:4–22 (Akinfiresoye). The question under Part 2 is not whether the Government can identify **a** positive study; it is whether the asserted medical use has **credible scientific support**. Where the affirmative finding depends on a methodology that permits favorable studies to be credited without accounting for contrary evidence, the Government has not carried even HHS's own Part 2 burden.

III. MARIJUANA LACKS ACCEPTED SAFETY FOR USE AND ABUSE CAN PRODUCE DEPENDENCE MORE SEVERE THAN THE "MODERATE OR LOW PHYSICAL DEPENDENCE OR HIGH PSYCHOLOGICAL DEPENDENCE" PERMITTED BY SCHEDULE III.

To transfer a drug out of Schedule I, the Government must demonstrate it has "accepted safety for use . . . under medical supervision." 21 U.S.C. § 812(b)(1)(C). If that requirement is satisfied, placement in one of remaining schedules turns in part on the degree of dependence that abuse of the drug may cause: Schedule II applies where abuse "may lead to severe psychological or physical dependence," while Schedule III applies where abuse "may lead to moderate or low physical dependence or high psychological dependence." *Id.* § 812(b)(2)(C)–(3)(C). The hearing evidence demonstrated that marijuana lacks accepted safety for use and carries a risk of dependence more severe than Schedule III will permit.

In the single sentence that the 2024 NPRM devotes to the third component of Schedule I, § 812(b)(1)(3), it asserts (relying on Gov. Ex. 3 at 65 (2023 Recommendation)) that marijuana has

an accepted safety for use for the same indications for which marijuana has a CAMU. Gov. Ex. 1 at 20 (2024 NPRM). This ipse dixit is not enough, particularly because it marks a departure from the Government's longstanding position. In prior scheduling proceedings, the Government concluded that marijuana lacked an accepted safety for use under medical supervision because physicians could not be assured of "a consistent and predictable potency" or that the substance was "free of contamination." 66 Fed. Reg. 20038, 20052 (Apr. 18, 2001); *see also* 44 Fed. Reg. 36123, 36126 (June 20, 1979) (concluding no accepted safety for use under medical supervision because of "the variability of THC content in natural [marijuana] plant materials"); *accord NORML v. Bell*, 488 F. Supp. 123, 140 (D.D.C. 1980). The 2024 NPRM does not identify any factual development eliminating that concern. To the contrary, it acknowledges marijuana's continuing "high variability" and recognizes that variability as a "major consideration for the potential variability of drug effects and safety." Gov. Ex. 1 at 10. Yet the NPRM then concludes, without reconciling those premises or explaining the change from prior agency practice, that marijuana now has an "accepted safety for . . . use . . . under medical supervision." *Id.* at 20. Where the agency's present conclusion rests alongside the very safety concern that previously compelled the opposite result, a reasoned explanation for the change is necessary. DEA's failure to provide one would be arbitrary and capricious. *See Encino Motorcars, LLC*, 579 U.S. at 222; *Ramaprakash*, 346 F.3d at 1124.

The record also supports the conclusion that marijuana abuse "*may* lead to severe psychological or physical dependence," § 812(b)(2) (emphasis added), which would preclude placement less restrictive than Schedule II. Even the Government's own witness, Dr. Chiapperino, acknowledged that continuous marijuana use produces physical dependence and a recognized withdrawal syndrome, and that marijuana is associated with cannabis use disorder at a "fairly high rate." Tr. 81:1–13; *see also* Tr. 79:4–13 (physical dependence). More importantly, the testimony

established substantial psychological dependence. DEA's Dr. Akinfiresoye described cannabis use disorder as a condition "characterized by psychological dependence" and testified that roughly 30 percent of regular users develop cannabis use disorder, that millions of Americans suffer from it, and that marijuana produces more such cases than any other illicit drug. Tr. 1396:11–1398:14. Dr. Madras further testified that an estimated 30 to 50 percent of daily users develop cannabis use disorder and that the addiction potential "increases dramatically with daily use." Tr. 1252:8–20. Dr. D'Souza likewise testified that some users experience withdrawal symptoms sufficiently severe to drive them back to cannabis after attempting to quit, with withdrawal sometimes involving significant disturbances of sleep, appetite, and mood. Tr. 2266:18–2267:15.

Whatever may be said about the average user, the statutory question is whether abuse "may lead to" severe psychological or physical dependence. The record conclusively establishes that the answer is "yes." Marijuana abuse can produce severe cannabis use disorder marked by compulsive use, craving, tolerance, withdrawal, and inability to stop.

CONCLUSION

The Government has not carried its burden to establish a justification for rescheduling marijuana under the criteria established by the Act, and the Tribunal should recommend that marijuana stay in Schedule I.

August 17, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on August 17, 2026, I caused a copy of the foregoing document to be delivered by email to the following recipients:

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