BEFORE THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:

Schedules of Controlled Substances:
Proposed Rescheduling of Marijuana

DEA Docket No. 1362
Hearing Docket No. 26-96

JOINT CLOSING ARGUMENT AND POST-HEARING BRIEF FILED BY DESIGNATED PARTIES DUID VICTIM VOICES AND KENNETH FINN, M.D.

Patrick D. Kenneally
IL Bar #6286573
patrick.kenneally@burkegroup.law
Connor W. Mighell
TX Bar #24110107
connor.mighell@burkegroup.law
BURKE LAW GROUP, PLLC
205 N Michigan Avenue, Suite 810
Chicago, Illinois 60601
Telephone: (832) 987-2214
Fax: (832) 793-0045

David Evans
NJ Bar #019631974
203 Main Street, #250
Flemington, NJ 08822
drugfreesc@aol.com

COUNSEL FOR DESIGNATED PARTIES

INTRODUCTION

Every day, walking through DEA Headquarters, the participants in this hearing passed a beautiful tribute to the faces of those killed by fentanyl. While the gesture is sincere and touching, it cannot be ignored that those faces are, in part, the product of the agency's own documented failures: opiate production quotas set too high for too long, and inadequate and delayed action against major distributors shipping suspicious volumes of opioids. The same wall of faces could just as easily be assembled for the many and growing memorial roll of young people whose minds and lives have been destroyed by marijuana. This includes Johnny Stack, the families documented in Dr. Finn's eighty-plus parent affidavits, and the victims of drugged driving crashes that Ed Wood catalogued. The agency now, through this proceeding, has an opportunity to limit the number of faces that will one day have to be added to that wall, rather than later acknowledge and pay homage to those fellow citizens we lost, again, due to institutional inaction in the face of a clear and present danger.

Designated Parties DUID Victim Voices and Kenneth Finn, M.D. hereby submit this Joint Closing Argument and Post-Hearing Brief to this tribunal. This brief principally centers on the testimony and exhibits of Dr. Kenneth Finn, M.D., Laura Stack, and Edward Wood—the witnesses presented by these Designated Parties.

The sole issue before this tribunal is whether marijuana, excluding FDA-approved marijuana-containing products and state-regulated medical marijuana products placed in Schedule III by the Attorney General's April 22, 2026 Order,[1] should be transferred from Schedule I to

[1] The exclusion of these two categories does not reflect a considered scheduling determination on the merits. It reflects only the Acting Attorney General's Order of April 22, 2026, which placed FDA-approved marijuana-containing drug products and state-licensed medical marijuana into Schedule III. Tr. Day 1 at 8:1–18, 22–25; 9:1–25. That Order is the subject of three pending petitions for review in the United States Court of Appeals for the District of Columbia Circuit:

Schedule III. The burden of proof in this proceeding rests squarely and exclusively on the Government. The Government failed to carry its burden on all findings required for rescheduling to Schedule III under 21 U.S.C. § 812(b)(3). In fact, the testimony of its own witnesses, combined with the extensive evidence placed before this tribunal by the interested parties, compels the conclusion that marijuana should not be rescheduled.

The Government confirmed that marijuana does not pass the well-established five-part test for "currently accepted medical use" that it must pass in order to be rescheduled. Instead, the Government admitted its rescheduling endeavor depends entirely on a novel analytical framework that has never been subjected to notice-and-comment rulemaking, lacks any foundation in prior agency practice, and was engineered to reach a predetermined outcome.

On abuse potential, the Government's comparator methodology is fundamentally flawed, relying on substances that are pharmacologically distinct from marijuana—including alcohol, which is not a controlled substance and is not typically used as a CSA scheduling comparator. The Government cannot carry its burden on comparative abuse potential through a methodology that its own proponent admits is unreliable.

Finally, regarding dependence, the record demonstrates that the Government systematically ignored or underweighted the grave safety and public health consequences of marijuana abuse—including psychosis, schizophrenia, suicidality, cardiovascular harms, impaired driving, diversion, and devastating workplace and transportation safety consequences. These

---

States of Nebraska, Indiana & Louisiana v. U.S. Department of Justice, No. 26-1130 (D.C. Cir. filed May 22, 2026); *New Directions Addiction Recovery Services v. Trump*, No. 26-1136 (D.C. Cir. filed May 28, 2026); and *Smart Approaches to Marijuana v. U.S. Department of Justice*, No. 26-1106 (D.C. Cir. filed May 4, 2026). Dr. Kenneth Finn, a Designated Party here, is a petitioner in No. 26-1136. The lawfulness of the April 2026 Order is therefore unresolved, and nothing in this proceeding should be understood to treat that Order as a settled or validly reached determination that any form of marijuana has a currently accepted medical use.

harms are well-documented in the evidentiary record through the expert testimony of Dr. Kenneth Finn (pain medicine, public health effects), the victim testimony of Laura Stack (psychosis and suicide), and the expert testimony of Edward Wood (impaired driving), as well as the peer-reviewed literature and real-world data they—and all interested parties—presented to this tribunal.

DUID Victim Voices and Kenneth Finn, M.D. (collectively, the "Designated Parties") will detail how the Government has not met its burden of proof in their brief below. Additionally, the Designated Parties have included a comprehensive analytical summary demonstrating the deficiencies in the Government's eight-factor analysis, attached hereto as Exhibit A. The Designated Parties urge this tribunal to recommend against the proposed rescheduling of marijuana from Schedule I to Schedule III.

LEGAL BACKGROUND

In the marijuana rescheduling proceeding, the Government bears the burden of proof as the proponent of the proposed rule to transfer marijuana from Schedule I to Schedule III. 5 U.S.C. § 556(d); 21 C.F.R. § 1316.56. As stated in the ALJ's Preliminary Order, Hearing Docket No. 26-96 at 2, "The Government, as the proponent of the proposed rule, has the burden of proof." As the burdened party, the Government bears the obligation to present witnesses and documentary evidence sufficient to support the proposed rescheduling. ALJ Standing and Prehearing Order, Hearing Docket No. 24-44, at 124–125.

Because this is a formal rulemaking conducted "on the record after opportunity for a hearing" under 21 U.S.C. § 811(a), the APA requires that the final rule may not be issued "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); *see also* OLC Opinion dated April 11, 2024, at 6, 9-10. The NPRM itself acknowledged that the Attorney

General must "make particular findings, based on substantial evidence, that correspond to the schedule in which the drug is to be placed." 89 Fed. Reg. 44,597, 44,599 (May 21, 2024); OLC Opinion at 6.

The substantial evidence standard requires the decision-maker to take into account "whatever in the record fairly detracts from [the evidence's] weight." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). The Government therefore cannot selectively rely on favorable evidence; rather, it must demonstrate that its conclusions are reasonable when the entire record, including contrary evidence presented by the Designated Parties, is considered as a whole. OLC Opinion at 9-10. Although it is a standalone standard for the agency's fact-finding and for judicial review, in practice, "substantial evidence" is functionally equivalent to a preponderance-of-the-evidence standard. *See Steadman v. SEC*, 450 U.S. 91 (1981).

ISSUE PRESENTED

The issue in this case is narrow. First, what is not at issue: 1) FDA-approved marijuana-containing medical products and 2) state-regulated medical marijuana products. Both of these categories of marijuana have already been addressed elsewhere and are excluded from the evidence and testimony in this proceeding. Prelim. Order at 2, *citing* 91 Fed. Reg. 22,714 (2026). At issue, rather, is "…whether the remainder of marijuana, as defined in the CSA, should be transferred from its current place on Schedule I of the list of controlled substances to Schedule III." *Id*.

Generally, the "remainder of marijuana" includes recreational or adult-use cannabis sold under state law as well as illicit or black-market marijuana. More specifically, it encompasses every product derived from the cannabis plant (other than hemp below the statutory THC threshold) that is neither an FDA-approved drug product nor covered by a qualifying state medical marijuana license, including any product containing any amount of delta-9 THC.

The breadth of substances and products slated for rescheduling is staggering. It ranges from a microdose edible containing gelatin, sugar, and 1 mg of THC; to high-potency concentrates exceeding 90 percent THC in which a single hit can deliver 50 mg or more of THC; to cannabis flower containing over 600 distinct chemical compounds; to cannabis beer containing both THC and alcohol; to street cannabis dusted with Xanax or similarly adulterated with Schedule III, IV, V, or other substances. Tr. Day 7 at 1516; HHS Rec. at 21. There is no limitation by route of administration, chemical composition, dose, formulation, product labeling, or advertising.

For all of these substances at once, the ALJ must determine whether HHS and DEA sufficiently applied the eight-factor analysis under 21 U.S.C. § 811(c) to support the three specific findings required for placement in Schedule III pursuant to 21 U.S.C. § 812(b)(3). Those three findings are: (1) the substance has a potential for abuse less than the drugs or other substances in Schedules I and II; (2) the substance has a currently accepted medical use in treatment in the United States; and (3) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence. *Id.*

The eight factors under 21 U.S.C. § 811(c) are: (1) actual or relative potential for abuse, (2) scientific evidence of its pharmacological effects, (3) the state of current scientific knowledge, (4) its history and current pattern of abuse, (5) the scope, duration, and significance of abuse, (6) what, if any, risk there is to the public health, (7) its psychic or physiological dependence liability, and (8) whether the substance is an immediate precursor of a substance already controlled under this subchapter.

With respect to Finding 1 (Abuse Potential), the NPRM and HHS Basis for Recommendation expressly rely on Factors 1, 4, 5, and 6. 89 Fed. Reg. 44,597, 44,603-08 (May 21, 2024); HHS Rec. at 9-10, 62-63. With respect to Finding 2 (Currently Accepted Medical Use),

HHS primarily drew on Factors 2 and 3. HHS Rec. at 29, 64; NPRM at 44,617-18; OLC Opinion (quoted in Prehearing Statement, P. Drum Exhibit 3, at 51). With respect to Finding 3 (Dependence/Safety Potential), HHS relied most directly on Factor 7, with supporting mechanism-of-action evidence from Factor 2. HHS Rec. at 58; NPRM at 44,618 (citing HHS Basis for Recommendation at 64-65).

STANDARD OF REVIEW

In determining whether the Government has carried its burden under the substantial evidence standard, the record must be evaluated as a whole. The record in this proceeding contains voluminous and often conflicting data, studies, and testimony. The following considerations, each firmly grounded in administrative law, provide a structured framework for assessing the quality, completeness, and reasoning of the agency's presentation when considering whether the government has met its burden.

1. Analytical Deficiencies: Unconvincing or insufficient evidence due to analytical errors, cherry-picking data, or methodological flaws. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359 (1998); 21 U.S.C. § 811(c)(1); *State Farm*, 463 U.S. at 52; *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87 (1983).
2. Unreasoned Conclusions: Failure to provide a reasoned explanation for key conclusions, including reliance on assumptions not supported by record evidence or drawing unreasonable or speculative inferences. *State Farm*, 463 U.S. at 43; *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962); *SEC v. Chenery Corp.*, 318 U.S. 80 (1943); 5 U.S.C. § 557(c).

3. Stale or Selective Evidence: Presenting old, stale, or outdated evidence when newer, better, or more reliable evidence is available, or over-reliance on limited or non-representative data sources while discounting broader, more probative datasets without justification. *Universal Camera Corp.*, 340 U.S. at 488; *State Farm*, 463 U.S. at 43.
4. Failure to Consider Relevant Evidence: Failure to consider or properly weigh clearly relevant evidence or factors. 21 C.F.R. § 1316.59; *State Farm*, 463 U.S. at 43; 5 U.S.C. § 556(d).
5. Inconsistent Agency Positions: Inconsistency with the agency's own prior decisions or positions, where the same type of analysis or similar evidence was previously found insufficient or the agency has taken contrary positions without adequate explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009); *State Farm*, 463 U.S. at 57.
6. Procedural Irregularities or Bias: Procedural irregularities or failure to follow the agency's own regulations or procedures, or evidence of bias or predetermined outcome. 21 C.F.R. Part 1316, Subpart D; *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954); *Withrow v. Larkin*, 421 U.S. 35 (1975); 5 U.S.C. §§ 556, 556(b).
7. Countervailing Evidence: Failure to adequately rebut or overcome substantial countervailing evidence in the record. *Universal Camera Corp.*, 340 U.S. at 488; *State Farm*, 463 U.S. at 43; 5 U.S.C. § 556(d).

ARGUMENT

I. The Government's Unexplained Decision To Adopt A Novel Test for Currently Accepted Medical Use Independently Demonstrates That It Cannot Carry Its Burden Of Proof

Even before any evaluation of the underlying scientific evidence, the Government's unexplained departure from its own longstanding analytical framework independently establishes that it has not carried its burden. An agency may not discard prior findings and analytical frameworks without providing a reasoned explanation. *Fox Television Stations,* 556 U.S. at 515; *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). The Government's only provided reasoning for abandoning its prior framework was the unbacked assertion that it was "impermissibly narrow." 48 Op. O.L.C. __, at *12 (Apr. 11, 2024). HHS's unexplained reversal on the currently accepted medical use ("CAMU") standard is the hallmark of arbitrary and capricious decision-making. On this basis alone, the ALJ should recommend against rescheduling.

HHS's recommendation represents a sharp and unexplained departure from the consistent analysis applied by both HHS and DEA across nine prior marijuana rescheduling proceedings. In those decisions, both agencies applied the established five-part test for currently accepted medical use—upheld by the D.C. Circuit as consistent with the CSA—and both concluded that marijuana lacked a currently accepted medical use because there was no consensus of medical opinion, no adequate and well-controlled studies proving efficacy, and no consistent chemical composition permitting reliable medical conclusions. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994); 81 Fed. Reg. 53,767, 53,778, 53,780, 53,836 (Aug. 12, 2016); 76 Fed. Reg. 40,552, 40,558, 40,560 (July 8, 2011).

The last formal rejection occurred in 2016. Much of the scientific literature now cited to support a different outcome was already available at that time. In the present recommendation, HHS abandons the five-part test without reasoned explanation and invents an entirely new, far more permissive two-part standard. HHS Rec. at 2, 21; FDA Memo (Aug. 28, 2023). It then applies that standard for the first time to any substance to determine that marijuana suddenly has a CAMU.

The doublespeak inherent in the new test is revealing. In the HHS Recommendation and in testimony, the Government repeatedly describes the clinical evidence that cannabis can treat any particular indication as "mixed" and "inconclusive." Under the five-part test that both agencies applied for decades, that characterization would have been fatal. Under the newly invented two-part test, the same "mixed" and "inconclusive" evidence is suddenly deemed "credible" scientific support. That is not a change in the science; it is a change in the standard—one that happens to favor the Government's preferred policy outcomes. This is unlawful. *See Chenery*, 318 U.S. at 94.

The Government's own witnesses confirm the game-changing magnitude of this departure. Dr. Dominic Chiapperino, the FDA scientist who supervised the eight-factor analysis, testified that he had applied the five-part CAMU test 127 times in scheduling other substances. Tr. Day 2, at 416. He further testified that the two-part test was "established in 2023," only two months before the analysis was completed, that FDA was "directed to use the two-part test," and that the five-part test was never written up or applied to marijuana in this proceeding. Tr. Day 1, at 53; Day 2, at 415–16, 419. When pressed on whether marijuana would have passed the five part test applied in every other scheduling action, Dr. Chiapperino conceded that the clinical studies "were not large enough to pass an FDA approval as an adequate, well controlled study," that marijuana's chemistry was "not" known and reproducible, and that "on the basis of the first element alone . . . it would have been difficult for marijuana to pass the five-part test." Tr. Day 2, at 429, 435–36. Asked to confirm that marijuana "would not have passed," he answered: "Would not have passed. Sure." *Id.* at 436.

Dr. Luli R. Akinfiresoye, a Ph.D. pharmacologist in DEA's Drug and Chemical Evaluation Section for over ten years, reached the same conclusion. She prepared a 2024 scientific evaluation applying the established five-part test because "it's been upheld in court previously" and was

"consistent with what [DEA had] always done." Tr. Day 6, at 1342, 1356.[2] She described the five-part test as "a more comprehensive test" and confirmed, factor by factor, that marijuana failed every element: chemistry known and reproducible; adequate safety studies; adequate and well-controlled studies proving efficacy; acceptance by qualified experts; and widely available scientific evidence. *Id.* at 1358, 1363, 1367, 1376–77. Like Dr. Chiapperino, she made clear that marijuana would not have passed the five-part test that both agencies had applied for decades.

Cross-examination of Dr. Chiapperino further revealed how little the two-part test requires. He confirmed that a positive finding may rest on a single favorable clinical study that need not be adequate, need not be well controlled, need not be well designed, need not demonstrate reproducible results, need not involve consistent chemistry, and need not meet the standard required for FDA approval. Tr. Day 2, at 374–75, 379, 382, 408, 463. He characterized Part 2 as "not as rigorous in the standard of evidence." *Id.* at 410, 429. As counsel observed, the data considered by the Government "would not have justified a finding of a currently accepted medical use under the test that FDA and HHS and DEA used in 2015, which is the only test that those entities had ever used up until this case. If you don't have stronger data, then how do you get to a different result? Well, we know. You change the test." Tr. Day 5, at 1180.

The manner in which this proceeding was initiated raises further serious concerns of predetermined outcome. Unlike every prior marijuana rescheduling petition, this review was not triggered by new scientific evidence submitted by a private party. It was directed by the President based on an explicit policy preference to loosen federal restrictions. *See Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/. The Government's

[2] See All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133 (D.C. Cir. 1994).

own witnesses confirmed that FDA was "directed to use the two-part test," that the test was created only two months before the analysis was completed, and that the established five-part test was never applied to marijuana in this proceeding. Tr. Day 1, at 53; Day 2, at 415–16, 419.

In summary, HHS invented a weaker CAMU test, applied an evidentiary bar so low that its own architect could not defend it under questioning, selectively omitted evidence critical in every prior proceeding, and produced an analysis whose lead scientist conceded would have reached the opposite conclusion under the established standard. An agency may not rearrange its standards and ignore inconvenient precedent to accommodate political preferences; such conduct violates the fundamental requirements of reasoned decision-making under the APA and the CSA. *Accardi*, 347 U.S. 260; *Withrow*, 421 U.S. 35; 5 U.S.C. §§ 556, 556(b).

As such, the Government cannot demonstrate that rescheduling of marijuana is warranted because its decision to use an unprecedented and unbacked two-part test for CAMU is arbitrary, capricious, and without any reasoned explanation.

II. The Government Did Not Meet Its Burden Of Proof Under Any Of The Statutory Factors For Rescheduling

As detailed above, the CSA contains three findings that the Department of Health and Human Services ("HHS") must make before rescheduling a substance to Schedule III. *See* 21 U.S.C. § 812(b)(3). The Government has not carried its burden of proof as to any of them.

A. Finding 1: The Government Failed to Prove Abuse Potential Is Lower Than Schedule I or II

Finding 1 requires HHS to evaluate marijuana's actual or relative potential for abuse and determine that the substance has a potential for abuse less than the drugs or other substances in Schedules I and II. As stated, with respect to Finding 1 (Abuse Potential), the NPRM and HHS Basis for Recommendation expressly rely on Factors 1, 4, 5, and 6. NPRM, 89 Fed. Reg. 44,597, 44,603-08 (May 21, 2024); 21 U.S.C. § 811(c) (listing factors).

At the outset, the Government failed to carry its burden on this finding. First, HHS employed a fundamentally mismatched set of comparators while abandoning the Schedule I hallucinogens that both HHS and DEA had treated as the relevant benchmarks in the 2011 and 2016 decisions. Second, the agency's assessment of relative risk rests on a rank-order metric that systematically ignores the characteristic harms of marijuana.

Either defect, standing alone, is sufficient to defeat the Government's showing under Factor 1. Even if those defects are not treated as independently dispositive, the subsequent examination of the underlying evidence HHS itself identified as supporting its recommendation demonstrates that the agency's conclusion remains weak, incomplete, and insufficient to support its burden under the substantial-evidence standard. The analysis that follows addresses both methodological failures in turn and then turns to that underlying evidence.

The Government's eight-factor data analysis for Finding 1—relying on NSDUH, NPDS, NEDS, TEDS, FAERS, NVSS-M, and related epidemiological databases—is systematically critiqued on a source-by-source basis in Exhibit A. That analysis demonstrates that (1) each dataset HHS relied upon suffers from fundamental methodological deficiencies, (2) more recent data uniformly cuts against HHS's conclusions, (3) HHS failed to consider clearly relevant evidence available in the record, and (4) substantial countervailing evidence from the hearing record—including testimony and exhibits admitted at the hearing—directly contradicts or undermines the Government's position on each source. The Designated Parties incorporate Exhibit A in full and urge the tribunal to review the detailed source-by-source critique therein. The tribunal should afford the Government's epidemiological presentation little, if any, weight.

a. The Government Used the Wrong Comparators

Under Factor 1, the abuse potential of a substance must be evaluated relative to other drugs. While HHS has discretion in selecting comparators, that discretion is constrained by the statute

itself. Factor 1 requires assessment of the substance's actual or relative potential for abuse in comparison to drugs already controlled in Schedules I and II. 21 U.S.C. § 811(c)(1). Before any weighing of the underlying epidemiological data, the Government failed to carry its burden on Factor 1 because it did not employ the proper comparators necessary to support a finding that marijuana's abuse potential is consistent with Schedule III placement.

The comparator set HHS selected for Factors 1, 4, 5, and 6 is grossly mismatched to the substance under review and constitutes an unexplained departure from the agency's own prior practice. For those factors, HHS relied primarily on heroin, fentanyl, oxycodone, hydrocodone, cocaine, and alcohol, along with limited reference to ketamine—high-overdose-mortality opioids and stimulants. HHS Recommendation at 6, 10; *see also* Tr. Day 1 at 74:17-22. Dr. Chiapperino confirmed this and stated directly that no other Schedule I substances were used as comparators. Tr. Day 1 at 244:5-7; 273:17–23.

HHS largely ignored the Schedule I hallucinogens and related compounds that both HHS and DEA treated as the relevant comparators in the 2011 and 2016 decisions. 76 Fed. Reg. 40,552, 40,561, 40,571 (July 8, 2011); 81 Fed. Reg. 53,767, 53,782, 53,825 (Aug. 12, 2016). Those earlier analyses benchmarked marijuana against MDMA, GHB, LSD, and PCP, along with other hallucinogens and inhalants. *Id*. This is not a small detail.

Marijuana is itself classified within the CSA's hallucinogen category, a point Dr. Chiapperino confirmed on cross-examination. When counsel asked, "when you're looking for appropriate comparators, ideally, you look to drugs in the same pharmacological class, correct," Dr. Chiapperino answered, "Yes." When asked, "Which, in the case of marijuana, is hallucinogens, correct," he answered, "It is controlled under the CSA paragraph for hallucinogens, yes." Tr. Day 2 at 534:1-13. Shockingly, however, the comparator set did not include the hallucinogens

psilocybin, LSD, peyote, mescaline, MDMA, and DMT, Schedule I substances, and PCP, Schedule II. 21 U.S.C. § 812; 21 C.F.R. § 1308.11. Dr. Chiapperino further admitted that several Schedule I hallucinogens do not share the overdose profile that dominated HHS's metrics—making overdose an irrelevant metric when considering rescheduling of a hallucinogen. Tr. Day 2 at 532:22–533:6.

Had HHS included the broader universe of hallucinogens as comparators, consistent with its own 2011 and 2016 methodology, the relative-risk conclusion would indisputably have been reversed rather than confirmed. HHS's own TEDS data shows that hallucinogens as a class, a group encompassing more than forty Schedule I substances, accounted for only 0.13% of all substance-abuse treatment admissions (1,899 out of approximately 1.4 million), compared to 139,481 admissions, or roughly 73 times as many, for marijuana. NPRM, 89 Fed. Reg. at 44,611; Exhibit A at 12–14.

Similarly, CDC WONDER mortality data shows only 25 total overdose deaths involving LSD or other unspecified hallucinogens in 2021, compared to 1,159 deaths involving cannabis derivatives in the same year, a disparity of roughly 46 to 1. HHS Rec. at 52–53; 89 Fed. Reg. at 44,612; Exhibit A at 23–25. The notion that marijuana has "lower" abuse potential than these co-scheduled substances is not merely unsupported; it is contradicted by every available metric. When marijuana is compared to the substances with which it actually shares a schedule and pharmacological classification—Schedule I hallucinogens—the Government's conclusion falls apart.

Dr. Bertha Madras of Harvard Medical School, one of the world's foremost experts on drug abuse liability,[3] testified unequivocally that cannabis was higher in likelihood of abuse than "hallucinogens in general" and specifically LSD and MDMA. Tr. Day 10 at 2264:19–23; 2265:5–6; 2265:9–10. Comparing marijuana to other Schedule I substances on psychosis risk further demolishes the Government's position. Tr. Day 10 at 2274:5-17 (Dr. Madras testifying that "[t]he risk of developing schizophrenia seems to be highest with cannabis relative to other drugs"). Dr. Finn's testimony corroborated this conclusion, explaining that cannabis use disorder now affects up to 30 percent of users—"rates that meet or beat alcohol and opioids"—and that the threat from marijuana is compulsive escalation to high-potency products leading to psychosis. Tr. Day 7 at 1517:23–1518:8.

HHS's own 2016 analysis explicitly cautioned against exactly the kind of comparison it now relies on. HHS and DEA jointly concluded in 2016 that "comparisons between marijuana and the diverse array of Schedule II substances is difficult, because of the pharmacologically dissimilar actions of substances in Schedule II of the CSA," expressly noting that opioids like oxycodone and fentanyl, stimulants like cocaine, and dissociative anesthetics like PCP have mechanisms of

---

[3] In *United States v. Pickard*, 100 F. Supp. 3d 981 (E.D. Cal. 2015), DEA Ex. 2D at 54, the United States defended marijuana's Schedule I classification against a constitutional challenge and called a single expert to do so: Dr. Bertha Madras, a professor of psychobiology at Harvard Medical School. *Id.* (citing Madras Decl. ¶ 1, ECF No. 324). Dr. Madras served as Deputy Director for Demand Reduction for the White House Office of National Drug Control Policy from 2005 to 2008, *id.* ¶ 6, has testified before legislative bodies on proposed medical marijuana bills, and has presented to government agencies internationally, *id.* ¶ 8. She had not conducted studies with marijuana in human subjects. *Pickard*, Hr'g Tr. 754–55, 827. She opined "that the science strongly supports a conclusion that marijuana has a high potential for abuse, has no currently accepted medical use in the United States, and that sufficient assurances of safety for use of marijuana under medical supervision are lacking." Madras Decl. ¶ 13

action "wholly different from one another, and they are different from tetrahydrocannabinol (THC) and marijuana as well." 81 Fed. Reg. at 53,706-07. That same analysis concluded that because the mechanisms of action of Schedule II substances are "completely different" from marijuana's cannabinoid-receptor mechanism, "the differences in the mechanisms of action in the various classes of Schedule II substances make it inappropriate to compare the range of those substances with marijuana." *Id.*

Dr. Akinfiresoye's independent five-factor evaluation likewise never adopted this comparator set, further underscoring that this methodology reflects a choice specific to the two-part test's proponents rather than a course DEA's own scientific staff would have taken. Tr. Day 6 at 1339-41, 1362-63.

Alcohol is an especially inappropriate comparator, and HHS's own recommendation concedes as much. HHS acknowledged that "although alcohol is well known to be abused, it was explicitly exempted from control under the CSA when it was enacted," and that "[t]ypically, substances that are not controlled under the CSA are not utilized as comparator drugs for scheduling placement considerations because they may not have been formally evaluated for abuse potential in standard preclinical and clinical abuse-related studies." HHS Recommendation at 6. HHS included alcohol anyway, over its own stated methodological reservation, "because of its extensive availability and use in the United States." *Id.* Neither HHS nor DEA used alcohol as a benchmark for scheduling decisions in the 2011 or 2016 proceedings. Alcohol is, in any event, entirely irrelevant—its analysis in the agency's recommendation should be entirely disregarded as Factor 1 requires only an assessment of relative potential for abuse compared to substances controlled in Schedules I and II. The only rational purpose served by including alcohol was to

make marijuana appear comparatively benign by association with a substance notorious for its harms but exempt from the scheduling framework entirely.

The agency's decision to abandon the Schedule I hallucinogen comparators it had previously employed, substitute a set of high-mortality opioids and stimulants its own prior analysis said were pharmacologically inappropriate for comparison to marijuana, and add an unscheduled substance it acknowledged was methodologically atypical, all without reasoned explanation, is arbitrary and capricious. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). A true relative analysis under Factor 1 requires comparison to substances with comparable pharmacological and risk profiles. Because the Government's relative-abuse and public-health findings rest on this distorted comparator set, those findings cannot be supported by substantial evidence when the record is viewed as a whole. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). The selective choice of comparators therefore constitutes an abuse of discretion that independently undermines the Government's ability to carry its burden of proof on the core findings required for Schedule III placement. HHS offered no reasoned explanation for reversing this long-standing analytical framework. That failure alone renders its Finding 1 arbitrary, capricious, and unlawful.

b. The Government's Factor 1 Assessment Rests on a Fundamentally Flawed Metric

In the critical section of its analysis supporting a Schedule III recommendation, HHS concluded that although marijuana has a high prevalence of nonmedical use, its "profile of and propensity for serious outcomes" is sufficiently limited to justify Schedule III rather than Schedule I or II placement. In support, HHS stated:

> To illustrate this point, when a rank ordering of selected drugs that are abused was compared for various epidemiological measures, it showed that marijuana was

> among the drugs at the very lowest ranking for: poison control abuse cases, likelihood that any use would lead to a poison control call, accidental/unintentional poisoning, utilization-adjusted rates of unintentional exposure, utilization-adjusted and population-adjusted rates for ED visits and hospitalizations, likelihood of being diagnosed with serious SUD, deaths reported to poison control centers, and overdose deaths when used with other drugs or as a single substance (as total numbers and when utilization-adjusted). By contrast, heroin, oxycodone, and cocaine typically occupy the highest ranks.
>
> HHS Rec. at 9–10.

Before examining the details of that rank-order exercise, one inexplicable and glaring methodological defect must be noted—a defect so pronounced, it is difficult to overstate how thoroughly it undermines the entire analysis. Specifically, the agency's comparative assessment of "serious outcomes" is built exclusively on metrics that systematically ignore the characteristic harms of marijuana.

Put simply, HHS disregarded the evidence of the harms marijuana is known to produce—addiction, serious mental illness (including psychosis and schizophrenia), harm to developing brains, depression and suicidality, cognitive impairment, and short- and long-term cardiovascular injury—and instead evaluated marijuana solely against the acute harms characteristic of cocaine and heroin (overdose, acute poisoning, and emergency utilization). HHS Rec. at 9–10, 62–63; Exhibit A at 25–31.

This is analogous to comparing the public-health dangers of cigarettes to those of another substance while ignoring the risk of lung cancer. Or, flipping the analysis, evaluating fentanyl relative to marijuana and concluding that fentanyl is less dangerous solely because it produces far

lower rates of conversion to schizophrenia, while ignoring overdose deaths. This indefensible and tendentious approach is so characteristically manipulative and has so long been used as a form of sophistry that it has a name denoting a recognized form of fallacious thinking: it is a category error. In other words, the problem is evaluated using measures that belong to an entirely different kind of problem.

When the characteristic harms of marijuana are properly considered, the public-health risk and potential for abuse are stark and catastrophic. On psychosis, Dr. Madras testified that the association with schizophrenia is "extremely strong," with odds ratios rising from two to four to six as use starts younger, becomes more frequent, and involves higher-potency products, and that most psychiatrists view cannabis as a component cause, not mere association. Tr. Day 5 at 1262:18–1264:8. The Hjorthøj Danish cohort of nearly 6.9 million people estimated that up to 30 percent of schizophrenia cases in young men aged 21–30 are attributable to cannabis use disorder. Dr. Finn Ex. 15 at 1, 6; Tr. Day 7 at 1646:22–1647:9; Tr. Day 7 at 1517:9–14.

The EU-GEI study found daily high-potency cannabis (THC ≥10%) carried an adjusted odds ratio of 4.8 for psychotic disorder, and that eliminating high-potency cannabis could prevent 12.2 percent of first-episode cases overall, 30.3 percent in London, and 50.3 percent in Amsterdam. Dr. Finn Ex. 17 at 1–2, 6. Controlled laboratory administration of THC induced dose-dependent psychosis-like symptoms in healthy volunteers, and conversion from cannabis-induced psychosis to chronic schizophrenia exceeds that of any other substance. Tr. Day 10 at 2253:6–17, 2271:4–25, 2280:19–2281:9. As if broadcasting that this omission was knowing and deliberate, HHS's 2023 review nevertheless omitted the entire seven-paragraph discussion of psychosis that appeared in its own 2015 analysis. *See* Exhibit A at 26–27.

On depression and suicidality, a JAMA Psychiatry meta-analysis of 23,317 individuals found adolescent cannabis use significantly raised odds of later depression, suicidal ideation, and suicide attempts. Dr. Finn Ex. 35 at 1, 4. Multiple systematic reviews confirm the link. Tr. Day 7 at 1654:23–1655:13. In Colorado, marijuana is the number-one substance in completed teen suicides, far ahead of alcohol: "Marijuana is now the number one substance found in completed teen suicide in the state of Colorado. Historically, it was alcohol. Around 2012, that data flipped." Tr. Day 7 at 1659:7-13, 1660:14–16; 2131:19–21, 2132:13–17. Toxicology data from the Colorado Violent Death Reporting System confirm that marijuana now exceeds alcohol in youth suicides by a ratio of more than two to one. Wood Ex. 45 at 33–34.

Among veterans, cannabis use disorder was associated with a 68 percent increase in suicidal ideation and a 230 percent increase in lifetime attempts even after controlling for PTSD and depression. Tr. Day 9 at 1967:11–20. Shi & Li (2025) examined national data and found cannabis use associated with 83% increased odds of suicide (aOR=1.83). Dr. Finn Ex. 47. National cannabinoid prevalence in suicide fatalities tripled from 8% in 2006 to 23% in 2017. *Id.* With approximately 49,000 annual suicides in the United States, a 23% THC-positive rate implies over 11,000 annual suicides associated with marijuana. Exhibit A at 30–31. That figure dwarfs the 5,957 total overdose deaths involving marijuana that HHS cites over a full decade (2012–2021). HHS Rec. at 52–53. Yet HHS did not analyze, or even acknowledge, this pathway. None of these outcomes appears in HHS's ranking.

On cardiovascular harm, a 2024 Journal of the American Heart Association study of over 430,000 adults found daily cannabis use is associated with a 25 percent increase in myocardial infarction and a 42 percent increase in stroke after controlling for tobacco and other risk factors. Tr. Day 9 at 1949:3–1950:7. A 2025 analysis of four million records found users aged 18–50 had

six times higher odds of heart attack, four times higher odds of ischemic stroke, double the risk of heart failure, and three times the risk of a major cardiovascular event. Tr. Day 4 at 843:6–844:17. The Government's own witness conceded that HHS never specifically considered chronic marijuana use and adverse cardiac events. Tr. Day 2 at 360:15–361:7. An analysis that "never specifically considered" cardiovascular morbidity and mortality for a substance now used daily by 17.7 million Americans cannot constitute "substantial evidence" of anything relating to that substance's risk to public health.

Finally, the analysis is silent on cannabis-impaired driving. Three peer-reviewed studies each found roughly two additional traffic fatalities per billion vehicle miles traveled after recreational commercialization, projecting more than 6,000 additional deaths annually if expanded nationwide. Tr. Day 6 at 1443:6–18. Washington State THC-positive driver fatalities more than doubled in the first year of commercialization while total fatalities also rose. Tr. Day 6 at 1456:6–24. In Colorado, traffic fatalities with marijuana-positive drivers rose from 55 in 2013 to 131 in 2020. Wood Ex. 45, at 5–7. No reliable roadside test for THC impairment exists. These preventable deaths fall entirely outside HHS's overdose-focused metrics. The Government "entirely failed to consider drugged driving safety implications of rescheduling" and that neither HHS nor DEA directly addressed this risk. Tr. Day 6 at 1440:21–25; 1442:11–25.

Edward Wood, founder of DUID Victim Voices, put a human face on those statistics. He testified that his son Brian—a talented video game designer whose wife was eight months pregnant—was killed instantly in 2010 when two drug-impaired drivers, both positive for marijuana and methamphetamine, lost control of their vehicle on a Washington State highway. The vehicle went airborne and crashed through Brian's windshield. Brian never knew he was the father of the baby girl he wanted. Tr. Day 6 at 1431:21–1438:5. Wood testified that rescheduling

would "dramatically increase the consumption of marijuana" and therefore the number of impaired-driving fatalities. Tr. Day 6 at 1438:13–18.

As Edward Wood's testimony demonstrates, the epidemiological data is not abstract. It manifests daily in clinical settings and in the destroyed lives of real families. The record contains the firsthand testimony of a front-line psychiatrist and sworn affidavits from dozens of parents whose children were ruined—and who themselves were left immiserated—by precisely the harms HHS elected not to measure.

Dr. Elizabeth Stuyt, a board-certified psychiatrist with more than three decades of experience treating co-occurring disorders, served for twenty years as medical director of Colorado's only long-term inpatient program for patients who had failed every other level of care. After commercial dispensaries opened in 2014, she began seeing clinical presentations she had never encountered: "the worst psychosis, fixed delusions, and violence I had encountered—worse than what I had seen from methamphetamine or alcohol." Patients arrived cognitively impaired by high-THC products, suffered intense withdrawal, and clung to the belief that cannabis was "medicine." She treated young people with fixed delusions that the CIA had implanted electrodes in their brains. While she has seen drug-induced psychosis from methamphetamine, cocaine, and alcohol, "the worst psychotic symptoms in my experience accompany CUD." Many of those patients progressed to lifelong schizophrenia or bipolar disorder. Dr. Finn Ex. 110 (Stuyt Aff.) ¶¶ 13, 22–23.

The parent affidavits compiled by Laura Stack of Johnny's Ambassadors reveal the same pattern, repeated across states and family backgrounds: a previously healthy, high-functioning adolescent or young adult begins using high-potency cannabis, progresses to concentrates, develops cannabis use disorder, descends into psychosis marked by paranoia and fixed delusions,

and either dies by suicide during a psychotic episode or converts permanently to schizophrenia or bipolar disorder. In case after case there is no prior psychiatric history. Physicians repeatedly confirm the psychosis was cannabis-induced. The young person cannot stop. Stack Ex. 2–86; Tr. Day 7 at 1718–23.

Stack's own son followed that trajectory. An honor-roll student and scholarship recipient, he began using at fourteen, progressed to 80–90 percent concentrates, developed cannabis-induced psychosis, and jumped from a six-story building at age nineteen. Tr. Day 7 at 1692–1714. Three days before his death he told his mother: "You told me weed would hurt my brain, and it's ruined my mind and my life. You were right all along." Tr. Day 7 at 1711:1–6.

The pattern recurs without meaningful variation. A Connecticut son suffered a catastrophic psychotic break after purchasing high-potency flower from a licensed dispensary; Yale Psychiatric Hospital physicians were "unequivocal" that the break would not have occurred without high-potency cannabis and reported that most young adult males presenting there are psychotic from marijuana alone. Stack Ex. 16. Two Pennsylvania brothers, using high-THC wax and dabs, each cycled through more than a dozen facilities; both converted from cannabis-induced psychosis to permanent serious mental illness and now receive Social Security disability. Stack Ex. 76. A successful engineer has been involuntarily hospitalized six times for psychosis, each time with cannabis as the only drug in his system. Stack Ex. 42. An Army veteran with two college degrees left a suicide note stating: "Marijuana killed my soul + ruined my brain." Stack Ex. 36. A nineteen-year-old put a gun to his head after five years of heavy use that "destroyed [his] mental health and drove him into psychosis." Stack Ex. 13.

These are not rare cases. They are the predictable, recurring human consequences of a substance whose characteristic harms—addiction, mental health destruction, and devastating life

consequences—HHS simply chose not to count, an omission explainable only by blind incompetence or design.

Moreover, HHS's heavy reliance on utilization-adjusted rates is utterly misplaced. A utilization rate merely measures the likelihood of a serious outcome per use. In short, it answers a question almost no one is asking. The agency has told us nothing the world did not already know: a single episode of marijuana use is far less likely to kill the user than a single episode of fentanyl or heroin use. That fact does not meaningfully illuminate the public-health threat. The proper inquiry is not the danger of any one isolated exposure. It is the aggregate harm—or, in other words, how many people are dying, becoming severely psychiatrically impaired, or having their lives profoundly damaged as a result of each substance. Marijuana's vastly higher prevalence and frequency of use more than offset its lower per-episode lethality. Relying on utilization-adjusted metrics is akin to declaring commercial aviation more dangerous than driving because a single plane crash is more likely to be fatal, while ignoring the far greater number of deaths that actually occur as a result of driving.

HHS, and anyone else willing to consider the point, knows full well that if it applied the same analysis (evaluating a substance solely through the lens of the acute dangers most characteristic of opioids and cocaine) to any Schedule I or II hallucinogen (LSD, mescaline, and the like), it would reach the identical result. In fact, it nearly admits as much. After extending the comparison to Schedule III (ketamine) and Schedule IV substances (benzodiazepines, zolpidem, tramadol) as well as additional Schedule II drugs (fentanyl, hydrocodone), HHS acknowledges that the resulting rank orders do not consistently align with existing CSA scheduling, yet nevertheless concludes that the overall profile of serious outcomes supports Schedule III placement for marijuana.

When the chosen metrics produce rankings that systematically fail to track existing schedules, the proper inference is not that the schedules are wrong and must be revised to match the rankings. The proper inference is that the metrics are inadequate to the regulatory task. They do not capture the dependence liability, psychiatric morbidity, developmental risk, and chronic harms that the CSA requires the agency to evaluate. Using those same mismatched rankings to "reconcile" the data and place marijuana in Schedule III is circular: the agency first selects outcomes poorly suited to marijuana's pharmacology, observes that the resulting hierarchy diverges from current schedules, and then treats that divergence as evidence that marijuana's schedule should change.

In short, the rank-order analysis does not demonstrate that marijuana's abuse potential and harm profile are most appropriately controlled in Schedule III. It demonstrates only that acute-toxicity metrics, applied across pharmacologically dissimilar substances, yield inconsistent and incomplete results. Under the CSA, the agency must evaluate marijuana according to the ways in which it produces dependence, serious adverse effects, and public-health risk—not according to the ways in which opioids and stimulants produce theirs. The present analysis fails that requirement.

Dr. Chiapperino's own admissions confirm that the comparator selection was outcome-determinative, as he conceded that even though DEA "look[s] to drugs in the same pharmacological class" when finding appropriate comparators, and even though marijuana was "controlled under the CSA paragraph for hallucinogens," no hallucinogens were included as comparators. Tr. Day 2 at 534:1–13. In other words, HHS (1) chose metrics that primarily capture opioid and stimulant harms; (2) chose opioids and stimulants as comparators; (3) found that marijuana produces fewer opioid-type and stimulant-type harms than opioids and stimulants; and

(4) concluded that marijuana therefore has lower abuse potential. That tautological line of thinking is irrelevant to whether marijuana should be rescheduled.

c. Regarding Factor 4, Marijuana Use Has Reached Unprecedented Levels

Regarding Factor 4, the most alarming indicator of marijuana's abuse trajectory is the explosion of daily and near-daily use—the consumption pattern most strongly associated with cannabis use disorder, cognitive impairment, psychosis, and physical dependence. By 2022, 17.7 million Americans reported daily or near-daily marijuana use, compared to 14.7 million daily or near-daily alcohol users. Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 42; Wood Exs. 44, 70. This represents a twentyfold increase from 0.9 million daily users in 1992.

Dr. Finn, drawing on his clinical experience treating chronic pain patients in Colorado, testified that this unprecedented escalation in daily use is a clinical reality he witnessed firsthand as patients presented with compulsive, high-frequency marijuana consumption patterns. Tr. Day 7 at 1586. The Caulkins study, presented through Wood's testimony, spanning more than 1.6 million survey respondents from 1979 to 2022, confirmed that daily and near-daily use increased approximately fifteenfold between 1992 and 2022, with clear inflection points at 1996 (California medical marijuana), 2009 (Ogden memo), and 2014 (commercial retail). Tr. Day 6 at 1445-47; see also Dr. Finn Ex. 109 (Rossheim Aff.) ¶¶ 40-41.

Wood testified that "[a]ny reasonable person looking at this would expect that if you now change the schedule of a drug from Schedule I, being the most dangerous category we have, to Schedule III saying, let's bless this as a medicine … any reasonable person would expect that will increase more." Tr. Day 6 at 1447:9–12. Yet HHS failed to analyze this critical metric. When asked for marijuana's 21+ day use rate, Dr. Chiapperino was unable to provide it. Tr. Day 1 at 272:4-7. He conceded that daily use is "one of the most important considerations" for cannabis use disorder (Tr. Day 1 at 271-72). HHS simply did not analyze it. See Exhibit A at 6.

HHS's failure to account for this unprecedented escalation is independently fatal. An agency cannot carry its burden under the substantial evidence standard while ignoring the most probative measurement of the very thing it is evaluating.

The most direct measure of problematic use—the rate of cannabis use disorder among users—has exploded. See Tr. Day 7 at 1517:23–1518:1. Dr. Finn explained that the threat from addiction "is not through withdrawal that's rough, or calls to poison control, or overdose counts. The threat is that the steady use—more and more, and higher and higher potency—leads to disease, most starkly in the form of psychosis." Tr. Day 7 at 1517:3–8.

A substance that now addicts a quarter to a third of its users—a rate approaching that of tobacco—cannot rationally be found to have abuse potential lower than Schedule I hallucinogens, most of which produce no physical dependence whatsoever.

d. Conclusion as to Finding 1

The Government has failed to carry its burden of proving Finding 1. The record evidence, properly analyzed, demonstrates the following:

- Factor 1: HHS employed a methodologically indefensible comparator set that violated basic pharmacological principles, departed from its own prior practice without explanation, and was structurally designed to minimize marijuana's apparent abuse potential. When the correct comparators—Schedule I hallucinogens—are employed, marijuana's abuse potential is demonstrably higher, not lower.
- Factor 4: Every metric of use patterns—prevalence, frequency, daily use, persistence, and cannabis use disorder rates—shows dramatic escalation while comparator drugs decline. HHS relied on stale data, failed to analyze the most critical metric (daily use), and ignored survey limitations that systematically undercount the most severely affected populations.

- Factor 5: As demonstrated in Exhibit A, poison control exposures, emergency department visits, and treatment admissions all show escalating—not diminishing—harms. Utilization-adjusted metrics show marijuana exceeding alcohol and approaching cocaine in emergency severity. Pediatric poisonings are increasing by thousands of percent. Single-substance data confirm these harms are attributable to marijuana alone. *See* Exhibit A (NPDS, NEDS, TEDS, and related tables).
- Factor 6: HHS ignored marijuana's primary lethal pathways—suicide, psychosis, cardiovascular disease, and impaired driving—by confining its analysis to acute overdose metrics. The unrebutted evidence in the record demonstrates over 11,000 associated suicide deaths annually, a causal relationship with schizophrenia affecting up to 30% of young male cases, dramatically elevated cardiovascular risk, and projected thousands of additional traffic fatalities with nationwide commercialization.

Each of these failures independently defeats Finding 1. Together, they demonstrate that HHS's recommendation rests on methodological error, selective data presentation, wholesale analytical omission, and unjustified departure from prior agency practice. The Government has not merely failed to provide substantial evidence for Finding 1—the record affirmatively refutes it. This tribunal should so find.

B. Finding 2: The Government Failed to Prove Currently Accepted Medical Use

To carry its burden on Finding 2, the Government must demonstrate by substantial evidence that marijuana has a "currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3)(B). It has failed to do so.

As demonstrated in Section I, HHS's reversal of its consistent three-decade CAMU determination rests not on new science but on the invention of a permissive two-part standard that has no basis in the CSA, DEA regulations, or binding precedent. That analysis need not be repeated

here. What follows addresses the substance of the Government's CAMU finding on the merits, including its reliance on Factors 2 and 3 of the eight-factor analysis.

The Government's own evidence, examined under any rigorous framework, reveals fatal deficiencies: (1) no widespread acceptance of marijuana as medicine by the medical profession; (2) no credible scientific evidence establishing efficacy for "pain"—the Government's strongest claimed indication; (3) systematic disregard of safety risks that would ordinarily preclude a finding of accepted medical use; and (4) an unbridgeable mismatch between the narrow, controlled preparations actually studied and the vast statutory category of "marijuana" proposed for rescheduling.

As a threshold matter, state-program usage does not constitute medical consensus. The Government's Part 1 equates "widespread current experience" in state-authorized programs with accepted medical practice. But these programs involve a tiny fraction of physicians, operate without prescriptions specifying dose or route, and are dominated by certification mills. The perverse consequence of HHS's revised standard is that it incentivizes state programs to act in ongoing defiance of the CSA to manufacture evidence of a CAMU—a result manifestly at odds with the statute's purpose. *See* Tr. Day 7 at 1515:17–23; 1592–1594; 1617–1618.

a. The Government's CAMU Finding Cannot Support Schedule III

The government's CAMU finding rests on an evidentiary foundation that cannot support the schedule placement it seeks. HHS built its conclusion exclusively from clinical studies of low-potency preparations, yet the rescheduling it recommends would apply to the entire statutory category of marijuana under 21 U.S.C. § 802(16)(A). As discussed, that category is deliberately capacious, including high-potency concentrates, novel formulations, street cannabis, cannabis beer and other infused beverages, and mixtures such as cannabis mixed with alcohol or dusted with Xanax. The overwhelming majority of these products, however, were never studied and bear little

resemblance to those examined in the trials. What "credible" evidence was entered into the record that a 90% delta-9 THC concentrate product was medicine? What "credible" evidence was entered into the record that beer infused with delta-9 THC was medicine?

Dr. Finn testified that the clinical studies FDA and HHS relied upon used THC concentrations ranging from approximately 3.5 percent to a maximum of 10 percent, levels the researchers themselves considered "too high," while dispensary marijuana now routinely contains 15 to 20 percent THC and concentrates reach as high as 90 percent. Tr. Day 5, at 1232-33. He stated that these studies "don't resemble what's in dispensaries at all currently." *Id*. at 1233. Dr. Finn further testified that HHS reviewed 27 randomized controlled trials for pain, 18 of which showed no benefit and 1 showed worsening—meaning "two-thirds of the studies they looked at showed no benefit in pain." Tr. Day 7 at 1624–25. Counsel underscored the point: "dispensary products swing wildly from very little THC to concentrates north of 90 percent and from products with very few chemical components to products with hundreds, and this is where the government's case breaks down," because "the reviews the FDA leaned on never studied the actual products on the shelves." Tr. Day 7, at 1516. *See* Exhibit A at 25–26 (documenting HHS's failure to account for modern THC potency in its pharmacological analysis).

Under the substantial evidence standard, the agency must show that the whole record supports the finding actually made. *Universal Camera Corp.*, 340 U.S. at 488. A finding that the broadly defined category of "marijuana" has a currently accepted medical use cannot rest on studies of 3.5 to 10 percent THC preparations when the category includes products exceeding 90 percent THC, street-level material, and drug mixtures for which the record shows no clinical evidence. The evidence simply does not extend to the full breadth of the product category the government seeks to reschedule in a single undifferentiated action.

The problem is foundational. Cannabis as a statutory class is too broad and chemically varied to support a single CAMU determination. The Government's approach "is the equivalent of saying drinking a handle of Wild Turkey may have a medical application because there are some inconclusive and highly contested studies that a glass of red wine is good for your heart." Tr. Day 7 at 1516:21–25. Even if carefully controlled, low-potency preparations of some component parts of the cannabis plant may have medical utility, that cannot support a CAMU determination for a capacious statutory category dominated by high-potency, chemically complex, and often adulterated products that were never studied.

This mismatch supplies an independent basis to conclude that the Government has not carried its burden. Substantial evidence of medical application is required for the substance being rescheduled, not merely for some tiny subset of products within a chemically heterogeneous class.

Dr. Akinfiresoye's testimony supports this position. She testified that marijuana failed the fourth factor (acceptance by qualified experts) because "marijuana is not a drug. It's not an approved drug. It's not a drug. As such it cannot—it does not have—a doctor cannot write a prescription for it." Tr. Day 6, at 1376. When asked whether "because it's not a molecule, it can't pass the test," she agreed: "It could if you find—if it becomes a drug, but it's not a drug. So, yeah, I don't see how it can." *Id*. Her framing distinguishes a "drug," understood in medical terms, as a defined chemical entity or molecule, from marijuana, an undifferentiated botanical material containing over 600 distinct compounds. Tr. Day 9, at 1902. That distinction is corroborated by the separate scheduling of single-molecule products such as dronabinol (Marinol and Syndros), Cesamet, and Epidiolex, which FDA and DEA treat as chemically distinct from marijuana itself even though, as Dr. Chiapperino acknowledged, dronabinol is "chemically identical to compounds in marijuana." Tr. Day 2, at 482.

The statutory definition of "marijuana" under 21 U.S.C. § 802(16)(A) does not identify a single active chemical entity but an entire botanical organism and everything derived from it. Treating this heterogeneous mixture of compounds, present in wildly varying ratios and concentrations, as one drug with one uniform pharmacological profile and one CAMU determination is analytically incoherent and provides an insufficient basis upon which to carry the Government's burden under a whole-record, substantial-evidence standard. *Universal Camera Corp.*, 340 U.S. at 488; Tr. Day 6, at 1362-63, 1367, 1376-77.

With those defects established, the analysis turns to Factors 2 and 3—the "scientific evidence of [the drug's] pharmacological effect" and "the state of current scientific knowledge regarding the drug"—which bear directly on whether marijuana satisfies the CAMU requirement. 21 U.S.C. § 811(c)(2), (3). On the whole record, the Government has not met its burden.

b. No Widespread Medical Experience

The Government's Part 1 analysis rests on the premise that "widespread current experience with medical use" at the state level is a valid proxy for accepted medical use under the CSA. The Government's own data refute that premise. The numbers do not show that the medical profession has accepted marijuana; they show only that a small fraction of the population uses marijuana under the loose rubric of state programs, and an even smaller fraction of physicians participate.

i. The Registered Patient Population Is a Tiny Fraction of the United States

HHS concluded in Part 1 that more than 30,000 health care practitioners ("HCPs") are authorized to recommend marijuana for more than six million registered patients. HHS Rec. at 81–83. But six million registered patients represents approximately 1.8% of the U.S. population—hardly a foundation for concluding that the medical profession has embraced marijuana as an accepted treatment.

More critically, the National Survey on Drug Use and Health ("NSDUH") data presented in the HHS Recommendation itself demonstrates that the vast majority of marijuana users do not use the substance under medical guidance. In 2021, of 43.784 million past-year marijuana users, 85.8% (37.572 million) reported nonmedical use only. A mere 4.502 million (10.2%) reported use only as recommended by an HCP, and 2.750 million (6.3%) reported both medical and nonmedical use. HHS Rec. at 127. These figures reveal that even among the already-small population of marijuana users, medically recommended use is a marginal phenomenon.

HHS's International Cannabis Policy Study ("ICPS") data further undermines the Government's position. Among self-identified exclusive medical cannabis users, only 56.8% had ever asked a licensed health professional for a recommendation. HHS Rec. at 122. Thus, nearly half of those who call their use "medical" have never even consulted a health professional about it. This is not the hallmark of accepted medicine.

ii. Physician Participation Is Negligible

The hearing evidence conclusively established that only a vanishingly small percentage of physicians participate in state medical-marijuana programs. Dr. Kenneth Finn, a board-certified physician specializing in pain medicine and physical medicine and rehabilitation who has practiced for more than three decades and served as past President of the American Board of Pain Medicine, testified at length regarding the structure and reality of state programs. Tr. Day 7 at 1514–16; 1594. He is the chief editor of the first comprehensive peer-reviewed medical reference ever written on the subject, *Cannabis and Medicine: An Evidence-Based Approach*. *Id.* at 1514. His testimony was unrebutted on this point.

Dr. Finn testified that physician participation rates are as follows: approximately 3.4% of active physicians in New York publicly participate in the state medical marijuana program; just 3.6% of direct-care physicians in Florida are approved to order medical marijuana; and under 2%

of all licensed Colorado physicians issue marijuana recommendations. Tr. Day 7, at 1617–1618. Counsel's opening statement for Dr. Finn underscored the point: "In New York and Florida, a little over 3 percent of physicians take part in the medical program. In Colorado, under 2 percent. In Colorado, 3 physicians, 3 out of more than 17,000 licensed state physicians, wrote a quarter of all marijuana recommendations in a single year." Tr. Day 7 at 1515:17–23.

Even more telling is the extreme concentration of recommendations among a handful of high-volume certifiers. Dr. Finn testified that in Colorado, three physicians made more than one-fourth of all marijuana recommendations in 2022. In Florida, 88% of medical certifications came from just 21% of qualified physicians. In Oregon, nine doctors approved more than half of the state's medical marijuana patients. Tr. Day 7, at 1617–1618. Dr. Finn and his counsel identified this prescribing pattern for what it is: "the profile of a pill mill." Tr. Day 7 at 1515:6–7. This is not the pattern of a substance that has been accepted by the medical profession; it is the pattern of a certification mill that commoditizes access without meaningful clinical engagement.

iii. State-Program Recommendations Are Not Medical Practice

Dr. Finn's testimony established that state-program recommendation patterns bear no resemblance to ordinary medical practice. He testified that marijuana is typically "recommended," not prescribed; that there is no prescription specifying dose, frequency, route of administration, or strength; that in Colorado even an optometrist—not a physician—can recommend marijuana; and that his own Colorado medical-marijuana card was approved for "severe pain" in approximately sixty seconds via telehealth without any meaningful clinical review. Tr. Day 7, at 1592–1594, 1608–1618. Because marijuana is dispensed without the information contained in a valid prescription or an FDA package insert, physicians who recommend it lose the informational

protections they would have when prescribing an FDA-approved medication, exposing them to liability.[4]

Dr. Finn recounted his personal experience investigating Colorado's program via a telehealth encounter with a doctor licensed to provide him marijuana: "She never asked about prior treatments, about what medication I may be on, if I have had any imaging of my knee, and if I did what the results were. She never asked whether I had minimal, mild, moderate, or severe pain." Tr. Day 7, at 1592–1594. The entire encounter lasted approximately sixty seconds. This is not a bona fide doctor-patient relationship; it is rubber-stamping.

HHS itself acknowledged that it could not conclusively determine whether HCP clinical experience was sufficient to evaluate longer-term toxicities and potential harms. HHS Rec. at 83,

[4] The April 2026 Attorney General's Order compounds this problem by affirmatively displacing the federal prescribing framework. On April 22, 2026, the Acting Attorney General issued a final rule placing FDA-approved marijuana-containing drug products and state-licensed medical marijuana into Schedule III. Tr. Day 1 at 8:1–18, 22–25; 9:1–25. That Order provides that "[n]otwithstanding Part 1306 or any other provision of these rules," a certification or other document that state law deems sufficient to obtain marijuana for medical purposes "shall be sufficient to permit dispensing of marijuana." April Order at 11; NDASA Prehearing Statement, Dkt. No. 1362, Hearing Docket No. 26-96, at 17. The Order thus instructs that 21 C.F.R. Part 1306—the federal rules governing the process and procedure for dispensing controlled substances by prescription—simply does not apply. A valid prescription under Part 1306 must identify the drug name, strength, dosage form, quantity prescribed, directions for use, and refills authorized. 21 C.F.R. § 1306.05; NDASA Prehearing Statement at 18. A state marijuana certification supplies none of it. Nor does the Order require FDA-style labeling: no indications and usage, dosage and administration, contraindications, warnings and precautions, adverse reactions, drug interactions, use in specific populations (including pregnancy, nursing mothers, and pediatric and geriatric use), abuse and dependence, overdosage, clinical pharmacology, or patient counseling information. *Compare* 21 C.F.R. § 201.57 (content and format of labeling for prescription drugs), *with* NDASA Prehearing Statement at 18. Nor does the Order require the adequate and well-controlled studies that 21 C.F.R. § 314.126 demands before a substance may be held out as an effective medicine. NDASA Prehearing Statement at 19. The result is a category of purported "medicine" for which there is no accepted dosing guidance, no standardized patient information, and no way for a Medical Review Officer to assess whether a given certification is medically legitimate or whether a safety concern exists. *Id.* Whatever else Dr. Finn's sixty-second telehealth encounter demonstrates, it is not the practice of medicine as federal law defines it.

119. HHS further conceded that HCP-level data on recommendations for specific conditions was unavailable, so it resorted to using patient-reported qualifying conditions as a surrogate measure. HHS Rec. at 81. The Government thus cannot identify what physicians actually know or believe about marijuana's efficacy for the conditions it asserts—pain, anorexia, and nausea—because it has no data on physician-level clinical experience with those specific conditions.

The Government has not shown widespread physician acceptance for the conditions HHS claims satisfy CAMU. The evidence shows diffuse state-program use driven by a tiny cadre of high-volume certifiers operating outside the norms of medical practice. This does not satisfy the CAMU standard under any defensible interpretation of § 812(b).

c. No Credible Scientific Evidence for Pain Treatment

Pain is the Government's strongest claimed indication for marijuana. The NPRM itself concedes that "[t]he largest evidence base for effectiveness exists for marijuana use within the pain indication." 89 Fed. Reg. at 44,618. If the evidence for pain fails, the Government's entire Part 2 analysis collapses. It does fail. The three principal bodies of evidence relied upon by HHS—the National Academies of Sciences, Engineering, and Medicine ("NASEM") report, the University of Florida ("UF") systematic review, and the Agency for Healthcare Research and Quality ("AHRQ") review—individually and collectively do not support a finding of currently accepted medical use for pain.

From the outset, "pain" is not a single condition that can be grouped into a category or traced to a single cause. Pain encompasses dozens of distinct pathologies—neuropathic pain, musculoskeletal pain, visceral pain, inflammatory pain, cancer pain, migraine, and many others—each with different mechanisms, different neural pathways, and different treatment responses. That marijuana may show a marginal signal in one narrow subtype (HIV-associated peripheral neuropathy) says nothing whatsoever about whether it can treat migraines, lower back pain,

fibromyalgia, irritable bowel syndrome, or any other pain condition. In fact, the primary symptom of IBS is pain, and HHS's own review found no indication that marijuana is effective for it. The Government cannot bootstrap a finding of "currently accepted medical use" for "pain" writ large from evidence that, at best, suggests a weak effect in a single uncommon neuropathic condition.

i. The Government's Pain Evidence Rests on a Single Weak Meta-Analysis

HHS places great weight on NASEM's 2017 finding of "substantial evidence" that cannabis is effective for treating chronic pain. But NASEM itself explicitly identifies the Whiting et al. (2015) systematic review as the primary evidentiary basis for that conclusion. The NASEM report's "substantial evidence" finding therefore rises or falls with Whiting. When Whiting is examined on its own terms, the evidence collapses.

Dr. Finn testified that HHS relied on a "very narrow diagnosis—HIV-associated peripheral neuropathy"—and that he had "never or almost never treated that condition in decades of pain practice." Tr. Day 7, at 1628. He further testified that the Whiting paper reviewed 28 RCTs, that "[n]one" of those tested THC concentrations like those sold at dispensaries, that only "[f]our" involved smoked cannabis flower, and that "[v]ery few" found marijuana effective for pain. Tr. Day 7 at 1627:15–1628:11. The one positive Abrams study "used 3.5% THC, was inpatient, lasted five days, and treated HIV-associated peripheral neuropathy"—a narrow indication with little bearing on the chronic pain conditions for which the overwhelming majority of marijuana patients qualify. *Id.* This is not a condition from which one can extrapolate a broad finding of efficacy for "pain" writ large. *See* Exhibit A at 25–26, 32.

The Whiting meta-analysis examined 79 trials, of which only 28 addressed pain. Of those 28, only a fraction were actually pooled. The headline pain result came from far fewer studies: 7 nabiximols trials plus 1 inhaled-cannabis trial produced the odds ratio of 1.41 (95% CI 0.99–2.00)

for a 30%-or-greater improvement in pain, and only that single inhaled-cannabis trial (Abrams 2007, n=50) contributed to the effect estimates for smoked cannabis. A separate pooled analysis of 6 trials found a mean reduction of only −0.46 points on a 0–10 numerical rating scale (95% CI −0.80 to −0.11). The remaining approximately 20 of the 28 pain trials were not pooled at all, for reasons of outcome heterogeneity, crossover design, or incomplete reporting. Of the 28, neuropathic pain was studied in 17, and only 5 evaluated smoked or vaporized plant material—13 investigated nabiximols (an oromucosal spray that is not "marijuana" as defined by the CSA). Only four involved smoked cannabis. Only one—Abrams 2007—found a beneficial effect, and it used marijuana containing just 3.5% THC administered in a controlled inpatient setting over five days to treat HIV-associated peripheral neuropathy. HHS Rec. at 181–182; Tr. Day 7 at 1627–28.

Critically, that flagship odds ratio of 1.41 has a confidence interval that touches 1.00, meaning it did not reach conventional statistical significance. Later reviewers noted exactly this point, citing the 0.99 to 2.00 interval as evidence that the result is not statistically significant. Several secondary sources have described Whiting's pain finding as "statistically significant," but that characterization is a misreading of the confidence interval that has propagated widely. The Government cannot carry its burden of proving currently accepted medical use on the basis of a single pooled estimate that fails to achieve statistical significance.

The Andreae meta-analysis fares no better. It examined just five randomized controlled trials ("RCTs"), none with more than 50 subjects, two with fewer than 30, none lasting longer than six weeks, none involving state-dispensary products, and none testing THC concentrations above 10%. HHS Rec. at 182–183; Tr. Day 5 at 1231–33. These are pilot-level studies that can at most suggest a hypothesis for further investigation; they cannot establish accepted medical use.

ii. The University of Florida Review Found Inconclusive Results

HHS acknowledged that the University of Florida ("UF") systematic review "identified some data supporting effectiveness of marijuana" but "ultimately concluded the results are inconclusive or mixed." HHS Rec. at 26, 113. This characterization alone should be fatal to a CAMU finding—a treatment whose own government-commissioned reviewer characterizes as having "inconclusive or mixed" results cannot be said to have an "accepted" medical use.

The specific findings from the UF review confirm its weakness. For pain measured on a Visual Analog Scale ("VAS"), the UF pooled estimates were not statistically significant, and heterogeneity was significant, meaning the pooled estimate "may not represent a true effect." HHS Rec. at 163. For pain measured on a Numeric Rating Scale ("NRS"), only 2 of 11 RCTs showed improvement, 1 showed worsening, and 8 showed no statistically significant change. The overall quality of evidence was rated low, driven by moderate-to-high concerns across four of five risk-of-bias domains. HHS Rec. at 165, 167.

HHS acknowledged that the overall UF effectiveness conclusions for pain found "mixed or inconclusive results across studies" and that the "VAS trend did not reach significance." HHS Rec. at 176. The Government cannot convert "mixed or inconclusive" into "currently accepted" through mere relabeling.

iii. The AHRQ Review Identified Only Small Effects with Limiting Side Effects

The Agency for Healthcare Research and Quality review found "some support for the use of marijuana-related products in the treatment of pain, but overall concluded these effects were small and the increased risk of dizziness, nausea, and sedation may limit the benefit." HHS Rec. at 26, 114. A treatment whose benefits are "small" and whose side effects "may limit the benefit"

has not achieved accepted medical status—it is, at best, an experimental candidate warranting further study.

iv. Hearing Testimony Confirmed the Studies' Fatal Limitations

Dr. Finn provided extensive, unrebutted testimony establishing the systematic flaws in the literature relied upon by HHS. He testified that:

- The NASEM report relied on isolated cannabinoids, nabiximols, and very few smoked-cannabis trials; that small Center for Medicinal Cannabis Research ("CMCR") neuropathic-pain trials had 25 or 30 patients; that they were short, lasting days to a few weeks; and that they used NIDA-supplied cigarettes with fixed THC concentrations. Tr. Day 5, at 1231.
- The studies were "low-dose compared with dispensary products, small-n, non-blinded, involved experienced users," and had other methodological flaws. Tr. Day 5, at 1233.
- The 28 RCTs identified in Whiting "did not test THC concentrations like dispensary products"; only four involved smoked cannabis; very few found marijuana effective for pain; and the one positive Abrams study "used 3.5% THC, was inpatient, lasted five days, and treated HIV-associated peripheral neuropathy." Tr. Day 7, at 1627–1628.

In summary, a narrow signal in HIV neuropathy derived from low-THC or pharmaceutical preparations, involving small sample sizes, short durations, blinding problems, and yielding mixed or inconclusive outcomes, cannot—as a matter of law or science—establish that marijuana has a currently accepted medical use for pain treatment in the United States. Exhibit A at 32 (Finding 2 summary). Dr. Finn testified that "not a single medical organization dealing with pain, including

the International Association for the Study of Pain, the American Academy of Pain Medicine, the American Chronic Pain Association, endorses dispensary marijuana." Tr. Day 7 at 1516:7–12. When every authority that treats the illness does not recommend the substance, that is not a currently accepted medical use.

d. **No Credible Evidence for Anorexia Indication**

Anorexia is the Government's fallback. Having failed to carry its burden on pain, its lead indication, the Government retreats to an indication supported by materially less. For anorexia there is no AHRQ support at all: HHS itself describes that review as addressing "cannabis and other plant-based treatments for chronic pain." HHS Rec. at 72. And HHS never found accepted medical use for "anorexia" in any general sense. It defined the indication as "anorexia related to a medical condition" and stated that it "does not represent anorexia nervosa." HHS Rec. at 25 n.10, 64; 89 Fed. Reg. at 44,617. Anorexia is a symptom, not a disease, and HIV wasting, cancer cachexia, and end-of-life cachexia share no common mechanism, population, or endpoint.

i. Three RCTs, no meta-analysis

UF started with 4,086 publications and ended with three randomized trials. Every observational study was thrown out for "critical risk of bias." HHS Rec. at 33–34, 116. UF could not pool the three survivors, finding "insufficient studies of moderate or high quality to support the calculation of meta-analytic estimates for any of the outcomes within the anorexia indication." HHS Rec. at 34–35. Only one rating rose to "moderate," and it was for calories eaten, a stand-in for weight gain rather than weight gain itself. Appetite, quality of life, and body weight were all "low quality." No trial improved appetite or quality of life to a significant degree, and the cancer trial did no better than placebo. HHS Rec. at 35–36. The two trials that did show something studied 30 and 10 subjects, all daily smokers of many years, given government cigarettes topping out at 3.9% THC, a fraction of what dispensaries sell today. HHS 2015 Review at 21–24.

ii. NASEM

NASEM found only "limited evidence"—weak evidence carrying "significant uncertainty due to chance, bias, and confounding factors"—for HIV/AIDS, and "insufficient evidence to support or refute" effectiveness for cancer-associated anorexia-cachexia. NASEM at 8–9, 13–14, 128. The cancer evidence was negative. In *Strasser*, 164 of 243 patients completed, intent-to-treat analysis showed no difference in appetite, quality of life, or toxicity, and the data review board halted recruitment early. NASEM at 95–96. In Jatoi, an older, non-cannabis appetite drug worked better than synthetic THC: 75% of patients on that drug reported better appetite, versus 49% on dronabinol, and 11% gained meaningful weight, versus 3%. NASEM at 96–97.

iii. FDA

FDA's own review "showed mixed results for these indications." HHS Rec. at 26–27, 76. Dr. Chiapperino admitted that anorexia was one of them, and that UF and FDA never agreed. Tr. Day 2 at 506–512. FDA found the data on the plant itself "more limited" and found no high-quality evidence that it works. HHS Rec. at 80–81. The *Wang* analysis found no real appetite effect (MD 0.27, 95% CI −0.51 to 1.04), and turned positive only after the authors dropped the largest trial. Of the four trials *Whiting* assessed for appetite and weight, every one tested synthetic dronabinol; only a single trial tested inhaled marijuana at all, and what little weight it produced was fat rather than the lean body mass that defines wasting. *Id.*; Day 2 at 510–511. Approved labeling cannot fill the gap. Marinol and Syndros are standardized synthetic products approved for anorexia with weight loss in AIDS—"not general anorexia," as Dr. Drum testified. HHS Rec. at 88; Tr. Day 9 at 1915. Nor does safety cure the efficacy defect: HHS conceded safety data were "generally scarce," that state surveys omitted patients who discontinued use, and that most professional organizations do not recommend marijuana. HHS Rec. at 27–28, 92–93; Tr. Day 2 at 514–516. An indication reached only after the primary one fails must still be proved, and this one is not.

e. HHS Ignored Safety Risks

A finding of currently accepted medical use necessarily requires weighing the substance's therapeutic benefits against its risks. No rational medical professional "accepts" a treatment whose dangers exceed its benefits. Yet HHS's Part 2 analysis systematically minimized, excluded, or ignored categories of safety risk that are both well-documented in the scientific literature and central to the question of whether marijuana can be responsibly used as medicine.

i. HHS's Own Methodology Required Safety Consideration

HHS stated that factors weighing against a positive Part 2 finding included "unacceptably high safety risks," "negative efficacy findings," and "professional organizations recommending against use." HHS Rec. at 26, 113, 119–120, 199. Yet having articulated these criteria, HHS proceeded to disregard them.

Despite acknowledging that the "vast majority of professional organizations did not recommend the use of marijuana in their respective specialty" and that the American Psychiatric Association ("APA") "specifically recommended against it," HHS concluded that no safety concerns precluded medical use for the selected indications. HHS Rec. at 27–28, 115–116, 201. The APA has stated unequivocally: "There is no current scientific evidence that cannabis is in any way beneficial for the treatment of any psychiatric disorder," and accordingly, "the APA does not endorse cannabis as medicine." Am. Psychiatric Ass'n, Position Statement in Opposition to Cannabis as Medicine (May 2019). HHS's dismissal of this opposition is unexplained and unreasoned.

ii. HHS Omitted Categories of Risk Previously Central to DEA/HHS Analysis

In its 2011 and 2016 analyses, DEA and HHS addressed a broad range of safety risks including adolescent neurodevelopmental harms, prenatal exposure, respiratory harms, automobile

crashes, and psychosis and schizophrenia. *See* 81 Fed. Reg. at 53,774–75, 53,830; 76 Fed. Reg. at 40,555, 40,561. The 2023 Recommendation omitted these entire categories of risk without explanation. Exhibit A at 25–31 (documenting factor-by-factor omissions in the Additional Risk Tables).

Instead, HHS adopted a methodologically indefensible comparator analysis—measuring marijuana's safety not against a placebo or against doing nothing, but against substances with the highest overdose and hospitalization profiles, including fentanyl, opioids, cocaine, heroin, ketamine, benzodiazepines, zolpidem, tramadol, and alcohol. HHS Rec. at 10, 28. That marijuana causes fewer acute overdose deaths than fentanyl or heroin tells us nothing about whether it has an acceptable safety profile for medical use. No rational physician evaluates a treatment's safety by asking only whether it kills fewer patients than the deadliest substances known.

iii. Cannabis Use Disorder Is a Serious and Prevalent Risk

The hearing record established that cannabis use disorder ("CUD") affects a substantial portion of users. Testimony established that CUD prevalence has increased from approximately 9.4% to between 24% and 30% of users, and in some medical cannabis user populations can be even higher, including veterans over age 35. Tr. Day 5 at 1246.

A 2023 study of nearly 6.9 million people linked CUD and schizophrenia and estimated that up to 30% of young male schizophrenia cases may have been prevented absent cannabis use. Tr. Day 7 at 1517:9–14; Dr. Finn Ex. 19. Over eighty parent affidavits documenting marijuana-induced psychosis were submitted in the hearing record. Stack Ex. 2–86; Tr. Day 7 at 1718–23.

Opposing expert testimony stated that "risk-benefit is appropriate to medical-use analysis," that "psychiatric risks should be considered," and that "evidence for psychiatric risks with marijuana is stronger than evidence for benefits." Tr. Day 10 at 2295. HHS performed no meaningful risk-benefit analysis addressing these documented harms.

f. Finding 2: Conclusion

The Government has failed to carry its burden of proving, by substantial evidence on the whole record, that marijuana has a currently accepted medical use in treatment in the United States. The deficiencies are cumulative and reinforcing:

- The medical profession has not accepted marijuana as a treatment for any condition. Only a tiny fraction of physicians participate in state programs, and those programs bear no resemblance to the practice of medicine. HHS cannot identify physician-level clinical experience with the specific conditions it asserts.
- The scientific evidence for marijuana's efficacy as a pain treatment is mixed and inconclusive by the Government's own admission. The strongest signal derives from a handful of small, short-duration studies of low-potency preparations for a narrow condition—HIV-associated neuropathic pain—that cannot support a broad CAMU determination.
- The two-part CAMU standard applied by HHS was invented for this proceeding, has no statutory or regulatory basis, and was designed to reach a predetermined outcome. As demonstrated in Section I, the Government's own expert conceded that marijuana would not have passed the test applied in every prior CAMU determination.
- HHS systematically ignored safety risks—including cannabis use disorder affecting up to 30% of users, psychosis, schizophrenia, and neurodevelopmental harms—that any rational risk-benefit analysis would weigh against the asserted therapeutic benefit.

- The substances actually studied in the literature (low-potency research-grade marijuana, nabiximols, nabilone, and dronabinol) bear no resemblance to the variable, high-potency products encompassed by the statutory category of "marijuana." Extrapolating from controlled pharmaceutical preparations to the entire genus is a part-to-whole fallacy that cannot survive scrutiny.

For all of the foregoing reasons, the Designated Parties respectfully submit that the tribunal should recommend against Finding 2 and against the proposed transfer of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

C. Finding 3: The Government Failed to Prove Dependence Liability Supports Schedule III Placement

For Finding 3, HHS relied most directly on Factor 7, the statutory inquiry into marijuana's "psychic or physiological dependence liability," to support the conclusion that marijuana belongs in Schedule III. The Government's proof fails at that point because the record establishes that marijuana produces both psychological dependence and physical dependence, that Cannabis Use Disorder is widespread and increasingly severe, and that the Government's analysis minimized those facts by comparing marijuana to the wrong drugs and by ignoring the populations most vulnerable to dependence.

a. Cannabis Use Disorder Prevalence Is Substantial and Directly Undercuts the Government's Showing

The most current scientific literature in the record establishes that Cannabis Use Disorder ("CUD") is not a marginal or rare outcome of marijuana use. Dr. Madras testified that earlier estimates placed cannabis dependence among users at approximately 9.4 percent, but that current prevalence is "skyrocketing to between 24 to 30 percent," with some medical-use populations showing still higher rates. Tr. Day 5, at 1246:22-1247:5. Dr. Akinfiresoye likewise confirmed on cross-examination that the percentage of CUD among regular or daily users is much higher than

ten percent, that CUD prevalence is "about 30 percent," and that, in absolute numbers, CUD affects more people than any other illegal drug. Tr. Day 6, at 1397:13-20. Those admissions are direct evidence of psychic dependence liability because CUD is the DSM-5 framework for the addiction-like dependence state HHS itself identified as relevant to Factor 7.

Nor can the Government salvage its position by emphasizing that many CUD cases are "mild." The record shows that CUD is defined by continued use despite harmful consequences, failed quit attempts, tolerance, craving, withdrawal, and impairment, and Dr. Madras explained that CUD "essentially boil[s] down to uncontrollable use despite adverse consequences." Tr. Day 5, at 1250. The Government's own HHS recommendation acknowledges that some individuals who use marijuana for its rewarding effects go on to develop CUD, that marijuana was the third most frequently reported primary substance in treatment admissions after alcohol and heroin, and that CUD demonstrates marijuana's capacity to produce psychological dependence. HHS Rec. at 58–59. HHS further reported that up to 40 to 50 percent of regular marijuana users may experience physical dependence, that a meta-analysis found withdrawal symptoms in 47 percent of frequent users, and that 90 percent of individuals diagnosed with CUD also reported physical dependence. 89 Fed. Reg. at 44,615; HHS Rec. at 60–61. Those figures refute, rather than support, a finding that marijuana's dependence liability is meaningfully lower than the relevant Schedule I or II comparators.

The Government's argument also fails because the trend evidence is worsening, not improving. Record evidence shows that CUD prevalence among adolescents and young adults is converging with alcohol use disorder, that severe and moderate CUD are numerically higher than alcohol use disorder, and that CUD prevalence far exceeds other illicit substance use disorders. *See generally* Dr. Finn Ex. 114. The 2023 NSDUH data cited in the DEA scientific review

classified 19.2 million people as having dependence on or abuse of marijuana in the past year, representing 6.8 percent of the population age 12 or older. *See* Tr. Day 5 at 1251:20–1252:18; HHS Rec. at 58–59. A record that shows tens of millions of users, roughly thirty percent CUD prevalence among current users, and high rates of physical dependence among those with CUD cannot satisfy the Government's burden to prove a materially lower dependence profile under Factor 7.

b. The Proper Comparison Is to Schedule I Hallucinogens and Psychedelics, Not to Opioids or Other High-Dependence Schedule II Drugs

As detailed in Section II.A, the Government's dependence analysis is also defective because it used a comparator set that was structurally designed to make marijuana appear safer than it is. HHS compared marijuana principally to heroin, fentanyl, oxycodone, hydrocodone, cocaine, ketamine, benzodiazepines, zolpidem, tramadol, and alcohol, while largely excluding the Schedule I hallucinogens and psychedelics that prior DEA and HHS analyses had used as natural benchmarks. HHS Rec. at 6. Those earlier analyses benchmarked marijuana against MDMA, GHB, LSD, and PCP, along with other hallucinogens and inhalants. 76 Fed. Reg. at 40,561, 40,571; 81 Fed. Reg. at 53,782, 53,825. That choice matters because opioids and stimulants generate dependence and acute harms through pharmacological pathways that are fundamentally different from marijuana's cannabinoid-receptor mechanism.

The Government's own prior analysis warned against precisely this comparison. In 2016, HHS stated that comparisons between marijuana and the diverse array of Schedule II substances were difficult because opioids, stimulants, depressants, dissociative anesthetics, coca leaves, and poppy straw affect the body in a manner "completely different" from THC and marijuana. 81 Fed. Reg. at 53,706-07. HHS concluded in that earlier analysis that differences in mechanisms of action made it inappropriate to compare the range of Schedule II substances with marijuana. *Id.* The

current recommendation reversed that methodology without a reasoned explanation, even though the substantial-evidence standard requires the decision-maker to consider evidence that detracts from the agency's conclusion and to assess the whole record. *Universal Camera Corp.*, 340 U.S. at 488.

c. The hearing record demonstrates that the Government's comparator selection excluded the very drugs most relevant to a Schedule I comparison. Dr. Madras's Testimony Confirms That Marijuana's Dependence Mechanisms Are Serious and That the Government's Contrary Showing Is Insufficient

Dr. Madras's testimony supplies a direct scientific explanation for why the Government's Factor 7 finding cannot be sustained. Her research focuses on the effects of addictive and therapeutic drugs on the brain. Tr. Day 5, at 1190:19-1191:7; 1202:1-11. Her expertise therefore goes to Factor 7, which concerns psychiatric and physiological dependence liability.

Dr. Madras testified that THC is the marijuana constituent with addictive potential, while CBD is not intoxicating and does not share that addictive profile. Tr. Day 5, at 1211:20-22. She further testified that THC impairs cognition, can promote anxiety, and is psychotomimetic, meaning it can produce symptoms of psychosis. *Id.* at 1211:22-1212:6. That testimony undermines any attempt to treat "marijuana" as a benign, uniform botanical category, because the relevant dependence and psychiatric-risk profile depends on THC content, route of administration, frequency of use, and user vulnerability.

Her testimony also squarely connects potency to dependence. Dr. Madras explained that higher THC potency influences the progression to CUD and is associated with increased risks of psychosis, anxiety, earlier schizophrenia onset, impaired memory, emergency care, social problems, more use, and progression to addiction. Tr. Day 5, at 1253:23-1254:7. She testified that THC potency has risen dramatically over recent decades and that "the more potent, the greater high, the more tolerance, the more addiction, the more users, the more profit." Tr. Day 5, at

1254:22-25. That is dependence evidence, not collateral policy commentary, because tolerance, repeated use, and addiction are precisely the mechanisms that Factor 7 is meant to capture.

The Government's contrary argument rests heavily on the assertion that marijuana withdrawal is relatively mild compared with alcohol or heroin withdrawal. HHS Rec. at 61, 64-65; 89 Fed. Reg. at 44,615. That framing is legally and scientifically insufficient because Factor 7 does not ask only whether a drug kills users during withdrawal; it asks whether marijuana creates psychic or physiological dependence liability. 21 U.S.C. § 811(c)(7). HHS itself acknowledged that chronic marijuana use can produce both psychic and physical dependence, that marijuana withdrawal includes sleep difficulty, appetite and weight loss, craving, irritability, anger, anxiety, and restlessness, and that severity may increase with exposure. HHS Rec. at 59-61, 64-65. By reducing the inquiry to whether marijuana withdrawal resembles alcohol withdrawal or heroin withdrawal, the Government measured the wrong endpoint.

Dr. Madras's testimony further shows why the Government cannot meet its burden by relying on population averages while ignoring high-risk users. She testified that daily users may develop CUD at rates of 30 to 50 percent. Tr. Day 5, at 1252:19-20. She also testified that medical-marijuana states show considerably higher CUD prevalence, especially among younger age groups. Tr. Day 5, at 1252:21-1253:13. That evidence directly contradicts HHS's effort to characterize marijuana dependence as "relatively mild for most individuals," because the CSA inquiry must consider dependence liability in the real population using the drug, including frequent users, high-potency users, adolescents, and medical users.

Finally, Dr. Madras's testimony cannot be dismissed as speculative or isolated. Her testimony is corroborated by the record literature showing that nationally representative data suggest as many as 30 percent of cannabis users may develop CUD, that minors develop CUD at

twice the adult rate, and that CUD prevalence among medical cannabis users may range from 25 to 29 percent. *See* Finn Ex. 114. It is also corroborated by HHS's own acknowledgement that up to 40 to 50 percent of regular users may experience physical dependence and that 90 percent of individuals diagnosed with CUD reported physical dependence. HHS Rec. at 60-61. Taken together, Dr. Madras's testimony and the broader record show that marijuana's dependence liability is substantial, mechanistically grounded, worsening with potency and frequency, and not demonstrably lower than the dependence liability of appropriate Schedule I comparators.

For these reasons, the Government has not carried its burden on Finding 3. The record does not establish that marijuana's psychic or physiological dependence liability is materially lower than the relevant Schedule I or II substances, and it affirmatively shows that marijuana produces widespread CUD, substantial physical dependence among regular users and those with CUD, heightened adolescent dependence vulnerability, and greater abuse liability than Schedule I hallucinogens. The ALJ should therefore reject the Government's Factor 7 showing and conclude that the proposed Schedule III placement is unsupported by substantial evidence on the whole record.

D. The Government's Failure To Substantively Address Factor 5 Is Fatal

The Government bears the burden of proof as the proponent of the proposed rescheduling rule. 5 U.S.C. § 556(d); 21 C.F.R. § 1316.56. To carry that burden under the substantial evidence standard, the Government must demonstrate that its conclusion is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Universal Camera Corp.*, 340 U.S. at 488. An agency may not "entirely fail[] to consider an important aspect of the problem." *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (quoting *State Farm*, 463 U.S. at 43).

The scope, duration, and significance of abuse is the fifth of eight statutorily mandated factors under 21 U.S.C. § 811(c). It is not optional, and it is not merely one consideration among

many that the agency may weigh or disregard at will. It is a factor Congress directed the agency to consider. The Government cannot carry its burden while leaving a mandatory factor unanalyzed. Where, as here, the Government's own analysis contains no substantive engagement with the scope, duration, and significance of marijuana abuse—merely a comparative exercise designed to minimize marijuana's apparent harm relative to harder drugs—the agency has "entirely fail[ed] to consider an important aspect of the problem." *Michigan*, 576 U.S. at 752.

In crafting its recommendation, HHS analyzed various datasets that ranked heroin and cocaine (as well as alcohol) as having the greatest adverse medical consequences, including for serious medical outcomes and death. HHS Rec. at 11. Yet HHS offers no analysis whatsoever of the impact of higher THC levels on the scope, duration, or significance of abuse. *Id*. at 37–45. The data are in the record; HHS simply chose not to engage with them.

HHS also fails to mention schizophrenia anywhere in its Factor 5 analysis. HHS does not deny prior findings that marijuana use may exacerbate symptoms in individuals with schizophrenia and precipitate psychotic disorders. Nor does HHS contend with the finding that one-fifth of schizophrenia cases among young males might be prevented by averting marijuana abuse. *See* Tr. Day 7 at 1517:9–14; Dr. Finn Ex. 15 (Hjorthøj Danish national cohort study); Exhibit A at 26–27.

This failure to substantively engage with Factor 5 is an independent and sufficient basis for recommending against rescheduling. The tribunal need look no further: a scheduling determination built on an analysis that ignores one of the statute's mandatory factors cannot satisfy the substantial evidence standard as a matter of law.

III. Rescheduling Marijuana Will Have Concrete, Foreseeable, and Catastrophic Real-World Consequences

The Government knows it cannot and has not met its statutory burden of proof to reschedule marijuana. So, it has attempted to characterize the proposed rescheduling of marijuana

from Schedule I to Schedule III as a narrow, technical regulatory adjustment— a ministerial act that would leave the federal prohibition on nonmedical use formally intact and produce no practical impact on public access, consumption, or health. That characterization forms no part of the standard under which rescheduling should take place. It is also refuted by the record.

The evidence establishes that rescheduling would produce profound real-world consequences through three reinforcing pathways: 1) it would confer a federal imprimatur of medical legitimacy on a substance that does not meet the scientific standards for safe and effective medicine; 2) it would foreseeably increase cannabis consumption; and 3) it would accelerate the cultural normalization that has already eroded public-health messaging to the point of a mental health epidemic.

A. The Imprimatur of Medicine

Schedule III classification means something. It declares under the authority of the foremost health institution in the world that a substance has "a currently accepted medical use in treatment in the United States" and "a potential for abuse less than the drugs or other substances in schedules I and II." 21 U.S.C. § 812(b)(3). The public does not parse the Code of Federal Regulations. As Dr. Matthew Rossheim testified, "public interpretation is unlikely to mirror that legal nuance; many consumers may reasonably infer that, if the federal government moved marijuana from Schedule I to Schedule III, marijuana is medically legitimate, safer than previously believed, or less harmful than other controlled substances." Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 31.

Multiple research groups have recognized the term "medical marijuana" itself as misleading "because state-program products are not approved by the U.S. Food and Drug Administration, lack rigorous evidence for most claimed uses, and differ fundamentally from the few approved cannabinoid drugs." Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 37. Research further demonstrates that marijuana use "is perceived as more moral and less addictive, harmful, and

impairing when designated as 'medical.'" *Id.* Rescheduling adds a layer of federal "accepted medical use" recognition without resolving these evidentiary gaps and thereby fuels public misconceptions.

Dr. Stuyt confirmed the clinical reality. She opined that rescheduling "would reinforce a false public perception that high-THC products are safe and effective for medical use." Dr. Finn Ex. 110 (Stuyt Aff.) ¶ 23. Her patients already refused to believe cannabis was causing their psychosis or suicidal ideation because they regarded it as "medicine." *Id.* ¶¶ 13, 22.

Pharmacist Dr. Phillip Drum testified that "by making it a Schedule III, it confirms its medical use status," and warned that parents "have been duped into believing the minimal risk of a hallucinogenic substance" and that the deception "will only increase when marijuana is federally deemed a medicine." Tr. Day 9 at 1886:4–10; 2000:13–14.

Hsu and colleagues concluded that "clinical evidence does not support cannabis or cannabinoids as effective treatments for most conditions that qualify patients for state medical cannabis programs." Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 36. The Government's own witness conceded that the HHS recommendation did not limit its finding of "currently accepted medical use" to any particular product type, potency, or formulation. Rather, the finding applies to "marijuana as a category." Tr. Day 1 at 213:6–8. The federal imprimatur of medical legitimacy would therefore extend, without distinction, to 90-percent THC concentrates and dabs; the very products most likely to produce psychosis, schizophrenia, and suicide in the record before this Court.

B. Increased Use

The Government cannot credibly maintain that rescheduling will not increase marijuana use. The evidence is overwhelming that policy liberalization and use move together, and that federal signals have been among the most powerful inflection points in that trajectory.

Dr. Rossheim opined that "the available evidence supports a reasonable expectation that rescheduling would likely increase nonmedical use over time through two reinforcing pathways: (1) increased commercialization; and (2) reduced perceived risk and medical normalization." Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 8.

On commercialization, rescheduling would relieve state-licensed cannabis operators of the crushing tax burden imposed by Internal Revenue Code § 280E. Dr. Rossheim identified this as "the most concrete commercial mechanism, because it would immediately reduce the effective tax rate of state-licensed marijuana businesses, improve margins, and accelerate the reinvestment of revenue into retail expansion, marketing, and product development." *Id.* ¶ 11. The cannabis-specific evidence on retail availability, marketing exposure, and price sensitivity is now sufficient to conclude that increased commercial capacity will translate into increased consumption. *Id.* ¶¶ 19–30.

Edward Wood presented data demonstrating that each federal signal of marijuana tolerance has produced a measurable inflection in daily and near-daily use. Wood testified further that rescheduling "would dramatically increase the consumption of marijuana, which would therefore gradually dramatically increase also the number of people that would choose to drive after having been impaired by marijuana." Tr. Day 6 at 1438:13–18. The Caulkins analysis of more than 1.6 million survey respondents spanning 1979 to 2022 showed that daily or near-daily cannabis use increased approximately fifteen-fold between 1992 and 2022, with identifiable inflection points at 1996 (California's adoption of medical marijuana), 2009 (the Ogden memo), and 2014 (the commencement of commercial retail sales). Tr. Day 6 at 1446:11–1447:8; Dr. Finn Ex. 109 (Rossheim Aff.) ¶¶ 40–41. Wood testified: "Any reasonable person looking at this would expect that if you now change the schedule of a drug from Schedule I, being the most dangerous category

we have, to Schedule III saying, let's bless this as a medicine … any reasonable person would expect that will increase more." Tr. Day 6 at 1447:9–12.

By 2022, the estimated number of Americans reporting daily or near-daily cannabis use (approximately 17.7 million) exceeded for the first time the number reporting daily or near-daily alcohol use (approximately 14.7 million). Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 42. Daily or near-daily use is the pattern most strongly associated with cannabis use disorder, psychosis, and related harms.

The 2025 Monitoring the Future report documented that perceived risk of regular marijuana use among 12th graders fell from 58 percent in 2000 to 36 percent in 2024. *Id.* ¶ 33. In 2024, far fewer 12th graders perceived great risk from regular marijuana use (36 percent) than from regular use of heroin (84 percent), cocaine (80 percent), or cigarettes (70 percent).

The National Academies of Sciences, Engineering, and Medicine found that after cannabis policy liberalization, "the perceived risk of cannabis declines, use among adults increases, cannabis-related traffic collisions increase, and cannabis-related hospital visits increase." *Id.* ¶ 39. Dr. Nora Volkow, Director of the National Institute on Drug Abuse, published in the New England Journal of Medicine that "as policy shifts toward legalization of marijuana, it is reasonable and probably prudent to hypothesize that its use will increase and that, by extension, so will the number of persons for whom there will be negative health consequences." Dr. Finn Ex. 97 (Volkow et al., 2014) at 7.

C. Cultural Normalization

Cultural normalization is not merely a byproduct of rescheduling, it is the mechanism through which rescheduling produces its most devastating effects.

Dr. Rossheim testified that Schedule III classification "would convey to the public a medical legitimacy that can influence nonmedical use in at least four ways: first, it can reduce

perceived harm by framing marijuana as therapeutic; second, it can increase social acceptability by making use easier to discuss with clinicians, family members, employers, and peers; third, it can support product innovation that resembles conventional health products, including condition-specific branding; and fourth, it can expand the consumer base through 'wellness' or symptom-management narratives." Dr. Finn Ex. 109 (Rossheim Aff.) ¶ 35.

Laura Stack testified to this normalization from the ground level. Her son rationalized his addiction precisely because marijuana carried a medical designation: "He always would say, I love marijuana. . . . [C]ome on, Mom, you know, this stuff is legal. You know, God made it. It grows in the ground. It's natural, it's medical, it helps people. Obviously this isn't hurting me." Tr. Day 7 at 1684:19–1685:1. The more than eighty parent affidavits submitted through Stack's testimony report the same refrain from family after family. Their children believed the product was safe because it was sold in licensed dispensaries, recommended by physicians, and designated as "medical." *See, e.g.* Stack Ex. 4 (Peterson Aff.) at 1; Stack Ex. 21 (Sierra Aff.) at 4; Stack Ex. 8 (Hudock Aff.) at 3. Summing up, Stack testified that in 2024, the most recent SAMHSA data showed "nearly three million teens used marijuana in the past year, and they said 45 percent of them, ages 12 through 17, had cannabis use disorder or problematic use." Tr. Day 7 at 1717:23–1718:4.

In Colorado, eleven percent of high-school-aged drivers reported driving after marijuana use, reflecting "a growing cultural acceptance of marijuana use and driving." Wood Ex. 1 (Colorado DUI Report 2018) at 7. Wood testified that rescheduling "would dramatically increase the consumption of marijuana, which would therefore gradually dramatically increase also the number of people that would choose to drive after having been impaired by marijuana." Tr. Day 6 at 1438:13–18. Wood's testimony established that no scientifically valid per se safety net for

marijuana-impaired driving exists, unlike alcohol: "Until there is a reliable, objective, validated technology that enables us to define that somebody is impaired by drugs, it is my belief that it is illogical, it is immoral, and it is irresponsible to promote, enable, or assist the continued commercialization of marijuana." Tr. Day 6 at 1440:14–19.

The impaired driving consequences of rescheduling are compounded by the fact that many states would be forced to amend their DUI laws, and the record establishes they are unable to do so wisely. Wood testified that all states with zero-tolerance laws for THC would need to amend those statutes if marijuana is reclassified as a legitimate medicine, because it becomes untenable to maintain a zero-tolerance law for a federally recognized medication. Tr. Day 6 at 1447:21–1448:9; Wood Ex. 87 at 6. States that have attempted to amend their laws in response to marijuana legalization have demonstrated their inability to do so on a sound scientific basis. Illinois adopted a 15 ng/mL THC per se law after legalizing marijuana, which was vetoed by the governor after lobbying from the scientific community; the legislature then substituted a 5 ng/mL limit with no data to determine whether innocent drivers are convicted or guilty drivers exonerated. Kentucky dropped its effort to implement a 5 ng/mL THC per se law after learning it was scientifically invalid. South Carolina has been unable to pass a THC per se law despite efforts by its law enforcement division. Pennsylvania has attempted to limit THC convictions to drivers "rendered incapable of safe driving"—a definition Wood testified is inappropriate for a substance whose impairment clues are subtle. Tr. Day 6 at 1449:15–1451:9; Wood Ex. 87 at 26–27.

Wood further testified that until a reliable, objective, validated technology is developed to measure, document, and prove that a driver is impaired by marijuana or other drugs, it is "illogical, immoral, and irresponsible" to further aid the commercialization of marijuana. Day 6 at 1440:14–19; Wood Ex. 87 at 31–32. The Government's rescheduling analysis entirely failed to address this

reality. Tr. Day 6 at 1440:21–25; Wood Ex. 7 at 3. When the Government's witness was asked on cross-examination whether the rescheduling analysis considered the marijuana-impaired driving safety implications, the witness admitted it had not. Tr. Day 2 at 206:12–22. This omission of a safety problem that could cause over 6,000 additional traffic deaths per year if marijuana commercialization is extended nationwide renders the Government's analysis arbitrary, capricious, and in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). Wood Ex. 87 at 2, 5.

The consequences for workplace safety are equally concrete. Jo McGuire, representing the National Drug and Alcohol Screening Association, testified that rescheduling to Schedule III would eliminate the legal authority for mandatory marijuana testing of seven to nine million safety-sensitive federal employees, because the executive order authorizing federal drug testing is limited to Schedule I and II substances. Tr. Day 4 at 1007:8–1009:14. "Moving marijuana to Schedule III will end testing for safety-sensitive employees," Ms. McGuire testified—meaning that airline pilots, train engineers, school bus drivers and commercial truck drivers would no longer be subject to mandatory marijuana screening. Tr. Day 4 at 1059:8 to 1060:2.

IV. Conclusion

This is not merely an academic or regulatory exercise. Recreational marijuana marketed as medicine is, at worst, a lie, and at best, unproven. Nor does this case advance any interest that outweighs the dangers. Research is progressing without impediment, as the hundreds of studies introduced during these proceedings attest. No one contests that. State recreational programs are operating in an orderly, uninterrupted, and largely profitable manner. No one contests that. What remains, and what this case is actually about, is tax breaks, more profit for the industry, and less public funding to address the very harms that recreational marijuana will inevitably cause. To do so, to further unleash the prodigious market and primal chemical forces based on a three-year-old,

deeply flawed analysis resting on outdated data and the anecdotes of a witness with a vested interest in cannabis, is not enough to carry the burden and is to invite the whirlwind.

No matter how the industry wishes to spin marijuana nor the technical statutory designation, the meaning of which is far removed from the understanding of those it will affect, the truth remains the truth. Uncertainty and risk remain uncertainty and risk. And the burden remains the burden. The only question left is who will bear them: the Government and an industry that profits from the product, or the Laura Stacks of the world and the faces on a future wall whose fate will be sealed by rescheduling.

Designated Parties urge this tribunal to recommend against rescheduling marijuana.

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2026 I electronically filed the foregoing Brief and its attendant Exhibit with the tribunal via email to the DEA Judicial Mailbox at ECF-NPRM@dea.gov and simultaneously served the Brief and its attendant Exhibit by email upon the Government and all parties of record as follows:

The Government — dea.registration.litigation@dea.gov, James.J.Schwartz@dea.gov; Jarrett.T.Lonich@dea.gov; Alexis.B.Attanasio@dea.gov; Kayla.L.Kreinheder@dea.gov; David.C.Maley@dea.gov; Lisa.K.Man@dea.gov; Stacy.M.Race@dea.gov; Mack.J.Swan@dea.gov

National Drug & Alcohol Screening Association — jomcguire@ndasa.com; thinkon908@aol.com

Tennessee Bureau of Investigation — jacob.durst@ag.tn.gov; reed.smith@ag.tn.gov

Smart Approaches to Marijuana — pphilbin@torridonlaw.com; jmcnichols@torridonlaw.com; charrington@torridonlaw.com

States of Nebraska, Idaho, and Indiana — zachary.pohlman@nebraska.gov; Michael.Zarian@ag.idaho.gov; Blake.Lanning@atg.in.gov; pphilbin@torridonlaw.com; jmcnichols@torridonlaw.com; charrington@torridonlaw.com; tzhorton@torridonlaw.com

DUID Victim Voices — edwood27@icloud.com;

Kenneth Finn, M.D. — kfinn0731@gmail.com

Phillip A. Drum, PharmD — phillipdrum@comcast.net

/s/Patrick D. Kenneally

Patrick D. Kenneally