UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 24-44** **Administrative Law Judge** **John J. Mulrooney, II**

HEMP FOR VICTORY AND VILLAGE FARMS' JOINT MOTION REQUESTING SUPPLEMENTATION OF THE RECORD AND DISQUALIFICATION AND REMOVAL OF DEA FROM THE ROLE OF PROPONENT OF THE RULE IN THESE PROCEEDINGS

This administrative process will decide one question: whether marijuana belongs in schedule I of the Controlled Substances Act ("CSA") like heroin, schedule II like fentanyl, or whether it should be in schedule III as our leading health agencies (including the U.S. Department of Health and Human Services ("HHS"), and the Food and Drug Administration ("FDA")) have recommended. That is a serious question worthy of robust debate. But instead of admitting doctors, researchers, and scientists as designated participants who could shed light on that question, DEA has stacked the deck with people and organizations without standing and devoid of any relevant testimony to offer in an effort to influence the outcome before this Tribunal has had an opportunity to evaluate any evidence. This process has been anything but typical for a democratic republic.

In its October 31, 2024 Preliminary Order, this Tribunal expressed concern that the way in which the Administrator of the Drug Enforcement Administration ("DEA" or the "Agency") referred this matter for hearing was irregular and undermined this Tribunal's ability to discharge its duty to maintain a complete record and ensure fairness and transparency in these proceedings. Preliminary Order, at 3. Those concerns were justified, as were the initial steps this Tribunal took to address them. Unfortunately, as we explain in detail below, the irregularities go far deeper, and additional corrective action is necessary. Designated Parties, Hemp for Victory and Village Farms International, Inc. ("Village Farms"), jointly file this motion to bring those additional irregularities to this Tribunal's attention, to build a record without gaps and prejudice, and to seek the immediate disqualification and removal of the DEA Chief Counsel's Office from defending the Proposed

Rule. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597 (May 21, 2024) ("NPRM" or "Proposed Rule").

I. Facts and Procedural History

A. DOJ—Not DEA—Promulgates an NPRM Proposing to Reschedule Marijuana to Schedule III.

On October 6, 2022, President Biden announced a three-step plan to "end [the federal government's] failed approach [to marijuana]." The White House, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/. Part of that "failed approach," the President explained, was marijuana's schedule I status under the Controlled Substances Act ("CSA"). *Id.* In his view, it made no sense for marijuana to be in "the classification meant for the most dangerous substances" and one that is even stricter "than the classification of [schedule II substances] fentanyl and methamphetamine—the drugs that are driving our overdose epidemic." *Id.* Accordingly, he requested that the "Secretary of [HHS] and the Attorney General . . . initiate the administrative process to review expeditiously how marijuana is scheduled under federal law." *Id.*

Under 21 U.S.C. § 811(b), "before" initiating formal rulemaking proceedings to reschedule a drug and "after gathering the necessary data," DEA[1] must request from HHS a scientific and medical evaluation and scheduling recommendation. In the wake of the President's October 6, 2022, directive, HHS began preparing its evaluation and recommendation, but as time passed, the public and some lawmakers grew impatient. At a July 27, 2023, House Judiciary Committee hearing, for example, Rep. Matt Gaetz asked the DEA Administrator, Anne Milgram, why marijuana was still in schedule I.[2] The Administrator responded that HHS's review was underway.[3] When Gaetz expressed concern that there was no timeline for HHS to complete its review, the Administrator confirmed that she would urge HHS to provide one.[4]

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[1] The CSA vests the Attorney General with the authority to schedule, reschedule, or decontrol drugs. 21 U.S.C. § 811(a). The Attorney General has delegated that authority to the DEA Administrator, *see* 28 C.F.R. § 0.100, but also retains the authority to schedule drugs under the CSA in the first instance, *see* 28 U.S.C. §§ 509, 510.

[2] Forbes Breaking News, *JUST IN: Matt Gaetz Asks DEA Chief Point Blank Why Marijuana Is Still Classified A Schedule 1 Drug*, YOUTUBE (July 27, 2023), https://www.youtube.com/watch?v=1orQCtFYImQ, at 0:50.

[3] *Id.* at 1:00.

[4] *Id.* at 1:20.

When asked about the rest of the process, the Administrator explained that "under the law and regulations," once HHS's review was complete and sent to DEA, "we then do what is known as an eight-factor review,"[5] referring to the eight factors HHS and DEA are required to consider in the scheduling process under 21 U.S.C. § 811(b)–(c). Then, she explained, there would be a period for notice and public comment.[6] "As head [of] the DEA," she concluded, "I will ultimately be responsible for signing off on what the scheduling is."[7] When pressed for her personal view of the appropriate scheduling classification for marijuana, the Administrator declined to answer, emphasizing that it would be improper for her to "prejudge it at this time."[8] She did, however, assure Rep. Gaetz that she would "keep an open mind" throughout the process.[9]

About a month later, HHS completed its scientific and medical evaluation and scheduling recommendation and transmitted them to DEA. In a letter dated August 29, 2023, Admiral Rachel L. Levine, M.D., HHS's Assistant Secretary for Health, recommended that DEA transfer marijuana to schedule III. *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023) ("August 2023 Letter"). HHS found that marijuana has "a potential for abuse less than the drugs or other substances in [s]chedules I and II"; marijuana has a "currently accepted medical use [("CAMU")] in treatment in the United States," *see* 21 U.S.C. § 812(b)(1)(B); and the abuse of marijuana may lead to "moderate or low physical dependence or high psychological dependence." Memorandum for DEA, from HHS, *Re: Basis for the Recommendation to Reschedule Marijuana to Schedule III of the Controlled Substances Act*, at 62–64. Accordingly, and consistent with the scheduling requirements in § 812 of the CSA, HHS recommended that DEA place marijuana in schedule III. *See* 21 U.S.C. 812(b)(3); August 2023 Letter.

Not once in its history as an agency had DEA ever rejected an HHS scheduling recommendation. This time, however, DEA did not just disagree with HHS's views, it opposed them so vehemently that the Attorney General had to refer the interagency dispute to the Office of Legal Counsel for resolution. Proposed Rule at 44,599 (citing *Questions Related to the Potential*

[5] *Id.* at 2:00.

[6] *Id.* at 2:15.

[7] *Id.* at 2:30.

[8] *Id.* at 2:25.

[9] *Id.* at 3:00.

Rescheduling of Marijuana, 45 Op. O.L.C. __ (Apr. 11, 2024) ("OLC Op.")). Among other things, DEA argued that U.S. treaty obligations required the Agency to keep marijuana in schedule I or schedule II. OLC Op. at 28 (noting that both HHS and the State Department—but not DEA—argued that treaty requirements did not impede the transfer of marijuana to schedule III).

DEA also insisted that HHS had used the wrong legal standard to conclude that marijuana has a CAMU. OLC Op. at 12 (noting HHS's view that "DEA's approach to CAMU is impermissibly narrow and that HHS's two-part inquiry is a permissible way to establish that a drug has a CAMU"); *id.* at 19 (noting "DEA's exclusive reliance on FDA approval and its five-part test" as the only permissible means for establishing CAMU); *id.* (concluding that "DEA's approach conflicts with the text of section 812(b)"). According to DEA, HHS should have applied the five-part test DEA itself had established in the early 1990s. *Id.* at 2 ("Since 1992, . . . DEA has determined that a drug has a CAMU only if either the [FDA] has approved the drug for marketing in interstate commerce under the Food, Drug, and Cosmetic Act ('FDCA'), 21 U.S.C. § 301 *et seq.*, or the drug meets a five-part test that tracks the 'core standards developed under the FDCA.'" (quoting Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,503–04, 10,506 (Mar. 26, 1992)). Critically, that test guarantees that marijuana could never have a CAMU because, among other reasons, it is a plant and therefore does not have "repeatable chemistry"—one of the five DEA-created requirements. *See* 57 Fed. Reg. at 10,504 (discussing the requirement under DEA's five-part test that "the drug's chemistry be known and reproducible"); *id.* at 10,507 (discussing the repeatable chemistry requirement and concluding that when it comes to marijuana, "[i]t is not possible to reproduce the drug in dosages which can be considered standardized by any currently accepted scientific criteria"). That is important because DEA's commitment to the proposition that marijuana lacks a CAMU necessarily means that the Agency is also committed to keeping marijuana in schedule I—the only schedule, according to DEA at least, for substances with any abuse potential and no CAMU. *See, e.g.*, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688, 53,689 (Aug. 12, 2016) ("Congress established only one schedule, Schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.'" (quoting 21 U.S.C. § 812(b)). In short, DEA did not merely disagree with the standards HHS applied in its analysis. It disagreed with its schedule III recommendation as well.

On April 11, 2024, however, the Office of Legal Counsel ("OLC") issued a formal opinion affirming HHS's decisions on the disputed issues.[10] OLC agreed with HHS that DEA's five-part CAMU test was "impermissibly" narrow, and HHS's alternative two-part test was lawful. *See* OLC Op. at 1. OLC also rejected DEA's argument that U.S. treaty obligations barred DEA from placing marijuana in schedule III. *Id.* Yet, despite this apparent setback, DEA persisted in its opposition to schedule III undeterred, forcing the Attorney General to take the unprecedented step of having the Department of Justice ("DOJ") promulgate the Proposed Rule itself and under his signature. Proposed Rule at 44,622 (reflecting the signature of the Attorney General instead of the DEA Administrator).

In doing so, the Attorney General explained that "[t]he CSA vests the Attorney General with the authority to schedule, reschedule, or decontrol drugs." Proposed Rule at 44,601 (citing 21 U.S.C. § 811(a)). The Attorney General has since delegated that authority to the DEA Administrator. *Id.* (citing 28 C.F.R. § 0.100). "[B]ut, [the Attorney General] also retains the authority to schedule drugs under the CSA in the first instance." *Id.* (citing *2*8 U.S.C. §§ 509, 510). According to the NPRM, DEA did *not* conduct an eight-factor analysis as the statute requires. DOJ did that work itself. *Id.* at 44,601 ("DOJ has reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and has conducted a separate review of the eight factors identified in 21 U.S.C. 811(c)."). Having conducted that review, the Attorney General expressly concurred with HHS's conclusions that, for purposes of assessing whether it was appropriate to initiate rulemaking proceedings, marijuana met all three requirements for schedule III placement. *Id.* at 44,616 ("The Attorney General concurs with HHS's recommendation, for purposes of initiation of these rulemaking proceedings, that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II"); *id.* at 44,619 ("[T]he Attorney General concurs with HHS's conclusion, for purposes of the initiation of these rulemaking proceedings, that there is a CAMU for marijuana."); *id.* ("[T]he Attorney General concurs with HHS's conclusion that the abuse of marijuana may lead to moderate or low physical dependence, depending on frequency and degree of marijuana exposure."). Although the Attorney General's legal conclusions are binding on DEA, the NPRM notes DEA's continued unwillingness to accept

[10] OLC's formal opinions are binding on the entire Executive Branch unless overruled by the Attorney General or the President. *See Cherichel v. Holder*, 591 F.3d 1002, 1016 n.17 (8th Cir. 2010) (noting that "OLC opinions are generally binding on the Executive branch"); *Public Citizen v. Burke*, 655 F. Supp. 318, 321–22 (D.D.C. 1987) (same).

the schedule III proposal. *Id.* at 44,601 ("DEA has not yet made a determination as to its views of the appropriate schedule for marijuana.").

Despite Section 811's command that DEA gather necessary data *before* initiating rulemaking proceedings and before obtaining HHS's "evaluation," the NPRM revealed that DEA had not done so. Instead, the Agency waited until the NPRM to flag several categories of evidence that it "anticipate[d]" it would receive at later stages of the rulemaking process and that, in its view, would bear on the scheduling decision, including:

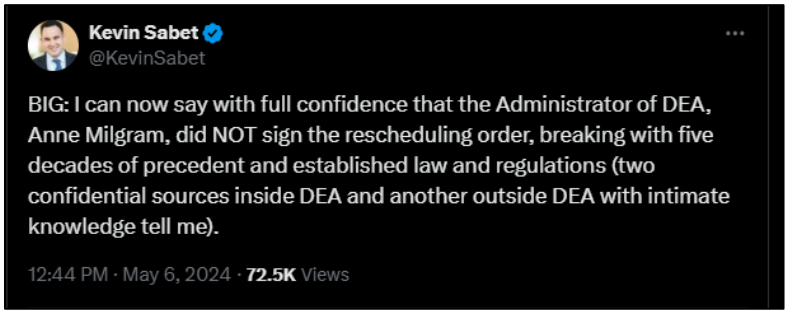
- "additional data on seizures of marijuana by law enforcement, cannabis-related ED visits, as well as updated epidemiological survey data since 2022" (*id.* at 44,602);
- "additional data on diversion from State programs and DEA-registered manufacturers" (*id.*);
- "additional data" showing that "[marijuana] has reinforcing effects characteristic of drugs of abuse," and "[d]ata on marijuana seizures [and] widespread availability and trafficking" (*id.* at 44,603);
- "additional data on marijuana's pharmacological effects" (*id.* at 44,605);
- "additional data on other marijuana constituents, routes of administration of marijuana, and the impact on Δ9-THC potency" (*id.* at 44,607);
- additional data regarding marijuana's history and pattern of abuse (*id.* at 44,610);
- "additional information regarding the scope, duration, and significance of marijuana abuse" (*id.* at 44,613);
- "additional data on public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of Δ9-THC potency" (*id.* at 44,614); and
- "additional psychic or physiological dependence liability may be appropriate for consideration" (*id.* at 44,615).

Because DEA failed to gather this data in advance as the statute requires, HHS was unable to consider it when developing its evaluation and recommendation. HHS's views of any such data and its implications for the scheduling analysis will therefore never be part of the rulemaking record.

B. Prominent Marijuana Prohibitionist Group, Smart Approaches to Marijuana, Bragged About Their Advance Knowledge of This Irregularity.

Despite the lack of historical precedent for any of this in DEA's more than half a century of administering the CSA, not everyone was surprised. Indeed, one prominent marijuana prohibitionist group knew all this would happen well in advance and bragged on social media about its insider knowledge.

Over a week before DOJ published the NPRM in the Federal Register, Dr. Kevin Sabet, President and CEO of Smart Approaches to Marijuana ("SAM"), took to X.com to brag that he had "BIG" news from "two confidential sources inside DEA . . . with intimate knowledge" that "the Administrator of DEA, Anne Milgram, did NOT sign the rescheduling order."[11]



Ten days later, when DOJ published the NPRM, Dr. Sabet reminded everyone that he knew all this in advance from his ex parte communications with his "confidential" DEA sources, emphasizing the NPRM's confirmation that "DEA has not made a determination as to its views of the appropriate schedule for marijuana."[12]

[11] @KevinSabet, X (May 6, 2024, 12:44 PM), https://x.com/KevinSabet/status/1787569052782846142.

[12] @KevinSabet, X (May 16, 2024, 12:38 PM), https://x.com/KevinSabet/status/1791191462597796137.

When the news media—and the public—finally learned all this, Dr. Sabet linked to the coverage and correctly reminded everyone that "[y]ou can believe me from a week or two ago, or you can believe the AP now. Either way it's the same!"[13]

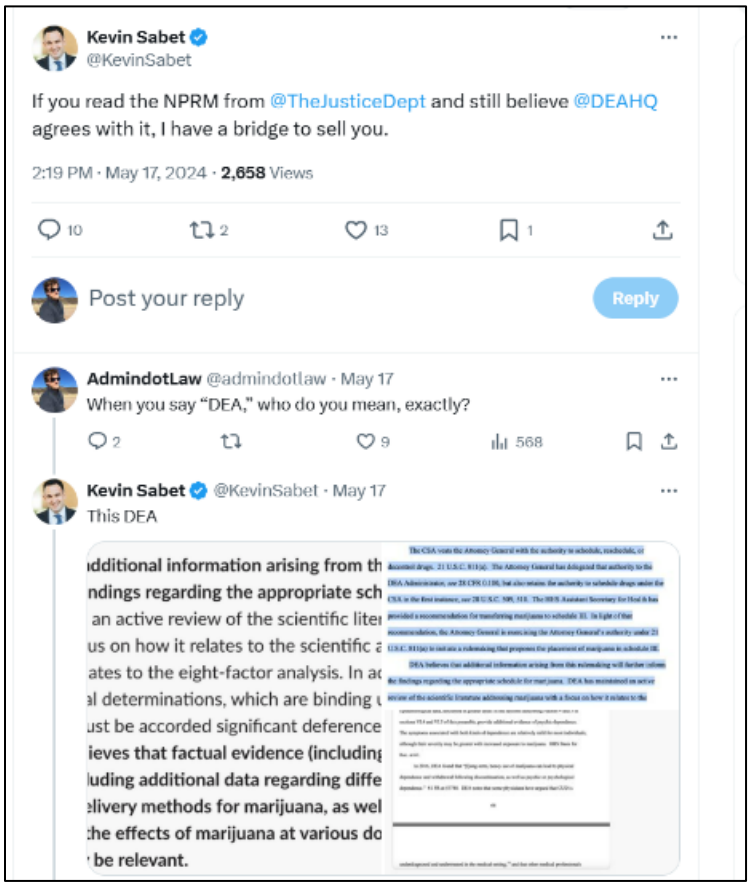
When asked in a tweet, "How did you know all this over a week before the AP?" Dr. Sabet responded that he "[has] friends in low places."[14] Indeed.

With his insider knowledge of the NPRM and DEA's internal view of the rulemaking, Dr. Sabet had a message for supporters of the Proposed Rule who might somehow still be operating under the delusion that DEA had maintained an open mind regarding the schedule III proposal,

[13] @KevinSabet, X (May 20, 2024, 1:31 PM), https://x.com/KevinSabet/status/1792654527486898626.

[14] @KevinSabet, X (May 20, 2024, 7:51 PM), https://x.com/KevinSabet/status/1792704695108354297.

taunting that "[i]f you read the NPRM from @TheJusticeDept and still believe @DEAHQ agrees with it, I have a bridge to sell you."[15]



In a June 2024 webinar discussing marijuana rescheduling, SAM's second in command, Luke Niferatos, seized on DEA's comments and request for data and proclaimed that DEA was "giving a roadmap for how to rebut their own Proposed Rule."[16] SAM then implored its followers to do DEA's bidding by tracking down the missing information DEA had requested.[17] SAM was joined on that webinar by Dr. Russel Kramer and Sue Thau, representatives of the International Academy on the Science and Impact of Cannabis ("IASIC") and the Community Anti-Drug Coalitions of America ("CADCA"), respectively.[18]

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[15] @KevinSabet, X (May 17, 2024, 2:19 PM), https://x.com/KevinSabet/status/1791533950948807061.

[16] Smart Approaches to Marijuana, *SAM Webinar: Rescheduling of Marijuana*, YOUTUBE (June 17, 2024), https://www.youtube.com/watch?v=3NWSz5LXRa4, at 24:25.

[17] *Id.*

[18] *Id.* Because of these ex parte communications, SAM has a conflict of interest. This Tribunal should direct SAM to preserve its records so that the full extent of its improper contacts with DEA can be included in the administrative record.

In promulgating the Proposed Rule, the Attorney General emphasized that he was "exercising the Attorney General's authority under 21 U.S.C. 811(a) to initiate a rulemaking that proposes the placement of marijuana in schedule III." Proposed Rule at 44,601. He also made clear that *DOJ*—not DEA—would promulgate any final rule that the administrative process might eventually produce. *See, e.g.*, *id.* at 44,621 ("DOJ is specifically soliciting comments on the economic impact of this proposed rule. *DOJ* will revise this section at the final rule stage if warranted after consideration of any comments received.") (emphasis added); *id.* at 44,599 n.9 (acknowledging that DOJ's role as proponent of the Proposed Rule will continue "for the entirety of the rulemaking process" and emphasizing that at later stages of the process, "outside participants may submit additional scientific and medical evidence . . . that *DOJ* would need to consider") (emphasis added) (citing OLC Op. at 25); Proposed Rule at 44,599 ("HHS's scientific and medical determinations are binding on DOJ until an NPRM is published, and, in addition, *DOJ* must accord 'significant deference' to HHS's scientific and medical determinations *throughout the rulemaking process*.") (emphases added) (quoting OLC Op. at 25–26).

While the NPRM contemplates DOJ's role as the proponent of the rule continuing through the promulgation of a final rule, it also reserves a discrete role for DEA in the process. Specifically, the Attorney General explained that "[t]he decision whether an in-person hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator of DEA." Proposed Rule at 44,598. If the DEA Administrator does "grant an in-person hearing," he continued, "DEA will publish a notice of hearing on the proposed rulemaking in the Federal Register." *Id.* (citing 21 C.F.R. §§ 1308.44(b), 1316.53).

At the same time, however, the Attorney General made clear that the designated Administrative Law Judge ("ALJ") would "preside over the hearing," and would "have all powers necessary to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order." *Id.* (citing 21 C.F.R. § 1316.52). Those powers include "the power to hold conferences to simplify or determine the issues in the hearing or to consider other matters that may aid in the expeditious disposition of the hearing; . . . sign and issue subpoenas to compel the production of documents and materials to the extent necessary to conduct the hearing; . . . rule on procedural items; and take any action permitted by the presiding officer under DEA's hearing procedures and the APA." *Id.* (citations omitted). Finally, he required "a courtesy copy of requests for hearing and

waivers . . . be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152." *Id.*

C. The DEA Administrator Selects, Without Explanation, Twenty-Five Entities, Including SAM and Other Prohibitionist Organizations SAM Works Closely With, to Participate in a Hearing on Marijuana Rescheduling.

On August 29, 2024, the DEA Administrator determined that an in-person hearing was appropriate and issued a General Notice of Hearing ("GnoH") setting a December 2, 2024 commencement date at the DEA Hearing Facility. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70,148, 70,148–49 (Aug. 29, 2024). The GnoH permitted "[i]nterested persons," as defined in 21 C.F.R. § 1300.01(b), "[to] file requests for a hearing," referencing DEA's regulation defining an "interested person" to mean "any person adversely affected or aggrieved by any rule or proposed rule issuable under 21 U.S.C. § 811." *Id.* at 70,149 (citations omitted). "Interested persons" seeking to participate in the rescheduling hearing were instructed to submit a filing: "(1) stat[ing] with particularity the interest of the person in the proceeding; (2) stat[ing] with particularity the objections or issues concerning which the person desires to be heard; and (3) stat[ing] briefly the position of the person regarding the objections or issues." *Id.*

About two months later, this Tribunal issued a Preliminary Order in this case, announcing that the DEA Administrator had designated this Tribunal to hear this case and explaining that "[o]n October 29, 2024," "two letters from the DEA Administrator were hand-carried to the DEA Office of Administrative Law Judges." Preliminary Order, at 1, 2 (citing Preliminary Order Attachments 1, 2). One letter (the "Participant Letter" or "PL") designated a list of 25 parties ("Designated Participants" or "DPs") that the DEA Administrator had "determined . . . will be participants at the hearing." *Id.*, and *id.* Attach. 1 (the PL). The DEA Administrator included SAM, IASIC, and CADCA on this list. *See* PL. The other letter "directed the utilization of livestreaming throughout the hearing proceedings." Preliminary Order, Attach. 2. This Tribunal attached both letters to the Preliminary Order "as the record has no indication as to whether either or both documents were served on the Designated Participants or any of those who sought to be DPs." Preliminary Order, at 2.

D. This Tribunal Orders the Designated Participants and the Government to Provide Some of the Information That the Administrative Procedure Act Requires for a Fair Hearing.

This Tribunal went on to express concerns about the state of the record in the wake of the Administrator's letters. *Id.* Part of the problem, it explained, was the lack of any "indication in the four corners of the [Administrator's letter] as to whether the 'participants' support or oppose the NPRM or how the 'participants' satisfy the 'interested person' definition set forth in the regulations." *Id.* (citing 21 C.F.R. §§ 1300.01(b), 1308.44(a)–(b)). In addition, "[w]hile the NPRM directed that the Office of Administrative Law Judges be served with a courtesy copy of any hearing request filing(s), the GnoH contained no such requirement." *Id.* As a result, this Tribunal had no "documentation related to whether/how the Designated Participants would be 'adversely affected or aggrieved' by the proposed regulation change in the NPRM, or any other particularly helpful information." In fact, "the Agency has furnished this tribunal with no correspondence from itself or the Designated Participants that was generated in response to the GnoH." *Id.* n.4. "To the extent that [the interested person status of any of the Designated Participants] has been adjudicated, it is not transparent in the present record." *Id.* at 3. Thus, "[t]o effectively preside over this hearing, additional information [needed to] be furnished to this tribunal forthwith." *Id.*

It therefore ordered those DPs who sought to participate in these hearing proceedings to file a brief notice by November 12, 2024, providing six categories of information: (1) the DP's contact information and the general nature/principal mission of their practice, profession, or business; (2) a notice of appearance for their counsel of record; (3) the date that they properly filed a request for hearing and/or participation with the DEA; (4) why/how they would be sufficiently "adversely affected or aggrieved" by the proposed scheduling action to qualify as an "interested person" under the regulations; (5) whether they support or oppose the rescheduling action the DEA seeks in the NPRM; and (6) any known conflicts of interest with DEA or DOJ leadership or personnel that may require disclosure. *Id.*

It further ordered the Government to file by the same date "a notice of appearance for its counsel(s) of record as well as any known conflicts of interest that may require disclosure." *Id.* at 3–4. It did not, however, order the Government to declare whether it supports or opposes the proposed rescheduling action. Finally, this Tribunal ordered that the December 2, 2024 hearing set in the GnoH would be a preliminary hearing and directed the DPs to "come prepared with January-

February 2025 availability dates regarding their counsel and any witness such DP will seek to present at the hearing on the merits." *Id.* at 4.

By November 12, 2024, the DPs had submitted their responsive filings. The Government likewise filed a "notice of appearance for DEA attorneys James J. Schwartz, Jarrett T. Lonich and S. Taylor Johnston." Gov't.'s Notice of Appearance at 1.

II. Argument

A. The DEA Administrator's Designation of Participants Was Unlawful.

The DEA Administrator's selection of twenty-five DPs for participation in these proceedings was unlawful for at least four reasons. First, it usurped this Tribunal's authority as the Presiding Officer. *See* Proposed Rule at 44,598 (directing DEA to "designate an Administrative Law Judge ('ALJ') to preside over [any] hearing" granted and declaring that the ALJ's powers include authority to "take any action permitted by the presiding officer under DEA's hearing procedures and the APA") (citing 21 C.F.R. § 1316.52). When a matter is referred to an ALJ for hearing, the Agency may not attempt to influence or coerce the ALJ's exercise of their authority as the Presiding Officer. 5 U.S.C. § 556(b) ("The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner.").[19] Thus, by ruling in the first instance on the requests to participate in the hearing that she received, the DEA Administrator usurped this Tribunal's authority to "regulate the course of the hearing" and "rule on procedural items" as necessary to "conduct a fair hearing." *Id.* § 556(c)(5); 21 C.F.R. § 1316.52. Such intrusions on ALJ authority to decide issues in a hearing in the first instance are unlawful. *See, e.g.*, *See v. Washington Metro. Area Transit Auth.*, 36 F.3d 375, 382 (4th Cir. 1992) (agency attempt to decide relevant labor market in the first instance "constituted an improper usurpation of the ALJ's authority in administrative proceedings"); *Dep't of Labor v. Cargill, Inc.*, 689 F.2d 819, 821 (9th Cir. 1982) (holding that because ALJ had authority

[19] *See also* Final Report of the Attorney General's Committee on Administrative Procedure 56 (Jan. 22, 1941), https://www.regulationwriters.com/downloads/apa1941.pdf ("It is clear that when a controversy reaches the stage of hearing and formal adjudication the persons who did the actual work of investigating and building up the case should play no part in the decision. This is because the investigators, if allowed to participate, would be likely to interpolate facts and information discovered by them ex parte and not adduced at the hearing, where the testimony is sworn and subject to cross-examination and rebuttal. In addition, an investigator's function may in part be that of a detective, whose purpose is to ferret out and establish a case. Of course, this may produce a state of mind incompatible with the objective impartiality which must be brought to bear in the process of deciding.").

to decide particular issue in the first instance, agency had "no authority to usurp his role in this respect").

The Administrator's usurpation of this Tribunal's authority by making decisions related to the DP list is especially problematic because the Administrator did not include her reasons for designating the parties she selected for participation. Nor did she include copies of all requests for hearing and/or to participate that the Agency received or DEA's decisions granting or denying each of them. As a result, there is no record that might enable this Tribunal or a federal court to assess the propriety of DEA's decisions to exclude the parties it chose to exclude or even to know how many parties it excluded. This lack of transparency is alarming, undemocratic, and betrays notions of good governance.

Second, the Administrator's usurpation of this Tribunal's authority also impedes this Tribunal's ability to ensure fairness and transparency in these proceedings. *See id.* § 556(b) (requiring impartiality in ALJ decision making). Without knowing who DEA excluded and why, there is no way to assess whether and to what extent the Agency's decisions are arbitrary and capricious, the subject of bias, or otherwise unlawful. If, for example, DEA included parties with expertise on a particular topic but only if they opposed the Proposed Rule while also excluding parties with even more expertise on that same topic if they supported the Proposed Rule, then there would be a powerful case to be made that the Agency's decisions were arbitrary and capricious. Likewise, if the Agency excluded states that support the Proposed Rule (e.g., Colorado) but included states that oppose it (e.g., Nebraska and Tennessee), then there would be reason to doubt that such a decision was the product of reasoned decision-making.[20] *See, e.g.*, 32 Charles Alan Wright & Charles H. Koch, Federal Practice and Procedure § 8248, at 431 (2006) (discussing the bedrock principle of administrative law that an agency must "treat like cases alike"); *see also Univ. of Tex. M.D. Anderson Cancer Ctr. v. United States HHS*, 985 F.3d 472, 479 (5th Cir. 2021) (same); *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005) ("An agency must provide an adequate explanation to justify treating similarly situated parties differently."); Wright & Koch, Federal Practice & Procedure § 8248, at 431 ("General principles of administrative law hold that an agency must be consistent . . . ."). Without knowing who DEA excluded and why, however, that sort of agency error is virtually impossible to detect.

[20] There are no Destinated Participants who are responsible for their state medical marijuana programs.

Third, the Administrator's decision violates 5 U.S.C. § 555(e)'s command that agencies provide "[p]rompt notice . . . of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding" along with "a brief statement of the grounds for denial." Undersigned counsel represents or are aware of several parties who requested hearings and/or to participate in these proceedings and yet to this day have never received any response from DEA. The Administrator's letter amounts to a constructive denial of these parties' requests, but because DEA did not provide the requesting parties with prompt notice of that denial along with a brief statement of the grounds supporting it, the Administrator's decision violates 5 U.S.C. § 555(e).

Fourth, although Hemp for Victory, Village Farms, and this Tribunal lack a complete record of the requests DEA received and the DEA's decisions granting or denying them, those portions of the Administrator's decisions regarding who may and may not participate in these proceedings that Hemp for Victory and Village Farms are aware of are arbitrary and capricious in several respects:

- The Administrator provided some requesting parties notice of her decision denying their requests but withheld her decisions denying other parties' requests without explanation. Not only does this violate the core principle of reasoned decisionmaking that agencies must treat like cases alike, but it also raises the natural concern that the Administrator seeks to thwart judicial review of denials that would be especially difficult to defend.
- The Administrator granted participation to some parties only to exclude other seemingly similarly situated parties. *Contra Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d at 776 ("An agency must provide an adequate explanation to justify treating similarly situated parties differently."). Thus, for example, she permitted the state of Nebraska to participate but never responded to (and thus constructively denied) Colorado's request without notice or explanation. While Colorado's request and the Administrator's apparent denial of it are not in this record, the obvious difference between Nebraska and Colorado relevant to these proceedings is that Nebraska has no medical marijuana program and opposes

the Proposed Rule, while Colorado has ten years of experience with a regulated medical marijuana market and supports the Proposed Rule.[21]

- The Administrator granted participation to several parties who plainly do not qualify as "interested persons" under DEA regulations and also have only irrelevant testimony to offer. *See* 21 C.F.R. § 1300.01(b).[22]

In its Preliminary Order, this Tribunal directed the DPs to explain why they qualify as "interested persons" entitled to participate in these proceedings and declare whether they support or oppose the Proposed Rule. Preliminary Order, at 3. As this Tribunal recognized, doing so was necessary to "effectively preside over this hearing." *Id.* Because the record remains incomplete, however, this Tribunal must take additional corrective action to ensure that all requests for hearing and/or to participate that DEA received are included in the record along with DEA's decisions granting or denying them and a brief statement of DEA's grounds for any denials. In addition, this Tribunal should review all requests in the first instance to ensure that the proper parties are participating in these proceedings. For instance, movants are not aware of one DEA-licensed researcher who was admitted as a Designated Party.[23]

B. DEA's Ex Parte Communications with Designated Party Smart Approaches to Marijuana Are Unlawful.

The APA and DEA regulations prohibit ex parte communications and require that they be disclosed and made part of the administrative record. *See* 5 U.S.C. § 557(d); 21 C.F.R. § 1316.51(c).[24] SAM's President, Dr. Kevin Sabet, has bragged on social media about his ex parte

[21] The State of Colorado's request dated Sept. 30, 2024 is attached as Exhibit A.

[22] A list of those DPs and the reasons they are not "interested persons" is attached as Exhibit B.

[23] MedPharm and Dr. Sue Sisley are both licensed researchers who filed timely petitions to participate, and neither received any notice from DEA that they were excluded or why.

[24] 21 C.F.R. § 1316.51(c) provides that "[i]f any official of the Administration is contacted by any individual in private or public life concerning any substantive matter which is the subject of any hearing, at any time after the date on which the proceedings commence, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file." DEA regulations define "proceeding" to mean "all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21 U.S.C. 811), commencing with the publication by the Administrator of the proposed rule, amended rule, or repeal in the Federal Register." 21 C.F.R. § 1300.01. Leaving aside the fact that the Administrator did not publish the Proposed Rule in the Federal Register here, movants acknowledge that the ex parte communications they have been able to unearth so far occurred days *before* DOJ published the Proposed Rule in the Federal Register. While perhaps not expressly barred by the DEA regulation barring ex parte communications, movants assert that those contacts between SAM and DEA are nevertheless improper. Moreover, the existence of those ex parte communications

communications with "confidential sources inside" regarding the Administrator's views and intentions with respect to the Proposed Rule. *See supra* n.11 (citing @KevinSabet, May 6, 2024). Yet neither SAM nor DEA has disclosed those communications or made them part of the record in these proceedings. As a result, there is no way for this Tribunal or a reviewing court to know the extent of DEA's improper contacts with private parties regarding the issues that will ultimately decide the outcome of this administrative process. Dr. Sabet's social media posts invite relevant additional questions: What other ex parte communications has DEA had with SAM? When did they occur? Who are SAM's "confidential DEA sources"? Is SAM the only private party with whom DEA has had ex parte communications regarding issues critical to this administrative process? To what extent have any such communications influenced DEA or given the parties with whom it communicated an unfair advantage in this adversarial process?

Regarding that last point, there is concrete reason to suspect that DEA's improper contacts with private parties who oppose marijuana rescheduling have tainted the list of DPs that DEA has permitted to participate in these proceedings. As discussed above, the NPRM flagged several categories of data and evidence that DEA "anticipate[d]" it would receive during the remainder of the rulemaking process and that, in its view, would bear on the scheduling decision, including "updated epidemiological survey data since 2022" (Proposed Rule at 44,602), "additional data" showing that "[marijuana] has reinforcing effects characteristic of drugs of abuse" (*id.* at 44,603), "[d]ata on marijuana seizures [and] widespread availability and trafficking" (*id.*), and "additional data on public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of Δ9-THC potency" (*id.* at 44,614).

Notably, data meeting any of these descriptions would tend to undermine the Proposed Rule. To the extent that these categories of data were, in fact, "necessary" to the scheduling process, DEA's attempt to gather them through the NPRM was improper. Section 811(b) of the CSA directs DEA to "gather[] the necessary data" "*before* initiating proceedings [through an NPRM] under subsection (a) to control a drug" and *before* "request[ing] from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled." (emphasis added). Congress required DEA to gather the

gives rise to a credible concern that DEA had subsequent ex parte communications with SAM (and perhaps others) after DOJ published the Proposed Rule in the Federal Register. Because neither SAM nor DEA has disclosed any such communications, this Tribunal must permit an investigation into the matter to be certain the full extent of DEA's improper communications with third parties are made part of the record.

necessary data first for a reason—namely, so that HHS could consider it as part of its scientific and medical evaluation and scheduling recommendation.

By waiting until the publication of the NPRM—and thus *after* DOJ had initiated proceedings under § 811(a)—to flag categories of supposedly "necessary data," DEA ensured that HHS would not get to respond to that data in its recommendation and evaluation. Even worse, DEA effectively turned the NPRM into a blueprint for the Prohibitionists it apparently was communicating with behind the scenes. As SAM's second in command, Luke Niferatos, acknowledged on a webinar with IASIC and CADCA, DEA was "giving a roadmap for how to rebut their own Proposed Rule."[25] Then the DEA Administrator selected without explanation SAM, IASIC, and CADCA as "Designated Participants" in these proceedings. *See* PL.

In light of this evidence of improper ex parte communications between DEA and private parties, this Tribunal must take all steps necessary to ensure that all such communications are discovered and included in the administrative record. *See, e.g.*, *Portland Audubon Soc'y v. The Endangered Species Comm.*, 984 F.2d 1534, 1548–49 (9th Cir. 1993) (to prevent ex parte contacts from thwarting judicial review, tribunal must supplement the record to include the improper communications); *PATCO v. Fed. Labor Relations Auth.*, 685 F.2d 547 (D.C. Cir. 1982) (requiring disclosure of ex parte communications to further the interests of openness and provide parties the opportunity to respond). Unless and until that happens, there will effectively be two records of these proceedings: one that is public and incomplete and another that is secret, complete, and available only to those in the know. Or as Dr. Sabet put it, those with "friends in low places."[26]

Hemp for Victory and Village Farms request that this Tribunal use every tool at its disposal to uncover each instance of improper contact between DEA and prohibitionists and determine whether those contacts influenced the Designated Participants list created by the Administrator. Requiring disclosure of the ex parte contacts is what the law demands, and because sunlight is the best disinfectant, it will restore confidence in these proceedings. *See* 5 U.S.C. § 557(d); 21 C.F.R. § 1316.51(c).

[25] *See SAM Webinar: Rescheduling of Marijuana*, *supra* n.16, at 24:25.

[26] *See* @KevinSabet, *supra* n.14.

C. DEA Is Not the Proponent of the Proposed Rule and Therefore May Not Shoulder the Burden of Proof in These Proceedings.

This Tribunal's October 31, 2024, Preliminary Order emphasized the importance of the role of the "proponent" of the Proposed Rule in these proceedings. Preliminary Order, at 3–4, 4 n.9. Under the APA and DEA regulations, the proponent of a rule bears the burden of proof, which, in this case, means the burden of demonstrating that substantial evidence supports the proposed transfer of marijuana from schedule I to schedule III. *See* 21 U.S.C. § 811(b) ("If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a)."); Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV, 76 Fed. Reg. 77,330, 77,333 (Dec. 12, 2011) ("Because I hold that the record as a whole contains substantial evidence to support the findings required to control carisoprodol and place it in schedule IV of the CSA, I will issue a rule placing carisoprodol in schedule IV.").

In its Preliminary Order, this Tribunal appeared to treat DEA as the proponent of the Proposed Rule. *See, e.g.*, Preliminary Order, at 3 (ordering DPs to provide this Tribunal with certain information, including "whether the DP supports or opposes the rescheduling action the *DEA seeks* in *its* NPRM") (emphases added). That assumption is understandable. After all, the agency with delegated authority to implement a statute is, ordinarily, the proponent of rules promulgated under that statute, and for over fifty years, DEA has been the proponent of every proposed scheduling rule promulgated under the CSA. As Hemp for Victory and Village Farms explain next, however, this is no ordinary case, and DEA cannot act as the proponent of the NPRM at issue here because (1) it did not propose the NPRM—DOJ did—and (2) DEA's actions throughout the administrative process demonstrate beyond cavil that the Agency *opposes* the proposed transfer of marijuana to schedule III and is compromised. As a result, treating DEA as the proponent of the Proposed Rule would, under these extraordinary and unprecedented circumstances, violate the APA and DEA regulations and render these proceedings a sham. Lawyers from DOJ—not DEA—must therefore defend this rule.

Throughout this administrative process—and its history as an Agency for that matter—DEA has actively opposed marijuana rescheduling. When HHS transmitted its schedule III

recommendation and 252-page scientific and medical evaluation to DEA, the Agency refused to accept HHS's analysis, leading the Attorney General to refer the interagency dispute to OLC for resolution. *See* Proposed Rule, 89 Fed. Reg. at 44,599 ("The Attorney General then sought the legal advice of the [OLC] at DOJ on questions relevant to this rulemaking proceeding."). When OLC sided with HHS almost across the board, DEA still refused to support rescheduling, forcing the Attorney General to step in again, this time to promulgate the NPRM on behalf of DOJ and under his own signature. *See id.* at 44,622 (reflecting the signature of the Attorney General instead of the DEA Administrator). Finally, in case these signals of discontent were somehow unclear, the NPRM itself removed any doubt by acknowledging that "DEA has not yet made a determination as to its views of the appropriate schedule for marijuana." *Id.* at 44,601.

Two of these steps are unprecedented and the third is nearly so. Not once in the CSA's history has DEA ever rejected an HHS scheduling recommendation. Nor has DEA opposition to a scheduling action required the Attorney General to sign a rescheduling NPRM himself. While OLC has not made all of its opinions public, Hemp for Victory and Village Farms are aware of only one historical instance of the Attorney General referring an interagency dispute over the standards applicable in the scheduling context to OLC for resolution.[27]

DEA's doubly anomalous behavior in these proceedings is all the more remarkable because the Attorney General's legal conclusions are binding on DEA. Thus, once the Attorney General concurred with the key findings underlying HHS's schedule III recommendation, DEA no longer had any discretion in the matter. By persisting in its oppositionist crusade anyway, thus forcing the Attorney General to promulgate and sign the Proposed Rule himself, DEA revealed that it is more committed to thwarting this Proposed Rule than it is to following the law or maintaining an open mind.

Because DEA is the *opponent* of the Proposed Rule and not its proponent, the Agency cannot bear the burden of proof in these proceedings. Under the APA and DEA's own regulations, that role must be filled by a party that actually proposed a rule transferring marijuana to schedule III. There are only two entities that qualify: (1) DOJ, the agency that actually proposed the NPRM,

[27] *See* Memorandum for John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, Re: Petition to Decontrol Marihuana; Interpretation of Section 201 of the Controlled Substances Act of 1970 at 12–13 (Aug. 21, 1972), https://www.justice.gov/olc/media/1359191/dl?inline (resolving a dispute between DEA's predecessor agency, the Bureau of Narcotics and Dangerous Drugs, and the Special Action Office for Drug Abuse Prevention, a predecessor to what is today the Office of National Drug Control Policy).

and (2) Hemp for Victory, the only party to these proceedings that has, in fact, filed a petition and proposed a schedule III rule.[28] Therefore, unless DOJ is willing to enter an appearance in these proceedings, this Tribunal must permit Hemp for Victory to act as proponent of the rule going forward.

The proponent of the rule designation is no mere technicality. Because that party bears the burden of proof, this Tribunal has permitted them more witnesses and more counsel at the hearing. Given its steadfast opposition to the proposed transfer of marijuana to schedule III, DEA is the last party on Earth that should be permitted to act as proponent of the Proposed Rule in these proceedings.[29] Not only would permitting DEA to remain in that role violate the APA and DEA regulations, but it would also vitiate any chance this Tribunal might have of ensuring a fair and transparent hearing or developing a complete administrative record. After all, the entire point of the formal rulemaking process is to put the Proposed Rule to the test of a rigorous adversarial process. If the supposed champion of the Proposed Rule is, in fact, its greatest opponent, however, the entire process will be a farce.

Permitting DEA to remain the proponent of the Proposed Rule would also undermine the actual and perceived legitimacy of these proceedings. DEA's opposition to the proposed placement of marijuana in schedule III is no secret. Indeed, no disinterested observer aware of DEA's actions during this administrative process could believe that DEA would use its privileged position, additional witnesses, and extra counsel at the upcoming hearing for any purpose other than the one it has pursued every step of the way so far: to thwart the Proposed Rule by any means necessary. The predictable result would be an unfair process, a lopsided, contrived, and incomplete record, an unjust final rule, and an inevitable petition for review in federal court. Compared to its informal notice-and-comment cousin, formal rulemaking—with its adversarial hearings, cross examination, and procedural safeguards—is supposed to *enhance* the quality, transparency, and legitimacy of the rules it produces. Unless DEA is removed from the role of proponent of the rule, those purposes

[28] Hemp for Victory submitted to DEA a petition to initiate rulemaking to deschedule or reschedule marijuana on November 15, 2023. In its petition, a copy of which is attached as Exhibit C, Hemp for Victory included the text of a schedule III proposed rule. *See* Ex. C at 4.

[29] DEA has thwarted this process in other ways. For instance, DEA has refused to provide documents regarding ex parte communications pursuant to two valid Freedom of Information Act requests and, in violation of FOIA and DOJ policy, has not replied with any objections or exceptions.

will be defeated before the hearing in this case commences. DOJ therefore must take over as proponent of the rule.

D. DEA is Compromised and Should Be Barred From Further Participation in These Proceedings.

Agencies that have predetermined issues necessarily fail to exercise the reasoned decisionmaking the APA requires. Indeed, an agency decisionmaker violates the Due Process Clause when they act with an "unalterably closed mind" and are "unwilling or unable to consider rationally argument that [the proposed rule] is unnecessary." *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170, 1174 (D.C. Cir. 1979). Where "clear and convincing" evidence supports such a finding, the agency decisionmaker must be excluded from the administrative process. *See, e.g.*, *Alaska Factory Trawler Ass'n v. Baldridge*, 831 F.2d 1456, 1467 (9th Cir. 1987) (citing *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979)).

The evidence that DEA has an "unalterably closed mind" regarding the proposed transfer of marijuana to schedule III in this case is nothing short of overwhelming. DEA's biased opposition to placing marijuana in schedule III runs so deep that neither the scientific analysis and recommendation of HHS nor the binding legal conclusions of OLC, DOJ, and the Attorney General *combined* could sway it even to take the threshold step of initiating proceedings. Dr. Sabet himself understood just how closed DEA's mind was even before the NPRM appeared in the Federal Register, mocking anyone who "read the NPRM from @TheJusticeDept and still believe @DEAHQ agrees with it" that he "ha[s] a bridge to sell you."[30] He was correct. DEA made up its mind to oppose this Proposed Rule a long time ago.

DEA has thwarted legal process, has violated basic rules of transparency, and cannot be entrusted to defend this Proposed Rule. Because there is clear and convincing evidence that DEA is compromised regarding the Proposed Rule, this Tribunal should exclude it from further participation in these proceedings and place DOJ in the position to defend the rule.

III. Conclusion and Relief Requested

For the reasons stated above, Hemp for Victory and Village Farms request that this Tribunal replace DEA with DOJ and/or Hemp for Victory as proponent of the NPRM and further order that the record include:

[30] *See* @KevinSabet, *supra* n.15.

All requests for hearing and/or participation in these proceedings filed with DEA;

A record of the decisions made by the Administrator regarding why certain parties were designated as participants and others were not; and

Any ex parte communications between DEA and third parties.

Finally, Hemp for Victory and Village Farms request that this Tribunal order SAM and DEA to preserve its records.

Dated: November 18, 2024

By: */s/ Shane Pennington*

Shane Pennington
PORTER WRIGHT MORRIS & ARTHUR LLP
2020 K Street, NW, Ste. 600
Washington, D.C. 20006
SPennington@porterwright.com

Counsel of Record for Designated Participants Village Farms and Intervenor MedPharm

Tristan Cavanaugh
PORTER WRIGHT MORRIS & ARTHUR LLP
2020 K Street, NW, Ste. 600
Washington, D.C. 20006
TCavanaugh@porterwright.com

Counsel of Record for Designated Participant Village Farms

Andrew J. Kline
PERKINS COIE LLP
1900 Sixteenth Street, Suite 1400
Denver, Colorado 80202-5255
AKline@perkinscoie.com

Counsel of Record for Designated Participants Hemp for Victory and Intervenor MedPharm

Abdul Kallon
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, Washington 98101-3099
AKallon@perkinscoie.com

Counsel of Record for Designated Participant Hemp for Victory

Sopen Shah
PERKINS COIE LLP
33 East Main Street, Suite 201
Madison, WI 53703-3095
SShah@perkinscoie.com

Counsel for Designated Participant
Hemp for Victory

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 18, 2024, caused a copy of the foregoing to be delivered to the following recipients:

1. DEA Government: James Schwartz, Esq., via email at james.j.schwartz@dea.gov and dea.registration.litigation@dea.gov;
2. Village Farms International: Shane Pennington and Tristan Cavanaugh, via email at spennington@poterwright.com and tcavanaugh@porterwright.com;
3. National Cannabis Industry Association: Aaron Smith, Michelle Rutter, Nikolas S. Komyati, William Bogot, and Khurshid Khoja, via email at aaron@thecannabisindustry.org, michelle@thecannabisindustry.org, nkomyati@foxrothschild.com, wbogot@foxrothschild.com, and khurshid@greenbridgelaw.com;
4. American Academy of Hospice and Palliative Medicine: Chad Kollas, via email at wchill@aahpm.org;
5. Cannabis Bioscience International Holdings: John Jones and Dante Picazo, via email at ir@cbih.net;
6. Hemp for Victory: Robert Head, Andrew J. Kline, and Abdul Kallon, via email at robert@bluecordfarms.com, akline@perkinscoie.com, and akallon@perkinscoie.com;
7. State of Connecticut: Erin Gorman Kirk, via email at erin.kirk@ct.gov;
8. Massachusetts Cannabis Advisory Board: Ellen Brown, Timothy Swain, and Shawn Hauser, via email at ellen@greenpathtraining.com, t.swain@vicentellp.com, and s.hauser@vicentellp.com;
9. Veterans Initiative 22: Shanetha Lewis, via email at info@veteransinitiative22.com;
10. The Doc App. Dba and My Florida Green: Jason Castro and Nicholas Garulay, via email at jasoncastro@myfloridagreen.com and Nick@TheDocAppt.net;
11. The Commonwealth Project: Katy Green and Kelly Fair, via email at kag@platinumadvisors.com and at Kelly.Fair@dentons.com;
12. Saint Michael's College: Ari Kirshenbaum and Rafe Pedersen, via email at mslade@cannabispublicpolicyconsulting.com and at Rafe.Petersen@hklaw.com;
13. National Drug and Alcohol Screening Association: Jo McGuire, via email at jomcguire@ndasa.com;
14. Smart Approaches to Marijuana: Patrick Philbin and Chase Harrington, via email at pphilbin@torridonlaw.com and charrington@torridonlaw.com;
15. International Academy on the Science and Impact of Cannabis: Roneet Lev, via email at roneetlev@gmail.com;

16. Cannabis Industry Victims Educating Litigators: David Evans and Kenneth Finn, via email at thinkon908@aol.com and kfinn@springsrehab.net;
17. National Transportation Safety Board: Jennifer Homendy, Stephanie E. Masker, Phillip Drum, and David G. Evans, via email at executivesecretariat@ntsb.gov, correspondence@ntsb.gov, stephanie.masker@ntsb.gov, phillipdrum@comcast.net, and thinkon908@aol.com;
18. State of Nebraska: Zachary A. Viglianco and Eric J. Hamilton, via email at zachary.viglianco@nebraska.gov and eric.hamilton@nebraska.gov;
19. International Association of Chiefs of Police: Gene Voegtlin, via email at voegtlin@theiacp.org;
20. Drug Enforcement Association of Federal Narcotics Agents: Gregory J. Cherundolo, via email at marshallfisher@rocketmail.com and at executive.director@afna.org;
21. Community Anti-Drug Coalitions of America: Sue Thau and David G. Evans, via email at suerthau@gmail.com, thinkon908@aol.com, and cdoarn@cadca.org;
22. Tennessee Bureau of Investigation: Reed N. Smith and Jacob Durst, via email at Reed.Smith@ag.tn.gov, Jacob.Durst@ag.tn.gov, and kim.litman@tbi.tn.gov; and
23. National Sheriffs' Association: Sheriff Jim Skinner, via email at sheriffskinner@collincountytx.gov, jskinner@sheriffs.org, and ykaraman@sheriffs.org.

Andrew J. Kline

Exhibit A

JARED POLIS
GOVERNOR

136 STATE CAPITOL
DENVER, COLORADO 80203

TEL 303-866-2471
FAX 303-866-2003

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Notice of Appearance (Docket No. DEA-1362)

Dear Administrator Milgram,

The State of Colorado requests to appear in the matter of The Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule") currently scheduled to take place on December 2, 2024.

(A) The State of Colorado has standing to participate in this administrative hearing as an "interested person" defined under 21 CFR 1300.01(b). The State is requesting the below listed parties participate at the hearing to offer distinct factual evidence and expert opinion regarding the rescheduling of marijuana. The State's status as an "interested person" as defined in §1300.01, and the status of the representatives requesting to participate in the hearing on behalf of Colorado, are detailed further below.

The State's public officials who have a role in administering, overseeing and advising on the success of Colorado's marijuana framework, as well as the people of Colorado, will be adversely affected or otherwise aggrieved by the Proposed Rule if marijuana remains a Schedule I Controlled Substance.

Colorado's legal marijuana industry has generated over $16.3 Billion in sales over the past 10 years and has generated over $2.7 Billion in state tax and fee revenue. This industry has contributed to well over 40,000 jobs of just those directly involved in the industry, in addition to the tens of thousands of professionals in ancillary industries who support the marijuana industry. As this sector continues to grow at a rapid pace, the State is concerned that a federal rescheduling determination that lacks important insights and subject matter expertise from Colorado officials will introduce significant risks to the State's marijuana framework, the ability to continue to effectively carry out regulatory and policy responsibilities on behalf of the State, and the programs that marijuana tax revenue has funded to support communities across Colorado.

(B) Colorado possesses a cadre of subject matter experts who can provide unique insight related to medical marijuana. The State has had a robust medical program for 24+ years with licensed healthcare professionals and providers making recommendations to treat symptoms related to Autism, Cachexia, Cancer, Glaucoma, HIV/AIDS, Muscle Spasms, PTSD, Seizures, Severe Nausea and Chronic/Severe pain and as an option to avoid using opioids. The State leads a strong medical program with over 63,000 current registered medical marijuana patients including over 22,400 patients who have the qualifying condition of anything for which an opioid may be

prescribed. Given the country's opioid epidemic, our evidence of marijuana having medical utility and abuse potential far below opioids would inform DEA's process.

Our data is relevant, unique and, non-duplicative of any other state and our experts are well suited to inform the administrative process as the DEA considers the rescheduling of marijuana under the Controlled Substances Act.

The DEA's notice of rulemaking directly referenced Colorado data that our experts are prepared to address. Specifically, the notice of proposed rulemaking reference of public health risks associated with driving under the influence of marijuana, cited traffic deaths in Colorado. The data cited in the notice lacks important context that must be considered in this rulemaking. The public officials listed herein as interested parties are prepared to provide the context and additional data on traffic safety necessary to inform the rescheduling determination.

In addition, the State has robust data on youth use, which is directly relevant to DEA's analysis regarding abuse potential. Notably, the questions we ask in our Healthy Kids Colorado Survey has more specific survey questions related to use and perceptions of use than SAMSHA's National Survey on Drug Use and Health and CDC's Youth Risk Behavior Surveillance System. Importantly, our data will show that youth use has not increased post legalization. Colorado youth continue to use marijuana at lower rates than their peers nationally. While we acknowledge harms associated with illicit use, the overwhelming conclusions demonstrate that the legalization of marijuana in our state is contributing to decreased youth use, not the opposite.

(C) Our public officials have significant subject matter expertise regulating the medical and adult-use markets over the past decade and are prepared to testify regarding data attributable to medical use in treatment in the United States and relative abuse potential of marijuana. Our State is particularly well situated to provide this insight as we are one of the first states to legalize and regulate medical marijuana and the first to legalize adult-use.

For more than 10 years, our Senior Director of Enforcement at the Marijuana Enforcement Division (MED), Dominique Mendiola, has served as a regulator for the MED. Mendiola is also the current President of the Cannabis Regulators Association (CANNRA), a national association of agencies responsible for regulating cannabis and cannabinoids. She has a perspective that is relevant and distinct from other state regulators. Other states have and continue to look at Colorado as a role model for what their state can do to protect public health. A federal rescheduling consideration that lacks clear guidance on how priorities and roles will change presents uncertainties and risks that can compromise the diligent efforts she and her MED team have made on behalf of the State.

Ean Seeb is our Governor's Special Advisor on Cannabis and Natural Medicine. He brings unique insights having been both an early industry operator in Medical and Adult-Use marijuana and has been part of our senior policy team for over half a decade, during which time the State has evolved on dozens of marijuana laws and regulations. As an advisor and partner to agencies charged with administering the State's marijuana program, a federal rescheduling consideration that references incomplete Colorado data and that lacks clear guidance on how priorities and roles will change under a proposed rescheduling presents similar uncertainties that will impact Seeb's ability to most effectively carry out his role on behalf of the State.

For the above reasons, the State of Colorado is filing this written request to have the parties referenced above participate at the upcoming Administrative Law Hearing scheduled December, 2nd, 2024. This notice of intention to participate conforms with 21 CFR 1308.44(b), by describing (a) the identity and interests of the parties who will participate in the hearing on behalf of the State of Colorado; (b) the details of the objections and issues concerning the matters to be heard; and (c) the positions of the parties regarding their objections and issues they are prepared to speak about in the hearing.

I look forward to your response, which I'm confident will align with the DOJ's commitment to conducting a transparent, balanced, and well-informed proceeding.

Respectfully,

Jared Polis
Governor
State of Colorado

All notices to be sent pursuant to this hearing should be addressed to the addresses listed below:

Governor Jared Polis
Colorado State Capitol
200 East Colfax Avenue, Room 136
Denver, CO. 80203
governorpolis@state.co.us

Ean Seeb
Colorado State Capitol
200 East Colfax Avenue, Room 127
Denver, CO. 80203
ean.seeb@state.co.us

Dominique Mendiola
1697 Cole Boulevard, #200
Lakewood, CO. 80401
dominique.mendiola@state.co.us

Exhibit B

Certain Designated Participants Are Not "Interested Persons" and Should Not Participate in the Hearing

The following Designated Participants are not sufficiently "adversely affected or aggrieved" by the Proposed Rule as to qualify as an "interested person" under DEA regulations. *See* 21 C.F.R. § 1300.01(b) (defining "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811"). Therefore, this Tribunal should exclude each from the proceeding.

A. Smart Approaches to Marijuana ("SAM")

SAM is a political organization comprising other organizations and individuals that oppose marijuana legalization and de-regulation. SAM "envisions a society where marijuana policies are aligned with the scientific understanding of marijuana's harms, and the commercialization and normalization of marijuana are no more." Smart Approaches to Marijuana, *SAM's Staff and Advisory Board*, https://learnaboutsam.org/about/ (last accessed Nov. 18, 2024). The organization's self-proclaimed mission is to decrease marijuana use. *Id.* In its Designated Participant Notice, SAM complained that transferring marijuana to schedule III would mean that trafficking in marijuana would no longer be subject to the tax penalty established under § 280E of the Tax Code. 26 U.S.C. § 280E. According to SAM, removing that tax penalty would increase the cash flow of marijuana businesses, which, the argument goes, would lead to increased marijuana use. SAM's basic theory is that rescheduling marijuana will supercharge the industry and wreak havoc on American society. Contrary to SAM's claims, it is not an "interested person."

First, SAM falls outside the "zone of interests" under the CSA and thus does not have standing. To fall within the zone of interest, SAM would either need to be "regulated by the particular agency action being challenged" or "considered to be protected by the statute in question." *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998). SAM, a political organization formed to influence marijuana policy, is not regulated by the agency action it challenges, nor is its protection under the CSA at any greater risk than that of the general public at large. It is not a DEA registrant and does not take part in any of the activities that the CSA regulates. It does not

manufacture, possess, distribute, import, or use scheduled drugs in its operations. It is more properly categorized as an ancillary party: one whose operations relate to the CSA but are not governed or regulated by it. Consequently, its operations fall outside the CSA's scope. Whether marijuana is rescheduled or not, SAM's current operations, advocating and lobbying, will remain unchanged. Therefore, SAM is not within the zone of interests covered by the CSA.

Parties with such a generalized, undifferentiated interest do not fall within the zone of interests. *See Nat'l Federation of Federal Employees v. Cheney*, 883 F.2d 1038, 1047 (D.C. Cir. 1989) (holding that "Appellants may have 'interests,' but for zone of interest purposes we must look to their particular interests, not the interests amounting to generalized grievances of all citizens"). Put simply, SAM's interests, however heartfelt they may be and regardless of their prudence as a policy matter, fall outside the zone of interest. Because SAM has not and cannot demonstrate that its "particular interest alleged to [be] injured . . . [falls] within the respective zone of interests intended to be protected or regulated" by the CSA, it is not an interested person. *Id.* (quoting *Haitian Refugee Center v. Gracey*, 809 F.2d 794, 812 (D.C. Cir. 1987)).

Second, there is no causal connection between the Proposed Rule and adverse effects on SAM's operations. The Proposed Rule itself states that the "manufacture, distribution, dispensing, and possession of marijuana would [remain] subject to applicable criminal prohibitions under the CSA." *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597, 44,621 (May 21, 2024) ("Proposed Rule"). SAM cannot show concrete and particularized injury beyond a feared setback to its social interests and policy objectives. Even if DEA were to transfer marijuana to schedule III, SAM would suffer no direct monetary setback, no operational setback, and no property-related consequence. In fact, SAM would not even suffer setback to its advocacy and lobbying positions. Under the CSA, the penalties associated with marijuana-related violations are the same whether marijuana is listed in schedule I or schedule III. *See, e.g.*, 21 U.S.C. § 841. As a result, the incentives established by the CSA with respect to marijuana violations would not change at all in a post-schedule III world. Nor is it otherwise obvious that transferring marijuana to schedule III would increase CSA-compliant marijuana use.

The Supreme Court recently rejected a similar claim to Article III standing based on an alleged injury to an association's moral, legal, or policy goals. In *FDA v. Alliance for Hippocratic Medicine*, the Supreme Court rejected a medical association's claim of standing to challenge the Food and Drug Administration's ("FDA") regulation of mifepristone, a drug used to terminate pregnancies. 602 U.S. 367 (2024). The regulations at issue made it easier for women to access and doctors to prescribe mifepristone. *Id.* at 373. The plaintiffs, a group of doctors and medical associations that neither use nor prescribe mifepristone, filed suit to challenge the regulations. *Id.* at 374. The Supreme Court held that the plaintiffs, unregulated parties seeking to challenge the FDA's regulation of others, did not have standing. *Id.* The thrust of the plaintiffs' injury allegations, "that they are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used by others," were not, according to the Court, the kind of injuries that lead to or demonstrate the causation prong of standing. *Id.* at 386. "Because the plaintiffs do not prescribe, manufacture, sell, or advertise mifepristone or sponsor a competing drug," the Court concluded that they "suffer no direct monetary injuries . . . [n]or do they suffer injuries to their property or the value of their property, from FDA's actions." *Id.* at 385–86. Without alleging that the FDA's actions would cause them to act contrary to their conscience, the plaintiffs' alleged conscience injuries were insufficient. The plaintiffs "[did] not have standing to sue simply because others are allowed to engage in certain activities—at least without the plaintiffs demonstrating how they would be injured by the government's under-regulation of others." *Id.* at 393. "Nor may citizens sue merely because their legal objection is accompanied by a strong moral, ideological, or policy objection to a government action." *Id.* at 381.

Third, SAM's testimony is not relevant to these proceedings. *See* 5 U.S.C. § 556(d) (requiring that rulemaking proceedings must provide for the exclusion of "irrelevant" evidence). SAM's participation would not add any relevant data to the most significant issues presumably being considered by this Tribunal. SAM's concerns about the Proposed Rule's tax implications do not change the standing analysis. First, SAM's concerns are speculative. It has no evidence that

tax savings for the marijuana industry would necessarily lead to increased marijuana use. Furthermore, any additional use of state-regulated marijuana products (the ones produced and sold by tax-paying marijuana companies) that might result would, in all likelihood, be offset by a proportional decrease in the use of unregulated illicit products. That would be an obvious win for public health and safety and the rule of law. The point for present purposes, though, is that even in SAM's nightmare scenario, there is no reason to believe that net marijuana use would actually increase.

Finally, there is no reason to assume that any increased use that might result from transferring marijuana to schedule III would constitute the sort of abuse or diversion that the CSA prohibits. It is entirely possible, for example, that marijuana companies would use the tax savings to promote use of marijuana in federally legal research. Or they could invest the savings in different things entirely, like fighting to end the use of unregulated products or pursuing improvements to state marijuana regulations. In short, SAM's tax-related concerns are purely speculative and irrelevant and therefore cannot support SAM's claim to standing.

Fourth, SAM's participation would be duplicative and inefficient. DEA has clarified the purpose of this hearing is to "'reciev[e] factual evidence and expert opinion regarding' whether marijuana should be transferred to schedule III of the list of controlled substances." *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 70,148, 70,149 (Aug. 29, 2024) ("Notice of Hearing") (quoting 21 C.F.R. § 1308.42). To that end, 21 C.F.R. § 1316.52 directs and empowers the Presiding Officer "to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order." The Presiding Officer may therefore endeavor to "settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing." 21 C.F.R. § 1316.52. Section 1316.59 directs the Presiding Officer to "admit only evidence that is competent, relevant, material and not unduly repetitious." *Id.* Here, if SAM were permitted to participate in the hearing, its involvement would be counterproductive and inefficient. SAM has already offered its evidence and comments into the record. As a political association organized for policy and regulatory reform, SAM lacks scientific

and medical expertise related to the matters noticed for the hearing. It does not have the independent factual and expert opinion required to participate in the hearing. As with its comments, SAM's participation would be limited to compiling and presenting the independent factual and expert opinion evidence of others. Not only would this presentation be repetitive, but it would also stagnate the hearing and presentation of new, independent evidence on issues and arguments not yet raised. SAM's participation would therefore contravene the terms of the Notice of Hearing and 21 C.F.R. § 1316.52 and frustrate the efficient administration of these proceedings.

Finally, for the myriad reasons stated herein, SAM's involvement would cast an air of impropriety over the entire rulemaking process. This Tribunal should therefore exercise its discretion to exclude SAM from the hearing.

B. The Tennessee Bureau of Investigation ("TBI")

TBI is a Tennessee state agency with statutory authority to conduct criminal investigations and make arrests for various crimes in that state. In its Designated Participant Notice, TBI claims that "the proposed rule would adversely affect TBI operations." TBI is incorrect.

TBI argues that it operates a forensic crime lab and "process[es] more than 30,000 drug submissions annually, a significant number of which are marijuana-related." TBI goes on to argue that "[r]escheduling marijuana . . . would strain drug enforcement activities" and require "significant time and resources to reassess enforcement priorities, personnel assignments, and adjust asset allocations in response to any rescheduling." Again, TBI's assertion is wrong.

Contrary to TBI's claims, TBI is not an "interested party" for three reasons.

First, TBI falls outside the "zone of interests" under the CSA." To fall within the zone of interest, TBI would either need to be "regulated by the particular agency action being challenged" or "considered to be protected by the statute in question." *MD Pharm., Inc.*, 133 F.3d at 12. DEA does not regulate state law enforcement agencies, and neither does the Proposed Rule. Moreover, the rescheduling of marijuana from schedule I to Schedule III would not legalize marijuana, nor would it affect TBI's ability to enforce state law.

Second, there is no causal connection between the Proposed Rule and adverse effects on TBI's "drug enforcement resources." TBI is a *state* agency, and if the state decides to prioritize marijuana enforcement, even after the federal government changes its scheduling status, that is the *state's* prerogative. TBI has made bald assertions that rescheduling to schedule III at the federal level will lead the agency to "reassess enforcement priorities" and "adjust asset allocations." Regardless of the implementation of the Proposed Rule, TBI—as a law enforcement arm of that state's government—could "reassess enforcement priorities" and "adjust asset allocations" to enforce Tennessee's laws, which are not affected by the Proposed Rule. TBI also fails to consider the language of the Proposed Rule itself, which states the "manufacture, distribution, dispensing, and possession of marijuana would [remain] subject to applicable criminal prohibitions under the CSA," even under the Proposed Rule. Proposed Rule at 44,621.

Third, TBI's testimony is not relevant to these proceedings. *See* 5 U.S.C. § 556(d) (requiring that rulemaking proceedings must provide for the exclusion of "irrelevant" evidence). The State of Tennessee is particularly ill-suited to participate because it does not have a state-regulated medical marijuana program. The primary issue before this Tribunal is whether marijuana should be rescheduled from schedule I to schedule III. To inform that decision, two considerations are primary: (1) is there "currently accepted medical use in treatment in the United States" ("CAMU") sufficient to find that marijuana has known medical utility and should thus be removed from schedule I, and (2) is marijuana's "abuse potential" lower than that of controlled substances in schedules I and II? TBI has no applicable expertise on either subject, and thus TBI should be excluded from participating in this process.

C. Drug Enforcement Association of Federal Narcotics Agents ("DEAFNA")

DEAFNA is a law enforcement fraternal organization, which consists of former and current federal narcotics law enforcement personnel. In its Designated Participant Notice, DEAFNA claims that "changes to drug scheduling has a direct impact on our members' ability to implement the necessary regulatory controls which will take years to implement and will come at an

unreasonable financial cost." Even assuming the truth of that assertion, DEAFNA itself is not an "interested person" and should not be permitted to participate in the administrative proceeding.

DEAFNA fails to meet the "interested person" standard for four reasons.

First, DEAFNA concedes that its participation in the hearing is merely derivative from the interests of the DEA itself. By its own admission, DEAFNA is adversely affected by the Proposed Rule only because its members will have to implement new "regulatory controls." To be precise, those controls would be implemented by the DEA—a federal agency—not the DEAFNA organization. Any costs of these controls' implementation would be borne by the federal agency, not DEAFNA. Therefore, DEAFNA itself is not "adversely affected" by the Proposed Rule and, by definition, is not an "interested party."

Second, DEAFNA's position contradicts DEA regulations and the Administrative Procedure Act ("APA") and presents an untenable conflict of interest. DEAFNA purports to be a representative of active DEA agents. The participation of active DEA agents contesting a rule that the agency is obligated to defend is directly contrary to law. 21 CFR § 1316.56 (requiring that the proponent of a rule carry the burden of proof); *see also* 5 U.S.C. § 556(d).

Third, DEAFNA falls outside of the zone of interests. The proposed agency action does not regulate DEAFNA, nor does the CSA protect it in any way. In fact, neither the CSA nor the Proposed Rule would require DEAFNA or its members to take any action or refrain from taking any action. Any changes in regulatory controls would apply to DEA license holders—not DEA agents in the field. And, any financial costs would be borne by the agency, not by individual agents, whether active or retired. It is also not at all clear how active federal law enforcement agents and retiree members of DEAFNA would have to change any of their procedures to enforce the CSA as it relates to marijuana. But, even assuming that DEA agents had to change their procedures as a result of rescheduling, they are public servants tasked with carrying out policy decisions made by others in their chain of command. Moreover, the rescheduling of marijuana from schedule I to schedule III would not legalize marijuana, nor would it affect anyone's ability to enforce federal laws that prohibit the unlawful trafficking in a controlled substance. DEA is not currently enforcing

the CSA against state-regulated entities, and that is unlikely to change as a result of any scheduling modification. Thus, DEAFNA does not have standing to participate and should be excluded by this Tribunal.

Fourth, DEAFNA cannot offer relevant testimony. *See* 5 U.S.C. § 556(d). As discussed above, the primary issue before this Tribunal is whether marijuana should be rescheduled from schedule I to schedule III, with a focus on marijuana's CAMU and its abuse potential. DEAFNA possesses no applicable expertise on either subject, and thus DEAFNA should be excluded from participating in this administrative process.

D. The Community Anti-Drug Coalitions of America ("CADCA")

CADCA is a substance use and prevention association representing over 7,000 individual coalitions. In its Designated Party Notice, CADCA claims that the Proposed Rule would adversely affect its members because "moving marijuana to Schedule III will further exacerbate the ***belief*** that botanical marijuana is medicine" and would "further reduce the ***perception*** of harm and risk associated with marijuana among youth, young adults and adults." (emphases added). CADCA asserts that the organization and its members must demonstrate certain metrics in the population-level perception and use of marijuana, lest they risk the "ability to retain federal, state and local funding." Not only are CADCA's assertions speculative and self-serving, but also they are not based on the legal standard to show that CADCA is an "interested person."

CADCA is not an "interested person" for three reasons.

First, CADCA's core point, that moving marijuana to schedule III will exacerbate the "belief" that marijuana is medicine, is speculative and has no bearing on whether CADCA is adversely affected by the Proposed Rule. The subjective and speculative "belief" that "marijuana is medicine" ignores the reality of (i) HHS's scientific and medical determinations, which "must be accorded significant deference throughout the rulemaking," Proposed Rule at 44,601, and (ii) the 38 state-level programs for medicinal use of marijuana. By its own admission, CADCA is concerned about the *perception* of marijuana—this rulemaking process should be about the facts, not subjective (and inaccurate) perceptions and belief.

Second, CADCA argues that it *might* risk funding if the organization or its members fail to meet certain metrics regarding the perception of marijuana and use of this controlled substance. Not only does CADCA's theory lack factual foundation, but also this self-serving rationale misses a fundamental conclusion that HHS reached. As noted in the Proposed Rule, "HHS found that the risks to the public health posed by marijuana are low compared to other drugs of abuse." Proposed Rule at 44,614. So, CADCA is arguing that it and its members should participate in the rulemaking because CADCA *might* lose funding because individuals believe the accurate statement that *the public health risks of marijuana are relatively low*—a conclusion that DEA itself must treat with "significant deference." Notwithstanding the speculative and self-serving nature of this assertion, CADCA's refutation of a statement to which DEA must give significant weight is not a sufficient basis to allow CADCA to participate.

Third, CADCA falls outside the zone of interests. DEA does not regulate members of CADCA, nor does the Proposed Rule. CADCA also failed to present a concrete and particularized injury that even could be redressed by the rulemaking process. Thus, CADCA does not have standing to participate and should be excluded from participation in these proceedings.

E. International Association of Chiefs of Police ("IACP")

IACP is a non-profit organization for police leaders. In its Designated Party Notice, the IACP does not actually attempt to demonstrate that it is an interested party. While IACP lists nine items of concern, it makes no attempt to demonstrate that the IACP or its members would be "adversely affected or aggrieved" because of those concerns. Because IACP's Designated Party Notice fails to articulate how it or its members would be "adversely affected or aggrieved," IACP cannot meet the standards for an "interested person" under the APA or applicable DEA regulations. Therefore, the participation of the IACP would be contrary to law and violative of the APA.

IACP is also not an "interested person" because it falls outside the zone of interests. IACP would not be subject to regulation under the Proposed Rule, nor would its members.

F. National Sheriffs Association ("NSA")

NSA is a professional trade association dedicated to serving sheriffs and their affiliates through education, training, and general law enforcement informational resources. In its Designated Participant notice, NSA asserts that the organization and its members are "interested persons" with standing to participate because "[r]educing restrictions [on marijuana] will increase the number of persons with marijuana intoxication and the degree of their intoxication in public and on the roads," increasing the "enforcement burden and the burden to respond to traffic accidents." NSA also asserts, without any evidence, that arrests will increase, and thus rescheduling will create a strain on staff.

Pursuant to this Tribunal's Order, the NSA as a Designated Participant had the burden to establish its eligibility as an "interested person." Preliminary Order, at 3. By failing to cite *any* evidence for its bald assertions, the NSA has failed to meet this burden. The NSA also ignores the fact that that even under the Proposed Rule, the "manufacture, distribution, dispensing, and possession of marijuana would [remain] subject to applicable criminal prohibitions under the CSA." Proposed Rule at 44,621. The rescheduling of marijuana from schedule I to schedule III would not legalize the use of marijuana and would still allow law enforcement to combat drug use and control the legitimate and illegitimate trafficking of controlled substances.

In addition to failing to cite any evidence to support its speculative claims, the NSA is not an "interested person" because it falls outside the zone of interests. NSA would not be regulated by the Proposed Rule.

G. Cannabis Industry Victims Educating Litigators ("CIVEL")

CIVEL asserted to the Tribunal that it "represents the victims of the marijuana industry" and is a "marijuana industry victims' advocacy organization." Specifically, CIVEL opposes the Proposed Rule because it could "reduce the perception of its dangerousness and lower medical standards for deciding what is a medicine."

CIVEL also states in a conclusory fashion that it has "a direct and particularized interest in the implementation of federal and state law regarding marijuana in all of its forms." This *ipse dixit*

approach is insufficient to meet CIVEL's burden under this Tribunal's Preliminary Order to demonstrate its status as an "interested person." *See* Preliminary Order, at 3.

CIVEL is not an "interested person" for three additional reasons.

First, CIVEL's participation—like that of CADCA—is improper as it could only serve to attempt to refute HHS' scientific and medical determinations, which "must be accorded significant deference throughout the rulemaking." Proposed Rule at 44,601. But, CIVEL—an organization dedicated to the education of attorneys to bring suits against the marijuana industry[1]—is not well-positioned to provide evidence regarding CAMU or to refute HHS' scientific and medical evidence. Indeed, HHS concluded, and the Attorney General agreed in the NPRM, that there is a currently accepted medical use of marijuana in the United States. Proposed Rule at 44,619 ("[T]he Attorney General concurs with HHS's conclusion, for purposes of the initiation of these rulemaking proceedings, that there is a CAMU for marijuana.").

Second, CIVEL's basis for its participation is based on speculation and faulty logic. CIVEL argues that it should participate because the Proposed Rule could reduce the *perception* of the purported "dangerousness of marijuana" or "lower medical standards for deciding what is a medicine." CIVEL is wrong. The Proposed Rule, and this rulemaking process, does not and cannot turn on perceptions or beliefs; it must be based on facts and evidence. *See* 5 U.S.C. § 556(c)(3) (requiring an agency to "receive relevant evidence"). In addition, the Proposed Rule does nothing whatsoever to reduce the standard for determining what is a medicine. CIVEL's participation based on this faulty premise is simply irrelevant to this rulemaking. *See* 5 U.S.C. § 556(d) (requiring that rulemaking proceedings must provide for the exclusion of "irrelevant" evidence).

Third, CIVEL falls outside the zone of interests. The Proposed Rule would not regulate CIVEL, nor does the CSA protect it in any way. In fact, neither the CSA nor the Proposed Rule would require CIVEL to take any action or refrain from taking any action.

H. PHILLIP DRUM, PHARMD

Phillip Drum is a DEA-licensed pharmacist in California.

[1] CIVEL, *Legal Primer*, https://perma.cc/T9RR-HBXY.

Mr. Drum is not an "interested person" and should not be permitted to participate in this rulemaking process.

Mr. Drum had the burden, under this Tribunal's Order, to demonstrate that he was "adversely affected or aggrieved" by the Proposed Rule. Preliminary Order, at 3. In his Designated Participant Notice, Mr. Drum offered no insight into how he is "adversely affected or aggrieved," and therefore he has failed to meet his burden.

Further, Mr. Drum is a pharmacist, and his daily operations as a pharmacist will remain unchanged regardless of the Proposed Rule. The process for dispensing FDA-approved drugs and controlled substances under the CSA simply is not in play in these proceedings.

Mr. Drum also falls outside the zone of interests. While Mr. Drum does hold a DEA license, he has not articulated how the Proposed Rule would directly affect him. While holding a DEA license places him under DEA's regulatory jurisdiction, DEA regulations applicable to him will not change as a result of this rulemaking process, and he has not demonstrated the sort of actual harm necessary to establish standing or warrant his inclusion at this hearing.

Notably, the Administrator excluded parties with DEA registrations to study and manufacture marijuana from these proceedings without explanation and failed even to include those parties' requests to participate in the administrative record. If those parties, who unquestionably fall within the heartland of the zone of interests may not participate, it is hard to understand why Mr. Drum should be treated differently. 2 Charles Alan Wright & Charles H. Koch, Federal Practice and Procedure § 8248, at 431 (2006) (discussing the bedrock principle of administrative law that an agency must treat like cases alike"); *see also Univ. of Tex. M.D. Anderson Cancer Ctr. v. United States HHS*, 985 F.3d 472, 479 (5th Cir. 2021) (same); *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005) ("An agency must provide an adequate explanation to justify treating similarly situated parties differently."); Wright & Koch, Federal Practice & Procedure § 8248, at 431 ("General principles of administrative law hold that an agency must be consistent . . . .").

Exhibit C

November 15, 2023

Anne Milgram, Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

Re: *Petition to initiate rulemaking proceedings to deschedule marijuana or, alternatively, to transfer marijuana from schedule I to schedule III, IV, or V, and for joinder in pending rescheduling proceedings.*

Dear Administrator Milgram:

The undersigned ("Petitioners") hereby petition to initiate formal rulemaking proceedings for the issuance of an amendment of a rule or regulation under Section 201 of the Controlled Substances Act ("CSA") and to repeal a rule under 5 U.S.C. § 553(e). Specifically, Petitioners seek removal of "marihuana" from schedule I. Petitioners seek a rule removing marihuana from control or, in the alternative, transferring marihuana from schedule I to schedule III, IV, or V.

Consistent with the CSA and U.S. Drug Enforcement Administration ("DEA") regulations, Petitioners attach the following exhibits and incorporate them as part of this petition:

Exhibit A1: The proposed rule in the form Petitioners propose.

Exhibit A2: The alternate proposed rule in the form Petitioners propose.

Exhibit A3: Repealing the definition of "medicinal cannabis" in the form Petitioners propose.

Exhibit B: A statement of the grounds on which Petitioners rely.

Petitioners request that the Administrator promptly notify them of acceptance or nonacceptance of the petition and, if not accepted, the reasons therefor.

Petitioners further request and move that they formally be joined as a party to any marijuana rescheduling proceeding currently pending before DEA, including the pending one

publicly referenced by Secretary Becerra,[1] that their grounds and arguments herein be incorporated into such proceedings, they receive notification of joinder, and that they receive all appropriate notices from the agency regarding the progress of the proceedings.

Finally, Petitioners petition and request repeal of 21 C.F.R. § 1318.02(b), to the extent the U.S. Department of Health and Human Services ("HHS") recommendation recently received by DEA concludes that marijuana has a "currently accepted medical use in treatment in the United States," for the reasons stated therein.

Introduction

In more than two-thirds of states, millions use marijuana[2] in treatment following a recommendation from a licensed physician. Most, if not all, these states have reticulated regimes governing and limiting medical-marijuana use. Every year since 2014, Congress has supported these regimes by approving a spending rider prohibiting the U.S. Department of Justice ("DOJ") from using appropriated funds to interfere with their enforcement. Indeed, no social issue unites more Americans than medical marijuana. Recent polls show that ***91%*** of Americans support medical use under these state-law regimes.[3] This level of support holds true among our nations' veterans as well.[4]

And yet, DEA insists marijuana has "no currently accepted medical use in treatment in the United States."[5] Rather than apply the statutory text, DEA claims "currently accepted medical use in treatment in the United States" requires meeting a five-part test that it admits cannot be squared with the statute's plain meaning. Petitioners request that DEA do what the statute commands and remove marijuana from schedule I.

DEA should remove marijuana from the schedules entirely. Across almost half the country, states have opted out of the federal government's failed prohibitionist regime. Millions of Americans, as a result, are using marijuana non-medically and responsibly under regulated regimes. With even more states opting out each year, marijuana and natural THC products have attained a cultural status akin to caffeine, alcohol, and tobacco. Can marijuana be abused? Absolutely. Should it be regulated? Definitely. Because a significant majority of Americans no

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1 *See* https://www.hhs.gov/sites/default/files/signed-ash-to-dea-letter-marijuana.pdf.

2 The statutory term for marijuana is "marihuana." In discussion, Petitioners use marihuana and marijuana interchangeably.

3 *See* https://www.pewresearch.org/fact-tank/2021/04/16/americans-overwhelmingly-say-marijuana-should-be-legal-for-recreational-or-medical-use/

4 *See, e.g.*, https://www.armytimes.com/veterans/2017/11/02/poll-more-than-90-percent-of-vets-support-medical-marijuana-research/ (over 80% back allowing federal doctors to prescribe).

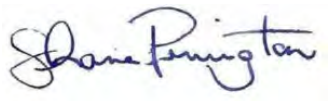
5 *See* 21 U.S.C. § 812(b)(1)(B).

longer consider marijuana a drug of abuse worthy of DEA's attention, however, it no longer has a legitimate place on the CSA's schedules.

Alternatively, DEA should transfer marijuana to schedule III, IV, or V based on scientific evidence related to its abuse potential and dependence risk. Placing it in schedule II alongside far more dangerous and addictive drugs like fentanyl would do nothing to make Americans safer. If anything, it would serve only to undermine the legitimacy of the federal scheduling regime, making it even harder for the federal government to address urgent national crises like opioid abuse effectively.

Respectfully submitted,

Matthew C. Zorn



Shane Pennington

Counsel for Petitioners Hemp for Victory[6] and Robert Head

All notices to be sent regarding this petition should be addressed to:

For Hemp for Victory and Robert Head:
Matthew Zorn
Yetter Coleman LLP
811 Main St., Ste. 4100
Houston, TX 77002
mzorn@yettercoleman.com

Shane Pennington
Porter Wright Morris & Arthur LLP
2020 K Street, NW, Suite 600
Washington, D.C. 20006
spennington@porterwright.com

[6] Hemp for Victory is a non-profit organization headquartered in Carrolton, TX that focuses on cannabis education and the positive impact of cannabis on the veteran community. *See* https://hemp4victory.info/about-us/.

Exhibit A1 – Proposed Rule

We propose the following: removing "marihuana" from schedule I [21 C.F.R. 1308.11(d)(23)].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

Exhibit A2 – Alternate Proposed Rule

We propose the following: removing "marihuana" from schedule I [21 C.F.R. 1308.11(d)(23)] and placing it in schedule [III, IV, or V].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

ADD: 21 C.F.R. 1308.[13, 14, 15] schedule [III, IV, V]: "… (f) Hallucinogenic substances. (1) … (3) Marijuana."

Exhibit A3 – Proposed Rule

The following is the proposed rule:

REMOVE: 21 C.F.R. 1318.02(b)

Exhibit B – Statement of Grounds

I. The Schedule I Factors

a. Marijuana has a "currently accepted medical use in treatment in the United States."

As of April 2023, at least 38 states, the District of Columbia, and 4 of 5 territories (Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands) have legalized medical marijuana. According to the plain and ordinary meaning of "accepted medical use in treatment," marijuana has a currently accepted medical use in treatment in the United States. In addition, because marijuana has an accepted medical use, the U.S. Pharmacopeia is currently in the process of establishing a monograph for cannabis (including marijuana) for medical use.

In the past, to determine whether a drug lacks a "currently accepted medical use in treatment in the United States"—the second required finding for placement in schedule I, *see* 21 U.S.C. § 812(b)(1)(B)—DEA has applied a five-part test of its own making:

1. the drug's chemistry must be known and reproducible;
2. there must be adequate safety studies;
3. there must be adequate and well-controlled studies proving efficacy;
4. the drug must be accepted by qualified experts; and
5. the scientific evidence must be widely available.

See 81 Fed. Reg. 53688, 53700 (Aug. 12, 2016) (citing *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)). *See also, e.g.*, 86 Fed. Reg. 60,761 at 762 n.5 (Nov. 4, 2021) ("[A] drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test[.]").

For at least the reasons stated by the petitioners in *Sisley v. DEA* (**Ex. 1**), which Petitioners incorporate here by reference, DEA's five-part test is unlawful. Most prominently, the test interprets § 812(b)(1)(B) in way that renders § 812(b)(1)(C) superfluous—a red flag that its interpretation cannot be right. *See, e.g.*, *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995) (courts avoid interpretations that "render[ ] some words altogether redundant"). This third requirement for placing a substance in schedule I expressly demands a finding regarding a substance's safety for use. *See* 21 U.S.C. § 812(b)(1)(C). Given all this, DEA's insistence that the second requirement (a lack of "currently accepted medical use") must also hinge in part on proof of safety for use makes no sense.

As Judge Watford explained after reviewing petitioners' arguments in *Sisley*:

> [I]n an appropriate case, the Drug Enforcement Administration may well be obliged to initiate a reclassification proceeding for marijuana, given the strength of petitioners' arguments that the agency has misinterpreted the controlling statute by concluding that

> marijuana "has no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B).[7]

Under any reasonable interpretation of "currently accepted medical use in treatment in the United States" based on the ordinary public meaning of those terms, DEA ***must*** reschedule marijuana.[8]

First, in more than two-thirds of the country, according to state law, marijuana use in treatment is accepted medical practice. *See, e.g.*, *Conant v. McCaffrey*, 2000 WL 1281174, at *14 (N.D. Cal. Sept. 7, 2000) (court applying plain and ordinary meaning to conclude that marijuana is a medically acceptable form of treatment in California and seven other states). State law, not DEA preference, determines what is legitimate medical practice in the United States, a reality DEA itself has acknowledged. In the opioid-prescription context, for example, DEA has emphasized that it

> does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies … collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower.

71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006). No doubt, the evidence will show that medical professionals have recommended marijuana for their patients under duly enacted state laws.[9] *See also, e.g.*, *United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016) ("no rational basis to conclude" that marijuana is not being currently used for medical purposes).

United States v. Moore, 423 U.S. 122, 141 (1975) is instructive. There, the Supreme Court explained that "provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." *Id.* The terms of the CSA reflect a congressional intent to align "accepted medical use" with accepted standards of professional practice as determined by state law. Here, it is accepted medical practice for physicians to recommend marijuana use for treatment of certain conditions, such as ameliorating chemotherapy's side-effects.

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[7] Judge Watford is not alone in flagging DEA's misinterpretation of the CSA. At oral argument in *Washington v. Barr*, 925 F.3d 109 (2d Cir. 2019), Judge Rakoff did as well. *See* https://ww3.ca2.uscourts.gov/decisions (oral argument recording).

[8] Indeed, because the five-part test as it stands is unlawful, we also ask that it be repealed or amended. 5 U.S.C. § 553(e).

[9] *See, e.g.*, https://www.cbsnews.com/news/survey-76-percent-of-doctors-approve-of-medical-marijuana-use/ (New England Journal of Medicine Poll: 76% of votes in favor of the use of marijuana for medicinal purposes); https://www.safeaccessnow.org/survey_majority_of_us_doctors_support_medical_marijuana_legalization (citing polls); https://www.liebertpub.com/doi/10.1089/can.2020.0165 (almost 70% of clinicians believe cannabis has medicinal uses).

Second, recognizing that marijuana has a currently accepted medical use, the U.S. Pharmacopeia in September 2022 published a proposed *Cannabis* Species Inflorescence monograph in the Herbal Medicines Compendium. The inclusion of cannabis in the U.S. Pharmacopeia is imminent.[10]

These circumstances establish a currently accepted medical use beyond cavil. As discussed in *Sisley*, during congressional hearings, the CSA's drafters explained that "you don't have to be a doctor to find out whether or not it has an accepted medical use in the United States or not" and the issue "is not something that you are going to create research on."[11] An agency memo drafted shortly after the CSA's passage (**Ex. 3**) underscores the point:

> As the situation stands presently, there is no medical use for marihuana in the United States. The Food and Drug Administration has not granted a New Drug Application for its use in medicine; ***marihuana is not listed in the United States Pharmacopeia***, the National Formulary, the American Drug Index, 1972, Drugs of Choice, 1972, or Physicians Desk Reference, 1972. In fact, both the United States Dispensatory and Remington's Pharmaceutical Sciences conclude that there is no rational or indispensable therapeutic use for marihuana in modern medicine.

This text, written around the time the CSA was enacted, focuses on the plain meaning of the relevant statutory language and makes the proper § 812(b)(1)(B) inquiry unmistakably clear. *See Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731, 1750 (2020) (the law's ordinary meaning at the time of enactment usually governs). And it does not suggest the five-part test. It instead accounts for evidence establishing acceptance among medical authorities.

In short, the five-part test as an exclusive means to test accepted medical use is unlawful. While FDA approval or satisfying the five-part test clearly suffices to show a currently accepted medical use in treatment, it cannot be *the only* way to make that showing. Here, when more than two-thirds of the states—the traditional and authoritative regulators of the medical practice—have adopted laws specifically allowing a drug to be used to treat specific conditions, DEA has no discretion to ignore the statute's plain text to conclude that marijuana lacks a "currently accepted medical use in treatment in the United States."[12]

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10 For substantially similar reasons, 21 C.F.R. § 1318.02(b) should be repealed.

11 Drug abuse control amendments—1970, Hearings, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 1) at 165 (1970).

12 DEA's own arguments in *In re: Marijuana Rescheduling* (**Ex. 2**) further support Petitioners' position. There, DEA emphasized the fact that parties disputed whether states had passed "research statutes" or "treatment statutes." DEA went on to explain that the reason it advocated for the same standards that FDA uses for medical acceptability was because those same standards "permeated themselves into the medical community and part of them have been incorporated into the standards that clinicians use to determine whether a drug has an accepted medical use." *Id.* at 36. In other words, DEA argued that FDA

FDA has long recognized state-level use of a substance in treatment as a viable means of demonstrating "currently accepted medical use in treatment in the United States" for purposes of 21 U.S.C. § 812(b)(1)(B). In 1982, for example, FDA concluded that drugs can "obtain[] 'accepted medical use'" for purposes of § 812(b)(1)(B) "by virtue of totally intrastate production and use." 47 Fed. Reg. 28,141, 28,150-51 (June 29, 1982). FDA's longstanding view is especially important in this context because the question of what constitutes "currently accepted medical use in treatment in the United States" implicates FDA's scientific and medical expertise as opposed to DEA's law-enforcement expertise, meaning DEA is statutorily bound to accept its legitimacy. *See* 21 U.S.C. § 811(b) ("The recommendations of the Secretary [and their delegee, FDA] to the Attorney General [and their delegee, DEA] shall be binding on the Attorney General [and his delegee, DEA] as to such scientific and medical matters . . . .").

On this point, the Supreme Court's decision in *Gonzales v. Oregon* is instructive. 546 U.S. 243, 258 (2006). There, the Court rejected the interpretation of the CSA as authorizing the Attorney General to "declar[e] illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." *Id.* at 245. Because the CSA refutes the notion that Congress intended to delegate to the Attorney General any authority to make binding judgments regarding the practice of medicine or science, the Court held the Attorney General's views on what constitutes a "legitimate medical purpose" were not authoritative. *Id.*

Addressing this question directly, the Supreme Court emphasized that "[i]n the scheduling context," the CSA requires DEA to yield to FDA's views on scientific and medical matters:

> The CSA allocates decision[ ]making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. 21 U.S.C. § 811(b). *See* H.R.Rep. No. 91–1444, pt. 1, p. 33 (1970), U.S. Code Cong. & Admin. News 1970, pp. 4566, 4600 (the section "is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of the Department of Health, Education, and Welfare").

Id. at 265. In fact, long before *Oregon*, DEA itself acknowledged that it had no delegated authority to make medical judgments or to regulate the practice of medicine, 57 Fed. Reg. at 10,505:

> Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to

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> standards serve as a proxy or indirect evidence for what the medical community accepts as having medical use when direct evidence of accepted medical use is not available.

determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

b. There is an accepted safety for use of marijuana under medical supervision.

For similar reasons, there is an accepted safety for use of marijuana under medical supervision. Contemporary evidence (including peer-reviewed clinical research) shows, for example, that marijuana use is generally safe.[13] Such research also does not associate medical-marijuana use with severe adverse events, even among those with mental disorders.[14]

Indeed, marijuana not only can be safely used under medical supervision, but in many instances, doctors recommend marijuana over approved pharmaceuticals as a safer, less-addictive alternative. For example, there is "substantial evidence that cannabis is an effective treatment for chronic pain in adults."[15] Some states permit marijuana recommendations in lieu of opioid prescriptions. There is substantial evidence that medical marijuana can substitute for opioid-based pain medications.[16]

c. Marijuana does not have a high potential for abuse.

In studies ranking the relative harmfulness of drugs, marijuana consistently ranks below drugs in schedules I and II.

In a study by Bonnet, Udo et al. (2020) entitled "Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction

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13 *See, e.g.*, Bonn-Miller, Marcel O et al. "The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial." *PloS one* vol. 16,3 e0246990. 17 Mar. 2021

14 *See, e.g.*, Hoch E, Niemann D, von Keller R, Schneider M, Friemel CM, Preuss UW, Hasan A, Pogarell O. How effective and safe is medical cannabis as a treatment of mental disorders? A systematic review. Eur Arch Psychiatry Clin Neurosci. 2019 Feb;269(1):87-105. doi: 10.1007/s00406-019-00984-4. Epub 2019 Jan 31. Erratum in: Eur Arch Psychiatry Clin Neurosci. 2019 Apr 5;: PMID: 30706168; PMCID: PMC6595000.

15 National Academies of Sciences, Engineering, and Medicine, The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research at 87-90 (2017); Romero-Sandoval, E Alfonso et al. "Cannabis and Cannabinoids for Chronic Pain." Current rheumatology reports vol. 19,11 67. (Oct. 5, 2017) (**Exhibit C)** (concluding that "scientific evidence presented demonstrates that inhaled cannabis is clinically useful for the treatment of chronic (neuropathic) pain, and seems to be safe and tolerable for long-term use under medical supervision").

16 E.g., Reiman A, Welty M, Solomon P. Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. Cannabis Cannabinoid Res. 2017 Jun 1;2(1):160-166. doi: 10.1089/can.2017.0012. PMID: 28861516; PMCID: PMC5569620.

Medicine Experts," for example, 30 substances were ranked according to harm to users and others.[17] Cannabis ranked below schedule I and II drugs such as heroin and methamphetamine and alongside schedule III drugs such as benzodiazepines and ketamine. Common experience dictates that marijuana has fewer relative harms than opioids.[18] Compared to benzodiazepines, marijuana also presents a lower potential for abuse and less risk of dependence. Indeed, research suggests medical marijuana can be used to discontinue benzodiazepine use.[19]

Other evidence underscores marijuana's low abuse potential. For example, Dr. Volkow recently stated that to her knowledge, there's "no evidence" that occasional adult marijuana use has harmful effects. This DEA cannot ignore: Dr. Volkow currently directs the National Institute of Drug Abuse and is an expert in marijuana research having authored dozens of articles on marijuana use, including Zehra, Amna et al. (2018) entitled "Cannabis Addiction and the Brain: a Review"[20] and Volkow, Nora D et al. (2016) entitled "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review."[21]

d. 21 U.S.C. § 811(d)(1) does not limit DEA's authority.

For at least the reasons stated by the petitioners in *Sisley v. DEA* (**Ex. 1**), section 811(d)(1) is unconstitutional. Petitioners hereby incorporate Shane Pennington & Matthew Zorn, *The Controlled Substances Act: An International Private Delegation That Goes Too Far*, 100 Wash. U. L. Rev. (2023) (https://wustllawreview.org/2023/05/19/the-controlled-substances-act-an-international-private-delegation-that-goes-too-far/) by reference.

Also, as noted by the agency, even if § 811(d)(1) does apply, DEA has discretion to control marijuana in schedule III, IV, or V, and simultaneously amend its regulations to require a permit to import or export marijuana, as it did with Epidiolex. 83 Fed. Reg. 48,950 (Sept. 28, 2018).

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17 Bonnet, Udo et al. "Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction Medicine Experts." Frontiers in psychiatry vol. 11 592199. 26 Oct. 2020, doi:10.3389/fpsyt.2020.592199.

18 Lake, Stephanie et al. "Evidence shows that cannabis has fewer relative harms than opioids." CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne vol. 192,7 (2020): E166-E167.

19 Purcell, Chad et al. "Reduction of Benzodiazepine Use in Patients Prescribed Medical Cannabis." Cannabis and cannabinoid research vol. 4,3 214-218. 23 Sep. 2019.

20 Zehra, Amna et al. "Cannabis Addiction and the Brain: a Review." *Journal of neuroimmune pharmacology: the official journal of the Society on NeuroImmune Pharmacology* vol. 13,4 (2018): 438-452.

21 Volkow, Nora D et al. "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review." *JAMA psychiatry* vol. 73,3 (2016): 292-7. doi:10.1001/jamapsychiatry.2015.3278

II. DEA Should Deschedule Marijuana.

Section 811(b) provides that if the Attorney General determines that the eight-factors listed in 811(c) and "all other relevant data" constitute "substantial evidence that the drug or other substance should be removed entirely from the schedules," then the Attorney General "shall initiate proceedings for control or removal." In the case of marijuana, substantial evidence outside of the Section 811(c) factors shows that marijuana should be removed entirely from the schedules and regulated by the states.

Not all drugs of abuse—even addictive ones—are controlled. Caffeine has addictive properties that may lead to physical dependence.[22] Caffeine intoxication may result in tachycardia, vomiting, cardiac arrhythmias, seizures, and in extreme doses, death.[23] Caffeine use disorder is a problematic pattern of caffeine consumption characterized by a persistent desire to cut down or control use of the substance along with unsuccessful efforts to do so despite problems caused or worsened by caffeine.[24] But caffeine is not scheduled because it is a commonly accepted drug. Most people who use caffeine do so safely every day. Many use caffeine socially, such as by drinking coffee in a café. Some use caffeine as a drug to start their day.

As of 2023, marijuana has achieved a cultural status similar to caffeine and tobacco. Almost 16% of Americans smoke marijuana[25]—***more than the number of Americans that smoke tobacco cigarettes***.[26] The vast majority of marijuana users use marijuana safely with no effects more serious than caffeine. Marijuana is used a social drug. In states where marijuana is legal, there are marijuana cafés or lounges. Marijuana can also be used as a drug before bedtime for sleep. For these reasons, nearly 60% of Americans believe marijuana should be removed from control.[27]

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22 *See, e.g.*, Gilliland K, Bullock W. Caffeine: a potential drug of abuse. Adv Alcohol Subst Abuse. 1983-1984 Fall-Winter;3(1-2):53-73. PMID: 6391103.

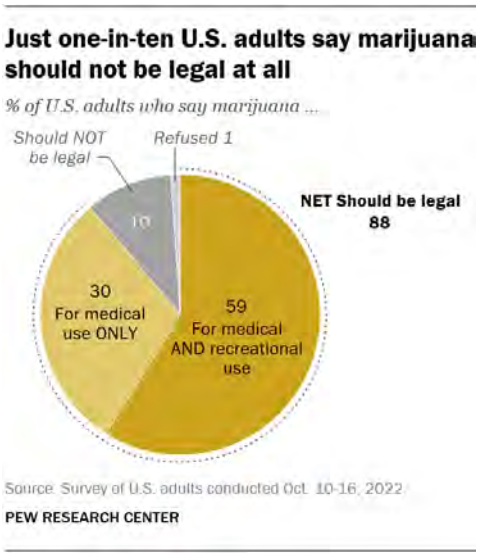
23 De Sanctis V, Soliman N, Soliman AT, Elsedfy H, Di Maio S, El Kholy M, Fiscina B. Caffeinated energy drink consumption among adolescents and potential health consequences associated with their use: a significant public health hazard. Acta Biomed. 2017 Aug 23;88(2):222-231. doi: 10.23750/abm.v88i2.6664. PMID: 28845841; PMCID: PMC6166148.

24 Addicott MA. Caffeine Use Disorder: A Review of the Evidence and Future Implications. Curr Addict Rep. 2014 Sep;1(3):186-192. doi: 10.1007/s40429-014-0024-9. PMID: 25089257; PMCID: PMC4115451.

25 https://news.gallup.com/poll/284135/percentage-americans-smoke-marijuana.aspx.

26 https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

27 https://www.pewresearch.org/fact-tank/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/ft_2022-11-22_marijuana_01a/.



Equally important, marijuana is treated differently from other drugs of abuse listed in the CSA. Every year Congress prohibits DOJ from spending funds to interfere with state medical marijuana programs. The Attorney General recently confirmed that marijuana enforcement continues to be a low priority for DOJ[28]—indeed, it is hard to see how DEA could summon the resources necessary to faithfully enforce the CSA as long as marijuana remains a controlled substance. And the President recently pardoned those convicted of simple marijuana possession.

Removing marijuana from the CSA does not mean that the law no longer sees marijuana as a drug that can be abused. The absence of caffeine or tobacco from the CSA's schedules certainly does not mean those drugs cannot be and are not abused. Nor would descheduling marijuana mean that marijuana should not—or would not—be regulated. Rather, descheduling would simply align federal marijuana law with what is by now beyond manifest: for marijuana, the CSA is no longer the appropriate regulatory framework; and DEA is no longer an appropriate regulator.[29]

III. Alternatively, Marijuana Should be Rescheduled.

Placement in schedule I "does not appear to flow inevitably from lack of a currently accepted medical use." *See Nat'l Org. for Reform of Marijuana L. (NORML) v. DEA*, 559 F.2d 735, 748 (D.C. Cir. 1977). "[T]he structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence." *Id.*

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28 https://www.judiciary.senate.gov/imo/media/doc/QFR%20Responses%202-28.pdf.

29 Many other abused drugs are not scheduled, such as nutmeg (routinely used in cooking) and nitrous oxide (routinely used as whipped cream chargers). Both have substantial non-medical uses and are sold by non-medical providers. The disruption that would be caused by scheduling these substances is "other relevant data" that weighs strongly against control.

As noted above, marijuana has a currently accepted medical use in treatment in the United States. But even if it did not, balancing of medical usefulness along with other considerations would justify downscheduling. In particular, marijuana has a low physical/psychological dependence risk compared to other drugs such as fentanyl.

a. **Schedule V or IV**

A drug in schedule V has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule IV. Compared to benzodiazapenes in schedule IV, marijuana has a low potential for abuse and lower psychological dependence. Marijuana use may produce some level of dependence, and cessation of use may produce withdrawal symptoms.[30] But dependence associated with marijuana use and marijuana withdrawal is far less significant than benzodiazepine dependence and benzodiazepine withdrawal.[31]

b. Schedule III

A drug in schedule IV has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule III. As discussed above, marijuana does not have the same potential for abuse as drugs in schedule II such as methamphetamine, cocaine, and fentanyl. Indeed, some evidence suggests cannabis use is associated with a reduced risk of opioid exposure.[32]

IV. Conclusion

The Administration has stated that "science will guide" the decision to reschedule marijuana. As important, the decision must be guided by law. Marijuana's current classification under the CSA as a schedule I substance is legally infirm. For this reason, it must be descheduled or, alternatively, rescheduled.

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30 *See, e.g.*, Connor JP, Stjepanović D, Le Foll B, Hoch E, Budney AJ, Hall WD. Cannabis use and cannabis use disorder. Nat Rev Dis Primers. 2021 Feb 25;7(1):16. doi: 10.1038/s41572-021-00247-4. PMID: 33627670; PMCID: PMC8655458.

31 *See* Baandrup L, Ebdrup BH, Rasmussen JØ, Lindschou J, Gluud C, Glenthøj BY. Pharmacological interventions for benzodiazepine discontinuation in chronic benzodiazepine users. Cochrane Database Syst Rev. 2018 Mar 15;3(3):CD011481. doi: 10.1002/14651858.CD011481.pub2. PMID: 29543325; PMCID: PMC6513394.

32 *See, e.g.*, Socías ME, Choi J, Lake S, Wood E, Valleriani J, Hayashi K, Kerr T, Milloy MJ. Cannabis use is associated with reduced risk of exposure to fentanyl among people on opioid agonist therapy during a community-wide overdose crisis. Drug Alcohol Depend. 2021 Feb 1;219:108420. doi: 10.1016/j.drugalcdep.2020.108420. Epub 2020 Dec 17. Erratum in: Drug Alcohol Depend. 2021 Apr 1;221:108547. PMID: 33342591; PMCID: PMC8006801.