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**

REQUEST FOR RECONSIDERATION IN LIGHT OF NEW EVIDENCE

Submitted by Village Farms International, Inc., Hemp for Victory, and OCO et al.

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INTRODUCTION

The Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*, regulates the manufacture, distribution, and use of certain substances. It categorizes them into five schedules, with substances in schedule I subject to the strictest controls and substances in schedule V subject to the least strict. Marijuana is currently in schedule I.

In 2022, the President directed the Secretary of the Department of Health and Human Services ("HHS") and the Attorney General to initiate administrative proceedings to review marijuana's scheduling. HHS—in coordination with the Food and Drug Administration ("FDA") and the National Institute on Drug Abuse—then compiled a 252-page scientific and medical evaluation of marijuana. Based on that evaluation, HHS recommended that marijuana be rescheduled to schedule III. The legal basis for HHS's recommendation was evaluated by the Department of Justice ("DOJ")'s Office of Legal Counsel ("OLC"), which concurred with HHS's analysis. Based on the recommendation of HHS and the legal opinion of their OLC, DOJ then issued a Notice of Proposed Rulemaking ("NPRM")—signed by the Attorney General—proposing that marijuana be rescheduled to schedule III ("Proposed Rule"). The NPRM emphasizes that HHS's scientific and medical determinations must be accorded "significant deference" throughout the rulemaking process. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597, 44599 (May 21, 2024) (hereinafter "NPRM"). This Tribunal is scheduled to preside over a hearing on the Proposed Rule beginning on January 21, 2025.

Shockingly, however, the Drug Enforcement Administration ("DEA") has obstructed the rulemaking process at every turn. As detailed in an earlier filing submitted to this Tribunal (the "Original Ex Parte Motion"), DEA refused to accept HHS's recommendation for the first time in its history; failed to gather data in accordance with statutory mandates; engaged in ex parte communications with organizations opposed to the rescheduling of marijuana ("anti-rescheduling organizations"); concealed the identities of the individuals and entities who asked to participate in the rulemaking proceedings; favored anti-rescheduling organizations in its selection of 25 Designated Participants ("DPs") for the hearing; and disfavored pro-rescheduling parties,

including DEA researchers, doctors, scientists, and the State of Colorado, which has competently regulated a medical marijuana program for over a decade.[1]

Since the Original Ex Parte Motion, newly discovered evidence of DEA's improper conduct and unalterably closed mind has come to light:

Untimely, biased, and legally-improper filing. In an exhibit filed with this Tribunal on January 2, 2025 (the "January 2 Exhibit"), DEA echoes anti-rescheduling talking points in attempting to show that marijuana has a high abuse potential and no currently accepted medical use. With respect to currently accepted medical use, DEA relies on a legal test that OLC *rejected* in a formal opinion binding on the entire Executive Branch. DEA's defiance of OLC's binding opinion is stunning proof of its open hostility to the Proposed Rule. So is the timing of the filing. DEA was statutorily required to submit any data it thought relevant *before* HHS's review and *before* the start of formal rulemaking proceedings. By waiting until practically the eve of the hearing to submit its data, DEA has thwarted HHS's review, sidestepped the notice-and-comment process, and deprived pro-rescheduling DPs of the fair and transparent hearing that the Administrative Procedure Act ("APA") and due process require. In so doing, DEA has violated the CSA, the APA, and its own regulations.

Additional evidence of ex parte and undisclosed communications. The Original Ex Parte Motion provided evidence of ex parte communications between DEA and anti-rescheduling DP Smart Approaches to Marijuana ("SAM"). Since then, additional damning evidence of ex parte and undisclosed communications has emerged, including: (1) DEA's concealment of roughly 100 requests to participate in the upcoming hearing; and (2) DEA's communication and coordination with at least one anti-rescheduling DP, the Tennessee Bureau of Investigation ("TBI"). This new evidence confirms that DEA has worked to stack the deck against the Proposed Rule by favoring

[1] *See* 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 (Nov. 18, 2024) ("Original Ex Parte Motion").

anti-rescheduling parties in its selection of hearing participants and obstructing a balanced and thoughtful process based on science and evidence.

Additional evidence of conflicts of interests. In recently published documents, DEA lists an anti-rescheduling DP—the Community Anti-Drug Coalitions of America ("CADCA")—as a resource for information on marijuana. And CADCA, in turn, has announced that it has been working as DEA's "partner" on matters related to fentanyl. Neither DEA nor CADCA has disclosed this potential conflict of interest to this Tribunal.

* * *

In light of this newly discovered evidence, Village Farms International, Inc. ("Village Farms") and Hemp for Victory (collectively with Village Farms, the "Movants") renew their request for relief from DEA's improper interference.[2] At a minimum, this Tribunal should postpone the upcoming hearing to allow for an investigation into DEA's conduct,[3] including its ex parte and undisclosed communications with anti-rescheduling organizations and other entities. As part of that investigation, this Tribunal should order DEA to disclose its communications and other relevant information;[4] allow for discovery;[5] hold an evidentiary hearing; and make on-the-record findings.[6] *See, e.g.*, *PATCO v. FLRA*, 672 F.2d 109, 113 (D.C. Cir. 1982) ("*PATCO I*") (ordering

[2] To the extent that this Tribunal views this renewed request for relief as a new motion such that Movants may not file it absent good cause, Movants submit that the newly discovered evidence of a widespread pattern of DEA wrongdoing that they present below suffices to meet that standard. In addition, Village Farms' submission to DEA and DOJ of a good faith affidavit alleging DEA bias, discussed further *infra* Part III.C.1., provides an independent basis for a continuance of the hearing and thus good cause for the filing of this renewed request for relief.

[3] *See, e.g.*, 21 C.F.R. § 1316.52(a) (empowering ALJ to "[a]rrange and change the date, time, and place of hearings (other than the time and place prescribed in § 1301.56) and prehearing conferences and issue notice thereof").

[4] *See, e.g.*, 21 C.F.R. § 1316.52(d) (empowering ALJ to "[s]ign and issue subpoenas to compel the attendance of witnesses and the production of documents and materials to the extent necessary to conduct administrative hearings pending before him").

[5] *See, e.g.*, 5 U.S.C. § 556(c)(4) (empowering ALJ to "take depositions or have depositions taken when the ends of justice would be served").

[6] *See, e.g.*, 21 C.F.R. § 1316.52(a) (empowering ALJ to "[a]rrange and change the date, time, and place of hearings (other than the time and place prescribed in § 1301.56) and prehearing conferences and issue notice thereof"); *id.* § 1316.52(b) (empowering ALJ to "[h]old conferences 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"); 5 U.S.C. § 556(c)(5) (empowering ALJ to "regulate the course of the hearing").

this relief in similar circumstances); 5 U.S.C. § 557(d)(1)(C) (requiring disclosure of improper ex parte communications so they may be placed in the record).

After the investigation, additional relief is warranted. This Tribunal should direct DEA, as it directed all DPs, to declare whether it supports or opposes the proposed transfer of marijuana to schedule III. *See* NPRM, 89 Fed. Reg. at 44598 (empowering ALJ to "require parties to state their position in writing" and giving ALJ "all powers necessary to conduct a fair hearing"); 5 U.S.C. § 556(c)(5) (empowering ALJ to "regulate the course of the hearing"). It should also exclude DEA's January 2 Exhibit from the record because it is untimely, constitutes improper hearsay, and violates the CSA and APA. *See* NPRM, 89 Fed. Reg. at 44598 (empowering ALJ to "receive, rule on, exclude, or limit evidence"); 5 U.S.C. § 556(c)(5) (empowering ALJ to "regulate the course of the hearing").

Finally, this Tribunal should disqualify DEA under 5 U.S.C. § 556(b) and remove it as the proponent of the rule under 5 U.S.C. § 556(d). An agency decisionmaker violates the Due Process Clause when it acts with an "unalterably closed mind" and is "unwilling or unable to consider rationally argument[s]" for or against a proposed rule. *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170, 1174 (D.C. Cir. 1979). Where, as here, "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). This Tribunal has authority to take that step under the APA, which empowers it to "regulate the course of the hearing," 5 U.S.C. § 556(c)(5), and the NPRM, which gives it "all powers necessary to conduct a fair hearing," 89 Fed. Reg. at 44598. DOJ—the actual proponent of the Proposed Rule—can and should take DEA's place in these proceedings.

While this Tribunal previously rejected similar requests for relief, it should reconsider its ruling in light of the newly discovered evidence and additional arguments presented in this motion. In the event this Tribunal declines to reconsider, however, Movants are simultaneously pursuing DEA's disqualification through the affidavit process contemplated by § 556(b) of the APA. *See* 5 U.S.C. § 556(b) ("On the filing in good faith of a timely and sufficient affidavit of personal bias

or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case."). To that end, Village Farms has attached as Exhibit 1 a good-faith affidavit of Dr. John Harloe in support of this motion alleging facts of "other [basis for] disqualification" of DEA from further participation in these proceedings. *Id.* Once this motion is filed, Movants will send a copy of this motion, the Original Ex Parte Motion, this Tribunal's Order denying the Original Ex Parte Motion (the "Ex Parte Order"), and Dr. Harloe's supporting affidavit to DEA and DOJ for a "determin[ation]" of disqualification under § 556(b).

PROCEDURAL HISTORY

Movants hereby incorporate by reference the factual background set forth in the Original Ex Parte Motion.

A. The Original Ex Parte Motion.

In their Original Ex Parte Motion, Movants requested supplementation of the administrative record and removal of the DEA from the position of proponent of the Proposed Rule under 5 U.S.C. § 556(d). First, Movants requested corrective relief to include in the otherwise-incomplete record all requests for hearing, requests to participate in these proceedings, and the DEA Administrator's decisions granting or denying participation in these proceedings.[7] Second, Movants requested limited discovery into the ex parte communications maintained between SAM (a DP in these proceedings) and DEA.[8] Third, Movants requested that this Tribunal bar DEA from proceeding in the role of proponent of the Rule under 5 U.S.C. § 556(d) because it neither supported nor proposed the Proposed Rule.[9]

In support of their arguments, Movants attached several social media posts from SAM's President and CEO, Dr. Kevin Sabet, in which he admitted having had ex parte communications

[7] *See* Original Ex Parte Mot. 18.

[8] *Id.*

[9] *Id.* at 19–21.

with DEA regarding its opposition to the schedule III proposal.[10] In one instance, Dr. Sabet declared that he had "BIG" news from "two confidential sources inside the DEA … with intimate knowledge" related to these proceedings.[11] Movants also detailed the exhaustive history of DEA's vehement opposition to the Proposed Rule, both in the lead up to DOJ's promulgation of the Proposed Rule and more generally.[12] Movants catalogued, for example, DEA's unprecedented behavior before DOJ released the Proposed Rule that forced the Attorney General himself—not his delegate, the DEA Administrator—to sign and promulgate the Proposed Rule.[13]

Following the Original Ex Parte Motion, this Tribunal granted leave to DEA and SAM to file responses.[14] Both responded, but neither denied having engaged in ex parte communications.[15] In the Ex Parte Order , this Tribunal found DEA's and SAM's tepid, qualified responses "noteworthy" because "neither of the responding parties denied that the purported *ex parte* communications took place, and neither provided the record (or the public) with the identities of the Government side of the equation or any details that would have at least aided in achieving some level of transparency regarding this issue." *See* Order Regarding Joint Ex Parte Motion 7 n.9 (Nov. 27, 2024) ("Ex Parte Order").

Even so, the Tribunal denied any relief.[16] The Tribunal allowed DEA to proceed as the "proponent" of the rule and thus shoulder the burden of proof, despite the fact that DEA did not

[10] *See id.* at 7–9.

[11] *See id.* at 7.

[12] *See id.* at 2–5.

[13] *See id*.

[14] *See* Briefing Order Regarding Hemp for Victory and Village Farms International's Joint Motion for Agency Disqualification and Record Supplementation (Nov. 20, 2024); Supplemental Briefing Order Regarding a Joint Motion Filed by Hemp For Victory and Village Farms International (Nov. 21, 2024).

[15] *See* Government Opposition to Hemp for Victory and Village Farms International's Joint Motion Requesting Supplementation of the Record and Disqualification and Removal of DEA from the Role of Proponent of the Rule in These Proceedings (Nov. 25, 2024); Response of Smart Approaches to Marijuana Pursuant to November 21, 2024 Order (Nov. 25, 2024).

[16] *See* November 27, 2024 Order Regarding Joint Ex Parte Motion at 2 (hereinafter, "Ex Parte Order ") ("[T]his tribunal is without the authority to grant the supplementation and removal relief sought (the only relief sought) by Movants.").

Movants sought additional relief in the Original Ex Parte Motion. *See, e.g.*, Original Ex Parte Motion 18 ("Hemp for

issue the Proposed Rule; has never said that it supports the rule; and lacks authority to issue the final rule.[17] The Tribunal also disclaimed the authority to order depositions despite the provision in 5 U.S.C. § 556(c)(4) allowing administrative law judges ("ALJs") to, *inter alia*, "take depositions or have depositions taken when the ends of justice would be served."[18] At the recent preconference hearing, this Tribunal asked DEA's counsel whether they supported rescheduling. DEA's counsel did not answer that question and instead responded only that DEA is the proponent of the Proposed Rule.[19]

B. Disclosure of further irregularities.

In the wake of this Tribunal's Ex Parte Order, further evidence of troubling irregularities in these proceedings has emerged.

1. Untimely and improper January 2 Exhibit.

On January 2, 2025, DEA submitted its final exhibit list, copies of exhibits intended to be introduced, and declarations for its two witnesses. Accompanying one of the declarations is an undated exhibit—purportedly prepared by DEA's Diversion Control Division but not attributed to any specific author or authors—entitled "Marijuana Scientific Data Review as it Relates to the

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Victory and Village Farms request that this Tribunal use every tool at its disposal to uncover each instance of improper contact between DEA and anti-rescheduling parties and determine whether those contacts influenced the Designated Participants list created by the Administrator."); *id.* ("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.") (citing cases); *id.* at 16 n.24 ("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.").

Hemp for Victory also separately requested discovery in its November 26, 2024 Prehearing Statement. *See* Prehearing Statement of Hemp for Victory 8. Movants flag this issue solely out of an abundance of caution given that they also request additional and very specific relief in this Renewed Motion. *See supra* 3–4.

[17] In the Proposed Rule, the Attorney General reserved to DOJ the authority to promulgate any final rule. *See, e.g.*, NPRM, 89 Fed. Reg. at 44621 ("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 44599 n.2 (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") (citing *Questions Related to the Potential Rescheduling of Marijuana*, 45 Op. O.L.C. 4, 25 (Apr. 11, 2024) (hereinafter, "OLC Op.")).

[18] Drug Enforcement Administration, *DEA To Hold Hearing On Rescheduling of Marijuana*, at 1:07:20, YOUTUBE (Dec. 2, 2024), https://www.youtube.com/watch?v=GBMHWru0FNo.

[19] *DEA To Hold Hearing On Rescheduling of Marijuana*, at 17:51, YOUTUBE (Dec. 2, 2024), https://www.youtube.com/watch?v=GBMHWru0FNo.

Controlled Substances Act." Gov. Ex. 4, Decl. of Luli Akinfiresoye, at 11. Were there any doubt regarding DEA's intractable hostility toward the Proposed Rule, this January 2 Exhibit extinguishes it.

In its 66-page January 2 Exhibit—an apparent attempt to complete an ex post facto 8-factor analysis—DEA attempts to show that marijuana has a high abuse potential and no currently accepted medical use. In reaching the latter conclusion, DEA relies on its so-called five-part test for currently accepted medical use. In doing so, DEA defies a formal opinion of DOJ's OLC, which adjudicated an interagency dispute between DEA and HHS over precisely this point. According to OLC, DEA's five-part test is "impermissibly narrow," and the "alternative, two-part inquiry proposed by [HHS, and applied and accepted by DOJ in the NPRM,] is sufficient to establish that a drug has a 'currently accepted medical use' even if the drug would not satisfy DEA's current approach." OLC Op. at 1.

OLC's legal conclusions in formal opinions like this one bind 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). This has not happened. In fact, the Attorney General has expressly accepted OLC's conclusions in the NPRM. NPRM, 89 Fed. Reg. at 44,619. DEA's defiance of law expressly adopted by the Attorney General himself—the fount of all DEA authority under the CSA, *see* 28 C.F.R. 0.100(b)—is proof of a hostility to the Proposed Rule so entrenched that DEA is prepared to defy the law to thwart it.

In the 66 pages that DEA devotes to this newly disclosed evidence, there is not one new study that casts doubt on HHS's most recent findings. In their initial submission disclosing exhibits, Hemp for Victory noticed more than 220 studies confirming HHS's conclusions that marijuana has an abuse potential less than substances in schedules I and II and a currently accepted medical use in treatment in the United States. DEA does not mention—much less address—even one of those studies. DEA makes no attempt to present a balanced case but simply retreads anti-

rescheduling DP talking points often backed by cryptic references to decades-old studies or, even worse, random anecdotes stumbled across through Google searches.

By way of example, DEA mentions the State of Colorado twenty-seven times in the January 2 Exhibit, to cast doubt on the success of the decade-old state-regulated program. Yet DEA makes no attempt to engage with the positive evidence from Colorado and summarily rejected Colorado's request to participate in this hearing.[20] Repeatedly, in its analysis, DEA acknowledges the relevance of that state-level experience and claims a dearth of the sort of state data that would be helpful in making various determinations at issue. But DEA fails to mention how it worked in secret to block that very same state data from making its way into these proceedings.

Evidence now shows that through its secret DP-selection process, DEA rejected Colorado's bid to present "important insights and subject matter expertise" from its longstanding medical marijuana program and to address references in the Proposed Rule to Colorado data on marijuana-related traffic deaths, *see* NPRM at 44,614—data that, according to Colorado, "lacks important context that must be considered in this rulemaking." *See* Original Ex Parte Mot. Ex. A (Sept. 30, 2024 Letter from Gov. Polis to DEA requesting that Colorado be permitted to participate in these proceedings and detailing Colorado's interested-person status). Despite DEA's claimed interest in state data and experience, the Administrator barred Colorado from presenting that data. And now, secure in the knowledge that the Administrator's secret selection process has guaranteed that Colorado will not be able to respond or defend itself, DEA reveals its plan to smear the state's successful regulatory program in these historic and very public proceedings.

The evidence also shows that DEA's treatment of Colorado is part of a bigger plan to subvert this administrative process to thwart the Proposed Rule. After blocking Colorado's efforts to stand up for its regulatory system and the Proposed Rule in these proceedings, DEA rolled out the red carpet for the State of Nebraska—an anti-rescheduling DP that is now working hand-in-hand with SAM, the anti-rescheduling DP whose President and CEO has bragged on social media

[20] DEA's decisions rejecting Colorado's bid for participation in the hearing process are attached as Exhibit 2.

about his confidential DEA sources and special insider knowledge of DEA's campaign of opposition to the Proposed Rule. Meanwhile—as explained further below—another Headquarters-level DEA official was working with anti-rescheduling DP TBI in secret to ensure it would be able to oppose the Proposed Rule in these proceedings.

While DEA has represented to this Tribunal that it is the "proponent" of the Proposed Rule and remains without a disqualifying conflict, this new filing confirms that DEA has always been—and remains—firmly opposed to the proposed transfer of marijuana to schedule III. As Movants have made clear, DEA's position as proponent of the Proposed Rule has been improper from the start. To permit it to maintain that position even after filing what amounts to an open declaration of war on the Proposed Rule would be a mockery of the adversarial process.

2. Additional evidence of ex parte communications.

On December 20, 2024, DEA's counsel in *Doctors for Drug Policy Reform v. DEA* filed an Opposition to Emergency Motion for an Injunction Pending Appeal ("DEA Opposition Brief"). No. 24-1365 (D.C. Cir. filed Nov. 17, 2024) (Document #2090852). Included with that filing was the Declaration of Heather Achbach ("Achbach Declaration"), the current Acting Section Chief of DEA's Diversion Control Division's Regulatory Drafting and Policy Support Section and one of DEA's designated witnesses in these proceedings. The DEA Opposition Brief and the Achbach Declaration reveal—for the first time—that DEA received "123 separate requests to participate in the [hearing currently before this Tribunal] from 163 total individuals and entities."[21]

Only a small minority of the requests referenced in DEA's Opposition Brief and the Achbach Declaration—and even fewer of DEA's responses to them—are in the administrative record. This omission deprives the Tribunal from important perspectives regarding the ultimate question in this matter, namely whether marijuana is appropriately placed in schedule III. As Movants explain in detail below, *see infra* Part I.A, the remainder qualify as improper ex parte communications under 5 U.S.C. § 557(d)(1)(C) and 21 C.F.R. § 1316.51(c).

[21] *See* Achbach Decl. at ¶ 3 (DEA Opposition Brief, Add. 2); DEA Opposition Brief at 2, 3, 9, 11, 15, 17, 18.

Further, after this Tribunal denied the Original Ex Parte Motion, Movants reviewed various filings submitted by DPs in these proceedings more closely and identified yet another critical and still-undisclosed ex parte communication between DEA another anti-rescheduling DP: TBI. In a recent filing, TBI explains that "[o]n June 19, 2024," it "requested a public hearing regarding the proposed rescheduling of marijuana ('Proposed Rule')." TBI Notice of Appearance and Statement of Interest 2 (Nov. 12, 2024). TBI then adds that on September 17, 2024, *after* the DEA Administrator had announced the hearing and just thirteen days *before* the deadline for interested persons to submit their requests to participate, it received a letter from DEA Deputy Assistant Administrator, Matthew Strait, "request[ing that] TBI provide[] supplemental information showing that it is an 'interested person' under 21 C.F.R. § 1300.01(b)." *Id.* TBI submitted the requested supplement on September 30, 2024, and DEA subsequently "granted TBI's request[.]" *Id.*

TBI attached its initial request for hearing, its response to Deputy Assistant Administrator Strait's September 17, 2024 letter inviting TBI to provide additional information, and the Administrator's decision granting TBI's request as exhibits to its November 12, 2024 filing with this Tribunal. Noticeably absent from the record, however, is Deputy Assistant Administrator Strait's letter itself. Movants and their counsel are not aware of any pre-rescheduling party having received such assistance from Deputy Assistant Administrator Strait or any other DEA official. In fact, pro-rescheduling parties, including the State of Colorado, the American Trade Association of Cannabis and Hemp ("ATACH"), and MedPharm, among numerous others, received no response at all—not of receipt of request to participate, consideration of such request, flawed or incomplete standing arguments in their petition, a request to correct any such flaws, or any communication whatsoever—until November 25, 2024, long after these proceedings were already underway.

Of course, no one would know about Deputy Assistant Administrator Strait's off-the-record coordination with TBI but for TBI's candid, though critically incomplete, disclosure in its November 12, 2024 filing. That is true because there was no transparency regarding why the Administrator usurped this Tribunal's role, how and why the Administrator created the DP list,

what criteria the Administrator used to determine the interested-person status of DPs and requesters not selected as DPs, why this Tribunal had no role in making any these determinations, why the Administrator excluded supporters of the Proposed Rule with legitimate claims to administrative standing (including DEA-registered marijuana researchers and a state with a long-standing medical program), or why DEA failed to notify all petitioning parties promptly of these decisions and the Administrator's rationale for them. Further, without discovery and/or an evidentiary hearing, the Tribunal, parties, and the public cannot be sure that DEA did not afford other anti-rescheduling parties similar preferential treatment. *See, e.g.*, *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.").

3. Additional evidence of undisclosed conflicts of interest.

DEA recently published two documents that confirm its hostility to the Proposed Rule and reveal a potential undisclosed conflict of interest. In November 2024, DEA published a document in which it insists that marijuana has no medical utility and high potential for abuse.[22] Likewise, in the newly released edition of its manual "Drugs of Abuse," DEA declares that because marijuana lacks FDA approval for interstate marketing as a drug, it necessarily lacks a currently accepted medical use under federal law.[23] In both documents, DEA lists an anti-rescheduling DP, CADCA, as a resource and reference for members of the public interested in information about marijuana.[24]

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[22] *Preventing Cannabis Use Among Youth and Young Adults*, U.S. DRUG ENFORCEMENT ADMINISTRATION (Nov. 2024), at 5, https://www.getsmartaboutdrugs.gov/sites/default/files/2024-12/Preventing-Cannabis-Use-Among-Youth-and-Young-Adults-November-2024.pdf.

[23] *See Drugs of Abuse: A DEA Resource Guide*, *2024 Edition* at 92 (hereinafter, "*Drugs of Abuse*"), https://www.dea.gov/sites/default/files/2024-12/2024-Drugs-of-Abuse-508.pdf (claiming that because "FDA has not approved a marketing application for any marijuana product for any clinical indication," marijuana "has no federally approved medical use for treatment in the U.S."); *but see* OLC Op. at 4–5 ("[W]e conclude, first, that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test.").

[24] *See Drugs of Abuse*, *supra* n. 23, at 114; *Preventing Cannabis Use Among Youth and Young Adults*, *supra* n. 22, at 7.

Still more evidence confirming DEA's apparent conflict emerged on December 12, 2024, when CADCA announced its ongoing "partner[ship]" with DEA on a national fentanyl summit despite being on the opposite side of the "v" from the Agency in these proceedings.[25]

LAW AND ARGUMENT

I. This Tribunal must take corrective action in response to DEA's ex parte communications.

A. DEA has engaged in extensive improper ex parte communications.

An "'ex parte communication' means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by [the APA]." 5 U.S.C. § 551(14). As this Tribunal explained in the Ex Parte Order, § 557(d)(1) of the APA and § 1316.51(c) of DEA regulations require disclosure of ex parte communications that (1) occur between certain parties, (2) pertain to certain subject matter, and (3) occur during a certain time period. *See* Ex Parte Order 3 (discussing the requirements of 5 U.S.C. § 557(d)(1) and 21 C.F.R. § 1316.51(c)). The 123 requests to participate, the Administrator's responses to them, and Deputy Assistant Administrator Strait's September 17, 2024 letter providing special assistance to TBI meet all three conditions.

1. Parties involved.

By its terms, 5 U.S.C. § 557(d) applies only to ex parte communications to or from an "interested person." However, "Congress did not intend … that the prohibition on ex parte communications would therefore have only a limited application." *PATCO II*, 685 F.2d at 562 (discussing § 557(d)'s legislative history). Congress enacted § 557(d) as part of the Government in the Sunshine Act, Pub. L. No. 94-409, § 4(a), 90 Stat. 1241, 1246 (1976). The House Report explains that Congress intended § 557(d)'s reference to "interested person" to be interpreted broadly:

[25] *DEA and CADCA Partner on 2024 National Family Summit on Fentanyl*, CADCA (Dec. 12, 2024) https://www.cadca.org/programs-in-action/dea-and-cadca-partner-on-2024-national-family-summit-on-fentanyl/.

> The term "interested person" is intended to be a wide, inclusive term covering any individual or other person with an interest in the agency proceeding that is greater than the general interest the public as a whole may have. The interest need not be monetary, nor need a person to [sic] be a party to, or intervenor in, the agency proceeding to come under this section. The term includes, but is not limited to, parties, competitors, public officials, and nonprofit or public interest organizations and associations with a special interest in the matter regulated. The term does not include a member of the public at large who makes a casual or general expression of opinion about a pending proceeding.

H.R. Rep. No. 880, Pt. I, 94th Cong., 2d Sess. 19-20 (1976), *reprinted in* Senate Comm. on Govt. Operations & House Comm. on Govt. Operations, 94th Cong., 2d Sess, Government in the Sunshine Act—S. 5 (Pub. L. 94-909): Source Book: Legislative History, Texts, and Other Documents 530–31 (Jt. Comm. Print 1976) ("Sunshine Act Sourcebook"). *Accord*, S. Rep. No. 354, 94th Cong., 1st Sess. 11, 36 (1975), Sunshine Act Sourcebook at 206, 231.

The parties seeking to participate in this hearing process clearly qualify as "interested person[s]" as the term is used in § 557(d)(1) and 21 C.F.R. § 1316.51(c). The very fact that they asked to participate in the ALJ hearing demonstrates that their interest in the proceedings far exceeds that of the general public.[26]

Nor can there be any doubt that the Administrator is a DEA "employee who is or may reasonably be expected to be involved in the decisional process of the proceeding." 5 U.S.C. § 557(d)(1)(B). After all, she decided who would participate in the hearing. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70149 (Aug. 29, 2024) (hereinafter, "Notice of Hearing") ("After the deadline to request to participate in the hearing, I will assess the notices submitted and make a determination of participants.").

[26] The construction of the term "interested person" in 5 U.S.C. § 557(d)(1) does not apply to 21 C.F.R. § 1308.44, the DEA regulation that permits "interested person[s]" to request or request to participate in a "hearing on a proposed rulemaking." The term "interested person" in § 1308.44 is subject to the definition provided in another DEA regulation. *See* 21 C.F.R. § 1300.01(b). Furthermore, unlike the APA's ex parte communication ban, the DEA regulation barring ex parte communications is not limited to communications between the Agency and an "interested person[]." *See* 21 C.F.R. § 1316.51(c) (barring ex parte communications between the Agency "any individual in private or public life.").

Accordingly, the undisclosed requests and responses qualify as communications between "interested person[s]" and a DEA official "who is or may reasonably be expected to be involved in the decisional process of the proceeding." 5 U.S.C. § 557(d)(1).

The same is true of Deputy Assistant Administrator Strait's September 17, 2024 letter. As a DP and an entity that both commented on the Proposed Rule and submitted a hearing request detailing its opposition to the schedule III proposal, TBI is a person with an interest in the agency proceeding that is greater than that of the general public. And Deputy Assistant Administrator Strait is a DEA "employee who is or may reasonably be expected to be involved in the decisional process of the proceeding." 5 U.S.C. § 557(d)(1)(B). Not only is he a senior DEA official in the Diversion Control Division at DEA Headquarters[27]—the DEA Division that the Proposed Rule singles out as the DEA point of contact for information about this administrative process—but he expressly involved himself in the decisional process of the proceeding by corresponding with TBI to bolster its bid to participate in the hearing process to oppose the Proposed Rule. Accordingly, Deputy Assistant Administrator Strait's September 17, 2024 communication with TBI meets § 557(d)(1)'s covered-parties requirement.

2. Subject matter.

Section 557(d)(1) prohibits communications "relevant to the merits of the proceeding." The congressional reports state that the phrase should "be construed broadly and … include more than the phrase 'fact in issue' currently used in [§ 554(d)(1) of] the Administrative Procedure Act." S. Rep. No. 354 at 36, Sunshine Act Sourcebook at 231; Hr. Rep. No. 880, Pt. I at 20, Sunshine Act Sourcebook at 531.

Under any reasonable construction of the term, the requests and responses are "relevant to the merits of the proceeding." 5 U.S.C. § 557(d)(1). The Administrator determined that a hearing was appropriate to "'receiv[e] factual evidence and expert opinion regarding' whether marijuana should be transferred to schedule III of the list of controlled substances." *See* Notice of Hearing,

[27] *See Importer of Controlled Substances Application: Curia New York, Inc.*, 89 Fed. Reg. 106589 (Dec. 30, 2024) (reflecting the signature of "Matthew Strait, Deputy Assistant Administrator").

89 Fed. Reg. at 70149 (quoting 21 C.F.R. § 1308.42). The content of that factual evidence and expert opinion will therefore hinge on what the persons and entities selected to participate ultimately produce.

Moreover, "in the case of formal proceedings" like this formal rulemaking process, the APA demands that "the factual support [for an agency's decision] be found in the closed record as opposed to elsewhere," making the importance of the record and who may—and may not—participate in the process of compiling it all the more critical to the ultimate outcome of the administrative process. *See, e.g.*, *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683 (D.C. Cir. 1984) (Scalia, J.); Aaron J. Nielson, *In Defense of Formal Rulemaking*, 75 Ohio St. L. J. 237, 270 (2014) ("A closed record is no small thing.").

Other aspects of the formal rulemaking process reinforce the importance of the Administrator's decisions regarding participation. One of formal rulemaking's key distinguishing features is the adversarial nature of the formal, trial-like hearing process it permits. That process enhances the transparency, and thus the legitimacy, of agency rules. Nielson, 75 Ohio St. L. J. at 281 ("[A] transparent process is not trivial; indeed, transparency is often a prerequisite for legitimacy.") (citations omitted). Formal rulemaking thus "has a unique capacity to address [Americans'] widespread distrust [of administrative decision-making] because while Americans may not trust the trial completely, they still trust it more than the administrative process." *Id.* at 280 (cleaned up).

Moreover, formal rulemaking's trial-like hearing procedures are especially useful in rooting out agency error, mistaken premises, and bias. Nielson, 75 Ohio St. L. J. at 265 ("[C]ross-examination of [agency] witnesses" helps "in exposing possible error, bias, or lack of solid foundation which cannot be effectively brought to light simply by introducing rebuttal argument against the generalized policy statements.") (internal quotation marks and citations omitted); *id*. at 270 (in cases of agency bias, "a judicial challenge to the agency's decision could be benefited if there is a transcript of what occurred"). Yet the hearing process is only as adversarial—and thus transparent and legitimate—as the parties selected to participate permit it to be. Without knowing

whom the Administrator excluded from participating and why, it is impossible to assess whether those decisions themselves were made in an arbitrary or biased manner. *See* Ex Parte Order 1 n.1 ("This forum has not been supplied with any such communications or any documentation from the pool of those selected and unselected, and is *unaware of the criteria employed*.") (emphasis added).

Because they bear directly on DEA's core decision-making process in ways that will predetermine the universe of evidence available for consideration in these proceedings as well as the adversarialness, transparency, and legitimacy of the proceedings themselves, the requests and responses at issue are "relevant to the merits of the proceeding." 5 U.S.C. § 557(d)(1). The same reasoning applies to Deputy Assistant Administrator Strait's September 17, 2024 letter to TBI.

3. Timing.

Under § 557(d)(1)(E), the ban on ex parte communications applies beginning:

> at such time as the agency may designate, but in no case … later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.

5 U.S.C. § 557(d)(1)(E). In its November 25, 2024 response to the Original Ex Parte Motion, SAM disputed whether this temporal requirement applied to the ex parte communications that its President and CEO revealed he had with "two confidential sources inside DEA … with intimate knowledge." *See* SAM Response 4–5; Original Ex Parte Mot. 7. This Tribunal was rightly skeptical of that argument, describing it as "a very restrictive view of the ethical obligations of a public servant, and perhaps less transparency than the public might expect from its government." Ex Parte Order 5. In any case, there can be no serious dispute that the requests and responses fall comfortably within the covered temporal range because they occurred after DOJ published the Proposed Rule in the Federal Register and the date when the DEA Administrator noticed the hearing.

Likewise, by the time the Administrator received the requests and issued responses, the communicants involved all had "knowledge that [a hearing] w[ould] be noticed." 5 U.S.C.

§ 557(d)(1)(E). The same can be said of Deputy Assistant Administrator Strait's September 17, 2024 letter to TBI.

In sum, the requests, responses, and Deputy Assistant Administrator Strait's letter to TBI occurred between covered parties, involved covered subject matter, and happened during the covered timeframe. Accordingly, they are prohibited ex parte communications under § 557(d)(1), and DEA must disclose them so that they may be made part of the record. *Id.* § 557(d)(1)(C).

B. Where there is reason to believe that improper ex parte communications may have occurred, a vigorous inquiry into the scope and nature of the problem is required.

Movants are not aware of any federal case involving so much evidence of such widespread ex parte communication in any formal adjudication or rulemaking. Thankfully, cases involving allegations of prohibited ex parte communications with agency decision-making are rare. When they do arise, however, courts have consistently held that immediate, forceful action is required at the agency and judicial level to investigate and uncover the scope, nature, extent, and effect of any and all improper contacts. Indeed, courts have held that an immediate and thorough probe is "essential" even when they are not convinced that any wrongdoing actually occurred. *See, e.g.*, *PATCO I*, 672 F.2d at 113.

Here, there is undisputed evidence of extensive ex parte communications. *A fortiori*, a probe at least as vigorous is required.

The D.C. Circuit's *PATCO* decisions are instructive. *See id.*; *PATCO II*, 685 F.2d 547. Those cases involved a petition for review of a final Federal Labor Relations Authority ("FLRA") order following a formal adjudication. There, as here, the administrative process was a matter of "intense public concern." *PATCO I*, 672 F.2d at 111. On the eve of oral argument, however, an Assistant Attorney General submitted documents to the court "indicat[ing] that a member of FLRA *may have been* involved in improper ex parte contacts." *Id.* (emphasis added). The court therefore delayed its decision on the merits "to permit further inquiry into the problem" and invited the petitioner "to submit whatever motions it felt appropriate." *Id.* at 112.

The petitioner sought an order permitting discovery, including the file the DOJ had compiled during its investigation of the alleged improper communications, documents reflecting any communications between the Executive Branch and FLRA members during the pendency of the proceedings, and answers to interrogatories regarding the possibility of ex parte contacts with FLRA members on the merits of the case. *See id.* FLRA's counsel "strenuously objected to any discovery whatsoever." *Id.* As part of a counterproposal, FLRA submitted an index enumerating and summarizing the contents of the investigatory file. If the court "were inclined to permit any further inquiry at all," counsel for FLRA suggested, then the court "should call for production in camera" of the documents and communications "that instigated the investigation." *Id*.

In light of the severity of the issue, the court called for further investigations and held petitioner's discovery motions in abeyance pending submission under seal of the relevant documents and communications. *Id*. After "careful study of the[] materials," the court was left "with a number of important but unanswered questions." *Id.* at 112–13. "[N]ot satisfied that the factual picture … [wa]s yet complete," the court decided that "a more extensive probe [wa]s imperative." *Id.* It therefore employed a procedure it had previously used "in analogous situations" and ordered "FLRA to hold, with the aid of a specially-appointed administrative law judge, an evidentiary hearing to determine the nature, extent, source and effect of all ex parte communications." *Id*. at 113 (citing *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.D.C. 1977); *Sangamon Valley Television Corp. v. United States*, 269 F.2d 221 (D.C. Cir. 1959)).

An "adversarial inquiry" was needed to "produce a vigorous and thorough airing sufficient to disclose whether any improper influence tainted FLRA's decision-making process." *Id.* Despite the fact that the court had not formed an opinion on whether anything improper had actually occurred, it deemed such measures "essential" as "[t]he facts may not be all in, and until unquestionably they are, no conclusion c[ould] be soundly drawn." *Id*.

Only after the special evidentiary hearing before an ALJ had run its course—and the court was "unquestionably" sure that the "facts [were] all in" regarding the scope, nature, extent, and effect of any and all ex parte communications—did it turn to the question of whether improper

communications had tainted the proceedings so as to require vacatur of the final FLRA order in *PATCO II*. *See PATCO I*, 672 F.2d at 113; *PATCO II*, 685 F.2d at 54.

While similar cases are rare, the *PATCO* decisions are not outliers. In *Gulf Oil Corp. v. U.S. Dep't of Energy*, for example, the D.C. Circuit held that a federal district court was justified in intervening in an ongoing formal adjudication to require that "an agency-appointed ALJ conduct discovery into … allegations [of document destruction and ex parte communications]." 663 F.2d 296, 313 (D.C. Cir. 1981). The case concerned the Department of Energy's adjudication of "alleged violations by seven major crude oil producers of mandatory crude oil pricing regulations[.]" *Id.* at 298. Before the proceedings could conclude, agency counsel moved to "'clarify the record' to include … ex parte memoranda" contemplated by § 557(d)(1)(C). *Id.* at 303.[28] In light of the disclosures, the crude oil producers sought—and the agency granted—"two depositions … and four interrogatories" to better understand the scope and nature of any agency wrongdoing. *Id.*

By that time, however, two of the producers had already filed a complaint in federal district court seeking a stay of the administrative proceedings pending the court's resolution of their additional requests for further investigation and discovery into the scope and nature of the alleged ex parte communications and document destruction. *Id.* at 304. The district court granted the producers' request. *Id.* Without immediate action, the court reasoned, there would be no way "to assure at the very least that [the producers] are not wholly denied an opportunity to develop facts supporting their claims." *Id.* at 305. Therefore, the court "directed the Secretary of Energy to appoint an independent ALJ 'for the sole purpose of supervising such further document and deposition discovery as the ALJ determines is appropriate and reasonable to develop fully all facts concerning ex parte contacts with the hearing officer and any destruction of relevant documents by agency personnel.'" *Id.* (cleaned up).

[28] *See also* 5 U.S.C. § 557(d)(1)(C) (directing agency officials who make or receive prohibited ex parte communications to "place on the public record of the proceeding: (i) all such written communications; (ii) memoranda stating the substance of all such oral communications; and (iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (i) and (ii) of this subparagraph").

The agency filed an immediate appeal to the D.C. Circuit, which "granted a stay pending appeal and sua sponte expedited th[e] case." *Id.* at 305–06. The D.C. Circuit "conclude[d] that the district court was justified on the basis of the evidence presented to it in intervening to assure that a full factual record of any misconduct would be preserved for use by the agency itself in the ongoing proceedings as well as for any later judicial review of that action." *Id.* at 307. That was so, the court explained, even though the district court had made no "findings that actual wrongdoing ha[d] taken place." *Id.*

While "subsequent events ha[d] sufficiently reduced the threat of substantial loss of … rights [to a fair proceeding]" by the time the D.C. Circuit issued its opinion, the court went on to explain that the district court's intervention "was originally justified," *id.*, because the district court had confronted "an agency proceeding in which it had reason to believe something *may* have gone fundamentally awry with the way in which the proceedings itself was being conducted," *id.* at 309 (emphasis added). Where that is so, immediate action is required to "prevent injustice" and ensure that "the proceeding [is] tried fairly" even if the evidence before the tribunal is insufficient to establish that any wrongdoing necessarily occurred. *Id.* at 309, 311.

These cases demonstrate that where there is even "reason to believe" that ex parte communications *may* have tainted a formal agency proceeding, an immediate inquiry is essential to ensure a fundamentally fair proceeding and preserve the record necessary to facilitate both agency decision-making and judicial review. *See id.* at 309. They also demonstrate that ALJs are the adjudicators best situated to oversee the required investigation—whether through a hearing, discovery, or both—into "the nature, extent, source, and effect of any and all ex parte communications." *PATCO I*, 672 F.2d at 113.[29]

[29] In the Ex Parte Order, this Tribunal concluded that when confronted with evidence of ex parte communications, its duty was to determine whether, "based on the papers [it] ha[d]," the "communication materially affected or will affect the way a given case is or has yet been decided." Ex Parte Order 7 (citing *Raz Inland Navigation Co., Inc. v. ICC*, 625 F.2d 258, 260–61 (9th Cir. 1980)). However, *Raz Inland* does not govern here—at least not yet. The standard discussed there applies to the distinct question whether evidence of ex parte communications requires setting aside agency action. *See Raz Inland*, 625 F.2d at 260–61 (analyzing whether, based on the three affidavits describing the ex parte communications it had before it, ex parte communications materially affected an agency's final order).

C. The compelling evidence of DEA wrongdoing at issue here requires an immediate evidentiary hearing and/or discovery to uncover the full scope of the Agency's secret machinations.

PATCO I, *PATCO II*, and *Gulf Oil* control here. Indeed, the case for immediate investigation and/or discovery into the widespread pattern of DEA ex parte communications is far stronger. *PATCO I* emphasized that an immediate special evidentiary hearing before an ALJ was "essential" even though the evidence of improper ex parte communications was not sufficient to form any "opinion on whether anything improper ha[d] actually occurred." 672 F.2d at 113 ("We are satisfied that these measures are *essential*, but hasten to emphasize that we have formed no opinion on whether anything improper has actually occurred.") (emphasis added). So, too, in *Gulf Oil. See* 663 F.2d at 309 (emphasizing that a special evidentiary hearing was appropriate where the district court merely had "reason to believe something *may* have gone fundamentally awry with the way in which the proceeding itself was being conducted") (emphasis added).

Here, by contrast, indisputable evidence shows wrongdoing "actually occurred," and on a broader scale that involves senior agency officials and more improper communications than had allegedly occurred in either *PATCO I* or *Gulf Oil*, a reality that is all the more startling given:

- DEA's refusal to disclose any of its known ex parte communications thus far;
- DEA's and SAM's "noteworthy" failure to "den[y] that the purported ex parte communications took place," Ex Parte Order 7 n.9;
- DEA's and SAM's failure to "provide[] the record (or the public) with the identities of the Government side of the equation or any details that would have at least aided in achieving some level of transparency regarding this issue," *id.*;
- The lack of *any* "indication in [DEA's Response to the Original Ex Parte Motion] that the Government has made even the mildest attempt to ascertain the truth and disclose it to the public and this tribunal," *id.* at 5;
- DEA's refusal to cooperate with FOIA requests seeking information related to the same subject matter;[30] and

[30] Wyld (an Oregon-based, multi-state-licensed cannabis company and member of ATACH, a trade organization whose request to appear in these proceedings was not granted) submitted two FOIA requests to DEA. The first, which Wyld filed on September 23, 2024, and was assigned Case No. 24-01177-F, sought ex parte communications between DEA and SAM, and is attached as Exhibit 3; DEA denied Wyld's request for expedited processing on September 26, 2024. The second, which Wyld submitted on October 8, 2024, and was assigned Case No. 25-00030-F, sought records

- Movants' inability to obtain any discovery or investigation into DEA's pattern of wrongdoing in these proceedings thus far.

That such compelling evidence of a pattern of DEA wrongdoing has emerged in this case is all the more remarkable given that unlike in *PATCO* and *Gulf Oil*, Movants have thus far been afforded *no* discovery or investigation into DEA's improper conduct whatsoever. *See PATCO I*, 672 F.2d at 111–13 (discussing DOJ and FBI investigation and subsequent disclosures that prompted the court to refer the matter to an ALJ for a special evidentiary hearing); *Gulf Oil*, 663 F.2d at 303 (discussing agency disclosures in the form of memoranda and the agency's subsequent allowance of depositions and interrogatories before the district court ordered the appointment of an ALJ for a special evidentiary hearing). For this reason alone, the *PATCO* cases and *Gulf Oil*

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of requests for hearing and/or to participate DEA received, and is attached as Exhibit 4; DEA granted Wyld's request for expedited processing on October 23, 2024. DEA's responses are attached as Exhibit 5. Despite granting expedited processing for Case No. 25-00030-F, DEA also assigned it to "the complex track" without explanation, and it was not until January 2, 2025 that DEA's PAL system indicated a status change to "In Process." DEA failed to make a determination within 20 days as required by 5 U.S.C. § 552(a)(6)(C)(i) regarding Case Nos. 24-01177-F and 25-00030-F.

On November 14, 2024, Hemp for Victory submitted a FOIA request seeking the same information as Case Nos. 24-01177-F and 25-00030-F. That request is attached as Exhibit 6. DEA assigned Hemp for Victory's request Case No. 25-00168-F, combined it with Case No. 24-011777-F, and administratively closed the request because both requests were deemed similar. That determination is attached as Exhibit 7. Although Wyld and Hemp for Victory are separate parties and filed separate requests, DEA took it upon itself to consolidate (and then close) the requests.

On October 29, 2024, Mr. Matthew Zorn submitted a FOIA request with a search query intended to capture emails related to the ex parte communications. That request is attached as Exhibit 8. After DEA did not timely issue a timely determination in response to Zorn's FOIA request or to an accompanying request to expedite, he sued in the United States District Court for the District of Columbia. Once in litigation, DEA promptly ran the search and informed him that the search returned hundreds of thousands of emails due, in part, to the fact that Zorn's request had not limited custodians to be searched but needed to be run agency-wide. That response is attached as Exhibit 9. Zorn then attempted to narrow his request accordingly by restricting his search to only those custodians engaged in the ex parte communications, but DEA refused to honor Zorn's narrowing in litigation and urged him to dismiss the case instead. Zorn then filed narrower requests separately (Case Nos. 25-00279 and 25-00280-F) and filed a request substantively identical to the HFV and Wyld requests (Case No. 25-00289-F). Those requests are attached as Exhibit 10. Now, DEA claims it cannot identify the DEA employees engaged in the ex parte communications because "DEA's counsel of record in the marijuana rescheduling proceedings has made no disclosure under 5 U.S.C. § 557(d) of ex parte contacts that have occurred pursuant to those proceedings" and because "DEA's FOIA Office is not in a position to be independently aware of any ex parte contacts that may have occurred." *See* Davis Decl. ¶¶ 13–16, attached as Exhibit 11. Zorn amended his complaint on January 2 to assert new causes of action against the agency and its employees, and his legal action remains pending. His Amended Complaint is attached as Exhibit 12.

Notably, *DOJ* expedited Zorn's request for the FOIA processing notes (Case No. 25-00234) on grounds that the subject matter the request is "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence"—inherently meaning the underlying Wyld request (and everybody's FOIA requests) deserved expedition—which stands in stark contrast to its denying the Wyld's expedition request. DOJ's response expediting Zorn's request is attached as Exhibit 13.

dictate that an immediate special evidentiary hearing and/or discovery into "the nature, extent, source and effect of all ex parte communications" is "essential." *PATCO I*, 672 F.2d at 113.

Moreover, while significant new evidence of DEA ex parte communications has emerged, "important but unanswered questions" remain regarding the nature and potential impact of DEA's secret machinations. *PATCO I*, 672 F.2d at 112–13. This Tribunal flagged several of them in its Order denying the Original Ex Parte Motion:

- Whether DEA "staff members … may have made the purported communication [with Dr. Sabet], or those who may have been advising the Administrator at the time she was making decisions about whether there would be a rescheduling action, and who (if anyone) would sign the NPRM," Ex Parte Order 4;
- "[W]hether Dr. Sabet's (apparently reliable inside source) was a person involved in the Agency adjudication," *id.* at 4–5;
- Whether Dr. Sabet's DEA sources "were … aware [at the time the ex parte communications occurred] that decisions in this matter were imminent," including "not only whether the DEA Administrator intended to sign and support the goal of the NPRM, but also, who would be ultimately identified as a Designated Participant (or at least, what criteria would be used in reaching that determination)," *id.* at 5; and
- The "context as to the conversation surrounding Dr. Sabet's social media announcements regarding his 'two confidential sources inside [the] DEA,' or why those sources would be close enough to the Administrator to render their obvious violations of her confidence to be deemed reliable," *id.* at 6 (citing Original Ex Parte Mot. at 7).

These questions remain unanswered, and their importance has increased in light of the newly discovered evidence discussed here. Consider, for example, Deputy Assistant Administrator Strait's September 17, 2024 ex parte communication with TBI. That letter shows a senior DEA official sufficiently interested in securing TBI's participation in these proceedings such that he gave it a second chance to bolster its request to participate with specific information. He provided this special dispensation to TBI through an improper off-the-record letter.

This raises another unanswered question: Was Deputy Assistant Administrator Strait one of Dr. Sabet's sources? If so, the importance of investigating and uncovering every detail about DEA's ex parte communications is even greater because there would be a direct connection between DEA's apparent opposition to the schedule III proposal in its communications with Dr. Sabet and its secret process for selecting DPs for the hearing process. Likewise, if Deputy Assistant

Administrator Strait was one of Dr. Sabet's sources, then there is strong reason to believe that both sides of the secret conversation were fully "aware [at the time the ex parte communications occurred] that decisions in this matter were imminent," including "not only whether the DEA Administrator intended to sign and support the goal of the NPRM, but also, who would be ultimately identified as a Designated Participant (or at least, what criteria would be used in reaching that determination)." Ex Parte Order 5.[31]

Put simply, new evidence strongly suggests that DEA is using its authority in these proceedings not to carry the burden of proof to justify finalizing the schedule III proposal but instead to subvert the process and thwart a proposal that it has vehemently opposed all along. As long as the Administrator, Deputy Assistant Administrator Strait, Dr. Sabet, and whoever else may be involved are permitted to keep their coordination and communication secret, no one—not Movants, the public, this Tribunal, or any future federal court on judicial review—will be able to say for sure. The *only* way to know is to investigate. Unless and until that process is "unquestionably" complete, there will be no way to ensure the fairness and transparency of this process, to preserve any meaningful opportunity for judicial review based on the whole record, or to salvage the public legitimacy of these proceedings.[32]

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[31] If Deputy Assistant Administrator Strait was *not* one of Dr. Sabet's confidential sources, a different but equally troubling reality emerges: That in addition to the Administrator's receipt of and responses to the requests, DEA's pattern of wrongdoing involves at least *three* other DEA employees, including one very senior official.

[32] *See, e.g.*, *PATCO II*, 685 F.2d at 654 n.32 ("We have also considered the effect of ex parte communications on the availability of meaningful judicial review. Where facts and arguments 'vital to the agency decision' are only communicated to the agency off the record, the court may at worst be kept in the dark about the agency's actual reasons for its decision. *United States Lines v. FMC*, 584 F.2d 519, 541 (D.C. Cir. 1978). At best, the basis for the agency's action may be disclosed for the first time on review. If the off-the-record communications regard critical facts, the court will be particularly ill-equipped to resolve in the first instance any controversy between the parties. *See id.* at 542. Thus, effective judicial review may be hampered if ex parte communications prevent adversarial decision of factual issues by the agency. *Cf.* 5 U.S.C. § 554(d)(1) (1976) (employee presiding at the reception of evidence may not consult a person or party on a fact in issue without notice and opportunity for all parties to participate)."); *Gulf Oil*, 663 F.2d at 303 ("In such cases courts have found judicious judicial intercession essential to ensure that the parties will eventually have an adequate remedy at law when the agency action is finally complete and ready for fullscale judicial review."); *id.* at 307 (noting that without immediate intervention to ensure development of the record with regard to potential ex parte communications, adequate judicial review will be thwarted as "years hence it will be impossible to reconstruct the proceeding to support their allegations of basic structural defects and infirmities").

D. This Tribunal has the duty and authority to grant the relief requested.

This Tribunal has repeatedly disclaimed authority to grant Movants' relief with respect to these troubling issues. *See, e.g.*, Ex Parte Order 2; *DEA To Hold Hearing On Rescheduling of Marijuana*, at 1:07:20, YOUTUBE (Dec. 2, 2024), https://www.youtube.com/watch?v=GBMHWru0FNo. Yet, the *PATCO* cases and *Gulf Oil* recognize that ALJs are both qualified and empowered to grant precisely the remedies Movants seek.

So too have other courts. In *North Carolina Environmental Policy Institute v. EPA*, for example, a single circuit judge concluded under Federal Rule of Appellate Procedure 18 that

> An ALJ conducting an on-the-record hearing, therefore, can and is obliged to explore the possibility of and protect against taint of the proceeding by ex parte communications when such a possibility is plausibly suggested by a party with standing to do so. Specifically, if warranted, an ALJ may, as has Judge Nissen here, require disclosure of all proscribed ex parte communications on the record before rendering final decision. *[United States Lines, Inc. v. Federal Maritime Comm'n*, 584 F.2d 519, 535 (D.C.Cir. 1978).] To ensure that any communications disclosed receive proper consideration, he or she may and should give parties an adequate opportunity to review them, comment upon them, and if appropriate order any further disclosures that may appear warranted. Finally, if warranted, an ALJ may order and conduct "an evidentiary hearing to determine the nature, extent, source and effect of any and all ex parte communications… ." *Professional Air Traffic Controllers Org. v. FLRA*, 672 F.2d 109, 113 (D.C. Cir. 1982).

881 F.2d 1250, 1258 (4th Cir. 1989).

Otherwise, any final rule issued would be *voidable* as the product of proceedings tainted by ex parte communications. *See, e.g., PATCO II*, 685 F.2d at 565; *Home Box Office, Inc.*, 567 F.2d at 54 (holding that "[e]ven the possibility that there is here one administrative record for the public and for this court and another for the [agency] and those 'in the know' is intolerable," and that "where, as here, an agency justifies its actions by reference only to information in the public file while failing to disclose the substance of other relevant information … a reviewing court cannot presume that the agency has acted properly.") Accordingly, this Tribunal has both the authority and the duty to grant the relief requested.

II. DEA's untimely and improper January 2 Exhibit should be excluded from the record.

This Tribunal should also exclude DEA's untimely and improper January 2 Exhibit from the record. It is hearsay and violates the CSA and APA by thwarting HHS's review and circumventing the notice-and-comment process.

A. DEA's filing is unreliable hearsay and should not be admitted into the record.

The January 2 Exhibit is rank hearsay, not currently part of the record, and therefore not properly submitted as an exhibit. The papers it cites *might* be admissible as exhibits, but DEA has not produced them to the Tribunal or the DPs. For that reason alone, the January 2 Exhibit should be excluded. It is simply too late in the game for DEA to be generating and producing new, undeclared exhibits.

Furthermore, hearsay is admissible in ALJ hearings only if it is reliable and trustworthy. Under the APA, "[a]ny oral or documentary evidence may be received" in a formal rulemaking hearing, "but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556(d); *see also Richardson v. Perales*, 402 U.S. 389, 409–10 (1971) (discussing § 556(d) and concluding that "[h]earsay … is thus admissible up to the point of relevancy"). Similarly, DEA regulations require this Tribunal to "admit only evidence that is competent, relevant, material and not unduly repetitious." 21 C.F.R. § 1316.59(a).

The document DEA has offered into evidence is undated and lacks any indication of authorship, making it impossible for this Tribunal to confirm its reliability or trustworthiness. Therefore, it should be excluded from the record. *See, e.g.*, NPRM, 89 Fed. Reg. at 44598 (empowering ALJ to "receive, rule on, exclude, or limit evidence"); 5 U.S.C. § 556(c)(5) (empowering ALJ to "regulate the course of the hearing").

B. DEA's ex post facto analysis violates the APA.

Under 21 U.S.C. § 811(b), "before initiating" formal rulemaking proceedings to reschedule a drug and "after gathering the necessary data," DEA must request from HHS a scientific and medical evaluation and scheduling recommendation. Despite § 811(b)'s command that DEA

gather necessary data before initiating rulemaking proceedings and before obtaining HHS's "evaluation," the Proposed Rule revealed that DEA had not done so. Instead, DEA waited until the Attorney General promulgated the Proposed Rule in the Federal Register 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. *See, e.g.*, NPRM, 89 Fed. Reg. at 44602 (noting that DEA anticipated receiving "additional data on seizures of marijuana by law enforcement, cannabis-related ED visits, as well as updated epidemiological survey data since 2022"); *id.* (noting that DEA anticipated receiving "additional data on diversion from State programs and DEA-registered manufacturers").

DEA has now come through on its promise to add this "evidence" later by submitting it less than three weeks before trial. 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 on DEA's submission and its implications for the scheduling analysis will therefore never be part of the rulemaking record.

Congress required the most formal and transparent process available under law for the promulgation of rules regarding the scheduling of drugs under the CSA. 21 U.S.C. § 811(a). It reserves those procedures for especially important agency rulemakings that, because of their political salience, technical complexity, and importance to the proper functioning of the statutory scheme, require enhanced safeguards. Such safeguards include an exclusive record and an adversarial hearing complete with an independent hearing officer, pre-trial conferences, burdens of proof and persuasion, proposed findings, and cross-examination. Running that procedural gauntlet requires an extraordinary investment of public and private resources, and it takes a very long time. In Congress's view, however, that investment is worth it because rules forged in the furnace of §§ 556 and 557's formal process are supposed to produce better policy—policy that benefits from the enhanced public legitimacy that only a transparent, adversarial process can provide.

DEA's secret machinations throughout this formal rulemaking, however, have subverted those procedures, stripping them of any semblance of transparency, rendering the promise of a decision based on a closed record virtually meaningless, and undermining their critical adversarial character. DEA has done all this because it knows full well that adhering to the APA's procedural requirements would mean not getting its way. The evidence of DEA's unlawful interference with this historic process is compelling, unprecedented, and anathema to the critical limits on agency power that Congress has deemed essential to preserving due process in administrative decision-making.

Finally, in every scheduling action in the past, DEA has completed and published its 8-factor analysis *with* the notice of proposed rulemaking. *See, e.g.*, *Denial of Petition To Initiate Proceedings To Reschedule Marijuana*, 81 Fed. Reg. 53688 (Aug. 12, 2016) (including July 2016 DEA 8-factor Analysis); *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II,* 79 Fed. Reg. 11037 (Feb. 27, 2024) (same). DEA's departure from that consistent practice is both unexplained and unexplainable.

This Tribunal should exclude the January 2 Exhibit from the record. *See, e.g.*, NPRM, 89 Fed. Reg. at 44598 (empowering ALJ to "receive, rule on, exclude, or limit evidence"); 5 U.S.C. § 556(c)(5) (empowering ALJ to "regulate the course of the hearing").

III. DEA's improper occupation of the proponent's role despite its steadfast opposition to the Proposed Rule has caused significant prejudice to Movants' procedural rights.

A. Newly-discovered evidence confirms that DEA's hostility toward the Proposed Rule continues unabated.

In their Original Ex Parte Motion, Movants provided evidence of DEA's longstanding opposition to the Proposed Rule. Original Ex Parte Mot. 2–13, 16–22. And as detailed above, that evidence has continued to accumulate. The evidence is now overwhelming that DEA is not participating in this administrative process with an open mind and must be disqualified from these proceedings.

First, despite its occupation of the role of proponent of the Proposed Rule in these proceedings, newly-discovered evidence reveals that DEA is working to support anti-rescheduling DPs and amplify their talking key talking points outside these proceedings. In the January 2 Exhibit and in recent publications, for example, DEA continues to insist that marijuana has no medical utility and a high potential for abuse.[33] These are positions that:

- HHS expressly rejected based on medical and scientific findings to which DEA continues to owe "significant deference";[34]
- DOJ has preliminarily rejected in the Proposed Rule, *see* NPRM, 89 Fed. Reg. at 44616, 44619; and
- Mirror those that have animated DEA's hostility to the proposed transfer of marijuana to schedule III from the start, *see, e.g.*, OLC Op. at 19 (noting that DEA's "main concern" with HHS's currently-accepted medical use analysis was "that it place[d] too much emphasis on state regulatory decisions").

They also bear an unmistakable resemblance to the positions the anti-rescheduling DPs have taken and intend to pursue in these proceedings. *Compare, e.g.*, Prehearing Statement of Smart Approaches to Marijuana (Nov. 26, 2024) at 2–4 (summarizing proposed testimony regarding marijuana's abuse potential) *with* January 2 Exhibit at 13–35, 40–66 (summarizing evidence making many of the same points). Indeed, in those same recent publications, DEA consistently lists anti-rescheduling DP CADCA—an organization that DEA is openly partnering

[33] *See, e.g.*, Gov. Ex. 4, Decl. of Luli Akinfiresoye (undated) at 36–39 (applying DEA's five-part test to assess whether marijuana has a currently accepted medical use even though OLC authoritatively rejected the application of that standard as "impermissibly narrow"); *id.* at 13–17 (analyzing marijuana's abuse potential); *Preventing Cannabis Use Among Youth and Young Adults*, *supra* n. 22, at 5.

[34] *See* NPRM, 89 Fed. Reg. at 44616 ("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 44619 ("The Attorney General has considered HHS's recommendations and conclusions and accords HHS's scientific and medical determinations binding weight until the initiation of the formal rulemaking process. *See* OLC Op. at *24."); *id.* ("Applying HHS's two-part test, and in light of OLC's legal opinion that the HHS's test is sufficient under the CSA, the Attorney General concurs with HHS's conclusion, for purposes of the initiation of these rulemaking proceedings, that there is a CAMU for marijuana."); *id.* at 44599 ("After the issuance of a notice of rulemaking proceedings, HHS's scientific and medical determinations are accorded 'significant deference' through the rest of the rulemaking process. OLC Op. at *26.").

with on fentanyl-related policy issues[35]—as a reference and source of information for members of public interested in more information about marijuana.[36, 37]

Second, newly-discovered evidence reveals that DEA used its secret DP-selection process to control participation in this hearing process to favor anti-rescheduling DPs. The Achbach Declaration reveals that the Administrator's off-the-record process to develop the DP list included involved improper ex parte communications with 163 entities comprising 123 requests for a hearing and/or to participate. *See* Achbach Decl. at ¶ 3; DEA Opposition Brief at 2, 3, 9, 11, 15, 17, 18. To this day, DEA has managed to keep critical information about that process secret, including the identities of the vast majority of the requestors, the evidence they intended to offer in the hearing process, and the Administrator's reasons for selecting some participants and excluding others.

Recently, however, Movants discovered evidence that another senior DEA official was part of the Administrator's secret process and engaged in improper off-the-record communications with anti-rescheduling DP, TBI, by providing special assistance to TBI in its bid to defeat the Proposed

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[35] *See DEA and CADCA Partner on 2024 National Family Summit on Fentanyl*, CADCA (Dec. 12, 2024) https://www.cadca.org/programs-in-action/dea-and-cadca-partner-on-2024-national-family-summit-on-fentanyl/#:~:text=CADCA's%20involvement%20in%20the%20Summit,drug%20epidemic%20through%20prevention%20strategies.

[36] *See Drugs of Abuse*, *supra* n. 23, at 114; *Preventing Cannabis Use Among Youth and Young Adults*, *supra* n. 22, at 7.

[37] These developments combined with DEA's continued occupation of the proponent's role cast doubt on DEA's and CADCA's recent representations to this Tribunal that they had no known conflicts of interest. *See* DEA Notice of Appearance (Nov. 12, 2024); CADCA Notice of Appearance, at 6 (Nov. 12, 2024).

The CADCA-DEA partnership raises another red flag as well. CADCA receives federal funding to "prevent[] substance use and misuse before it starts." *See* CADCA, https://www.cadca.org/about-us/ (last visited Jan. 5, 2025); *see also, e.g.*, Notice of Intent to Award, 89 Fed. Reg. 20672 (Mar. 25, 2024) ("This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award up to $675,000 per year for up to five (5) years to the Community-Based, Advocacy-Focused, Data-Driven, Coalition-Building Association (CADCA)."). As part of its mission, "CADCA supports adequate funding for all federal agencies and programs that promote substance misuse prevention, treatment, recovery support and research." *See Prevention Works*, CADCA, https://www.cadca.org/prevention-works/ (last visited Jan. 5, 2025). CADCA's lobbying efforts in that regard have reportedly helped DEA in the past. By way of example, *The Nation* reported in 2014 that CADCA's lobbying efforts secured DEA's authority—and, presumably, federal funding—to "target[] medical marijuana operations that are legal under state law." *See* Lee Fang, *The Real Reason Pot is Still Illegal*, THE NATION (Jul. 2, 2014), https://www.thenation.com/article/archive/anti-pot-lobbys-big-bankroll/. The fact that DEA has benefited (and stands to continue benefiting) from CADCA's lobbying efforts, which are decidedly opposed to the schedule III proposal, raises additional conflicts concerns.

Rule in this hearing process.[38] This new evidence reveals a direct connection between the Administrator's broader effort to keep the DP-selection process and related communications secret and the Agency's longstanding opposition to the schedule III Proposed Rule. It also shows that DEA's secret machinations are not the work of some rogue, low-level DEA employee but instead involve the Administrator herself and at least one other Headquarters-level official, Deputy Assistant Administrator Strait. And because it was a November 12, 2024 TBI filing in these proceedings that disclosed the fact that TBI's selection as a DP resulted from off-the-record assistance from Deputy Assistant Administrator Strait, there is every reason to believe that DEA's counsel in these proceedings have been aware of this pattern of DEA wrongdoing for some time.

While DEA has kept most details secret, this much is clear:

1. DEA has opposed transferring marijuana to schedule III throughout the administrative process and still does today;

2. DEA's control over the selection of DPs included off-the-record communications that directly benefited anti-rescheduling DPs; and

3. This was done by high-level DEA officials.

In sum, despite Movants' inability to obtain records from DEA through FOIA or further investigation into the matter from this Tribunal, there is compelling evidence that DEA's leadership manipulated the DP-selection process to assist the anti-rescheduling side. As already explained, that evidence is more than sufficient to require this Tribunal to hold an evidentiary hearing and/or order discovery to be certain that the full scope of DEA's wrongdoing is uncovered and made part of the record. *See supra* Part I. That the same evidence should likewise extinguish any lingering question this Tribunal or the public might have had about DEA's continued opposition to the Proposed Rule.

[38] *See* TBI Notice of Appearance and Statement of Interest 8 (September 30, 2024 Letter from TBI to Deputy Assistant Administrator Strait) ("I was surprised to see your September 17, 2024, letter … asking [TBI] to demonstrate that it is an 'interested person' and asking TBI to identify relevant information that it intends to present at the hearing.").

B. Newly-discovered evidence confirms that DEA's hostility toward the Proposed Rule has prejudiced—and will continue to prejudice—the pro-rescheduling DPs.

1. DEA has stacked the deck against the Proposed Rule by extending off-the-record assistance to anti-rescheduling DPs that was never offered to seemingly qualified pro-rescheduling DPs.

As already discussed, Deputy Assistant Administrator Strait's off-the-record communications with TBI helped that anti-rescheduling party in its bid to obtain DP status in these proceedings for the express purpose of thwarting the Proposed Rule. *See supra* Part I.A, C. Neither Movants nor any of the other pro-rescheduling parties they have communicated with received any similar dispensation from DEA. If DEA intended to be even-handed in its efforts to assist certain parties that offered particularly important points of view and/or expertise in their efforts to participate in these proceedings, it is difficult to understand how that could be possible.

Consider, for example, the Administrator's selection of the Nebraska to present evidence against the Proposed Rule while excluding Colorado, which would have presented "important insights and subject matter expertise" from its longstanding medical marijuana program and legal marijuana industry. *See* Original Ex Parte Mot. Ex. A (Sept. 30, 2024 letter from Gov. Polis to DEA requesting that Colorado be permitted to participate in these proceedings and detailing Colorado's interested-person status). According to DEA, Colorado "did not sufficiently establish that [the state] [is] an 'interested person' under DEA regulations and/or … did not sufficiently state with particularity the relevant evidence on a material issue of fact that [it] intended to present during the hearing."[39]

Yet those are precisely the same deficiencies that Deputy Assistant Administrator Strait invited TBI to address in a supplemental request. *See* TBI Notice of Appearance and Statement of Interest, Ex. 2 (September 30, 2024 Letter from TBI to Deputy Assistant Administrator Strait) ("I was surprised to see your September 17, 2024, letter … asking [TBI] to demonstrate that it is an 'interested person' and asking TBI to identify relevant information that it intends to present at the hearing."). The obvious question is why did DEA not give Colorado the same process? DEA's

[39] *See* Exhibit 2 (DEA's decisions rejecting Colorado's bid to participate in these proceedings).

disparate treatment of TBI and Colorado in this regard is all the more mysterious given the obvious probative value of the evidence Colorado sought to advance in the hearing. As Colorado's request explained, the Proposed Rule specifically referenced Colorado data on marijuana-related traffic deaths (*see* NPRM, 89 Fed. Reg. at 44614), data that Colorado sought to show "lack[ed] important context that must be considered in this rulemaking" (*see* Original Ex Parte Mot. Ex. A (Sept. 30, 2024 letter from Gov. Polis to DEA requesting that Colorado be permitted to participate in these proceedings and detailing Colorado's interested-person status)).

Because DEA did all this in secret and consistently refuses to address these discrepancies, Movants, this Tribunal, and the public have no choice but to scour the record for clues. In the case of Colorado's exclusion, the record does reveal one potential explanation for DEA's inclusion of TBI and Nebraska on the one hand, and exclusion of Colorado on the other. According to the OLC Opinion, DEA's "main concern" with HHS's currently accepted medical use analysis was "that it place[d] too much emphasis on state regulatory decisions." OLC Op. at 19. According to DEA, "HHS's emphasis on states [wa]s 'misplaced' because … the processes states follow for enacting legislation 'are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA.'" *Id.* (quoting DEA Response at 11). It therefore appears that DEA's longstanding hostility toward pro-rescheduling states explains its decision to select Nebraska and TBI but not Colorado. In other words, DEA *does* think state data is relevant, but only when that data supports the anti-rescheduling position.

This evidence of DEA bias against the "regulatory decisions" of pro-rescheduling states is particularly alarming because it rests on a DEA view that OLC considered and rejected. As OLC explained, accepting DEA's argument would "be inconsistent with both the role of states as the central regulators of medical practice … and the fact that they are afforded great leeway in adopting measures to protect the public health and safety." *Id.* (internal quotation marks omitted); *see also id.* at 13 (emphasizing that "an understanding of what the medical community accepts … naturally require[s] consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners") (citing *Gonzales v. Oregon*, 546 U.S. 243,

270 (2006) (emphasizing that the CSA "presume[s] and rel[ies] upon a functioning medical profession regulated under the States' police powers")). This would certainly explain DEA's extraordinary efforts to keep its decision-making process secret.

Nor is Colorado the only example of a seemingly qualified pro-rescheduling party that DEA excluded without the benefit of the kind of special assistance that TBI received in secret. Despite DEA's refusal to disclose the records underlying the development of the DP list, Movants are aware that DEA rejected several highly-qualified, pro-rescheduling applicants based on identical claims of deficient demonstrations of interested-person status and/or failure to identify relevant information to offer at the hearing. Such seemingly qualified pro-rescheduling parties include doctors, DEA-registered marijuana growers and scientific researchers, leading reform organizations, and a marijuana trade association with unparalleled experience and expertise in the on-the-ground realities of marijuana regulation.[40] Each of these pro-rescheduling parties offered scientific, medical, and/or regulatory expertise of central relevance to the key questions in issue in the hearing process. Yet DEA rejected each of their requests, citing the same deficiencies that Deputy Assistant Administrator Strait flagged in TBI's initial request. Unlike TBI, however, DEA did not invite *any* of these pro-rescheduling parties to amend their requests to shore up those supposed weaknesses.

2. By placing itself in the role of proponent of the Proposed Rule despite its obvious opposition to the schedule III proposal, DEA has undermined the pro-rescheduling DPs' significant procedural rights.

In light of the mounting evidence of DEA opposition to the Proposed Rule, the impropriety of its continued occupation of the role of proponent of the Proposed Rule in these proceedings is clearer than ever. The APA and DEA regulations require the "proponent of a rule" to bear the burden of proof. 5 U.S.C. § 556(d); 21 C.F.R. § 1316.56. The Attorney General's Manual on the APA clarifies that this "means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of

[40] The requests to participate submitted by Doctors for Drug Policy Reform, Dr. Sue Sisley, MedPharm, NORML, and ATACH, and DEA's rejections of the same, are attached as Exhibits 14–18.

some different result, also for that purpose have a burden to maintain." Attorney General's Manual 75 n.3 (quoting legislative history). Here, because DEA opposes the Proposed Rule despite its occupation of the proponent's role, the pro-rescheduling DPs are "proponents of some different result" than the one DEA seeks. *Id.* As such, they also "for that purpose have a burden to maintain," carrying the burden of proof with respect to the Proposed Rule on their own and without the help of the Proposed Rule's supposed proponent. *Id.*

This arrangement prejudices the pro-rescheduling DPs' procedural rights by saddling them with the entire burden of proof without the benefits normally afforded to the proponent of the rule to ensure they have a fair opportunity to carry that burden. As this Tribunal has explained, because the proponent of the Proposed Rule must bear the burden of proof, that party is permitted to "present the testimony of … more than one witness" at the hearing. Preliminary Order 4 n.3; *see also, e.g.*, Prehearing Ruling 4 (Dec. 4, 2024) (explaining limitations on presentation of evidence that will govern during the hearing and noting that "some additional latitude [will be] afforded to the Government as the burdened party"); Order Regarding Standing, Scope, and Prehearing Procedures 4 (Nov. 19, 2024) (hereinafter, "Order Regarding Standing") ("While the Government, as the burdened party, may present multiple witnesses, each of the remaining DPs (absent leave to the contrary granted by this tribunal) may present the testimony of a single witness."); *id.* ("The Government, as the burdened party, will present its evidence first.").

Here, though, because DEA opposes the Proposed Rule, it has made clear that it does not intend to make use of those advantages to support the Proposed Rule in any meaningful way. Instead, in its prehearing statement and December 13, 2024 supplemental filing, DEA revealed that it intends to:

1. Call just two witnesses (only one of whom will appear in person);
2. Call no medical doctors or scientists;
3. Offer no new evidence that could conceivably be expected to support schedule III; and
4. Offer several categories of evidence that SAM described as the key components of DEA's "roadmap for how to rebut the[] Proposed Rule." *Compare* Govt. Prehearing

Statement 4 (Nov. 26, 2024) (listing categories of evidence DEA intends to introduce) *with* Smart Approaches to Marijuana, *SAM Webinar: Rescheduling of Marijuana*, at 24:25, YOUTUBE (June 17, 2024), https://www.youtube.com/watch?v=3NWSz5LXRa4 (discussing those same categories of evidence and describing them as a DEA "roadmap for how to rebut the[] Proposed Rule").

No person could seriously describe this strategy as the work of an agency supportive of the Proposed Rule. It is instead the strategy of an agency that seeks to hold the proponent role in name only and without any inclination, much less a plan, to carry the burden of proof to justify a final rule transferring marijuana to schedule III. By holding the proponent role hostage with no intention of putting on a pro-rescheduling case, DEA has deprived the pro-rescheduling DPs of the procedural benefits of the proponent role that this Tribunal has acknowledged are essential to ensure the pro-rescheduling side has a meaningful opportunity to satisfy the burden of proof.

DEA's occupation of the proponent's role also now threatens the rescheduling DPs' right to cross-examine the Proposed Rule's biggest opponent. At the prehearing conference, when counsel for Village Farms requested the right to cross-examine DEA, arguing that despite its proponent status, DEA is and always has been the primary antagonist of the proposed transfer of marijuana to schedule III, this Tribunal denied his request, concluding that because DEA is the proponent, pro-rescheduling DPs may not cross-examine DEA's witnesses even if they put on evidence plainly antagonistic to the pro-rescheduling position.[41] For the reasons explained below, Movants respectfully request that this Tribunal reconsider that ruling.

Section 556(d) of the APA provides that "[a] party is entitled … to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d). In the words of the Senate Committee, "To the extent that cross-examination is necessary to bring out the truth, the party should have it." Sen. Doc. No. 248, 79th Cong., 2d Sess. 209 (1946). Emphasizing that "we are not to take so lightly th[at] command of Congress," the Second Circuit, in an opinion by Judge Friendly, held that an agency's refusal to permit a party to cross-examine an adverse government witness in a formal rulemaking proceeding is "egregious error" that

[41] Drug Enforcement Administration, *DEA To Hold Hearing On Rescheduling of Marijuana*, at 1:03:01, YOUTUBE (Dec. 2, 2024), https://www.youtube.com/watch?v=GBMHWru0FNo.

required a remand. *See Nat'l Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 798–99 (2d Cir. 1974).To permit DEA to use its proponent-in-name-only status to strip Movants of their statutory right to cross examine adverse witnesses would therefore be "egregious error." *See id.*

Finally, DEA's improper process for selecting the DPs in secret has already warped the record in these proceedings in critical ways. Section 556(e) of the APA dictates that "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title." 5 U.S.C. § 556(e). Undisclosed ex parte communications make it impossible to know whether a decision was in fact based on the "exclusive record" developed in the proceeding or instead the other, secret record developed by the agency but never disclosed.

This concern is heightened in cases like this one where so many of the improper contacts at issue are essential to understanding the basis for the hearing itself. Indeed, § 556(e) expressly includes "all papers *and requests* filed in the proceeding" in its definition of "the exclusive record for decision." *Id.* DEA's own regulations also flag records like the undisclosed requests and responses at issue here as essential components of the record. *See* 21 C.F.R. § 1316.59(f) ("The presiding officer shall file as exhibits copies of the following documents: … (5) Any other document necessary to show the basis for the hearing."). Movants have been deprived the ability to review this statutorily-required part of the administrative record.

DEA's refusal to disclose even the criteria it employed in selecting the DPs is especially problematic and has already made it impossible to assess the legitimacy of some of this Tribunal's critical rulings. Consider, for example, this Tribunal's November 19, 2024 Order Regarding Standing. There, this Tribunal set out a four-part test for assessing "the issue of whether the DPs have alleged sufficient APA standing to participate in this rescheduling hearing." Order Regarding Standing 8. The fourth factor considered "whether, in the discretion of the Agency, the participation of a particular requestor would meaningfully assist the decisionmaking and/or whether the interests of multiple requestors are amenable to consolidation or exclusion to accommodate orderly proceedings." *Id.* In applying that factor, this Tribunal explained that, as an

exercise of Agency discretion, DEA's selection of certain DPs was entitled to "a level of deference." *Id.* at 12. Of course, this Tribunal also recognized that discretion can be abused, meaning deference is appropriate only where "the discretion is exercised rationally." *Id.* (citations omitted); *see also id.* at 2 ("[E]ven when operating at the zenith of its powers, the agency is constrained to act within the parameters of the APA, the CSA, and any related regulations, and must refrain from actions which are arbitrary, capricious, and demonstrate an abuse of its Congressionally-authorized discretion.") (internal citations and quotation marks omitted).

On that basis, this Tribunal gave "significant deference" to the DEA's decisions to choose the 25 DPs that it did. *See, e.g.*, *id.* at 22 ("Furthermore, that the Administrator approved CADCA's status as a DP is entitled to significant deference."). Yet, because DEA conducted the DP-selection process in secret and has not disclosed the underlying communications as § 557(d)(1) requires, it is impossible to assess how or why the Administrator chose some parties over others.

Indeed, this Tribunal itself has repeatedly flagged this problem, including in the Order Regarding Standing itself. *See id.* at 13 ("[T]his tribunal has not been furnished with copies of the responses filed by the DPs with the Administrator."); Preliminary Order 2 ("Thus, this tribunal is not in possession of 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.") (internal citations omitted); *id.* at 2 n.4 ("Indeed, the Agency has furnished this tribunal with no correspondence from itself or the Designated Participants that was generated in response to the [General Notice of Hearing]."); Ex Parte Order 1 n.1 ("It appears that the DPs were notified of their selection via some manner of email communication. This forum has not been supplied with any such communications or any documentation from the pool of those selected and unselected, and is unaware of the criteria employed.").

In short, DEA's secret machinations have deprived this Tribunal, the parties, and the public of the records necessary to assess whether the Administrator's decisions selecting and excluding various DPs were arbitrary and capricious. And as Movants have explained, the few details that have emerged raise grave concerns that indeed they were. *See supra* Part III.A.

Left uncorrected, these issues will render the APA's "requirement that the agency decision be supported by 'the record' … almost meaningless" in this administrative process. *Portland Audubon Society*, 984 F.2d at 1548 (citing *Home Box Office, Inc.*, 567 F.2d at 54). *See also* 5 U.S.C. § 556(e) ("A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence."). This, in turn, will further prejudice Movants by dashing their ability to obtain meaningful judicial review.[42] Accordingly, immediate action from this Tribunal is essential to avoid irreparable harm and substantial prejudice to the significant procedural rights of the parties and the public.

C. This Tribunal should disqualify DEA from further participation in these proceedings or, in the alternative, order DEA to proceed as an anti-rescheduling party and not as proponent of the Proposed Rule.

1. Because there is clear and convincing evidence that DEA has an unalterably closed mind, this Tribunal should disqualify it from further participation in these proceedings.

Agencies that have predetermined issues necessarily fail to exercise the reasoned decision-making 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*, 627 F.2d at 1170, 1174. Where "clear and convincing" evidence supports such a finding, the agency decisionmaker must be excluded from the administrative process. *See, e.g.*, *Alaska Factory*, 831 F.2d at 1467 (citing *Ass'n of Nat'l Advertisers*, 627 F.2d at 1170).

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. It has engaged in widespread ex parte communications with anti-rescheduling parties to stack the deck

[42] *See, e.g.*, *PATCO II*, 685 F.2d at 654 n.32; *Gulf Oil*, 663 F.2d at 303, 307.

against the Proposed Rule in these proceedings. And despite insisting to this Tribunal that it is the proponent of the Proposed Rule, DEA has now revealed its intent to offer a barrage of evidence into the hearing obviously intended to undermine the schedule III proposal.

DEA has thwarted legal process, 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 it promulgated.

This Tribunal disclaimed any authority to disqualify DEA in the Ex Parte Order. Ex Parte Order 2. The NPRM confirms that this Tribunal has "all powers necessary to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order." NPRM, 89 Fed. Reg. at 44598 (citations omitted). Under the unprecedented circumstances presented here, there is simply no way this Tribunal could possibly do any of those things as long as DEA is permitted to continue participating.

Nevertheless, in light of this Tribunal's prior ruling disclaiming authority to grant the relief requested, Movants have concluded that they have no choice but to pursue the disqualification question through the affidavit process contemplated by § 556(b) of the APA. *See* 5 U.S.C. § 556(b) ("On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case."). To that end, Village Farms has attached as Exhibit 1 a good-faith affidavit of Dr. John Harloe in support of this motion and alleging facts of "other [basis for] disqualification" of DEA from further participation in these proceedings. *Id.* Once this motion is filed, Movants will send a copy of this motion, the Original Ex Parte Motion, the Ex Parte Order, and Dr. Harloe's supporting affidavit to DEA and DOJ for a "determin[ation]" of disqualification under § 556(b).

Movants respectfully request that this Tribunal continue the merits hearing currently scheduled to begin on January 21, 2025, pending DEA's and DOJ's "determin[ation of that] matter [presented by Dr. Harloe's affidavit]." 5 U.S.C. § 556(b).

2. At the very least, this Tribunal should order DEA to declare its opposition to the Proposed Rule on the record and then align DEA's party status in these proceedings with that of the DPs that share its view.

In the meantime, this Tribunal should direct DEA to disclose on the record whether it supports or opposes the proposed transfer of marijuana to schedule III and order it to proceed as a party alongside the other DPs that share its view. This Tribunal recently emphasized that DEA "is a party in this matter" and thus "will be afforded the same rights and obligations as the other parties." Order Regarding the Government's Subpoena Requests and Matters Raised in Its Supplemental Prehearing Statement 2 (Dec. 17, 2024). Every other party had to declare whether it supports or opposes the proposed transfer of marijuana from schedule I to schedule III. Preliminary Order 3 (Oct. 31, 2024). There is no reason DEA cannot do so as well.

Indeed, DEA is the last party that should be excused from that requirement. After all, formal rulemaking is designed to hold agencies accountable to the people. *See, e.g.*, *Go v. Holder*, 744 F.3d 604, 612 (9th Cir. 2014) ("[A]gencies are held accountable to the public through the formal rulemaking process[.]") (cleaned up). Thus, while this Tribunal may lack authority to direct DEA to take a particular position in these proceedings, basic fairness, transparency, and preservation of the critical adversarial character of these proceedings require proper party alignment.

Accordingly, in the event that neither DEA nor DOJ agree with Movants that DEA's prejudgment of the issues bar it from further participation in these proceedings, this Tribunal should direct DEA to proceed as an anti-rescheduling party alongside the DPs that share its view. DEA is free to oppose the schedule III proposal. If it chooses to participate in this proceeding, however, the APA's requirements of adversarialness, an exclusive record, and transparency dictate that that it must do so out in the open and on the record. It may not claim the mantle of proponent of the Proposed Rule only to work in secret with the anti-rescheduling DPs to thwart the schedule III proposal. The public and the parties have a right to know what DEA's views are on controversial matters of significant public importance—particularly when they are the subject of a high-profile and historic formal rulemaking process.

CONCLUSION

For the reasons stated in the Original Ex Parte Motion as well as those discussed further above, Movants respectfully request that this Tribunal:

1. Order DEA and all DPs to immediately disclose any ex parte communications relevant to the merits of these proceedings so that they may be made part of the administrative record;

2. Grant a brief continuance of the merits hearing currently scheduled to begin on January 21, 2025, to permit the parties and this Tribunal to investigate the nature, extent, source, and effect of any and all ex parte communications relevant to the merits of these proceedings that may have been made to or by any DEA employee and to take any additional remedial action that may be appropriate or required;

3. Schedule and hold an evidentiary hearing to determine the nature, extent, source, and effect of any and all ex parte contacts relevant to the merits of these proceedings that may have been made to or by any DEA employee;

4. To the extent necessary to fully uncover the nature, extent, source, and effect of DEA's ex parte communications, or in the event that this Tribunal does not grant the requested evidentiary hearing, permit Movants to conduct limited and targeted discovery, including a deposition of SAM and CADCA regarding any ex parte communications with DEA;

5. Make all written ex parte communications, memoranda documenting all oral ex parte communications, and this Tribunal's findings regarding the nature, extent, source, and effect of any and all ex parte communications part of the record of these proceedings;

6. Direct DEA, as it did all DPs, to declare whether it supports or opposes the proposed transfer of marijuana from schedule I to schedule III of the CSA, and make DEA's position a matter of record in these proceedings; and

7. In the event that this Tribunal denies the relief Movants have requested in 1–6 above, permit Movants to pursue an immediate interlocutory appeal of that decision to the Administrator consistent with 21 C.F.R. § 1316.62.

This requested relief is substantively identical to that ordered in *PATCO I* based on less compelling evidence than was present in this case. *See* 672 F.2d at 113; *see also Gulf Oil*, 663 F.2d at 313.

Movants additionally request that this Tribunal:

8. Exclude DEA's January 2 Exhibit from the record;

9. Remove DEA from the role of proponent of the Proposed Rule under 5 U.S.C. § 556(d);

10. Disqualify DEA under 5 U.S.C. § 556(b); and

11. Stay these proceedings until DEA and DOJ address Dr. Harloe's affidavit and the related request that DEA be disqualified from further participation in these proceedings in light of its unlawful interference with the administrative process and unalterably closed mind regarding the proposed transfer of marijuana to schedule III.

Dated: January 6, 2025

By: */s/ Shane Pennington*

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CERTIFICATE OF SERVICE

This is to certify that on January 6, 2025, the undersigned caused a copy of the foregoing to be delivered to the following recipients:

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