UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of **Schedules of controlled substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 26-96** CHIEF ADMINISTRATIVE LAW JUDGE DEREK C. JULIUS

GOVERNMENT'S RESPONSE TO NATIONAL DRUG & ALCOHOL SCREENING, DUID VICTIM VOICES, AND KENNETH FINN, M.D.'S MOTION SEEKING ADDITIONAL DISCOVERY, SUPPLEMENTAL BRIEFING, AND TO REOPEN THE PROCEEDINGS

The United States Department of Justice (DOJ), Drug Enforcement Administration (Government or DEA), by and through the undersigned attorneys, hereby responds to National Drug & Alcohol Screening (NDASA), DUID Victim Voices, and Kenneth Finn, M.D.'s (collectively, the Movants) Joint Motion Seeking Additional Discovery, Supplemental Briefing, and to Reopen the Proceedings. DEA respectfully opposes the Movants' Motion.

Neither the Administrative Procedure Act (APA) nor the Controlled Substances Act (CSA) provide for record supplementation and general discovery in rulemaking proceedings. Rather, under established law, the parties are entitled only to the disclosure of the documents and summary of the testimony upon which a party intends to rely. The only two exceptions to this blanket proposition are where a party makes a strong showing that: (1) the agency acted in "bad faith;" or (2) the record is so limited that it will frustrate effective judicial review. None of the moving parties have made the requisite showing here. The Movants' Motion should be denied.

BACKGROUND

On May 21, 2024, DOJ, through the DEA, issued a notice of proposed rulemaking (NPRM) in the *Federal Register* proposing to transfer marijuana and any drug containing a substance within the CSA's definition of marijuana from Schedule I to Schedule III. On August 29, 2024, DEA scheduled a hearing pursuant to the NPRM and published such notice in the *Federal Register* on August 29, 2024. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148 (2024).

On April 28, 2026, DOJ withdrew the Notice of Hearing and terminated all proceedings stemming from the August 29, 2024 Notice. *Schedules of Controlled Substances: Rescheduling of Marijuana; Withdrawal,* 91 Fed. Reg. 22,777, 22,778 (Apr. 28, 2026). That same day, then-acting Attorney General Todd Blanche issued a Notice rescheduling the hearing. *Id.* at 22,777. On June 24, 2026, the Government submitted its Prehearing Statement, which contained a list of witnesses, along with their anticipated testimony, including Exhibit One, which was a *Touhy* letter to address the three topics Dr. Dominic Chiapperino would be permitted to testify about outside of the voluminous report the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) compiled in support of its scientific and medical evaluation and ultimate rescheduling recommendation. The Movants identified their own witnesses and presented them, along with a significant written record, during the June 29 – July 15, 2026, hearing before Chief Administrative Law Judge Derek C. Julius.

On August 27, 2026, all parties submitted their post-hearing briefs. On September 28, 2026, the Movants submitted a Joint Motion Requesting Leave to File Supplemental Briefing, for Admission of Supplemental Exhibit, and for Stay of Proceedings. The Movants attached a report by the Government Accountability Office (GAO) dated September 23, 2026 (GOA Report or Report) as said supplemental exhibit and requested leave to file additional briefing based on

the Report. On September 29, 2026, Judge Julius issued an order staying the proceedings and ordering the government to respond to Movants' request.

On October 11, 2026, the Movants submitted an additional motion to re-open the proceedings for written discovery, testimony, briefing on the application of these additional materials to the scheduling matter and a stay of the proceedings until the additional materials, testimony, and briefing schedule concludes. Movants submitted five requests for documents and testimony, including a request for the identities of all persons who were involved in the selection, recommendation or drafting of the two-part Currently Accepted Medical Use (CAMU) test, along with all materials that explain why the two-part test was adopted (Req. No. 1); the identities of all persons who drafted the CAMU language in the HHS recommendation and the role various agencies and outside groups played in HHS's recommendation drafting (Req. No. 2); an explanation for why the HHS evaluation submitted in this matter differed from HHS's prior marijuana evaluations (Req. No. 3); criteria FDA used to assess the abuse potential and Schedule III comparisons (Req. No. 4); and the materials GAO reviewed and requested relative to all scheduling matters from any person, entity or group (Req. No. 5). On October 14, 2026, this Tribunal Ordered the Government to provide a response to the Movants' request.

ARGUMENT

I. The APA Disfavors Supplementing the Record and Discovery in Administrative Matters

A. Supplementing the Administrative Record

The agency is entitled to a "strong presumption of regularity that it appropriately designated the administrative record." *Swisher Int'l, Inc. v. FDA,* No. 22-cv-954 (CRC), 2023 U.S. Dist. LEXIS 178551, at *9 (D.D.C. Oct. 4, 2023)*, quoting Oceana, Inc. v. Ross,* 290 F. Supp. 3d 73, 77 (D.D.C. 2018). A party seeking to add materials to the administrative record must specifically

identify the materials to be supplemented and provide a sufficient reason to support their addition. To supplement the record, the Movants must show that the agency deliberately or negligently excluded documents that may have been adverse to its decision, background information is needed to determine whether the agency considered all the relevant factors, or that the agency failed to explain its administrative action so as to frustrate judicial review. *See Nat. Res. Def. Council, Inc. v. Doremus*, No. 20-cv-1150 (CRC), 2021 U.S. Dist. LEXIS 105921, at *6 (D.D.C. June 7, 2021).

B. Discovery

The APA does not provide for "discovery in the administrative process and the Federal Rules of Civil Procedure for discovery do not apply to administrative proceedings." *Silverman v. Commodities Futures Trading Comm'n*, 549 F.2d 28, 33 (7th Cir. 1977) (internal citations omitted); *see also N.L.R.B. v. Valley Mold Co.*, 530 F.2d 693, 695 (6th Cir. 1976) ("The [APA] does not confer a right to discovery in federal administrative proceedings."). Instead, "the extent of discovery that a party engaged in an administrative hearing is entitled to is primarily determined by the particular agency." *Mister Discount Stockbrokers, Inc. v. SEC*, 768 F.2d 875, 878 (7th Cir. 1985) (*quoting McClelland v. Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979)). "DEA's regulations do not . . . provide for broad-based discovery. Rather, consistent with the Due Process Clause, they provide only the right to receive in advance of the hearing a summary of the anticipated testimony of the Government's witnesses and copies of the Government's proposed exhibits." *Jones Total Health Care Pharmacy, L.L.C, and SND Health Care, L.L.C*., 81 Fed. Reg. 79,188, 79,198 (2016), pet. for rev. denied, 881 F.3d 823 (11th Cir. 2018). In APA cases, "depositions [and] …. wide-ranging document production of materials that may potentially lead to admissible evidence-do not apply." *Bark v. Northrop*, 2 F. Supp. 3d 1147,

1152 (D.Or. 2014) *quoting Comprehensive Community. Dev. Corp. v. Sebelius*, 890 F. Supp. 2d 305, 312 (S.D.N.Y. 2012).

There is a strong presumption against discovery because "[t]he [agency's] final decision in any hearing must survive review based on the evidence adduced in the hearing." *Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 350 (1st Cir. 2004); *Kravitz v. U.S. Dep't of Commerce*, 336 F. Supp. 3d 545, 570 (D.Md. 2018), *citing NVE, Inc. v. Dep't of Health & Human Servs*., 436 F.3d 182, 195 (3d Cir. 2006); *see also Tafas v. Dudas*, 530 F. Supp. 2d 786, 794 (E.D. Va. 2008) ("Because judicial review of agency action is generally limited to the administrative record, discovery is typically not permitted."). The party with the burden of proof in such proceedings "will have every incentive to proffer sufficient information to allow the agency to reach a reasoned decision. That same quantum of information should be adequate for a reviewing court to determine whether the agency's action is supportable." *Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 350 (1st Cir. 2004).

Discovery is available "only upon a showing that the agency engaged in 'bad faith or improper behavior' in compiling the record, or in 'the rare case in which the record is so bare as to frustrate effective judicial review.'" *Swisher,* 2023 U.S. Dist. LEXIS 178551 at *10, *quoting Community for Creative Non-Violence v. Lujan,* 908 F.2d 992, 997-98, (D.C. Cir. 1990). "Mere allegations" of bad faith will not overcome the presumption that government officials have acted properly and in good faith. *Kravitz*, 336 F.Supp. 3d. at 570, *quoting Mullins v. U.S. Dept. of Energy*, 50 F.3d 990, 990 (Fed. Cir. 1995). A party seeking discovery on a "bad faith" theory must make a "strong showing of bad faith or improper behavior before such inquiry may be made." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *see also Voyageurs Nat'l Park Ass'n v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004) ("Inquiry into the

mental processes of administrative decisionmakers is to be avoided unless it is the only way there can be effective judicial review.")

C. Application to Rulemaking

The record supplementation and discovery principles noted above apply equally in the rulemaking context. As a general matter, the same provisions of the APA and the DEA regulations that govern enforcement adjudications also govern rulemaking proceedings. *See* 5 U.S.C. § 556(a) (provisions applying to hearings "required by" 5 U.S.C. § 553 (rulemaking) and 5 U.S.C. § 554 (adjudications)); 21 C.F.R. § 1308.41 (DEA rulemaking hearings "shall be governed," in part, by the general DEA hearing regulations at 21 C.F.R. §§ 1316.41-67). Any right to (or procedure for) discovery and record supplementation in these proceedings would be found in either the APA hearing provisions or the DEA hearing regulations. And, as discussed above, there are no such provisions.

II. The Movants Are Not Entitled to Supplement the Record

Movants requested to supplement the Administrative Record with the GAO Report but did not identify a basis allowable under the APA. The Government neither agreed nor objected to the introduction of the Report, noting that the Report was clear on its face and required no further briefing. Now the Movants argue that the Report's addition to the administrative record, to which this Court has not ruled, necessitates significant discovery (written and testimonial) and supports further delay of this rescheduling process. To supplement the administrative record in an APA matter, the Movants must concretely identify the record to be added and cannot rely on broad categories of materials that are "likely" to exist. *Lee Mem'l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 47 (D.D.C. 2015). The only document specifically identified by Movants to supplement the record is the GAO Report. Notably, neither the Report nor Movants identify other records with any specificity to supplement the Record. The Report identifies the *absence* of policy and

procedure records, not the presence of those materials. Because DEA's final decision is based on the review of the evidence adduced at the hearing, and Movants have not identified any materials to supplement the record except for the GAO Report, Movants' record supplementation request is limited to the Report. *See Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 350 (1st Cir. 2004).

III. Movants Are Not Entitled to Discovery

While Movants reference their discovery requests as "limited" and "narrowly tailored," these requests are neither limited nor narrow. Instead, Movants seek broad categories of materials and testimony related to issues the parties addressed repeatedly at the hearing (Request Nos. 1 -4) and an additional request for GAO's materials for all scheduling matters in the prior six years from every entity GAO sought said information from, and the content of every GAO request for information (Request No. 5).[1] Dr. Chiapperino testified about the two-part CAMU test and when it was developed (Tr. 42-45, 411-413, 493), how it differed from other CAMU tests used (Tr. 53-64, 137-138, 159-162, 164-167, 251, 257, 371-385, 393-394, 405-11, 427-438, 464, 528-530), and the direction he received on its use (Tr. 412-413), which is responsive to Request No. 1. Dr. Chiapperino also identified the groups that participated in the scientific and medical evaluation and scheduling recommendation and the process for information exchange between agencies (Tr. 40-43, 444-445, 488-495), which is responsive to Request No. 2. Further, Dr. Chiapperino testified about what ailments and population groups were included in the clinical studies, surveys and other materials FDA assessed and why (Tr. 104-106, 125-126, 181, 251, 357, 360-361, 468, 478, 499, 508, 516, 528), along with the criteria FDA used to assess abuse potential (Tr. 51, 73-

[1] The Government is uncertain whether it can require GAO to produce their investigation file in the current rescheduling process and assumes for the purpose of this response alone that it has the authority to demand GAO's investigative materials that are not in DEA's possession, custody, or control.

80, 291-292, 519-523) and the comparator substances used (Tr. 74-80, 204, 244-245, 273, 282-292, 353-356, 387-393, 528, 532-535). This information is sought in Request Nos. 3 and 4.

Dr. Chiapperino did not specifically identify each and every person who was involved in the selection, recommendation, direction, drafting, and approval of the two-part CAMU test (Request No. 1). Likewise, he did not identify each and every person involved in the preparation and revision of the CAMU language used in the HHS recommendation or whether other agencies participated in HHS's drafting (Request No. 2). The Movants had full opportunity to cross-examine Dr. Chiapperino about the particulars of Request Nos. 1 and 2 and explore any avenues they believed to be fruitful. The Movants' request to reopen this line of inquiry – after they had the opportunity to do so – would give them a "second bite at the apple" to which they are not entitled.

Movants' last Request, Request No. 5, seeks GAO's investigative file relative to its recent Drug Scheduling Report. Given the GAO Report's clear findings, explanation about how it performed its review, and various appendixes and citations, the Government is uncertain what Movants believe is missing from the Report that require discovery to complete the administrative record.[2]

Movants argue that their disagreement with the Government's interpretation creates a material issue of fact that this Court must resolve by allowing Movants to engage in broad, general written discovery, witness depositions, and further briefing to the Tribunal during a stay implemented until they have concluded their discovery process. This is an obvious fishing expedition based on a Report that is clear on its face. The Report did not find any concerns with

[2] The Government assumes for the purpose of this response that the GAO investigation materials can be subpoenaed and that GAO would produce fulsome, unredacted materials.

the materials that make up the Movants' discovery requests, *e.g.*, the scientific or medical assessment the Government used in the marijuana rescheduling process, the Office of Legal Counsel memo regarding the two-part CAMU test nor FDA and DEA's reliance on the same, the manner in which HHS's recommendation was written in support of its rescheduling recommendation and the agencies involved in that assessment or production, the population groups and ailments reviewed by FDA in its scientific and medical review, the definition of "potential for abuse" identified in the NPRM and used in the rescheduling review, or the comparator drugs FDA used in its scientific and medical review. Movants' reliance on this Report as the basis for their general discovery requests is misplaced. The parties' disagreement about the Report's findings and its impact on FDA's scheduling recommendation do not create a material issue of fact.

Further, contrary to established law, Movants seek discovery while failing to cite to "bad faith" or to an insufficiently "sparse" administrative record. Movants are required to make a "strong showing" of improper behavior before the Tribunal can entertain discovery into an administrative record on a bad faith theory. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). At most, Movants allege that the GAO Report's recommendation that DEA and FDA memorialize the processes requires further discovery to aid the Tribunal because without the written memorialization, "[t]he tribunal has no fixed standard against which to measure" whether the Government's review was adequate. Movants' Motion to Reopen Hearing, p. 2. Movants argument that the lack of a written standard, after the same standard used was addressed throughout the hearing and addressed in voluminous written materials, fails to establish *any* showing of bad faith, let alone a strong showing.

Movants have also not shown that discovery is necessary because the record is "so bare as to frustrate effective judicial review." *Swisher*, 2023 U.S. Dist. LEXIS 178551 at *10. Dr. Chiapperino testified that he and his team spent ten months performing this review, including four break-out groups that met regularly to perform focused scientific reviews and assessments. (Tr. 42-45). HHS propounded a summary record that included voluminous materials, which summarized numerous studies, survey data, and findings along with citations to the individual studies reviewed because the record would be too difficult to review if all the materials cited were included. (Tr. 203-204). The parties then added to the administrative record during the hearing. The record herein does not "frustrate effective judicial review." *See Swisher*, 2023 U.S. Dist. LEXIS 178551 at *10. Movants have not met their burden.

Because the GAO Report does not create a material issue of fact sufficient to rebut the presumption against record supplementation or discovery in this administrative matter, and because Movants cannot show bad faith or a sparse record, their request to reopen this hearing to supplement the administrative record and engage in discovery must fail.

CONCLUSION

For the foregoing reasons, the Government requests that the Movants' Motion be denied in all respects.

Dated: October 20, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 20, 2026, I electronically submitted the foregoing Government's Response to the DEA Office of Administrative Law Judges via the DEA Judicial Mailbox, at ECF-NPRM@dea.gov, and so caused a copy to be delivered to the following recipients:

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Date: October 20, 2026 *<u>/s/ James J. Schwartz</u>*

James Schwartz