

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

In the Matter of:

*Schedules of Controlled Substances:
Proposed Rescheduling of Marijuana*

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

**REPLY IN SUPPORT OF MOTION TO REOPEN HEARING
FOR LIMITED PURPOSES AND FOR LIMITED DISCOVERY**

Interested Parties National Drug & Alcohol Screening Association (“NDASA”), DUID Victim Voices, and Kenneth Finn, M.D. (collectively, “Interested Parties”) reply to the Government’s October 20, 2026 response (“Gov’t Oct. 20 Resp.”).

The Government concedes the facts that decide this motion. First, it admits its witness never identified who selected, directed, drafted, or approved the two-part currently accepted medical use (“CAMU”) test, or whether other agencies shaped the CAMU language. Gov’t Oct. 20 Resp. at 8. That two-part test, whose origin is entirely unknown, decided the medical-use finding. FDA was “directed to use” it by someone midway through its evaluation, and its witness admitted marijuana “[w]ould not have passed” the five-part test it replaced. Tr. 412:13–19, 437:13–14. Second, the Government admits the GAO Report documents “the absence of policy and procedure records.” Gov’t Oct. 20 Resp. at 6–7. That absence *is* the finding. FDA has no written criteria for “potential for abuse,” including “abuse potential relative to other substances.” GAO Report at 14. Schedule III requires that comparison. 21 U.S.C. § 812(b)(3)(A). The Government cannot concede that no standard existed and then call the missing standard immaterial. Third, the Government admits that “DEA’s final decision is based on the review of the evidence adduced at the hearing,” Gov’t Oct. 20 Resp. at 7, and “[t]he party with the burden of proof” must “proffer sufficient information to allow the agency to reach a reasoned decision.” *Id.* at 5 (citation omitted). The party with the burden of proof is the Government. *See* 5 U.S.C. § 556(d); 21 C.F.R. § 1316.56.

If discovery were to show that the two-part test had no basis other than ensuring marijuana would pass, that someone outside HHS dictated it to FDA, and that the scientific consensus favored the five-part test for the CAMU determination, it is indisputable that the Government could not carry its burden. The Government shut down that inquiry during the hearing and now asks this tribunal to again foreclose inquiry into clearly relevant and potentially dispositive evidence.

The record lacks facts on a required finding. Reopening this hearing and allowing limited discovery can supply those facts. The tribunal should grant Interested Parties' motion.

I. THE RECORD RULE GOVERNS REVIEWING COURTS, NOT AN OPEN ADMINISTRATIVE PROCESS

Every limit the Government invokes comes from judicial review of a closed administrative record. *See* 5 U.S.C. § 706 (“the court shall review the whole record”). But this tribunal is compiling a record, not reviewing one. In a formal hearing, the transcript, exhibits, and papers filed “constitute[] the exclusive record for decision.” *Id.* § 556(e). No recommended decision has issued, and the record has not been certified. 21 C.F.R. §§ 1316.52, 1316.65(c). The Government’s own test asks whether the record would “frustrate effective judicial review.” Gov’t Oct. 20 Resp. at 10. That review will be confined to what this tribunal receives now. *See Walter O. Boswell Mem’l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (reviewing less than the full record “might allow a party to withhold evidence unfavorable to its case”).

Swisher, *Oceana*, *Doremus*, *Lee Memorial*, and *Community for Creative Non-Violence* each asked what a district court may add to a closed agency record. None involved a § 556 hearing before certification. The Government’s remaining out-of-circuit cases hold only that the Federal Rules do not govern agency hearings, which no one disputes.

II. THE APA AND DEA’S RULES AUTHORIZE WHAT THE MOTION REQUESTS

The Government says any discovery right would appear in the APA or DEA’s hearing rules, and “there are no such provisions.” Gov’t Oct. 20 Resp. at 6. Wrong. The Administrative Procedure

Act allows presiding officers in an administrative hearing to issue subpoenas, take depositions, receive evidence, regulate the hearing, and dispose of procedural requests. 5 U.S.C. § 556(c). Parties at a § 556 hearing may submit rebuttal evidence, conduct cross-examination, and contravene any official notice of material facts. *Id.* § 556(d)–(e).

The Government’s own authority also holds that the extent of discovery “is primarily determined by the particular agency.” Gov’t Oct. 20 Resp. at 4 (quoting *McClelland v. Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979)). Here, the particular agency has spoken. DEA’s rules authorize the presiding officer to issue subpoenas, direct witness testimony, and rule on evidence and procedural matters. *See* 21 C.F.R. § 1316.52. DEA’s rules also permit submission of previously unidentified evidence upon a showing of good cause. *See id.* § 1316.57. *Jones Total Health Care Pharmacy* acknowledged that discovery must be available when its denial would prejudice a party sufficiently to violate due process. *See* 81 Fed. Reg. 79,188, 79,198 (2016). Interested Parties seek identified materials and testimony that bears directly on disputed issues material to rescheduling. Moreover, this tribunal has already treated this request as within its authority to decide, calling it “a new substantive motion.” Order of Oct. 14, 2026, at 2.

III. THE GOVERNMENT LIMITED THE INQUIRY AND CANNOT NOW CITE THOSE LIMITS AS A REASON TO HALT IT

The Government says Interested Parties had a “full opportunity” to cross-examine Dr. Chiapperino and now seek “a second bite at the apple.” Gov’t Oct. 20 Resp. at 8. There was no first bite. The Government declared the two-part test off limits. Tr. 26:12–17, 97:8–17. FDA’s Touhy letter confined Dr. Chiapperino to three topics, ALJ Ex. 44, Attach. 1 at 1–2, and the Government invoked it against process questions, Tr. 107:5–108:1, 196:23–197:2, 1355:6–14. The witness stated that explaining “how the two part test became the documents that we gave to DEA” might breach his letter. Tr. 440:20–24. Section 556(d) guarantees cross-examination “required for a full and true disclosure of the facts.” A witness bound by a Touhy letter cannot disclose what lies outside it.

The Government's string cites show what the two-part test is and when it arrived. Gov't Oct. 20 Resp. at 7–8. They do not show who chose it or why. The Government, as proponent of the proposed rule, bears the burden of proof. 5 U.S.C. § 556(d). The policies the agencies gave GAO, and their comments on the draft Report, sit in the Government's own files and require no detour through GAO. GAO Report at 18–20.

IV. THE GOVERNMENT'S SHIFTING ACCOUNT OF THE REPORT CREATES DISPUTED FACTS

The Government calls the Report “clear on its face” and denies any “material issue of fact.” Gov't Oct. 20 Resp. at 8–9. On October 9 in its response to Interested Parties' prior Motion (“Gov't Oct. 9 Resp.”) the Government read the Report as a mere recommendation to memorialize procedures. *See* Gov't Oct. 9 Resp. at 3–5. Interested Parties covered how this reading creates a dispute of material fact in its Reply to that Response. Notably, the Report says DEA “does not have any policies or procedures regarding how its staff are to conduct evaluations or schedule substances,” and that FDA lacks written criteria for potential for abuse. GAO Report at 2, 12–14. FDA told GAO that gap “presented challenges for determining the relative abuse potential.” *Id.* at 14. Whether that admitted gap shaped the evaluation relevant to this proceeding, including its comparators and its omission of psychosis and prenatal exposure, is an open question of material fact. Tr. 104:17–106:1, 357:10–17. Additionally, how the Government's decision to use the novel two-part test instead of the traditional five-part test affected its recommendation to reschedule marijuana is a material fact requiring scrutiny.

A recommended decision must state findings “on all the material issues of fact . . . presented on the record.” 5 U.S.C. § 557(c)(3)(A). Without further fact-finding regarding the Government's process (or lack thereof), this tribunal cannot issue a recommended decision that meets this bar.

V. THE RECORD IS BARE ON THE DISPOSITIVE QUESTIONS

The Government’s lead case supports the motion. The Government cites *Overton Park* for a bad-faith requirement. Gov’t Oct. 20 Resp. at 5, 9. But that requirement applies only “where there are administrative findings that were made at the same time as the decision.” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Where those findings are missing, “the bare record may not disclose the factors that were considered,” and “the only way there can be effective judicial review” may be “examining the decisionmakers themselves.” *Id.* The Court reversed because the lower courts had ruled on less than the whole record. *Id.* at 419–20.

This record is missing a crucial finding: the written standard FDA used to judge abuse potential. GAO Report at 14. No bad-faith showing is required to fill that gap. Nor do Interested Parties’ requests probe mental processes. They seek facts: who chose the all important, decisive two-part CAMU test, who directed its use, when, and under what criteria. The Government’s summaries, *see* Gov’t Oct. 20 Resp. at 9–10, show what FDA reviewed. They do not show what standard FDA applied when reviewing. The Report identifies the documents that would: the July 17, 2023 “Part 1 Analysis” memorandum, FDA’s eight-factor SOPs, and the FDA–DEA and FDA–NIDA memoranda of understanding. GAO Report at 8, 12–15, 28 n.25. HHS has since committed to write the standard that should have governed this evaluation. *Id.* at 18. The existing administrative record is bare where it counts.

VI. CONCLUSION AND PRAYER FOR RELIEF

Interested Parties request that the Chief Administrative Law Judge grant the Motion to Reopen Hearing for Limited Purposes and for Limited Discovery; authorize limited discovery and testimony on the five identified subjects; admit or officially notice the GAO Report; continue the stay and hold the recommended decision and certification until that process closes; and grant such other relief as justice requires.

Date: October 21, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2026, I electronically filed the foregoing Reply with the tribunal via email to the DEA Judicial Mailbox at ECF-NPRM@dea.gov and simultaneously served the Reply by email upon the Government and all parties of record as follows:

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