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 BRIEF REGARDING THE WEIGHT AND EFFECT OF THE GAO REPORT

Interested Parties National Drug & Alcohol Screening Association ("NDASA"), DUID Victim Voices, and Kenneth Finn, M.D. (collectively, "Interested Parties") submit this reply to the Government's October 29, 2026 supplemental brief.

The Government fundamentally misapprehends the argument being made by Interested Parties and conflates our argument with some type of notice objection. The Government contends that it presented multiple exhibits along with testimony from Dr. Dominic Chiapperino detailing the process and analysis that led the Department of Health and Human Services to ultimately recommend that marijuana be transferred to Schedule III. Gov't Br. at 2.

But that addresses only what was measured, not why the chosen measure was valid. The GAO Report provides evidence that the Government's process was flawed, and cannot carry the burden of proof necessary to warrant rescheduling marijuana to Schedule III.

I. THE GAO REPORT DEMONSTRATES THAT THE PROCESS UNDERLYING THE GOVERNMENT'S PROPOSAL IS UNRELIABLE

Every analysis should answer two types of questions, often described as first-order or second-order questions. The first-order question asks what an evaluation shows at the object level. The second-order question asks how that object should be evaluated or measured. Measuring using the wrong method, even if done very precisely, still produces the wrong answer.

The weight of the GAO Report is decisive as to the second-order questions involved in this process, because it points out the fatal flaws in its methodology. When a problem is open-ended and

discursive, the analyst must choose the criteria, data, measurements, and comparisons. Without written guidance, those choices are left to the individual analyst. Those choices often decide the outcome, and any analysis that does not justify them at every important fork in the analytical road cannot be deemed reliable or sufficient.

As admitted by Drs. Chiapperino and Akinfiresoye, the end result of the Government's rescheduling analysis depends on the test or method of analysis applied. It follows that before the Government can prove its conclusion, it must first show that the test it applied was justified and appropriate. Ordinarily, that showing is made by pointing to an established procedure adopted in advance so it cannot be shaped to reach a desired result. Procedures developed by a body with the relevant expertise, through a deliberative and open process. Procedures published so anyone can apply them and check the work. Procedures applied consistently across cases, so like matters are treated alike.

Here, as noted in the GAO Report, no procedures were adopted in advance; many were devised inside a black box, amid political pressure, and in an *ad hoc* way specifically for this proceeding; and they departed in critical ways from past rescheduling analyses. The DEA and FDA lacked reproducible, reviewable written policies and procedures for making critical determinations directly relevant to the eight-factor statutory test and the requirements for Schedule III. GAO Report at 12–14, 18; 21 U.S.C. §§ 811(c)(1); 812(b)(3)(A). Incidentally, nothing indicates that DEA and FDA used a different set of internal written guidelines in the prior marijuana rescheduling attempts recounted in Interested Parties' brief. Those prior rulemakings are not at issue, but the sudden change in recommendation still requires explanation. A deficient process that produces opposite scheduling recommendations demonstrates the fatal flaw GAO identified: without written procedures, the route to this rescheduling proposal is not reproducible, reviewable, or sufficient to carry the Government's burden of proof.

So, yes, to directly answer the Government, Interested Parties knew what the yardstick was, just not why the Government felt it appropriate to use a "yardstick" at all as opposed to a meter-rule, scale, thermometer, or clock, or why it suddenly abandoned prior measures in favor of the "yardstick."

II. THE GAO REPORT CONFIRMS THE PROCEDURAL ISSUES SURROUNDING THE GOVERNMENT'S USE OF THE TWO-PART TEST

The Government asserts that the GAO Report contains "no substantive commentary (critical or otherwise)" about the two-part CAMU test. Gov't Br. at 5. That is incorrect. GAO found that FDA "does not have policies or procedures specifying how its staff are to conduct evaluations" or "make scheduling recommendations." GAO Report at 2, 13–14. The Report describes the two-part test as one that "has not replaced other methods for determining currently accepted medical use." *Id.* at 8. FDA therefore had more than one method available and had to choose among them. The GAO Report establishes that no written policy or procedure governed that choice.

Testimony at the hearing agrees with GAO's findings. Dr. Chiapperino testified that FDA began the marijuana evaluation in October or November 2022, before the two-part test existed, and that the formal instruction arrived in July 2023 when the Assistant Secretary for Health directed FDA to use the new two-part test at the eleventh hour, after most of FDA's work was done. Hrg. Tr. 410:23–413:16; 425:11–24. He also testified that FDA never completed a five-factor analysis for marijuana. *Id.* 426:11–13. He admitted marijuana "[w]ould not have passed" that test. *Id.* 436:15–437:14. In short: the Government's choice of test mattered.

Moreover, it is not as though the two-part test had stood the test of time or was widely agreed upon. The Government's own employee, DEA scientist Dr. Luli Akinfiresoye, testified that she and her DEA colleagues used the five-factor test because that is what DEA had always done, and that HHS's two-factor test made no scientific sense because it lacked chemistry, safety, and efficacy. *Id.* 1353:15–1356:25, 1359:19–1360:21. She also testified that DEA had not completed its own eight-

factor analysis when the NPRM issued, *id.* 1349:13–1350:10, and that DEA found no adequate and well-controlled studies proving marijuana's efficacy, *id.* 1367:18–1368:21.

The Government has never produced any policy, procedure, or underlying basis for its arbitrary, capricious, unexplained, unreasoned, and outcome-determinative two-part test decree. If such procedures or bases existed, the Government could have resolved this issue simply by producing them. It did not, because, as GAO found, they do not exist. ***What remains is the determinative methodological choice on which the entire decision to reschedule marijuana rested—the selection of the two-part test—and no one knows who ultimately made the choice or why***. If the one all-important decision determining this process is unknowable, unquestionable, and unreviewable, what has been the purpose of this exercise? The Government's hand-waving on this point is telling.

III. THE GOVERNMENT'S REMAINING ARGUMENTS ARE UNAVAILING

The Government's reliance on the GAO Report's summary of the 2024 Office of Legal Counsel ("OLC") opinion does not advance its position. OLC found the test legally permissible but did not purport to evaluate, and was not positioned to evaluate, whether the two-part CAMU test is scientifically rigorous, methodologically sound, or a prudent basis for determining that marijuana has a currently accepted medical use. GAO Report at 8–9. A legally permissible test can still receive little weight if the record does not show why it was chosen, that it was procedurally sufficient, how it was applied, or how it was reconciled with contrary agency evidence. *See* NDASA Ex. 8 at 3, 5–6, 8–10 (CIVEL 2024 Prehearing Statement showing that OLC opinion and two-part test were procedurally and scientifically insufficient with critical process gaps).

The Government cannot make process hard to examine and then claim GAO's independent process findings add nothing. Over and over, the Government told the tribunal the hearing was not about the legality of the two-part test and invoked Touhy limits when questioning reached process

topics, later data choices as part of the eight-part analysis, and whether marijuana would pass the five-factor test. Hrg. Tr. 26:12–17, 97:8–17, 101:1–8, 178:4–18, 419:19–23, 421:10–25. GAO then reviewed agency policies, procedures, data, and documents and interviewed DEA, FDA, HHS, and NIH officials and found the very process gaps Interested Parties had pointed out but were barred from examining. GAO Report at 19–20. Critical and decisive process gaps that affected critical and decisive decision-making—left entirely unexplained—render the Government unable to prove marijuana should be rescheduled.

IV. CONCLUSION

Interested Parties respectfully request that the tribunal recommend that the Administrator decline to adopt the proposed rescheduling of marijuana to Schedule III on this record.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 5, 2026, I electronically filed the foregoing Reply Brief with the tribunal via email to the DEA Judicial Mailbox at ECF-NPRM@dea.gov and simultaneously served the Reply Brief by email upon the Government and all parties of record as follows:

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CERTIFICATE OF COMPLIANCE

I hereby certify that this Reply Brief complies with the October 22, 2026 Order limiting briefs and replies on the GAO Report to no more than ten pages, double-spaced.

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