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**

RESPONSE OF SMART APPROACHES TO MARIJUANA AND THE OPPOSED STATES IN SUPPORT OF JOINT MOTION OF THE NATIONAL DRUG & ALCOHOL SCREENING ASSOCIATION, DUID VICTIM VOICES AND KENNETH FINN, M.D. FOR LEAVE TO FILE SUPPLEMENTAL BRIEFING

In accordance with the Tribunal's September 29, 2026 Order, Smart Approaches to Marijuana (SAM) and the States of Idaho, Indiana, and Nebraska (the Opposed States) submit this joint response in support of the September 28, 2026 Joint Motion of the National Drug & Alcohol Screening Association, DUID Victim Voices, and Dr. Kenneth Finn. SAM and the Opposed States support Movants' requests that the Tribunal (i) admit into evidence the report issued by the Government Accountability Office (GAO) on drug scheduling as Dr. Finn Exhibit 126,[1] and (ii) allow supplemental briefing on the import of the GAO Report to the present record in the rescheduling. Consistent with the Tribunal's determination that a stay is warranted to entertain the Joint Motion, SAM and the Opposed States also support extending the current stay through the deadline to submit any supplemental briefs.

1. Nine weeks after the hearing on the record, GAO published a report addressing several topics surrounding the process of drug (re)scheduling, including "the extent to which DEA

[1] *See* U.S. Gov't Accountability Off., GAO-26-108623, *Drug Scheduling: While DEA Decisions Have Aligned with Recent HHS Recommendations, Both Need Comprehensive Policies* 2 (2026) (GAO Rep.), perma.cc/K6DL-8UEH.

and HHS have policies and procedures related to evaluating and scheduling substances." GAO Rep. 2. It found that that DEA and FDA "do not have any policies or procedures" specifying how drug evaluations are to be conducted. *Id*. "[N]either DEA nor FDA have policies that describe the specific procedures staff should follow for fulfilling their responsibilities related to prepared scheduling evaluations and recommendations." *Id.* at 18. The FDA, in particular, "does not have policies or procedures that . . . outline how its staff are to conduct the eight-factor analysis or make scheduling recommendations." *Id.* at 14. The fixing of these deficiencies would improve consistency. "By developing policies and procedures" that give "clarity and standardization" FDA would "be able to better ensure that . . . staff can clearly and consistently carry out" the "drug evaluation." *Id.* Likewise, "[b]y developing policies and procedures" "DEA would be able to better ensure its staff can clearly and *consistently* carry out their various responsibilities." *Id.* at 13-14 (emphasis added).

2. The Report also revealed that FDA and DEA have no standardized means to evaluate marijuana's relative potential for abuse. According to the Report, "FDA does not have policies or procedures" that "clearly define the criteria and process for determining a substance's . . . abuse potential relative to other substances." *Id.* In other words, nothing stops the Government from arbitrarily altering the abuse profile of a drug by, for example, manipulating the comparators it selects in a given evaluation. The absence of standard policies for evaluating "relative" abuse potential affords FDA enormous discretion to isolate the most lethal substances as comparators (and ignore other Schedule II substances) to arrive at a pre-ordained conclusion that a substance without high overdose risk belongs in a less restrictive control schedule.

3. This is directly relevant the proposed findings of fact and conclusions of law advanced by SAM and the Opposed States. As the Tribunal will recall, chief among the arguments

by SAM and the Opposed States' was that HHS's eight-factor analysis of marijuana in August 2023—*i.e.*, the analysis giving rise to the current rescheduling—was not methodologically sound because, among other reasons, it differed dramatically, and without explanation, from HHS's previous own analyses of the same drug. As SAM and the Opposed States observed, HHS's eight-factor analysis (i) shunted consideration of marijuana's causal connection to psychosis (a risk previously found to be a crucial aspect of its abuse profile), (ii) discounted marijuana's overall societal impact in favor of its utilization-adjusted impact, and (iii) compared marijuana—for the first time ever—to a handpicked list of drugs with extremely high potential for lethal overdose and without pharmacological or other similarity to marijuana. Each of these dramatic shifts in analytical approach was easily accomplished because HHS had—and still has—*no written policies and procedures* standardizing how it conducts an eight-factor analysis. The lack of internal policies, in other words, explains how FDA was able to "depart from its usual mode of analysis" so readily. Post-Hr'g Br. at 52.

4. Importantly, the Government does not oppose admission of the GAO report into evidence. It does, however, contend that the Report is "immaterial" to the "analysis these agencies used" in this rescheduling proceeding. Opp. 2. The Government's argument here attacks a straw man. Contrary to the Government, GAO did not merely recommend that the Government agencies in question "memorialize" in writing "the Government's procedures." Opp. 5. It squarely concluded that DEA and FDA "do[] not have *any* policies" related to how scheduling evaluations are conducted. GAO Rep. 12 (emphasis added).[2] GAO found that DEA/FDA lack standardized,

[2] To the extent that the Government is making representations to the Tribunal that contradict what FDA and DEA told the GAO, that inconsistency independently counsels in favor of supplemental briefing.

repeatable evaluation processes. That deficiency infects all rescheduling determinations, and it explains why marijuana evaluations are inconsistent.

5. Indeed, the Government's opposition brief only underscores the potential value of supplemental briefing on the GAO Report's findings. It may be true that "[a]gency review does not become arbitrary and capricious if the process by which the Government performs its review is not memorialized" in writing. Opp. 5. But it is another thing entirely when an agency (i) publishes inconsistent evaluations of the same drug by (ii) shifting inputs and prioritizing different information and then (iii) GAO criticizes the same agency for risking inconsistency due to a lack of formal internal policies. *See, e.g.*, *Natl. Land for People, Inc. v. Bureau of Reclamation of Dept. of Int.*, 417 F. Supp. 449, 452 (D.D.C. 1976) (holding agency action arbitrary and capricious in part because of a "recent publication of the General Accounting Office [*i.e.*, the predecessor of the GAO] that "conclude[d] that [the agency's processes] should be improved and that written guidelines are needed setting forth the criteria and procedures used"); *cf. E. Fork Enters., Inc. v. EPA*, No. 24-60227, 2026 WL 2718464, at *15 (5th Cir. Sept. 15, 2026) (agency action arbitrary and capricious due in part to "selective use of data and failures to consider alternative acceptable data").

6. The Report is competent, relevant, and material evidence to proposed findings of fact and conclusions of law that directly bear on the Rescheduling determination before the Tribunal. It therefore satisfies the criteria set forth in 21 C.F.R. § 1316.59 and should be admitted into evidence. The Tribunal should also request supplemental briefing from the parties to address whether HHS's lack of internal written policies contributed to an evaluation of marijuana that departed from prior agency practice.

CONCLUSION

The Tribunal should admit the GAO Report into evidence, request supplemental briefing from the parties and extend the current stay through the deadline for such briefing.

October 13, 2026

Respectfully submitted,

/s/ *John M. McNichols*
John M. McNichols
Chase T. Harrington
T. Zachary Horton
TORRIDON LAW PLLC
801 Seventeenth Street NW,
Suite 1100
Washington, DC 20006

Counsel for the States of Idaho, Indiana, and Nebraska

/s/ *Patrick F. Philbin*
Patrick F. Philbin
John M. McNichols
Chase T. Harrington
TORRIDON LAW PLLC
801 Seventeenth Street NW,
Suite 1100
Washington, DC 20006

Counsel for Smart Approaches to Marijuana

CERTIFICATE OF SERVICE

I hereby certify that, on October 13, 2026, I caused a copy of the foregoing document to be delivered by email to the following recipients:

1. The Tribunal, by email to ECF-NPRM@dea.gov;
2. The Government, by email to
    a. The DEA Government Mailbox at dea.registration.litigation@dea.gov;
    b. James J. Schwartz, Esq., at James.J.Schwartz@dea.gov;
    c. Jarrett T. Lonich, Esq., at Jarrett.T.Lonich@dea.gov;
    d. Alexis B. Attanasio, Esq., at Alexis.B.Attanasio@dea.gov;
    e. Kayla L. Kreinheder, Esq., at Kayla.L.Kreinheder@dea.gov;
    f. David C. Maley, Esq., at David.C.Maley@dea.gov;
    g. Lisa K. Man, Esq., at Lisa.K.Man@dea.gov;
    h. Stacy M. Race, Esq., at Stacy.M.Race2@dea.gov;
    i. Mack J. Swan, Esq., at Mack.J.Swan@dea.gov
3. National Drug & Alcohol Screening Association;
    a. M. Jo McGuire at jomcguire@ndasa.com;
    b. David Evans, Esq. at thinkon908@aol.com;
4. Tennessee Bureau of Investigation, by email to
    a. Jacob Durst, Esq., at jacob.durst@ag.tn.gov;
5. DUID Victim Voices, by email to
    a. Ed Wood, at edwood27@icloud.com;
    b. Patrick D. Kenneally, at patrick.kenneally@burkegroup.law
    c. Connor Mighell, at connor.mighell@burkegroup.law
6. Kenneth Finn, M.D., by email to
    a. Patrick D. Kenneally, Esq., at patrick.kenneally@burkegroup.law

b. Connor Mighell, Esq., at connor.mighell@burkegroup.law

7. Phillip A. Drum, PharmD, *pro se*, by email at phillipdrum@comcast.net

October 13, 2026

John M. McNichols
John M. McNichols