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

PREHEARING RULING

On December 2, 2024, a preliminary hearing (the Preliminary Hearing) was conducted in the above-captioned matter at the Drug Enforcement Administration (DEA or Agency) Hearing Facility in Arlington, Virginia. 21 C.F.R. § 1316.54. The Preliminary Hearing was held as part of ongoing hearing proceedings being conducted in connection with the publication of a notice of proposed rulemaking (NPRM) issued by the Department of Justice. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597 (2024). The NPRM seeks to move marijuana from Schedule I of the Controlled Substances Act (CSA) to Schedule III. *Id.* The DEA Administrator subsequently determined that a hearing was appropriate and published her own order (General Notice of Hearing or GNoH) stating as much. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70148-49. The General Notice of Hearing fixed a December 2, 2024 commencement date. *Id.*

There has been a considerable level of spirited motion practice by the Designated Participants (and even numerous attempts from some outside that group). This Prehearing Ruling is issued pursuant to 21 C.F.R. § 1316.55.

I. Purpose

The NPRM and GNoH state that the purpose of this hearing is to receive factual evidence and expert opinion testimony regarding whether marijuana should be transferred to Schedule III

¹ The following cases were mentioned during the Preliminary Hearing: *Ester Mark, M.D.*, 86 Fed. Reg. 16760 (2021); *Gregg & Son Distributors*, 74 Fed. Reg. 17517 (2009); *Nicholas A. Sychak, d/b/a Medicap Pharmacy*, 65 Fed. Reg. 75959 (2000); *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (2024); *Axon Enter., Inc. v. FTC*, 598 U.S. 175 (2023); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Miami-Luken, Inc. v. DEA*, 900 F.3d 738 (6th Cir. 2018); and *McClelland v. Andrus*, 606 F.2d 1278 (D.C. Cir. 1979).

under the CSA in accordance with 21 U.S.C. §§ 811, 812. 89 Fed. Reg. at 44599; 89 Fed. Reg. at 70149.

II. Witnesses

All of the parties have noticed their intention to present testimony at the hearing. The parties are reminded that testimony not summarized in prehearing statements may (and likely will) be excluded at the hearing on the merits. All parties should endeavor to ensure that their witnesses do not stray outside their areas of expertise. Witnesses may be afforded the opportunity to provide video teleconference (VTC) testimony should a request be filed with this tribunal no later than 2:00 p.m. Eastern Time (ET) on December 13, 2024 (The Homework Date). Irrespective of whether a party has been granted leave to utilize VTC or will be present in court, any attorney/representative directing or cross-examining a witness must be physically present in the courtroom at the time of the examination.

The order of the parties' presentations is outlined *infra* and the following guidelines will apply to all parties, with the potential for some additional latitude afforded to the Government as the burdened party. Each party will have ninety (90) minutes to present the testimony of their witness. Before offering their witness, counsel may present a two (2) minute opening statement about their witness and any proposed exhibits to be sponsored through the witness. The parties are encouraged to consider whether there is merit in consolidation with other participants that have similar (or complimentary) litigation objectives, witnesses, and/or areas of interest. Consolidated parties will be afforded the opportunity to present the testimony of up to two (2) witnesses during the hearing, for a presentation not to exceed one hundred and twenty (120) minutes, should they avail themselves of the opportunity to consolidate.

At the conclusion of a party's presentation, counsel or the designated representative for that party may be afforded <u>either a ten (10) minute closing argument or the opportunity to submit a brief, not to exceed twenty-five (25) pages within five (5) business days of their witness's presentation. This binary argument option will apply to all parties, regardless of the number of witnesses testifying.</u>

The cross-examination of witnesses will generally be limited to matters covered on direct examination; however, if a party submits an affidavit or letter into evidence from a witness who also testifies in person, cross-examination as to matters referenced in the document may be

permitted, even if the witness does not refer to them in their direct testimony. As explained during the Preliminary Hearing, <u>cross-examination will be limited to twenty (20) minutes</u> for each party on the opposing side of the issue.

III. Documents

The parties have noticed their respective intentions to offer into evidence documents identified in their prehearing statements.² Further, all of the parties must serve each other with a copy (electronic or hardcopy) of the documents noticed in their respective prehearing statements no later than **January 3**, **2025**. The parties are reminded that documents not timely supplied to the other Designated Participants or the tribunal, may (and likely will) be excluded at the hearing. The parties are further reminded that inasmuch as these are formal rulemaking proceedings, a foundation must be laid for recognition as an expert as well as for each and every proposed exhibit as a condition precedent for inclusion in the record. 21 C.F.R. § 1316.59. A limited number of affidavits³ may be received into the record, subject to the evidentiary weight

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² For reasons that are not altogether apparent, although directed to do so in the November 19, 2024 Standing Order, the Government did not supply the complete list of documentary evidence it intended to offer into the record. Instead, the Government noticed a few documents and indicated below the line that notice of more documents could be forthcoming upon a supplemental filing date. In fairness to the Government's position, a supplemental prehearing statement date is not an uncommon feature of DEA administrative enforcement proceedings. There will be no supplemental prehearing statements in this formal rulemaking proceeding, and the Government is herein **DIRECTED** to furnish a complete list no later than **The Homework Date**. Further, as discussed at the Preliminary Hearing, the tribunal received several copies of proposed exhibits attached to the filings submitted in prehearing motion practice and none of those documents will be considered as part of the record. The process for submitting proposed exhibits for admission into the record is outlined later in this order.

³ During the Preliminary Hearing, the Government was granted leave to substitute an affidavit for the live testimony of one of its noticed witnesses, Heather Achbach, the Acting Section Chief of the DEA's Regulatory Drafting and Policy Support Section. This witness had been noticed to lay a foundation for comments (the Comments) filed by the American public in response to the NPRM. Mindful that this proposed exhibit has not yet been offered, for the planning purposes of all, as alluded to during the course of the Preliminary Hearing, it is quite unlikely that the Comments, which number well in excess of 43k, will be received into the hearing record. To be sure, NPRM comments play a vital role in the Administrative Procedure Act (APA) rulemaking process. They must be carefully analyzed by the proponent agency and responded to in detail in the final rule published in the Federal Register, but they are not admissible evidence at a hearing under the APA. 5 U.S.C. § 556(d)("A party is entitled to present his case ... by documentary evidence ... and to conduct such cross-examination as may be required for a full and true disclosure of the facts."); see also Attorney General's Manual on the APA § 7(c) (The admission of evidence at an APA hearing "does not extend to presenting evidence in affidavit or other written form so as to deprive the agency or opposing parties of opportunity for cross-examination, nor so as to force them to assume the expense of calling the affiants for cross-examination."); Basco v. Machin, 514 F.3d 1177, 1182 (11th Cir. 2008); J.A.M. Builders v. Herman, 233 F.3d 1350, 1354 (11th Cir. 2000); Keller v. Sullivan, 928 F.2d 227, 230 (7th Cir. 1991); Hoska v. Dep't of the Army, 677 F.2d 131 (D.C. Cir. 1982); Calhoun v. Bailar, 626 F.2d 145, 149 (9th Cir. 1980). Neither are the Comments admissible evidence under the DEA's own regulations. 21 C.F.R. § 1316.59(a) ("The [ALJ] shall admit only evidence that is competent, relevant, material and not unduly repetitious."). The Comments were never intended by Congress to be part of the APA hearing process. The APA unequivocally directs that a "rule [may not

adjustment specified in the regulations. 21 C.F.R. § 1316.58(b) ("Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination. . . .").

No later than the date fixed elsewhere in this order for the exchange of documents, each party is to file its noticed and proposed exhibits in the following manner: (1) each party will receive an email invitation to join the Department of Justice Enterprise File Sharing (JEFS) system, a secure commercial platform maintained by Box.com; (2) a party seeking to offer evidentiary exhibits must obtain a (free-of-charge) Box.com/JEFS account and must timely upload all proposed exhibits there; and (3) in addition to the electronic evidentiary submission on JEFS, each party must also timely provide three (3) complete sets of hard copies of all proposed exhibits to the Hearing Clerk.⁴ The submitted proposed exhibits (both hardcopy and electronic) must conform to the following specifications:

- Proposed exhibits must be pre-marked for identification with a docket number (e.g., Dkt. No. 23-42) and an exhibit number (e.g., [DP Name/Abbreviation] Ex. 1(ID) or Gov't Ex. 1 (ID)).⁵
- The pages of each proposed exhibit must be numbered. In addition, the first page of each proposed exhibit must state the total number of pages contained therein.

be] 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." 5 U.S.C. § 556(d). The 43k+ comments are not evidence, they cannot be. Congress understood that when it drafted the APA, as did the Agency when it drafted its regulations. If the Comments are not admissible evidence they cannot be considered in the recommended decision. Admitting the Comments into to a hearing record where they cannot be considered would indeed be a pointless exercise. On a more pragmatic level, to attempt to foist a gargantuan mass of inadmissible comments on the tribunal risks the appearance (even if subjectively unwarranted) of a dilatory tactic inflicted on the trier of fact by the agency that represents itself as the proponent of the rule. There is an additional dynamic that may bear some reflection. The DEA regulations require that in addition to the forwarding of evidence received into the record, where evidence is excluded, "if the excluded evidence consists of evidence in documentary or written form, a copy of such evidence *shall* be marked for identification and shall accompany the records as the offer of proof." 21 C.F.R. § 1316.60 (emphasis supplied). Thus, as directed elsewhere in this order, by regulation, three (3) complete hardcopies of the Comments would have to be supplied to the tribunal at the time they are offered, and forwarded to the Administrator for her review, even if rejected here. Some additional reflection upon this strategy on the part of the Government may be prudent.

DEA Headquarters

Attn: Hearing Clerk, Office of Administrative Law Judges

8701 Morrissette Drive

Springfield, Virginia 22152

⁴ Due to DEA email capacity limitations, unless otherwise directed by the tribunal, proposed evidentiary exhibits will not be accepted through ECF. Proposed exhibits should be provided in hard copy format, as well as through JEFS as described, *supra*. The parties are reminded that, because the mailing address is not the physical address of this office, some additional screening time is baked into the process. That said, any evidentiary exhibits timely received electronically will be considered timely. The evidentiary exhibits should be mailed to the Hearing Clerk's address, as follows:

⁵ Exclusive of audio/video recordings, exhibits provided in the form of compact disc (CD), PowerPoints, or other electronic versions will not be accepted, unless otherwise stated in this order or a subsequent one issued by the tribunal.

- All proposed hardcopy documentary exhibits must be supplied in a single-sided format and in an appropriately-sized three-ring binder.
- The electronic version of submitted evidentiary exhibits and the hardcopy binder must also include a Table of Contents listing the number of each proposed exhibit, a brief description of each proposed exhibit, and the number of pages in the proposed exhibit.

Proposed exhibits received after the <u>January 3, 2025</u> date fixed in this order for the service and exchange of documents (excluding exhibits to be utilized for cross-examination, rebuttal, and surrebuttal) may not (and likely will not) be admitted into evidence, absent a showing of good cause.

Each party should ensure that it has its own copy of all proposed exhibits for its own use during the hearing.⁶ Further, the parties must ensure that prior to any approved video teleconference testimony, each witness has been furnished with a useable copy (hard copy or otherwise) of any and all proposed exhibits (appropriately marked for identification) that may pertain to that witness's testimony.

IV. Hearing

Under the regulations,⁷ the notice of hearing fixes the place and time for hearing commencement.⁸ In this matter, the GNoH fixed the place of hearing at the DEA Hearing Facility in Arlington, Virginia. 89 Fed. Reg. at 70148-49. As discussed, *supra*, the DEA Hearing Facility will remain the venue throughout the hearing proceedings.⁹

In accordance with 5 U.S.C. § 554(b), the parties were consulted to ascertain the availability of their respective representatives and witnesses. Any party scheduled to present a witness must be present in the courtroom on that date, even if his/her/its witness will be appearing via VTC. Similarly, any representative seeking to cross-examine an opposing witness must likewise be present in the courtroom. Failure to appear, in the absence of good cause and granted by the tribunal in advance, will result in forfeiture of the opportunity to present a witness as well as the opportunity to cross.

⁸ As directed by the GNoH, the Preliminary Hearing commenced hearing proceedings on December 2, 2024. 89 Fed. Reg. at 70148-49.

⁶ The copies of the documents and/or affidavits exchanged by the parties ahead of the hearing are to serve as opposing parties' working copy during the hearing.

⁷ 21 C.F.R. § 1316.53.

⁹ As a reminder, no cell phone use in the courtroom will be permitted throughout the proceedings. No exceptions.

Accordingly, the hearing will commence on <u>January 21, 2025</u> at the DEA Hearing Facility. Proceedings will begin at <u>9:30 a.m. ET</u> each day and continue through <u>5:00 p.m. ET</u> daily from Tuesday through Thursday of each week. There will be a week-long recess from <u>February 11, 2025</u> through <u>February 13, 2025</u>. The table *infra* outlines the duration of the hearing on the merits in this case:

Week	Activity
1/21/2025—1/23/2025	Hearing
1/28/2025—1/30/2025	Hearing
2/4/2025—2/6/2025	Hearing
2/11/2025—2/13/2025	Break—No Hearing Proceedings
2/18/2025—2/20/2025	Haarin a
2/10/2025—2/20/2025	Hearing
2/25/2025—2/27/2025	Hearing Hearing

Based on the representations of the parties regarding their representative and witness availability during the Preliminary Hearing, the parties will present their cases in the following order and on the following days:

Presentation Date	Party Name
1/21/2025	Government
1/22/2025	Hemp for Victory (HFV)
1/23/2025	Cannabis Bioscience International Holdings (CBIH)
1/28/2025	Connecticut Office of the Cannabis Ombudsman (OCO); Ellen Brown; and The DocApp (collectively, OCO. <i>et al.</i>)
1/29/2025	National Cannabis Industry Association (NCIA)
1/30/2025	Village Farms International (VFI)
2/4/2025	The Commonwealth Project (TCP)
2/5/2025	Veterans Initiative 22 (VI22)

2/6/2025	Dr. Ari Kirshenbaum
2/18/2025	Tennessee Bureau of Investigation (TBI)
2/19/2025	International Association of Chiefs of Police (IACP)
2/20/2025	Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)
2/25/2025	Smart Approaches to Marijuana (SAM) and State of Nebraska (NE) (collectively, SAM, et al.)
2/26/2025	Community Anti-Drug Coalitions of America (CADCA)
2/27/2025	Cannabis Industry Victims Educating Litigators (CIVEL)
3/4/2025	Dr. Kenneth Finn
3/5/2025	National Drug and Alcohol Screening Association (NDASA)
3/6/2025	Dr. Phillip Drum

Pursuant to 21 C.F.R. § 1316.44 and 21 C.F.R. § 1316.53, regulatory provisions requiring publication of the time and place of the hearing in the Federal Register are waived.

V. Subpoenas

The parties are advised that any requests for subpoenas¹⁰ are to be filed no later than <u>The</u> <u>Homework Date</u>. Each subpoena shall be completed in advance by the party seeking it, and the completed subpoena shall be filed with this tribunal with a request for issuance.¹¹ As explained during the Preliminary Hearing, the authority of a DEA ALJ's subpoena authority extends only

¹⁰ 21 C.F.R. § 1316.52(d).

¹¹ To the extent that either party seeks to present witness testimony through VTC, the following language should be utilized to compel testimony by virtual attendance in a subpoena: "At the Drug Enforcement Administration Hearing Facility, located at 700 Army Navy Drive, 2nd Floor, Arlington, Virginia, 22202, by **VIRTUAL APPEARANCE** through a link to be furnished by the requesting party n/l/t one (1) day prior to the date and time of your scheduled appearance and testimony. The testimony will be recorded verbatim through a reporting company under contract with the United States Government."

as far as "to the extent necessary to conduct [the] administrative hearing[] pending before him." 21 C.F.R. § 1316.52(d).

The subpoena template may be found on the Office of Administrative Law Judges' website at https://www.dea.gov/administrative-law-judges. Subpoena requests that do not comply with these instructions will be returned to the requestor without further action. The party seeking to secure evidence through the use of a subpoena will be responsible for ensuring proper service.

VI. Motions

In view of the robust level of motion practice that has accompanied prehearing proceedings, as announced at the Preliminary Hearing, the time for seeking relief through motion practice has reasonably passed. The time has come to receive evidence and proceed with the hearing. Any further motions must be accompanied by a request to file out of time and supported by a demonstration of good cause that is likely to be narrowly construed.

VII. E-Filing

All proceedings will be governed by the provisions of 21 C.F.R. §§ 1316.41-1316.68.¹² The parties' attention is specifically directed to 21 C.F.R. § 1316.45, which provides, *inter alia*, that "[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk." In these formal rulemaking proceedings, documents (other than proposed evidentiary exhibits) <u>must be filed electronically</u>. The exclusive method of filing correspondence in these proceedings is as a PDF attachment via email to the DEA Judicial Mailbox (<u>ECF-DEA@dea.gov</u>). The forwarding email on all electronically-filed correspondence must indicate that it was simultaneously served on the opposing parties via email. The Designated Participants must ensure that all documents filed with the DEA Judicial Mailbox are simultaneously served on the Government Mailbox at (<u>dea.registration.litigation@dea.gov</u>). Any request(s) to modify email addresses of a party or counsel must be made on notice to this tribunal and the parties. The email receipt date reflected by the DEA Judicial Mailbox server shall conclusively control all issues related to the date of service of all filed correspondence, provided however, that correspondence received after 5:00

¹² Additional helpful information regarding DEA administrative proceedings may be found at the OALJ website, https://www.dea.gov/administrative-law-judges.

p.m., local Washington, D.C. time, will be deemed to have been received on the following business day. <u>Note</u>: While email is utilized as the method to forward documents for filing—as attachments—no substantive matter communicated through the body of a forwarding email will be considered. The parties are directed to refrain from including social security numbers or personally identifiable information in electronically-filed documents. Proposed exhibits will not be accepted via electronic filing, but must be filed in hard copy and through JEFS as detailed, supra.

Dated: December 4, 2024

JOHN J. MULROONEY, II Chief Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on December 4, 2024, caused a copy of the foregoing to be delivered to the following recipients: (1) Julie L. Hamilton, Esq., Counsel for the Government, via email at julie.l.hamilton@dea.gov; James J. Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; Jarrett T. Lonich, Esq., Counsel for the Government, via email at jarrett.t.lonich@dea.gov; and S. Taylor Johnston, Esq., Counsel for the Government, via email at stephen.t.johnston@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Shane Pennington, Esq., Counsel for Village Farms International, via email at spennington@porterwright.com; and Tristan Cavanaugh, Esq., Counsel for Village Farms International, via email at tcavanaugh@porterwright.com; (4) Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com; William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com; and Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com; (5) Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (6) Andrew J. Kline, Esq., Counsel for Hemp for Victory, via email at AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com; (7) Timothy Swain, Esq., Counsel for Veterans Initiative 22, via email at t.swain@vicentellp.com; Shawn Hauser, Esq., Counsel for Veterans Initiative 22, via email at s.hauser@vicentellp.com; and Scheril Murray Powell, Esq., Counsel for Veteran's Initiative 22, via email at smpesquire@outlook.com; (8) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; (9) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com; (10) David G. Evans, Esq., Counsel for Cannabis Industry Victims Educating Litigators, Community Anti-Drug Coalitions of America, Phillip Drum,

Kenneth Finn, International Academy on the Science and Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (11) Patrick Philbin, Esq., Counsel for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; and Chase Harrington, Esq., Counsel for Smart Approaches to Marijuana, via email at charrington@torridonlaw.com; (12) Eric Hamilton, Esq., Counsel for the State of Nebraska, via email at eric.hamilton@nebraska.gov; and Zachary Viglianco, Esq., for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; (13) Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (14) Gregory J. Cherundolo for Drug Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org and afna.org@gmail.com; (15) Reed N. Smith, Esq., Counsel for the Tennessee Bureau of Investigation, via email at Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; and (16) Matthew Zorn, Esq., Counsel for OCO et al, via email at mzorn@yettercoleman.com.

Quinn Fox Staff Assistant to the Chief Judge Office of Administrative Law Judges