

GOVERNMENT’S COMPLETE LIST OF WITNESSES AND DOCUMENTS

Pursuant to the Tribunal’s December 4, 2024, Prehearing Ruling, the United States Department of Justice, Drug Enforcement Administration (Government or DEA), by and through undersigned counsel, hereby submits the directed complete list of witnesses and documents in the above-captioned matter.

PROPOSED WITNESSES

1. Heather Achbach
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
2. Luli Akinfiresoye, Ph.D.
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
3. Douglas C. Throckmorton, M.D.
Center for Drug Evaluation and Research, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
4. Marta Sokolowska, Ph.D.
Center for Drug Evaluation and Research, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
5. Dominic Chiapperino, Ph.D.
Center for Drug Evaluation and Research Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
6. Patrizia Cavazzoni, M.D.
Center for Drug Evaluation and Research, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SUMMARY OF TESTIMONY

1. Heather Achbach

In addition to the subject and material previously noted by the Government regarding Ms. Achbach's testimony, the Government further notices that Ms. Achbach will testify through declaration, as well as provide testimony at the hearing. Ms. Achbach will also testify as to the manner by which DEA de-duplicated public comments and attachments to the NPRM in an effort to create a universe of only unique comments and attachments in response to the NPRM. The Government requests that Ms. Achbach be given permission to testify via video teleconference, if necessary.

2. Luli Akinfiresoye, Ph.D.

In addition to the subject and material previously noted by the Government regarding Dr. Akinfiresoye's testimony, the Government further notices that Dr. Akinfiresoye will testify through declaration.

3. Douglas C. Throckmorton, M.D. Marta Sokolowska, Ph.D. Dominic Chiapperino, Ph.D. Patrizia Cavazzoni, M.D.

The Government anticipates issuing subpoenas for testimony to the following employees of the Food and Drug Administration: Douglas C. Throckmorton, M.D., Marta Sokolowska, Ph.D. Dominic Chiapperino, Ph.D., and Patrizia Cavazzoni, M.D. It is anticipated that Dr. Throckmorton will be qualified as an expert in the regulation of research, development, manufacture and marketing of prescription controlled substances as well as the benefits of approved drugs outweighing their known risks. It is anticipated that Dr. Sokolowask will be qualified as an expert in drug abuse liability

and scheduling strategies, including on-medical use of substances with abuse potential, science-based assessment and management of drug abuse risks, and shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs. It is anticipated that Dr. Chiapperino will be qualified as an expert in organic chemistry. It is anticipated that Dr. Cavazzoni will be qualified as an expert in psychiatry, mood disorders, and neuropsychopharmacology.

It is anticipated that these witnesses will be able to provide testimony and discuss the scientific and medical evaluations in the HHS Eight Factor analysis that is the basis for the Notice of Proposed Rulemaking, including the novel two factor test applied by HHS for determination of “currently accepted medical use.”

The witnesses will further testify that the Eight Factor analysis consists of evaluating the following for the drug or substance in question:

1. Its actual or relative potential for abuse;
2. Scientific evidence of its pharmacological effect, if known;
3. The state of current scientific knowledge regarding the drug or other substance;
4. Its history and current pattern of abuse;
5. The scope, duration, and significance of abuse;
6. What, if any, risk there is to the public health;
7. Its psychic or physiological dependence liability; and
8. Whether the substance is an immediate precursor of a substance already controlled.

Taking each factor in turn, the Government anticipates the witnesses will testify to the following as to the Eight Factor analysis HHS applied to marijuana:

Factor 1: Marijuana’s Actual or Relative Potential for Abuse

The Government anticipates the witnesses will testify regarding evidence of the hazards of marijuana to individual health and public safety; the potential diversion of marijuana from legitimate drug channels; individuals taking marijuana on their own initiative rather than on the basis of medical advice; and, marijuana’s likelihood of abuse.

Factor 2: Scientific Evidence of Its Pharmacological Effects, If Known

The Government anticipates that the witnesses will discuss the neurochemistry and receptor pharmacology of marijuana, to include, the human behavioral and physical effects of marijuana.

Factor 3: The State of Current Scientific Knowledge Regarding the Drug or Other Substance

The Government anticipates the witnesses will testify to the chemistry of marijuana, the human pharmacokinetics of delta-9 THC, the administration of marijuana into the body, and the distribution, metabolism and excretion of marijuana.

The Government anticipates the witnesses will testify to the currently accepted medical use of marijuana. The Government anticipates the witnesses will testify regarding the widespread current experience with medical use of marijuana, currently a Schedule I controlled substance, in the United States by licensed health care practitioners operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine. Further, the Government anticipates the witnesses will testify regarding state medical marijuana programs.

Factor 4: Its History of Current Pattern of Abuse

The Government anticipates that the witnesses will testify regarding the history and patterns of marijuana use, including in relation to relevant comparator substances. The Government anticipates that the witnesses will testify regarding the considerations of federal and state-level history of marijuana, marijuana sources for nonmedical and medical use, and the current patterns of use and abuse of marijuana.

Factor 5: The Scope, Duration, and Significance of Abuse

The Government anticipates that the witnesses will testify regarding the epidemiological data on consequences of marijuana abuse.

Factor 6: What, if any, Risk There Is to the Public Health

The Government anticipates that the witnesses will testify regarding the considerations of the risks to public health posed by marijuana. The Government anticipates the witnesses will discuss such factors as the epidemiology of risk posed by marijuana to public health, demographics of marijuana use disorder, risk of hospitalization, risks from unintentional-general exposure to marijuana, and the risk of driving under the influence of marijuana. Additionally, the Government anticipates the witnesses will testify regarding the risks to public health posed by marijuana compared to other drugs of abuse.

Factor 7: Its Psychic or Physiologic Dependence Liability

The Government anticipates that the witnesses will testify to the psychic and physical dependence of marijuana, if any.

Factor 8: Whether the Substance is an Immediate Precursor of a Another Controlled Substance

The Government anticipates the witnesses will testify that marijuana is not an immediate precursor of another controlled substance.

DOCUMENTS

Proposed Government Exhibit No. 1: Notice of Proposed Rulemaking, published May 21, 2024 (92 pages).

Proposed Government Exhibit No. 2: Comments Received in Response to Notice of Proposed Rulemaking (11,775 pages).

Proposed Government Exhibit No. 3: Declaration of Ms. Heather Achbach (5 pages).

Proposed Government Exhibit No. 4: Declaration of Dr. Luli Akinfiresoye (4 pages); Attachment 1 to Akinfiresoye Decl. (Akinfiresoye C.V. - 6 pages); Attachment 2 to Akinfiresoye Decl. (Marijuana: Scientific Data Review as it Relates to the Controlled Substances Act - 97 pages).

Proposed Government Exhibit No. 5: HHS, Basis for Recommendation to Place Marijuana in Schedule III of the Controlled Substance Act, dated August 29, 2023 (252 pages).

OTHER MATTERS

The Government is offering the public comments to the NPRM as evidence in this hearing in accordance with the statement made in the NPRM. (“Comments on or objections to the proposed rule submitted under 21 CFR 1308.43(g) will be offered as evidence at the hearing.”) 89 FR 44597, 44598. Due to the importance of having the public comments to the NPRM be admitted into evidence for consideration by the decision makers,¹ but recognizing the

¹ The comments represent the views of the American public and, as stated by the Administrator of the Office of Information and Regulatory Affairs, “[b]roadening ... public participation and community engagement in the regulatory process is ... consistent with this Administration’s priorities on public engagement.” Memorandum from Richard L. Revesz, Administrator, Office of Information and Regulatory Affairs, on Broadening Public Participation and Community Engagement in the Regulatory Process (July 19, 2023), *available at* <https://www.whitehouse.gov/wp-content/uploads/2023/07/Broadening-Public-Participation-and-Community-Engagement-in-the-Regulatory-Process.pdf>.

volume of comments received by DEA to the NPRM, the Government seeks leave to file electronic copies of the comments into evidence, rather than paper hard copies.

Respectfully Submitted,

James J. Schwartz
James J. Schwartz
Jarrett T. Lonich
S. Taylor Johnston
Attorneys | Diversion Section
Drug Enforcement Administration
Office of Chief Counsel
8701 Morrissette Drive
Springfield, VA 22152
James.J.Schwartz@dea.gov

Dated: December 13, 2024

CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2024, I electronically submitted the foregoing GOVERNMENT'S COMPLETE LIST OF WITNESSES AND DOCUMENTS to the DEA Office of the Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, and simultaneously to:

1. 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;
2. Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com;
3. William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com;
4. Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com;
5. John Jones and Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net;
6. Andrew J. Kline, Esq., Counsel for Hemp for Victory, AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com;
7. Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov;
8. Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com;
9. Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com;
10. Jason Castro, Esq., Counsel for The Doc App., Inc. d/b/a My Florida Green, via email at jasoncastro@myfloridagreen.com;
11. Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com;
12. Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com;
13. 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;
14. 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;
15. Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov;

16. 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;
17. Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org;
18. Gregory J. Cherundolo for Drug Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org;
19. 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
20. Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; and
21. Jim Skinner for National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

December 13, 2024

Date

/s/ James J. Schwartz

Signature



U.S. Department of Justice
Drug Enforcement Administration
Office of Chief Counsel

www.dea.gov

Washington, D.C. 20537

December 13, 2024

The Honorable John J. Mulrooney, II
Chief Administrative Law Judge
Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537

**Re: Schedules of Controlled Substances:
Proposed Rescheduling of Marijuana
DEA Docket No. 1362; Hearing Docket No. 22-44**

To the Honorable Judge Mulrooney:

The Government respectfully requests, pursuant to 5 U.S.C. § 555(d), the Controlled Substances Act, 21 U.S.C. §§ 875 and 876 and 21 C.F.R. § 1316.52(d), that Hearing Subpoenas be issued to compel the following individuals to appear and give testimony at the hearing in the above referenced case, scheduled to begin at approximately 9:30 a.m., local time, on Tuesday, January 21, 2025, at the DEA Hearing Facility, 700 Army Navy Dr., Arlington, VA 22202.

The below listed individuals are witnesses identified in the Government's Complete List of Witnesses and Documents filed December 13, 2024. Their testimony is relevant to the proposed rescheduling of marijuana as described in the Government's Complete List of Witnesses and Documents. Specifically, it is anticipated these witnesses will testify regarding the scientific and medical evaluations in the Health and Human Services' (HHS) Eight Factor analysis that is the basis for the Notice of Proposed Rulemaking for the rescheduling of marijuana, including the novel two factor test applied by HHS for determination of "currently accepted medical use."

1. Douglas C. Throckmorton, M.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993.
2. Marta Sokolowska, Ph.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993.
3. Dominic Chiapperino, Ph.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

4. Patrizia Cavazzoni, M.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Please tender the requested subpoenas to the Government for appropriate service. The applicable subpoena forms are attached.

Respectfully Submitted,

James J. Schwartz

James J. Schwartz

CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2024, I electronically submitted the Government's Request for Subpoenas *SCHEDULES OF CONTROLLED SUBSTANCES: PROPOSED RESCHEDULING OF MARIJUANA, DEA DOCKET NO. 1362; HEARING DOCKET NO. 22-44*, to the DEA Office of the Administrative Law Judges *via* the DEA Judicial Mailbox at ECF-DEA@dea.gov and simultaneously to:

1. 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;
2. Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com;
3. William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com;
4. Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com;
5. John Jones and Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net;
6. Andrew J. Kline, Esq., Counsel for Hemp for Victory, AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com;
7. Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov;
8. Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com;
9. Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com;
10. Jason Castro, Esq., Counsel for The Doc App., Inc. d/b/a My Florida Green, via email at jasoncastro@myfloridagreen.com;
11. Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com;
12. Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com;
13. 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;
14. 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;
15. Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov;
16. 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;
17. Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org;

18. Gregory J. Cherundolo for Drug Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org;
19. Reed N. Smith, Esq., Counsel for the Tennessee Bureau of Investigation, via email at
20. Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; and
21. Jim Skinner for National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

James J. Schwartz
James J. Schwartz
Diversion Section
Office of Chief Counsel
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

**U.S. Department of Justice
Drug Enforcement Administration
Office of Administrative Law Judges**



In the Matter of: _____

Docket No. _____

SUBPOENA: *Requesting Testimony* **SUBPOENA DUCES TECUM:** *Requesting the Production of Records or Things*

TO:	<i>(name and address of person being subpoenaed)</i>
At the request of <input type="checkbox"/> Petitioner <input type="checkbox"/> Respondent <i>(party name)</i> _____	<i>(name, address and telephone number of contact person)</i>

You are hereby commanded, business and excuses being set aside, to appear as a witness on:
(date) _____, **at** *(time)* _____, **and then and there to testify at:** *(location)*

You are not required to appear in person if you produce the records described in the accompanying affidavit.
By _____ *(date)*, **send the records to:** *(location)*

You are ordered to appear in person and to produce the records described in the accompanying affidavit. The personal appearance of the custodian or other qualified witness and the production of the original records is required by this subpoena.

Witness Fees: Upon service of this subpoena, you are entitled to witness fees and mileage actually traveled both ways, as provided by law, if you so request. The party serving the subpoena is responsible for the payment of the applicable fees. *See 21 U.S.C. § 876; Fed. R. Civ. P. 45(b)(1).*

This subpoena is issued under the authority of the Administrative Procedure Act, 5 U.S.C. § 555(D), the Controlled Substances Act, 21 U.S.C. §§ 875-876 and 21 C.F.R. § 1316.52(D).

Issued: _____

U.S. Administrative Law Judge

DECLARATION FOR SUBPOENA DUCES TECUM

(Any party issuing a subpoena for production of books and/or records must complete this section.)

The undersigned states that the books, papers, documents and/or other things named below and requested by this subpoena are identifiable, material to the proper presentation of this case, and good cause exists for their production by reason of the following facts:

(Use additional pages, if necessary, and attach them to this subpoena.)

Executed *(day and month)* _____, *(year)* 20____,

at *(time and location)* _____.

I declare under penalty of perjury that the foregoing is true and correct.

(Signature of Declarant)

SERVICE OF SUBPOENA

I hereby certify that being a person over 18 years of age, I duly served a copy of the above subpoena by _____ on the person named herein on the _____ day of _____, 20_____.

(Signature)

(Printed Name)

(Official Title)

**U.S. Department of Justice
Drug Enforcement Administration
Office of Administrative Law Judges**



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You are hereby commanded, business and excuses being set aside, to appear as a witness on:
(date) _____, **at** *(time)* _____, **and then and there to testify at:** *(location)*

You are not required to appear in person if you produce the records described in the accompanying affidavit.
By _____ *(date)*, **send the records to:** *(location)*

You are ordered to appear in person and to produce the records described in the accompanying affidavit. The personal appearance of the custodian or other qualified witness and the production of the original records is required by this subpoena.

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at *(time and location)* _____.

I declare under penalty of perjury that the foregoing is true and correct.

(Signature of Declarant)

SERVICE OF SUBPOENA

I hereby certify that being a person over 18 years of age, I duly served a copy of the above subpoena by _____ on the person named herein on the _____ day of _____, 20_____.

(Signature)

(Printed Name)

(Official Title)

**U.S. Department of Justice
Drug Enforcement Administration
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You are hereby commanded, business and excuses being set aside, to appear as a witness on:

(date) _____, **at** *(time)* _____, **and then and there to testify at:** *(location)*

<input type="checkbox"/>	You are not required to appear in person if you produce the records described in the accompanying affidavit. By _____ <i>(date)</i> , send the records to: <i>(location)</i>
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(Official Title)

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Drug Enforcement Administration
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You are hereby commanded, business and excuses being set aside, to appear as a witness on:

(date) _____, **at** *(time)* _____, **and then and there to testify at:** *(location)*

<input type="checkbox"/>	You are not required to appear in person if you produce the records described in the accompanying affidavit. By _____ <i>(date)</i> , send the records to: <i>(location)</i>
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U.S. Administrative Law Judge

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