

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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| In the matter of |) | | | | |
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| Schedules of Controlled Substances: |) | | | | |
| Proposed Rescheduling of Marijuana |) | | | | |
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DEA Docket No. 1362
Hearing Docket No. 24-44

JOHN J. MULROONEY, II
CHIEF ADMINISTRATIVE LAW JUDGE

GOVERNMENT’S PREHEARING STATEMENT

Respectfully Submitted,

Dated: November 26, 2024

James J. Schwartz
Jarrett T. Lonich
S. Taylor Johnston
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Drug Enforcement Administration
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GOVERNMENT’S PREHEARING STATEMENT

Pursuant to the Tribunal’s November 19, 2024, Order Regarding Standing, Scope, and Prehearing Procedures, the United States Department of Justice, Drug Enforcement Administration (Government or DEA), by and through undersigned counsel, hereby submits the ordered Prehearing Statement in the above-captioned matter.

PROPOSED WITNESSES¹

1. Heather Achbach
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
2. Luli Akinfiresoye
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

SUMMARY OF TESTIMONY

1. **Heather Achbach**

Ms. Achbach will testify that she is currently Acting Section Chief of the Regulatory Drafting and Policy Support Section (DPW) of DEA’s Diversion Control Division. She will testify that she has been designated to act as the DEA Federal Register Liaison Officer to the Office of the Federal Register. In that capacity, she is authorized to sign and submit documents to the Office of the Federal Register as official documents of DEA.

¹ DEA made a request to the Department of Health and Human Services (HHS) and its operating division, the Food and Drug Administration (FDA), to provide witnesses to testify before the Tribunal regarding 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.” HHS rejected DEA’s request for witnesses from HHS (or its operating divisions). In the event DEA determines it is necessary to subpoena a witness or witnesses from HHS (or its operating divisions), DEA respectfully requests to reserve the ability to add that witness in a supplemental filing.

Ms. Achbach will testify that on May 21, 2024, a Notice of Proposed Rulemaking (NPRM) was published in the Federal Register, on behalf of DEA, proposing that marijuana be rescheduled under the Controlled Substance Act (CSA) from its current designation in Schedule I to Schedule III.

Ms. Achbach will testify that the NPRM permitted interested persons to file written comments on the proposed rescheduling action. She will testify that such comments could be submitted electronically through the Federal eRulemaking Portal (www.regulations.gov) or in paper directly to DEA. Ms. Achbach will testify that the deadline to file written comments was July 22, 2024. Ms. Achbach will authenticate and introduce a copy of the NPRM.

Ms. Achbach will testify that DEA received approximately 43,564 electronic comments and additional paper comments on the proposed rescheduling. Ms. Achbach will authenticate and introduce copies of the electronic and paper comments received by DEA in response to the NPRM.

Ms. Achbach will testify that during the rescheduling and rulemaking process, comments serve an important role in informing DEA of potential issues and of information the Agency may lack. She will further testify that the Agency does not provide any responses or guidance to the comments at the interim stage of the rescheduling or rulemaking process. She will testify that DEA provides its response to comments in the final published rule, which can include grouping the comments into categories and responding to those categories. She will further testify that the responses to comments in the final rule express DEA's official view as, in the usual course, the final rule is signed by the Administrator or the Administrator's designee.

2. Luli Akinfiresoye, Ph.D.

The Government anticipates that Dr. Akinfiresoye will testify either in person or directly by declaration, pursuant to 21 C.F.R. § 1316.58(b). Dr. Akinfiresoye will testify about her background and experience, including her experience with DEA. Dr. Akinfiresoye will testify that she is currently a pharmacologist in the Drug and Chemical Evaluation Section (DOE) of DEA's Diversion Control Division. Dr. Akinfiresoye will testify that, in her role with DOE, she is familiar with the fact that the Department of Health and Human Services submitted an 8-Factor Analysis (8FA) to support the rescheduling of marijuana from Schedule I to Schedule III and that the HHS 8FA is documented within the NPRM. Dr. Akinfiresoye will testify that DEA also regularly conducts its own 8FA regarding controlled substances and other substances. She will testify on the process by which DEA constructs its 8FA and what data DEA uses as part of that process.

Dr. Akinfiresoye will also testify that she is aware that the NPRM specifically seeks additional data upon which DEA can rely in making its determination as to whether marijuana should be rescheduled. Dr. Akinfiresoye will testify that, in her role with DEA, she and her DOE colleagues, regularly review the available scientific, medical, technical, and abuse-related information regarding controlled substances. In that role, Dr. Akinfiresoye will testify that DEA has accumulated and continues to accumulate data, studies and other information regarding marijuana. Dr. Akinfiresoye will testify that DEA has maintained an active review of the scientific, medical, and technical literature addressing marijuana with a focus on how it relates to the eight factors relevant to the control under the CSA. Dr. Akinfiresoye will testify regarding information within DEA's current state of knowledge, including the additional factual evidence noted above. Specifically, she will testify and provide data, studies and other information on the following topics identified by the NPRM:

- Marijuana’s Actual or Relative Potential for Abuse, including:
 - DEA collection of data regarding seizures of marijuana by law enforcement, additional data related to cannabis-related ED visits, as well as updated epidemiological survey data since 2022. 89 Fed. Reg. 44,597, 44,602 (2024).
 - additional data on diversion from State programs and DEA-registered manufacturers. 89 Fed. Reg. 44,597, 44,602 (2024).
- Scientific Evidence of Marijuana’s Pharmacological Effects. 89 Fed. Reg. 44,597, 44,605 (2024).
- The State of Current Scientific Knowledge Regarding Marijuana.
 - Specifically, additional data on other marijuana constituents, routes of administration or marijuana, and the impact on delta-9-tetrahydrocannabinol (Δ 9-THC) potency. 89 Fed. Reg. 44,597, 44,607 (2024).
- Marijuana’s History and Current Pattern of Abuse. 89 Fed. Reg. 44,597, 44,610 (2024).
- The Scope, Duration, and Significance of Abuse. 89 Fed. Reg. 44,597, 44,613 (2024).
- What, if Any, Risk There Is to the Public Health, including:
 - Additional data on public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of Δ 9-THC potency. 89 Fed. Reg. 44,597, 44,614 (2024).
- Marijuana’s Psychic or Physiological Dependence Liability. 89 Fed. Reg. 44,597, 44,615 (2024).

DOCUMENTS²

Proposed Government Exhibit No. 1: Notice of Proposed Rulemaking, published May 21, 2024 (26 pages)

Proposed Government Exhibit No. 2: Comments Received in Response to Notice of Proposed Rulemaking

Proposed Government Exhibit No. 3: Declaration of Ms. Luli Akinfiresoye

Proposed Government Exhibit No. 4: Ms. Luli Akinfiresoye C.V. (7 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); posted to regulations.gov in support of NPRM.

GOVERNMENT COUNSEL AND WITNESS NON-AVAILABILITY

The Government hereby provides notice that its counsels and witnesses have the following dates of conflict:

- 2024
 - *December 20-31*
- 2025
 - *January 1-3*
 - *January 13-17*
 - *January 14-16*
 - *January 27-31*
 - *March 5-14*
 - *March 24-28*

² The Government is still compiling documentation for this Matter and anticipates additional exhibits. The Government will provide an updated and accurate exhibit list in a supplemental filing at a date set by this Tribunal.

OTHER MATTERS

The Government reserves the opportunity to amend its instant pleading at a time and date specified by this Tribunal. The Government also requests that all notices in this matter be sent to James.J.Schwartz@dea.gov, Jarrett.T.Lonich@dea.gov, and Stephen.T.Johnston@dea.gov in addition to dea.registration.litigation@dea.gov.

Respectfully Submitted,

James J. Schwartz

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Jarrett T. Lonich

S. Taylor Johnston

Attorneys | Diversion Section

Drug Enforcement Administration

Office of Chief Counsel

8701 Morrisette Drive

Springfield, VA 22152

James.J.Schwartz@dea.gov

Dated: November 26, 2024

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2024, I electronically submitted the foregoing Government’s Prehearing Statement to the DEA Office of Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, and to caused a copy to be delivered to the following recipients: Shane Pennington for Village Farms International, via email at spennington@porterwright.com; Aaron Smith for National Cannabis Industry Association, via email at aaron@thecannabisindustry.org and michelle@thecannabisindustry.org; John Jones for Cannabis Bioscience International Holdings, via email at ir@cbih.net; Robert Head for Hemp for Victory, via email at robert@bluecordfarms.com; Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov; mzorn@yettercoleman.com; Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com; Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com, t.swain@vicentellp.com; Jason Castro for The Doc App. Db, My Florida Green, via email at jasoncastro@myfloridagreen.com; Katy Green for The Commonwealth Project, via email at kag@platinumadvisors.com; Ari Kirshenbaum for Saint Michael’s College, via email at msslade@cannabispublicpolicyconsulting.com; Jo McGuire for National Drug and Alcohol Screening Association, via email at jomcguire@ndasa.com; Patrick Philbin for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; Roneet Lev for International Academy on the Science and Impact of Cannabis, via email at roneetlev@gmail.com; David Evans for Cannabis Industry Victims Educating Litigators, via email at thinkon908@aol.com; Kenneth Finn, via email at kfinn@springsrehab.net; Jennifer Homendy for National Transportation Safety Board, via email at executivesecretariat@ntsb.gov and correspondence@ntsb.gov; Phillip Drum, via email at phillipdrum@comcast.net; Attorney General Mike Hilgers for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; International Association of Chiefs of Police, via email at voegtlin@theiacp.org; Drug Enforcement Association of Federal Narcotics Agents, via email at marshallfisher@rocketmail.com; Sue Thau for Community Anti-Drug Coalitions of America, via email at cdoarn@cadca.org; Tennessee Bureau of Investigation, via email at kim.litman@tbi.tn.gov.

November 26, 2024
Date

/s/ James J. Schwartz
Signature