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**

PREHEARING STATEMENT FOR THE STATES OF NEBRASKA, IDAHO, AND INDIANA

Pursuant to the Preliminary Order of June 18, 2026, Designated Parties the States of Nebraska, Idaho, and Indiana (the "Opposed States") hereby submit this Prehearing Statement in advance of the hearing in the above-captioned matter currently scheduled to commence on June 29, 2026.

I. ADDRESS, PHONE NUMBER, AND MISSION OF OPPOSED STATES

The principal mission of each Opposed State is to secure the public health, safety, morals, and welfare of their citizens through legislation, law enforcement, courts, and public administration. To promote that mission, each Opposed State prohibits or severely restricts the availability of marijuana within its borders, as marijuana causes our citizens psychiatric harm and is linked to increases in homelessness, traffic accidents, illegal drug trafficking, and other crime.

The Opposed States' addresses and phone numbers are as follows:

Nebraska Department of Justice
1445 K Street
Suite 2115
Lincoln, NE 68066
Phone: (402) 471-2683

Indiana Office of the Attorney General
302 W. Washington St., 5th Floor
Indianapolis, IN 46204
Phone: (317) 232-6201

Idaho Office of the Attorney General
700 West Jefferson Street
P.O. Box 83720
Boise, ID 83720-0010
Phone: (208) 334-2400

II. CURRENT ADDRESS OF OPPOSED STATES' WITNESSES

Both of Opposed States' witnesses are appearing voluntarily and do not require a subpoena:

Deepak Cyril D'Souza's address is Psychiatry Service 116A, VA Connecticut Healthcare System, 950 Campbell Avenue, West Haven, CT 06516

Sheriff William F. Honsal's address is 826 Fourth Street, Eureka CA 95501

III. OPPOSED STATES' WITNESS AND SUMMARY OF ANTICIPATED TESTIMONY.

A. Dr. Deepak Cyril D'Souza

Dr. Deepak Cyril D'Souza is the Vikram Sodhi '92 Professor of Psychiatry at Yale School of Medicine and the inaugural Director of the Yale Center for the Science of Cannabis and Cannabinoids. He is an internationally recognized expert on the neuropsychiatric effects of cannabis and cannabinoids. For nearly three decades, he has conducted clinical and translational research examining the acute and chronic effects of Δ9-tetrahydrocannabinol (THC) and other cannabinoids on cognition, psychosis, addiction, and brain function. His research spans controlled human laboratory studies, clinical trials, neuroimaging, electrophysiology, and epidemiology. He has authored more than 250 peer-reviewed scientific publications in leading medical and psychiatric journals. He is the editor of the book MARIJUANA AND MADNESS (3rd edition), a comprehensive, evidence-based, and timely resource on the relationship between marijuana and psychiatric illnesses. He also serves on the Physicians Advisory Board for the State of Connecticut's Medical Marijuana Program.

Dr. D'Souza is expected to testify regarding the pharmacology of cannabis and cannabinoids and the effects of THC on cognition, perception, behavior, and brain function.

He is expected to testify regarding the abuse liability of cannabis, drawing upon evidence from controlled human laboratory studies, brain imaging, and epidemiologic research. The available scientific evidence demonstrates that regular cannabis use can lead to cannabis use disorder in a substantial proportion of users. Compounding this problem is the current absence of FDA-approved pharmacological treatments for cannabis use disorder and limited efficacy of nonpharmacological treatments.

He is expected to summarize the scientific evidence regarding the principal public health risks associated with cannabis use, including:

(1) an increased risk of serious mental illnesses, particularly psychotic disorders in susceptible individuals;

(2) cannabis use disorder and addiction;

(3) driving impairment;

(4) adverse effects of cannabis exposure during adolescence and pregnancy on neurodevelopment; and

(5) acute and chronic impairments in learning, memory, and other cognitive functions.

Dr. D'Souza is expected to explain that these risks are influenced by factors including age at exposure, frequency of use, cannabis potency (THC content), route of administration, cumulative exposure, and individual susceptibility.

Dr. D'Souza is also expected to testify regarding the current evidence supporting the therapeutic use of cannabis and cannabinoid-based products for psychiatric disorders. Based on systematic reviews of randomized clinical trials, including reviews authored by his group and others, he is expected to testify that there is currently limited high-quality evidence supporting the efficacy of cannabis or cannabinoid products for the treatment of psychiatric disorders including

anxiety disorders, post-traumatic stress disorder, and depression. He is expected to explain that while many individuals report using cannabis to relieve stress, anxiety, sleep disturbance, pain, nausea, and other symptoms, most of the available evidence derives from observational studies rather than adequately powered randomized controlled trials. Accordingly, anecdotal reports and observational findings should not be equated with evidence of efficacy from well-controlled clinical trials, which are the gold-standard in the FDA approval process. Dr. D'Souza is also expected to testify that cannabis use in individuals with serious mental illness is associated with poorer clinical outcomes, including greater symptom severity, higher relapse rates, and worse functional outcomes.

Dr. D'Souza is expected to testify that cannabis and cannabinoid-based products, when proposed for therapeutic use, should be evaluated using the same scientific standards of safety and efficacy that are applied to all other medications, with regulatory and clinical decisions guided by the totality of the available scientific evidence.

B. Sheriff William F. Honsal

Born and raised in Humboldt County, Sheriff Honsal has served as the Sheriff of Humboldt County for almost a decade. In addition to his role as Sheriff, Honsal serves as a member of the Board of Directors and Tribal Liaison for the California State Sheriff's Association. He is actively involved in various organizations, including the Marijuana Impact Group for the High Intensity Drug Trafficking Areas (HIDTA) federal grant program and the Northern California Coalition to Safeguard Communities, on which he serves as president.

Sheriff Honsal is expected to testify that he has worked in law enforcement for approximately 31 years and has observed the evolution of marijuana cultivation and trafficking in California from a period when marijuana was entirely illegal to the present era of broad

legalization. Based on his experience, he believes that legalization and changes in marijuana laws contributed to a significant expansion of the illicit marijuana market rather than its elimination.

Sheriff Honsal is expected to testify that Humboldt County has long been a center of marijuana cultivation. During the 1960s and 1970s, members of the "back-to-the-land" movement relocated from urban areas, including San Francisco, to the rural and mountainous regions of Humboldt County where land was inexpensive and abundant. Many established self-sufficient farms and began cultivating marijuana for personal use. Over time, growers began selling marijuana in urban markets to support their lifestyles, and subsequent generations expanded cultivation operations to increase production and profits.

Sheriff Honsal is expected to testify that Humboldt County, together with Trinity and Mendocino Counties, became known as the "Emerald Triangle," which developed into the nation's primary source of illegally cultivated marijuana. Although federal and state agencies devoted substantial enforcement resources to the region during the 1980s, enforcement efforts were hindered by the area's vast geography, mountainous terrain, and sparse population. According to the Sheriff, Humboldt County alone encompasses approximately 4,000 square miles, making detection and enforcement difficult. The combined square miles and population of the "Emerald Triangle are approximately 11,000 square miles and 235,000 people. Massachusetts has roughly 30 times more people in about the same land/total.

Sheriff Honsal is expected to testify that California Proposition 215, enacted in 1996, was a turning point. Proposition 215 created a medical marijuana defense under California law and, in his view, opened the door to widespread abuse. He testified that the resulting "Green Rush" attracted individuals from across the United States to Humboldt County, as well as organized criminal groups, including Bulgarian, Chinese, and Russian organizations. These groups

purchased property throughout Northern California and used medical marijuana laws as cover for large-scale cultivation operations supplying national and international markets.

According to the Sheriff, marijuana prices during the height of the market reached approximately $5,000 per pound, creating substantial financial incentives for illegal cultivation. Despite conducting as many as 120 search warrants annually, law enforcement estimated that there were approximately 10,000 illegal grow sites in the county based on satellite imagery and other investigative methods.

Sheriff Honsal is expected to testify that the medical marijuana framework was frequently exploited by criminal enterprises. Because healthcare providers issued "recommendations" rather than prescriptions, there were no meaningful limits on dosage or quantity. He can testify that some recommendations authorized extraordinarily large quantities of marijuana. Some growers claimed authority to cultivate as many as 99 plants per patient and that individual plants could yield from one-quarter pound to as much as four pounds of marijuana. He will testify that there are cultivation sites capable of producing thousands of pounds of marijuana annually, particularly through indoor growing operations that can complete five or six harvest cycles each year.

The Sheriff is expected to testify that, once marijuana ceased being categorically illegal, criminal organizations exploited perceived loopholes in the medical marijuana laws to mass-produce marijuana for interstate and international distribution.

Sheriff Honsal is expected to testify concerning violence and labor exploitation associated with illegal marijuana cultivation. Many grow sites are located on large, remote parcels ranging from 40 to 160 acres, often behind locked gates, with limited access, poor communications, and no cellular service. As a result, violent crimes occurring on such properties may go unreported.

He will also testify that that gunfire is common in some cultivation areas and that authorities may never learn of many crimes occurring there.

Sheriff Honsal is expected to testify about specific investigations that, in his view, illustrate the dangers associated with illegal marijuana operations. In one homicide case, an operator allegedly brought laborers, including Guatemalan nationals who had entered the country illegally, to work at a cultivation site. On payday, the operator shot one worker and killed him, shot another worker through the face, and a third worker fled the scene.

In another investigation, law enforcement discovered approximately fifteen Central American individuals who had allegedly been transported illegally to work at a large cultivation compound resembling a small village. Workers were not permitted to leave the property and were paid pennies on the dollar. He will explain that loosening restrictions on marijuana lowers the price and increases the need for exploited labor.

The Sheriff testified regarding the involvement of organized criminal groups in marijuana cultivation. He will testify about a large Bulgarian criminal organization that allegedly purchased substantial amounts of property in the region and concealed illegal operations behind medical marijuana laws. He further recalled an investigation in which federal agents allegedly intercepted and tracked a contract killer traveling from Chicago to Humboldt County to carry out a murder connected to marijuana-related activities.

Finally, the Sheriff will testify that violence is common both at marijuana cultivation sites and during marijuana sales transactions. In his experience, violence is driven by financial motives and is frequently used by organized crime groups and drug trafficking organizations to control workers, eliminate competition, and protect profits. Based on his law enforcement experience, the

Sheriff will testify that that during the green rush approximately half of the homicides occurring in Humboldt County are attributable to the marijuana trade.

C. Rebuttal Testimony

As noted above, Opposed reserves the right to have Dr. D'Souza or Sheriff Honsal offer rebuttal testimony controverting the claims, opinions, and/or documentary evidence introduced by the Government or its witnesses.

D. Reservation of Rights

Opposed States reserve all rights to address additional points in response to the Government's presentation and this summary shall not operate as a waiver, limitation, or forfeiture of any argument, objection, testimony, evidence, or position that may be raised or offered at the hearing.[1]

IV. DOCUMENTARY EVIDENCE

Opposed States intend to submit into evidence the following exhibits:

Description	Length	Designation
Marijuana and Madness (3rd ed.), Cambridge University Press (2023)	39 pages	States-Exh. No. 1
Cannabis, cannabinoids and psychosis: a balanced view, World Psychiatry (2023)	2 pages	States-Exh. No. 2
The Psychotomimetic Effects of Intravenous Delta-9-Tetrahydrocannabinol in Healthy Individuals: Implications for Psychosis, Neuropsychopharmacology (2004)	15 pages	States-Exh. No. 3
Psychosis-Relevant Effects of Intravenous Delta-9-Tetrahydrocannabinol: A Mega Analysis of Individual Participant-Data from Human Laboratory Studies, International Journal of Neuropsychopharmacology (2020	12 pages	States-Exh. No. 4

[1] Opposed States reserve all rights to present any constitutional challenges to this Tribunal's authority, including claims under the Appointments Clause of Article II, *see Lucia v. SEC*, 585 U.S. 237 (2018), to any appropriate forum including to the Administrator and to the U.S. Court of Appeals for the D.C. Circuit.

Description	Length	Designation
Dose-Related Modulation of Event-Related Potentials to Novel and Target Stimuli by Intravenous Δ9-THC in Humans, Neuropsychopharmacology (2012)	15 pages	States-Exh. No. 5
Delta-9-Tetrahydrocannabinol Effects in Schizophrenia: Implications for Cognition, Psychosis, and Addiction, Biological Psychiatry (2005)	15	States-Exh. No. 6
Characterizing psychosis-relevant phenomena and cognitive function in a unique population with isolated, chronic and very heavy cannabis exposure, Psychological Medicine (2019)	8 pages	States-Exh. No. 7
Cannabis and Psychosis: Recent Epidemiological Findings Continuing the "Causality Debate", American Journal of Psychiatry (2022)	3 pages	States-Exh. No. 8
Cannabis and Psychosis: Recent Epidemiological Findings Continuing the "Causality Debate", American Journal of Psychiatry (2022)	11 pages	States-Exh. No. 9
Myran, Pugliese, Harrison, Solmi, Anderson, Fiedorowicz, et al., *Changes in Incident Schizophrenia Diagnoses Associated With Cannabis Use Disorder After Cannabis Legalization*, JAMA Network Open (2025)	15 pages	States-Exh. No. 10
Consensus paper of the WFSBP task force on cannabis, cannabinoids and psychosis, The World Journal of Biological Psychiatry (2022)	25 pages	States-Exh. No. 11
Preliminary in vivo evidence of lower hippocampal synaptic density in cannabis use disorder, Molecular Psychiatry (2020)	9 pages	States-Exh. No. 12
Rapid Changes in CB1 Receptor Availability in Cannabis Dependent Males after Abstinence from Cannabis, Biological Psychiatry: Cognitive Neuroscience and Neuroimaging (2016)	17 pages	States-Exh. No. 13
Cannabis and Driving, Frontiers in Psychiatry (2021)	17 pages	States-Exh. No. 14
Cannabis and Mental Health: A Review, JAMA Internal Medicine (2026)	11 pages	States-Exh. No. 15
Hsu, Shah, Jordan, Gold & Hill, *Therapeutic Use of Cannabis and Cannabinoids: A Review*, JAMA (2026)	15 pages	States-Exh. No. 16

Description	Length	Designation
Marijuana Legalization: Impact on Physicians and Public Health, Annual Review of Medicine (2016)	16 pages	States-Exh. No. 17
D'Souza, D. C., & Ranganathan, M. (2015). Medical marijuana: is the cart before the horse?. *Jama*, *313*(24), 2431-2432.	2 pages	States-Exh. No. 18
Wilkinson & D'Souza, *Problems With the Medicalization of Marijuana*, JAMA (2014)	2 pages	States-Exh. No. 19

June 24, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on June 24, 2026, I caused a copy of the foregoing document to be delivered by email to the following recipients:

1. 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;
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    a. Jacob Durst, Esq., at jacob.durst@ag.tn.gov;
4. Smart Approaches to Marijuana, by email to
    a. Patrick F. Philbin, Esq., at pphilbin@torridonlaw.com;
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    c. Chase T. Harrington, Esq., at charrington@torridonlaw.com;
5. The States of Nebraska, Idaho, Indiana, and Louisiana, by email to
    a. Zachary Pohlman, Esq., at zachary.pohlman@nebraska.gov;
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c. Blake Lanning, Esq., at Blake.Lanning@atg.in.gov;

d. Zachary Faircloth, Esq., at FairclothZ@ag.louisiana.gov;

6. DUID Victim Voices, by email to

a. Ed Wood, at edwood27@icloud.com;

b. Patrick D. Kenneally, Esq., at patrick.kenneally@burkegroup.law;

c. Connor Mighell, Esq., at connor.mighell@burkegroup.law;

7. 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;

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

June 24, 2026

Zachary B. Pohlman
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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**

PREHEARING STATEMENT OF SMART APPROACHES TO MARIJUANA

Pursuant to the Preliminary Order of June 18, 2026, Designated Party SAM, Inc. (d/b/a Smart Approaches to Marijuana, hereinafter "SAM") hereby submits this Prehearing Statement in advance of the Hearing in the above-captioned matter currently scheduled to commence on June 29, 2026.

I. ADDRESS, PHONE NUMBER, AND MISSION OF SMART APPROACHES TO MARIJUANA

SAM is a Virginia non-profit corporation whose mission is to combat marijuana abuse and addiction. SAM provides educational services to decision-makers, drug-prevention and addiction-recovery organizations, parents, and individuals affected by marijuana, including addiction-prevention training, policy education, and victim advocacy support. SAM also provides services to schools, parents, and individuals affected by marijuana, including addiction-prevention training and grief counseling. Among other things, SAM visits high schools to equip students and teachers with strategies to prevent marijuana addiction, and coordinates a nationwide Parent Action Network providing support services to parents of addicted children.

SAM's location and contact information is:

SAM, Inc.
c/o Luke Niforatos, Executive Vice President
107 S West St Suite 757

Alexandria, VA 22314
(202) 856-3308
Luke@learnaboutsam.org

II. CURRENT ADDRESS OF SAM'S WITNESSES

Dr. Bertha Madras's current address is McLean Hospital, 115 Mill Street, Belmont, MA 02478.

SAM respectfully requests a subpoena to compel attendance of Dr. Akinfiresoye. Dr. Akinfiresoye's current address is Drug & Chemical Evaluation Section, 8701 Morrissette Drive Springfield, VA 22152. Once the subpoena is issued, counsel for the Government has confirmed that they will route the subpoena to Dr. Akinfiresoye.

III. SAM'S WITNESS AND SUMMARY OF ANTICIPATED TESTIMONY.

SAM intends to call Dr. Bertha K. Madras, Ph.D., a Professor in the Department of Psychiatry at Harvard Medical School, to testify as an expert witness. Dr. Madras is an expert in the science of addiction and the effects of addictive substances on the brain. She previously served as the Deputy Director for Demand Reduction in the White House Office of National Drug Control Policy. The Department of Justice called Dr. Madras in *United States v. Schweder*, No. 2:11-cv-00449-KJM-16 (E.D. Cal. 2014) as its sole expert witness to defend the designation of cannabis as a Schedule I controlled substance.

SAM also intends to call Dr. Luli R. Akinfiresoye to testify as an expert witness. Dr. Akinfiresoye received a Bachelor of Science in biochemistry from Temple University in 2007, a Master of Arts in Clinical Chemistry from the University of Scranton in 2009, and Ph.D. in Pharmacology from Howard University College of Medicine in 2013. She has been employed by DEA since 2015 and was a witness for the Government at the prior rescheduling hearing (No. 24-44).

A. Summary of Dr. Madras's Testimony

Based on her years of research on addictive substances and review of the available scientific and medical literature on marijuana, Dr. Madras will testify that marijuana (1) has a high potential for abuse, (2) has no currently accepted medical use, and (3) lacks accepted safety for use under medical supervision, and thus does not meets the statutory standard for classification in any schedule other than Schedule I of the Controlled Substances Act. *See* 21 U.S.C. § 812(b). On these points, Dr. Madras will address both the current state of scientific knowledge on marijuana and the shortcomings in HHS's analysis of the medical utility of marijuana in its August 2023 Memorandum recommending rescheduling.[1] She may also offer rebuttal testimony to the claims, opinions, and documentary evidence introduced by the Government's witnesses.

Set forth below is a more detailed description of Dr. Madras's anticipated testimony, including references to the statutory factors that DEA is required to consider when scheduling or rescheduling a controlled substance.

1. Marijuana Has an Extremely High Potential for Abuse, Both on a Stand-Alone Basis and When Compared to Other Drugs.

Dr. Madras will testify that marijuana abuse and addiction are profound societal problems, far exceeding the rates (number of new users each year) and prevalence posed by other controlled substances. She will further testify that the consequences of addiction pose numerous health hazards, which rescheduling will only increase and exacerbate by reducing restrictions and thereby making marijuana more available. And not just to users, but to the people in close proximity to them, as well. These hazards and health risks are particularly grave as to specific vulnerable populations such as adolescents and developing fetuses.

a. Marijuana Poses Grave Risk of Dependence Liability in

[1] *See* Memorandum for DEA, from HHS, Re: Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act [hereinafter "HHS Recommendation"] (Aug. 29, 2023).

Comparison to Other Drugs.[2]

Dr. Madras will testify that current scientific research on marijuana demonstrates that its regular use—regardless of purpose, *e.g.*, medical, recreational, or other—carries an extremely high degree of liability for a use disorder, characterized by, among other things, loss of control, the inability to discontinue use, and behavioral consequences. Am. Psychiatric Ass'n, *DSM-5-TR* at 575–76 (5th ed. 2022). This is known as Cannabis Use Disorder (CUD), a clinical condition characterized by a spectrum of symptoms with considerable impairment.

As Dr. Madras will testify, the prevalence of CUD far exceeds the prevalence of addiction associated with other illicit substances. Indeed, as Dr. Madras will explain, the proportion of marijuana users who consume daily is similar to the percentage of heroin users who use heroin daily, higher than those who consume alcohol, and much higher than the daily use rate for those who use psychedelics or cocaine.

As Dr. Madras will further testify, CUD is a particularly pronounced problem among adolescents and young adults, and, indeed, youth are developing CUD at twice the rate of adults. Citing NSDUH statistics, she will show that CUD is more prevalent among adolescents 12–17 years (4.7% or 1.2 million teens) and among young adults (15.8% or 5.5 million people) than for alcohol use disorder (12–17 years old: 3% = 775,000) and young adults 18–25 (14.4% = 5 million). She will also opine that among all controlled substances, marijuana has by far the greatest number of new users each year, inasmuch as past-year new marijuana users number 3.7 million, 53% of whom started before 21 years old, with corresponding values for legal alcohol (4.2 million), pain relievers

[2] Dr. Madras's expert opinion on this subject will address the dependence liability and the abuse risks of cannabis, and thus will speak directly to factors 1, 2, 3, and 7 under 21 U.S.C. § 811.

(1.3 million), and hallucinogens (1.4 million) showing lower prevalence. For all the other drugs in Schedule I or II, the number of new users is less than 1 million.

This rate of abuse represents a dramatic increase in recent decades. As recently as 1994, the rate of use disorder for marijuana was only 9%, or below that of other illicit substances. She will explain that marijuana's increasing potency, greater access, and accessibility may be contributing to increased rates of marijuana dependence. Critically, she will testify that marijuana's dependence liability will grow worse if marijuana is transferred to Schedule III. She will explain how cross-breeding the different subspecies of marijuana is creating enormous variability in the chemical composition of botanical marijuana and increasing the concentration of delta-9-tetrahydrocannabinol (THC, the psychoactive, addictive cannabinoid) relative to cannabidiol (CBD). She will also summarize the current state of scientific research, which shows that: (i) marijuana carries significant risk of psychological and physical dependence; (ii) meta-analyses are increasingly equivocal about the benefits of marijuana; and (iii) the evidence of marijuana use having numerous health hazards is becoming stronger.

Finally, Dr. Madras will explain that HHS erred in failing to make comparisons of abuse potential with other Schedule I drugs with low rates of overdose death but with myriad other health impacts: namely, MDMA and LSD, among other hallucinogens and inhalants.

b. Marijuana Poses Serious Risks to Public Health.[3]

Dr. Madras will testify that marijuana poses numerous health hazards, and rescheduling will make those hazards more widespread by removing restrictions on marijuana commerce and by extending tax benefits to the marijuana industry, both of which will increase availability and consumption of marijuana.

[3] *See* 21 U.S.C. 811(c)(6).

First, marijuana use dramatically increases the risk of psychiatric problems. As Dr. Madras will testify, there is an emerging medical consensus that marijuana use plays a causal role (a component cause) in the development of psychosis and schizophrenia: According to the National Institutes of Health, marijuana users have psychotic disorders at a greater rate than any other recreational drug, including cocaine, methamphetamine, LSD, or PSP. While all drugs carry some degree of risk, marijuana has the highest conversion rate from psychosis to schizophrenia and bipolar disorder, and is also strongly associated with suicide.

Separate and apart from the psychiatric problems associated with marijuana use—*i.e.*, those related to a person's ability to perceive reality—are its related cognitive impairments, such as memory deficits, lowered IQ, and diminished academic performance. On this subject, Dr. Madras will testify that marijuana use also entails loss of IQ, poorer performance on attentional functioning, slower processing speed, and poorer verbal learning and memory. She will opine that the evidence suggests that age of onset, frequency of marijuana use, THC (but not CBD) content, and cumulative marijuana exposure can all contribute to these adverse outcomes in individuals without a known pre-existing medical condition or psychiatric disorder.

Dr. Madras will testify that marijuana use also carries risks to physical health (cardiovascular and pulmonary health) and can cause cyclical and severe nausea, vomiting, and intense abdominal pain among daily, long-term high-potency marijuana users—a condition referred to as cannabis hyperemesis syndrome. This condition can be life-threatening.

As to adolescents in particular, marijuana use has been linked to changes in brain structure, can produce negative effects on cognition, and is associated with lower educational achievement in high school and college. Dr. Madras will also explain that adolescents and young adults using marijuana are at a higher risk of developing psychiatric symptoms, including anxiety, depression,

and psychosis, worsening symptoms of schizophrenia, and risk of suicide. Marijuana use is related to poorer performance on measures of attentional functioning, and adolescent marijuana users have demonstrated, among other things, lifelong cognitive deficits.

Rescheduling marijuana will increase the risk of children being exposed to marijuana in utero. Dr. Madras will explain that marijuana use while pregnant results in higher risk of cesarean delivery, a higher risk of delivering a small-for-gestational-age infant with smaller head circumference, a higher risk of requiring admission into a neonatal intensive care unit, and higher risk of supplemental oxygen use at birth. She will also opine that THC passes the placental barrier during pregnancy and is associated with greater offspring psychopathology characteristics (psychotic-like experiences, internalizing, externalizing, attention, thought, and social problems), sleep problems, and increased body mass index, as well as lower cognition and gray matter volume.

Dr. Madras will explain that HHS's comparator analysis was flawed. HHS contrasted marijuana with potentially lethal substances, such as opioids and psychostimulants, while overlooking the growing evidence linking marijuana use and CUD with severe, disabling, chronic and sometimes fatal outcomes: risk of suicide, psychosis, schizophrenia, bipolar disorder, cognitive/memory impairment and reduced IQ, violence, childhood poisonings, amotivational syndrome, increased school absenteeism, school dropout, and reduced likelihood of obtaining high academic grades, graduating high school, enrolling in university, and obtaining postsecondary degrees, among other adverse behavioral sequalae. Dr. Madras will explain that using alcohol as a comparator to justify rescheduling marijuana is deeply flawed. She will also explain that, even if alcohol were a sound comparator, the rate of marijuana abuse is rapidly approaching that of alcohol. She will explain that recent data shows past-year, past-month, and daily marijuana use is increasing. She will also explain that marijuana abuse by adolescents is steadily increasing.

Dr. Madras will testify that marijuana-involved emergency department mentions have risen dramatically over the past decade, far more so than for alcohol, while emergency-department mentions have decreased for cocaine, another comparator.

2. Marijuana Does Not Have A "Currently Accepted Medical Use" or Accepted Safety for Use Under Medical Supervision.

Dr. Madras will testify that marijuana does not have a "currently accepted medical use" (CAMU) even under the contrived two-part test offered by HHS. She will also testify that marijuana lacks an accepted safety for use under medical supervision.

First, Dr. Madras will testify that marijuana exhibits significant variability in its chemical composition and in concentration of THC. Levels of the psychoactive substance within marijuana (delta-9 THC) can vary from below 1% to above 30%. Other compounds in marijuana botanicals (*e.g.*, cannabidiol) may also vary widely, depending on the breed of the plant. This variability makes it impossible to assure patient safety, to make judgments about drug–drug interactions, or to form sound judgments about the therapeutic benefits of marijuana.

Second, Dr. Madras will testify that a randomized clinical trial demonstrated that obtaining a medical marijuana card led to higher rates and severity of CUD, without significantly improving pain, anxiety, or depressive symptoms, although participants did self-report some relief from insomnia.

Third, Dr. Madras will testify that various products available in dispensaries (*e.g.*, concentrates, edibles, topicals, tinctures, oils, sublinguals, capsules, suppositories, vape cartridges) lack high quality scientific evidence to support recommendations for specific medical conditions. There are no enforced standards governing dosage, product purity, shelf life, composition, THC-to-CBD ratios, administration routes, usage frequency and duration, criteria for discontinuation

and tapering protocols. Unlike the rigorously defined practices associated with Schedule III drugs, marijuana recommendations fail to address these critical considerations.

Fourth, the second and third most common patient-reported qualifying conditions in 2022 were anxiety and PTSD, even though there exist no high-quality studies showing marijuana is effective in relieving anxiety or PTSD. Dr. Madras will testify that randomized controlled trials in patients with cancer or Central Nervous System disease showed no effect of cannabinoids on quality of life or mental well-being, with marijuana reported to have both anxiogenic and anxiolytic effects with chronic use and association with anxiety disorders.

As Dr. Madras will explain, the psychoactive effects of marijuana represent a significant obstacle to designing appropriate clinical trials. Studies suggest that between 20% and 50% of individuals report paranoia, persecutory ideas, or hallucinations while under the influence of marijuana, and other studies have observed memory impairment (delayed recall of information) while the subjects were under the influence. In long-term users seen after periods of withdrawal of at least 21 days, some components of executive function recover completely, but decision-making, concept formation, and planning deficits persist. These problems are more pronounced in the case of heavy users, whose side effects can include altered brain structure and brain circuits, impaired short-term memory, compromised judgment and decision-making, and mood effects that can range from severe anxiety manifesting as paranoia or even psychosis, especially after high doses.

In addition, some of the indications for medical use of marijuana approved by HHS have been for *chronic* conditions (*e.g.*, AIDS neuropathy, AIDS wasting, multiple sclerosis, chronic pain), which would necessarily entail *long-term* use, but there no long-term studies examining the effects of long-term marijuana use among people using marijuana for medical conditions, with

particular voids in long-term progression to addiction or cognitive impairment. Especially in view of marijuana's negative side-effects—in particular, the very high rate of dependency via CUD (30%)—one simply cannot be assured that marijuana can be safely used over the long term, even under medical supervision, which is all that it is contemplated for. In sum, Dr. Madras will testify that the regular use of marijuana for asserted medical purposes is so recent that there is inadequate data of its long-term effects on seriously ill people, especially among those who suffer cognitive impairment due to their disease (*e.g.*, HIV-AIDS, multiple sclerosis, Alzheimer's, certain seizure disorders).

Dr. Madras will testify that she is aware of no recent study with a large cohort of marijuana-naïve subjects that would compel the conclusion that there is an acceptable level of safety for use of all doses of marijuana under medical supervision. Without long-term studies and an assurance of consistent composition of the substance, and without proof that the substance is free of contamination or adulteration, one cannot conclude that there is an acceptable level of safety for marijuana's use under medical supervision. Marijuana's chemistry, manufacturing, and specifications must be further studied, developed, and chemical isolation of its cannabinoids should be encouraged.

Until reliable research into the long-term consequences of marijuana for asserted medical conditions is conducted, it is too soon to know what users are being exposed to. Many potential users are vulnerable, uninformed about the lack of safety and safeguards, and in a poor position to judge objectively and weigh the potential risks. They may also harbor psychiatric conditions, cognitive impairment, motor incoordination, or latent cardiovascular disease that can be exacerbated by marijuana use. Thus, at this time, there is a strong basis for concluding that adequate safety assurances for the use of marijuana, even under medical supervision, are lacking.

As Dr. Madras will testify, no major medical organization in the United States has endorsed the use of marijuana as medicine. This is because smoking a crude botanical plant as a form of therapy represents a step backwards from modern, evidence-based medicine. Since the 19th century, medical science has been premised on isolating and purifying individual compounds such that they can be tested at particular doses in response to particular conditions. The marijuana plant, by contrast, is comprised of more than 700 chemical compounds, the relative amounts of which depend on environmental factors like soil quality, microbial environment, and water supply. Moreover, marijuana growers can manipulate the germ seeds and thereby cause the THC content of particular plants to vary significantly. Thus, marijuana is nothing like a modern medical drug—a substance of known dose and reproducible chemistry—and there are no consensus or approved protocols for how it is to be used in terms of product form, composition of matter, purity, quantity, dosing regimen, or route of administration.

Dr. Madras will further opine that although around 100 systematic reviews examining the effectiveness of marijuana as therapy have been published, evidence supporting its use as a medicine remains of poor quality or is insufficient. She will challenge HHS's reliance on the 2017 report published by the National Academies of Science, Engineering, & Medicine on the Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research (NAS Report). She will also explain that the NAS Report's findings were flawed.[4] And as to smoked marijuana in particular—which is the most common route of administration, and which HHS also endorses—she will opine that the extensive reviews and meta-analyses do not

[4] For example, Marinol contains THC (delta-9-tetrahydrocannabinol), the most active constituent of marijuana, and is approved to treat nausea and wasting disease caused by AIDS. The FDA has also approved for the same purposes Nabilone (Cesamet), which contains a synthetic cannabinoid similar to THC.

support HHS's conclusion that it is safe or effective to treat chronic pain, anorexia, nausea, or vomiting.[5] Indeed, as Dr. Madras will further explain, for virtually all indications, there are FDA-approved safer alternative medications, and no evidence shows that smoked marijuana confers any advantage over these alternatives.

Dr. Madras will also opine that it is irresponsible (and dangerous) to draw medical conclusions from state-administered "medical" marijuana programs. Many marijuana-recommending physicians do not see their "patients" more than once, do not follow up on their medical status, and do not engage in standard medical recordkeeping. Moreover, nearly half of clinicians authorizing marijuana purchases are not medical doctors at all, but rather dentists, physician assistants, nurses, or other healthcare workers.

In this vein, the medical conditions and indications for which marijuana may be prescribed in such states are usually the result of state-specific legislative action not data derived from scientific studies and medical consensus. Thus, there is great variety from state to state in terms of the specific conditions for which marijuana is an authorized treatment, and, consequently, zero standardization in terms of patient screening (for contraindications), appropriate dosage, administration, or guidelines for tapering if symptoms improve or adverse effects become significant. Nor are marijuana dispensaries required to inform patients of risks or potential side effects—or to identify at-risk patients. In sum, there is no basis to equate state authorization or endorsement as a substitute for medical science or to conclude that it suggests medical legitimacy and safety.

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[5] In this regard, Dr. Madras's opinions are fully consistent with those of the International Association for the Study of Pain (IASP), which stated in 2021: "There is not enough high-quality human clinical safety and efficacy evidence to allow IASP to endorse the general use of cannabis and cannabinoids for pain at this time." IASP, *Cannabinoid Non-technical Summary* (2021), perma.cc/X46G-JL6J.

B. Summary of Dr. Luli R. Akinfiresoye's testimony

Dr. Akinfiresoye will testify about her background and experience, including her experience with DEA. Dr. Akinfiresoye is expected to testify that she is currently a pharmacologist in the Drug and Chemical Evaluation Section (DOE) of DEA's Diversion Control Division. Dr. Akinfiresoye is expected to 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 testify that she is aware that the NPRM in this matter 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. 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.

Dr. Akinfiresoye is expected to testify that marijuana has a substantial potential for abuse, a well-documented capacity to produce dependence, and a broad range of adverse health consequences affecting multiple organ systems and vulnerable populations.

On abuse potential, Dr. Akinfiresoye is expected to testify that marijuana is the most widely used illicit drug in the United States, with more than 61 million Americans reporting use in the previous year and millions initiating use annually, many before age 21. She is also expected to testify that marijuana has clear dependence liability. She will explain that repeated THC exposure alters brain reward pathways, producing reinforcing effects that can lead to CUD.

Dr. Akinfiresoye is expected to testify that there are numerous adverse health consequences associated with marijuana use. Acute intoxication can impair memory, judgment, motor coordination, attention, and decision-making, increasing risks for accidents and impaired driving. Chronic use is associated with measurable alterations in brain structure and function, including changes in gray and white matter, reduced hippocampal volume, cognitive deficits, lower IQ, impaired memory, and diminished executive functioning. She will discuss these impacts as they relate to adolescent exposure, as marijuana may interfere with normal brain development and increase vulnerability to psychiatric disorders later in life.

Dr. Akinfiresoye is expected to testify that credible scientific research links marijuana use to serious mental health risks, including psychosis, schizophrenia, depression, anxiety, bipolar disorder exacerbation, and suicidality. High-potency marijuana and early initiation of use appear to increase these risks.

Dr. Akinfiresoye is expected to testify that marijuana use is associated with increased heart rate, elevated risks of heart attack and stroke, chronic bronchitis, respiratory impairment, prenatal

complications, low birth weight, and adverse neurodevelopmental outcomes in offspring exposed during pregnancy.

C. Rebuttal Testimony

As noted above, SAM reserves the right to have Dr. Madras or Dr. Akinfiresoye offer rebuttal testimony controverting the claims, opinions, and/or documentary evidence introduced by the Government or its witnesses.

D. Reservation of Rights

SAM reserves all rights to address additional points in response to the Government's presentation, and this summary shall not operate as a waiver, limitation, or forfeiture of any argument, objection, testimony, evidence, or position that may be raised or offered at the hearing.[6]

IV. DOCUMENTARY EVIDENCE

SAM intends to submit into evidence the following exhibits:

Description	Length	Designation
Declaration of Bertha Madras, Ph.D, *United States of America v. Schweder et al.*, 2:11-cr-00449 (July 29, 2014), ECF No. 324	36 pages	SAM-Exh. No. 1 (Dr. Madras Declaration in *Schweder*)
Bertha K. Madras, Cannabis and Medicinal Properties (July 13, 2016)	26 pages	SAM-Exh. No. 2 (Dr. Madras 2016 Report)
Report of Bertha Madras (July 22, 2024)	31 pages	SAM-Exh. No. 3 (Dr. Madras 2024 Report)
Bertha K. Madras, Update of Cannabis and Its Medical Use, World Health Organization, 37th Expert Committee on Drug Dependence, Agenda Item 6.2 (2015)	41 pages	SAM-Exh. No. 4 (Dr Madras 2015 WHO Manuscript)

[6] SAM reserves all rights to present any constitutional challenges to this Tribunal's authority, including claims under the Appointments Clause of Article II, *see Lucia v. SEC*, 585 U.S. 237 (2018), to any appropriate forum including to the Administrator and to the U.S. Court of Appeals for the D.C. Circuit.

Description	Length	Designation
Curriculum Vitae of Bertha K. Madras, Ph.D.	73 pages	SAM-Exh. No. 5 (Dr Madras CV)
U.S. Drug Enforcement Administration, Preventing Cannabis Use Among Youth and Young Adults (Nov. 2024)	8 pages	SAM-Exh. No. 6 (DEA Preventing Cannabis Use Nov 2024)
Declaration of Luli R. Akinfiresoye, Ph.D., *In re Scheduling of Controlled Substances: Proposed Rescheduling of Marijuana*, DEA Docket No. 1362, Hearing Docket No. 24-44 (Dec. 23, 2024) (Gov't Ex. 4)	106 pages	SAM-Exh. No. 7 (Government Exhibit No. 4 in 2024 DEA Hearing – Luli Akinfiresoya Declaration)
U.S. Drug Enforcement Administration, Drugs of Abuse: A DEA Resource Guide (2024 ed.)	117 pages	SAM-Exh. No. 8 (DEA Drugs of Abuse 2024)
U.S. Drug Enforcement Administration, National Drug Threat Assessment (May 2025)	80 pages	SAM-Exh. No. 9 (2025 National Drug Threat Assessment)
Office of National Drug Control Policy, National Drug Control Strategy (2026)	195 pages	SAM-Exh. No. 10 (National Drug Control Strategy 2026)
Letter from U.S. Department of Health & Human Services to Chuck Rosenberg, Acting Administrator, Drug Enforcement Administration, Recommending That Marijuana Remain in Schedule I, with Accompanying Scientific and Medical Evaluation (June 25, 2015)	111 pages	SAM-Exh. No. 11 (HHS 2015 Recommendation)
U.S. Drug Enforcement Administration, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53,688 (Aug. 12, 2016) (Governors' petition; Docket No. DEA-426)	79 pages	SAM-Exh. No. 12 (2016 DEA Petition Denial including HHS Recommendation - Governors' Petition)
U.S. Drug Enforcement Administration, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53,767 (Aug. 12, 2016) (Krumm petition; Docket No. DEA-427)	79 pages	SAM-Exh. No. 13 (2016 DEA Petition Denial including HHS Recommendation - Krumm Petition)

Description	Length	Designation
U.S. Drug Enforcement Administration, Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act—Background, Data, and Analysis (July 2016)	66 pages	SAM-Exh. No. 14 (2016 DEA Decision to Maintain Marijuana in Schedule I)
Jean-François G. Morin et al., *A Population-Based Analysis of the Relationship Between Substance Use and Adolescent Cognitive Development*, 176 American Journal of Psychiatry 98 (2019)	9 pages	SAM-Exh. No. 15 (Morin Study on Substance Use and Adolescent Cognition)
Kelly C. Young-Wolff et al., *Adolescent Cannabis Use and Risk of Psychotic, Bipolar, Depressive, and Anxiety Disorders*, JAMA Health Forum (Feb. 2026)	11 pages	SAM-Exh. No. 16 (Young-Wolff Study on Adolescent Cannabis Use and Psychiatric Disorders)
David A. A. Baranger et al., *Association of Mental Health Burden With Prenatal Cannabis Exposure From Childhood to Early Adolescence: Longitudinal Findings From the Adolescent Brain Cognitive Development (ABCD) Study*, 176 JAMA Pediatrics 1261 (2022)	5 pages	SAM-Exh. No. 17 (Baranger Study on Prenatal Cannabis Exposure and Adolescent Mental Health)
Shelby R. Steuart et al., *Cannabis and Pediatric Cannabis Exposure – Evidence from America's Poison Centers*, 67 Journal of Child Psychology and Psychiatry 400 (2026)	13 pages	SAM-Exh. No. 18 (Steuart Study on Pediatric Cannabis Exposure from Poison Centers)
Kelly C. Young-Wolff et al., *Cannabis Retailer Advice on Blunt, Tobacco, and Cannabis Use During Pregnancy*, JAMA Network Open (Dec. 2025)	15 pages	SAM-Exh. No. 19 (Young-Wolff Study on Cannabis Retailer Advice in Pregnancy)
Carla J. Berg et al., *Cannabis Retailers' Marketing Practices and Compliance with State Regulations: A 2025 Point-of-Sale Audit in 5 U.S. Cities*, Addictive Behaviors (Feb. 2026)	10 pages	SAM-Exh. No. 20 (Berg Study on Cannabis Retailer Marketing and Compliance)

Description	Length	Designation
Jesse D. Hinckley et al., *Cannabis Use Is Associated With Depression Severity and Suicidality in the National Comorbidity Survey—Adolescent Supplement*, 1 JAACAP Open (June 2023)	21 pages	SAM-Exh. No. 21 (Hinckley Study on Cannabis Use and Adolescent Depression and Suicidality)
Substance Abuse & Mental Health Services Administration, *Drug Abuse Warning Network: National Estimates from Drug-Related Emergency Department Visits, 2023* (2024)	66 pages	SAM-Exh. No. 22 (Substance Abuse and Mental Health Services Administration - Drug Related ED Visits in 2023)
Ruixuan Li & Feng Tao, *Effects of Cannabis Exposure on Adolescent Health and Development: A Narrative Review*, 17 Current Drug Research Reviews 160 (2025)	10 pages	SAM-Exh. No. 23 (Li Literature Review on Cannabis and Adolescent Health)
Basel Thayyil & Kamran Yusuf, *Evidence on the Effect of In-Utero Cannabis Exposure in Neonates*, 45 Journal of Perinatology 1503 (2025)	10 pages	SAM-Exh. No. 24 (Thayyil Literature Review on In-Utero Cannabis Exposure in Neonates)
Kelly C. Young-Wolff et al., *Frequency of Preconception and Prenatal Cannabis Use and Nausea and Vomiting in Pregnancy*, 145 Obstetrics & Gynecology 519 (2025)	7 pages	SAM-Exh. No. 25 (Young-Wolff Study on Prenatal Cannabis Use and Nausea in Pregnancy)
Catherine Orr et al., *Grey Matter Volume Differences Associated with Extremely Low Levels of Cannabis Use in Adolescence*, 39 Journal of Neuroscience 1817 (2019)	11 pages	SAM-Exh. No. 26 (Orr Study on Cannabis Use and Adolescent Grey Matter)
Thanitsara Rittiphairoj et al., *High-Concentration Delta-9-Tetrahydrocannabinol Cannabis Products and Mental Health Outcomes: A Systematic Review*, 178 Annals of Internal Medicine 1429 (2025)	15 pages	SAM-Exh. No. 27 (Rittiphairoj Literature Review on High-THC Products and Mental Health)
Erica M. Wymore et al., *High Stakes: Exploring the Impact of Cannabis Use in Pregnancy and Lactation*, 26 NeoReviews 247 (2025)	17 pages	SAM-Exh. No. 28 (Wymore Article on Cannabis Use in Pregnancy and Lactation)

Description	Length	Designation
Devan Kansagara et al., *Cannabis and Mental Health: A Review*, 186 JAMA Internal Medicine 618 (2026)	11 pages	SAM-Exh. No. 29 (Kansagara Literature Review on Cannabis and Mental Health)
Substance Abuse & Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2024 National Survey on Drug Use and Health* (2025)	132 pages	SAM-Exh. No. 30 (Substance Abuse and Mental Health Services Administration - 2024 National Survey on Drug Use and Health)
Natasha E. Wade et al., *Longitudinal Neurocognitive Trajectories in a Large Cohort of Youth Who Use Cannabis: Combining Self-Report and Toxicology*, Neuropsychopharmacology (Apr. 2026)	10 pages	SAM-Exh. No. 31 (Wade Study on Youth Cannabis Use and Neurocognition)
Bertha K. Madras & Paul J. Larkin, *Rescheduling Cannabis—Medicine or Politics?*, 82 JAMA Psychiatry 934 (2025)	6 pages	SAM-Exh. No. 32 (Madras & Larkin Article on Rescheduling Cannabis)
André J. McDonald et al., *Age-Dependent Association of Cannabis Use with Risk of Psychotic Disorder*, 54 Psychological Medicine 2926 (2024)	11 pages	SAM-Exh. No. 33 (McDonald Study on Age and Cannabis-Related Psychosis Risk)
Shannon C. Miller et al., Letter to the Editor, *Research Limits on Knowledge of Benefit or Harm of Cannabis and Cannabinoids Use*, 335 JAMA 1447 (2026)	3 pages	SAM-Exh. No. 34 (Miller Letter on Limits of Cannabis Research)
Ryan S. Sultan et al., *Nondisordered Cannabis Use Among US Adolescents*, JAMA Network Open (May 2023)	13 pages	SAM-Exh. No. 35 (Sultan Study on Nondisordered Cannabis Use in Adolescents)
Sarah A. Keim et al., *Prenatal Cannabis Exposure and Executive Function and Aggressive Behavior at Age 5 Years*, 178 JAMA Pediatrics 1316 (2024)	10 pages	SAM-Exh. No. 36 (Keim Study on Prenatal Cannabis Exposure and Child Behavior)
Betsy Dickson et al., *Recommendations From Cannabis Dispensaries About First-Trimester Cannabis Use*, 131 Obstetrics & Gynecology 1031 (2018)	8 pages	SAM-Exh. No. 37 (Dickson Study on Dispensary Advice for First-Trimester Pregnancies)

Description	Length	Designation
Marie Stefanie Kejser Starzer et al., *Rates and Predictors of Conversion to Schizophrenia or Bipolar Disorder Following Substance-Induced Psychosis*, 175 American Journal of Psychiatry 343 (2018)	8 pages	SAM-Exh. No. 38 (Starzer Study on Schizophrenia or Bipolar Disorder Conversion After Substance-Induced Psychosis)
Maryam Sorkhou et al., *The Behavioral Sequelae of Cannabis Use in Healthy People: A Systematic Review*, Frontiers in Psychiatry, Art. No. 630247 (Feb. 2021)	19 pages	SAM-Exh. No. 39 (Sorkhou Literature Review on Behavioral Effects of Cannabis)
Marta Di Forti et al., *The Contribution of Cannabis Use to Variation in the Incidence of Psychotic Disorder Across Europe (EU-GEI): A Multicentre Case-Control Study*, The Lancet Psychiatry (Mar. 2019)	9 pages	SAM-Exh. No. 40 (Di Forti Study on Cannabis and Psychosis Incidence)
Connor Kubeisy, *The Drug Review: Marijuana Dispensaries Sell to Thousands of Minors Every Year*, Foundation for Drug Policy Solutions (Mar. 11, 2024)	10 pages	SAM-Exh. No. 41 (Kubeisy Article on Dispensary Sales to Minors)
Maddie O'Connell et al., *Trends in Cannabis-Related Attitudes and Behaviors Among Cannabis-Using Adolescent and Young Adult Outpatients Following Medical Cannabis Legalization in Massachusetts*, 43 Substance Abuse 328 (2022)	18 pages	SAM-Exh. No. 42 (O'Connell Study on Cannabis Attitudes After MA Legalization)
Jack Wilson et al., *The Efficacy and Safety of Cannabinoids for the Treatment of Mental Disorders and Substance Use Disorders: A Systematic Review and Meta-Analysis*, 13 The Lancet Psychiatry 304 (2026)	12 pages	SAM-Exh. No. 43 (Wilson Literature Review on Efficacy and Safety of Cannabinoids)
Demonstrative Slides of Dr. Madras	~90 pages	SAM-Exh. No. 44 (Dr. Madras's Slides)

June 24, 2026 Respectfully submitted,

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Counsel for Smart Approaches to Marijuana

CERTIFICATE OF SERVICE

I hereby certify that, on June 24, 2026, I caused a copy of the foregoing document to be delivered by email to the following recipients:

1. The Government, by email to
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9. Phillip A. Drum, PharmD, *pro se*, by email at phillipdrum@comcast.net

June 24, 2026

Patrick F. Philbin
Patrick F. Philbin

Exhibits for the National Drug & Alcohol Screening Association (NDASA)
In the Matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana
DEA Docket No. 1362; Hearing Docket No. 26-96

TABLE OF CONTENTS

NDASA For Identification Exhibit 9 Gov Ex. 4_Luli Akinfiresoya Declaration [106 Pages] - contains U.S.Department of Justice, DEA, Marijuana Scientific Data Review as it Relates to the Controlled Substances Act. Entered as an exhibit in the Matter of Docket No. DEA-1362, Docket No. 24-44 Notice of Proposed Rulemaking. Gov. Exhibit 4, page 34

NDASA – For Identification Exhibit 10. ACOEM's Concerns Regarding DOJ/DEA's Notice of Proposed Rulemaking "Schedules of Controlled Substances: Rescheduling of Marijuana" [2 Pages]

NDASA – For Identification Exhibit 11. NDASA Conference Presentation, May 2024: "Evolving Trends in Drugs of Abuse: Cannabinoids and Fentanyl" by Dr. David Kuntz, PhD, F-ABFT. Executive Director for Analytical Toxicology, Clinical Reference Laboratory [36 Pages]

NDASA – For Identification Exhibit 12. NDASA's comments Part 1 of 2 Response to the NPRM on Rescheduling. [10 Pages]

NDASA – For Identification Exhibit 13. American Trucking Associations' Letter to the Attorney General, DOT, HHS, regarding "Impact of Reported Marijuana Rescheduling on Public Safety and Safety-Sensitive Industries" (May 15, 2024) [3 Pages]

NDASA For Identification Exhibit 14 [3 pages] Specific slides from the "Regulatory Program Updates and Mandatory Guidelines Updates", presented on December 3, 2024, at the public session of the Federal Drug Testing Advisory Board (DTAB) meeting, by Ron Flegel, Director, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA, HHS

NDASA For Identification Exhibit 15 HHS Slides [5 Pages] Executive Order 12564: Drug Free Workplace Program in Executive Branch agencies. Limits testing authority to Schedule I or II drugs in the Controlled Substances Act

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**
	:	

DESIGNATED PARTICIPANT PREHEARING STATEMENT FROM THE NATIONAL DRUG & ALCOHOL SCREENING ASSOCIATION

In accordance with the Preliminary Order issued November 19, 2024, by Chief Administrative Law Judge Derek C. Julius, the National Drug & Alcohol Screening Association (NDASA) is hereby filing this Prehearing Statement. NDASA respectfully provides the following requested information:

1. The name, address, phone number, and general nature/principal mission of that Designated Party's practice, profession, or business

Designated Party.

M. Jo McGuire
1629 K Street NW
Suite 300
Washington, D.C. 20006,
719-290-0839

Relevant Curriculum Vitae

EDUCATION

Bachelor of Science, Colorado State University – Pueblo May 2023

Major – Sociology, Minor – Cannabis Studies, Magna Cum Laude

Presented academic research on the problems with impairment testing for cannabis to the 2023 Cannabis Research Conference, Denver, CO as recommended and sponsored by the Cannabis

Studies Department Chair.

PROFESSIONAL EXPERIENCE

National Drug & Alcohol Screening Association, Executive Director 2019 – Present

o Industry leader who initiated the founding of NDASA.
o Recognized industry expert who provides advice and consultation to NDASA members.
o Nationally recognized conference speaker and webinar presenter in issues pertaining to workplace safety including legalization trends, marijuana use by employees, and workplace policies.
o Works closely with Federal Agencies on the national opioid crisis and legal marijuana impacts to workplace policies and employer's rights to safe and drug free workplaces.
o Training expert overseeing the educational courses and certification activities of the industry's largest accreditation program.
o Appointed as 1 of a 12-member employer panel to present Global Recovery Friendly Workplace Initiatives to the Office of National Drug Control Policy, October 2024.

Five Minutes of Courage, President & CEO 2014 – Present

o Serving the drug and alcohol testing industry as an expert, who offers information, accessible support networks, consulting services, presentations, curricula, policy recommendations, and publications for the purpose of drug-free environments that support safety first.
o Provides up-to-date and accurate information on continuing lessons learned in Colorado's legalized cannabis culture; serving other states grappling with various forms of marijuana legalization and advising on policy practices that will continue to ensure public safety.
o Frequent public speaker on the impacts of legal marijuana to the workplace and drug use trends in the U.S.

The Safety Specialists (TSS Inc.), Senior Project Manager 2015 –2019

o Developed online training products, webinars and learning modules that meet DOT drug and alcohol compliance standards for the TSS customer base to include Designated Employee Representatives, Safety Managers and business owners.
o Oversaw key staff leadership development, marketing strategies and programs, as well as research of new products and technology in the drug and alcohol testing industry that improved services.
o Developed and presented education and awareness programs regarding workplace drug use outcomes, prevention strategies and best practice approaches for safe and drug free workplaces.

Conspire! to Hire, Director of Compliance & Corporate Training 2011 –2014

o Conference speaker at the state and national level on topics pertaining to: marijuana in

the workplace, drug and alcohol prevention for youth and families, recognizing signs and symptoms of substance abuse.
o Maintained annual professional certifications as a licensed trainer and for collections professionals per protocols for the legislative piece 49 C.F.R. § 40.
o Apprised customers and constituents of any updates to state and federal laws, serving as an expert to advise employers of sound policymaking for workplace safe and drug-free environments.

Safe2Tell Colorado, Program Director, Grant Writer 2005 – 2011
o Daily program management and implementation of statewide school safety and prevention initiative.
o As a result of this research, saw clear evidence and consistent patterns of marijuana use by the perpetrators of violent acts on schools.
o Oversaw and managed volunteer staff with particular attention to training system processes.
o Seasoned public speaker focused on training and awareness presentations with pre-and-test evaluations.

COMMUNITY EXPERIENCE & VOLUNTEER SERVICE

o National Marijuana Institute, Speaker's Bureau 2015 – Present
o Co-founded the National Drug & Alcohol Screening Association as a 501(c)6, served as the Board Chairwoman
o Board Member & Committee Chair, National Drug and Alcohol Screening Association
o Co-Chair of A Better Way Colorado, 2013-2016
o Board member for the National Drug and Alcohol Testing Industry Association (DATIA), 2012 – 2017
o Co-Chair of the International Marijuana Education and Outreach Committee (2012-Present)
o Steering Committee for Drive Smart Colorado, 2011 - Present
o Victim Assistance Program, Assistant Victim's Advocate, 2000 - 2002
o Board Member of the Community Alliance for Drug Free Youth, Science Team, participating in the United Nations Committee on Narcotic Drugs with a focus on sound policies for workplaces, communities and youth.

SPEAKING EXPERIENCE

Over 12 years of professional presentations pertaining to marijuana in the workplace, effects of legalization in Colorado, impact to youth & families, problems with testing for impairment, how drug testing works for cannabis, policy solutions for the workplace, and managing safety programs where marijuana is legal in hundreds of settings both live and webinar.

APPEARANCES IN DOCUMENTARY FILMS

o SideWayz Media, June 2020 Release, Documentary, "Smoke Screen" – featured interview and consultant
o Drug-Free Idaho, July 2018 Release, Documentary, "Chronic State" – featured interview
o Five Minute of Courage, 2019 Release, Documentary, "Not Just a Little Pot" – featured interview
o Main Street Stories, 2019 Release, Docuseries Interview "Marijuana Legalization and the Impact"

PUBLISHED ARTICLES

o OH&S Magazine, "Employers Must Put Safety First in a Drug-Friendly Culture"
o OH&S Magazine, "The HIGH Cost of Marijuana: What You Need to Know
o FOCUS Magazine, "If It's Legal, Why Test? How to Deal with the Marijuana Bully in the Workplace"
o OH&S Magazine "Maintaining Drug Free Workplaces Where Marijuana is Legal"
o HVACR Magazine, "Drug Policy Tips: Legal Implications of Your Company Policy"
o OH&S Magazine "Trends in Marijuana Legalization: A Wake-Up Call for Employers"
o Contributor to: "On Marijuana: A Powerful Examination of What Marijuana Mean to our Children, Our Communities, and Our Future" April 2015; Author Pamela McColl; Essay: "What are the Costs Associated with Marijuana Legalization?" (re-printed with permission from OH&S Magazine)
o FOCUS Magazine, "Marijuana Legalization and Workplace Drug Testing"
o White Paper Contributor, "Workplace Drug Testing in the Era of Legal Marijuana", Institutes for Behavioral Health
o HVACR Business, "Legal Does Not Mean Safe"
o Addiction Magazine, "Legalized Marijuana and Workplace Drug Testing"
o FOCUS Magazine, "How Should Marijuana Legalization Impact Workplace Drug Testing?"
o Occupational Health & Safety Magazine, "What are the Costs Associated with Marijuana Legalization?"

The name and current address of that Designated Party's witness and the general nature/principal mission of that witnesses's practice, profession, or business;

Patrice M. Kelly, Esq.
Patrice Kelly Consulting, LLC
4532 Cherry Hill Road, #533
Arlington, VA 22207

Recent relevant practice, profession

As the longest serving Director of the Office of Drug and Alcohol Policy and Compliance

(ODAPC) in the Office of the Secretary of the U.S. Department of Transportation, Patrice Kelly is a graduate of Boston College, and member of the Phi Beta Kappa Society. Patrice received her Juris Doctor degree from Georgetown University Law Center. Ms. Kelly has worked: on Wall Street; for Senator Ted Kennedy; and at the US Department of State; at the Supreme Court of the United States; and in law firms in Washington, DC. In private legal practice, she performed work for railroads and other transportation entities. During more than 30 years at DOT, Ms. Kelly has worked closely on writing and providing guidance on the DOT's drug and alcohol testing under 49 CFR Part 40. Ms. Kelly was the lead author of the DOT's oral fluid final rule, which became effective on June 1, 2023. Ms. Kelly served on an assignment to the National Drug and Alcohol Screening Association for 2 years, where she acted as the Senior Policy Executive Advisor and is now retired from the federal government, operating Patrice Kelly Consulting, LLC as the CEO.

2. A brief summary of what that Designated Party's witness(es) will testify;

Transportation Safety

Jo McGuire, the Executive Director of NDASA, will testify about the concerns of NDASA and its membership on several points related to the unintended consequences of the rescheduling of marijuana. Ms. McGuire will discuss the marijuana-related commercial transportation accidents that caused the United States Department of Transportation (DOT) to take action in 1988 and Congress to legislate in 1991.

Ms. McGuire will explain how the Notice of Proposed Rulemaking (NPRM) failed to address the unintended safety impact that rescheduling marijuana would have on transportation safety. The deterrent effect of marijuana testing for DOT-regulated and non-regulated entities has

been effective and has demonstrated success in averting catastrophic accidents of the nature we had seen in the 1980s, which we will detail below. Yet the NPRM failed to mention any of this.

Ms. McGuire will testify how employee marijuana use caused deadly marijuana-related crashes in the late 1980s, which caused the DOT to create drug testing requirements and precipitated Congressional legislation known as the Omnibus Transportation Employee Testing Act (OTETA). Specifically, marijuana-related crashes took place in: January, 1987 (Amtrak and Conrail crash in Chase, Maryland) in which 2 Conrail operators tested positive for marijuana (16 fatalities and 170 injuries); February, 1987 (Metro North crash in New York) in which the engineer tested positive for marijuana (30 injuries); in 1988 (Bronx, NY Metro-North commuter train crash) in which the engineer and 4 transit employees tested positive for marijuana and other drugs (1 fatality); in 1985 (Miami, FL collision involving two trains) in which one operator tested positive for marijuana and other drugs (16 injuries). All of these are cited in the Congressional Report for the Omnibus Transportation Employee Testing Act of 1991, Report of the Senate Committee on Commerce, Science and Transportation on S. 676, 102nd Congress, 1st Session, pages 5 – 6. NDASA – Exhibit 1 (26 Pages). Since the inception of DOT-regulated testing in 1989, which was affirmed by OTETA, the National Transportation Safety Board has not declared marijuana to be the cause of any large commercial transportation crashes. In short, marijuana use by DOT- regulated safety-sensitive employees operating in commercial transportation has been deterred in the industries subject to drug testing for marijuana (FAA, FRA, FMCSA, FTA, PHMSA, USCG).

The Federal Railroad Administration (FRA) began drug testing almost immediately after the Chase, Maryland train crash and the rest of DOT-regulated testing began in 1989. For more

than three decades since the inception of DOT-regulated drug testing, these protocols have effectively prevented marijuana-related fatalities in commercial transportation. Thus, the prevention resulting from DOT-regulated testing has created an outstanding record of safety that is at risk of being wholly undone by the rescheduling of marijuana. DOT-regulated drug testing for transportation safety-sensitive employees has long been integral to maintaining safety standards within the domestic transportation sector, protecting American's traveling public, as well as non-regulated workplaces in the United States, which have mirrored the excellence that DOT look-alike policies have provided for employee safety.

Concurring with the National Transportation Safety Board (NTSB), NDASA believes the Attorney General has demonstrated a dangerous blind spot on the impact of moving marijuana to Schedule III. The unintended consequences of such rescheduling would abruptly end the ability of DOT to conduct marijuana testing and achieve deterrence for transportation safety-sensitive employees, creating a terrible safety gap that would detrimentally impact our nation.

Transportation safety sensitive employees include, but are not limited to: airline pilots, air traffic controllers, school bus drivers, subway and train operators, ferry operators, pipeline operators and truck drivers. In addition, the air traffic controllers employed by the Federal Aviation Administration would no longer be subject to the deterrence and detection ensured by Federal marijuana testing. These safety-sensitive employees have been subject to testing for marijuana and other drugs since 1989.

Ms. McGuire will explain how the rescheduling of marijuana to Schedule III would abruptly end DOT-regulated testing for marijuana and would have a profoundly detrimental impact on transportation safety in the United States. This connection between the rescheduling of

marijuana and the impact on commercial transportation safety was never discussed in the NPRM and was an egregious oversight that affects the safety of the traveling public, transportation safety-sensitive employees, those on the roads, waterways, airways and land around and below their operational zones. This is a significant and dangerous oversight in the rulemaking that not only impacts NDASA's membership, but every person in the United States. NDASA raised these issues to the attention of the Attorney General and the DEA to prevent potentially catastrophic accidents and loss of life as a result of the rescheduling of marijuana.

This important connection to the rescheduling of marijuana and transportation safety that was not addressed in the NPRM was created through the Omnibus Transportation Employee Testing Act of 1991 (OTETA), Public Law 102-143, 105 Stat. 917 (Oct. 28, 1991), codified at 49 USC §§ 5331 (transit industry testing), 20140 (railroad industry testing), 31306 (motor carrier industry testing), and 45101-45105 (aviation industry testing). NDASA – Exhibit 2 (15 Pages). OTETA requires the DOT to follow the Substance Abuse and Mental Health Services Administration of HHS for the science of drug testing, including the drugs to be tested and the drug metabolite cutoff levels, which are set forth in the HHS Mandatory Guidelines. OTETA also requires DOT to use only HHS-certified laboratories for all drug testing required by DOT.

Ms. McGuire will testify about the connection between DOT and HHS and that HHS does not have authority to test for Schedule III drugs. The authority of HHS to test for and to certify laboratories for testing is provided by Executive Order 12564 – Drug-free Federal Workplace of Sept. 15, 1986 (E.O. 12564). NDASA – Exhibit 3. (6 Pages)

Under E.O. 12564, HHS is only authorized to test for drugs and certify laboratories to test for drugs that are in Schedule I or II of the Controlled Substances Act. Specifically, E.O. 12564,

Section 7(c) states: "For purposes of this Order, the term 'illegal drugs' means a controlled substance included in Schedule I or II, as defined by section 802(6) of Title 21 of the United States Code". Sections 3.2 (a) of both the HHS Mandatory Guidelines for Urine and the HHS Mandatory Guidelines for Oral Fluid state that an employee may be tested for "any drugs listed in Schedule I or II of the Controlled Substances Act."

If marijuana becomes a Schedule III substance, HHS would no longer be able to require testing for or to certify laboratories to test for marijuana. As a result, Ms. McGuire will testify that DOT immediately would no longer be able to test for marijuana because OTETA requires DOT to rely on HHS for the science of drug testing (the drug cutoff levels and scientific protocols), and DOT-regulated tests are required to be screened and confirmed at HHS certified laboratories. If a DOT-regulated safety-sensitive employee were to test positive for Schedule III marijuana, the testing would have occurred at a laboratory no longer certified by HHS and the test result would be legally unsustainable. Thus, the day after marijuana were to become a Schedule III drug, would be the day all mandated marijuana testing for safety-sensitive employees would legally cease.

Ms. McGuire is prepared to explain the safety consequences at risk with the elimination of federally regulated marijuana testing and the significant impact this would also have on non-DOT regulated workplace testing. Among the now 6,200 members of NDASA, there are airlines, railroads, trucking companies, home improvement retailers, laboratories, collection sites, Medical Review Officers, and many very small businesses who utilize drug testing and/or who perform drug testing services. The financial impact on these businesses was never considered or estimated in this NPRM, nor was there a request for public comment on this issue.

Ms. McGuire will underscore the profound unintended consequences of rescheduling. Specifically, if marijuana becomes a Schedule III substance, employees responsible for public safety would be able to use marijuana on-the-job and outside work hours, including just prior to assuming their work duties. Even those who may incur testing for at-risk behaviors would receive a "negative" drug test result as the Medical Review Officers would be required to recognize state-issued medical marijuana cards as a legal, valid prescription with HIPAA protections, giving the employer no clue their employee is operating under-the-influence.

Ms. McGuire will testify that non-regulated businesses follow the "standards" of DOT-regulated testing and often replicate the Federal testing panel used by both DOT for commercial transportation and HHS for Federal employee testing. Changing the panel to remove marijuana will impact the non-regulated workplace testing programs across the U.S. This will yield higher on-the-job accidents, injuries, worker compensation claims, and employer liability.

If there were a scientifically reliable method for determining actual marijuana impairment, this would likely be a different discussion. Of course, there is a reliable method for measuring alcohol impairment. However, impairment testing for marijuana has not been possible due to several complicating factors. An individual consuming marijuana is impacted much differently than a person consuming alcohol.

Evidence individuals are consuming marijuana in amounts sufficient to create a hazard to the safety of other individuals or to the community.

Ms. McGuire will testify regarding evidence that individuals are consuming marijuana in amounts sufficient to create a hazard to the safety of others and to the community. When HHS and DEA addressed this issue in 2016, they noted the abuse potential is complex when the

substance varies in potencies and there is no single measure of abuse potential. Ms. McGuire will provide pictorial and documentary evidence to show a variety of marijuana products are currently available. "Marijuana & Your Workplace Safety Policies: What Every Employer Needs to Know" NDASA-Exhibit 4. (62 Pages). She will discuss how varied products such as extracts result in a wide array of unpredictable physiological impacts on individuals who use them, without any consistency between consumers. This demonstrates we are not currently dealing with a benign substance but a powerfully potent drug that has been modified to create a more acute psychoactive effect. These complex issues increase the risk of marijuana use for safety-sensitive employees rather than diminishing the potential harms, simply because of a schedule change. Although individual state departments of labor have not publicly released marijuana-related incident data since 2012, Ms. McGuire will utilize public presentations by Quest Diagnostics Employer Solutions, NDASA-Exhibit 5 (53 Pages), and the 2024 Quest Diagnostics Drug Testing Index data, NDASA-Exhibit 6 (48 Pages), to show significantly increasing marijuana positive drug testing results in both Federally regulated testing by 83% and non-regulated post-accident tests by 56% which is at a 25-year high.

It should also be noted that one of the successes of the DOT mandated drug testing program has been the Return-to-Duty and Follow-up testing protocols facilitated by qualified Substance Abuse Professionals when an employee fails a drug test, per 49 CFR Part 40, Subpart O. According to American Substance Abuse Professionals, Inc. (ASAP) people in an employer-sponsored program have the highest rates of completion to recovery at 49%. Of the DOT marijuana cases handled by ASAP, 53% were attributed to marijuana test results. Without this successful intervention we will see risk mitigation, accountability and sustainable recovery

compromised. American Substance Abuse Professionals, Inc. Summary Report and Data NDASA-Exhibit 7. (5 Pages).

Whether there is significant diversion of marijuana from legitimate drug channels.

In her expert capacity, Ms. McGuire will address whether it is possible to create a presumption that there are currently "legitimate drug channels" for this Schedule I drug. Many of the current state-based dispensary systems have little-to-no enforcement on the requirement for any medical histories and only payment is required to the medical provider who issues permission for access and purchase of marijuana for ostensible medical purposes, allowing for the system to be abused by those with drug-seeking behaviors. Another issue compromising medical dispensing is that many states allow for in-home growth of marijuana plants, which is a breeding ground for diversion. Finally, the dispensing of marijuana as medicine by states that simultaneously offer the retail sale of recreational marijuana enforces the normalization of consuming medical products for recreational use. With an opiates crises ravaging this nation, it is utterly irresponsible for the DEA to support the recreational use of a substance that would be classified as a medicine. The duality of this messaging must be considered, and Ms. McGuire will address how this impacts workplace safety and safety policies, as employers feel pressured to remove THC from their drug testing protocols. These challenges further exacerbate the previously mentioned MRO concerns but also muddy the waters for what may or may not be a legitimate dispensing source for MRO authentication.

Whether individuals are taking marijuana on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of their professional practice.

Ms. McGuire will discuss the fact that the DEA indicates state-run dispensary programs

are sufficient to carry out the responsibility of managing a Schedule III substance. The DEA must be made aware that "medical practitioners" may include chiropractors, podiatrists, veterinarians, nurses, and even massage therapists, depending on how each state's regulatory oversight was framed. The lax definition of what constitutes a healthcare provider is furthermore confused by Federal law which may include therapists who are not qualified to prescribe medication and yet will be responsible for holding the safety of the transportation industry in their unskilled, untrained and unqualified hands. Once again, the NPRM failed to address any of this, thereby leading to an arbitrary and capricious outcome.

Marijuana's "Currently Accepted Medical Use (CAMU)

21 U.S.C.A. § 812 Schedules of controlled substances defines a Schedule III drug:

> (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
> (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Ms. McGuire will testify that the proposed new approach by DEA and HHS to deciding marijuana's "currently accepted medical use" (CAMU) is laid out in two parts.

> Part 1 of that inquiry asks whether licensed health care providers have "widespread current experience with medical use" of the drug "in accordance with implemented state authorized programs, where the medical use is recognized by entities that regulate the practice of medicine."
> If so, Part 2 of the inquiry asks whether there is "some credible scientific support for at l least one of the medical uses." NDASA- Exhibit 8 Page 3

Ms. McGuire will testify that while this shoddy two-step "test" reflects certain aspects of the popular view of marijuana and its advocacy by some for its use for medical purposes, it does not comport with the more evidence-based and law-based tests used for decades by both HHS

and the DEA to determine CAMU for drug scheduling purposes. NDASA- Exhibit 8 is a detailed response to the Department of Justice Office of Legal Counsel's opinion regarding this "two part" test. Note page 9.

Ms. McGuire will testify that 21 USC 811 currently requires the Attorney General to consider eight medical, scientific, and law enforcement factors regarding scheduling of a drug:

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.
8. Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Ms. McGuire will testify that a drug would have a CAMU if it satisfied a five part test:

1. the drug's chemistry is known and reproducible;
2. there are adequate safety studies;
3. there are adequate and well controlled studies proving efficacy;
4. the drug is accepted by qualified experts; and
5. scientific evidence about the drug is widely available. [FN1]

Ms. McGuire will testify that the DEA, in the prior 2024-25 DEA hearing used 9 as their exhibit 4. Note pages 36-39 of NDASA- Exhibit 9.

> Analysis of Currently Accepted Medical Use for Marijuana
> Traditionally, DEA and HHS have considered whether marijuana has a currently accepted medical use under Factor 3, State of the Current Scientific Knowledge Concerning the Substance, in addition to DEA's evaluation of whether the drug has a currently accepted medical use as one of the findings required for schedule placement under 21 U.S.C. 812(b).
> Historically, for substances that are not contained in an FDA-approved drug, DEA and HHS have applied a five-part test to determine whether the substance has a currently accepted medical use. Specifically, with respect to a drug that has not been approved by FDA, in order for that drug to have a currently accepted medical use in treatment in the United States, DEA and HHS have required that the substance demonstrate all of the five

following elements: (1) The drug's chemistry must be known and reproducible, (2) there must be adequate safety studies, (3) there must be adequate and well-controlled studies proving efficacy, (4) the drug must be accepted by qualified experts, and (5) the scientific evidence must be widely available.23

On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion that, among other things, concluded that the existing five-part test is sufficient to determine that a drug has a currently accepted medical use, but that limiting the analysis to the five-part test is "impermissibly narrow."24 OLC concluded that DEA also must consider "whether, at the present time, the medical community widely understands that a drug has a 'use in treatment in the United States.'"25 OLC specified that "there is no single right answer as to *how* specifically DEA should make this determination."

The DEA document then goes on to explain the 5 part test and why marijuana does not currently meet those standards. For example for item 1 "chemistry is known and reproducible" it ends with:

As per the Code of Federal Regulations (CFR) in 21 CFR 314.50(d)(l)(i), "adequate information regarding the chemistry, manufacturing, and control of a drug substance includes synthesis, purification, identity, strength, quality, and purity of the drug substance, as well as stability, sterility, particle size, and crystalline form of the drug product." There are limited data regarding these elements for marijuana.

For item 2 "adequate safety studies," it states:

The considerable variation in the chemistry of marijuana results in differences in safety, biological, pharmacological, and toxicological parameters among the various marijuana samples. Based on criteria for an adequate and well-controlled study for purposes of determining the safety and efficacy of a human drug as defined in 21 CFR 314.126, there are limited published studies in which safety or effectiveness of purified marijuana has been evaluated.

For item 3 "studies proving efficacy" it states:

There are no adequate and well-controlled studies that determine marijuana's efficacy.

For item 4 drug is "accepted by qualified experts;" it states:

Currently, there is no consensus of opinion among experts concerning the medical utility of marijuana for use in treating specific, recognized disorders

For item 5 "scientific evidence about the drug is widely available" it states:

The currently available data and information on marijuana is not sufficient to address the chemistry, pharmacology, toxicology, and effectiveness.

Ms. McGuire will testify that this DEA document was published after the HHS and DEA NRPM in 2024 and that the document is contrary to the government's case in several sections. She will also testify that in 2016 the DEA and HHS and FDA found that marijuana was properly scheduled in Schedule I. [FN2]

Ms. McGuire will testify that marijuana fails to meet every benchmark required for recognition as a legitimate medication that is FDA-approved to treat even a single condition, let alone dozens of conditions.

Concerns for Medical Review Officers (MRO)

Ms. McGuire defines MRO as:

§ 4:253. Medical review officers—In general
All Federal agency and federally regulated drug-testing programs that come under Executive Order 12564 and the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug-testing Programs must use a Medical Review Officer (MRO) to review drug test results. These include all drug-testing programs required by the federal Department of Transportation such as those for motor carriers, airlines, maritime, railroads, pipelines, and mass transit.[FN3]

The American College of Occupational and Environmental Medicine (ACOEM) states,

We are uncertain as to how an MRO (Medical Review Officer) would verify the validity of a medical prescription for marijuana, given the current patchwork of state regulations and systems that primarily rely on dispensaries." ACOEM has further concerns that should not be ignored because they are problematic for the validation of marijuana use in testing programs for safety-sensitive workers. As written, in relying on the state regulatory networks, the NPRM wholly ignores the lack of data on the potential side effects, contaminants, lack of prescriptive instruction, guidelines or standards, and adverse drug interaction with prescribed medications, not to mention the variability of potencies. *ACOEM's Concerns Regarding DOJ/DEA's NPRM "Schedules of Controlled Substances: Rescheduling of Marijuana"* NDASA-Exhibit 10 (2 Pages).

According to the HHS MRO Manual, an MRO must consider if prescriptions are valid.

4.5.3 Prescriptions

> If the donor claims to have taken a prescribed medicine that contains either the drug reported positive or a substance that can metabolize to that drug, the donor should provide the medicine container with the appropriately labeled prescription (or the label from the container), a copy of the medical record documenting the valid medical use of the drug during the time of the drug test, or other information acceptable to the MRO. There is an additional concern in the case of invalid results. Certain antibiotics and nonsteroidal anti- inflammatory drugs (NSAIDs) are known to cause immunoassay interferences. In those cases of potential interference, the verification of prescriptions or medical records should be completed in the same manner as a positive test result.
>
> When reviewing the positive test result, the MRO will take all reasonable and necessary steps to verify the authenticity of all prescriptions, medical records, and other medical information provided by the donor that may be relevant to determining whether a legitimate medical explanation for the positive drug test exists. Contact with the prescribing physician may be helpful for the MRO in coming to this decision if the donor has provided any consent that may be required.
>
> If a donor does not possess a valid prescription that would supply a legitimate medical explanation for the positive drug test result, the specimen should be reported as positive.[FN4]

Ms. McGuire will testify that the rescheduling Order removes federal informational protections for physicians regarding prescriptions and patient information. The Order on page 11 states:

> (5) Prescriptions. Notwithstanding Part 1306 or any other provision of these rules, a certification or other document (including an electronic document) that state law deems sufficient for a user to obtain marijuana or products containing marijuana for medical purposes shall be sufficient to permit dispensing of marijuana...[FN5]

Ms. McGuire will testify that the Order is telling the states to ignore federal law 21 CFR 1306 the "Process and procedures for dispensing, by way of prescribing and administering controlled substances." The Order only requires limited information to obtain marijuana. There is no information about the drug that is provided in a normal valid prescription or FDA package insert.

Ms. McGuire will testify that 21 USC 1306 authorizes the DEA to regulate the prescribing, dispensing, and administration of controlled substances. Under 21 CFR 1306 the prescription must also include:

Drug Name
Strength
Dosage Form
Quantity Prescribed
Directions for Use
Number of Refills Authorized (if any)

FDA Patient Information Requirements

Ms. McGuire will testify that the Order does not require the standard package inserts for state "medical" marijuana that provide details on medicines such as the FDA package inserts. Such information is necessary to guide MROs in deciding if a prescription is medically needed and to alert the MRO to any safety concerns Ms. McGuire will testify that the required patient information is:

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS 5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Labor and Delivery
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
9 DRUG ABUSE AND DEPENDENCE
9.1 Controlled Substance
9.2 Abuse
9.3 Dependence
10 OVERDOSAGE
11 DESCRIPTION

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
12.4 Microbiology
12.5 Pharmacogenomics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
14.1 [text]
14.2 [text]
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION [FN6]

Deadly Interactions Between Marijuana and Prescription Drugs

Ms. McGuire will testify that the first rule of medicine is to do no harm! The DEA in the prior 2024-25 DEA hearing stated these problems with marijuana and drug interactions:

> Therefore, the concomitant use of cannabis with prescription drugs may lead to cannabis-drug interactions and increased toxicity. NDASA-Exhibit 9. page 34

No dosing guidance

There is no accepted dosing or patient information guidelines for "medical" marijuana, and this makes the entire prescription procedures very problematic for MROs to determine the legitimacy of prescriptions.

Ms. McGuire will testify that the DEA Order does not define or require adequate and well-controlled studies. According to federal law 21 C.F.R. 314.126, adequate and well-controlled studies to decide what is a medicine are quite complicated and marijuana has not met these standards. Ms. McGuire will testify that neither DOJ or DEA or HHS cites these studies on the clinical experience with marijuana for all medical conditions.

The state of current scientific knowledge regarding marijuana.

Ms. McGuire will provide expert testimony to substantiate that there are a broad range of contemporary and dangerously high potency products within the CSA's definition of marijuana. Since there are vast differences in the effects of marijuana based on THC levels and various methods of administration (e.g., smoking, vaping, dabbing, wax, edibles, etc.), our expert testimony and documentary evidence would provide a demonstration of how employers struggle to recognize marijuana use that is occurring during work hours with high potency products that are problematic for enforcing safety standards. "Marijuana & Your Workplace Safety Policies: What Every Employer Needs to Know" NDASA-Exhibit 4. (62 Pages). Changing state laws have already created confusion about employer's rights and while the Federal testing program is preeminent to state laws, rescheduling without science-based evidence of the risks of high potency marijuana will have employers facing even greater challenges in understanding what types of boundaries may be enforced to protect workplace safety and the public they serve.

Ms. McGuire will also address the following statement: "DEA anticipates that additional data on other marijuana constituents, routes of administration of marijuana, and the impact on D9-THC potency may be appropriate for consideration." She will testify that industry experts have presented findings that Delta 8 and Delta 10 THC have similar effects and safety concerns as Delta 9 while THC-O-Acetate causes LSD like responses and is three times as potent. NDASA Conference Presentation, May 2024, Hershey, PA: "Evolving Trends in Drugs of Abuse: Cannabinoids and Fentanyl" by Dr. David Kuntz, PhD, F-ABFT. Executive Director for Analytical Toxicology, Clinical Reference Laboratory, NDASA – Exhibit 11. (36 Pages).

Determination of Appropriate Schedule for marijuana

Ms. McGuire would offer expert testimony and documentary evidence to show marijuana continues to maintain the high potential for abuse that HHS and DEA found in 2016. Also, the availability of marijuana and marijuana-derived products with extremely high levels of THC produce higher degrees of negative outcomes for the safety of those around the people who use marijuana.

In considering the appropriate scheduling for marijuana, Ms. McGuire will explain the recommendations NDASA discussed on pages 7 – 10 in Part 1 of 2 of its comments to the NPRM. NDASA-Exhibit 12. (10 Pages).

These two recommendations will be offered to address the unintended consequences of rescheduling.

Recommendation # 1

Ms. McGuire will testify that NDASA recommends the final rule maintain the status quo by retaining marijuana in Schedule I. The current rulemaking could be withdrawn or finalized with no change to the current status of marijuana as Schedule I.

The United States Congress has multiple legislative actions pending on marijuana from rescheduling (H.R. 610: "Marijuana 1-to-3 Act of 2023"), H.R. 610, to allowing limited use for veterans (H.R. 2682: "Veterans Medical Marijuana Safe Harbor Act"), to not allowing legalization (H.R. 5323: "Stop Pot Act of 2023"), to the full legalization of marijuana (H.R. 5601: "Marijuana Opportunity Reinvestment and Expungement Act" or the "MORE Act"). Consequently, it would be practical to withdraw this NPRM and allow the Legislative Branch to address the policy and legal issues surrounding the scheduling and/or legalization of marijuana.

Recommendation # 2

Ms. McGuire will testify that rescheduling marijuana to Schedule II could be a way to address the issues. While NDASA does not recommend recscheduling marijuana to Schedule II versus maintaining the status quo of Schedule I, as a first choice, it would be more preferable than moving marijuana to Schedule III.

Moving marijuana to Schedule II of the Controlled Substances Act (CSA) would keep marijuana testing within the current authority HHS has been granted under E.O. 12564. As long as marijuana remains in CSA Schedules I or II, HHS will have the authority to continue to test for and certify laboratories to test for marijuana. This would retain marijuana in the DOT-regulated drug testing panel and continue the more than three decades of effective deterrence of marijuana use among transportation safety-sensitive employees.

Ms. Kelly will testify as to the legal authority for federal drug testing. NDASA-Exhibits 12, 13, 14, 15.

Conclusion

Ms. McGuire's testimony will cover multiple blindsides in the NPRM – from safety to false assumptions to impact on NDASA's members large and small. NDASA believes this rulemaking is arbitrary and capricious in its failure to assess the impact on the affected members of NDASA and the dangers presented from removing the deterrence in the commercial transportation sector and Federal air traffic controllers.

Assuming arguendo that the NPRM would proceed with this rescheduling action, NDASA would appreciate consideration of the alternatives suggested above. If marijuana becomes a Schedule III substance and there is not at a minimum, a safety carve-out solution, NDASA

remains greatly concerned about transportation and workplace safety.

3. A list noticing all documentary evidence, including affidavits and other proposed exhibits, intended to be offered into evidence, specifying the number of pages in each.

NDASA – For Identification Exhibit 1: Omnibus Transportation Employee Testing Act of 1991, Report of the Senate Committee on Commerce, Science and Transportation on S. 676, 102nd Congress, 1st Session. [26 pages]
https://www.transportation.gov/sites/dot.gov/files/docs/Omnibus_Act_Congressional_Rpt.pdf

NDASA – For Identification Exhibit 2: Omnibus Transportation Employee Testing Act of 1991 (OTETA), Public Law 102-143, 105 Stat. 917 (Oct. 28, 2991), codified at 49 USC §§ 5331 (transit), 20140 (railroads), 31306 (motor carriers), and 45101-45105 (aviation). [15 pages]
https://www.transportation.gov/sites/dot.gov/files/docs/199111028_Omnibus_Act.pdf

NDASA – For Identification Exhibit 3: Exec. Order No. 12564 (Sep. 15, 1986), 51 FR 32889 (Sept. 15, 1986). [6 pages]
https://www.archives.gov/federal-register/codification/executive-order/12564.html

NDASA – For Identification Exhibit 4. "Marijuana & Your Workplace Safety Policies: What Every Employer Needs to Know" by Jo McGuire, BS, CSAPA, July 2024 [62 Pages]

NDASA – For Identification Exhibit 5. NDASA Conference Presentation, May 2024, Hershey, PA: "Quest Diagnostics Insights: Drug Testing Trends in the Workforce" Quest Employer Solutions [53 Pages]

NDASA – For Identification Exhibit 6. Quest Diagnostics Drug Testing Index Report 2024 [48 Pages]
https://www.questdiagnostics.com/business-solutions/employers/drug-screening/knowledge-center/drug-testing-index

NDASA – For Identification Exhibit 7. American Substance Abuse Professionals, Inc. Summary Report and Data (Report on success rates of referral and treatment for workplace testing Return-to-Duty and Follow-up programs). [5 Pages]

NDASA For Identification Exhibit 8 CIVEL Prehearing Statement page [70 Pages] Detailed legal critique of the DOJ April 11, 2024 Office of Legal Counsel opinion "Questions Related to the Potential Rescheduling of Marijuana" OLC opinion is also attached. It does not comport with the more evidence based and law-based tests used for decades by both HHS and the DEA to determine CAMU for DEA scheduling purposes

NDASA For Identification Exhibit 9 Gov Ex. 4_Luli Akinfiresoya Declaration [106 Pages] - contains U.S.Department of Justice, DEA, Marijuana Scientific Data Review as it Relates to the

Controlled Substances Act. Entered as an exhibit in the Matter of Docket No. DEA-1362, Docket No. 24-44 Notice of Proposed Rulemaking. Gov. Exhibit 4, page 34

NDASA – For Identification Exhibit 10. ACOEM's Concerns Regarding DOJ/DEA's Notice of Proposed Rulemaking "Schedules of Controlled Substances: Rescheduling of Marijuana" [2 Pages]

NDASA – For Identification Exhibit 11. NDASA Conference Presentation, May 2024: "Evolving Trends in Drugs of Abuse: Cannabinoids and Fentanyl" by Dr. David Kuntz, PhD, F-ABFT. Executive Director for Analytical Toxicology, Clinical Reference Laboratory [36 Pages]

NDASA – For Identification Exhibit 12. NDASA's comments Part 1 of 2 Response to the NPRM on Rescheduling. [10 Pages]

NDASA – For Identification Exhibit 13. American Trucking Associations' Letter to the Attorney General, DOT, HHS, regarding "Impact of Reported Marijuana Rescheduling on Public Safety and Safety-Sensitive Industries" (May 15, 2024) [3 Pages]

NDASA For Identification Exhibit 14 [3 pages] Specific slides from the "Regulatory Program Updates and Mandatory Guidelines Updates", presented on December 3, 2024, at the public session of the Federal Drug Testing Advisory Board (DTAB) meeting, by Ron Flegel, Director, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA, HHS

NDASA For Identification Exhibit 15 HHS Slides [5 Pages] Executive Order 12564: Drug Free Workplace Program in Executive Branch agencies. Limits testing authority to Schedule I or II drugs in the Controlled Substances Act

4. Hearing Date Availability of In Person Attendees and Witnesses of NDASA.

Ms. McGuire

JUNE 29, 30 and JULY 1, 2, 6, 7, 8, 9, 10, 13, 14

Ms. Kelly

Ms. Kelly is available for all of the dates of June 29 – July 13th.

Counsel attendees for all dates:

Patrick D. Kenneally

Connor Mighell

David G. Evans

5. District Court Intervention. NDASA does not intend to seek the intervention of a U.S.

District Court in accordance with Axon Enterprise, Inc. v. FTC, 598 U.S. 175 (2023).

I respectfully request that the court enter my written testimony and exhibits into evidence,

M. Jo McGuire
Digitally signed by M.Jo McGuire
June 23,2026, 16:50
M. Jo McGuire, Executive Director
National Drug & Alcohol Screening Association

Footnotes

1. Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131,1135 (CA DC 1994)

2. Department of Justice, Drug Enforcement Administration, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 FR 53767-01, 2016 WL 4240243(F.R.)(Friday, August 12, 2016)

3. Drug Testing Law, Technology, and Practice, Thomson-Reuters, 1990

4. Drug Testing Law Technology and Practice, Medical Review Officer Manual for Federal Agency Workplace Drug Testing Programs

5. Drug Enforcement Administration, Department of Justice, Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana from Schedule I to Schedule III; Corresponding Change to Permit Requirements, 91 FR 22714-01, 2026 WL 1135003(F.R.), Tuesday, April 28, 2026, page 1

6. Guidance for Industry, Labelling for Human Prescription Drug and Biological Products, page 30, https://www.fda.gov/media/71836/download

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**
	:	

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on June 23, 2026, caused a copy of the foregoing NDASA Prehearing Statement and exhibits to be delivered to the following parties:

(1) The Government, via email to. i. The DEA Government Mailbox at dea.registration.litigation@dea.gov;
ii. James.J.Schwartz@dea.gov;
iii.Jarrett.T.Lonich@dea.gov;
iv. Alexis.B.Attanasio@dea.gov;
v. Kayla.L.Kreinheder@dea.gov;
vi. David.C.Maley@dea.gov;
vii. Lisa.K.Man@dea.gov;
viii. Stacy.M.Race@dea.gov;
ix. Mack.J.Swan@dea.gov;

(2) National Drug & Alcohol Screening Association, via email to i. M. Jo McGuire at jomcguire@ndasa.com;
ii. David Evans, Esq. to thinkon908@aol.com;
iii. Patrick Kenneally, Esq. to patrick.kenneally@burkegroup.law
iv. Connor Mighell, Esq. to connor.mighell@burkegroup.law

(3) Tennessee Bureau of Investigation, via email to i. Jacob Durst, Esq., at jacob.durst@ag.tn.gov;

(4) Smart Approaches to Marijuana, via email to i. Patrick F. Philbin, Esq., at pphilbin@torridonlaw.com;
ii. John M. McNichols, Esq., at jmcnichols@torridonlaw.com;
iii. Chase T. Harrington, Esq., at charrington@torridonlaw.com;

(5) The States of Nebraska, Idaho, Indiana, and Louisiana, via email to i. Zachary Pohlman, Esq., at zachary.pohlman@nebraska.gov;
ii. Michael Zarian, Esq., at Michael.Zarian@ag.idaho.gov;
iii. Blake Lanning, Esq., at Blake.Lanning@atg.in.gov;
iv. Zachary Faircloth, Esq., at FairclothZ@ag.louisiana.gov;

(6) DUID Victim Voices, via email to i. Ed Wood, at edwood27@icloud.com;

(7) Kenneth Finn, M.D., *pro se*, via email at kfinn0731@gmail.com; and

(8) Phillip A. Drum, PharmD, *pro se*, via email at phillipdrum@comcast.net

(9) The court ECF-NPRM@dea.gov

ECF-NPRM@dea.gov, Thinkon908@aol.com, jomcguire@ndasa.com, jacob.durst@ag.tn.gov, pphilbin@torridonlaw.com, jmcnichols@torridonlaw.com, charrington@torridonlaw.com, zachary.pohlman@nebraska.gov, Michael.Zarian@ag.idaho.gov, Blake.Lanning@atg.in.gov, FairclothZ@ag.louisiana.gov, edwood27@icloud.com, kfinn0731@gmail.com, phillipdrum@comcast.net, dea.registration.litigation@dea.gov, James.J.Schwartz@dea.gov, Jarrett.T.Lonich@dea.gov, Alexis.B.Attanasio@dea.gov, Kayla.L.Kreinheder@dea.gov, David.C.Maley@dea.gov, Lisa.K.Man@dea.gov, Stacy.M.Race@dea.gov, Mack.J.Swan@dea.gov, patrick.kenneally@burkegroup.law, connor.mighell@burkegroup.law

I further certify that Ms. McGuire authorized me to digitally sign for her.

Thank you.

David G. Evans

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

June 23, 2026

Joseph A. Bondy
Joseph A. Bondy, PLLC
43 W. 43rd Street
Suite 379
New York, NY 10036
(212) 219-3572
josephbondy@mac.com

Dear Joseph Bondy,

This is in response to your June 19, 2026 letter requesting reconsideration of the Drug Enforcement Administration's (DEA) denial of your request, on behalf of the National Organization for the Reform of Marijuana Laws (NORML), to participate in a hearing on the notice of proposed rulemaking (NPRM) to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA, which is currently scheduled to begin on June 29, 2026. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 FR 44597 (May 21, 2024) (NPRM); *Schedules of Controlled Substances: Rescheduling of Marijuana*, 91 FR 22777 (Apr. 28, 2026) (Notice of Hearing). For the reasons stated below, and the reasons set forth in DEA's denial letter dated June 17, 2026, DEA denies your request for reconsideration.

DEA regulations define an "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable" under 21 U.S.C. 811. 21 CFR 1300.01(b). Similar to your request to participate in the hearing on the NPRM, you state in your request for reconsideration that "NORML is the nation's oldest and most prominent marijuana-law-reform organization representing cannabis consumers," and that its "members include adult cannabis consumers, patients, caregivers, attorneys, advocates, and participants in state-regulated cannabis systems." You again claim that NORML is an "interested person" that is adversely affected and aggrieved by the NPRM because transferring marijuana from schedule I to schedule III "would preserve federal illegality for cannabis activity outside federally authorized medical, research, or registrant channels." According to you, the proposed rule "would continue federal-state conflict, public confusion, stigma, collateral consequences, and consumer-safety harms." In other words, "NORML's members would remain subject to

federal controlled-substance status and the legal consequences that flow from it."[1] Therefore, NORML claims that it "objects to schedule III as the proposed endpoint and seeks to present evidence and argument that marijuana should be removed from the CSA schedules and regulated through cannabis-specific federal controls adequate to protect public health, consumer safety, product integrity, youth prevention, research access, and anti-diversion interests, while also addressing any applicable treaty obligations through the least restrictive lawful domestic mechanism."

Upon careful consideration, DEA concludes that your request for reconsideration, like your request for participation, fails to sufficiently explain how or why NORML is adversely affected or aggrieved *by the promulgation of a rule* transferring marijuana, as listed in 21 CFR 1308.11(d)(23), marijuana extracts, as defined in 21 CFR 1308.11(d)(58), and naturally derived delta-9-tetrahydrocannabinols from schedule I to schedule III of the CSA. You unambiguously state that "NORML supports removal from schedule I," and that "[s]chedule III may be better than schedule I." You further reiterate NORML's position that transferring marijuana to schedule III only offers "partial relief," and that "complete relief" requires that marijuana "be removed from the CSA schedules and regulated under a cannabis-specific federal framework better suited to cannabis, consumers, public health, state-law reality, and contemporary science." While you contend that "NORML's position is . . . directly adverse to the proposed rule" because it wants marijuana removed from the CSA schedules entirely, NORML has failed to demonstrate in either its participation request or its reconsideration request that it is adversely affected or aggrieved *by the proposed rule*, as opposed to the status quo of marijuana remaining in schedule I.

Moreover, the purpose of the hearing is to "receive *factual evidence and expert opinion* regarding whether marijuana should be transferred to schedule III of the list of controlled substances." NPRM, 89 FR at 44599 (cleaned up) (emphasis added); Notice of Hearing, 91 FR at 22778 (cleaned up) (emphasis added). As DEA stated in its denial of your request to participate in the hearing, the issue of whether marijuana can be removed entirely from the CSA schedules is a *question of law* that is *outside the purpose of this hearing*. Indeed, NORML acknowledges the legal nature of the issue presented by "descheduling," including the United States' compliance with its international legal obligations. *See, e.g.*, Request for Reconsideration at 4 ("The question is whether cannabis must remain in a CSA schedule in order to be controlled."); *id.* ("NORML recognizes that current treaty obligations may require the United States to maintain controls over cannabis. . . . But the existence of treaty obligations does not answer the domestic-law question whether cannabis must remain in schedule III, or in any CSA schedule."); *id.* at 5 ("NORML recognizes that current treaty obligations may limit the United States' ability to authorize non-medical adult-use cannabis under existing

[1] In your request for reconsideration, you again assert that NORML is "injured in its own right" because a "final schedule III rule that medicalizes marijuana while leaving adult-use consumers federally exposed would require NORML to devote additional organizational resources to public education, legal referrals, member communications, administrative advocacy, litigation support, chapter coordination, legislative advocacy, and correction of public confusion concerning the scope and consequences of federal rescheduling." These assertions of NORML's perceived impact to its advocacy efforts do not fall within the zone of interest the CSA was designed to regulate or protect and do not qualify NORML as an interested person under 21 CFR 1300.01(b). *See Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 883 (1990); *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972); *Bonds v. Tandy*, 457 F.3d 409, 414 (5th Cir. 2006).

international law absent treaty modernization, reinterpretation, amendment, reservation, withdrawal and reaccession, or other lawful diplomatic action. . . . But that point . . . establishes only that treaty implementation is a serious legal and policy issue requiring a complete record and reasoned agency analysis").

Again, as DEA noted in its June 17, 2026 denial letter, the U.S. Court of Appeals for the D.C. Circuit, DEA, DOJ's Office of Legal Counsel, and the Department of State have all recognized that the United States cannot comply with its legal obligations under the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151, if marijuana, as defined in 21 U.S.C. 802(16), was removed entirely from the CSA schedules. *See Nat'l Org. for Reform of Marijuana Laws v. Drug Enforcement Admin.*, 559 F.2d 735, 751 & n.71 (D.C. Cir. 1977); *Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements,* 83 FR 48950 (Sept. 28, 2018); *Petition to Decontrol Marijuana; Interpretation of Section 201 of the Controlled Substances Act of 1970,* Op. O.L.C. at *12-13 (Aug. 21, 1972); *Notice of Proposed Hearing*, Letter from Department of State, 39 FR 23072 (June 26, 1974).

Finally, in the alternative, NORML requests that the Administrator immediately refer its request to the Administrative Law Judge (ALJ) designated to preside over the hearing, along with a certification for interlocutory review pursuant to 21 CFR 1316.62. Because the determination of interested persons is made by the Administrator under 21 CFR part 1308 and pursuant to the Acting Attorney General's Notice of Hearing, *see Schedules of Controlled Substances Rescheduling of Marijuana*, 91 FR 22777 (Apr. 28, 2026), and not the ALJ, 21 CFR 1316.62 is not applicable and your alternative request for immediate referral and certification for interlocutory review is denied.

Accordingly, DEA denies your request for reconsideration to participate in the hearing on the NPRM.

Sincerely,

Terrance C. Cole
Administrator